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	January 18, 2023
TO	Veterinary Medical Board (Board
FROM	Leah Shufelt, RVT, Chair Multidisciplinary Advisory Committee (MDC)
SUBJECT	**Agenda Item 6.E. Recommendation on California Horse Racing Board Regulatory Proposal to Amend CCR, Title 4, Section 1867 Regarding Prohibited Veterinary Practices**

Background

During the spring of 2022, the California Horse Racing Board (CHRB), the California Veterinary Medical Association (CVMA), the University of California, Davis, School of Veterinary Medicine (UCD SVM), and several equine veterinarians raised concerns to the Veterinary Medical Board (Board) about how the Veterinary Medicine Practice Act (Practice Act) was being applied to racetrack veterinarians and the equine veterinary community. CHRB had concerns about overlap of two boards regulating the practice of veterinary medicine at CHRB-regulated facilities. CVMA and equine veterinarians felt that they were being held to a companion animal standard of practice.

In order to avoid inadvertently jeopardizing the Board's ability to fairly deliberate and rule on pending disciplinary items or matters, the Board's Executive Officer and Executive Committee recommended to the Board at the July 2022 meeting that they request the Multidisciplinary Advisory Committee (MDC) immediately form a subcommittee to hold a series of meetings with Board staff and legal counsel and solicit input from all relevant stakeholders (CVMA, CHRB, etc.) on these issues and then bring any recommendations to the Board at a future meeting.

Immediately following the July 2022 meeting, the MDC Chair appointed Marie Ussery, RVT, and Richard Sullivan, DVM, to form the Equine Practice Subcommittee (Subcommittee). Over the next two months, the Subcommittee met with Board staff to gain insight into the timeline and specific issues that created conflict between the Board and the equine veterinary community. The Subcommittee then met with representatives from CVMA, CHRB, and UCD SVM. The Subcommittee provided an update to the MDC at its October 18, 2022 meeting.

With respect to racetrack veterinarians, the September 28, 2022 meeting with CHRB staff mainly centered around the interpretation of CCR, title 4, section 1867, subsection (b), which states, in pertinent part, the following:

For purposes of this division, prohibited veterinary practices means

…

(b) The possession and/or use on the premises of a facility under the jurisdiction of the Board of any drug, substance or medication that has not been approved by the United States Food and Drug Administration (FDA) for use in the United States.

…

The Board interprets this regulation as written. However, CHRB publicly has contended that the regulation "permits such use where non-FDA-approved medications exist – a circumstance commonly present in equine practice." During the September 28, 2022 meeting, CHRB's Executive Director acknowledged that no such exemption from the regulation is actually present in the regulation. The Subcommittee notes that CHRB was aware of issues regarding drug compounding before the prohibition on non-FDA approved drugs went into effect. In 2018, when CHRB reviewed public comments on proposed amendments to CCR section 1867, Wedgwood Pharmacy said that subsection (b) of section 1867 "effectively prohibits the use of compounded preparations by requiring the use of FDA approved medications only."

Yet, CHRB sent out an advisory, attached, to racetrack veterinarians stating that compounded medications are not FDA approved, but lawfully prescribed, compounded medications manufactured according to Federal and State guidelines do not violate the regulation and compounded medications drug compounding was acceptable under the regulation. Notably, the plain language of CCR, title 4, section 1867, subsection (b), prohibits the possession and/or use at a CHRB regulated facility of any drug, substance, or medication that has not been approved by the FDA for use in the U.S. Since CHRB's advisory interprets the regulation to create an exemption from that regulation for non-FDA approved compounded medications, and that advisory was not adopted as a regulation, that advisory would be an underground regulation under the Administrative Procedure Act. (Gov. Code, §§ 11342.600, 11340.5, subd. (a); CCR, tit. 1, § 250, subs. (a)(1).)

CHRB staff and the Subcommittee agreed that amendments to CCR, title 14, section 1867 would be necessary to allow racetrack veterinarians to administer or dispense non-FDA-approved medications to equine patients.

CHRB also raised concerns similar to CVMA relating to preventative medicine, the veterinarian-client-patient relationship (VCPR), and recordkeeping requirements. CHRB and the Subcommittee also discussed potential impacts of HISA on these issues. The September 28, 2022 meeting concluded with an agreement to continue working together with the hope of addressing their concerns and reducing the public rhetoric between the two boards, as the common goal is for the health and safety of the horses.

Update

CCR, Title 4, Section 1867 Rulemaking
In November 2022, CHRB staff sent to the Subcommittee proposed amendments to CCR, title 14, section 1867, subsection (b). CHRB is planning to amend their regulation as an "emergency" regulation, and the Subcommittee strongly agrees with that approach.

The Subcommittee reviewed CHRB's regulatory proposal and recommended several changes and raised concerns as follows:

- How easily will the CHRB or VMB be able to verify whether the drug was properly manufactured? – VMB does not inspect California licensed pharmacies.
- What are the federal and state guidelines referenced in this provision? Shouldn't this be federal and state laws and regulations?
- The possession or use of compounded drugs should be limited to patient-specific prescriptions. Following GFI 256 guidance, veterinarians at racetracks should not be using office stock – this regulation should address this issue. Note: Any compounded drugs used for office stock must be on the GFI 256 nominated drug list.
- For consistency with federal guidelines and California requirements, new subdivision (b)(1) should include the following limitations on the use/possession of compounded drugs:

  (A) There are no other human or animal drugs approved by the FDA and available to satisfy the need for the compounded drug; and

  (B) The drug is compounded by a California licensed veterinarian or California licensed pharmacy in full compliance with California laws and regulations governing drugs, pharmacy, and veterinary medicine. [This language would mirror the requirements in GFI 256, pp. 8-13.]

The Subcommittee also questioned the word "manufactured" in the proposed regulation, since neither CHRB nor the Board has any authority to inspect compounding pharmacies in California.

CHRB accepted two of the Subcommittee's recommendations to be added to section 1867, subsection (b), as follows:

(A) There are no other human or animal drugs approved by the FDA and available to satisfy the need for the compounded drug; and

(B) The drug is compounded by a California licensed veterinarian or California licensed pharmacy.

The final CCR section 1867 regulatory language submitted to CHRB for review and approval at their November 22, 2022 meeting stated as follows (additions in underlined text):

> (b) The possession and/or use on the premises of a facility under the jurisdiction of the Board of any drug, substance or medication that has not been approved by the United States Food and Drug Administration (FDA) for use in the United States.
>
> (1) Possession or use of any compounded drug, substance, or medication, manufactured according to Federal and State laws and regulations, shall not be considered a prohibited veterinary practice if:
>
> (A) There are no other human or animal drugs approved by the FDA and available to satisfy the need for the compounded drug; and
>
> (B) The drug is compounded by a California licensed veterinarian or California licensed pharmacy.

The final regulatory proposal did not include the Subcommittee's recommendation to define the difference between compounding "office stock" and prescribing a compounded preparation for an individual horse. According to FDA's Guidance for Industry (GFI) # 256, which will be enforced starting in April 2023, there is a restricted list of compounded preparations (five at the present time) that a veterinarian can have as "office stock." Whereas, if a veterinarian is compounding for an individual horse, there are no restrictions if there is a veterinarian-client-patient relationship (VCPR). Since the regulatory proposal addresses drug compounding issues for equine medicine, the Subcommittee felt that this would be a great opportunity to get this information out to equine veterinarians.

CHRB's November 22, 2022 Meeting Agenda Item 20 addressed the proposed regulatory amendments to CCR section 1867, subsection (b), and in the meeting materials (p. 729) for this Item, under the heading "ISSUE," stated the following: "The California Veterinary Medical Board provided feedback on the proposed amendments, and that feedback was considered in the proposal before the Board. Given the present, severely negative impact on CHRB licensed veterinarians due to this incorrect interpretation by the California Veterinary Medical Board, these regulatory changes, if approved by the Board, will be pursued in an emergency fashion."

With respect to the statement in the CHRB meeting materials, above, regarding the purported "incorrection interpretation" of the regulation by the Board, the Subcommittee notes that during the Subcommittee's September 28, 2022 meeting with CHRB staff, their attorney did not argue that the Board's interpretation was wrong. In fact, CHRB staff conceded that the plain language of the CCR, title 4, section 1867, subsection (b), does not provide for any drug compounding exemption from the regulation's prohibition on the possession and/or use at a CHRB regulated facility of any drug, substance, or

medication that has not been approved by the FDA for use in the U.S. As such, the Board's interpretation of section 1867, subsection (b), is correct. Yet, at the November 22, 2022 meeting on Item 20, CHRB's general counsel stated that CHRB staff was seeking emergency rulemaking authority because "[r]ecently, the California Veterinary Medical Board has interpreted our regulation to prohibit compounded medications. And although we disagree with this interpretation, we're seeking to clarify the regulation and do so on an expedited basis to prevent further licensed veterinarians from having accusations filed against them." (Transcript of CHRB Nov. 22, 2022 Meeting, p. 47, ll. 18-23.)

To correct the record and advise CHRB of additional requested amendments, the Subcommittee decided to make a public comment at CHRB's November 22, 2022 meeting. Based on the Subcommittee's belief that public comments could be provided by teleconference during CHRB's November 22, 2022 meeting, Dr. Sullivan was prepared to provide the Subcommittee's comments virtually in connection with Agenda Item 20. Unfortunately, that option was not available at the time of the meeting. Rather, CHRB announced during the meeting that the public had to be present, sign-in, and state that the individual wanted to comment on an agenda item, indicate the agenda item number, and public comments were limited to two minutes. As such, the Subcommittee was unable to testify because neither member of the Subcommittee was in Sacramento that day. On December 20, 2022, the Subcommittee sent a letter, attached, to the CHRB Executive Director describing the comments the Subcommittee had intended to provide at the November 22, 2022 CHRB meeting.

CHRB Staff Concerns with Board Regulations

The September 22, 2022 meeting with CHRB staff included discussion of their concerns similar to CVMA relating to preventative medicine, the veterinarian-client-patient relationship (VCPR), and recordkeeping requirements. The Subcommittee has drafted a comprehensive legislative proposal, discussed in greater detail under Agenda Item 4.A., to resolve CHRB's and CVMA's concerns regarding preventative medicine and the VCPR. The proposal, among other things, would provide as follows:

- Define a "herd" to refer "to any group of animals of the same species and located at the same geographic location."
- Define "client" to mean the owner of the animal and separately provide for client authorization given to an agent for purposes of establishing a VCPR.
- Clarify the VCPR requirement for herds and address for preventative medicine in that language.

Recordkeeping requirements are proposed to be reviewed and revised at a later date through regulation.

Subcommittee Recommendations

CCR, Title 4, Section 1867 Rulemaking

Since the Subcommittee was unable to testify at the November 22, 2022 CHRB meeting, the Subcommittee recommends the Board submit the attached letter to provide comments to CHRB on its CCR, title 4, section 1867 rulemaking during the 45-day public comment period. To date, neither the emergency rulemaking nor the regular rulemaking have been posted to the CHRB website.

Legislative Amendments

As discussed above, the Subcommittee is proposing legislative amendments under a separate agenda item to address CHRB, and other stakeholder, concerns with preventative medicine and VCPR requirements. The Subcommittee will seek MDC discussion and action on the recommendation for a legislative proposal under that agenda item.

Action Requested

If the Board agrees with the MDC that the Board should send to the CHRB comments on CHRB's rulemaking, please entertain a motion for the Board to send the attached letter to CHRB providing comments on the CCR, title 4, section 1867 rulemaking during the 45-day comment period on the rulemaking.

Attachments

1. September 22, 2022 CHRB Advisory on CHRB Rule 1867
2. December 20, 2022 Subcommittee Letter to CHRB re November 22, 2022 CHRB Meeting Comments
3. Proposed Board Letter to CHRB and Board Recommendations for Revisions on CHRB Amendments to CCR, Title 4, Section 1867 Rulemaking

STATE OF CALIFORNIA **GAVIN NEWSOM, GOVERNOR**

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CHRB ADVISORY SEPTEMBER 22, 2022

TO: CHRB Licensed Veterinarians

FROM: C. Scott Chaney, CHRB Executive Director

Re: CHRB Rule 1867

The California Horse Racing Board (CHRB) would like to reaffirm its interpretation of Rule 1867, subsection (b). Specifically, subsection (b) prohibits, "The possession and/or use on the premises of a facility under the jurisdiction of the Board of any drug, substance or medication that has not been approved by the United States Food and Drug Administration (FDA) for use in the United States." Compounded medications are not FDA approved. The CHRB's longstanding interpretation of subsection (b) is that lawfully prescribed, compounded medications which are manufactured according to Federal and State guidelines do not violate this regulation. The CHRB recognizes that compounded medications are necessary for the safe and effective treatment of horses. These medications contain approved Federal Food and Drug Administration (F.D.A.) substances, which have been compounded to achieve proper dosages for safe and effective equine treatment and are necessary for equine veterinarians to effectively treat various medical conditions. Use of compounded medications in the manner described is not a violation of CHRB regulations.

Extra-label use of medication for therapeutic purposes, based on a diagnosis and VCPR, in equine patients is permitted through AMDUCA[1]. The CHRB regulation permits such use where no FDA-approved medications exist – a circumstance commonly present in equine practice.

If there are specific questions pertaining to compliance with Rule 1867, veterinarians are encouraged to contact the Official Veterinarian prior to administration. The entirety of Rule 1867 is attached for reference.

1 **Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA)**

Rule No.	Rule Title
1867	Prohibited Veterinary Practices.
Rule Text	For purposes of this division, prohibited veterinary practices means: (a) The possession and/or use on the premises of a facility under the jurisdiction of the Board of any drug, substance, doping agent, or medication specified below for which a recognized analytical method has not been developed to detect and confirm its administration; or the use of which may endanger the health and welfare of the horse, or the safety of the rider or driver, or alter equine performance. (1) Erythropoietin (EPO) and analogs; (2) Darbepoietin and analogs; (3) Venoms or derivatives thereof; (4) Growth hormone and analogs and growth hormone releasing factory including growth hormone releasing hormone GHRH, and its analogs, except platelet rich plasma and autologous conditioned plasma, are permitted provided such treatment is pursuant to a valid veterinary prescription made in accordance with all rules and regulations in this division, and the treatment is reported to the Official Veterinarian on form CHRB-60 (Rev. 7/15) (Trainer Medication Report), regardless of whether or not the horse is treated within or outside of a licensed inclosure; (5) Ractopamine and ractopamine metabolites or analogs; (6) Zilpaterol and zilpaterol metabolites or analogs; (7) Aminoimidazole carboxamide ribonucleotide (AICAR); (8) Hemopure; (9) Myo-Inositol Trispyprophosphate (ITPP); (10) Oxyglobin; (11) Thymosin beta; (b) The possession and/or use on the premises of a facility under the jurisdiction of the Board of any drug, substance or medication that has not been approved by the United States Food and Drug Administration (FDA) for use in the United States. (c) The presence of any drug, substance or medication described in subsections (a)(1) through (a)(11), and subsection (b) of this regulation in any test sample obtained consistent with Rules 1858, 1859, 1859.1, and 1859.25 of this article, and the provisions of this article, shall apply to such sample in the same manner as if the horse were entered to race (See Title 4, California Code of Regulations, section 1843.3). The Board may grant an exception to this subsection if the person or persons seeking the exemption submits written documentation that demonstrates an FDA exemption has been obtained.

#

December 20, 2022

Via Email

Scott Chaney
Executive Director
California Horse Racing Board
1010 Hurley Way, Suite 300
Sacramento, CA 95825
cschaney@chrb.ca.gov

RE: Comments on CHRB Amendments to CCR, Title 4, Section 1867

Dear Mr. Chaney:

The Equine Practice Subcommittee (Subcommittee) of the Multidisciplinary Advisory Committee (MDC) of the Veterinary Medical Board (VMB) is providing these comments regarding the California Horse Racing Board's (CHRB) proposed amendments to California Code of Regulations (CCR), title 4, section 1867, subsection (b). Based on our belief that public comments could be provided by teleconference during CHRB's November 22, 2022 meeting, Dr. Sullivan was prepared to provide these comments virtually in connection with Agenda Item No. 20. Unfortunately, that option was not available at the time of the meeting. Therefore, the Subcommittee is submitting our prepared comments in writing now, as a preview of the public comments we intend to submit during the regular rulemaking process.

"*The Subcommittee is comprised of two members and is tasked with hearing from stakeholders about their concerns with the Veterinary Medicine Practice Act and the statutes and regulations as applied to equine veterinary practices. The Subcommittee would like to thank Dr. Blea, Executive Director Scott Chaney, and staff of the California Horse Racing Board for meeting with the Equine Practice Subcommittee on September 28, 2022. It was a very engaging meeting in which we were able to openly discuss issues, and the Subcommittee is convinced that we can work together to address them. We have also met with the California Veterinary Medical Association and the School of Veterinary Medicine at Davis. We will continue to meet with the stakeholders as we address their concerns on equine veterinary practice issues.*

There are four issues that we would like to raise about the Agenda Item 20 meeting memo and proposed regulatory text.

First, with respect to the meeting memo, we would like to clarify that the feedback on the proposed changes to CCR, title 4, section 1867, subsection (b), that was provided to

CHRB was from the Subcommittee. Neither the MDC nor the VMB have reviewed or approved the Subcommittee's recommendations.

Second, when we discussed the interpretation of CCR section 1867, subsection (b) at our September 28 meeting with CHRB representatives, we understood that CHRB staff agreed with VMB's interpretation of the plain language of the regulation. The VMB is not the only entity that has interpreted it this way.

In 2018, when CHRB reviewed public comments on proposed amendments to CCR section 1867, Wedgwood Pharmacy said that subsection (b) of section 1867 'effectively prohibits the use of compounded preparations by requiring the use of FDA approved medications only.' CHRB's advisory to track veterinarians regarding compounding deviates from the plain text of the regulation, and saying otherwise could be construed as an underground regulation.

Third, with respect to the proposed regulatory text, even though CHRB has accepted a couple of the Subcommittee's recommendations to section 1867, subsection (b), we would encourage you to reconsider our other recommendations.

We believe that it is important to explain the federal Food and Drug Administration's (FDA) GFI (Guidance for Industry) #256 as it relates to drug compounding, which FDA will start enforcing in April 2023. There is a significant difference between compounding Office Stock from bulk substances and compounding for an individual horse. There are restrictions on what preparations that can be compounded for Office Stock; presently there are only five preparations for equines. However, if a veterinarian is compounding for an individual horse, there are no federal restrictions other than the requirements for an examination and diagnosis. In other words, if an equine veterinarian has a compounded drug for multiple horses at their clinic or in their vehicle, and it is not one of the drugs on FDA's list, it is a violation. But if it is being prescribed for one horse, it is fine. This regulation would be a great vehicle to get this information to all equine veterinarians.

Fourth, the amendments to subsection (b)(1) of the regulation would authorize possession or use of any compounded drug manufactured according to federal and state guidelines. We question how CHRB or VMB will be able to verify whether the drug was properly manufactured, since neither board can inspect California licensed pharmacies. For this reason, we recommend subsection (b)(2) include language requiring the drug to be compounded by a California licensed veterinarian or California licensed pharmacy in full compliance with California laws and regulations governing drugs, pharmacy, and veterinary medicine. This language would mirror the requirements in GFI 256, pages 8-13.

We look forward to continuing our work with all equine stakeholders, including the CHRB, to address this regulation and other issues that have been raised."

Sincerely,

Richard Sullivan, DVM
Marie Ussery, RVT
Equine Practice Subcommittee
Multidisciplinary Advisory Committee
Veterinary Medical Board

Scott Chaney
Executive Director
California Horse Racing Board
1010 Hurley Way, Suite 300
Sacramento, CA 95825
cschaney@chrb.ca.gov

RE: Comments on CHRB Proposed Amendments to CCR, Title 4, Section 1867

Dear Mr. Chaney:

The Veterinary Medical Board (Board) hereby submits its comments and recommended revisions to the California Horse Racing Board's (CHRB) proposed amendments to California Code of Regulations (CCR), title 4, section 1867 to address specific concerns of the Board.

Since the regulatory amendments deal with compounding drugs for horses, the Board believes the regulation should conform to federal law and clarify the difference between compounding "office stock" for use on multiple horses versus compounding a drug for an individual horse. According to the U.S. Food and Drug Administration (FDA) Guidance for Industry (GFI) #256, which will be enforced starting April 2023, there is a significant difference regarding office stock and individual use compounding.

First, FDA GFI #256, page 2, states that "drugs compounded from bulk drug substances violate the [Federal Food, Drug, and Cosmetic Act (FD&C Act)] because they are not approved or indexed, are not made according to [current good manufacturing practice (CGMP)], and cannot satisfy the FD&C Act's adequate directions for use provision (which requires, among other things, that a prescription drug have FDA-approved labeling)." The FDA GFI #256 further states that "[t]he policies described in this document are intended to protect human and animal health by limiting the use of animal drugs compounded from bulk drug substances to when a veterinarian, acting within a valid veterinarian-client-patient relationship (VCPR), determines there is no medically appropriate human or animal drug that is FDA-approved, conditionally approved, or indexed to treat the animal (referred to as 'FDA-approved or indexed drugs' in this document)." (*Id.*)

FDA GFI #256 has a restricted list of drugs that can be compounded for office stock for use on horses; presently, there are only five such drugs. However, if a veterinarian is compounding a drug for an individual horse, there are no restrictions. That means that if a veterinarian has office stock at their facility or on their vehicle and it is not one of the five drugs listed, it is a violation of federal law. However, if the veterinarian is compounding a drug for an individual horse, there are no restrictions other than having established a VCPR prior to compounding the drug.

To properly clarify federal law restrictions affecting possession or use of a compounded drug and protect the equine animal patients, the Board proposes the regulation be amended, as shown on the attached proposal.

The Board also questions the CHRB's proposed amendment to add "manufacturing" in CCR, title 4, section 1867, subsection (b)(1), since neither the Board, nor CHRB, can inspect California licensed pharmacies. For this reason, we recommend subsection (b)(2) include language requiring the drug to be compounded by a California licensed veterinarian or California licensed pharmacy in full compliance with California laws and regulations governing drugs, pharmacy, and veterinary medicine. This language would mirror the requirements in FDA GFI 256, pages 8-13.

The Board welcomes the opportunity to work with CHRB to resolve the concerns raised above.

Sincerely,

President
Veterinary Medical Board

Vice President
Veterinary Medical Board

Encl.: Recommended Revisions to Regulatory Amendments of California Horse Racing Board to California Code of Regulations, Title 4, Section 1867

VETERINARY MEDICAL BOARD
RECOMMENDED REVISONS TO REGULATORY AMENDMENTS
OF CALIFORNIA HORSE RACING BOARD TO
CALIFORNIA CODE OF REGULATIONS, TITLE 4, SECTION 1867

CHRB amendments shown in black underlined text for additions and ~~black strikethrough text~~ for deletions.

VMB proposed amendments shown in *blue italic text* for additions and ~~red strikethrough text~~ for deletions.

Amend CCR, title 4, section 1867 as follows:

1867. Prohibited Veterinary Practices.

[…]

(b) The possession and/or use on the premises of a facility under the jurisdiction of the Board of any drug, substance or medication that has not been approved by the United States Food and Drug Administration (FDA) for use in the United States.

(1) Possession or use of any compounded drug, substance, or medication~~,~~ ~~manufactured according to Federal and State laws and regulations,~~ shall not be considered a prohibited veterinary practice if *all of the following are satisfied*:

(A) There are no other human or animal drugs approved by the FDA and available to satisfy the need for the compounded drug~~; and~~.

(B) The drug is compounded by a California licensed veterinarian or California licensed pharmacy *in full compliance with California laws and regulations governing drugs, pharmacy, and veterinary medicine*.

(C) The drug is compounded for an individual animal patient and not used as office stock, unless the compounded drug is listed for use on horses on the FDA List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood Producing Animals.

(D) All ingredients used in the compounded drug meet standards set in any applicable USP-NF monograph and comply with all requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

(F) The compounded drug is not a copy of a marketed FDA-approved or indexed drug, unless the compounder has documented the reason(s) why a marketed FDA-approved or indexed drug can be used as the source(s) of the active ingredients.

(I) The label of the compounded drug complies with a federal and state laws.

(c) All adverse events associated with a compounded drug shall be reported to the FDA on Form FDA 1932a online within 15 business days.

(d) A drug compounded pursuant to subsection (b) shall only be dispensed as follows:

(i) By the pharmacy, after receipt of a prescription for an individual animal patient from a veterinarian who has established a veterinarian-client-patient relationship, directly to the prescribing veterinarian or the animal patient owner or authorized agent of the owner.

(ii) By the veterinarian to the animal patient owner or authorized agent of the owner.

(~~c~~*e*) The presence of any drug, substance or medication described in subsections (a)(1) through (a)(11), and subsection (b) of this regulation in any test sample obtained consistent with Rules 1858, 1859, 1859.1, and 1859.25 of this article, and the provisions of this article, shall apply to such sample in the same manner as if the horse were entered to race (See Title 4, California Code of Regulations, section 1843.3). ~~The Board may grant an exception to this subsection if the person or persons seeking the exemption submits written documentation that demonstrates an FDA exemption has been obtained.~~

Authority cited: Sections 19440, 19562, 19580 and 19582, Business and Professions Code. Reference: Sections 19580, 19581 and 19582, Business and Professions Code.