Veterinary Medical Board
BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY • GAVIN NEWSOM, GOVERNOR
DEPARTMENT OF CONSUMER AFFAIRS • VETERINARY MEDICAL BOARD
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MEMORANDUM

DATE	December 31, 2020
TO	Veterinary Medical Board
FROM	Justin Sotelo, Lead Administrative & Policy Analyst
SUBJECT	**Agenda Item 11.E. Sections 2090-2095, Article 11, Division 20, Title 16 of the CCR Regarding Drug Compounding**

Background

The Drug Compounding regulatory proposal was originally approved by the Board in October 2017. The language was later revised and approved again on October 10, 2019 and January 30, 2020. On March 12, 2020, the regulatory package was submitted to the Department of Consumer Affairs (DCA) Director and approved on March 22, 2020. On April 20, 2020, the package was submitted to the Business, Consumer Services, and Housing Agency (Agency) and approved on June 23, 2020.

The package was then submitted to the Office of Administrative Law (OAL) on June 30, 2020, and published on July 17, 2020. The 45-day public comment period closed on August 31, 2020, and the Board received three written comments (two comments in support of the proposed language, and one comment in support with recommendations). On October 22, 2020, the Board approved responses (Attachment 1) to the comments received and approved Modified Text (Attachment 2) to resolve the concerns raised.

The 15-day public comment period on the Modified Text closed on December 4, 2020. The Board received one written comment with recommendations on the Modified Text (Attachment 3). Upon addressing the comment with recommendations, staff will incorporate the Board's responses into the Final Statement of Reasons (FSR), which will be included in the final rulemaking package.

Summary of Comments with Recommendations Regarding the Modified Text and Proposed Responses

In accordance with Government Code section 11346.9, subdivision (a)(3), the Board, in its FSR supporting the rulemaking, must summarize each objection or recommendation made regarding the specific adoption, amendment, or repeal proposed, together with an

explanation of how the proposed action has been changed to accommodate each objection or recommendation, or the reasons for making no change.

The Board received written comments from the Animal Health Institute (AHI) (Attachment 3), which provided recommendations regarding the Modified Text. The Board is asked to review the recommendations and proposed responses for inclusion in the Board's FSR for this rulemaking.

Recommendations: Summarized below are the recommendations provided by AHI during the 15-day public comment period.

1. AHI asserts that the use of bulk substances should be a last resort and recommends the use of bulk substances should conform to a list of approved bulk substances that may be included in final federal guidance.

   Proposed Response: The Board believes that veterinarian drug compounding from bulk substances will be an infrequent occurrence based on typical veterinarian practice over the past 40 years. As such, it appears veterinarians already compound from bulk substances as a last resort. Further, at AHI's recommendation, the Board added and circulated as Modified Text California Code of Regulations (CCR), title 16, section 2091, subsection (c), which would prohibit a veterinarian from performing drug compounding unless there are no other human or animal drugs approved by the United States Food and Drug Administration (FDA) and available to satisfy the need for the compounded drug preparation. This added provision sufficiently restricts the use of drug compounding, including preparations made from bulk substances, to only circumstances where the veterinarian is unable to prescribe, dispense, or administer an FDA-approved human or animal drug to treat the animal patient.

   The FDA has stated that a List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals or Antidotes for Food-Producing Animals will be finalized after the draft GFI #256, Compounding Animal Drugs from Bulk Substances is finalized. (U.S. FDA, Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals or Antidotes for Food-Producing Animals (Nov. 19, 2019) <https://www.fda.gov/animal-veterinary/animal-drug-compounding/bulk-drug-substances-compounding-office-stock-drugs-use-nonfood-producing-animals-or-antidotes-food> [as of Dec. 9, 2020].) The draft GFI is still under review and has yet to be enacted. If the Board's proposal included reference to a draft list associated with a draft guidance document, the proposal would suffer a consistency insufficiency when reviewed by the OAL. Government Code sections 11349 and 11349.1 require regulatory proposals to be reviewed for consistency, meaning that the proposal must be in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions, or other provisions of law. Given the uncertainty of the draft GFI and list, the Board is unable to incorporate a reference to the draft list in the Board's proposed regulations.

2. AHI recommends the provision for non-sterile drugs in proposed CCR, section 2091, subsection (e), clarify that only FDA-approved animal and human drugs be used for non-sterile compounds when they offer the needed active pharmaceutical ingredients (APIs). AHI asserts that while the requirement for sourcing bulk API's from FDA-regulated facilities is a good step, it is no guarantee of quality or actual oversight by the FDA. AHI states that while the FDA inspects and registers manufacturing facilities, they do not approve APIs; rather, the API manufacturing and control process is approved as part of the federal Center for Veterinary Medicine's (CVM) animal drug product approval process. AHI asserts that being an FDA-registered facility does not mean the facility is approved to make the specific API purchased in bulk by compounders. AHI argues that the manufacturing process for a unique molecule is, by definition, unique, which is why the FDA has chemistry, manufacturing, and control requirements that every manufacturer must meet for every individual product it makes. In addition, AHI notes that the facility, whether domestic or foreign, must be physically inspected to ensure compliance for all products manufactured at that facility. Under the current system, AHI argues that even if one assumes a compounding pharmacy bought an API from an FDA-registered facility, that API could have been manufactured in a severely inadequate process lacking the necessary controls for quality, consistency, purity, and stability. AHI alleges that this thorough vetting by the CVM animal drug product approval process is lacking in drug substances used for compounded formulas sourced from FDA-registered manufacturing facilities and circumvents the agency's role of ensuring safe drug products marketed in the United States for the treatment of animals.

   Because of this gap, AHI argues there is simply no way for veterinarians to know the origin or quality of the API they might purchase and use in the preparation of non-sterile compounds to give to their patients. When these non-sterile compounds are used as office stock, AHI believes they should contain only substances that appear on the Approved List of Bulk Substances proposed by FDA, but not yet adopted.

   Proposed Response: With respect to the Board's veterinarian licensees who perform drug compounding, the Board has carefully crafted regulatory language to address the issues raised by AHI, and at AHI's request, the Board included in the Modified Text proposed for CCR, title 16, section 2091, subsection (f), to clarify that APIs for non-sterile compounded drug preparations must be purchased from an FDA-registered facility. However, the Board recognizes that the FDA and CVM oversee and regulate prescription drugs, APIs, drug manufacturers, manufacturing facilities, and the API manufacturing and control process. The Board does not seek to provide oversight and regulation in these fields otherwise occupied by the FDA and CVM and recommends that AHI seek amendments to the federal regulations to enhance consumer protections regarding quality, consistency, purity, and stability controls in the API manufacturing process. Further, for the reasons stated above, the Board is unable to include references to the FDA's draft list.

Action Requested

The Board is asked to consider and approve the proposed responses to the written comments with recommendations received during the 15-day public comment period, and direct staff to incorporate the responses into the FSR when proceeding with the final rulemaking package.

Attachments:
1. Board-Approved Responses to Public Comment, as detailed in October 14, 2020 Memorandum
2. Modified Text
3. Letter from Animal Health Institute, dated December 4, 2020

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MEMORANDUM

DATE	October 14, 2020
TO	Veterinary Medical Board
FROM	Justin Sotelo, Lead Administrative & Policy Analyst
SUBJECT	**Agenda Item 9.G. Sections 2090-2095, Article 11, Division 20, Title 16 of the CCR Regarding Drug Compounding**

Background

The Drug Compounding regulatory proposal was originally approved by the Board in October 2017, but language was later revised and approved again on October 10, 2019 and January 30, 2020. On March 12, 2020, the regulatory package was submitted to the Department of Consumer Affairs (DCA) Director and approved on March 22, 2020. On April 20, 2020, the package was submitted to the Business, Consumer Services, and Housing Agency (Agency) and approved on June 23, 2020.

The package was then submitted to the Office of Administrative Law (OAL) on June 30, 2020, and published on July 17, 2020. The 45-day public comment period closed on August 31, 2020, and the Board received three written comments (two comments in support of the proposed language (**Attachment 1**), and one comment in support with recommendations (**Attachment 2**)). Upon addressing the comment with recommendations, staff will incorporate the Board's responses into the Final Statement of Reasons (FSR), which will be included in the final rulemaking package.

Summary of Comment with Recommendations Regarding the Proposal and Proposed Responses

In accordance with Government Code section 11346.9, subdivision (a)(3), the Board, in its FSR supporting the rulemaking, must summarize each objection or recommendation made regarding the specific adoption, amendment, or repeal proposed, together with an explanation of how the proposed action has been changed to accommodate each objection or recommendation, or the reasons for making no change.

The Board received a written comment from the Animal Health Institute (AHI) (**Attachment 2**), which provided several recommendations regarding the proposed regulatory language. The Board is asked to review the recommendations and proposed responses thereto for inclusion in the Board's FSR for this rulemaking. The proposed

revisions to the regulatory text to resolve some of these recommendations are provided in the next section.

Recommendations: Summarized below are the recommendations provided by AHI during the 45-day public comment.

1. AHI cautions the Board against finalizing its regulations prior to the United States Food and Drug Administration (FDA) finalizing Guidance for Industry #256 (draft GFI), as AHI believes the proposed regulations must be consistent with federal guidance regarding compounding from bulk drug substances. AHI asserts that the federal guidance makes it clear that compounding animal preparations from bulk drug substances is illegal. However, AHI notes that because not all active ingredients needed to care for animal patients can be found in approved products, FDA uses enforcement discretion to allow for limited compounding from bulk substances. AHI contends that the draft GFI provides clear guidelines for compounding from bulk that will be allowed by enforcement discretion and that which will remain legally enforceable.

   Proposed Response: As discussed in greater detail in the Initial Statement of Reasons (**Attachment 4**) prepared for this rulemaking, California licensed veterinarians have been compounding drugs for their animal patients for many years. Yet, the California State Legislature only recently acknowledged and authorized veterinarian drug compounding. Senate Bill (SB) 1193 (Hill, Chapter 484, Statutes of 2016) enacted statutory authority for a licensed veterinarian or supervised registered veterinary technician (RVT) to compound drugs for animal use pursuant to the Code of Federal Regulations (CFR), title 21, section 530, and in accordance with regulations promulgated by the Board.

   SB 1193 did not provide specific definitions, practice provisions, or compounding processes. Rather, SB 1193 left these provisions up to the Board's regulations to address, at minimum, the storage of drugs, level and type of supervision required for compounded drugs by an RVT, and the equipment necessary for the safe compounding of drugs. (Business and Professions Code (BPC) § 4826.5.) After considerable deliberation on drug compounding issues and the provisions necessary to ensure consumer and animal safety, the Board's regulatory proposal is moving forward through the regulatory process.

   At the same time, the draft GFI has proceeded on its own rulemaking path. The draft GFI was published for public comment on November 19, 2019, has yet to be adopted, and is pending its latest public comment period, which closes on October 15, 2020. Given the uncertainty of whether the draft GFI will be adopted, the Board believes it must continue moving this regulatory proposal forward to ensure the safety of California consumers and their animals.

2. AHI asks the Board to adopt provisions of federal guidance related to the use of bulk substances in animal drug compounding. AHI offers the following

recommendations to ensure uniformity with federal guidance on bulk drug substances:

a. AHI notes that the draft GFI limits compounding for office stock to a list of substances on the FDA's "List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals or Antidotes for Food Producing Animals" (List). AHI contends that this limitation should be added to the California regulations.

   Proposed Response: The FDA has stated that the List will be finalized after the draft GFI is finalized. (U.S. FDA, Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals or Antidotes for Food-Producing Animals (Nov. 19, 2019) <https://www.fda.gov/animal-veterinary/animal-drug-compounding/bulk-drug-substances-compounding-office-stock-drugs-use-nonfood-producing-animals-or-antidotes-food> [as of Oct. 12, 2020].) The draft GFI is still under review and has yet to be enacted. If the Board's proposal included reference to a draft list associated with a draft guidance document, the proposal would suffer a consistency insufficiency when reviewed by the OAL. Government Code sections 11349 and 11349.1 require regulatory proposals to be reviewed for consistency, meaning in harmony with, and not in conflict with or contradictory to existing statutes, court decisions, or other provisions of law. Given the uncertainty of the draft GFI and List, the Board is unable to incorporate a reference to the draft List in the Board's proposed regulations.

b. AHI states that the proposed regulation refers to, but does not define, office stock. AHI asserts that the draft GFI makes it clear that office stock are drugs dispensed to the animal owner/caretaker or another veterinarian in the same practice and not to a third party. AHI recommends including a similar definition of office stock in the proposed regulation and, also, specifically prohibit the compounding of copies or near-copies of FDA approved products.

   Propose Response: The Board agrees that the proposed regulation should be clarified to define office stock and exclude compounded drug preparations to be dispensed or transferred to a distributor, retailer, or veterinarian at another veterinary premises. The Modified Text adds new subsection (e) to proposed California Code of Regulations (CCR), title 16,[1] section 2090 to define "office stock" to mean 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. This definition of office stock intentionally excludes distribution or transfer to a distributor, retailer, or veterinarian at another premises so that such conduct is not authorized under the rulemaking. [See proposed revisions to proposal submitted below for Board review and approval.]

[1] All further references to the CCR refer to title 16.

With respect to addressing compounding of copies or near-copies of FDA approved drugs, BPC section 4826.5 only allows drugs to be compounded pursuant to CFR, title 21, section 530, which prohibits compounding unless there is no approved new animal or approved new human drug available in the dosage form and concentration that will appropriately treat the condition diagnosed. (CFR, tit. 21, § 530.13, subd. (b)(2).) If an FDA-approved drug is available to treat the animal patient, that drug must be used rather than a compounded drug prepared to copy the otherwise available FDA-approved drug. Although a veterinarian would be prohibited from compounding a preparation to copy an FDA-approved drug, the Modified Text resolves this issue by clarifying, in proposed CCR section 2091, new subsection (c), that a veterinarian cannot perform drug compounding unless there are no other human or animal drugs approved by the FDA and available that satisfy the need for the drug preparation.

c. AHI notes that the proposed regulation allows compounding in "veterinary premises," which is broadly defined elsewhere in statute and regulation. However, AHI points out that the rationale document (Initial Statement of Reasons – **Attachment 4**) uses the term "veterinary office." AHI asserts that a definition of "veterinary premise" should be included to guard against the establishment of a single person "clinic" becoming a front for a commercial compounding operation.

   Propose Response: A veterinarian may only practice veterinary medicine, including drug compounding for prescribing, dispensing, and administering medication for animal patients, from a veterinary premises registered with the Board. (BPC § 4853.) The term "veterinary premises" is defined in statute. (BPC § 4853, subd. (b).) The proposed regulations do not authorize a veterinarian to compound drug preparations in, or from a location that is not registered or identified and declared as associated with, a registered veterinary premises. Accordingly, the Board is rejecting the recommendation to add a duplicative definition of veterinary premises in the proposed regulations.

d. AHI raises concern about potential changes to the veterinarian-client-patient relationship (VCPR) due to expanded interest in telemedicine, along with the advent of medical technology, like wearable diagnostics. AHI recommends that the Board consider a definition of VCPR specific to compounding to avoid an unintentional expansion of veterinary compounding should the state change the definition of the VCPR in the future.

   Proposed Response: Although the California State Legislature identified the VCPR requirement in statute, the VCPR is defined in regulation. (BPC §§ 4830, subd. (a)(2), 4875.1, subd. (a)(7); CCR, tit. 16, § 2032.1.) Since the California State Legislature has left the definition of the VCPR up to the Board to determine, and the Board has defined both the VCPR and telemedicine in CCR section 2032.1, the Board is rejecting this recommendation. In the event

the expansion of telemedicine affects the VCPR, the Board will consider those affects in relation to drug compounding.

e. AHI notes that proposed CCR section 2090, subsection (a) appears to define the type of compounding allowable by federal law under the Animal Medicinal Drug Use Clarification Act (AMDUCA). For additional clarity, AHI recommends that for non-sterile compounding, the active ingredients must originate in an FDA-approved veterinary product or products. When approved veterinary products are not available, FDA-approved human products should be used.

   AHI further notes that, in the rare event that needed active ingredients are not available in veterinary or human products approved by FDA, proposed CCR section 2090, subsection (b) would allow compounding from bulk active ingredients for non-sterile preparations. Given the added risk associated with this source, AHI contends the regulations should require that bulk active pharmaceutical ingredients (APIs) be purchased from an FDA-registered facility, records (including invoices, bills of lading, etc.) should be kept to prove the origin of the APIs, and state inspections of veterinary facilities should include inspection of compliance with these requirements.

   Proposed Response: The Board agrees the proposal should be clarified. The Modified Text would add new subsection (f) to proposed section 2091 and require APIs to be purchased from an FDA-registered facility, and require all records of those purchases to be kept for three years. However, the Board already inspects veterinary premises to ensure compliance with all statutory and regulatory requirements. Therefore, it is unnecessary to add a requirement in this proposal for the Board to inspect the veterinary premises for compliance with the drug compounding regulations.

f. AHI states that proposed CCR section 2095 allows, but does not require, veterinarians to include reports of drug contraindications and adverse events in the quality assurance documentation. As the draft GFI requires reporting of adverse events and establishes a specific form and timeline for doing so, AHI recommends that this requirement also be included in the regulations.

   Proposed Response: The draft GFI includes an adverse event reporting requirement and would rely on the FDA reporting process currently in place. However, the Board has no current process to receive reports of adverse drug affects, has no statutory authority to receive such reports, and is not equipped or staffed to receive or investigate individual adverse events involving drug compounding. Accordingly, the Board must reject this recommendation.

Proposed Revisions to the Regulatory Proposal for Board Consideration

To resolve some of the concerns raised above and better clarify the proposal, the Board is being asked to consider modifications to the proposed regulatory language that would:

1. Make minor, technical revisions to proposed CCR section 2090, subsection (c).
2. Add new subsection (e) to proposed CCR section 2090 to define "office stock" and limit the individuals to whom such compounded drug preparations may be distributed.
3. Revise proposed CCR section 2091, subsection (a) to remove overbroad and unnecessary language.
4. Add new subsection (c) to proposed CCR section 2091 to clarify that a veterinarian cannot perform drug compounding unless there are no other human or animal drugs approved by the FDA and available to satisfy the need for the preparation.
5. Revise CCR section 2091, subsection (c) to:
    a. Reletter the subsection as (d) and make a clarifying revision.
    b. Strike paragraph (2) due to redundancy; the provisions in this paragraph are being moved up to new subsection (c).
6. Revise CCR section 2091, subsection (d) to reletter the subsection as (e) and make minor, clarifying revisions.
7. Add new subsection (f) to proposed CCR section 2091 to clarify that active pharmaceutical ingredients (APIs) for non-sterile compounded drug preparations must be purchased from an FDA-registered facility. The proposal would require those records to be maintained for three years to prove the origin of those ingredients. This three-year time frame conforms to the medical record retention requirement established in CCR section 2032.3,subsection (b).
8. Revise proposed CCR section 2092, subsection (e) to make a technical revision in paragraph (1), and strike paragraph (6), which is duplicative of paragraph (3).
9. Revise proposed CCR section 2094 to specify the labeling requirements for a dispensed compounded drug preparation.
10. Add new subsection (b) to proposed CCR section 2094 to specify the labeling requirements for a compounded drug preparation that is not dispensed.

Action Requested

The Board is asked to consider and approve the proposed responses to the written comment with recommendations received during the 45-day public comment period, and direct staff to incorporate the responses into the FSR when proceeding with the final rulemaking package.

Additionally, the Board is asked to review and consider a motion to approve the proposed Modified Text for a 15-day 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 regulatory changes, as modified, and also delegate to the Executive Officer the authority to make any technical or non-substantive changes that may be required in completing the rulemaking file.

Attachments:

1. Comments in Support from: (1) Jon Klingborg, DVM, Valley Animal Hospital of Merced; and (2) Michael Blaire, R. Ph., FIACP, Vice President, Government and Regulatory Affairs, Wedgewood Village Pharmacy, LLC
2. Comment in Support with Recommendations from Ronald B. Phillips, Vice President, Legislative and Public Affairs, Animal Health Institute
3. Notice of Proposed Changes
4. Initial Statement of Reasons
5. Proposed Modified Text

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

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.

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~~.

(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) 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.

(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 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 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.

ANIMAL HEALTH INSTITUTE

Representing manufacturers of animal health products

December 4, 2020

Justin Sotelo
Veterinary Medical Board
1747 North Market Blvd., Suite 230
Sacramento, CA 95834

Re: NOTICE OF PROPOSED REGULATORY ACTION CONCERNING: Title 16, Division 20, Article 11. Veterinary Compounding

The Animal Health Institute (AHI) submits these comments regarding the proposed regulatory action on Title 16, Article 11 for Compounding in a Veterinary Premise.

AHI is the US trade association for research-based manufacturers of animal health products – the pharmaceuticals, biological products, and feed additives used in modern food production, and the medicines that keep livestock and pets healthy. Our members are sponsors for a majority of the pioneer animal drugs approved by FDA.

As stated in previous comments, AHI supports the effort by the California Veterinary Medical Board to clarify the ability of veterinarians to compound medications in their practices for a specific patient and under a valid veterinary-client-patient-relationship.

We appreciate the responsiveness of the Veterinary Medical Board in responding to previous stakeholder comments and offer these comments on the most recent modifications.

The modifications create separate paragraphs for sterile and non-sterile drugs in Section 2091. While FDA approved drugs must be used as the source of ingredients for sterile compounds, the only requirement for non-sterile is sourcing of active pharmaceutical ingredients from FDA registered facilities. We suggest the rules clarify that FDA approved animal and human drugs be used for non-sterile compounds when they offer the needed API. The use of bulk substances should be a last resort, and should conform to any list of approved bulk substances that may be included in final federal guidance.

While the requirement for sourcing these bulk API's from FDA-regulated facilities is a good step, it is no guarantee of quality or oversight by FDA. While FDA does register manufacturing facilities, they do not "approve" APIs; rather the API manufacturing and control process is approved as part of CVM's animal drug product approval process. Moreover, being a registered facility does not mean that the facility is approved to make the specific API purchased in bulk by compounders. The manufacturing process for a unique molecule is, by definition unique. That is why FDA has chemistry, manufacturing, and control (CMC) requirements that every manufacturer must meet for every individual product it makes. In addition, the facility, whether domestic or foreign, must be physically inspected to ensure GMP compliance for all products

manufactured at that facility. Under the current system, even if one assumes a compounding pharmacy bought an API from an “FDA registered facility”, that API could have been manufactured in a severely inadequate process lacking controls for quality, consistency, purity, and stability. This thorough vetting process by FDA is clearly lacking in drug substances used for compounded formulas and circumvents the agency's role of ensuring safe drug products marketed in the USA for the treatment of animals.

Because of this gap, there is simply no way for veterinarians to know the origin or quality of the API they might purchase and use in the preparation of products to give to their patients. When these products are used as office stock, we believe only substances that appear on the Approved List of Bulk Substances proposed by FDA should be allowed.

Again, thank you for the opportunity to comment.

Sincerely,

Ronald B. Phillips