

INITIAL STATEMENT OF REASONS

Rule 1867.1 Use of Bisphosphonates Prohibited

SPECIFIC PURPOSE OF THE REGULATION

The addition of Rule 1867.1, Use of Bisphosphonates Prohibited, will prohibit the administration of bisphosphonates to any horse within a CHRB inclosure and prohibit any licensee from bringing into the inclosure a horse that has been administered a bisphosphonate within the previous six months. The proposed regulation will allow the administration of methylene diphosphonate in combination with radionuclide technetium 99m for nuclear imaging purposes.

PROBLEM

Bisphosphonates are a class of bone modifying drugs that have been used to treat specific bone disorders in people. In horses, bisphosphonates are used to treat similar problems, like navicular disease¹. Bisphosphonates, however, inhibit the normal bone repair process so their use has generally been restricted to horses that are four years or older. In younger horses, bisphosphonate use could lead to disturbed growth and joint development as well as the accumulation of microdamage in the bone tissue. Since 2015 the British Horse Racing Authority has restricted the use of bisphosphonates in horses younger than three-and-a-half years old. The New York State Gaming commission has included bisphosphonates in its list of blood doping agents and has provided that the administration of bisphosphonates to a horse under four years of age is an unacceptable practice due to the high risk of serious injury or death from its effects on bone growth and strength. The proposed addition of Rule 1867.1 would prohibit the use of bisphosphonates in race horses within a CHRB inclosure and prohibit a horse that has been administered a bisphosphonate with the previous six months from being shipped onto a CHRB inclosure. The proposed regulation will allow the administration of methylene diphosphonate in combination with radionuclide technetium 99m for nuclear imaging purposes.

NECESSITY

Subsection 1867.1(a) provides that bisphosphonates may not be administered to any horse within a CHRB inclosure. The Board has specifically prohibited the use of bisphosphonates within the inclosure based on its concerns regarding the potential for use of the drug substances to harm the health and safety of horse and rider. In addition to bisphosphonates' effect on bone growth, the drug substances may mitigate pain. The potential for pain relief with the use of bisphosphonates on young horses could result in race horses with mild injuries continuing to train and race with the increased probability for mild injuries to become catastrophic.

¹ Navicular disease in the horse is a group of related conditions affecting the navicular bone and associated structures in the foot. It most commonly describes an inflammation or degeneration of the navicular bone and its surrounding tissues, usually on the front feet. It can lead to significant lameness.

Subsection 1867.1(b) provides that no licensee shall bring into a CHRB inclosure a horse that has been administered a bisphosphonate within the previous six months. This provision is necessary to protect the health and welfare of the horse and rider. Bisphosphonates are a class of bone-modifying drugs that have been used as a supplemental treatment for specific bone disorders in human medicine. The drugs work specifically at the cellular level and act to block a certain type of bone cell called an osteoclast². Osteoclasts are important in the remodeling of bone because they act to clean up any diseased, weakened or damaged bone before any new bone can be laid down by the osteoblasts³. Bisphosphonates act on damaged bone by shutting down the osteoclast process. The body can lay down bone, just not in a “normal” way. Bisphosphonates inhibit part of the normal remodeling osteogenesis process. It is believed that bisphosphonate use in immature animals could lead to disturbed growth and joint development and the accumulation of microdamage in the bone tissues. There is the potential for adverse effects in race horses that are still growing. In the extreme, accumulated microdamage could combine and promote bone fracture. Fracture healing may be delayed in horses that sustain a fracture. Additionally, there is evidence that bisphosphonates relieve pain. Race horses with mild injuries could continue to train and race, increasing the potential for mild injuries to become catastrophic. The clinical duration of bisphosphonates to inhibit normal bone repair is unknown, especially in horses. It is estimated to be six to eight months; however, six months is the best-informed estimate of inhibition of bone repair. By prohibiting a horse that has been administered bisphosphonates from entering a CHRB inclosure for six months, the provisions of subsection 1867.1(b) will act to protect horse and rider from the potentially catastrophic effects of bisphosphonate use in race horses.

Subsection 1867.1(c) allows for the administration of methylene diphosphonate when used in combination with radionuclide technetium 99m for nuclear imaging purposes. Methylene diphosphonate is a chemical compound (methylene bound to two phosphonate groups) used together with the radionuclide technetium 99 (Tc 99m) to locate areas of bone abnormalities. The substance is administered intravenously, and skeletal uptake occurs. Nuclear imaging produces images by detecting radiation from different parts of the body after a radioactive tracer material is administered. The Board has determined it is necessary to allow the administration of methylene diphosphonate for the health and safety of the horse.

BENEFITS ANTICIPATED FROM THE REGULATORY ACTION

The proposed addition of Rule 1867.1 provides that bisphosphonates may not be administered to any horse within a CHRB inclosure. Additionally, no horse that has been administered a bisphosphonate within the previous six months shall be brought into a CHRB inclosure. The administration of methylene diphosphonate when used in

² Osteoclast: large cells that dissolve the bone. Osteoclasts come from the bone marrow and are related to white blood cells. They are formed from two or more cells that fuse together. Osteoclasts absorb bone tissue during growth and healing.

³ Osteoblast: cells that form new bone.

combination with radionuclide technetium 99 for nuclear imaging purposes is allowed. The proposed addition of Rule 1867.1 promotes the health and safety of race horses, which is jeopardized if they workout or race when they are not sound do to the administration of unauthorized medications or drug substances. Keeping race horses healthy protects the economic interest of owners and ensures that there is adequate horse inventory. Ensuring that horses entered to race are sound also promotes jockey/driver safety. Accordingly, the proposed regulation benefits the health and welfare of California residents and improves worker safety. Sound, healthy horses result in a favorable public response to horse racing, which could result in an increase in wagering activity, and a positive economic impact for the industry.

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

RMTC Racing Medication & Testing Consortium: Bisphosphonates: A dense Issue in equine veterinary care: DVM360 2/26/19.

RMTC Racing Medication & Testing Consortium: Advisory Warning – Bisphosphonates: New York Gaming Commission 3/28/19

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 elimination of jobs within the State of California.
- The proposed regulation will not have an impact on the creation of new businesses or the elimination of existing businesses in the State of California.
- The proposed regulation will not have an impact on the expansion of existing businesses in the State of California.
- The proposed regulation will benefit the State of California by helping to ensure the health and safety of horse and rider. The proposed regulation will not benefit the State of California's environment.

The Board has made the initial determination that the proposed addition of Rule 1867.1 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 proposed regulation will prohibit the administration of bisphosphonates to any horse within a CHRB inclosure and prohibit any licensee from bringing into the inclosure a horse that has been administered a bisphosphonate within the previous six months. The proposed regulation will allow the administration of methylene diphosphonate in combination with radionuclide technetium 99m for nuclear imaging purposes. The regulation deals solely with the administration of bisphosphonates to race horses; therefore, the Board has determined that the Rule 1867.1 will not have an adverse economic impact.

Purpose:

The proposed addition of Rule 1867.1 will ensure that horses will not be administered bisphosphonates within a CHRB inclosure. Additionally, no horse that has been administered bisphosphonates within the previous six months will be brought into a CHRB inclosure. To ensure the health and safety of the horse, however, methylene diphosphonate may be administered when used in combination with the radionuclide technetium 99m for nuclear imaging purposes. The purpose of the proposed regulation is to protect the health and safety of horse and rider by ensuring that bisphosphonates are not used within a CHRB inclosure. The Board has determined that because bisphosphonates have the potential to inhibit the natural healing process for bone, particularly in horses under four years old, and has the potential to mask pain, its use within a CHRB inclosure shall be prohibited. Additionally, as the clinical duration of bisphosphonates to inhibit normal bone repair is unknown, especially in horses, the Board has determined that no horse that has been administered bisphosphonates within the previous six months shall be brought into a CHRB inclosure. The proposed regulation, however, will allow the administration of methylene diphosphonate for the purposes of nuclear imaging. In this regard, the regulation will help protect the health and safety of horse and rider. The regulation will ensure that a drug substance whose administration to horses under four years is an unacceptable practice will not be administered to a horse within a CHRB inclosure.

The Creation or Elimination of Jobs Within the State of California

The addition of Rule 1867.1 will prohibit the administration of bisphosphonates to any horse within a CHRB inclosure and prohibit any licensee from bringing into the inclosure a horse that has been administered a bisphosphonate within the previous six months. The proposed regulation will allow the administration of methylene diphosphonate in combination with radionuclide technetium 99m for nuclear imaging purposes. The proposed regulation will impact trainers who are found to have administered bisphosphonates to a horse within a CHRB inclosure, or whose horses test positive for the presence of bisphosphonates in official blood or urine samples. The proposed regulation will also affect owners and trainers whose horses have been administered bisphosphonates within six months of being brought into a CHRB inclosure. The proposed regulation will not have an effect on any other type of California business. Therefore, the CHRB has determined that this regulatory action will not have a significant impact on the creation or elimination of jobs in the State of California.

The Creation of New Businesses or the Elimination of Existing Businesses within the State of California

The addition of Rule 1867.1 will prohibit the administration of bisphosphonates to any horse within a CHRB inclosure and prohibit any licensee from bringing into the inclosure

a horse that has been administered a bisphosphonate within the previous six months. The proposed regulation will allow the administration of methylene diphosphonate in combination with radionuclide technetium 99m for nuclear imaging purposes. The proposed regulation will impact trainers who are found to have administered bisphosphonates to a horse within a CHRB inclosure, or whose horses test positive for the presence of bisphosphonates in official blood or urine samples. The proposed regulation will also affect owners and trainers whose horses have been administered bisphosphonates within six months of being brought into a CHRB inclosure. The proposed regulation will impact trainers who are found to have administered bisphosphonates to a horse within a CHRB inclosure, or whose horses test positive for the presence of bisphosphonates in official blood or urine samples. The proposed regulation will also affect owners and trainers whose horses have been administered bisphosphonates within six months of being brought into a CHRB inclosure. The proposed regulation only has an effect on a limited number CHRB licensees, and as such only has an effect on horseracing and not any other type of California business. Therefore, the CHRB has determined this regulatory proposal will not have an impact on the creation of new businesses or the elimination of existing businesses in the State of California.

The Expansion of Businesses Currently Doing Business Within the State of California

The addition of Rule 1867.1 will prohibit the administration of bisphosphonates to any horse within a CHRB inclosure and prohibit any licensee from bringing into the inclosure a horse that has been administered a bisphosphonate within the previous six months. The proposed regulation will allow the administration of methylene diphosphonate in combination with radionuclide technetium 99m for nuclear imaging purposes. The proposed regulation will impact trainers who are found to have administered bisphosphonates to a horse within a CHRB inclosure, or whose horses test positive for the presence of bisphosphonates in official blood or urine samples. The proposed regulation will also affect owners and trainers whose horses have been administered bisphosphonates within six months of being brought into a CHRB inclosure. The proposed regulation will impact trainers who are found to have administered bisphosphonates to a horse within a CHRB inclosure, or whose horses test positive for the presence of bisphosphonates in official blood or urine samples. The proposed regulation will also affect owners and trainers whose horses have been administered bisphosphonates within six months of being brought into a CHRB inclosure. The proposed regulation only has an effect on a limited number CHRB licensees, and as such only has an effect on horseracing and not any other type of California business. Therefore, the CHRB has determined that the proposed regulatory action is not relevant to the expansion of businesses currently doing business in the State of California.

Benefits of the Regulation to the Health and Welfare of California Residents, Worker Safety, and the State's Environment

The proposed addition of Rule 1867.1 will protect the health and safety of California's race horses, jockeys and exercise riders. Bisphosphonates inhibit the normal bone repair

process, so their use has generally been restricted to horses that are four years or older. In younger horses, bisphosphonate use could lead to disturbed growth and joint development as well as the accumulation of microdamage in the bone tissue. There is evidence that bisphosphonates relieve pain. Race horses with mild injuries could continue to train and race, increasing the potential for mild injuries to become catastrophic. The prohibition on the use of bisphosphonates will ensure that horses entered to race are sound and will also promote jockey/driver safety. Accordingly, the proposed regulation benefits the health and welfare of California residents and improves worker safety. The regulation does not benefit the state's environment.

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

The Board has determined that no reasonable alternative it considered or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to 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.

REASONABLE ALTERNATIVES TO THE PROPOSED REGULATORY ACTION

The proposed addition of Rule 1867.1 was discussed at the June 2019 Regular Board Meeting. No alternatives to the recommendation were proposed by the Board or by any other individual or entity at the meeting. No subsequent alternative recommendations were made prior to the notice. The Board invites any interested party to submit comments which offer any alternative proposal.

California Horse Racing Board
October 18, 2019