Veterinary Medical Board
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MEMORANDUM

DATE	July 9, 2021
TO	Veterinary Medical Board (Board)
FROM	Karen Halbo, Regulatory Counsel, Attorney III Legal Affairs Division, Department of Consumer Affairs
SUBJECT	**Agenda Item 9.C. Sections 2090-2095, Article 11, Division 20, Title 16 of the California Code of Regulations (CCR) Regarding Drug Compounding**

Background

The Drug Compounding regulatory proposal was originally approved by the Board in October 2017. The language was revised and approved again on October 10, 2019, and January 30, 2020. On March 22, 2020, the regulatory package was approved by the Department of Consumer Affairs (DCA) Director and on June 23, 2020, was approved by the Business, Consumer Services, and Housing Agency (Agency). The package was published by the Office of Administrative Law (OAL) on July 17, 2020, and the 45-day public comment period closed on August 31, 2020.

On October 22, 2020, the Board approved responses to the comments received and approved Modified Text to resolve the concerns raised. The 15-day public comment period on the Modified Text closed on December 4, 2020. On January 28, 2021, the Board voted to adopt the response to the one written comment received. Staff then incorporated the Board's responses into the Final Statement of Reasons (FSR), and submitted the final rulemaking package documents for Legal Affairs Division (LAD), DCA Director, and Agency review.

LAD has raised concerns about six portions of the Modified Text that may be questioned during OAL's final review. To resolve LAD's concerns, attached is the Second Modified Text for the Board to consider. If the Board approves the proposed changes, the Second Modified Text will be posted for another 15-day public comment period.

Summary of Concerns Raised by LAD and How Second Modified Text Addresses Those Issues

LAD reviewers noted portions of the Text contain language or lack clarity such that OAL reviewers are likely to request changes to the Text, for the reasons set out below. The

proposed revisions are described, as well. All sections referenced below are proposed to be added to CCR, title 16, division 20, unless otherwise indicated.

Section 2091(a):

This subsection presently reads: “(a) A veterinarian shall ensure the safety and efficacy of a compounded drug preparation.” This subsection is not clear as to how a veterinarian would accomplish this. Adding the phrase, “through reliance on drug compounding standards in the profession and in accordance with section 2032” clarifies how a veterinarian may accomplish the task.

Section 2091(b):

This subsection presently reads: “A veterinarian shall not perform drug compounding when the complexity of the drug compounding exceeds the veterinarian’s knowledge, skill, facilities, or available equipment.” This subsection lacks clarity, as it does not specify if this language applies to only sterile compounding, non-sterile compounding, or to both.

A similar lack of clarity was pointed out in section 2091(c), which immediately follows this subsection. Adding the phrase, “sterile or non-sterile” to this subsection would both clarify that this subsection applies to both types of compounding and keep this subsection consistent with section 2091(c).

Section 2091(c):

This subsection presently reads: “(c) A veterinarian shall not perform drug compounding unless there are no other human or animal drugs approved by the United States Food and Drug Administration (FDA) and available that satisfy the need for this preparation.” This subsection lacks clarity, as it does not specify if this language applies to only sterile compounding, non-sterile compounding, or to both.

It appears this section was intended to apply to both sterile and non-sterile compounding. There is an FDA guidance document that has not yet been adopted that forbids compounding any drugs, sterile or non-sterile, that are approved by the FDA. Adding the phrase, “sterile or non-sterile” to this subsection would clarify that the subsection applies to both types of compounding and eliminates this potential concern.

Section 2093(c):

The subsection presently reads: “(c) The expiration date may be extended if the product’s integrity, potency, and quality are measurable and demonstrable.” LAD pointed out that in the Initial Statement of Reasons (ISOR), it was explained that the veterinarian must research and document the reason or reasons for extending the expiration date. This raised clarity and consistency issues for the ISOR to discuss a requirement not in the regulatory text.

Upon re-examination, it was decided to strike all of subsection (c). Subsections (a) and (b) establish that the outermost expiration dates to be either the shortest expiration date or beyond use date of any ingredient, or 180 days for non-sterile compounded preparations and 30 days for sterile compounded preparations. At this time, in the interests of consumer protection, all of subsection (c), allowing veterinarians to extend the expiration date a compounded preparation beyond the limits imposed in subsections (a) and (b), should be deleted.

Section 2095(c)

The subsection presently reads: "(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." OAL has previously rejected the phrase "as soon as possible", as the regulated community cannot discern what that means without a clear outermost timeframe being provided.

Upon re-examination, it was decided to replace "as soon as possible" with the term "immediately." This is consistent common practice and provides greater consumer protection.

Section 2095(d):

The Board does not have the authority to declare the records of a quality assurance program to be exempt from discovery as "peer review documents." Accordingly, the portions of the subsection that seek to accomplish this, and the language that assumes such protection exists, must be struck from this subsection.

Code of Civil Procedure section 2017.010 in the Discovery Act states:

> "Unless otherwise limited by order of the court in accordance with this title, any party may obtain discovery regarding any matter, not privileged, that is relevant to the subject matter involved in the pending action or to the determination of any motion made in that action, if the matter either is itself admissible in evidence or appears reasonably calculated to lead to the discovery of admissible evidence. Discovery may relate to the claim or defense of the party seeking discovery or of any other party to the action. Discovery may be obtained of the identity and location of persons having knowledge of any discoverable matter, as well as of the existence, description, nature, custody, condition, and location of any document, electronically stored information, tangible thing, or land or other property."

The Court of Appeal has stated that this means, "In litigation, the courts and parties must look to the Evidence Code to determine whether records are privileged and therefore not discoverable under Code of Civil Procedure section 2017, subsection (a)." (Renumbered as Code Civ. Proc., § 2017.010.) (*Marylander v. Superior Court* (2000) 81 Cal.App.4th 1119, 1125.) "Instead, Evidence Code section 1040, the official information

privilege, 'represents *the exclusive means by which a public entity may assert a claim of governmental privilege based on the necessity for secrecy.*'" (*Ibid*, citing *Shepherd v. Superior Court,* 17 Cal.3d 107, 123; emphasis in original.)

Evidence Code section 1040 states, in pertinent part:

> (b) A public entity has a privilege to refuse to disclose official information, and to prevent another from disclosing official information, if the privilege is claimed by a person authorized by the public entity to do so and either of the following apply:
>
> (1) Disclosure is forbidden by an act of the Congress of the United States **or a statute of this state**." (Emphasis added.)

Proposed section 2095, subsection (d) was drafted to mirror the discovery protections drug compounding quality assurance programs receive in BPC section 4125 under the Pharmacy Law, which forbids the disclosure in discovery. Because the Veterinary Medicine Practice Act does not have a statute forbidding such disclosure, and BPC section 4125 cannot be interpreted to apply to veterinarian drug compounding, the language protecting these records from discovery, or which assume such protection exists, must be struck from the regulatory proposal.

After removing the language for which the Board lacks authority, section 2095, subsection (d) will read: "(d) The board may review records generated for and maintained as a component of the ongoing quality assurance program 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."

If the Second Modified Text is sent out for a 15-day public comment period with the language for which the Board lacks authority in section 2095, subsection (d) struck and the other five changes discussed above included, this regulation package can move forward through the final phase of the review process.

Action Requested

The Board is asked to consider a motion to approve the proposed second modified text for a 15-day public comment period, and if there are no adverse comments received during that 15-day public comment period, delegate to the Executive Officer the authority to adopt the proposed second modified text, and also delegate to the Executive Officer the authority to make any technical or nonsubstantive changes that may be required in completing the rulemaking file.

Attachment:
1. Proposed Second Modified Text

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

SECOND MODIFIED TEXT

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

Modifications to the proposed regulatory language are shown in double underline for new text and ~~double strikethrough~~ for deleted text.

Second Modifications to the proposed regulation text are shown in *italicized double underline* for new text and ~~*italicized double 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 animal 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.

(b) "Compounding" also means preparing a compounded drug preparation from bulk substances by a licensed veterinarian, who has established a veterinarian-client-patient relationship for the animal patient or prepares the compounded drug preparation for office stock, or by a registered veterinary technician under the direct supervision of that veterinarian.

(c) "Compounding" does not include:
(1) Reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal, topical, or injectable administration.~~, nor does it include~~
(2) T~~t~~he sole act of tablet splitting or crushing, capsule opening.~~, or the~~
(3) A~~a~~ddition of flavoring agent(s) to enhance palatability.;

(d) "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.

(e) "Office stock" means a compounded drug prepared without a patient-specific prescription that may be dispensed only to a client, client's representative, or other veterinarian at the same veterinary premises.

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~~*, through reliance on drug compounding standards in the profession and in accordance with section 2032*.

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

(c) A veterinarian shall not perform *either sterile or non-sterile* drug compounding unless there are no other human or animal drugs approved by the United States Food and Drug Administration (FDA) and available that satisfy the need for this preparation.

(d) Sterile drug 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 for this preparation.~~
(2~~3~~) There is historical documentation of the need, safety, and efficacy of the preparation.

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

(f) For non-sterile compounded drug preparations, active pharmaceutical ingredients (APIs) shall be purchased from an FDA-registered facility, and all records of such purchases shall be maintained for three (3) years to prove the origin of the APIs.

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~~who 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.

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

(b) All other compounded drug preparations shall be labeled with the following information:

(1) Name, strength, and quantity of each ingredient.
(2) Expiration date.
(3) Lot number or control number assigned by the preparer.
(4) Name or initials of the preparer.
(5) Date of drug preparation.

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 *immediately* ~~*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) *The board may review* ~~R~~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*~~ 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.