

FINAL STATEMENT OF REASONS

UPDATED INFORMATIVE DIGEST

There have been no changes in applicable laws or to the effect of the proposed regulations from the laws and effects described in the Notice of Proposed Action.

The Board adopted Rule 1858, Test Sample Required; Rule 1859, Taking, Testing and Reporting of Samples; Rule 1859.1, Out-of-Competition Testing Procedures and Requirements; Rule 1859.25, Split Sample Testing; Rule 1867, Prohibited Veterinary Practices; and Rule 1869, Prohibited Drug Substances in Out-of-Competition Testing, at its December 13, 2018 Regular Board Meeting.

INCORPORATED BY REFERENCE

All documents contained within the rulemaking file have been made available by request throughout the rulemaking period.

LOCAL MANDATE DETERMINATION

The adoption of Rule 1858, Rule 1859, Rule 1859.1, Rule 1859.25, Rule 1867, and Rule 1869, does not impose any mandate on local agencies or school districts.

SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE ORIGINAL NOTICE PERIOD OF MARCH 23, 2018 TO DECEMBER 3, 2018.

Comment: Michael Blaire; Wedgewood Pharmacy, Email dates November 19, 2018: "We are concerned that the California Horse Racing Board's (CHRB) proposal to amend Title 4 of the California Code of Regulations, Article 15, Rule 1867: Prohibited Veterinary Practices and Rule 1869: Prohibited Drug Substances in Out-of-Competition Testing contains language that will effectively deny access to these important medications."

Response: The Board disagrees. The proposed language does not mention compounded medications. Compounded medications can still be used under the proposed regulations so long as all substances making up the compounded medication have been approved by the Federal Food and Drug Administration (FDA). This complies with federal law.

Comment: Michael Blaire; Wedgewood Pharmacy, Email dates November 19, 2018: "The CHRB's proposed amendments conflict with ARCI's model language on this subject, thereby restricting the veterinarian's therapeutic judgment and jeopardizing the health of the animal athlete."

Response: The Board disagrees. The Association of Racing Commissioners International (ARCI) Model Rules also require FDA approval and forbid possession or use of non-FDA approved drugs unless the commission specifically agrees. The Board believes the proposed amendments do conform with the ARCI as the proposed amendments also require FDA approval

which is in conformity with federal law. Regardless of conformity, however, the Board believes that the proposed regulations will not restrict a veterinarian's therapeutic judgement, as the substance the veterinarian uses still must be legally compounded under federal law.

Comment: Michael Blaire; Wedgewood Pharmacy, Email dates November 19, 2018: "1867(b) - This section effectively prohibits the use of compounded preparations by requiring the use of FDA approved medications only. This section should be removed."

Response: The Board's proposed amendments do not impact this section. As such, the Board does not need to address this comment per Cal. Gov. Code 11346.9.

Comment: Michael Blaire; Wedgewood Pharmacy, Email dates November 19, 2018: "1869(a)(1)(A)(i) – This section requires the use of an FDA approved product only and should be removed. Removal would not change the intent of the general section, as it would still require a veterinarian/patient relationship and a veterinarian prescription."

Response: The Board disagrees. The Federal Food and Drug Administration (FDA) maintains sole authority to approve drug substances. The proposed amendment does not prohibit the use of compounded medication so long as the medication is comprised of FDA approved substances. The Board disagrees with the characterization that the proposed language limits the use to FDA approved products only, as it confuses the issue. Federal law requires all drugs to be approved by the FDA. If that drug is then compounded, or mixed with other substances, federal law requires all substances making up that compounded drug to have been approved by the FDA. For these reasons, the Board believes the proposed language complies with current federal law.

Comment: Michael Blaire; Wedgewood Pharmacy, Email dates November 19, 2018: "1869(a)(6)(A)(i) – This section requires the use of an FDA approved product only and should be removed. Removal would not change the intent of the general section, as it would still require a veterinarian/patient relationship and a veterinarian prescription."

Response: The Board disagrees as the cited section does not require the use of an FDA approved product. This comment is misplaced.

Comment: Michael Blaire; Wedgewood Pharmacy, Email dates November 19, 2018: "1869(a)(13)(B)(ii)(b) – To remain consistent with ARCI's Model Rules on this subject, remove "have been approved by the FDA for use in the United States, and."

Response: The Board disagrees. The ARCI Model Rules also require FDA approval and forbid possession or use of non-FDA approved drugs unless the commission specifically agrees. The Board believes the proposed amendments do conform with the ARCI as the proposed amendments also require FDA approval which is in conformity with federal law.

Comment: Michael Blaire; Wedgewood Pharmacy, Email dates November 19, 2018: "We firmly believe that the CHRB is creating a situation that is compromising the health and safety of the racing athletes and creating dangerous situations with their proposed amendments to the

above mentioned rules effectively denying access to important compounded medications that veterinarians deem necessary for their patients.”

Response: The Board disagrees. The proposed amendments do not restrict the access or use of compounded medication. The proposed amendments only require that if compounded medications are used they be comprised of FDA approved substances which is mandated by federal law. Furthermore, the Board disagrees with the claim that these proposed amendments create a situation that is compromising the health and safety of the racing athletes. The proposed regulations will effectively curtail unscrupulous medication practices occurring outside of the current testing window, which create a far greater risk to the health and safety of the equine athlete.

SUMMARY AND RESPONSE TO COMMENTS RECEIVED AT THE DECEMBER 13, 2018 REGULATORY HEARING.

Comment: pages 28-29 of transcript: Commissioner Maas stated that he was interested in hearing a response to the claim that some therapeutic drugs would be excluded by this regulation.

Equine Medical Director Doctor Rick Arthur stated that compounded medications are required to be compounded in accordance with state and federal regulation. Dr. Arthur further stated that he could not think of any therapeutic medications that would not meet this requirement. Dr. Scott Stanley of University of California, Davis, agreed that so long as the medication is a permitted, legal compounded preparation, you can use it.

Response: The Board agrees. The proposed language does not mention compounded medications. Compounded medications can still be used under the proposed regulations so long as all substances making up the compounded medication have been approved by the FDA. This complies with federal law.

Comment: pages 29 -30 of transcript: Commissioner Maas inquired about the ARCI argument put forth by Wedgewood Pharmacy.

Staff Attorney Robert Brodник responded that the ARCI model rule allows for FDA approval and forbids possession or use of non-FDA approved drugs unless the commission specifically agrees.

Response: The Board agrees. The ARCI Model Rules also require FDA approval and forbid possession or use of non-FDA approved drugs unless the commission specifically agrees. The Board believes the proposed amendments do conform with the ARCI as the proposed amendments also require FDA approval which is in conformity with federal law.

Comment: pages 30-31 of transcript: Commissioner Auerbach commented that the Board “was not talking about companies that follow the rules all the time and are very careful with what they put in these medications. And I think that what we’re trying to do is address abuses to the potential for other groups trying to produce medication and not used approved substances and approved amounts.”

Dr. Scott Stanley agreed stating that there are cases in other jurisdictions where illegally compounded products have been prepared for illicit purposes.

Response: The Board agrees. The proposed language does not mention compounded medications. Compounded medications can still be used under the proposed regulations so long as all substances making up the compounded medication have been approved by the FDA. This complies with federal law.

Comment: page 31-32 of transcript: Chairman Winner asked whether we have any cases where this has been a problem.

Dr. Stanley commented that mostly it's a preparation failure rather than an illegal medication. Equine Medical Director Dr. Rick Arthur, commented the only compounded medication violation was for a substance Dyphylline, but it is an FDA-approved drug, so it would meet these particular requirements.

Response: The Board agrees. The proposed language will not prohibit compounded medication so long as all substances making up the compounded medication have been approved by the FDA, which complies with Federal Law.

The adoption of Rule 1858, Rule 1859, Rule 1859.1, Rule 1859.25, Rule 1867, and Rule 1869 has no significant adverse economic impact on small business.

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ALTERNATIVE DETERMINATION

The Board has determined that no alternative would be more effective in carrying out the purpose for which the regulation was proposed, would be as effective and less burdensome to affected private persons than the proposed regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. The addition of Rule 1859.1, Out-of-Competition Testing Procedures and Requirements, will establish procedures by which the Board will collect out-of-competition test samples, as well as penalties for failing to make a horse available for out-of-competition testing, or causing interference or obstruction of the sampling process. The addition of Rule 1869, Prohibited Drug Substances in Out-of-Competition Testing, will list all medications, drugs, and other substances that are prohibited from being present in an out-of-competition test sample. The proposed rule will also describe exceptions for certain therapeutic medications in cases where specific procedural and reporting requirements are followed by the trainers and/or their veterinarians. The amendment of Rule 1858, Test Sample Required, will clarify the Board's authority to collect official blood, urine, and other biological test samples, and will describe specifically which horses are eligible for out-of-competition testing. The amendment to Rule 1859, Taking, Testing and Reporting of Samples, will make minor technical changes to existing language to ensure out-of-competition testing procedures do not conflict with existing official test sample collection requirements. The

amendment to Rule 1859.25, Split Sample Testing, will extend the same split sample process and rights currently in place for post-race testing to licensees who have a horse in their custody that test positive for a prohibited substance in an out-of-competition test sample. The amendment to Rule 1867, Prohibited Veterinary Practices, will add a number of medications and drug substances to the current prohibited list, and extend the regulation's application to substances detected in out-of-competition test samples. The Board invited interested persons to present statements or arguments with respect to alternatives to the proposed regulations at the scheduled hearing or during the written comment period. No alternatives were proposed.

No alternatives that would lessen any adverse economic impact on small business were proposed.