NOTE: Government Code section 11340.85 requires the Board to post all notices, initial statement of reasons and texts of rules noticed to the public until 15 days after the proposed regulations are filed with the Secretary of State by the Office of Administrative Law.

CALIFORNIA HORSE RACING BOARD
TITLE 4, DIVISION 4, CALIFORNIA CODE OF REGULATIONS

NOTICE OF PROPOSAL TO AMEND
RULE 1844, AUTHORIZED MEDICATION

The California Horse Racing Board (Board/CHRB) proposes to amend the regulation described below after considering all comments, objections or recommendations regarding the proposed action.

PROPOSED REGULATORY ACTION

The proposed amendment to Rule 1844, Authorized Medication, would revise the levels of specified authorized medications in subsection 1844(e) and add additional drug substances to subsection 1844(f).

PUBLIC HEARING

The Board will hold a public hearing starting at 9:30 a.m., Thursday, June 19, 2014, or as soon after that as business before the Board will permit, in the Baldwin Terrace Room at the Santa Anita Park Race Track, 285 West Huntington Drive, Arcadia, California. At the hearing, any person may present statements or arguments orally or in writing about the proposed action described in the informative digest. It is requested, but not required, that persons making oral comments at the hearing submit a written copy of their testimony.

WRITTEN COMMENT PERIOD

Any interested persons, or their authorized representative, may submit written comments about the proposed regulatory action to the Board. The written comment period closes at 5:00 p.m., on June 2, 2014. The Board must receive all comments at that time; however, written comments may still be submitted at the public hearing. Submit comments to:

Erica Ward, Regulation Analyst
California Horse Racing Board
1010 Hurley Way, Suite 300
Sacramento, CA 95825
Telephone (916) 263-6025
Fax: (916) 263-6022
E-Mail: esward@chrb.ca.gov
AUTHORITY AND REFERENCE


Business and Professions Code sections 19940 and 19562 authorize the Board to adopt the proposed regulation, which would implement, interpret or make specific sections 19580 and 19581, Business and Professions Code.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Business and Professions Code section 19440 provides that the Board shall have all powers necessary and proper to enable it to carry out fully and effectually the purposes of this chapter. Responsibilities of the Board shall include adopting rules and regulations for the protection of the public and the control of horse racing and pari-mutuel wagering. Business and Professions Code section 19562 states the Board may prescribe rules, regulations and conditions under which all horse races with wagering on their results shall be conducted in California. Business and Professions Code section 19580 requires the Board to adopt regulations to establish policies, guidelines, and penalties relating to equine medication to preserve and enhance the integrity of horse racing in California. Business and Professions Code section 19581 provides that no substance of any kind shall be administered by any means to a horse after it has been entered to race, unless the Board has, by regulation, specifically authorized the use of the substance and the quantity and composition thereof. Board Rule 1844, Authorized Medication, names drug substances and medications authorized by the Board that may be administered to safeguard the health of the horse entered to race. The rule lists the drug substances that may be found in official test samples and the level at which such drugs may occur.

The proposed amendment to Rule 1844 will bring the regulation in line with current research regarding therapeutic medications for equines, and with the recommendations of the Racing Medication Testing Consortium’s National Uniform Medication Program. The proposed amendment will provide guidance to trainers, horsemen, and veterinarians regarding the administration of specific therapeutic drug substances and medications to horses entered to race, and the levels of such substances that may be present in official post race test samples. The proposed amendment to subsection 1844(e)(1) changes the allowable level of Acepromazine from 20 to 10 nanograms per milliliter. Under a new subsection 1844(e)(4), the allowable level of Procaine has been changed from 50 to 25 nanograms per milliliter. The allowable level is the level at which a medication or drug substance may be present in an official test sample. Research has demonstrated that at the current allowable level for these therapeutic drug substances, administration may occur within 48 hours of a race, which is prohibited under Rule 1843.5, Medication, Drugs and Other Substances. Lowering the allowable level of these therapeutic drug substances will require that the substances be administered outside the 48 hour time line, as provided under Rule 1843.5. Therapeutic medications such as Acepromazine and Procaine are appropriately administered to alleviate pain and to permit or promote healing; however, Rule 1843.5 provides that drugs, medications or any other substances shall not be administered by any means to a horse within 48 hours of the post time of the race in which the horse is entered, except as specified. The proposed amendment to Rule 1844 provides
appropriate withdrawal times if the medications are used properly. Therapeutic positive test results are the bulk of CHRB medication violations, and most of these violations are the result of inadvertent mistakes with therapeutic medications. Lowering the allowable levels of Acepromazine and Procaine will help horsemen avoid inadvertent positives.

The proposed amendments to subsections 1844(e)(3), 1844(e)(5), and 1844(e)(6) remove the medications Promazine, Atropine, and Benzocaine. These medications are not included in the Racing Medication Testing Consortium Uniform Medication Program. Promazine is no longer commercially available in the United States and Atropine, while available, has never been present in any post race test samples to date. Its use provides a significant concern for cardiovascular, respiratory, and central nervous system issues. Benzocaine is commercially available, but no information on it has been found to justify its inclusion as a recognized therapeutic medication in equines. The Board’s Equine Medical Director stated that Benzocaine is not approved for use in horses by the Federal Drug Administration (FDA), is not effective, and in the last seven years, there has been only one Benzocaine violation in which the drug was found in excess of the threshold.

The proposed amendment to subsection 1844(e)(9) changes the level of Clenbuterol allowed in post race urine test samples from 5 nanograms to 140 picograms per milliliter, and the amended subsection 1844(f) removes Clenbuterol as a drug that may be found in blood test samples. These changes are necessary because Clenbuterol has been abused for its androgenic side effects which mimic anabolic steroids. Androgenic-anabolic steroids are synthetic derivatives of the male hormone testosterone. They can exert strong effects that may be beneficial for athletic performance. This is supported in the research study: The Effect of Chronic Clenbuterol Administration on Mucociliary Clearance and Body Fat in Adult Horses. Clenbuterol is also banned by the World Anti-Doping Association (WADA) as an anabolic agent as listed in The World Anti-Doping Code: The 2014 Prohibited List International Standard. To prevent its use as an anabolic agent the recommended time of administration of the substance is outside of 14 days prior to racing. Clenbuterol is only detectable in blood for 3-7 days, therefore it will not be present in any blood test samples 14 days after administration. A finding of Clenbuterol in a blood test sample will indicate the drug was administered in violation of the Board’s rules. Because Clenbuterol does have legitimate clinical use in small airway disease such as allergic or infectious bronchitis, the Board will continue to allow the use of Clenbuterol when clinically appropriate. Clenbuterol is approved by the FDA for use in horses. The proposed amendment to subsection 1844(e)(9) allows 140 picograms of Clenbuterol per milliliter in urine. The proposal allows a 14 day withdrawal time and is supported in the Maddy Equine Laboratory study: Detection, Pharmacokinetics and Cardiac Effects Following Administration of Clenbuterol to Exercised Horses. The amendment to Rule 1844 provides racing regulators an opportunity to see if Clenbuterol can be administered appropriately for its intended use, as a bronchodilator to treat small airway disease.

The proposed amendment to subsection 1844(e)(10) removes Stanozolol from the list of drugs allowed in official urine test samples. The amendment also eliminates the one exception to non-endogenous anabolic steroids in Rule 1844. Stanozolol is a manufactured anabolic steroid. It was used in racing until 2008 when a threshold level was established in Rule 1844 to restrict its use. At that time, other manufactured anabolic steroids were banned. The new restriction
allowed Stanozolol at the 1 nanogram per milliliter level and established a roughly 30 day withdrawal period as a step towards eliminating the drug. As an anabolic steroid, Stanozolol is a recognized performance enhancing drug. The national (and international) consensus is anabolic steroids have no place in athletic competition. Steroids like Stanazolol need to be eliminated prior to racing because they can provide an unfair advantage. Eliminating the threshold for Stanozolol eliminates the anabolic steroid from any use at any time prior to racing.

Subsection 1844(e)(11) adds Omeprazole and subsection 1844(e)(15) adds Butorphanol to the list of drugs permitted in official urine test samples. Omeprazole is commonly used for the treatment and prevention of equine stomach ulcers and Butorphanol is a commonly used sedative/tranquilizer approved for use in horses. The amendments are consistent with the National Uniform Medication Program recommendations. The proposed amendments will also help deter race day administration of Omeprazole and Butorphanol because, if administered on race day, the drugs will exceed the proposed allowed levels in the urine test samples, resulting in a violation.

The proposed amendment to Rule 1844 will modify subsection 1844(f) to add 15 drug substances that may be present at specified levels in the official blood test sample. Subsection 1844(f)(1-15) adds specified drug substances, their metabolites, and analogs that may be found in official blood test samples. This amendment is in line with the National Uniform Medication Program recommendation. The Racing Medication Testing Consortium has conducted research on these therapeutic drugs to establish the blood thresholds. Whenever possible, therapeutic drugs should be regulated in the blood. Blood is a cleaner and a more pharmacologically stable testing matrix than urine. Blood testing is not possible in all drugs based on a number of factors related to testing sensitivity and drug metabolism. The original thresholds proposed in the mid 1990’s have very little solid scientific drug administration to back them up. At that time, the laboratory sensitivity was not adequate to find any of these drugs in blood unless at very high levels. Today, the technology has changed and blood testing is very sensitive and accurate. It is the preferable testing matrix in horse racing for therapeutic medications, when possible. The proposed amendment to subsection 1844(f)(1-15) will reflect current research and the National Uniform Medication Program recommendations.

The Association of Racing Commissioners International is composed of the governmental regulators of horse and greyhound racing in the United States, Canada, Mexico, Jamaica, and Trinidad-Tobago. Association of Racing Commissioners International collaborates with other racing industry organizations who share its common goal of ensuring integrity in racing. Association of Racing Commissioners International is a not-for-profit trade association with no regulatory authority. Its members individually possess regulatory authority within their jurisdictions and solely determine whether or not to adopt Association of Racing Commissioners International recommendations on policies and rules.

The Racing Medication and Testing Consortium strives to develop and promote uniform rules, policies and testing standards at the national level; coordinate research and educational programs that seek to ensure the integrity of racing and the health and welfare of racehorses and participants; and to protect the interests of the racing public. The Racing Medication Testing Consortium was founded in 2001 by representatives of a broad spectrum of racing-related groups
who participated in an industry effort to determine potential consensus points on the most basic elements of a uniform national medication policy for racehorses. The Racing Medication and Testing Consortium is incorporated as a 501 (c) (3) charitable organization with both scientific and educational purposes. It is governed by a board of directors consisting of 24 industry stakeholder groups.

The National Uniform Medication Program was recommended by the Racing Medication and Testing Consortium and approved by the Association of Racing Commissioners International and includes regulatory levels and restricted administration times for controlled therapeutic medications.

POLICY STATEMENT OVERVIEW OF ANTICIPATED BENEFITS OF PROPOSAL

The proposed amendment to Rule 1844 promotes the safety and welfare of horse and rider. The amendment provides guidelines for treating horses with medications in a manner that will increase the safety and welfare of both equine and human athletes. Strong pain-masking medications are sometimes used inappropriately to allow horses to train and race, before they are fully healed from an injury. Masking a horse’s condition with pain-masking medications has the potential to cause additional injuries to occur. Using pain-masking medications before a horse is fully healed can place a horse at a higher risk for breakdown, which can cause injury to horse and rider. The proposed amendment to Rule 1844 is based on solid research that provides sound recommendations to trainers, owners, and veterinarians, so that therapeutic medications can be used appropriately. The proposed amendment will also provide clarity for horsemen because it is in line with the National Uniform Medication Program recommendations of the Racing Medication Testing Consortium. Regardless of which state they are from, trainers and owners will be clear on what the rules for authorized medications are because other states are implementing, or have already implemented, similar rules. The proposed amendment to Rule 1844 can help to reduce medication violations and promote medication safety, as owners and trainers will not be forced to change medications as they move across the country and into California. This will help increase efficiency in the enforcement of the Board’s medication rules and regulations because out-of-state owners and trainers will be familiar with authorized medications. If trainers and owners are complying with the Board’s rules, the public will have more confidence in California horse racing, which may result in increased wagering. An increase in wagering will have a positive economic impact on the industry by increasing handle, which in turn increases purses and commissions.

Consistency with Existing State Regulations: During the process of developing the regulation and amendments, the Board has conducted a search of any similar regulations on this topic and has concluded that the regulation is neither inconsistent nor incompatible with existing state regulations.

DISCLOSURE REGARDING THE PROPOSED ACTION

Mandate on local agencies and school districts: none.

Cost or savings to any state agency: none.
Cost to any local agency or school district that must be reimbursed in accordance with Government Code Sections 17500 through 17630: none.

Other non-discretionary costs or savings imposed upon local agencies: none.

Cost or savings in federal funding to the state: none.

The Board has made an initial determination that the proposed amendment to Rule 1844 will not have a significant statewide adverse economic impact directly affecting business including the ability of California businesses to compete with businesses in other states.

The following studies/relevant data were relied upon in making the above determination: none.

Cost impact on representative private persons or businesses: None

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.

Significant effect on housing costs: none.

RESULT OF ECONOMIC IMPACT ANALYSIS

The adoption of the proposed amendment to Rule 1844 will not (1) create or eliminate jobs within California; (2) create new businesses or eliminate existing businesses within California; or (3) affect the expansion of businesses currently doing business within California. The proposed amendment to Rule 1844 promotes the safety and welfare of horse and rider. The amendment provides guidelines for treating horses with medications in a manner that will increase the safety and welfare of both equine and human athletes. Strong pain-masking medications are sometimes used inappropriately to allow horses to train and race, before they are fully healed from an injury. Masking a horse’s condition with pain-masking medications has the potential to cause additional injuries to occur. Using pain-masking medications before a horse is fully healed can place a horse at a higher risk for breakdown, which can cause injury to horse and rider. The proposed amendment to Rule 1844 is based on solid research that provides sound recommendations to trainers, owners, and veterinarians, so that therapeutic medications can be used appropriately. The proposed amendment will also provide clarity for horsemen because it is in line with the National Uniform Medication Program recommendations of the Racing Medication Testing Consortium. Regardless of which state they are from, trainers and owners will be clear on what the rules for authorized medications are because other states are implementing, or have already implemented, similar rules. The proposed amendment to Rule 1844 can help to reduce medication violations and promote medication safety, as owners and trainers will not be forced to change medications as they move across the country and into California. This will help increase efficiency in the enforcement of the Board’s medication rules and regulations because out-of-state owners and trainers will be familiar with authorized medications. If trainers and owners are complying with the Board’s rules, the public will have more confidence in California horse racing, which may result in increased wagering. An increase in wagering will have a
positive economic impact on the industry by increasing handle, which in turn increases purses and commissions.

Effect on small businesses: none. The proposal to amend Rule 1844 does not affect small businesses because horse racing is not a small business under Government Code Section 11342.610.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code Section 11346.5, subdivision (a)(13), the Board must determine that no reasonable alternative considered by the Board, 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 action is proposed, or would be as effective and less burdensome on affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Board invites interested persons to present statements or arguments with respect to alternatives to the proposed regulation at the scheduled hearing or during the written comment period.

CONTACT PERSON

Inquiries concerning the substance of the proposed action and requests for copies of the proposed text of the regulation, the initial statement of reasons, the modified text of the regulation, if any, and other information upon which the rulemaking is based should be directed to:

Erica Ward, Regulation Analyst
California Horse Racing Board
1010 Hurley Way, Suite 300
Sacramento, CA 95825
Telephone: (916) 263-6025
E-mail: esward@chrb.ca.gov

If the person named above is not available, interested parties may contact:

Harold Coburn,
Manager
Telephone: (916) 263-6397

AVAILABILITY OF INITIAL STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATION

The Board will have the entire rulemaking file available for inspection and copying throughout the rulemaking process at its offices at the above address. As of the date this notice is published in the Notice Register, the rulemaking file consists of this notice, the proposed text of the
regulation, and the initial statement of reasons. Copies may be obtained by contacting Erica Ward, or the alternative contact person at the address, phone number or e-mail address listed above.

AVAILABLE OF MODIFIED TEXT

After holding a hearing and considering all timely and relevant comments received, the Board may adopt the proposed regulation substantially as described in this notice. If modifications are made which are sufficiently related to the originally proposed text, the modified text, with changes clearly marked, shall be made available to the public for at least 15 days prior to the date on which the Board adopts the regulations. Requests for copies of any modified regulation should be sent to the attention of Erica Ward at the address stated above. The Board will accept written comments on the modified regulation for 15 days after the date on which it is made available.

AVAILABLE OF STATEMENT OF REASONS:

Requests for copies of the final statement of reasons, which will be made available after the Board has adopted the proposed regulation in its current or modified form, should be sent to the attention of Erica Ward at the address stated above.

BOARD WEB ACCESS

The Board will have the entire rulemaking file available for inspection throughout the rulemaking process at its web site. The rulemaking file consists of the notice, the proposed text of the regulation and the initial statement of reasons. The Board’s web site address is: www.chrb.ca.gov.

INITIAL STATEMENT OF REASONS

RULE 1844. AUTHORIZED MEDICATION.

SPECIFIC PURPOSE OF THE REGULATION

The proposed amendment to Rule 1844, Authorized Medication, will revise subsection 1844(e) by deleting specific drug substances that may be found in an official urine test sample. The allowable levels of Acepromazine, Procaine and Clenbuterol under subsection 1844(e) will also be modified. In addition, the proposed amendment will revise subsection 1844(f) by removing Clenbuterol as a drug substance that may be found in an official blood test sample, and adding 15 drug substances that may be present at specific levels in the official blood test sample.
PROBLEM

Rule 1844 provides the therapeutic drug substances and medications authorized by the Board for administration to horses entered to race, and that may be present in the official urine and/or blood test samples at specified levels. The therapeutic drug substances and medications authorized under Rule 1844 have historically been aligned with the recommendations of the Association of Racing Commissioners International Model Rules, as well as the guidelines provided by the Racing Medication Testing Consortium. Ongoing research conducted by the Racing Medication Testing Consortium (and others) regarding the efficacy of therapeutic medications and drug substances, and advances in technology, that have vastly improved the ability to detect the presence of drug substances in official test samples, necessitate the periodic revision of the Board’s medication regulations. The Racing Medication Testing Consortium’s initiatives have resulted in its National Uniform Medication Program, which includes regulatory levels and restricted administration times for controlled therapeutic medications. One of the objectives of the Racing Medication Testing Consortium is to implement its program nationwide to bring consistency and uniformity to the various racing state’s medication practices and regulations. The proposed amendment to Rule 1844 will revise the regulation to update the therapeutic drug substances and medications that may be present at specified levels in the official urine and blood test samples. The proposed amendment to Rule 1844 will also bring the Board’s listing of authorized medications in line with the recommendations of the Racing Medication Testing Consortium and the National Uniform Medication Program.

NECESSITY

The proposed amendment to Rule 1844 will bring the regulation in line with current research regarding therapeutic medications for equines, and with the recommendations of the Racing Medication Testing Consortium’s National Uniform Medication Program. The proposed amendment will provide guidance to trainers, horsemen, and veterinarians regarding the administration of specific therapeutic drug substances and medications to horses entered to race, and the levels of such substances that maybe present in official post race test samples. The proposed amendment to subsection 1844(e)(1) changes the allowable level of Acepromazine from 20 to 10 nanograms per milliliter. Under a new subsection 1844(e)(4), the allowable level of Procaine has been changed from 50 to 25 nanograms per milliliter. The allowable level is the level at which a medication or drug substance may be present in an official test sample. Research has demonstrated that at the current allowable level for these therapeutic drug substances, administration may occur within 48 hours of a race, which is prohibited under Rule 1843.5, Medication, Drugs and Other Substances. Lowering the allowable level of these therapeutic drug substances will require that the substances be administered outside the 48 hour time line, as provided under Rule 1843.5. Therapeutic medications such as Acepromazine and Procaine are appropriately administered to alleviate pain and to permit or promote healing; however, Rule 1843.5 provides that drugs, medications or any other substances shall not be administered by any means to a horse within 48 hours of the post time of the race in which the horse is entered, except as specified. The proposed amendment to Rule 1844 provides appropriate withdrawal times if the medications are used properly. Therapeutic positive test results are the bulk of CHRB medication violations, and most of these violations are the result of
inadvertent mistakes with therapeutic medications. Lowering the allowable levels of Acepromazine and Procaine will help horsemen avoid inadvertent positives.

The proposed amendments to subsections 1844(e)(3), 1844(e)(5), and 1844(e)(6) remove the medications Promazine, Atropine, and Benzocaine. These medications are not included in the Racing Medication Testing Consortium Uniform Medication Program. Promazine is no longer commercially available in the United States and Atropine, while available, has never been present in any post race test samples to date. Its use provides a significant concern for cardiovascular, respiratory, and central nervous system issues. Benzocaine is commercially available, but no information on it has been found to justify its inclusion as a recognized therapeutic medication in equines. The Board’s Equine Medical Director stated that Benzocaine is not approved for use in horses by the Federal Drug Administration (FDA), is not effective, and in the last seven years, there has been only one Benzocaine violation in which the drug was found in excess of the threshold.

The proposed amendment to subsection 1844(e)(9) changes the level of Clenbuterol allowed in post race urine test samples from 5 nanograms to 140 picograms per milliliter, and the amended subsection 1844(f) removes Clenbuterol as a drug that may be found in blood test samples. These changes are necessary because Clenbuterol has been abused for its androgenic side effects which mimic anabolic steroids. Androgenic-anabolic steroids are synthetic derivatives of the male hormone testosterone. They can exert strong effects that may be beneficial for athletic performance. This is supported in the research study: The Effect of Chronic Clenbuterol Administration on Mucociliary Clearance and Body Fat in Adult Horses. Clenbuterol is also banned by the World Anti-Doping Association (WADA) as an anabolic agent as listed in The World Anti-Doping Code: The 2014 Prohibited List International Standard. To prevent its use as an anabolic agent the recommended time of administration of the substance is outside of 14 days prior to racing. Clenbuterol is only detectable in blood for 3-7 days, therefore it will not be present in any blood test samples 14 days after administration. A finding of Clenbuterol in a blood test sample will indicate the drug was administered in violation of the Board’s rules. Because Clenbuterol does have legitimate clinical use in small airway disease such as allergic or infectious bronchitis, the Board will continue to allow the use of Clenbuterol when clinically appropriate. Clenbuterol is approved by the FDA for use in horses. The proposed amendment to subsection 1844(e)(9) allows 140 picograms of Clenbuterol per milliliter in urine. The proposal allows a 14 day withdrawal time and is supported in the Maddy Equine Laboratory study: Detection, Pharmacokinetics and Cardiac Effects Following Administration of Clenbuterol to Exercised Horses. The amendment to Rule 1844 provides racing regulators an opportunity to see if Clenbuterol can be administered appropriately for its intended use, as a bronchodilator to treat small airway disease.

The proposed amendment to subsection 1844(e)(10) removes Stanozolol from the list of drugs allowed in official urine test samples. The amendment also eliminates the one exception to non-endogenous anabolic steroids in Rule 1844. Stanozolol is a manufactured anabolic steroid. It was used in racing until 2008 when a threshold level was established in Rule 1844 to restrict its use. At that time, other manufactured anabolic steroids were banned. The new restriction allowed Stanozolol at the 1 nanogram per milliliter level and established a roughly 30 day withdrawal period as a step towards eliminating the drug. As an anabolic steroid, Stanozolol is a
recognized performance enhancing drug. The national (and international) consensus is anabolic steroids have no place in athletic competition. Steroids like Stanazolol need to be eliminated prior to racing because they can provide an unfair advantage. Eliminating the threshold for Stanozolol eliminates the anabolic steroid from any use at any time prior to racing.

Subsection 1844(e)(11) adds Omeprazole and subsection 1844(e)(15) adds Butorphanol to the list of drugs permitted in official urine test samples. Omeprazole is commonly used for the treatment and prevention of equine stomach ulcers and Butorphanol is a commonly used sedative/tranquilizer approved for use in horses. The amendments are consistent with the National Uniform Medication Program recommendations. The proposed amendments will also help deter race day administration of Omeprazole and Butorphanol because, if administered on race day, the drugs will exceed the proposed allowed levels in the urine test samples, resulting in a violation.

The proposed amendment to Rule 1844 will modify subsection 1844(f) to add 15 drug substances that may be present at specified levels in the official blood test sample. Subsection 1844(f)(1-15) adds specified drug substances, their metabolites, and analogs that may be found in official blood test samples. This amendment is in line with the National Uniform Medication Program recommendation. The Racing Medication Testing Consortium has conducted research on these therapeutic drugs to establish the blood thresholds. Whenever possible, therapeutic drugs should be regulated in the blood. Blood is a cleaner and a more pharmacologically stable testing matrix than urine. Blood testing is not possible in all drugs based on a number of factors related to testing sensitivity and drug metabolism. The original thresholds proposed in the mid 1990’s have very little solid scientific drug administration to back them up. At that time, the laboratory sensitivity was not adequate to find any of these drugs in blood unless at very high levels. Today, the technology has changed and blood testing is very sensitive and accurate. It is the preferable testing matrix in horse racing for therapeutic medications, when possible. The proposed amendment to subsection 1844(f)(1-15) will reflect current research and the National Uniform Medication Program recommendations.

The Association of Racing Commissioners International is composed of the governmental regulators of horse and greyhound racing in the United States, Canada, Mexico, Jamaica, and Trinidad-Tobago. Association of Racing Commissioners International collaborates with other racing industry organizations who share its common goal of ensuring integrity in racing. Association of Racing Commissioners International is a not-for-profit trade association with no regulatory authority. Its members individually possess regulatory authority within their jurisdictions and solely determine whether or not to adopt Association of Racing Commissioners International recommendations on policies and rules.

The Racing Medication and Testing Consortium strives to develop and promote uniform rules, policies and testing standards at the national level; coordinate research and educational programs that seek to ensure the integrity of racing and the health and welfare of racehorses and participants; and to protect the interests of the racing public. The Racing Medication Testing Consortium was founded in 2001 by representatives of a broad spectrum of racing-related groups who participated in an industry effort to determine potential consensus points on the most basic elements of a uniform national medication policy for racehorses. The Racing Medication and
Testing Consortium is incorporated as a 501 (c) (3) charitable organization with both scientific and educational purposes. It is governed by a board of directors consisting of 24 industry stakeholder groups.

The National Uniform Medication Program was recommended by the Racing Medication and Testing Consortium and approved by the Association of Racing Commissioners International and includes regulatory levels and restricted administration times for controlled therapeutic medications.

BENEFITS ANTICIPATED FROM THE REGULATORY ACTION.

The proposed amendment to Rule 1844 promotes the safety and welfare of horse and rider. The amendment provides guidelines for treating horses with medications in a manner that will increase the safety and welfare of both equine and human athletes. Strong pain-masking medications are sometimes used inappropriately to allow horses to train and race, before they are fully healed from an injury. Masking a horse’s condition with pain-masking medications has the potential to cause additional injuries to occur. Using pain-masking medications before a horse is fully healed can place a horse at a higher risk for breakdown, which can cause injury to horse and rider. The proposed amendment to Rule 1844 is based on solid research that provides sound recommendations to trainers, owners, and veterinarians, so that therapeutic medications can be used appropriately. The proposed amendment will also provide clarity for horsemen because it is in line with the National Uniform Medication Program recommendations of the Racing Medication Testing Consortium. Regardless of which state they are from, trainers and owners will be clear on what the rules for authorized medications are because other states are implementing, or have already implemented, similar rules. The proposed amendment to Rule 1844 can help to reduce medication violations and promote medication safety, as owners and trainers will not be forced to change medications as they move across the country and into California. This will help increase efficiency in the enforcement of the Board’s medication rules and regulations because out-of-state owners and trainers will be familiar with authorized medications. If trainers and owners are complying with the Board’s rules, the public will have more confidence in California horse racing, which may result in increased wagering. An increase in wagering will have a positive economic impact on the industry by increasing handle, which in turn increases purses and commissions.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS OR DOCUMENTS.

In proposing the amendment to Rule 1844, the Board relied on:

- The results of its Economic Impact Assessment prepared pursuant to Government Code section 11346.3(b); the RMTC National Uniform Medication Program;
- Identification of Acepromazine and Its Metabolites in Horse Plasma and Urine by LC–MS/MS and Accurate Mass Measurement;
- Regulatory Significance of Procaine Residues in Plasma and Urine Samples: Preliminary Communication;
• Plasma Concentration and Local Anesthetic Activity of Procaine Hydrochloride Following Subcutaneous Administration to Horses;
• The Effect of Chronic Clenbuterol Administration on Mucociliary Clearance and Body Fat in Adult Horses;
• The World Anti-Doping Code: The 2014 Prohibited List International Standard; and
• Detection, Pharmacokinetics and Cardiac Effects Following Administration of Clenbuterol to Exercised Horses.

The Board did not rely on any other technical, theoretical, and/or empirical study, reports or documents in proposing the amendment to Rule 1844.

RESULTS OF ECONOMIC IMPACT ASSESSMENT.

The results of the Board’s Economic Impact Assessment as required by Government Code Section 11346.3(b) are as follows:

• The proposed regulation will not impact the creation or eliminate jobs within the State of California, or the creation of new businesses or the elimination of existing business or the expansion of businesses in California.
• The proposed addition to Rule 1844 will not impact the creation of new businesses or eliminate existing businesses in California.
• Rule 1844 will not impact the expansion of businesses currently doing business in California.
• The proposed regulation will benefit the health and welfare of riders who are California residents and will not benefit the State’s environment.

The Board has made an initial determination that the proposed addition to Rule 1844 will not have a significant statewide adverse economic impact directly affecting business including the ability of California businesses to compete with businesses in other states. The amendment to Rule 1844 will revise the levels of specified authorized medications and add additional drug substances to bring Rule 1844 in line with the National Uniform Program recommendations.

ALTERNATIVE TO THE PROPOSED REGULATORY ACTION THAT WOULD LESSEN ANY ADVERSE IMPACT ON AFFECTED PRIVATE PERSONS OR BUSINESSES.

The Board has determined that there were no alternatives considered which would be more effective in carrying out the purposes of the proposed regulation or would be more effective and less burdensome to affected private persons or businesses than the proposed regulation.

REASONABLE ALTERNATIVES TO THE PROPOSED REGULATORY ACTION.

The proposed addition to Rule 1844 was discussed at the May 22, 2013 and the November 20, 2013 Medication and Track Safety Committee Meetings and the November 21, 2013 Regular Board Meeting. No alternatives to the recommendation were proposed by the Board or by any other individual or entity at either meeting. No subsequent alternative recommendations were
California Horse Racing Board  
April 18, 2014

CALIFORNIA HORSE RACING BOARD  
TITLE 4. CALIFORNIA CODE OF REGULATIONS  
ARTICLE 15. VETERINARY PRACTICES  
PROPOSED AMENDMENT OF  
RULE 1844. AUTHORIZED MEDICATION.

1844. Authorized Medication.

Consistent with the intent of these rules, drug substances and medications authorized by the Board for use may be administered to safeguard the health of the horse entered to race provided that:

(a) No person shall administer a drug substance to any horse entered to race except upon authorization of the official veterinarian in conformance with these rules.

(b) No drug substance, other than authorized bleeder medication, shall be administered to a horse entered to race within 24 hours of the race in which entered.

(c) Not more than one approved non-steroidal anti-inflammatory drug substance (NSAID) may be administered to a horse that is entered to race and shall be only one of the following authorized drug substances:

(1) Phenylbutazone in a dosage amount that the test sample shall contain not more than 2 micrograms of the drug substance per milliliter of blood plasma or serum.
(2) Flunixin in a dosage amount that the test sample shall contain not more than 20 nanograms of the drug substance per milliliter of blood plasma or serum.

(3) Ketoprofen in a dosage amount that the test sample shall contain not more than 10 nanograms of the drug substance per milliliter of blood plasma or serum.

(4) Metabolites or analogues of approved NSAIDs may be present in post race test samples.

(d) If the official chemist reports that a blood test sample contains an authorized NSAID in excess of the limit for that drug substance under this rule, the official veterinarian shall, in conjunction with the veterinarian who administered or prescribed the authorized drug substance, establish a dosage amount or time of administration of the drug substance that will comply with the limits under this rule; or the official veterinarian may, if in his/her judgment no such reduced dosage amount or amendment to time of administration will result in a test sample level within the limits of this rule, withdraw authorization for the use of any one NSAID.

(e) Official urine test samples may contain one of the following drug substances, their metabolites or analogs, in an amount that does not exceed the specified levels:

1. Acepromazine; 25 \( \leq 10 \) nanograms per milliliter
2. Mepivacaine; 10 nanograms per milliliter
3. Promazine; 25 nanograms per milliliter
4. Albuterol; 1 nanogram per milliliter
5. Atropine; 10 nanograms per milliliter
6. Benzocaine; 50 nanograms per milliliter
7. Procaine; 50 25 nanograms per milliliter
8. Salicylates; 750 micrograms per milliliter
(96) Clenbuterol; 5 nanograms 140 picograms per milliliter

(10) Stanazolol; 1 nanograms per milliliter

(7) Omeprazole; 1 nanogram per milliliter

(448) Nandrolone; 1 nanograms per milliliter for geldings, fillies and mares; 45 nanograms for males other than geldings.

(429) Boldenone; 15 nanograms per milliliter in males other than geldings.

(4310) Testosterone; 20 nanograms per milliliter in geldings.

(A) Testosterone at any level in males other than geldings is not a violation of this regulation.

(4411) Testosterone; 55 nanograms per milliliter in fillies or mares.

(4512) Butorphanol 300 nanograms per milliliter

(f) Official blood test samples may contain clenbuterol in an amount not to exceed 25 picograms per milliliter of serum or plasma. the following drug substances, their metabolites and analogs, in an amount that does not exceed the specified levels in serum or plasma:

(1) Bethamethasone; 10 picograms per milliliter

(2) Dantrolene; 100 picograms per milliliter

(3) Detomidine; 1 nanogram per milliliter

(4) Dexamethasone; 5 picograms per milliliter

(5) Diclofenac; 5 nanograms per milliliter

(6) Dimethylsulfoxide (DMSO); 10 micrograms per milliliter

(7) Firocoxib; 20 nanograms per milliliter

(8) Lidocaine; 20 picograms per milliliter

(9) Methocarbamol; 1 nanogram per milliliter
(10) Methylprednisolone; 100 picograms per milliliter
(11) Glycopyrrolate; 3 picograms per milliliter
(12) Prednisolone; 1 nanogram per milliliter
(13) Triamcinolone Acetonide; 100 picograms per milliliter
(14) Xylazine; 10 picograms per milliliter of serum or plasma
(15) Butorphanol; 2 nanograms per milliliter

(g) Official blood test samples shall not contain any of the drug substances, or their metabolites or analogs listed in subsection (e)(1)-(8), and (e)(10)-(14).

(h) Procaine, following administration of procaine penicillin, is an authorized medication provided:
   (1) Official blood test samples shall not contain any procaine, or its metabolites or analogs in excess of 25 nanograms per milliliter.
   (2) all procaine penicillin administrations have been reported pursuant to Rule 1842 of this division,
   (3) procaine penicillin was not administered after entry to race,
   (4) the horse was under surveillance for a minimum of six hours prior to racing.

(i) All expenses related to surveillance and testing for procaine under subsection (h) of this regulation shall be paid by the owner of the horse.

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