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	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

Valley Animal Hospital
58 W. 16th Street, Merced
209. 384.7387

ATTN: Veterinary Medical Board

RE: Drug Compounding

As a practicing small animal veterinarian, I am challenged every day to provide necessary medications to animals ranging in size from a few ounces (e.g. cute fuzzy newborn kittens) up to 150 pounds (really big dogs!)

The ability to compound medications— both sterile and non-sterile compounding— is critically important for my animal patients and the People who care for those animals.

These Compounding regulations are reasonable and have the benefit of history— the profession has been compounding in this manner for years and we have decades of anecdotal data regarding the safety and efficacy of compounding as described within proposed CCR 2090 - 2095.

Sincerely,

Jon Klingborg, DVM

wedgewood PHARMACY

GREAT CARE, DELIVERED.™

DEPARTMENT OF CONSUMER AFFAIRS
VETERINARY MEDICAL BOARD
1747 North Market Blvd., Suite 230
Sacramento, CA 95834-2978

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

Dear Mr. Sotelo and Members of the Board:

I write on behalf of Wedgewood Village Pharmacy, LLC, a California licensed, non-resident pharmacy engaged in the practice of compounding sterile and non-sterile medications for animal use.
We appreciate the opportunity to comment on the proposed language for Sections 2090-2096, Article 11, Division 20, Title 16 of the CCR regarding drug compounding in veterinary facilities. We are writing in support of the proposed language, as we believe it is critical for veterinarians to have the ability to compound medications they require for their patients' immediate use. However, it is incumbent on the veterinarian to ensure that these medications are provided in a manner consistent with the Board's mission to protect the public safety.

Compounded medication is essential to the practice of veterinary medicine because, unlike medical doctors, veterinarians treat a wide variety of species, all of varying sizes, each of which face their own unique set of health conditions and diseases and which require specific types, amounts, dosages, and dosage forms of medications. Inherently, commercially available drugs cannot satisfy the wide variety of animal patient needs. As a result, compounded drugs are used where, in the judgment of veterinarians, there is no suitable commercially manufactured drug product available to appropriately treat their animal patients. But, the unique nature of veterinary medicine requires not only access to compounded medication, but ***immediate*** access to compounded medications for "office use," *i.e.* compounded medication that is readily available, in the veterinarian's office or to travel with the veterinarian, to treat

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animal patients in off-site or emergency situations. Without access to compounded medications for office use animal patients would not receive the medical treatment they often desperately need. Therefore, we applaud the Veterinary Medical Board for taking the steps necessary to ensure that veterinarians always retain the ability to compound medications within their own facilities for administration or dispensing to their patients.

Likewise, we commend the Board for recognizing the need for animal medications to be compounded from bulk drug substances [2090(a)(4)]. For over 2 decades it has been contested whether The Food and Drug Administration (FDA) has authority to regulate the practice of compounding medications for animals. Nowhere in the language of the Animal Medicinal Drug Use Clarification Act (AMDUCA) is compounding even mentioned. It is only in the implementing regulations that FDA inserted Section 530.13(a) which, although it cannot be construed as permitting compounding of animal drugs from bulk drug substances, it does not prohibit it either. Furthermore, there is no scientific evidence to support the idea that compounding from bulk drug substances is less safe than using finished product as starting material. In fact, several studies show that the potency of drugs compounded using finished product as starting material varied as much as $\pm$ 20%. Additionally, many commercially available finished products contain excipient materials that can reduce the palatability of compounded preparations. In some cases, these excipients can be toxic to animals.

Because veterinarians and veterinary facilities will be required to comply with the compounding standards established by the United States Pharmacopoeia (USP) General Chapters <795>, <797> and <800>, we would anticipate that compounding in veterinary facilities would be reserved for those urgent situations when an FDA-approved product or a compounded preparation from a compounding pharmacy cannot be obtained in a timely manner. We would not want to see veterinary clinics compounding transdermal gels, eye drops or multi-dose injectable preparations without the proper training, equipment and environmental controls. These concerns are addressed in Section 2091, and we hope that the Veterinary Medical Board will devote the resources to ensure practitioner compliance.

In conclusion, we reiterate our support for the proposed language. In the pursuit of optimal patient care, veterinarians must be guaranteed the right to compound preparations in veterinary facilities. Furthermore, it is the veterinarian, not a Federal agency, who should decide the best therapeutic option for a patient, and how that therapeutic option shall be obtained. We hope that the board finds the information herein to be useful in its discussions and would be happy to appear or provide additional information or comments.

Respectfully Submitted,

Michael Blaire, R. Ph., FIACP
Vice President: Government and Regulatory Affairs

ANIMAL HEALTH INSTITUTE
Representing manufacturers of animal health products

August 26, 2020

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

Re: NOTICE OF PROPOSED REGULATORY ACTION CONCERNING: Title 16, 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.

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.

Safe and effective medicines are important tools for veterinarians. While approval by the Food and Drug Administration provides these guarantees of safety and effectiveness, an approved drug is not always available to treat an animal condition. In these instances, veterinarians need access to compounded medicines.

AHI supports veterinarians' use of legal compounding to meet patient specific medical needs. Veterinarians' ability to manipulate an approved drug to meet medical needs for a specific patient in spelled out in the Animal Medicinal Drug Use Clarification Act (AMDUCA). The language being proposed allows this type of compounding to be performed by veterinarians in their places of business, and AHI fully supports this practice.

The draft proposal also allows for compounding from bulk active ingredients. As the Veterinary Medical Board has acknowledged, compounding animal drugs from bulk substances is currently the issue of Draft Guidance for Industry #256 by the FDA's Center for Veterinary Medicine. We caution against finalizing these draft rules prior to FDA finalizing GFI #256 as we believe these rules must be consistent with federal guidance regarding compounding from bulk drug substances.

The federal guidance makes it clear that compounding animal preparations from bulk drug substances is illegal. However, 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. Draft GFI #256 provides clear guidelines for compounding from bulk that will be allowed by enforcement discretion and that which will remain legally enforceable.

The federal rules are necessary because some pharmacies have used this regulatory discretion as a license to act like a drug manufacturer. They use bulk substances as active ingredients to produce large batches of drugs that are copies or near copies of approved drugs. These compounds have not been tested like FDA-approved drugs have been and do not carry the guarantees of safety and efficacy like FDA approved drugs. Errors in the preparation of such compounds have resulted in at least three instances of horses across several states dying or being euthanized due to the harm caused by these compounded products.

We ask that California, in developing rules, adopt provisions of federal guidance related to the use of bulk substances in animal drug compounding. We offer the following suggestions to ensure uniformity with federal guidance on bulk drug substances, should the Board decide to move ahead before the Federal guidance is finalized:

The draft proposal requires compounding from bulk for office stock to be done by or under the supervision of a veterinarian. In addition, draft GFI #256 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." This limitation should be added to the California regulations.

The draft regulation refers to, but does not define, office stock. Draft GFI #256 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. We suggest a similar definition of office stock be included in the regulation. In addition, the definition should specifically prohibit the compounding of copies or near-copies of FDA approved products. Such a definition will also meet the MDC-stated desire that the regulations not allow for commercial compounding.

The proposed rules allow compounding in "veterinary premises," which is broadly defined elsewhere in statute and regulation. The rationale document uses the term "veterinary office." We recommend a definition of "veterinary premise" to guard against the establishment of a single person "clinic" becoming a front for a commercial compounding operation.

We strongly support the requirement of a valid VCPR between the compounding veterinarian and patient. This requirement will help prevent commercial compounding in a small animal setting but is less of a hurdle in an equine setting, where compounding abuses have led to horse deaths. While California currently has strict rules regarding establishment of a VCPR, we note that the expanded interest in telemedicine along with the advent of medical technology like wearable diagnostics could lead to changes in the definition of a VCPR. We recommend the board consider a definition of VCPR specific to compounding to avoid an unintentional expansion of veterinary compounding should the state change this definition in the future.

Section 2090 (a) appears to define the type of compounding allowable by federal law under the Animal Medicinal Drug Use Clarification Act (AMDUCA). For additional clarity we recommend a requirement 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.
In the rare event that needed active ingredients are not available in veterinary or human products approved by FDA, Section 2090 (b) allows compounding from bulk active ingredients for non-sterile preparations. Given the added risk associated with this source, the rules should require that bulk API 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.

Finally, Section 2095 allows, but does not require, veterinarians to include reports of drug contraindications and adverse events in the quality assurance documentation. As GFI #256 requires reporting of adverse events and establishes a specific form and timeline for doing so, we ask that this requirement be included in the regulations.

California's effort will clarify the ability of veterinarians to compound patient specific medicine in-house while federal efforts are making progress to better regulate commercial compounding from bulk drug substances. More specifically, the Food and Drug Administration's Guidance 256, once finalized, will allow veterinarians meet medical needs of patients while not allowing commercial compounders to endanger animal health by acting like unregulated drug manufacturers. We agree with the sentiments of the Multidisciplinary Advisory Committee (MDC) as recorded in the rationale document that the proposed California regulations are not intended to allow commercial drug compounding but are to be limited to compounding drugs in a veterinary office for the treatment of an animal patient. AHI applauds the Board's decision to comply with federal guidance and appreciate the opportunity to offer these recommendations to achieve that end.

Thank you for the opportunity to provide comments.

Sincerely,

Ronald B. Phillips
Vice President, Legislative and Public Affairs

TITLE 16
VETERINARY MEDICAL BOARD

NOTICE OF PROPOSED REGULATORY ACTION CONCERNING

Article 11. Compounding in a Veterinary Premises
Definitions, § 2090
Veterinary Drug Compounding, § 2091
Policies and Procedures, § 2092
Expiration Dates, § 2093
Labeling of Compounded Preparations, § 2094
Quality Assurance, § 2095

NOTICE IS HEREBY GIVEN that the Veterinary Medical Board ("Board") is proposing to take the action described in the Informative Digest.

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, 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 August 31,2020**, or must be received by the Board at the hearing, should one be scheduled.

AVAILABILITY OF MODIFICATIONS

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 will be available for 15 days prior to its adoption from the person designated in this Notice as the Contact Person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

AUTHORITY AND REFERENCE

Pursuant to the authority vested by section 4826.5 of the Business and Professions Code (BPC), and to implement, interpret, or make specific that section, the Board is considering adopting article 11 of division 20 of title 16 of the California Code of Regulations (CCR)[1], and adopting sections 2090, 2091, 2092, 2093, 2094, and 2095 of article 11 of division 20 of title 16 of the CCR.

INFORMATIVE DIGEST

BPC section 4826.5 authorizes veterinarians and registered veterinary technicians (RVTs) to provide limited drug compounding services for animal patients and requires the Board to adopt regulations defining the parameters of drug compounding services in veterinary premises. As such, the Board has promulgated regulations that provide minimum standards for drug compounding services performed by veterinarians and RVTs in veterinary premises.

This regulatory proposal will adopt CCR sections 2090, 2091, 2092, 2093, 2094, and 2095 to define drug compounding in veterinary premises and the parameters of a veterinarian or RVT providing drug compounding services, mandate that veterinary premises develop policies regarding drug compounding services, identify expiration dates for sterile and non-sterile drugs, enforce labeling requirements for compounded drugs, and require quality assurance protocols for drug compounding.

POLICY STATEMENT OVERVIEW/ANTICIPATED BENEFITS OF PROPOSAL

The primary mission of the Board is to protect consumers and animals through the development and maintenance of professional standards. This regulatory proposal promotes the health, safety, and welfare of consumers and their animals by clarifying the requirements as mandated in BPC section 4826.5 regarding drug compounding in veterinary medicine. By adopting the proposed regulations, the Board seeks to ensure that all veterinarians and RVTs providing drug compounding services have completed the necessary training requirements and 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.

Consistency and Compatibility with Existing State Regulations

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

[1] All CCR references are to title 16 unless otherwise noted.

FISCAL IMPACT ESTIMATES

The Board will be required to ensure compliance with the proposed regulations through routine inspections of veterinary premises. Any workload and costs are anticipated to be minor and absorbable within existing resources.

Fiscal Impact on Public Agencies Including Costs or Savings to State: The Board anticipates minor and absorbable enforcement-related workload and costs to implement the proposed regulations. Additional costs may be incurred in future Fiscal Years, and the Board may be required to request additional resources through the annual budget process for additional staff to accommodate the review and inspections of the veterinary premises providing drug compounding services.

Cost or Savings in Federal Funding to the State: None

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

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

Business Impact:

The Board has made an initial determination that the proposed regulations will not have a significant adverse economic impact directly affecting businesses, including the ability of California businesses to compete in other states. 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 Board is informed that drug compounding already occurs in veterinary premises. The regulatory proposal would provide 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. The Board is informed that drug compounding already occurs in veterinary premises. The regulatory proposal would provide minimum standards for drug compounding at veterinary premises, and for veterinarians and RVTs wishing to provide drug compounding services.

Effect on Housing Costs: None

EFFECT ON SMALL BUSINESS

The Board has determined that the proposed regulations will not affect small businesses. The proposed regulations would set minimum standards for veterinary premises to adhere to, if they wish to provide drug compounding services, but the Board is informed that drug compounding already occurs in veterinary premises.

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 creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Benefits of Regulation:

This regulatory proposal focuses on developing 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.

CONSIDERATION OF ALTERNATIVES

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.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations, and any document incorporated by reference, and of the initial statement of reasons, 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 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 person named below or by accessing the website listed below.

CONTACT PERSON

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

Name:	Justin Sotelo
Address:	Veterinary Medical Board 1747 North Market Blvd., Suite 230 Sacramento, CA 95834
Telephone No.:	916-515-5238
Fax No.:	916-928-6849
E-Mail Address:	Justin.Sotelo@dca.ca.gov

The backup contact person is:

Name:	Timothy Rodda
Address:	Veterinary Medical Board 1747 North Market Blvd., Suite 230 Sacramento, CA 95834
Telephone No.:	916-515-5227
Fax No.:	916-928-6849
E-Mail Address:	Timothy Rodda@dca.ca.gov

Website Access: Materials regarding this proposal can be found at https://vmb.ca.gov/laws_regs/proposed_regs.shtml.

Veterinary Medical Board
Department of Consumer Affairs

Initial Statement of Reasons

Hearing Date: No hearing has been scheduled for the proposed action.

Subject Matter of Proposed Regulations: Drug Compounding

Sections Affected: California Code of Regulations (CCR), Title 16, Division 20, Article 11, Sections 2090, 2091, 2092, 2093, 2094, and 2095[1]

Background and Problem Statement:
Business and Professions Code (BPC) section 4800.1 mandates that the protection of the public shall be the highest priority of the Veterinary Medical Board (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. The Board enforces the Veterinary Medicine Practice Act (Act) and oversees veterinary licensees, veterinary technician registrants, veterinary premises, and veterinary assistant controlled substance permit holders.

The conversation regarding Drug Compounding in veterinary premises originated at the October 20, 2014 Veterinary Medical Board, Multidisciplinary Advisory Committee (MDC) meeting. The conversation evolved due to a concern in the veterinary community about the ability to compound drugs and the quality of the drugs from existing compounding facilities. It was identified at this meeting that the current authority for veterinarians to compound drugs was incomplete, and there is a need for further clarification. Previously, veterinarians could compound medications through a limited exemption identified in the Pharmacy Law (BPC sections 4051, 4052, and 4127 and CCR sections 1735-1735.8 and 1751), but no specific grant of authority existed in the Act authorizing licensed veterinarians to compound drugs for animal patients. The MDC identified that there was a lack of statutory authority for veterinarians to provide limited compounding services in their practices. Additional concerns raised by the MDC included restrictions on dispensing a 72-hour supply of medications to a patient and the need to develop a veterinarian-client-patient relationship (VCPR) prior to dispensing medications. The MDC voted to recommend that the Board pursue developing a legislative proposal that would provide statutory authority for veterinarians to compound medications within the limitations of federal law.

At the April 28-29, 2015 meeting, the Board discussed the recommendation from the MDC to develop a legislative proposal to allow veterinarians to compound drugs. The Board agreed with the MDC that there was a need to further investigate this issue, but could only do so with the proper statutory authority. The Board unanimously agreed to

[1] All CCR references are to title 16 unless otherwise noted.

move forward with pursuing a legislative proposal to provide an outlet for veterinarians to compound drugs for animal patients. The Board delegated Board staff to work with the California Veterinary Medical Association (CVMA) to develop legislative language and appointed a legislative committee to review legislation of interest.

At the July 21-22, 2015 Board meeting, proposed statutory language regarding drug compounding by veterinarians was presented to the Board for their consideration. The Board identified some concerns with the proposed language, including a lack of defined terms, storage requirements, and the limitations of dispensing only 72-hours of compounded medication. The Board determined that the proposed language required further revisions and delegated to the MDC and CVMA to work on revising the proposed statutory language.

Following the July Board meeting, an MDC subcommittee met with the Executive Officer of the California State Board of Pharmacy (Board of Pharmacy) and its Deputy Attorney General (DAG) to discuss a statutory proposal for limited drug compounding by veterinarians and to discuss compliance issues provided for in pharmacy laws and regulations. This meeting determined that some of the Board's concerns, including the restrictions of dispensing a 72-hour supply to a patient, was not intended to be a dispensing restriction imposed on a veterinarian. Following the meeting, the Board of Pharmacy's DAG drafted proposed language for the MDC's consideration.

At the January 19, 2016 meeting, the MDC discussed current issues regarding veterinary compounding and the proposed language developed by the Board of Pharmacy's DAG (see Tab D.4). The MDC discussed the federal regulation authorizing veterinarian drug compounding (21 CFR § 530.13) and how to address the identified issues without going beyond the federal prohibition on bulk drug compounding. The MDC recommended changes to the proposed statutory language and identified that some of the language should be handled through regulations to provide additional specificity and clarification. The MDC agreed on the recommended changes and to forward the statutory language to the Board for their review and consideration.

The Board reviewed the recommendations from the MDC regarding the proposed statutory language at the January 20-21, 2016 meeting. The Board voted to present the language as presented to the Legislative Subcommittee to carry a bill to authorize veterinarians to compound drugs.

Senate Bill (SB) 1193 (Hill, Chapter 484, Statutes of 2016) incorporated the Board's proposed language to authorize limited compounding by veterinarians. The Board discussed SB 1193 at the April 20-21, 2016 meeting and requested amendments to SB 1193 to allow a broader grant of authority for veterinarians to compound drugs with a provision that, by regulation, the Board and Board of Pharmacy would work together to define the limitations of the drug compounding authority of veterinarians. The Board voted to revise the proposed statutory language and request amendments to SB 1193.

At the July 19, 2016 meeting, the MDC discussed the 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,"[2]and proposed Pharmacy Board regulations regarding drug compounding for consideration when developing drug compounding regulations for veterinary medicine. The proposed regulations included a definition of compounding that was modeled upon the Board of Pharmacy regulations (CCR section 1735). Public comments received included concerns regarding the quality of products received from existing compounding pharmacies, when the veterinarians are unable to compound their own medications. The MDC also discussed whether to define bulk compounding and determine its necessity in regulations.

At the January 17, 2017 meeting, the MDC reviewed SB 1193, which was approved by the Governor and went into effect on January 1, 2017, and provided statutory authority for the Board to create regulations that would clarify the process for veterinarians to compound drugs. The MDC and members of the public reviewed the proposed regulatory language and suggested several substantive revisions, but agreed to continue reviewing the proposed regulatory language at subsequent meetings to ensure all issues were addressed.

On April 14, 2017, an MDC subcommittee met with the 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. At the April 18, 2017 meeting, the MDC discussed the details of the meeting with the Board of Pharmacy and continued to review the proposed regulatory language for drug compounding. The MDC also discussed the United States Pharmacopeia (USP) 800 that would be introduced and impact a veterinarian's ability to compound chemotherapy and hazardous drugs.

At the July 25, 2017 meeting, the MDC revisited the topic of drug compounding and clarified that the regulations were not intended for commercial drug compounding, but are to be limited to compounding drugs in a veterinary office for the treatment of an animal patient. The MDC made amendments to the proposed regulatory language and voted to move the language forward to the Board for their consideration.

The Board reviewed the MDC approved language at the October 18-19, 2017 meeting. The Board discussed the language and made minor revisions to include reference to new CCR section 2095, subsection (d) regarding animal patient records. The Board moved to accept the proposed regulatory language as amended and directed Board staff to proceed with developing the regulatory file.

[2] On November 7, 2017, the FDA announced withdrawal of draft guidance document #230 and stated its intention to issue a new draft for public comment in 2018. Subsequently, an FDA draft guidance document #256 was established and released for public comment in November of 2019.

At its October 9-11, 2019 meeting, the Board reviewed the proposal to determine whether the Board of Pharmacy should be authorized to inspect the premises. As BPC section 4170, subdivision (b), provides that the Board is charged with the enforcement of the Pharmacy Law as to the Board's respective licensees, and only the Board is authorized to enforce the Veterinary Medicine Practice Act, and drug compounding statute thereunder, the Board determined it unnecessary to provide inspection authority to the Board of Pharmacy. Accordingly, the Board removed the Board of Pharmacy from the proposal and adopted the proposal on October 10, 2019.

At its January 30-31, 2020 meeting, the Board was notified that since it last met, the U.S. Department of Health and Human Services, FDA, Center for Veterinary Medicine, released a new draft guidance #256 on "Compounding Animal Drugs from Bulk Drug Substances." The Board reviewed a copy of the FDA draft guidance and a redline of proposed text, prepared by Board counsel, which revised the drug compounding text approved by the Board on October 10, 2019, in accordance with the FDA draft guidance. The Board discussed the FDA's proposed guidance for requiring direct supervision of an RVT performing bulk substance compounding preparations for individual animal patient dispensing and office stock and determined the policy was sound and should be included in the proposal. Accordingly, on January 30, 2020, the Board voted to approve the proposed amended drug compounding text and proceed with the rulemaking process.

Problem: SB 1193 enacted a new statute, BPC section 4826.5, which authorized drug compounding by veterinarians and supervised RVTs. However, that statute does not provide specific definitions, practice provisions, or compounding processes. Although the Pharmacy Law and its supporting regulations provide specific definitions, practice provisions, and compounding processes, those laws do not fit well with the limited scope of drug compounding provided by veterinarians. Veterinarians who provide compounded drugs to clients for use on animal patients provide a limited service that does not extend into commercial compounding or compounding services provided at the level of pharmacies.

The regulatory proposal is intended to provide guidance and an enforcement mechanism for inspectors to determine whether veterinarians and RVTs are compounding drugs in accordance with their scope of practice, experience, and premises. The rulemaking is necessary to provide veterinarians with guidance on the proper procedures for storing, handling, and preparing compounded drugs.

SPECIFIC PURPOSE, ANTICIPATED BENEFIT, AND RATIONALE:

A. Adopt Article 11 of Division 20 of Title 16 of the CCR: Compounding in a Veterinary Premises

1. Purpose: The purpose of adopting a new Article 11 for Compounding in a Veterinary Premises is to organize the seven new regulation sections under one heading.

2. Anticipated Benefit: The Board anticipates the proposal will aid consumers, veterinarians, RVTs, Deputy Attorneys General, and the Board to easily find all of the regulations applicable to drug compounding in a veterinary premises.

3. Rationale: The proposal is necessary to make obvious for all users of the CCR where the regulations applicable to drug compounding in a veterinary premises are located. As there are seven new regulations that all inform drug compounding in a veterinary premises, the Board determined it necessary to create a new Article 11 under which the drug compounding regulations in this proposal would be placed.

B. Adopt Section 2090 of Article 11 of Division 20 of Title 16 of the CCR: Definitions

1. Purpose: The purpose of adopting CCR section 2090 is to provide definitions that support new Article 11 relating to drug compounding in veterinary medicine to satisfy the requirements of SB 1193 that the Board promulgate drug compounding regulations.

2. Anticipated Benefits: The Board anticipates that veterinarians, RVTs, and consumers will benefit from defined terms for drug compounding.

3. Rationale: The proposal is necessary to provide definitions for use in the new drug compounding regulations required to be promulgated by SB 1193.

C. Adopt Section 2090, Subsection (a)(1)-(4)

1. Purpose: The purpose of this subsection is to make specific the scope of new veterinary drug compounding authority by defining the term “compounding.”

2. Anticipated Benefits: The Board anticipates that veterinarians, and the RVTs they supervise, will benefit from a specific definition of the meaning of “compounding” relevant to the new drug compounding authority provided to veterinarians and their supervised RVTs in BPC section 4826.5. The Board anticipates that consumers and their animals will also benefit from a definition of compounding when performed by veterinarians and RVTs.

3. Rationale: This proposal is necessary to implement, interpret, and make specific the statutory drug compounding provisions established in BPC section 4826.5. Although prescribing and drug compounding veterinarians are subject to the Pharmacy Law and its supporting regulations and federal laws, and must follow the drug compounding standards established by the United States Pharmacopeial Convention (USP), these laws do not provide clear guidance to California veterinarians on how the Board regulates drug compounding performed at a veterinary premises. To devise an appropriate definition of “compounding” in a veterinary premises, the Board began with the definition of

"compounding" provided in CCR, title 16, division 17, article 4.5, section 1735, Compounding in Licensed Pharmacies. The definition was revised to apply to drug compounding in a registered veterinary premises performed by a licensed veterinarian who has established a veterinary-client-patient relationship (VCPR) for the patient, or an RVT under the direct or indirect supervision of that veterinarian. These revisions were necessary to differentiate the pharmacy setting, where drugs are compounded pursuant to a written order received from a prescribing licensed health care professional, from the veterinary premises setting, where drugs are compounded by the treating health care professional (veterinarian) for use on individual patients.

Under the Board's regulations, CCR section 2032.1, a veterinarian is prohibited from administering, prescribing, dispensing, or furnishing a drug for the prevention, cure, or relief of a wound, fracture or bodily injury or disease of an animal without first establishing a VCPR. A VCPR is established by the client authorizing the veterinarian to assume responsibility for making medical judgments regarding the health of the animal, including the need for medical treatment, the veterinarian has sufficient knowledge of the animal and is personally acquainted with the care of the animal, as specified, by virtue of an examination or by medically appropriate and timely visits to the premises where the animals are kept, and the veterinarian has assumed responsibility for making medical judgments regarding the health of the animal and has communicated with the client a course of treatment appropriate to the circumstance. Notably, the establishment of the VCPR is a significant difference from what a pharmacist is required to do prior to compounding a drug for another practitioner's patient. However, since the veterinarian may be both the prescriber and the "pharmacist," it is necessary to require the veterinarian to properly prescribe and compound the appropriate drug for use on their established patient.

In addition, the definition of "compounding" in the veterinary premises would list the same activities, paragraphs (1) through (4), that are listed under the pharmacy regulation, since the compounding activity is the same in either a veterinary premises or a pharmacy.

D. Adopt Section 2090, Subsection (b)

1. Purpose: The purpose of this subsection is to make specific the scope of new veterinary drug compounding authority by defining the term "compounding."

2. Anticipated Benefits: The Board anticipates that veterinarians, and the RVTs they supervise, will benefit from a specific definition of the meaning of "compounding" relevant to the new drug compounding authority provided to veterinarians and their supervised RVTs in BPC section 4826.5. The Board anticipates that consumers and their animals will also benefit from a definition of compounding when performed by veterinarians and RVTs.

3. Rationale: This proposal is necessary to implement, interpret, and make specific the statutory drug compounding provisions established in BPC section 4826.5. In addition to the rationale provided above for the adoption of CCR section 2090, subsection (a), this subsection is necessary to establish the level of supervision required for compounding bulk substances. In the newly released "Draft Guidance on Compounding Animal Drugs from Bulk Substances," the FDA authorizes veterinarians to compound bulk substances for patient-specific prescriptions or for office stock (without patient-specific prescriptions). The FDA defines a bulk drug substance as any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug. (21 CFR § 207.3(a)(4).) In developing the Guidelines, the FDA noted that:

> [T]here are many different species of animals, each with a variety of diseases and conditions for which there are no FDA-approved, conditionally approved, or indexed drugs. While there are cases in which FDA-approved animal or human drugs can be used to treat an animal under the extralabel use provides of the [Food, Drug and Cosmetics Act] and related regulations, FDA recognizes that there are circumstances in which no FDA-approved, conditionally approved, or indexed drug (including the extralabel use of an FDA-approved animal or human drug) can be used to treat an animal with a particular condition. In those limited circumstances, an animal drug compounded from bulk drug substances may be a medically appropriate treatment.

The FDA's Guidelines advise that compounding of animal drugs from bulk substances should be compounded by or under the direct supervision of a veterinarian for either patient-specific prescriptions or office stock. Following the release of the FDA's Guidelines, the Board determined, at its January 30, 2020 meeting, that the drug compounding proposal should be revised to specifically require direct supervision for bulk drug compounding. Accordingly, the proposal creates subsection (b) to provide for bulk drug compounding under direct supervision of a veterinarian separate from subsection (a), which would require indirect supervision of a veterinarian.

E. Adopt Section 2090, Subsection (c)

1. Purpose: The purpose of this subsection is to make specific the new drug compounding authority by defining what is not included in the term "compounding."

2. Anticipated Benefits: The Board anticipates that veterinarians, and the RVTs they supervise, will benefit from a specific definition of the meaning of "compounding" relevant to the new drug compounding authority provided to veterinarians and their supervised RVTs in BPC section 4826.5. The Board anticipates that consumers and their animals will also benefit from a definition of compounding by

clear Board oversight of the drug compounding activities that can and cannot be performed by veterinarians and their RVTs.

3. Rationale: This subsection is necessary to limit the scope of compounding, which would not include reconstitution of a drug pursuant to a manufacturer's direction for oral, rectal, topical, or injectable administration, or the sole act of tablet splitting or crushing, capsule opening, or the addition of flavoring agents to enhance palatability. These are activities that do not otherwise require mixing drugs or determining measurements of the mixed drugs, and these activities are similarly excluded from the definition of "compounding" in licensed pharmacies.

F. Adopt Section 2090, Subsection (d)

1. Purpose: The purpose of this subsection is to make specific the new drug compounding authority by defining a drug's "expiration date."

2. Anticipated Benefits: The Board anticipates that veterinarians, and the RVTs they supervise, will benefit from a specific definition of the meaning of "expiration date" relevant to the new drug compounding authority provided to veterinarians and supervised RVTs in BPC section 4826.5. The Board anticipates that consumers and their animals will also benefit from a definition of an expiration date, so animals are less likely to receive expired drugs.

3. Rationale: This subsection is necessary to make clear when a drug cannot be administered or dispensed following the drug's compounding. The pharmacy regulation (CCR section 1735.1, subsection (b)) contains a similar definition for "beyond use date," which the Board initially considered but determined did not fit well into veterinary practice. Veterinary drug labeling software used at veterinary premises typically assigns an "expiration date," not a "beyond use date." Further, "expiration date" corresponds with the existing labeling requirements for dispensed drugs under CCR section 2032.2, subsection (b)(6). In addition, the use of "expiration date" would aid in distinguishing a drug compounded in a veterinary premises rather than in a pharmacy.

G. Adopt Section 2091 of Article 11 of Division 20 of Title 16 of the CCR: Veterinary Drug Compounding

1. Purpose: The purpose of adopting CCR section 2091 is to establish limitations on the scope of veterinarian and supervised RVT drug compounding in order to satisfy the requirements of SB 1193 that the Board promulgate drug compounding regulations.

2. Anticipated Benefits: The Board anticipates that veterinarians, RVTs, and consumers will benefit from a well-defined scope of drug compounding practice at a veterinary premises that ensures the safety and efficacy of a compounded drug preparation.

3. Rationale: This subsection is necessary to provide safety measures for drugs compounded by a veterinarian.

H. Adopt Section 2091, Subsection (a)

1. Purpose: The purpose of this subsection is to establish safety and drug efficacy requirements for drugs compounded in a veterinary premises.

2. Anticipated Benefits: The Board anticipates that consumers and their animals will benefit from Board oversight of the safety and efficacy of drug preparations compounded by veterinarians and their RVTs.

3. Rationale: This subsection is necessary to implement, interpret, and make specific the statutory drug compounding provisions established in BPC section 4826.5. Although prescribing and drug compounding veterinarians are subject to the Pharmacy Law and its supporting regulations and federal laws, and must follow the drug compounding standards established by the USP, these laws do not provide clear guidance to California veterinarians on how the Board regulates drug compounding performed at a veterinary premises. To establish the limited scope of drug compounding by veterinarians, the Board determined it necessary to require a veterinarian to ensure the safety and efficacy of the compounded drug preparation. This necessarily includes requiring the veterinarian to avoid known drug incompatibilities and inappropriate complications. These provisions are specific to drug compounding in veterinary premises, where commercial and/or complex drug compounding is not intended.

I. Adopt Section 2091, Subsection (b)

1. Purpose: The purpose of this subsection is to limit the drug compounding in veterinary premises to simple compounding procedures appropriate to the veterinarian's knowledge, skill, facilities, and available equipment.

2. Anticipated Benefits: The Board anticipates that consumers and their animals will benefit from a limit on the complexity of drug compounding authorized in veterinary premises. The Board also anticipates that veterinarians, RVTs, veterinary assistants, clients, and their animals will benefit from a safe, appropriate environment where drug compounding practices cannot exceed the veterinarian's knowledge, skill, facilities, or available equipment.

3. Rationale: This proposal is necessary to limit the scope of drug compounding performed in a veterinary premises to only those compounds that the complexity of the compounding does not exceed the veterinarian's knowledge, skill, facilities, or available equipment. These provisions are specific to drug compounding in veterinary premises, where commercial and/or complex drug compounding is neither intended nor allowed.

J. Adopt Section 2091, Subsection (c)

1. Purpose: The purpose of this subsection is to establish limitations on sterile drug compounding in a veterinary premises.

2. Anticipated Benefits: The Board anticipates that consumers and their animals will benefit from Board oversight of sterile drug preparations compounded by veterinarians and RVTs. The Board also anticipates that veterinarians, RVTs, veterinary assistants, clients, and their animals will benefit from safe, appropriate sterile drug compounding.

3. Rationale: This subsection is necessary to establish limitations on sterile compounding performed in a veterinary premises. Recognizing that drug compounding in a veterinary premises is significantly less complex than in a pharmacy, this proposal is necessary to limit sterile compounding for immediate use except when the dilution of the ingredients is essential for the safe administration of the drug preparation, there are no other human or animal drugs that satisfy the need of the drug preparation, and there is a historical documentation of the need, safety, and efficacy of the preparation. These provisions are specific to drug compounding in veterinary premises, where commercial and/or complex drug compounding is neither intended nor allowed, and provide sufficient leeway for rare circumstances when a veterinarian may need to prepare a sterile compound for treatment of an animal patient.

K. Adopt Section 2091, Subsection (d)

1. Purpose: The purpose of this subsection is to establish limitations on sterile drug compounding in a veterinary premises to only compounding of drugs approved by the FDA.

2. Anticipated Benefits: The Board anticipates that consumers and their pets will benefit from Board oversight of sterile drug preparations compounded by veterinarians and RVTs. The Board also anticipates that veterinarians, RVTs, veterinary assistants, clients, and their animals will benefit from safe, FDA approved sterile drug compounding.

3. Rationale: This subsection is necessary to establish limitations on sterile compounding performed in a veterinary premises. Recognizing that drug compounding in a veterinary premises is significantly less complex than in a pharmacy, this proposal is necessary to limit sterile compounding to the use of only FDA-approved drugs in sterile compounded drug preparations. These provisions are specific to drug compounding in a veterinary premises, where commercial and/or complex drug compounding is neither intended nor allowed.

L. Adopt Section 2092 of Article 11 of Division 20 of Title 16 of the CCR: Policies and Procedures

1. Purpose: The purpose of adopting CCR section 2092 is to establish requirements for written policies and procedures for the safe compounding of drugs in a veterinary premises.

2. Anticipated Benefits: The Board anticipates that consumers and their animals will benefit from policies and procedures used by veterinarians and RVTs when compounding drugs for use on animal patients. The Board also anticipates that veterinarians and RVTs will benefit from established policies and procedures that all veterinarians and supervised RVTs can follow at the veterinary premises.

3. Rationale: This subsection is necessary to establish written policies and procedures for drug compounding in a veterinary premises. The section is based on CCR section 1735.5, compounding policies and procedures in a pharmacy, with minor revisions suitable for the non-commercial, non-complex drug compounding in a veterinary premises.

M. Adopt Section 2092, Subsection (a)(1) through (3)

1. Purpose: The purpose of this subsection is to establish requirements for a written manual that would contain the veterinary premises' policies and procedures.

2. Anticipated Benefits: The Board anticipates that consumers and their animals will benefit from a written policies and procedures manual used by veterinarians and RVTs when compounding drugs for use on animal patients as the manual should provide consistency and uniformity in the drug preparations. The Board also anticipates that veterinarians and RVTs will benefit from established policies and procedures that all veterinarians and supervised RVTs can follow at the veterinary premises.

3. Rationale: This subsection is necessary to establish written policies and procedures for drug compounding in a veterinary premises. The section is based on CCR section 1735.5, compounding policies and procedures in a pharmacy, with minor revisions suitable for the non-commercial, non-complex drug compounding in a veterinary premises. The written manual would have to contain all of the following: (1) a list of the requirements of a formula document, the requirements established for expiration dates, and labeling requirements; (2) policies and procedures for training RVTs who may perform compounding drug preparations; and (3) policies and procedures for a quality assurance program. Each of these requirements is necessary to ensure the safety of the drug preparation and safety of the individuals preparing the drug compounds.

N. Adopt Section 2092, Subsection (b)(1) through (6)

1. Purpose: The purpose of this subsection is to establish requirements for a formula document that must be maintained for each compounded drug preparation.

2. Anticipated Benefits: The Board anticipates that consumers and their animals will benefit from written formula documents for each compounded drug preparation made by veterinarians and RVTs when compounding drugs for use on animal patients, as the document should provide consistency and uniformity in the drug preparations. The Board also anticipates that veterinarians and RVTs will benefit from established compounded drug preparation formula documents that all veterinarians and supervised RVTs can follow at the veterinary premises.

3. Rationale: This subsection is necessary to establish requirements for written formula documents that must be maintained for each compounded drug preparation. The section is based on CCR section 1735.2, subdivision (e), compounding limitations and requirements in a pharmacy. The formula document for each compounded drug preparation would have to contain all of the following: (1) active ingredients to be used, (2) equipment to be used; (3) the expiration date of the preparation; (4) inactive ingredients to be used; (5) specific compounding steps to be used to prepare the drug; and (6) instructions for storage, handling, and administration of the compounded preparation. The Board determined that each of these requirements is necessary to ensure the safety of the drug preparation and safety of the individuals preparing the drug compounds. In addition, the proposal is necessary to satisfy the requirements in BPC section 4826.5 that requires the Board's drug compounding regulations to address the storage of drugs and the equipment necessary for the safe compounding of drugs.

O. Adopt Section 2092, Subsection (c)

1. Purpose: The purpose of this subsection is to authorize a veterinary premises to include their formula documents in the written policies and procedures manual.

2. Anticipated Benefits: The Board anticipates that consumers and their animals will benefit from a written policies and procedures manual that contains the formula document for each compounded drug preparation made by veterinarians and RVTs when compounding drugs for use on animal patients, as the manual should help provide consistency and uniformity in the drug preparations. The Board also anticipates that veterinarians and RVTs will benefit from established compounded drug preparation formula documents that all veterinarians and supervised RVTs can follow at the veterinary premises.

3. Rationale: This subsection is necessary to establish written policies and procedures for drug compounding in a veterinary premises. The proposal would authorize a veterinary premises to maintain their compounded drug preparations

in the written policies and procedures manual. The Board determined that having one location that contains all of the formula documents is beneficial to the veterinarians and supervised RVTs preparing drug compounds, and helps to ensure the safety of the drug preparation.

P. Adopt Section 2092, Subsection (d)

1. Purpose: The purpose of this subsection is to authorize a veterinary premises to include in the patient's medical record the formula record for a drug compounding preparation that is not routinely used.

2. Anticipated Benefits: The Board anticipates that consumers and their animals will benefit from the ability of the veterinary premises to maintain uncommon drug compounding preparation formula records within the animal patient's medical record. The Board also anticipates that veterinarians and RVTs will benefit from immediate access through the patient's medical record to the formula record.

3. Rationale: This subsection is necessary to authorize a veterinary premises to maintain in a patient's medical record the uncommon formula record for the drug compounding preparation to be used for an individual animal patient. This subsection is based on CCR section 1735.2, subdivision (f), which authorizes a pharmacy that does not routinely compound a particular drug preparation to maintain the master formula record on the prescription document itself. The Board determined that maintaining the uncommon formula record in the animal patient's medical record is appropriate and helpful when the client returns to the veterinary premises for refills of the uncommon drug compounding preparation.

Q. Adopt Section 2092, Subsection (e)(1) through (6)

1. Purpose: The purpose of this subsection is to establish the recordation in the animal patient's medical record of specified information of the compounded drug preparation prepared for that patient.

2. Anticipated Benefits: The Board anticipates that consumers and their animals will benefit from the list of information provided in this subsection; in the event of an adverse reaction to the compounded drug, the veterinary staff would be better prepared to treat the animal patient with the specific drug compounding information documented in the patient's record. The Board also anticipates that veterinarians and RVTs will benefit from immediate access through the patient's medical record to the drug compounding information.

3. Rationale: This subsection is necessary to require specific drug compounding preparation information to be recorded in the animal patient's medical records. This subsection is based on CCR section 1735.3, subdivision (a), which provides a list of specific information that must be recorded in the pharmacy records for each compounded drug preparation. In addition, CCR section 1735.3, subdivision (b), requires pharmacies to maintain records of the proper storage of

drug products and components used in compounding. Similarly, the Board determined that the patient's medical record should also contain information on the proper storage of the compounded drug preparation. The Board determined that maintaining compounded drug preparation information specific to each instance of a compounded drug preparation is necessary for immediate access to the drug information in the event the animal patient has an adverse reaction to the compounded drug.

R. Adopt Section 2092, Subsection (f)

1. Purpose: The purpose of this subsection is to establish that the veterinarian who performs or supervises the compounding of drug preparations is responsible for training and supervision of the RVT who is compounding the drug preparation and proper storage of the drugs used in compounding and the compounded drug preparations.

2. Anticipated Benefits: The Board anticipates that consumers and their animals will benefit from proper RVT supervision and training in drug compounding preparations and storage. The Board also anticipates that RVTs will benefit from training and supervision by the veterinarian.

3. Rationale: This subsection is necessary to assign to the supervising veterinarian the responsibility of training and supervision of the RVT who compounds drugs. This subsection is also necessary to comply with the mandate of SB 1193 that requires the Board's regulations to address the storage of drugs and the level and type of supervision of RVTs who prepare drug compound preparations.

S. Adopt Section 2093 of Article 11 of Division 20 of Title 16 of the CCR: Expiration Dates

1. Purpose: The purpose of adopting CCR section 2093 is to determine the expiration dates for both sterile and non-sterile compounded drug preparations to ensure that veterinarians are providing medication safe for use on animal patients that could be otherwise harmful or damaging to the animal patient.

2. Anticipated Benefits: The Board anticipates that consumers and their animals will benefit from established expiration dates for sterile and non-sterile compounded drug preparations. The Board also anticipates that veterinarians and supervised RVTs will benefit from specific expiration date requirements provided in this section.

3. Rationale: This section is necessary to ensure that veterinarians adhere to specific expiration dates that protect their animal patients from expired drugs. This section is based upon the pharmacy regulation, CCR section 1735.2, subdivision (i), which specifies the beyond use dates for sterile and non-sterile compounded drug preparations. It is necessary to modify the pharmacy

regulation to reflect the common veterinary premises use of the term expiration date, which is also used in veterinary software.

T. Adopt Section 2093, subdivision (a)(1) through (2)

1. Purpose: The purpose of this subsection is to establish expiration dates for non-sterile compounded drug preparations to ensure that veterinarians are providing medication safe for use on animal patients that could be otherwise harmful or damaging to the animal patient.

2. Anticipated Benefits: The Board anticipates that consumers and their animals will benefit from established expiration dates for non-sterile compounded drug preparations. The Board also anticipates that veterinarians and supervised RVTs will benefit from specific expiration date requirements provided in this subsection.

3. Rationale: This subsection would establish that the expiration date shall not exceed either 180 days from the date the preparation is compounded or the shortest expiration date of any ingredient in the non-sterile compounded drug preparation. This subsection is necessary to ensure that veterinarians adhere to specific expiration dates that protect the animal patients from expired drugs. This subsection is based upon the pharmacy regulation, CCR section 1735.2, subsection (i)(1), which specifies the beyond use dates for non-sterile compounded drug preparations. It is necessary to modify the pharmacy regulation to reflect the common veterinary premises use of the term expiration date, which is also used in veterinary software, as well as establish appropriate expiration dates for the less complex drug compounding preparations performed at a veterinary premises.

U. Adopt Section 2093, subdivision (b)(1) through (2)

1. Purpose: The purpose of this subsection is to establish expiration dates for sterile compounded drug preparations to ensure that veterinarians are providing medication safe for use on animal patients that could be otherwise harmful or damaging to the animal patient.

2. Anticipated Benefits: The Board anticipates that consumers and their animals will benefit from established expiration dates for sterile compounded drug preparations. The Board also anticipates that veterinarians and supervised RVTs will benefit from specific expiration date requirements provided in this subsection.

3. Rationale: This subsection would establish that the expiration date shall not exceed either 30 days from the date the preparation is compounded or the shortest expiration date of any ingredient in the non-sterile compounded drug preparation. This subsection is necessary to ensure that veterinarians adhere to specific expiration dates that protect the animal patients from expired drugs. This subsection is based upon the pharmacy regulation, CCR section 1735.2, subsection (i)(2), that specifies the beyond use dates for sterile compounded

drug preparations. It is necessary to modify the pharmacy regulation to reflect the common veterinary premises use of the term expiration date, which is also used in veterinary software, as well as establish appropriate expiration dates for the less complex drug compounding preparations made at a veterinary premises.

V. Adopt Section 2093, subdivision (c)

1. Purpose: The purpose of this subsection is to establish when an expiration date for non-sterile or sterile compounded drug preparations could be extended and ensure that veterinarians are providing medication safe for use on animal patients that could be otherwise harmful or damaging to the animal patient.

2. Anticipated Benefits: The Board anticipates that consumers and their animals will benefit from the veterinarian's ability to extend an expiration date for a non-sterile or sterile compounded drug preparations. The Board also anticipates that veterinarians and supervised RVTs will benefit from the ability to extend the expiration date of the compounded drug preparation in certain circumstances.

3. Rationale: This subsection would establish that the expiration date of a non-sterile or sterile compounded drug preparation may be extended if the product's integrity, potency, and quality are measurable and demonstrable. This subsection is based upon the pharmacy regulation, CCR section 1735.2, subsection (i)(1)(G), which provides that a non-sterile compounded drug preparation beyond use date may be extended if the pharmacist researches drug-specific and general stability documentation and literature, analyzes the documentation and literature, and maintains documentation of the research, analysis, and conclusion. This subsection is also based upon CCR section 1735.2, subsection (i)(3), which authorizes extension of a beyond use date for sterile compounded drug preparations when the extension is based on suitability, integrity, and stability tests. The drug compounding performed in a veterinary premises is not as complex as that performed in a pharmacy, so the Board determined that the expiration dates of sterile and non-sterile drug compounding preparations could be extended if the product's integrity, potency, and quality are measurable and demonstrable. This standard would necessitate the veterinarian to research and document the reasoning behind extending the expiration of the compounded drug preparation, which effectively resolves extended expiration dates in the veterinary premises setting.

W. Adopt Section 2094 of Article 11 of Division 20 of Title 16 of the CCR: Labeling and Compounded Preparations

1. Purpose: The purpose of adopting CCR section 2094 is to provide specific requirements for a veterinarian to label all compounded drugs and to ensure that the veterinarian performing drug compounding is adhering to the same labeling requirements established for drugs dispensed to clients for use on animal patients.

2. Anticipated Benefits: The Board anticipates that consumers and their animals will benefit from properly labeled compounded drug preparations performed at the veterinary premises.

3. Rationale: This subsection is necessary to establish labeling requirements for compounded drug preparations performed at a veterinary premises. As the Board has already established labeling requirements for drugs dispensed to clients for use on animal patients, the Board determined these same labeling requirements are necessary for compounded drug preparations.

X. Adopt Section 2095 of Article 11 of Division 20 of Title 16 of the CCR: Quality Assurance

1. Purpose: The purpose of adopting CCR section 2095 is to establish quality assurance requirements and procedures for documenting and assessing medication errors resulting from compounded drug preparations made at a veterinary premises.

2. Anticipated Benefits: The Board anticipates that the health, safety, and welfare of consumers and their animals will benefit from quality assurance requirements for compounded drug preparations that would provide accountability, records, and client communication.

3. Rationale: This section is necessary to ensure that medication errors in compounded drug preparations are evaluated, documented, and communicated to clients to avoid injury or mitigate any medication errors. This section is based on the pharmacy regulation, CCR section 1711, which establishes quality assurance program requirements in pharmacies.

Y. Adopt Section 2095, subsection (a)

1. Purpose: The purpose of this subsection is to require veterinary premises where drug compounding is performed to establish a quality assurance program to document and assess medication errors in drug compounding preparations to determine the cause and appropriate response.

2. Anticipated Benefits: The Board anticipates that the health, safety, and welfare of consumers and their animals will benefit from quality assurance requirements for compounded drug preparations that would provide accountability, records, and client communication.

3. Rationale: This section is necessary to establish the responsibility of a veterinary premises where drug compounding is performed to ensure that medication errors in compounded drug preparations are evaluated, documented, and communicated to clients to avoid injury or mitigate the medication errors. This section is based on the pharmacy regulation, CCR section 1711, subdivision (a), which requires pharmacies to establish quality assurance program requirements.

Z. Adopt Section 2095, subsection (b)

1. Purpose: The purpose of this subsection is to establish the reason for requiring the quality assurance programs to be established at a veterinary premises where drug compounding is performed.

2. Anticipated Benefits: The Board anticipates that the health, safety, and welfare of consumers and their animals will benefit from quality assurance requirements for compounded drug preparations that would provide accountability, records, and client communication.

3. Rationale: This section is necessary to instruct veterinary premises and veterinarians as to the purpose of the quality assurance program, which will inform them of what actions are necessary when a medication error occurs. This section is based on the pharmacy regulation, CCR section 1711, subdivision (e), which establishes the primary purpose of a quality assurance review in pharmacies.

AA. Adopt Section 2095, subdivision (c)

1. Purpose: The purpose of this subsection is to establish the veterinarian's responsibilities to the client when the veterinarian determines that a medication error in a compounded drug preparation has occurred.

2. Anticipated Benefits: The Board anticipates that the health, safety, and welfare of consumers and their animals will benefit from assigning responsibility to a veterinarian who determines that a medication error has occurred and requiring the veterinarian to communicate as soon as possible to the client that a medication error has occurred.

3. Rationale: This subsection is necessary to ensure that the client is notified as soon as possible when a medication error in a compounded drug preparation has occurred. This subsection is based on CCR section 1711, subdivision (c)(2), which requires a pharmacist to communicate to the patient the fact that a medication error has occurred. This subsection is also necessary to inform the client of what steps are required to avoid injury to the animal patient or to mitigate the error, which is also a requirement in the pharmacy law.

BB. Adopt Section 2095, subdivision (d)

1. Purpose: The purpose of this subsection is to ensure confidentiality protection for records generated and maintained as a component of the ongoing quality assurance program.

2. Anticipated Benefits: The Board anticipates that veterinarians will maintain better records for the quality assurance program and will be less inhibited in documenting medication errors by making those records confidential. The Board

also anticipates that the health, safety, and welfare of consumers and their animals will benefit from veterinarians properly documenting medication errors.

3. Rationale: This subsection is necessary to ensure that medication errors in compounded drug preparations are well documented and peer reviewed. This subsection is based on the pharmacy law, BPC section 4125, subdivision (b), which establishes the same confidentiality protection for records generated and maintained as part of a pharmacy's ongoing quality assurance program. As in the pharmacy law, the subsection maintains the ability of the Board's authority to review these records as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the veterinary premises (e.g., the federal Drug Enforcement Agency). Further, this subsection maintains client access to the animal patient's medical records.

CC. Adopt Section 2095, subsection (e)

1. Purpose: The purpose of this subsection is to inform veterinary premises and veterinarians that reports of drug contraindications and adverse reactions may be included in the quality assurance documentation.

2. Anticipated Benefits: The Board anticipates that this provision would benefit veterinarians who would have access to a more complete quality assurance program that includes reports of drug contraindications and adverse reactions. The Board anticipates that the health, safety, and welfare of consumers and their animals will benefit from veterinarians who are informed through the quality assurance program of drug contraindications and adverse reactions to drugs used in compounded drug preparations.

3. Rationale: This section is necessary to encourage veterinary premises and veterinarians to maintain a robust quality assurance program by including reports of drug contraindications and adverse reactions in the quality assurance documentation.

Underlying Data

- October 20, 2014 MDC Meeting Agenda; Relevant Meeting Materials; and Meeting Minutes
- April 28-29, 2015 Board Meeting Agenda; Relevant Meeting Materials; and Meeting Minutes
- July 21-22, 2015 Board Meeting Agenda; Relevant Meeting Materials; and Meeting Minutes
- January 19, 2016 MDC Meeting Agenda; Relevant Meeting Materials; and Meeting Minutes
- January 20-21, 2016 Board Meeting Agenda; Relevant Meeting Materials; and Meeting Minutes

- April 20-21, 2016 Board Meeting Agenda; Relevant Meeting Materials; and Meeting Minutes
- July 19, 2016 MDC Meeting Agenda; Relevant Meeting Materials; and Meeting Minutes
- January 17, 2017 MDC Meeting Agenda; Relevant Meeting Materials; and Meeting Minutes
- April 18, 2017 MDC Meeting Agenda; Relevant Meeting Materials; and Meeting Minutes
- July 25, 2017 MDC Meeting Agenda; Relevant Meeting Materials; and Meeting Minutes
- October 18-19, 2017 Board Meeting Agenda; Relevant Meeting Materials; and Meeting Minutes
- October 9-11, 2019 Board Meeting Agenda; Relevant Meeting Materials; and Meeting Minutes
- January 30-31, 2020 Board Meeting Agenda; Relevant Meeting Materials; and Draft Meeting Minutes

Business Impact

The Board has made an initial determination that the proposed regulations will not have a significant adverse economic impact directly affecting businesses. The Board is informed that drug compounding already occurs in veterinary premises. These regulations provide specific regulations for drug compounding in the limited setting of a veterinary premises so that these veterinary premises are not required to piece together the relevant drug compounding requirements under the pharmacy law and its supporting regulations.

Economic Impact Analysis

This regulatory proposal will have the following effects:

- It will not create or eliminate jobs within the State of California because the proposed regulations apply to veterinary premises where drug compounding occurs. The regulatory proposal benefits veterinary premises by providing drug compounding provisions specific to veterinary premises and eliminates the need for these veterinary premises to attempt to conform to the drug compounding provisions already established under the pharmacy law.

- This proposal will not create new businesses or eliminate existing businesses within the State of California because the regulation is not a requirement for all veterinarians or veterinary premises, but only applies to veterinary premises where drug compounding already occurs. The regulatory proposal benefits veterinary premises by providing drug compounding provisions specific to veterinary premises and eliminates the need for these veterinary premises to attempt to conform to the drug compounding provisions already established under the pharmacy law.

- It will not affect the expansion of businesses currently doing business within the State of California because it only applies to veterinary premises where drug compounding is performed. The regulatory proposal benefits veterinary premises by providing drug compounding provisions specific to veterinary premises and eliminates the need for these veterinary premises to attempt to conform to the drug compounding provisions already established under the pharmacy law.

- This regulatory proposal would benefit the health, safety, and welfare of California residents and their animals because it provides Board oversight over veterinarians, RVTs, and veterinary premises that provide drug compounding preparations for use on animal patients and specifies requirements for safe, effective drug compounding.

- This regulatory proposal may benefit worker safety at veterinary premises as it establishes requirements, policies, and procedures to be followed by veterinarians and supervised RVTs when making a compounded drug preparation.

- This regulatory proposal does not affect the state's environment because it regulates drug compounding performed inside a veterinary premises.

Overview

There are approximately 3,500 veterinary premises, 12,400 veterinarians, and 7,200 registered veterinary technicians (RVTs) in California. The proposal will impact all animal hospitals and individual licensed veterinarians and RVTs, by allowing veterinarians, RVTs and veterinary premises to provide drug compounding services. This proposal would impact businesses ranging from small private businesses to corporations that own veterinary hospitals. The Board estimates approximately 80 to 90 percent (2800 or 3150) of the approximately 3,500 veterinary practices are small businesses. The Board does not anticipate the creation or elimination of businesses as a result of the proposal.

Economic Impact Assessment of Benefits

The Board has determined the proposal would benefit the health, safety, and welfare of California consumers and their animals because it provides Board oversight over veterinarians, RVTs, and veterinary premises that provide drug compounding preparations for use on animal patients and specifies requirements for safe, effective drug compounding. This 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 for animals. This proposal does not affect the state's environment. The Board anticipates that consumers and their animals would benefit from increased access to compounded drugs for animals. The Board also anticipates that veterinarians, RVTs, and veterinary premises will benefit from clarification as to how to safely perform drug compounding for animal patients.

Requirements for Specific Technologies or Equipment

This regulatory proposal does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the regulation has been proposed or as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific.

Set forth below are the alternatives that were considered and the reason the alternative was rejected or adopted:

1. Adopt all or most of the pharmacy drug compounding regulations and modify them to apply to veterinary premises. This alternative was rejected because the drug compounding provisions applicable to pharmacies requires significantly more regulation than drug compounding in a veterinary premises requires. Pharmacists perform commercial, complex, and hazardous drug compounding preparations, which is not performed at veterinary premises. To address the safety of drug compounding preparations performed in a veterinary premises, the Board determined that some of the pharmacy laws and regulations were appropriate, with modifications, and this rulemaking reflects those laws and regulations the Board found to be applicable to drug compounding at a veterinary premises.

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.