

Jobs Impact

The Board does not anticipate that the proposed amendment will increase or decrease jobs in the State.

Agriculture Industry Impact

The proposed amendment will have no impact on the agriculture industry in the State.

Regulatory Flexibility Statement

The proposed amendment applies to all licensed pharmacists and pharmacies in the State, some of which may operate as "small businesses" within the meaning of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. As the proposed amendment will impose no new costs or reporting, recordkeeping, or compliance requirements, and as the Board does not believe that licensees will need to employ any professional services to comply with the proposed amendment, a regulatory flexibility analysis is not required.

Housing Affordability Impact Analysis

The proposed amendment will have an insignificant impact on affordable housing in New Jersey and there is an extreme unlikelihood that the proposed amendment would evoke a change in the average costs associated with housing because the proposed amendment concerns standards for prescription container integrity.

Smart Growth Development Impact Analysis

The proposed amendment will have an insignificant impact on smart growth and there is an extreme unlikelihood that the proposed amendment would evoke a change in housing production in Planning Areas 1 or 2, or within designated centers, under the State Development and Redevelopment Plan in New Jersey because the proposed amendment concerns standards for prescription container integrity.

Full text of the proposal follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

SUBCHAPTER 5. RETAIL FACILITY REQUIREMENTS

13:39-5.8 Minimum equipment and supplies; cleanliness

(a) All prescription areas shall contain the following minimum equipment and supplies, which shall be stored, so as to be readily accessible:

1.-10. (No change.)

11. Two Drug Utilization Review Council Placards and the 29th edition of the list of "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book," incorporated herein by reference, as amended and supplemented[, consistent with Department of Health and Senior Services rules set forth at N.J.A.C. 8:71-1]. The Orange Book can be obtained by contacting the Superintendent of Documents, Government Printing Office, PO Box 371954, Pittsburgh, PA 15250-7954, (202) 512-1800 or toll free (866) 512-1800, and is available on-line at <http://www.fda.gov/cder/orange/default.htm> and at <http://www.fda.gov/cder/ob/default.htm>;

12. Assorted stock of prescription containers and child safety closures or caps that meet the **standards on light resistance, tightness, and water vapor permeation of Chapter 661 and moisture permeability of Chapter 671 of the United States Pharmacopoeia/National Formulary [standards on light resistance and tightness], 2014 edition, which are both incorporated herein by reference, as amended and supplemented, and are available for purchase at the United States Pharmacopoeia/National Formulary website at www.usp.org**; and

13. (No change.)

(b)-(c) (No change.)

(a)

NEW JERSEY RACING COMMISSION**Thoroughbred Racing****Intent of Medication Rules; General Provisions; Penalties; Anabolic Steroids****Proposed Amendments: N.J.A.C. 13:70-14A.1, 14A.7, and 14A.17**

Authorized By: New Jersey Racing Commission, Frank Zanzuccki, Executive Director.

Authority: N.J.S.A. 5:5-30.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2014-093.

Submit written comments by August 15, 2014, to:

Michael Vukcevic, Deputy Director
Department of Law and Public Safety
New Jersey Racing Commission
P.O. Box 088
Trenton, New Jersey 08625-0088

The agency proposal follows:

Summary

Subchapter 14A, Medication and Testing Procedures, sets forth the rules of the New Jersey Racing Commission (Commission) concerning administration of medication and foreign substances to thoroughbred racing horses and the penalties associated with the same. The Commission proposes amendments to the subchapter to codify portions of the Association of Racing Commissioners International (RCI) Model Rules on Medications and Prohibited Substances in order to ensure proper administration of medications, protect the health of the horses, and protect the integrity of the sport.

N.J.A.C. 13:70-14A.1, Intent of medication rules; general provisions, is proposed for amendment at subsection (b). Existing subsection (b) provides that "[o]n the day of the race, irrespective of the date, time and method of administration, no horse entered to start in or participating in any race shall carry in its body any drug and/or substance foreign to the natural horse, excepting external rubs and innocuous compounds as defined in this section and as otherwise provided for in these rules." Subsection (b) also lists 13 examples of drugs and/or substances foreign to the natural horse that are prohibited. These examples are: articles meeting the definition of drug as set forth in N.J.A.C. 13:70-2.1; chemical substances; stimulants; depressants; anesthetics; tranquilizers; anti-inflammatories; erythropoietin (epogen, EPO); pain killers; sodium bicarbonate (baking soda); confectionery sugar; stamina builders; and mixtures, compounds or solutions commonly referred to as "milkshakes," which contain any prohibited drug and/or substance.

Proposed new paragraph (b)14 encompasses 26 medications that are prohibited when these medications test at or above the threshold level, which the rule incorporates as discussed below. The proposed amendment incorporates by reference 26 medications categorized as Controlled Therapeutic Medications that have been identified and recognized by RCI as being necessary for the routine treatment of illness or injury in the race horse. Although these medications have been recognized as necessary for the routine treatment of illness or injury in the race horse, research has determined that these medications may impact a race horse's performance on race day. As a result, in order to maintain the integrity of the sport, these medications are permissible only when a race horse tests below the threshold levels set forth in the RCI Controlled Therapeutic Medication Schedule, Version 2.1 (Revised April 17, 2014) (Schedule), which is incorporated by reference, as amended and supplemented, through the proposed amendment on the day of a race. It is important to note that the dosage and method of administration included in the Schedule in the column "Dosing Specifications" specific to each medication, as well as the pre-race periods of time designated in the column "Withdrawal Guideline," are guidelines provided by RCI offering advisory recommendations as to the dose, method of administration, and time of administration that, if complied with, are

likely to result in a race day test result that is lower than the threshold level set in the “Threshold” column. A race day test result that is at or above the levels set forth in the “Threshold” column shall be considered a violation of N.J.A.C. 13:70-14A.1(b), even if the licensee or licensees involved assert that they complied with the guidelines set forth in the “Dosing Specifications” and “Withdrawal Guideline” columns in the Schedule.

During the pendency of this proposed rulemaking, the Commission intends to issue written warnings when race horses test at or above the threshold levels for the 26 medications in the Schedule. Upon the effective date of the amendments, penalties will be imposed for any violations of this rule.

The proposed amendment to the rule identifies that the RCI Controlled Therapeutic Medication Schedule, Version 2.1 may be obtained from the RCI’s website at <http://arcicom.businesscatalyst.com/assets/arcicom-controlled-therapeutic-medication-schedule---version-2.1.pdf>. The Commission is incorporating the RCI Controlled Therapeutic Medication Schedule, Version 2.1, by reference, as amended and supplemented. To the extent that the RCI supplements and amends the schedule, it is an individual’s responsibility for reviewing the Controlled Therapeutic Medication Schedule for such supplements and amendments.

The Commission is proposing amendments to N.J.A.C. 13:70-14A.7, Penalties, at subsection (c) and (d) to address situations concerning individuals who repeatedly violate the medication rules. The proposed amendments would address these situations by imposing enhanced penalties. The proposed amendments are intended to act as a deterrent for individuals considering violating the medication rules and will also prevent repeat offenders from participating in horse racing for significant periods of time by imposing lengthier suspensions for multiple medication violations. The proposed amendment to N.J.A.C. 13:70-14A.7(c) incorporates by reference, RCI Model Rule ARCI-011-020B(13), Multiple Medication Violations (MMV) (Version 5.7, Approved April 9, 2014), as amended and supplemented by the RCI (“ARCI-011-020B(13)” or “RCI-MMV”). To the extent the RCI updates the RCI-MMV, it is an individual’s responsibility to remain current on the content of said rule.

ARCI-011-020B(13)(a) provides for enhanced penalties to be imposed upon trainers responsible for horses with test results that violate the medication rules of the Commission or any comparable rule of any other racing commission or turf governing body by containing evidence of substances that are set forth in the Alphabetical Substance List in the RCI Uniform Classification Guidelines for Foreign Substances and Recommended Penalties and Model Rule (Version 7.00, Revised January 2014) (Alphabetical List). The Alphabetical List can be found at <http://arcicom.businesscatalyst.com/assets/uniform-classification-guidelines-%2c-version-07-00.pdf>, pages 1 through 11. The Alphabetical List contains a chart identifying foreign substances that may be detected in equine blood or urine samples. The Alphabetical List assigns a “Penalty Class” of A, B, C, or D to each foreign substance. Because the Alphabetical List is material to the provisions of ARCI-011-020B(13), the Commission also proposes to incorporate it by reference, as amended and supplemented. To the extent RCI updates the Alphabetical List, it is an individual’s responsibility to remain current on the content of the Alphabetical List.

ARCI-011-020B(13)(a) provides that a trainer who receives a penalty in connection with a horse testing positive for a medication that is included in the Alphabetical List shall be assigned points based upon the medication’s penalty classification. The points imposed by the chart in ARCI-011-020B(13)(a) are divided into three columns: “Class,” which lists the four penalty classes A, B, C, and D; “Points If Controlled Therapeutic Substance,” which imposes points for violations involving a medication with a penalty classification of A, B, C, or D that is also a Controlled Therapeutic Substance identified in the proposed amendment to N.J.A.C. 13:70-14A.1 as discussed above; and “Points If Non-Controlled Substances,” which imposes points for all other medication testing violations. No Controlled Therapeutic Substance identified in the Alphabetical List is classified with a Class A penalty. As a result, the RCI-MMV does not impose any points for this column. The RCI-MMV provides that an individual shall be assigned six points for a violation that involves a Non-Controlled Substance categorized with a Class A penalty. The RCI-MMV provides that an individual shall be assigned two points

for a violation that involves a Controlled Therapeutic Substance with a Class B penalty and four points for a violation that involves a Non-Controlled Substance with a Class B penalty. The RCI-MMV provides that an individual shall be assigned one point for a violation that involves a Controlled Therapeutic Substance with a Class C penalty and two points for a violation that involves a Non-Controlled Substance with a Class C penalty. Finally, the RCI-MMV provides that an individual shall be assigned one-half of a point for a violation that involves a Controlled Therapeutic Substance with a Class D penalty and one point for a violation that involves a Non-Controlled Substance with a Class D penalty.

ARCI-011-020B(13)(b) provides that the point value assigned to a medication violation shall be included in the Stewards’ or Commission ruling. Additionally, ARCI-011-020B(13)(b) provides that the Stewards’ or Commission ruling shall determine, in cases of multiple positive tests as described in ARCI-011-020B(13)(d), whether or not those multiple positive tests shall constitute a single violation. ARCI-011-020B(13)(b) provides that the ruling shall be posted on the official website of the Commission, as well as the official website of RCI. The ruling shall also note if any appeal is pending. ARCI-011-020B(13)(b) also provides that no points shall be applied until a final adjudication by the Racing Commission or court, if applicable, of the enforcement of any such violation. A violation shall be considered to have reached final adjudication upon entry of its associated points in the RCI database.

ARCI-011-020B(13)(c) provides that a trainer’s cumulative points for violations in all racing jurisdictions shall be maintained and certified by RCI. The establishment of a universal database maintained by RCI would create uniformity among the jurisdictions. ARCI-011-020B(13)(c) provides that once all appeals are waived or exhausted, the points shall immediately become part of the trainer’s official RCI record and shall subject the trainer to mandatory enhanced penalties imposed by the Stewards or Commission, as provided in the RCI-MMV. Appeals are considered waived when the imposed fine is paid or suspension served. Appeals are exhausted when the highest State authority that is pursued renders its decision. As noted above, the recording of points in the RCI database related to a violation is considered the final adjudication of that violation.

ARCI-011-020B(13)(d) permits that multiple positive test results for the same medication incurred by a trainer prior to delivery of official notice by the Commission may, at the discretion of the Commission, be treated as a single violation. ARCI-011-020B(13)(d) permits the Commission discretion when there is evidence that the second and/or subsequent violations occurred before the trainer received notice of the initial violation.

ARCI-011-020B(13)(e) provides that the official RCI record of the violations shall constitute prima facie evidence of a trainer’s past record of violations and cumulative points. As such, the existence of violations on a trainer’s official RCI record creates a basis for the Commission to impose enhanced penalties in accordance with the RCI-MMV, in addition to the penalty for the underlying offense. ARCI-011-020B(13)(e) also provides that a licensed trainer does not have the right to appeal a violation for which all remedies have been exhausted or for which the appeal time has expired as provided by applicable law.

ARCI-011-020B(13)(f) provides that the Stewards or the Commission shall include all points for violations in all racing jurisdictions as contained in the trainer’s official RCI record when determining whether the mandatory enhancements provided in the RCI-MMV shall be imposed. ARCI-011-020B(13)(f) prevents a racing commission or jurisdiction from haphazardly picking and choosing which violations from other jurisdictions are to be considered and which violations are not to be considered, regardless of reason. The intent of ARCI-011-020B(13)(f) is to ensure that multiple medication violations by trainers across various jurisdictions are addressed in a uniform manner.

ARCI-011-020B(13)(g) sets forth enhancements that shall be imposed upon a licensed trainer based upon the cumulative points contained in his or her official RCI record, in addition to the penalty for the underlying offense. ARCI-011-020B(13)(g) contains a table that sets forth the length of the suspension imposed in relation to the number of cumulative points in the trainer’s official RCI record. The table contains two columns, a “Points” column and a “Suspension in days” column. Specifically, the

chart indicates the following: if an individual has three-to-5.5 cumulative points, a 30-day suspension shall be imposed in addition to the penalty imposed for the underlying offense; if an individual has six-to-8.5 cumulative points, a 60-day suspension shall be imposed in addition to the penalty imposed for the underlying offense; if an individual has nine-to-10.5 cumulative points, a 180-day suspension shall be imposed in addition to the penalty imposed for the underlying offense; and, if an individual has 11 or more points, a 360-day suspension shall be imposed in addition to the penalty imposed for the underlying offense. ARCI-011-020B(13)(g) provides that penalties imposed for multiple medical violations are not a substitute for the current penalty system and are intended to be an additional uniform penalty when the licensee has more than one violation for the relevant time period in which the licensee exceeds the permissible number of points. The enhanced penalties have been introduced to address those individuals who repeatedly violate the medication rules. It is the Commission's intent that the incorporation by reference of ARCI-011-020B(13), as amended and supplemented, will act as a deterrent for those individuals and others from repeatedly violating the medication rules, thereby protecting the health of the race horse and the integrity of racing.

ARCI-011-020B(13)(h) provides that the suspension periods set in the chart described in ARCI-011-020B(13)(g) are to run consecutive to any suspension imposed for the underlying offense. ARCI-011-020B(13)(h) ensures that ARCI-011-020B(13) will have the intended effect as a deterrent to those who consistently violate the medication rules and those who consider violating the medication rules, by having a more serious impact on those trainers who repeatedly violate the medication rules.

ARCI-011-020B(13)(i) requires that the Stewards' or Commission's rulings shall distinguish between the penalty for the underlying offense and any enhancement penalty imposed as a result of the trainer's cumulative points. Compliance with ARCI-011-020B(13)(i) will resolve any confusion that may arise from the Commission's simultaneous decisions imposing a penalty for the underlying offense, as well as an enhanced penalty as a result of the trainer's cumulative record for multiple medication violations.

ARCI-011-020B(13)(j) sets forth the expungement schedule for the enhanced penalties imposed as a result of a trainer's cumulative points for multiple medication violations. The schedule consists of two columns. The first column, "Penalty Classification," sets forth the Penalty Classes A, B, C, and D for medications listed in the Alphabetical List. The second column, "Time to Expungement," sets forth the number of years points shall remain on a trainer's cumulative record before the trainer can take action to have those points removed. ARCI-011-020B(13)(j) provides that any individual who has been assigned points for multiple medication violations may petition RCI to expunge those points after a predetermined period of time. Specifically, an individual may petition RCI for an expungement of points assigned as a result of a Penalty Class B violation after three years. An individual may request expungement of points assigned as a result of a Penalty Class C violation after two years. Finally, an individual may request expungement of points assigned as a result of a Penalty Class D violation after one year. However, violations that fall into Penalty Class A are permanent and shall not be expunged.

Existing N.J.A.C. 13:70-14A.7(c) provides that "[a]ny individual suspended or disciplined in any fashion for a second or subsequent violation of N.J.A.C. 13:70-14A.6(a), (b), (d) or any comparable rule of any other racing commission or turf governing body may be deemed a repetitive offender" and that "[a] second or subsequent violation of [N.J.A.C.] 13:70-14A.6 may constitute grounds for further disciplinary action by the Commission." The proposed amendment to N.J.A.C. 13:70-14A.7(c) would delete the phrase "a second or subsequent violation of N.J.A.C. 13:70-14A.6(a), (b), (d)" and replace it with the broader language "multiple violations of this subchapter," which will include violations of ARCI-011-020B(13). The proposed amendment would delete the word "may" in the first sentence and replace it with "shall" to reflect the intention of the Commission that these enhanced penalties imposed in accordance with ARCI-011-020B(13) are mandatory. The proposed amendment would also delete the word "repetitive" and replace it with "repeat" for grammatical purposes. Moreover, the proposed amendment to N.J.A.C. 13:70-14A.7(c) will add the following language after the word offender, "and shall be subject to enhanced penalties

pursuant to RCI Model Rule ARCI-011-020B(13), Multiple Medication Violations (MMV) (Version 5.7, Approved April 9, 2014), which is incorporated herein by reference, as amended and supplemented, or as otherwise ordered by the Commission or its Stewards." The proposed amendment also provides how to obtain the full text of ARCI-011-020B(13). Currently, it can be found on pages 272-273 of the RCI Model Rules. The website link for chapters five through 11 of the Model Rules (where ARCI-011-020B(13) can be viewed) is http://www.ua-rtip.org/sites/ua-rtip.org/files/Flat%20Racing%20Chapters_5-11.pdf. The discretion afforded to the Commission or its Stewards acknowledges the language of N.J.A.C. 13:70-16, which grants broad discretion in determining appropriate penalties for violations by licensees. The inclusion of this language is to acknowledge situations where the Commission or its Stewards may order additional penalties not discussed by ARCI-011-020B(13). The proposed amendment would also delete the last sentence of the subsection as it is redundant.

It must be noted, the Commission is proposing to adopt, through incorporation, all amended and supplemented versions of ARCI-011-020B(13), Multiple Medical Violations (MMV). It is important to note that as ARCI-011-020B(13) is amended or supplemented by RCI, the page number where it appears on the website may change. It is the Commission's intention to incorporate these changes as they occur. As such, individuals are responsible for keeping current on any and all changes to ARCI-011-020B(13).

Further, the proposed amendment to N.J.A.C. 13:70-14A.7(c) provides that the Commission may, within its discretion, consider evidence of compliance with the guidelines set forth in the "Dosing Specifications" and "Withdrawal Guideline" columns as mitigating factors, when appropriate, in determining the penalty to be imposed for a violation of the "Threshold" column levels. This provides the Commission the opportunity to positively consider a licensee's attempts to comply with the rule, when evidence of such attempts is presented to the Commission. The Commission's intent in proposing this amendment is to make racing safer for the race horses. However, it is also important to provide the Commission discretion to mitigate the penalty for a threshold violation for those licensees who put forth a good faith effort to comply with the rules. If licensees know that their good faith efforts to comply with the rules will be taken into consideration, it is more likely they will abide by the medication rules. It must be noted that in instances where the enhanced penalty schedule is triggered based on a licensee's cumulative points record (as discussed below), the ability to mitigate only applies to the penalty for the underlying offense and not the penalty imposed as a result of a licensee's cumulative points record. As discussed above, a penalty imposed as a result of a licensee's cumulative points record is mandatory.

Further, N.J.A.C. 13:70-14A.7(d) is proposed for amendment. Existing subsection (d) provides that "[h]orses owned wholly or in part by persons suspended for violation of N.J.A.C. 13:70-14A.6(a), (b) or (d) are ineligible to start during the period of such suspension, unless sold to a bona fide purchaser." It also provides that "[h]orses trained by a person suspended for such a violation, wherein the trainer does not have an ownership interest, are automatically eligible to start when placed in the hands of a licensed trainer approved by the Stewards." The amendment would delete the language concerning a "violation of N.J.A.C. 13:70-14A.6(a), (b) or (d)" and replace it with language that provides for "violations of this subchapter or any comparable rule of any other racing commission or turf governing body" to encompass all penalties associated with medication violations within this subchapter, including, but not limited to, the incorporation by reference of ARCI-011-020B(13); the Alphabetical List; and the Schedule. The proposed amendment would also add the language "or as ordered by the Commission or its Stewards," after the phrase "such suspension" in the first sentence to acknowledge that the Commission and its Stewards have the discretion, as appropriate, to determine a horse ineligible to start for violations of this Commission's medication rules or any comparable rule of other racing jurisdictions regardless of whether or not a suspension has been imposed, as authorized by N.J.A.C. 13:70-16. Additionally, the words "a violation" in the second sentence of subsection (d) will be deleted and replaced with "violations."

With respect to substantive changes, N.J.A.C. 13:70-14A.9, Administering medication to respiratory bleeders; standards for the administration of non-steroidal anti-inflammatory drugs (NSAID) and anti-ulcer medications; environmental contaminants, is proposed for amendment at subsections (d), (f), and (g). The third sentence of existing subsection (d) provides that “[q]uantitation of furosemide in serum or plasma shall be performed and concentrations may not exceed 100 nanograms of furosemide per milliliter of serum or plasma.” The proposed amendment would delete the language “may not exceed 100 nanograms of furosemide per milliliter of ...” This language is to be deleted from the rule because the Schedule sets forth the threshold levels for furosemide to which the industry in this State is to adhere, rendering the threshold levels set forth in this section unnecessary. Additionally, language has been added referencing the thresholds incorporated by N.J.A.C. 13:70-14A.1(b)14, as well as language clarifying that a positive result will occur should the threshold be met or exceeded, not just exceeded. As a result of these changes, the third sentence of subsection (d) will provide that “[q]uantitation of furosemide in serum or plasma shall be performed and concentrations must be below the serum or plasma threshold concentrations authorized in N.J.A.C. 13:70-14A.1(b)14.” Moreover, presently, the last sentence of subsection (d) includes language that if a sample “... exceeds a level of 100 nanograms per milliliter of serum or plasma (100 ng/mL), ...” or there is no furosemide detected, the trainer and all other responsible persons are subject to penalties set forth in subsection (e). The amendment would delete the quoted language and add the following language in its place “... is at or above the permitted serum or plasma threshold concentrations authorized in N.J.A.C. 13:70-14A.1(b)14 ...” to reflect that a positive result occurs at or above the thresholds set forth in the Schedule, which is incorporated by reference in N.J.A.C. 13:70-14A.1(b)14.

Existing subsection (f) addresses the presence of non-steroidal anti-inflammatories (NSAIDs) in the serum or plasma of a horse on race day and the conditions regarding the presence of NSAIDs in a horse on race day. Those conditions are set forth in Paragraph (f)1 through 3. Paragraph (f)1 provides that an approved NSAID is permissible in a particular amount on race day if the NSAID level does not exceed permitted serum or plasma threshold concentrations and is administered by a particular method. The proposed amendment would delete “... does not exceed the following ...” and add language to reflect the position that a positive result occurs when the threshold concentration authorized by N.J.A.C. 13:70-14A.1(b)14 is met or exceeded. As a result, paragraph (f)1 would provide that “[t]he NSAID level is below the permitted serum or plasma threshold concentrations authorized in N.J.A.C. 13:70-14A.1(b)14 ...” Additionally, subparagraphs (f)1i and ii set forth the threshold concentrations for Phenylbutazone and Flunixin. The proposed amendment would delete both subparagraph (f)1i and ii in their entirety to reflect the intention of the Commission to utilize the threshold concentrations authorized in N.J.A.C. 13:70-14A.1(b)14. Existing paragraph (f)3 provides that “[t]he presence of more than one of the two approved NSAID or any unapproved NSAID(s) in the post-race serum or plasma sample is not permitted.” The proposed amendment would delete the word “two” to ensure consistency with those substances authorized in N.J.A.C. 13:70-14A.1(b)14. The proposed amendment would also replace “NSAID” with “NSAID(s)” to make it grammatically correct.

The first part of existing subsection (g) provides that “In the event post-race testing determines that the threshold levels set forth for the two permitted NSAID(s) were exceeded, there is evidence of more than one of the two permitted NSAID(s) or there is evidence of an unapproved NSAID ...” The proposed amendments will delete “... set forth for the two permitted NSAID(s) were exceeded ...” and replace the deleted language with “... authorized in N.J.A.C. 13:70-14A.1(b)14 have been met or exceeded ...” in order to make this subsection consistent with N.J.A.C. 13:70-14A.1(b)14, as well as the Commission’s intent that a positive result occur at or above the threshold. Additionally, the word “two” will be deleted to remain consistent with those medications authorized in N.J.A.C. 13:70-14A.1(b)14.

N.J.A.C. 13:70-14A.17, Anabolic steroids, is proposed for amendment at subsections (c) and (d). Existing subsection (c) provides that “[t]ests results identifying the presence of boldenone, nandrolone, stanozolol and testosterone shall not constitute a violation of this section if the level of

these permitted anabolic steroids test at or below” established thresholds set forth in the subsection. The proposed amendment would delete stanozolol and its threshold entirely from the subsection. The deletion of stanozolol is necessary as it is no longer manufactured. Moreover, the proposed amendment would delete the phrase “at or below” and replace it with the word “below” to reflect that only a test result below the threshold is acceptable and, therefore, not a violation.

Presently, the first sentence of subsection (d) provides that “[a]ny blood samples containing one of the four anabolic steroids listed in (c) above that quantitatively measures above the threshold levels shall constitute a violation of this section.” The proposed amendment would delete the word “four” and replace it with the word “three” throughout subsection (d) to reflect the deletion of the anabolic steroid, Stanozolol. Additionally, the word “above” would be deleted and replaced with “at or above” to reflect that a test result at or above the established threshold is a positive test result and, therefore, constitutes a violation. The third sentence of subsection (d) provides that “[a]ny samples identifying the presence of one of the four permitted anabolic steroids, even if it tests at or below the threshold level, shall constitute a violation of this section if the samples also indicate the presence of any other anabolic steroid.” The proposed amendment would also delete the phrase “at or below” and replace it with the word “below” to reflect that a test result at or above the regulatory threshold is a positive test result and, therefore, a violation.

As the Commission has provided a 60-day comment period for this notice of proposal, this notice is excepted from the rulemaking calendar requirements.

Social Impact

There are multiple benefits to amending the rules to extend the current restrictions and protections regarding medications and their administration periods and the penalties imposed as a result of multiple medical violations. Primarily among these benefits is protecting the integrity of horse racing by attempting to ensure that none of the horses participating in a race have an unfair competitive edge over its competitors. By protecting the integrity of the sport, the wagering public is reassured of the fairness of each event and the money it wagers on the outcome. Additionally, the amendments are proposed to ensure the safety and health of the race horses and humans who compete. In light of the potential for intentional or unintentional doping of race horses near a race date, these restrictions on medications and, specifically, the establishment of regulatory thresholds, are additional steps to secure a race horse’s health on race day. Moreover, by establishing thresholds for certain medications, it provides some leeway for prohibited medications or otherwise occurring chemical compounds that may exist as a result of environmental contamination or the natural care of the race horse. Further, the amendments will mirror the rules and regulations of other jurisdictions and the Model Rules of the RCI, creating a more uniform application and enforcement of rules and regulations regarding medication administration and administration time periods.

In a similar vein, providing enhanced penalties through the proposed amendments to N.J.A.C. 13:70-14.7 is a positive step to ensuring the safety of the horse and rider. Permitting an enhanced penalty schedule for those licensees who accumulate multiple medical violations or are “repeat offenders” has great potential to deter those individuals from continuing to violate the rules, thereby ensuring the integrity of the sport of horse racing and maintaining the trust of the wagering public. There is limited potential for negative social impact. While initially the amendments may result in race horses being scratched on race day, the overall social impact is extremely positive in that it will strengthen the wagering public’s belief of fairness in horse racing.

Economic Impact

The list of permitted medications and chemical substances must be updated to reflect advances in testing and realities of the environment of horse racing. The integrity of the sport of horse racing and the safety of the horses must be ensured to continue to encourage the public to participate in betting on live races. The proposed amendments would do that, while also creating a positive economic impact. Specifically, the more detailed medication restrictions and penalty enhancements will strengthen the wagering public’s trust in the fairness of the sport. Additionally, should owners, trainers, and veterinarians utilize the

recommended administration times for the list of 24 substances, it is unlikely that a positive test result will occur. To this extent, it is unlikely that the proposed amendments will result in any additional costs to owners, trainers, or veterinarians. In fact, compliance with the recommended administration times is likely to minimize chances for a violation to occur and, subsequently, fines and suspensions associated with such violations. However, the converse is also true. In the event owners, trainers, and veterinarians choose to ignore the recommended administration times, there is a higher likelihood of violations of the established thresholds, increasing potential fines and suspensions as discussed below.

The implementation of the testing and the restricted administration time period may result in increased funds to be allotted to the Backstretch Fund through monetary fines imposed for violations. N.J.S.A. 5:5-44.8.a states that “[n]otwithstanding the provisions of any other law to the contrary, whenever the New Jersey Racing Commission imposes a monetary penalty on any licensee for a violation of the provisions of P.L.1940, c.17 (C.5:5-22 et seq.), or any regulation promulgated thereunder, the penalty shall be deposited in the Backstretch Fund established pursuant to subsection b. of section 1 of P.L.1993, c.15 (C.5:5-44.8).” The Backstretch Fund, created in the Department of the Treasury, contains moneys to be used to promote the health, safety, or welfare of “backstretch employees” which N.J.S.A. 5:5-44.8.b defines to mean “any person employed at the racetrack as a stable hand, groom, walker or exerciser or in any similar position designated by the commission which involves the handling or care of horses.” The implementation of enhanced penalties for multiple medical violations may also result in increased funds being allotted to the Backstretch Fund.

Subjecting licensees to enhanced penalties in the form of an additional suspension will have an economic impact on those licensees, since they will not be able to participate in racing, and therefore, will most likely be unpaid for the period of time they are suspended. This potential negative economic impact on licensees will serve as a deterrent and, therefore, have a positive social impact as discussed above. Further, by adopting the penalty classifications and enhanced penalties for multiple violations in relation to the use and administration of medications, there will be greater uniformity across racing jurisdictions, providing licensees with consistency in application of the rules. As noted above, as it becomes clear that these amendments are protecting the integrity and fairness of the sport, it is likely that there will be increased revenue from the wagering public.

Federal Standards Statement

A Federal standards analysis is not required as there are no Federal standards or requirements applicable to the proposed amendments. The Racing Commission proposes these amendments pursuant to the rule-making authority set forth in N.J.S.A. 5:5-30.

Jobs Impact

The proposed amendments are not anticipated to create new jobs nor result in the loss of jobs in the racing industry. It is anticipated that the proposed amendments may result in additional job responsibilities for certain employees of the Racing Commission, but these responsibilities should be marginal and can be attended to by existing staff.

Agriculture Industry Impact

The proposed amendments will not have an impact on the agricultural industry in the State.

Regulatory Flexibility Analysis

The proposed amendments impose reporting, recordkeeping, and compliance requirements on racehorse veterinarians, owners, and trainers, some of whom operate as small businesses as defined in the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq., as discussed in the Summary above. The proposed amendments, in order to achieve successful monitoring and administration of the medication rules, must be applied uniformly to all parties because the goal is to ensure compliance by all individuals responsible for the health and welfare of the race horse. For this reason, the proposed amendments do not provide a differing or lesser compliance standard based upon business size. No additional professional services are required for compliance.

Housing Affordability Impact Analysis

The proposed amendments will not impact affordable housing in New Jersey and would not evoke a change in average costs associated with housing because the proposed amendments extend the current restrictions and protections regarding medications and their administration periods in regard to racehorses and the penalties imposed as a result of violations of these restrictions. These proposed amendments regulate the sport of horse racing and have no impact on the affordability of housing in New Jersey.

Smart Growth Development Impact Analysis

The proposed amendments have no impact on the achievement of Smart Growth Development in the State of New Jersey and would not evoke a change in housing or other types of development recommended for Planning Areas 1 or 2, or designated centers, under the State Development and Redevelopment Plan because the proposed amendments extend the current restrictions and protections regarding medications and their administration periods in regard to racehorses and the penalties imposed as a result of violations of these restrictions. These proposed amendments regulate the sport of horse racing.

Full text of the proposal follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

SUBCHAPTER 14A. MEDICATION AND TESTING PROCEDURES

13:70-14A.1 Intent of medication rules; general provisions

(a) (No change.)

(b) On the day of the race, irrespective of the date, time, and method of administration, no horse entered to start in or participating in any race shall carry in its body any drug and/or substance foreign to the natural horse, excepting external rubs and innocuous compounds as defined in this section and as otherwise provided for in [these rules] **this chapter**. Examples of drugs and/or substances foreign to the natural horse, and thus prohibited pursuant to this section, are as follows:

1.-11. (No change.)

12. Stamina builders; [and]

13. Mixtures, compounds, or solutions commonly referred to as “milkshakes,” which contain any prohibited drug and/or substance[.]; **and**

14. Controlled therapeutic medications equal to or in excess of the threshold levels set in the Association of Racing Commissioners International (RCI) Controlled Therapeutic Medication Schedule (Schedule), version 2.1 (Revised April 17, 2014), which is incorporated herein by reference, as amended and supplemented. The Schedule can be accessed at <http://arcicom.businesscatalyst.com/assets/arci-controlled-therapeutic-medication-schedule---version-2.1.pdf>.

(c)-(d) (No change.)

(e) An external rub or innocuous compound is a single substance, mixture of substances, or compound [which] **that** does not contain any of the [13] examples of prohibited items as set forth in (b) above, or additionally, any other substance foreign to the natural horse [which] **that** alters its normal physiological state.

13:70-14A.7 Penalties

(a)-(b) (No change.)

(c) Any individual suspended or disciplined in any fashion for [a second or subsequent violation of N.J.A.C. 13:70-14A.6(a), (b), (d)] **multiple violations of this subchapter** or any comparable rule of any other racing commission or turf governing body [may] **shall** be deemed a [repetitive] **repeat** offender[. A second or subsequent violation of 13:70-14A.6 may constitute grounds for further disciplinary action by the Commission.] **and shall be subject to enhanced penalties pursuant to RCI Model Rule ARCI-011-020B(13), Multiple Medication Violations (MMV) (version 5.7, Approved April 9, 2014), which is incorporated herein by reference, as amended and supplemented, or as otherwise ordered by the Commission or its Stewards (see N.J.A.C. 13:70-16). RCI Model Rule ARCI-011-020B(13), Multiple Medication Violations (MMV) may be accessed at [http://ua-rtip.org/sites/ua-rtip.org/files/Flat%20Racing%20Chapters%20\(5-11\).pdf](http://ua-rtip.org/sites/ua-rtip.org/files/Flat%20Racing%20Chapters%20(5-11).pdf).** The Commission may, at its discretion, consider evidence of

compliance with the guidelines set forth in the “Dosing Specifications” and “Withdrawal Guideline” columns of the Schedule as mitigating factors, when appropriate, in determining the penalty to be imposed for a violation of the levels listed in the “Threshold” column.

(d) Horses owned wholly or in part by persons suspended for violations [of N.J.A.C. 13:70-14A.6(a), (b) or (d)] of this subchapter or any comparable rule of any other racing commission or turf governing body are ineligible to start during the period of such suspension or as ordered by the Commission or its Stewards, unless sold to a bona fide purchaser (see N.J.A.C. 13:70-16). Horses trained by a person suspended for such [a] violations, wherein the trainer does not have an ownership interest, are automatically eligible to start when placed in the hands of a licensed trainer approved by the Stewards. (See N.J.A.C. 13:70-13A for rules concerning [Appeals] appeals.)

13:70-14A.9 Administering medication to respiratory bleeders; standards for the administration of non-steroidal anti-inflammatory drugs (NSAID) and anti-ulcer medications; environmental contaminants

(a)-(c) (No change.)

(d) Post race urine and blood samples may be taken by or under the supervision of the State Veterinarian from all horses treated with furosemide to control respiratory bleeding pursuant to the requirements set forth in (b) above. Post-race test results must show a detectable concentration of furosemide in the serum, plasma, or urine sample taken from a furosemide treated horse. Quantitation of furosemide in serum or plasma shall be performed and concentrations [may not exceed 100 nanograms of furosemide per milliliter of] **must be below the serum or plasma threshold levels authorized in N.J.A.C. 13:70-14A.1(b)14.** In the event a post-race analysis of a blood sample reveals that the concentration of furosemide [exceeds a level of 100 nanograms per milliliter of serum or plasma (100ng/mL)] **is at or above the permitted serum or plasma threshold levels authorized in N.J.A.C. 13:70-14A.1(b)14,** or in the event that a post-race analysis of a blood or urine sample reveals no detectable concentration of furosemide, the trainer and other persons charged with responsibility, including, without limitation, licensed, practicing veterinarians, shall be liable [to] for the penalties as set forth in (e) below.

(e) (No change.)

(f) Notwithstanding anything to the contrary [herein] in this section or in N.J.A.C. 13:70-14A.1, no penalty shall be imposed where on the day of the race, a horse carries in its body either Phenylbutazone or Flunixin, both [NSAID(s)] NSAIDs, under the following conditions:

1. The NSAID level [does not exceed the following] **is below the permitted serum or plasma threshold [concentrations] levels authorized in N.J.A.C. 13:70-14A.1(b)14,** which are consistent with administration by a single intravenous injection that follows the FDA-approved dose regimen for each product(s) at least 24 hours before the post time for the race in which the horse is entered[:];

[i. Phenylbutazone (or its metabolite oxphenylbutazone) – two micrograms per milliliter (two µg/mL);

ii. Flunixin – 20 nanograms per milliliter (20 ng/mL);

2. (No change.)

3. The presence of more than one of the [two] approved NSAIDs or any unapproved NSAID(s) in the post-race serum or plasma sample is not permitted. The use of all but one of the approved NSAIDs shall be discontinued at least 48 hours before the post time for the race in which the horse is entered.

(g) In the event post-race testing determines that the threshold levels [set forth for the two permitted NSAID(s) were] **authorized in N.J.A.C. 13:70-14A.1(b)14 have been met or exceeded,** there is evidence of more than one of the [two] permitted NSAID(s) present or there is evidence of an unapproved NSAID, the stewards shall penalize the trainer and other persons charged with responsibility, including, without limitation, licensed, practicing veterinarians, as follows, regardless of whether or not the same horse is involved:

1.-2. (No change.)

(h)-(k) (No change.)

13:70-14A.17 Anabolic steroids

(a)-(b) (No change.)

(c) Test[s] results identifying the presence of boldenone, nandrolone, [stanozolol] and testosterone shall not constitute a violation of this section if the level of these permitted anabolic steroids test [at or] below the following **threshold** levels in blood plasma:

Boldenone - 200 picograms/milliliter (200 pg/mL);

Nandrolone - 200 picograms/milliliter (200 pg/mL);

Intact Male Horses: 500 picograms/milliliter (500 pg/mL);

All Other Horses: 200 picograms/milliliter (200 pg/mL);

[Stanozolol - 200 picograms/milliliter (200 pg/mL);]

Testosterone -

Intact Male Horses: 2,000 picograms/milliliter (2,000 pg/mL);

All Other Horses: 200 picograms/milliliter (200 pg/mL).

For the purposes of this section, “intact male horse” shall mean a male horse that has not been gelded.

(d) Any blood samples containing one of the [four] **three** anabolic steroids listed in (c) above that quantitatively measures **at or** above the threshold levels shall constitute a violation of this section. Any samples identifying the presence of more than one of the [four] **three** permitted anabolic steroids shall constitute a violation of this section regardless of the **threshold** levels identified in the sample. Any samples identifying the presence of one of the [four] **three** permitted anabolic steroids, even if it tests [at or] below the threshold level, shall constitute a violation of this section if the samples also indicate the presence of any other anabolic steroid.

(e)-(j) (No change.)

(a)

NEW JERSEY RACING COMMISSION

Standardbred Racing

Intent of Medication Rules; General Provisions;

Penalties; Anabolic Steroids

Proposed Amendments: N.J.A.C. 13:71-23.1, 23.7, and 23.16

Authorized By: New Jersey Racing Commission, Frank Zanzuccki, Executive Director.

Authority: N.J.S.A. 5:5-30.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2014-094.

Submit written comments by August 15, 2014, to:

Michael Vukcevic, Deputy Director
 Department of Law and Public Safety
 New Jersey Racing Commission
 P.O. Box 088
 Trenton, New Jersey 08625-0088

The agency proposal follows:

Summary

Subchapter 23, Medication and Testing Procedures, sets forth the rules of the New Jersey Racing Commission (Commission) concerning administration of medication and foreign substances to standardbred racing horses and the penalties associated with the same. The Commission proposes amendments to the subchapter to codify portions of the Association of Racing Commissioners International (RCI) Model Rules on Medications and Prohibited Substances in order to ensure proper administration of medications, protect the health of the horses and protect the integrity of the sport.

N.J.A.C. 13:71-23.1, Intent of medication rules; general provisions, is proposed for amendment at subsection (b). Existing subsection (b) provides that “[o]n the day of the race, irrespective of the date, time and method of administration, no horse entered to start in or participating in any race shall carry in its body any drug and/or substance foreign to the natural horse, excepting external rubs and innocuous compounds as defined in this section and as otherwise provided for in these rules.”