STATE OF CALIFORNIA--OFFICE OF ADMINISTRATIVE LAW

NOTICE PUBLICATION/REGULATIONS SUBMISSION

REGULAR (See instructions on reverse)

STD. 400 (REV. 10/2019)

For use by Secretary of State only

OAL FILE NUMBERS	NOTICE FILE NUMBER	REGULATORY ACTION NUMBER	EMERGENCY NUMBER
	Z- 2020-0701-01	2021-1112-01S	

For use by Office of Administrative Law (OAL) only

OFFICE OF ADMIN. LAW
2021 NOV 15 PM 2:32

NOTICE | REGULATIONS

ENDORSED - FILED
in the office of the Secretary of State
of the State of California
JAN 04 2022
1:11 PM

AGENCY WITH RULEMAKING AUTHORITY: Veterinary Medical Board, Department of Consumer Affairs

AGENCY FILE NUMBER (If any):

A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)

1. SUBJECT OF NOTICE	TITLE(S)	FIRST SECTION AFFECTED	2. REQUESTED PUBLICATION DATE

3. NOTICE TYPE	4. AGENCY CONTACT PERSON	TELEPHONE NUMBER	FAX NUMBER (Optional)
☐ Notice re Proposed Regulatory Action ☐ Other			

OAL USE ONLY	ACTION ON PROPOSED NOTICE	NOTICE REGISTER NUMBER	PUBLICATION DATE
	☐ Approved as Submitted ☐ Approved as Modified ☐ Disapproved/ Withdrawn		

B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)

1a. SUBJECT OF REGULATION(S): Drug Compounding

1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S):

2. SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) **(Including title 26, if toxics related)**

SECTION(S) AFFECTED (List all section number(s) individually. Attach additional sheet if needed.)

ADOPT: 2090, 2091, 2092, 2093, 2094, 2095

AMEND:

TITLE(S): 16

REPEAL:

3. TYPE OF FILING

- ☒ Regular Rulemaking (Gov. Code §11346)
- ☐ Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code §§11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute.
- ☐ Emergency Readopt (Gov. Code, §11346.1(h))
- ☐ Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100)
- ☐ Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §§11349.3, 11349.4)
- ☐ File & Print
- ☐ Print Only
- ☐ Emergency (Gov. Code, §11346.1(b))
- ☐ Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1)
- ☐ Other (Specify)

4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs. title 1, §44 and Gov. Code §11347.1)
11/19/2020 - 12/4/2020; 7/28/2021 - 8/12/2021

5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100)

- ☒ Effective January 1, April 1, July 1, or October 1 (Gov. Code §11343.4(a))
- ☐ Effective on filing with Secretary of State
- ☐ §100 Changes Without Regulatory Effect
- ☐ Effective other (Specify)

6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY

- ☐ Department of Finance (Form STD. 399) (SAM §6660)
- ☐ Fair Political Practices Commission
- ☐ State Fire Marshal
- ☒ Other (Specify) Kimberly Kirchmeyer, Director, Department of Consumer Affair

7. CONTACT PERSON	TELEPHONE NUMBER	FAX NUMBER (Optional)	E-MAIL ADDRESS (Optional)
Justin Sotelo	(916) 282-6911	(916) 928-6849	justin.sotelo@dca.ca.gov

8. I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.

SIGNATURE OF AGENCY HEAD OR DESIGNEE	DATE
	9/9/2021

TYPED NAME AND TITLE OF SIGNATORY: Jessica Sieferman, Executive Officer, Veterinary Medical Board

For use by Office of Administrative Law (OAL) only

ENDORSED APPROVED

JAN 04 2022

Office of Administrative Law

STATE OF CALIFORNIA--OFFICE OF ADMINISTRATIVE L

REGULAR

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2021 NOV 12 AM 11:55

NOTICE | REGULATIONS

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OAL USE ONLY	ACTION ON PROPOSED NOTICE	NOTICE REGISTER NUMBER	PUBLICATION DATE
	☐ Approved as Submitted ☐ Approved as Modified ☐ Disapproved/ Withdrawn	2020, 29-Z	7/17/2020

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Justin Sotelo	(916) 282-6911	(916) 928-6849	justin.sotelo@dca.ca.gov

8. I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.

For use by Office of Administrative Law (OAL) only

SIGNATURE OF AGENCY HEAD OR DESIGNEE:

DATE: 9/9/2021

TYPED NAME AND TITLE OF SIGNATORY: Jessica Sieferman, Executive Officer, Veterinary Medical Board

VETERINARY MEDICAL BOARD

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Drug Compounding

Section(s) Affected: Title 16, Division 20, Article 11, of the California Code of Regulations (CCR)[1] sections 2090-2095.

Updated Information:

The Initial Statement of Reasons is included in the file. The information contained therein is updated as follows:

The 45-day public comment period began on July 17, 2020 and ended on August 31, 2020 ("first public comment period"). The Veterinary Medical Board (Board) did not hold a hearing. The Board received three written comments (two comments in support, and one comment in support with recommendations). On October 22, 2020, the Board approved Modified Text to address the recommendations received and issues raised during the 45-day public comment period and to better clarify the proposal.

First Modified Text

For the reasons set forth below and in the responses to comments listed below for the first public comment period, on November 19, 2020, the Board issued a 15-day Notice of Modified Text to:

1. Make minor, technical and grammatical revisions to proposed Title 16, California Code of Regulations (CCR) section 2090, subsection (c) (by deleting "nor does it include" and "or the" from the originally proposed section and capitalizing the first letters in subdivisions (c)(2) and (c)(3)).

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 ("including, but not limited to, avoiding known drug incompatibilities and inappropriate complications" was struck).

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.

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

5. Revise CCR section 2091, subsection (c) to:
   a. Re-letter the subsection as (d) and make a clarifying revision to add the word "drug" before the word "compounding."
   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 re-letter the subsection as (e) and make minor, clarifying revisions to add the word "sterile" before the word "drugs" and strike the word "United States Food and Drug Administration" and replace with the word "FDA".

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) (deleting "that" and adding "who"), and strike paragraph (6) relating to "proper storage" of the compounded drug preparation, which is duplicative of paragraph (3).

9. Revise proposed CCR section 2094 to specify the labeling requirements for a dispensed compounded drug preparation. As proposed, CCR section 2094 required all compounded drug preparations be labeled in compliance with CCR section 3032.2, which lists 7 categories of information required on the labels of all dispensed drugs. Subject matter expert veterinarians pointed out that compounded drugs are often created in batches. Customarily, if there are leftovers from a batch of a compounded drug preparation, it is kept on hand and made available as needed to fill prescriptions for other animal patients for as long as the component ingredients are not expired. The Board found it necessary to revise CCR section 2094 and split the section into two subdivisions to address this customary practice. Subsection (a) was amended to clarify that CCR section 3032.2 label requirements apply to all dispensed compounded preparations.

10. Add new subsection (b) to proposed CCR section 2094 to specify the labeling requirements for all other compounded drug preparations that are not dispensed. Subsection (b) was added to require leftover portions of compounded drug preparations that are not dispensed be labeled with 5 categories of information. The required information of date of preparation; name, strength, and quantity of each ingredient; and expiration date allows a veterinarian to determine whether or not the ingredients of the compounded drug preparation have expired. The required information of the lot or control number of the batch and the name or initials of the preparer allows a veterinarian to track back who compounded a drug preparation if there are questions about a compounded drug preparation.

The first 15-day public comment period closed on December 4, 2020.

During the first 15-day public comment period, the Board received one written comment with recommendations. On January 28, 2021, the Board approved responses to the written comment with recommendations, which are provided below. No further modifications were made to the language as a result of the written comment received.

Second Modified Text

In response to issues raised by the Department of Consumer Affairs' Legal Affairs Division, the Board, on July 22, 2021, approved second modifications to the proposed language. More specifically, the second modifications would address the issues raised as follows:

Section 2091(a):

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

Section 2091(b):

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

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

Section 2091(c):

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

It appears this section was intended to apply to both sterile and non-sterile compounding. There is an FDA guidance document that has not yet been adopted that

forbids compounding any drugs, sterile or non-sterile, that are approved by the FDA. Adding the phrase, “sterile or non-sterile” to this subsection would clarify that the subsection applies to both types of compounding and eliminates this potential concern.

Section 2093(c):

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

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

Section 2095(c):

The subsection presently reads: “(c) When a veterinarian determines that a medication error has occurred, the veterinarian shall as soon as possible, communicate to the client or the client’s representative the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.” Concerns were raised that the “as soon as possible” language may be considered unclear, as the regulated community cannot discern what that means without a clear outermost timeframe being provided. Upon re-examination, it was decided to replace “as soon as possible” with the term “immediately.” This is consistent common practice and provides greater consumer protection.

Section 2095(d):

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

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

> “Unless otherwise limited by order of the court in accordance with this title, any party may obtain discovery regarding any matter, not privileged, that is relevant to the subject matter involved in the pending action or to the determination of any motion made in that action, if the matter either is itself admissible in evidence or appears reasonably calculated to lead to the discovery of admissible evidence.

> Discovery may relate to the claim or defense of the party seeking discovery or of any other party to the action. Discovery may be obtained of the identity and location of persons having knowledge of any discoverable matter, as well as of the existence, description, nature, custody, condition, and location of any document, electronically stored information, tangible thing, or land or other property."

The California Court of Appeal has stated that this means, "In litigation, the courts and parties must look to the Evidence Code to determine whether records are privileged and therefore not discoverable under Code of Civil Procedure section 2017, subsection (a)." (Renumbered as Code Civ. Proc., § 2017.010.) (*Marylander v. Superior Court* (2000) 81 Cal.App.4th 1119, 1125.) "Instead, Evidence Code section 1040, the official information privilege, 'represents *the exclusive means by which a public entity may assert a claim of governmental privilege based on the necessity for secrecy*.'" (*Ibid*, citing *Shepherd v. Superior Court*, 17 Cal.3d 107, 123; emphasis in original.)
Evidence Code section 1040 states, in pertinent part:
(b) A public entity has a privilege to refuse to disclose official information, and to prevent another from disclosing official information, if the privilege is claimed by a person authorized by the public entity to do so and either of the following apply:
(1) Disclosure is forbidden by an act of the Congress of the United States or **a statute of this state**." (Emphasis added.)

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

After removing the language for which the Board lacks authority, section 2095, subsection (d) will read: "(d) The board may review records generated for and maintained as a component of the ongoing quality assurance program as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the veterinary premises. Nothing in this section shall be construed to prohibit a client or client's representative from accessing records of the animal patient pursuant to subsection (b) of section 2032.3."

The Board issued a 15-day Notice of Second Modified Text on July 28, 2021 to make these changes, and that public comment period closed on August 12, 2021.

During the second 15-day public comment period, the Board received two written comments with recommendations. The first comment with recommendations did not pertain to the second modifications to the proposed language, and the Board is therefore not required to respond to the comment. The second comment with recommendations was considered by the Board on October 21, 2021; the Board

approved responses to the written comment and no further modifications were made to the language. The Board further authorized the Executive Officer to adopt the proposed second modified text as written, and delegated to the Executive Officer the authority to make any technical or non-substantive changes that may be required in completing the rulemaking file.

Local Mandate:

A local mandate is not imposed on local agencies or school districts.

Fiscal Impact:

The proposed regulations do not result in a fiscal impact to the state. Because veterinarians are currently authorized to compound drugs under statutory authority and have done so for many years, and because the Board has historically regulated drug compounding through its inspections and enforcement-related activities, the Board does not anticipate the regulations will result in additional workload or costs.

Consideration of Alternatives:

No reasonable alternative to the regulatory proposal that was considered or that has otherwise been identified and brought to the attention of the Board would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective or less burdensome to affected private persons than the proposed regulation, or would be more cost-effective 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.

The following alternative was considered and rejected for the reasons discussed in the Initial Statement of Reasons, Board meeting minutes, or responses to comments: 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 premise 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 applicable to drug compounding in veterinary premises.

All recommendations provided during this rulemaking were considered by the Board (discussed below).

Summary of Comments and Responses

No objections were received; however, some recommendations for alternative approaches were received.

Comments received during the 45-day comment period:

Two letters of general support were received from Jon Klingborg, Doctor of Veterinary Medicine, Valley Animal Hospital of Merced and Michael Blaire, R. Ph., FIACP, Vice President, Government and Regulatory Affairs, Wedgewood Village Pharmacy, LLC.

One letter of support with recommendations was received from Ronald B. Phillips, Vice President, Legislative and Public Affairs, Animal Health Institute (AHI). The summarized recommendations and Board responses are as follows:

Summary of Recommendation One (1):
AHI cautions the Board against finalizing its regulations prior to the 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.

Board Response to Recommendation One (1):
As discussed in greater detail in the Initial Statement of Reasons 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.

Summary of Recommendations Two (2)(a) through (f):
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:

Summary of Recommendation Two (2)(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.

Board Response to Recommendation Two (2)(a):
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 Office of Administrative Law (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.

Summary of Recommendation Two (2)(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.

Board Response to Recommendation Two (2)(b):
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 CCR, title 16, 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.]

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.

Summary of Recommendation Two (2)(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) 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.

Board Response to Recommendation Two (2)(c):
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.

Summary of Recommendation Two (2)(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.

Board Response to Recommendation Two (2)(d):
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.

Summary of Recommendation Two (2)(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 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.

Board Response to Recommendation Two (2)(e):
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.

Summary of Recommendation Two (2)(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.

Board Response to Recommendation Two (2)(f):
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.

Comments received during the first 15-day comment period:

One letter with recommendations regarding the Modified Text was received from AHI. No text changes were made in response to these recommendations. The summarized recommendations and Board responses are as follows:

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

Board Response to Recommendation One (1):
The Board believes that veterinarian drug compounding from bulk substances will be an infrequent occurrence based on typical veterinarian practice over the past 40 years. As such, it appears veterinarians already compound from bulk substances as a last resort. Further, at AHI's recommendation, the Board added and circulated as Modified Text CCR, title 16, section 2091, subsection (c), which would prohibit a veterinarian from performing drug compounding unless there are no other human or animal drugs approved by the FDA and available to satisfy the need for the compounded drug preparation. This added provision sufficiently restricts the use of drug compounding, including preparations made from bulk substances, to only circumstances where the veterinarian is unable to prescribe, dispense, or administer an FDA-approved human or animal drug to treat the animal patient.

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

Summary of Recommendation Two (2):
AHI recommends the provision for non-sterile drugs in proposed CCR, section 2091, subsection (e), clarify that only FDA-approved animal and human drugs be used for non-sterile compounds when they offer the needed active

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

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

Board Response to Recommendation Two (2):
With respect to the Board's veterinarian licensees who perform drug compounding, the Board has carefully crafted regulatory language to address the issues raised by AHI, and at AHI's request, the Board included in the Modified Text proposed for CCR, title 16, section 2091, subsection (f), to clarify that APIs for non-sterile compounded drug preparations must be purchased from an FDA-registered facility. However, the Board recognizes that the FDA and CVM oversee and regulate prescription drugs, APIs, drug manufacturers, manufacturing facilities, and the API manufacturing and control process. The Board does not seek to provide oversight and regulation in these fields otherwise occupied by the FDA and CVM and recommends that AHI seek amendments to the federal regulations to enhance consumer protections regarding quality, consistency, purity, and stability controls in the API manufacturing process. Further, for the reasons stated above, the Board is unable to include references to the FDA's draft list.

Comments received during the second 15-day comment period:

Two letters with recommendations regarding the Second Modified Text were received from Philip C. Tillman, DVM and Kelly O'Brien, Director of Public Affairs for MARS Veterinary Health (MVH).

Dr. Tillman's comment was irrelevant because it was outside the scope of the specific adoption, amendment, or repeal being proposed in the Second Modified Text. Accordingly, the Board did not modify the proposed regulations to accommodate the recommendation.

The summarized MVH recommendations and Board responses are provided below. No text changes were made in response to these recommendations.

Summary of Recommendation One (1):
California Code of Regulations (CCR), title 16, section 2091, subsection (a). In reference to proposed CCR, title 16, section 2091, subsection (a), MVH asserts there are no adequate standards for compounding veterinary drugs, and it is unclear if the Board's intention is to comply with state standards, U.S. Food and Drug Administration (FDA) Guidance, and/or United States Pharmacopeia (USP) standards. MVH asserts veterinarians do not have sufficient guidance to be responsible for the safety and efficacy of compounded medications. MVH recommends the Board wait until such standards are finalized or clarify that veterinarians are responsible for meeting USP standards once they are developed.

Board Response to Recommendation One (1):
The proposed regulations are intended to allow veterinarians to do the basic compounding they have done for years. As noted in the Initial Statement of Reasons for this rulemaking, the conversation regarding drug compounding in veterinary premises originated at the October 20, 2014 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. During that meeting, it was noted that the current authority for veterinarians to compound drugs was incomplete, and there was 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 Veterinary Medicine Practice 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.

To provide statutory veterinary drug compounding authority, BPC section 4826.5 went into effect on January 1, 2017, and required the Board to promulgate regulations to address specified issues regarding the safe compounding of drugs.

The Board's proposed drug compounding regulations have been in process since that time.

While better guidance may be provided by USP in the future, the Board does not choose to delay any longer the promulgation of drug compounding regulations. The proposed regulations address the issues the Board is obligated by statute to address in a rulemaking. If better standards become available in the future, the Board is not averse to amending these regulations. However, the hope of clear standards at some point in the future does not satisfy the Board's present statutory obligation to promulgate drug compounding regulations for veterinarians now.

The veterinary drug compounding statute, BPC section 4826.5, authorizes a licensed veterinarian or supervised registered veterinary technician (RVT) to compound drugs for animal use pursuant to Code of Federal Regulations, title 21, section 530 and in accordance with regulations promulgated by the Board. Veterinarians are required to perform all aspects of veterinary medicine in a manner consistent with current veterinary medical practice in this state. (CCR, tit. 16, § 2032.) The Second Modified Text amended proposed CCR, title 16, section 2091, subsection (a) to establish minimum drug compounding standards in the same way all veterinary medical practice is required to be performed. Given the continued evolution of drug compounding noted by MVH, the Board believes requiring veterinarians to adhere to minimum drug compounding standards in the profession is sufficient and accommodates future developments in drug compounding standards. As such, the Board declines to revise the proposed regulation to accommodate the recommendation.

Notably, the veterinary drug compounding statute and proposed regulations do not require a veterinarian to perform drug compounding. If a veterinarian is unsure of the minimum drug compounding standards in California, the veterinarian should not perform drug compounding and, instead, may issue a prescription to a pharmacy for drug compounding.

Summary of Recommendation Two (2):
CCR, title 16, section 2092, subsection (b). MVH states that consistency, uniformity, and quality standards are important in preparing compounded medication. MVH recommends, prior to enacting CCR, title 16, section 2092, subsection (b), the Board should seek to establish additional monographs for common compounded animal drugs, in partnership with USP, the American Veterinary Medical Association (AVMA), and the FDA. MVH asserts that helping develop monographs would ensure consistency among California veterinarians in drug compounding and make it much easier for veterinarians to comply with the requirements in proposed CCR, title 16, sections 2092, subsection (b), and 2091, subsection (b).

Board Response to Recommendation Two (2):
In the Second Modified Text, no changes were made to proposed CCR, title 16, section 2092, subsection (b), which would establish what information must be included in formula documents. As such, MVH's recommendation is irrelevant because it falls outside the scope of the specific adoption, amendment, or repeal being proposed in the Second Modified Text. Accordingly, the Board declines to revise the proposed regulation to accommodate the recommendation.

Summary of Recommendation Three (3):
CCR, title 16, section 2093. In reference to proposed CCR, title 16, section 2093, MVH states that beyond-use dates are more common and more useful for compounded drugs. MVH recommends using beyond-use dates because it aligns with USP standards and would be beneficial to clients and their pets.

Board Response to Recommendation Three (3):
As discussed in greater detail in the ISR at pages 14-16, the Board chose to use the term "expiration date," instead of the term "beyond use date," to reflect the common usage of "expiration date" at veterinary premises and in veterinary software. Additionally, the only change in the Second Modified Text to proposed CCR, title 16, section 2093 was the elimination of subsection (c), which would have allowed expiration dates for compounded preparations to be extended under specific circumstances. The MVH recommendation does not address the extension of either expiration dates or beyond use dates and, thus, is irrelevant because it falls outside the scope of the specific adoption, amendment, or repeal being proposed in the Second Modified Text. Accordingly, the Board declines to revise the proposed regulation to accommodate the recommendation.

Summary of Recommendation Four (4):
In reference to proposed CCR, title 16, section 2095, MVH states that it does not believe it will be in the best interest of the profession, veterinarians, clients, or their pets to have veterinarians create their own monographs, and improperly compounding drugs can lead to dire consequences and negatively impact pet health. MVH recommends the Board work with USP, AVMA, and FDA to develop monographs for compounded veterinary drugs and refers back to the recommendation MVH makes concerning CCR, title 16, section 2092.

Board Response to Recommendation Four (4):
In the Second Modified Text, changes were made to proposed CCR, title 16, section 2095, subsections (c) and (d). The change to subsection (c) required that when a medication error is determined to have occurred, the client must be notified "immediately," which is sooner than the previous language allowing notification "as soon as possible." The change to subsection (d) eliminated language by which the Board sought to make peer review documents exempt from discovery, an action beyond the Board's regulatory power.

However, the MVH recommendation that the Board should assist in developing monographs for compounding veterinary drugs does not address either of the changes made in proposed CCR, title 16, section 2095, subsections (c) and (d). As such, the MVH recommendation is irrelevant because it falls outside the scope of the specific adoption, amendment, or repeal being proposed in the Second Modified Text. Accordingly, the Board declines to revise the proposed regulation to accommodate the recommendation.