RULE MAKING ACTIVITIES

Each rule making is identified by an I.D. No., which consists of 13 characters. For example, the I.D. No. AAM-01-96-00001-E indicates the following:

AAM -the abbreviation to identify the adopting agency
01 -the *State Register* issue number
96 -the year
00001 -the Department of State number, assigned upon receipt of notice.
E -Emergency Rule Making—permanent action not intended (This character could also be: A for Adoption; P for Proposed Rule Making; RP for Revised Rule Making; EP for a combined Emergency and Proposed Rule Making; EA for an Emergency Rule Making that is permanent and does not expire 90 days after filing.)

Italics contained in text denote new material. Brackets indicate material to be deleted.

Department of Economic Development

PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED

Empire State Post Production Tax Credit Program

I.D. No. EDV-03-15-00001-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed Action: Addition of Part 230 to Title 5 NYCRR.

Statutory authority: L. 2010, ch. 57 as amd. by L. 2013, ch. 59

Subject: Empire State Post Production Tax Credit Program.

Purpose: Establish application procedure for the Empire State Post Production Tax Credit Program.

Substance of proposed rule (Full text is posted at the following State website:www.esd.ny.gov): The Empire State Post Production Tax Credit Program is a tax credit designed to attract film and television production companies to the State of New York so as to secure the associated economic and employment benefits for New Yorkers.

1) The regulation defines important terms, including, but not limited to "certificate of conditional eligibility," "completion of a qualified film," "post production costs," "qualified film production company," "qualified post production facility," and "third party verification." Of particular note, the definition of "post production costs" includes post production costs for musical composition except for expenditures for the salaries of music composers.

2) The regulation indicates that only authorized applicants, qualifying film production companies scheduled to begin post production within one hundred eighty (180) days, may apply for program benefits.

3) The regulation delineates the application process for participation in the program. An authorized applicant is to submit an initial application prior to completion of principal photography. The New York State Department of Economic Development ("DED") may waive this requirement if the applicant can show exigent circumstances, and has not yet incurred qualified post production costs in New York. Applicants may be required to supplement their application with an interview with DED.

4) The regulation directs DED to assess initial applications to determine whether they are: (1) complete; (2) not premature [i.e., submitted no more than one hundred eighty (180) days prior to the commencement of post production]; (3) submitted prior to the end of principal photography; (4) submitted by a qualified production company; (5) in relation to a qualified film the applicant plans to complete; (6) projecting the applicant's qualified production costs at a qualified post production facility in the production of a qualified film to equal or exceed 75% of the projected total post production costs, or projecting the applicant's visual effects or animation at a qualified post production facility to meet or exceed $3 million or 20% of the total post production costs for visual effects or animation paid or incurred in the post production of a qualified film at any post production facility, whichever is less; (7) supported by an attestation that the applicant did not submit false or misleading information to DED; (8) supported by certification that the applicant will purchase taxable tangible property and services, defined as qualified post production costs, only from companies registered to collect and remit New York state and local sales and use taxes; and (9) supported by a showing of the applicant's intent to comply with the end credit requirements by either including in the end credits of each qualified film the phrase "This Production Participated in the New York State Governor's Office for Motion Picture & Television Development's Post Production Credit Program" and a logo provided by the Governor's Office of Motion Picture and Television Development, or by including a New York promotional video approved by the Governor's Office of Motion Picture and Television Development in each film distributed on the secondary market.

5) The regulation provides that, after review of the applicant's application, DED shall advise the applicant as to whether the applicant's initial application meets the Program requirements. DED may issue a certificate of conditional eligibility to an applicant if that applicant's initial application meets the Program requirements.

6) DED evaluates final applications to determine whether: (1) the application is complete; (2) a qualified film was produced and completed; (3) the authorized applicant met the abovementioned requirements as to incurring qualified post production costs attributable to the use of tangible property or the performance of services at a qualified post production facility; (4) the authorized applicant did not knowingly submit false or misleading information; and (5) the applicant supplied documentation that the end credit requirements have been met. The Department may accept from an applicant a voluntary third party verification, performed by a qualified certified public accountant, as part of an applicant's final application.

7) DED is to issue a certificate of tax credit to applicants whose final applications are approved, and a notice of disapproval stating the reason for the disapproval to any applicants whose final applications are not approved. Copies of certified tax credits are to be forwarded to the Department of Taxation and Finance.

8) The regulation provides that DED is to allocate tax credits each year in such a way as to give priority to applicants whose applications are approved at the earliest dates. In the event that an applicant's tax credit would exceed the maximum annual tax credit under the program, $7 million in 2013 and 2014, and $25 million in 2015-2019, that applicant is to be given priority for a tax credit in the immediate succeeding year.

9) Applicants are required to retain records of any qualified post production costs used to calculate their potential or actual benefit(s) under the program for a minimum of three (3) years from the date the applicant claims the tax credit. Applicants are to make records available to DED during normal business hours at an office of the applicant's within the

State or, if no such office is available, at a mutually agreeable and reasonable venue within the State for the three year period.

10) An applicant may appeal a denial by DED of its final application, or a calculation by DED of a tax credit. Appeals of denials of applications must be sent to DED within thirty (30) days of the date of the denial letter, and appeals of tax credit determinations must be sent to DED within thirty (30) days of the issuance of the certificate of tax credit. Failure to appeal within the thirty (30) day period constitutes a waiver of an applicant's right to appeal.

11) The regulation describes the appeal process for appeals pursuant to timely appeal letters. The Commissioner of DED is to appoint an independent hearing officer to render a recommendation to the Commissioner. The Commissioner is to issue a final decision on the appeal within sixty (60) days of receiving the hearing officer's recommendation. A copy of the final decision must be delivered to the applicant within ten (10) days of the Commissioner's final order.

12) The regulation directs DED to file a quarterly report with the director of the Division of the Budget and the chairmen of the Assembly Ways and Means Committee and Senate Finance Committee within fifteen (15) days after the close of each calendar quarter. The report must indicate: (1) the total dollar amount of certificates of tax credits issued during each month of the calendar quarter, broken down by month; (2) the number of film projects which have been issued certificates of tax credits of less than $1 million per project and the total dollar amount of credits issued to those projects; (3) the number of film projects which have been issued certificates of tax credits of $1 million or more but less than $5 million per project and the total dollar amount of credits issued to those projects; (4) the number of film projects which have been issued certificates of tax credits of $5 million or more per project and the total dollar amount of credits issued to those projects; (5) for each film project which has been issued a certificate of tax credit, an itemization of labor information and expenditures; and (6) information on the identity, residency, and value of tax benefits received for each participant receiving tax credits under the program.

13) The regulation requires DED to file a report on a biennial basis with the director of the Division of the Budget and the chairs of the Assembly Ways and Means Committee and Senate Finance Committee within fifteen (15) days after the close of every other calendar year, with the coverage period for the first report spanning two (2) years beginning January 1, 2013. The report is to be prepared by a third-party auditor. This report must contain: (1) information as to the efficiency of program operations, reliability of financial reporting, compliance with laws and regulations, and distribution of assets and funds; (2) an economic impact study prepared by an independent third-party; and (3) any other information the Commissioner deems to be useful in analyzing the effects of the program.

Text of proposed rule and any required statements and analyses may be obtained from: Thomas P. Regan, NYS Department of Economic Development, 625 Broadway, 8th Floor, Albany, NY 12245, (518) 292-5123, email: tregan@esd.ny.gov

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement

STATUTORY AUTHORITY:

Chapter 57 of the Laws of 2010, as amended by Chapter 59 of the Laws of 2013, requires the Commissioner of the Department of Economic Development to promulgate regulations establishing the application process for the Empire State Post Production Tax Credit Program. These procedures include the process for applying for tax credits under the program, standards for the assessment of applications, and other provisions deemed necessary and appropriate. This regulatory impact statement is submitted in conjunction with the submission of a permanent regulation.

LEGISLATIVE OBJECTIVES:

The proposed rule is in accord with the public policy objectives the New York State Legislature sought to advance by enacting the Empire State Post Production Tax Credit Program. The program provides qualified film and television production companies with tax incentives to utilize New York State businesses in the post production of qualified films and television shows. It is the public policy of New York to attract post production work to the state; particularly the Upstate region. The tax benefits available under this program are intended to make New York a more desirable location for the post production of qualified films and television shows, and to secure employment for New Yorkers in post production jobs attracted via the tax benefits. The proposed rule helps to further such objectives by describing qualifying expenses which may be applied towards the tax credit, establishing the application process for the program, and clarifying how applications will be evaluated.

NEEDS AND BENEFITS:

The rulemaking is necessary in order to implement the statute contained in Section 31 of Article 1 of the Tax Law, creating the Empire State Post Production Tax Credit Program. The statute authorizing the program directs the Commissioner of the Department of Economic Development to establish procedures for the implementation and execution of the program.

New York has long been a leading destination for film and television production. However, incentive programs offered by competitor states have lured film and television production companies away from New York. Accordingly, New York has adopted its own package of tax incentives for film and television production companies that make qualifying film production-related expenditures in the State. The Empire State Post Production Tax Credit Program is the latest incentive to be made available to film and television production companies conducting production activities in New York.

The Empire State Post Production Tax Credit Program will promote economic development and job creation in New York, and particularly the Upstate region, through tax benefits to film and television production companies that are conditioned on those companies incurring qualified post production expenses in New York. These incentives are critical to maintaining and growing New York's presence in the film and television production industries, and securing the economic benefits associated with vibrant activity in the film and television production fields. These goals cannot be achieved without first establishing procedures for the acceptance and evaluation of applications for Empire State Post Production Tax Credits.

The proposed regulation defines expenditures that qualify for tax credits under the program, and establishes the application procedures by which film and television production companies will obtain tax credits. These rules allow for the prompt and efficient commencement of the Empire State Post Production Tax Credit Program, ensure that qualifying expenses are limited to those which will truly promote the New York film and television production industries, and promote the general welfare of New Yorkers.

COSTS:

I. Costs to private regulated parties (the business applicants): None. The proposed regulation will not impose any additional costs to eligible business applicants.

II. Costs to the regulating agency for the implementation and continued administration of the rule: None.

III. Costs to the State government: None.

IV. Costs to local governments: None. The proposed regulation will not impose any costs on local governments.

LOCAL GOVERNMENT MANDATES:

None. There are no local government mandates associated with the Empire State Post Production Tax Credit Program.

PAPERWORK:

The rule establishes qualification rules and application procedures for the Empire State Post Production Tax Credit Program. These regulations establish paperwork burdens that include materials to be submitted as part of applications, additional documents the Commissioner may request from applicants as part of his evaluation of applications, and certain records that must be maintained by program participants for auditing purposes.

DUPLICATION:

The proposed rule will create a new section of the existing regulations of the Commissioner of the Department of Economic Development, Part 230 of 5 NYCRR. Accordingly, there is no risk of duplication in the adoption of the proposed rule.

ALTERNATIVES:

No alternatives were considered with regard to creating a new regulation in response to the statutory requirement. The regulation interprets the Empire State Post Production Tax Credit Program requirements as to the application process for tax credits under the program. This action is necessary in order to clarify how qualifying film production companies may obtain tax benefits under the program, and is required by the legislation establishing the Empire State Post Production Tax Credit Program.

FEDERAL STANDARDS:

There are no federal standards applicable to the Empire State Post Production Tax Credit Program; it is purely a state program that offers tax benefits to film and television production companies with qualifying expenses. Therefore, the proposed rule does not exceed any federal standard.

COMPLIANCE SCHEDULE:

The affected agency (Department of Economic Development) and any film and television production company applicants will be able to achieve compliance with the regulation as soon as it is implemented.

Regulatory Flexibility Analysis

Participation in the Empire State Post Production Tax Credit Program is entirely at the discretion of qualifying film and television production companies. Neither statute nor the proposed rule impose any obligation on any local government or business entity to participate in the program. The proposed rule does not impose any adverse economic impact or compli-

ance requirements on small businesses or local governments. In fact, the proposed rule may have a positive economic impact on small businesses. Small businesses may enjoy increased business if they provide to film and television companies products or services that constitute qualifying expenses for post production tax credits under the program.

Because it is evident from the nature of the proposed rule that it will have either no impact or a positive impact on small businesses and local government, no further affirmative steps were needed to ascertain that fact and none were taken. Accordingly, a regulatory flexibility analysis for small business and local government is not required and one has not been prepared.

Rural Area Flexibility Analysis

The Empire State Post Production Tax Credit Program is open to participation from any film or television production company that meets the qualification requirements. The location in which film and television production companies incur qualifying post production expenses is irrelevant, so long as the expenses meet program qualification requirements. The regulation will not have a substantial adverse economic impact on rural areas. Accordingly, a rural flexibility analysis is not required and one has not been prepared.

Job Impact Statement

The proposed rule establishes application procedures for film and television production companies to apply for benefits under the Empire State Post Production Tax Credit Program, as well as standards for the assessment of applications by the Commissioner of the Department of Economic Development. The Empire State Post Production Tax Credit Program provides tax incentives to film and television production companies that incur qualifying post production expenses in New York. The program aims to attract post production work to the state so as to stimulate economic activity and create jobs. The regulation will not have a substantial adverse impact on jobs and employment opportunities; rather, the program is intended to create jobs. Because it is evident from the nature of the rulemaking that it will have either no impact or a positive impact on job and employment opportunities, no further affirmative steps were needed to ascertain that fact and none were taken. Accordingly, a job impact statement is not required and one has not been prepared.

Department of Financial Services

NOTICE OF ADOPTION

Replacement of Life Insurance Policies and Annuity Contracts

I.D. No. DFS-44-14-00003-A

Filing No. 2

Filing Date: 2015-01-05

Effective Date: 2015-04-21

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of Part 51 (Regulation 60) of Title 11 NYCRR.

Statutory authority: Financial Services Law, sections 202 and 302; Insurance Law, sections 301, 2123, 2403 and 4226

Subject: Replacement of life insurance policies and annuity contracts.

Purpose: To allow immediate binding of coverage; reduce wait time to obtain new coverage; minimize need for revised disclosure statements.

Substance of final rule: Sections 51.1 through 51.8, and Appendices 10A, 10B, 10C and 11, are amended for technical purposes and clarification.

Section 51.1 states the purpose of Part 51.

Section 51.2 provides definitions.

Section 51.3(a) provides exemptions from the requirements of the regulation and is amended to provide additional conditional exemptions, including where an application for new coverage is made to an authorized insurer that is part of the holding company system of the existing insurer, and when new coverage is being issued pursuant to a plan approved by the Superintendent for the insurer to meet its obligations under Insurance Law section 3220(a)(6).

Section 51.4 permits alternate procedures under certain circumstances and is amended by separating the section into new subdivisions (a) and (b). New subdivision (b)(2) permits the use of alternate procedures when the insurer solicits the application by mail or other methods without agent or broker involvement and, at the customer's request, there is subsequent limited agent or broker involvement to provide customer assistance or administrative support, provided that the Disclosure Statement is signed by the agent or broker and presented to the policyholder or contractholder.

Section 51.5 addresses duties of insurance agents and brokers and contains several amendments:

Section 51.5(c)(2) is amended by separating the notification and document submission requirements in subdivision (c)(2) into new paragraphs (2) and (3) of subdivision (c);

Section 51.5(c)(3) is renumbered as 51.5(c)(4) and is amended by removing the agent or broker's duty to present a completed Disclosure Statement to an applicant no later than when the applicant signed the application;

Section 51.5(c)(4) is renumbered as 51.5(c)(5) and is amended by removing the agent or broker's duty to have an applicant acknowledge that the completed Disclosure Statement was received and read;

Section 51.5(c)(5) is renumbered as 51.5(c)(6) and is amended by removing the agent or broker's duty to submit the completed Disclosure Statement with the application to the replacing insurer; and

Section 51.5(c)(7) is new and requires each agent or broker to submit to the replacing insurer, prior to policy or contract delivery, an accurate and complete Disclosure Statement signed by the agent or broker.

Section 51.6 addresses duties of insurers and contains several amendments:

Sections 51.6(a)(3), 51.6(b)(8) (as renumbered), and 51.6(c)(1) are amended by replacing the record retention language with a reference to the relevant regulation;

Section 51.6(b)(2) is amended by removing the replacing insurer's duty to require, with or as a part of each application, proof of receipt by the applicant of the completed Disclosure Statement;

Section 51.6(b)(3) is renumbered as section 51.6(b)(4). A new section 51.6(b)(3) is added to require the replacing insurer to require the agent or broker, prior to policy or contract delivery, to provide an accurate and complete Disclosure Statement signed by the agent or broker;

Section 51.6(b)(4) is renumbered as section 51.6(b)(6) and is amended to require a replacing insurer to furnish to a replaced insurer, within ten days of policy or contract delivery, the completed Disclosure Statement and a list of sales material used in the sale with an offer to provide such material within ten days of a request for the material;

Section 51.6(b)(7) is repealed. Section 51.6(b)(5) is renumbered as section 51.6(b)(7) and is amended to require a replacing insurer to submit annual electronic reports, by February 1 of each year, to the Superintendent indicating which insurers have failed to provide the information required under section 51.6(c)(2);

Section 51.6(b)(5) is new and requires a replacing insurer to deliver the completed Disclosure Statement to the policyholder or contractholder no later than the time of policy or contract delivery. Where the insurer requires the Disclosure Statement to be signed by the applicant, a copy of the applicant-signed Disclosure Statement shall be provided to the applicant at the time the applicant signs the Disclosure Statement;

Section 51.6(b)(6) is renumbered as section 51.6(b)(8);

Section 51.6(b)(9) is repealed. Section 51.6(b)(8) is renumbered as section 51.6(b)(9); and

Section 51.6(b)(10) is new and requires a replacing insurer to provide a revised Disclosure Statement no later than the time of delivery of the policy or contract to the owner if an initial Disclosure Statement was provided to the applicant prior to the issuance of the policy or contract and the policy or contract is issued other than as applied for, except when the change resulted from changes in the amount of expected initial or additional premiums or changes in amounts of exchanges pursuant to Internal Revenue Code section 1035 rollovers or transfers that do not impact the key benefits and features of the policy or contract as applied for.

Appendices 10A ("Disclosure Statement"), 10B ("Disclosure Statement: Annuity-to-Annuity Replacement Only"), 10C ("Important Notice Regarding Replacement or Change of Life Insurance Policies or Annuity Contracts") and 11 ("Definition of Replacement") are repealed and new Appendices 10A, 10B, 10C and 11 are added, reflecting changes to the forms resulting from the amendments to the regulation.

Final rule as compared with last published rule: Nonsubstantive changes were made in sections 51.3(a), 51.4(b)(1), 51.6(b)(10), 51.7(a)(1), 51.8, Appendixes 10A, 10B and 10C.

Text of rule and any required statements and analyses may be obtained from: Michael Maffei, New York State Department of Financial Services, One State Street, New York, NY 10004, (212) 480-5027, email: michael.maffei@dfs.ny.gov

Revised Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

The minor revisions made to the adopted rulemaking from the proposed version are not substantive and were made for the purpose of clarification. Therefore, the changes made to the last published rulemaking do not necessitate revision to the previously published RIS, RFA, RAFA and JIS.

Initial Review of Rule
As a rule that requires a RFA, RAFA or JIS, this rule will be initially reviewed in the calendar year 2018, which is no later than the 3rd year after the year in which this rule is being adopted.

Assessment of Public Comment
The Department of Financial Services ("Department") received public comments on its proposed Third Amendment to 11 NYCRR 51 (Insurance Regulation 60) from two industry trade associations.

A trade association representing affected insurance producers submitted a comment supporting the proposed amendment to Insurance Regulation 60. It commented that "the proposed regulatory changes strike the proper balance between the consumers' ability to complete a desired transaction in a timely fashion and continue to be protected from inappropriate and/or misleading sales by having the requisite information to make informed decisions. . . ."

A trade association representing New York authorized life insurers commented that it supported the proposed amendment to Insurance Regulation 60, especially the provisions that provide life insurers the flexibility to determine at which point during a replacement transaction the requisite Disclosure Statement needs to be delivered to the applicant (§§ 51.5(c)(7), 51.6(b)(3), and 51.6(b)(5)). In addition, the trade association requested clarification of § 51.6(b)(10), with respect to when a revised Disclosure Statement must be provided if the policy or contract as issued differs from the coverage that had been applied for. The Department revised the amendment to clarify that the revised Disclosure Statement could be provided at the insurer's option earlier than the delivery of the policy or contract but no later than the date of such delivery.

New York State Gaming Commission

NOTICE OF ADOPTION

Restricted Time Periods for Clenbuterol Use on Standardbred Racehorses

I.D. No. SGC-49-13-00009-A
Filing No. 1108
Filing Date: 2014-12-31
Effective Date: 2015-04-01

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of section 4120.2(g)(5); and addition of section 4120.2(k) to Title 9 NYCRR.

Statutory authority: Racing, Pari-Mutual Wagering and Breeding Law, sections 103(2), 104(1), (19) and 122

Subject: Restricted time periods for clenbuterol use on standardbred racehorses.

Purpose: To enhance the integrity and safety of standardbred horse racing.

Text or summary was published in the December 4, 2013 issue of the Register, I.D. No. SGC-49-13-00009-RP.

Final rule as compared with last published rule: No changes.

Revised rule making(s) were previously published in the State Register on December 4, 2013.

Text of rule and any required statements and analyses may be obtained from: Kristen Buckley, Acting Secretary, New York State Gaming Commission, 1 Broadway Center, PO Box 7500, Schenectady, NY 12305-7500, (518) 388-3407, email: gamingrules@gaming.ny.gov

Initial Review of Rule
As a rule that does not require a RFA, RAFA or JIS, this rule will be initially reviewed in the calendar year 2019, which is no later than the 5th year after the year in which this rule is being adopted

Assessment of Public Comment
The Commission received public comments, including as part of the record of its duly noticed legislative rulemaking public hearing held on January 21, 2014, from standardbred industry representatives who were concerned about a proposed national threshold for clenbuterol and a proposed corresponding ban against racing a horse within 14 days of any administration of clenbuterol. They commented that this ban would prevent a horse from racing on the industry-standard weekly basis when properly treated with clenbuterol for a respiratory disorder, which is the approved and widely practiced use of this drug in standardbred racing. The Commission responded to these comments by revising its proposal by eliminating the proposed threshold and limiting the proposed 14-day ban to horses that have to requalify following a lay-off of 30 days or more. The revisions to the rule recognize that regularly racing horses do not have sufficient time between races, particularly because the Commission already bans any use of the drug for 96 hours before a horse's next race, to gain the muscle building effects of clenbuterol. Any respiratory disorders that arise while returning from a long lay-off can be reasonably treated by alternative methods of treatment.

A further assessment of the public comments is provided in the following official Fact Finding in regard to this legislative rulemaking proposal that the Commission, based on decades of institutional knowledge and close supervision of standardbred horse racing in New York, the veterinary expertise of Equine Medical Director Scott Palmer, D.V.M., and consultation with internationally-renowned equine pharmacologist, toxicologist, and equine practices scientific consultant, George A. Maylin, D.V.M., M.S., Ph.D, made on December 22, 2014.

The Commission made the following rulemaking fact finding with regard to this rulemaking:

Agency Finding K:

Clenbuterol is a bronchodilator that is Federal Drug Administration-approved for use in horses and is widely used for a few days after a standardbred horse's weekly pari-mutuel horse race. Clenbuterol can be misused, however, in a manner that has an anabolic effect and creates serious possible health risks for a horse. While the Commission's existing 96-hour restricted time period limits such misuse of this beneficial drug in regularly racing standardbred horses, a standardbred horse has not raced for 30 or more days has had an opportunity for a misuse of clenbuterol with anabolic effects. Current research indicates that such an anabolic effect requires six consecutive days of treatment and will dissipate within 14 days. As a result, a 14-day restricted time period for horses that have not raced for 30 or more days (and re-qualify, as they must) is appropriate. The restriction of clenbuterol for 14 days before a standardbred horse's next race when a horse is returning from a substantial layoff, when combined with a requirement that the drug may be used only for treating respiratory disorders and under a veterinarian's supervision, will effectively preclude the abuse of clenbuterol without unduly interfering with its beneficial use.

NOTICE OF ADOPTION

Per Se Regulatory Standardbred Thresholds for Equine Drugs

I.D. No. SGC-49-13-00011-A
Filing No. 1109
Filing Date: 2014-12-31
Effective Date: 2015-04-01

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of section 4120.2; renumbering of section 4120.3 to 4120.18; and addition of new section 4120.3 to Title 9 NYCRR.

Statutory authority: Racing, Pari-Mutual Wagering and Breeding Law, sections 103(2), 104(1), (19) and 122

Subject: Per se regulatory standardbred thresholds for equine drugs.

Purpose: To enhance the integrity and safety of standardbred horse racing by adopting permissive thresholds for 16 accepted medications.

Text of final rule: Section 4120.3 ("Other prohibitions") would be renumbered Section 4120.18.

Section 4120.2(h) would be renumbered Section 4120.2(n).

A new Section 4120.3 would be added to read as follows [note that subparagraphs (6), (8) and (15) are inserted in this new rule by other rulemaking filed today]:

§ 4120.3. Equine drug thresholds; per se

(a) A horse shall have raced in violation of this section if any of the following substances is found, by the laboratory conducting tests for the commission, to be present in a race-day urine or blood sample taken from such horse at a concentration in excess of a threshold listed below. The test result of such laboratory shall include an assessment of the measurement uncertainty and imprecision of the quantitative threshold for the substance.

(1) Acepromazine: 10 ng/ml HEPS in urine;
(2) Butorphanol:
(i) 300 ng/ml of total butorphanol in urine; or
(ii) 2 ng/ml of free butorphanol in plasma;
(3) Dantrolene: 100 pg/ml of 5-hydroxydantrolene in plasma;

(4) Detomidine:
(i) 1 ng/ml of any metabolite of detomidine in urine; or
(ii) any detomidine in plasma;
(5) Diclofenac: 5 ng/ml in plasma;
(7) Firocoxib: 20 ng/ml in plasma;
(9) Furosemide: 100 ng/ml in plasma and a specific gravity of urine less than 1.010;
(10) Glycopyrrolate: 3 pg/ml in plasma;
(11) Ketoprofen: 10 ng/ml in plasma;
(12) Lidocaine: 20 pg/ml of total 3-hydroxylidocaine in plasma;
(13) Mepivacaine:
(i) 10 ng/ml of total hydroxymepivacaine in urine; or
(ii) any hydroxymepivacaine in plasma;
(14) Methocarbamol: 1 ng/ml in plasma;
(16) Omeprazole: 1 ng/ml of omeprazole sulfide in urine;
(17) Phenylbutazone: 2 mcg/ml in plasma;
(18) Procaine penicillin: 25 ng/ml of procaine in plasma; and
(19) Xylazine: 10 pg/ml of total xylazine and its metabolites in plasma.
(b) A laboratory finding that a horse has not exceeded a threshold set forth in this section shall not constitute a defense to a violation of any other section of this subchapter.

Final rule as compared with last published rule: Nonsubstantive changes were made in sections 4120.2(o), and 4120.3(a).

Text of rule and any required statements and analyses may be obtained from: Kristen Buckley, Acting Secretary, New York State Gaming Commission, 1 Broadway Center, PO Box 7500, Schenectady, NY 12305-7500, (518) 388-3407, email: gamingrules@gaming.ny.gov

Revised Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

The changes made to the rulemaking proposal do not require a revised RIS, RFA, RAFA or JIS as they are non-substantive in nature; therefore, the impact on small businesses, local governments, jobs, or rural areas remains the same as presented in the rule as originally proposed in the State Register on December 4, 2013.

The non-substantive changes were to renumber the proposed Section 4120.2(o) as 4120.2(n), to renumber the proposed paragraphs (6) through (16) of Section 4120.3(a) to permit the insertion in alphabetical order of paragraphs (6), (8) and (15) that have been adopted in other rulemaking, and to reword the technical description of laboratory test results (e.g., changing the word "evaluation" to "assessment") in Section 4120.3(a).

Initial Review of Rule

As a rule that does not require a RFA, RAFA or JIS, this rule will be initially reviewed in the calendar year 2019, which is no later than the 5th year after the year in which this rule is being adopted.

Assessment of Public Comment

The Commission received public comments that are included in the record of its duly noticed legislative rulemaking public hearing held on January 21, 2014, in regard to these proposed 16 thresholds for standardbred racing. Representatives of the standardbred industry were concerned about having sufficient information about drug regimens to avoid causing a threshold violation. One practicing veterinarian noted that the dosage or means of administration studied in research relied upon by the Racing Medication and Testing Consortium ("RMTC") to derive these thresholds were different from typical racetrack usages of some drugs, such as methocarbomol and detomidine, respectively. RMTC representatives described the origin and assurances of their withdrawal guidelines and associated thresholds. RMTC indicated that its withdrawal guidelines give sufficient warning provided RMTC's dose and route of administration specifications are followed, and further that these 16 thresholds excepting firocoxib are consistent with affecting race performance by being pharmacologically active. No other public comments were received.

The Commission proposed per se threshold rules for these 16 drugs to complement the Commission's restricted time period rules, which perform the essential function of providing a simple instruction for trainers to follow for when to stop the administration of various drugs before a horse's next race. The per se threshold rules are intended to ensure that drugs will not be used in a manner that could endanger a horse and jockeys or manipulate the outcome of pari-mutuel horse races. They will simplify the administrative adjudication of equine rule violations by making it an automatic rule violation to exceed threshold. The adoption of the thresholds nationally will also make it easier for trainers to race in New York and elsewhere. Although trainers who participate in other states are explicitly not assured that using these 16 drugs at recommended withdrawal times will prevent the occurrence of a positive post-race test, trainers may rely on the Commission's restricted time periods, when following accepted veterinary practices (e.g., clinical doses), to ensure their compliance with these thresholds in all states.

A further assessment of the public comments is provided in the following official Fact Findings in regard to this legislative rulemaking proposal that the Commission, based on decades of institutional knowledge and close supervision of standardbred horse racing in New York, the veterinary expertise of Equine Medical Director Scott Palmer, D.V.M., and consultation with internationally-renowned equine pharmacologist, toxicologist, and equine practices scientific consultant, George A. Maylin, D.V.M., M.S., Ph.D, made on December 22, 2014.

The Commission made the following rulemaking fact findings with regard to this rulemaking (with numbering in Agency Finding A based on each drug's paragraph number in the final rule):

Agency Finding A:

A horse will not incur a positive laboratory finding in excess of the following thresholds, following an administration of the drug in which the drug regimen is consistent with accepted veterinary practice, e.g., the administration of a clinical dose, provided that the drug is not administered within the Commission's restricted time periods (including as adopted on December 22, 2014):

(1) acepromazine [96 hours]: 10 ng/ml HEPS in urine
(2) butorphanol [96 hours]: 300 ng/ml of total butorphanol in urine or 2 ng/ml of free butorphanol in plasma
(3) dantrolene [72 hours]: 100 pg/ml of 5-hydroxydantrolene in plasma
(4) detomidine [96 hours]: 1 ng/ml of any metabolite of detomidine in urine or any detomidine in plasma
(5) diclofenac [48 hours]: 5 ng/ml in plasma
(7) firocoxib [14 days]: 20 ng/ml in plasma
(9) furosemide [4 – 4.5 hours]: 100 ng/ml in plasma and a specific gravity of urine less than 1.010
(10) glycopyrrolate [96 hours]: 3 pg/ml in plasma
(11) ketoprofen [48 hours]: 10 ng/ml in plasma
(12) lidocaine [96 hours]: 20 pg/ml of total 3-hydroxylidocaine in plasma
(13) mepivacaine [96 hours]: 10 ng/ml of total hydroxymepivacaine in urine or any hydroxymepivacaine in plasma
(14) methocarbamol [72 hours]: 1 ng/ml in plasma
(16) omeprazole [24 hours]: 1 ng/ml of omeprazole sulfide in urine
(17) phenylbutazone [48 hours]: 2 mcg/ml in plasma;
(18) procaine penicillin [7 days]: 25 ng/ml of procaine in plasma
(19) xylazine [96 hours]: 10 pg/ml of total xylazine and its metabolites in plasma.

Agency Finding B:

If there is a positive laboratory finding in excess of a foregoing threshold, then the administration of such drug had the potential to affect the race performance of such horse.

Agency Finding C:

If there is a positive laboratory finding in excess of a foregoing threshold, assuming an administration of the drug in which the drug regimen is consistent with accepted veterinary practice, then a violation of the Commission's restricted time period for such drug occurred.

NOTICE OF ADOPTION

To Limit the Use of the Corticosteroid Methylprednisolone Acetate (*e.g.,* Depo Medrol) in Standardbred Racing

I.D. No. SGC-49-13-00014-A
Filing No. 1115
Filing Date: 2014-12-31
Effective Date: 2015-04-01

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of section 4120.2(e)(9); and addition of sections 4120.2, (e)(21), (m) and 4120.3(a)(15) to Title 9 NYCRR.

Statutory authority: Racing, Pari-Mutual Wagering and Breeding Law, sections 103(2), 104(1), (19) and 122

Subject: To limit the use of the corticosteroid methylprednisolone acetate (*e.g.,* Depo Medrol) in standardbred racing.

Purpose: To enhance the integrity and safety of standardbred horse racing with new corticosteroid rules.

Text of final rule: Paragraph (15) would be added to subdivision (a) of the proposed new section 4120.3 as follows:

§ 4120.3. Equine drug thresholds; per se

(a) A horse shall have raced in violation of this section if any of the following substances is found, by the laboratory conducting tests for the commission, to be present in a race-day urine or blood sample taken from such horse at a concentration in excess of a threshold listed below. The test result of such laboratory shall include an assessment of the measure-

ment uncertainty and imprecision of the quantitative threshold for the substance.

(15) Methylprednisolone: 100 pg/ml in plasma

Subdivision (e) of Section 4120.2 would be amended as follows:

(e) The following substances are permitted to be administered by any means until 48 hours before the scheduled post time of the race in which the horse is to compete:

***

(9) hormones and non-anabolic steroids, e.g., progesterone, estrogens, chorionic gonadotropin, glucocorticoids [(e.g., Prednisolone, Depomedrol)], except in joint injections as restricted in subdivision (i) of this section;

***

(21) notwithstanding paragraph (9) of this subdivision, the corticosteroid methylprednisolone (e.g., Depo Medrol) is not a substance that is permitted to be administrated by any means until 48 hours before the scheduled post time of the race in which the horse is to compete.

A new subdivision (m) would be added to section 4120.2 as follows:

(m) A horse may not race after an administration of any formulation of methylprednisolone (e.g., Depo Medrol) unless such horse subsequently tests below the threshold set forth in section 4120.3 of this Part for such drug in a test conducted by or for the commission at the sole expense of the trainer of the horse, and is released to race by the presiding judge.

Final rule as compared with last published rule: Nonsubstantive changes were made in sections 4120.2(e)(25), (l) and 4120.3(a).

Text of rule and any required statements and analyses may be obtained from: Kristen Buckley, Acting Secretary, New York State Gaming Commission, 1 Broadway Center, PO Box 7500, Schenectady, NY 12305-7500, (518) 388-3407, email: gamingrules@gaming.ny.gov

Revised Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

The changes made to the rulemaking proposal do not require a revised RIS, RFA, RAFA or JIS as they are non-substantive in nature; therefore, the impact on small businesses, local governments, jobs, or rural areas remains the same as presented in the rule as originally proposed in the State Register on December 4, 2013.

The non-substantive changes were to renumber the proposed Section 4120.2(e)(25) as 4120.2(e)(21), the proposed Section 4120.2(l) as 4120.2(m), and the proposed Section 4120.3(a)(22) as 4120.3(a)(15), and to reword the technical description of laboratory test results (e.g., changing the word "evaluation" to "assessment") in Section 4120.3(a).

Initial Review of Rule

As a rule that does not require a RFA, RAFA or JIS, this rule will be initially reviewed in the calendar year 2019, which is no later than the 5th year after the year in which this rule is being adopted.

Assessment of Public Comment

The Commission received public comments that are included in the record of its duly noticed legislative rulemaking public hearing held on January 21, 2014. Standardbred industry representatives stated that joint injections with corticosteroids, one such corticosteroid being methylprednisolone (e.g., Depo-Medrol), should not be regulated with thresholds and restrictions that prevent their use with a horse that races on the industry-standard weekly basis. Many testified from personal experience or statistical data that standardbred horses are very unlikely to experience a catastrophic injury as a result of a corticosteroid treatment, corticosteroids provide effective treatment of joint soreness, failing to treat joint soreness may cause a catastrophic injury as a horse shifts too much weight to other limbs, and the financial considerations faced by standardbred owners if banned from using any corticosteroid joint injections with a horse racing on a weekly basis may result in turning to other treatments that are dangerous to the health of the horse and the integrity of racing. One practicing veterinarian noted that the Commission had proposed thresholds for five corticosteroids but none for other commonly used corticosteroids, and observed that thresholds that did not account for the treatment of multiple joints between races were too strict and would cause inadvertent threshold violations. Representatives of the Racing Medication and Testing Consortium ("RMTC") recognized special concerns with RMTC's recommended threshold and withdrawal guideline for joint administrations with Depo-Medrol, for which research was based on treating only one or two joints using just one (e.g., a dose calculated by a horse's weight) clinically accepted veterinary practice. RMTC indicated, including in its written materials for the public hearing, that this corticosteroid could not be used intramuscularly without greatly extending its withdrawal time, that its clearance time more than doubled when the research joint injection dose was increased from 100 to 200 mg, and that a large number of threshold violations occurred at first when the proposed threshold had been adopted in one state. RMTC further indicated that while the proposed threshold for this drug was derived for a pre-selected withdrawal period of seven days, to provide a sufficient period of time before entering to race for a thoroughbred horse to be evaluated after its treatment, a test result in excess of this threshold would not prove an administration of the drug occurred within such time period. Rather, a test result not in excess of the proposed threshold for this drug is consistent with no methylprednisolone having been administered within seven days of the horse's race.

The Commission has concluded that further study is appropriate before adopting its proposed lengthier restricted time periods for all corticosteroid joint and systemic administrations and four corresponding thresholds, but methylprednisolone causes further concern because it has a serious potential degenerative effect with long-term use. The adoption of the proposed national threshold for methylprednisolone and a protective use restriction, accordingly, is appropriate to curtail the widespread use of this drug, allowing its use in circumstances when a trainer and veterinarian find its efficacy is sufficiently valuable to off-set a period of race ineligibility, while imposing no similar restrictions on the use of other common corticosteroids (e.g., joint therapy with betamethasone or triamcinolone acetonide, systemic use of dexamethasone or prednisolone) that present a much lower risk of joint degeneration. The use restriction for methylprednisolone performs the essential function of providing a simple instruction for trainers to follow for when it is permissible to race a horse after the administration of this drug and ensures that a trainer who complies will not incur a threshold violation with the drug.

A further assessment of the public comments is provided in the following official Fact Findings in regard to this legislative rulemaking proposal that the Commission, based on decades of institutional knowledge and close supervision of thoroughbred horse racing in New York, the veterinary expertise of Equine Medical Director Scott Palmer, D.V.M., and consultation with internationally-renowned equine pharmacologist, toxicologist, and equine practices scientific consultant, George A. Maylin, D.V.M., M.S., Ph.D, made on December 22, 2014.

The Commission made the following rulemaking fact findings with regard to this rulemaking:

Agency Finding L:

Methylprednisolone is a corticosteroid that the Commission finds requires the strictest regulation because of various factors, e.g., (1) the drug can be particularly harmful to the long term health of treated joints and tissues, (2) the drug has the potential to affect race performance for an unusually long period of time, (3) the drug will persist in the bodily system of a horse for an unusually long period of time, particularly if some of the drug is injected outside of the joint capsule. Methylprednisolone is a particularly harmful corticosteroid in terms of potential degenerative effect from long-term use, and the needless degeneration of joints aided by injudicious use of methylprednisolone is a serious equine health and safety concern. There are several other corticosteroids that widely used for treating race horses that are not as long-lasting or potentially degenerative, e.g., joint therapy with betamethasone or triamcinolone acetonide, systemic use of dexamethasone or prednisolone, and that present a much lower risk of joint degeneration. Even when administered systemically, methylprednisolone can circulate into joint capsules and contribute to potential joint degeneration. The adoption of the proposed threshold and use restriction for methylprednisolone is appropriate to curtail the widespread use of this drug, allowing its use in circumstances when a trainer and veterinarian find its efficacy is sufficiently valuable to off-set a period of race ineligibility.

Agency Finding M:

The following threshold for methylprednisolone is reasonable because it is consistent with proscribing the administration of even a small clinical dose in a single joint within seven days before a horse's next race and prevents the clinical use of this particular corticosteroid in a regularly (weekly) racing standardbred horse. The Commission lacks sufficient scientific data to create a threshold for methylprednisolone that is violated only by an administration within such time period because of various factors, e.g., (1) multiple joints are often treated; (2) certain joints are interconnected; (3) various size doses are consistent with accepted veterinary practice; (4) other substances may be included with a corticosteroid in a joint injection. The most reasonable threshold for standardbred racing for methylprednisolone is a threshold that at least proscribes the efficacious use of clinical doses of the drug within seven days of racing.

15. Methylprednisolone: 100 pg/ml in plasma

Agency Finding N:

The Commission's use restrictions for each drug are designed to provide the horseperson with an assurance that a horse will not incur a positive laboratory finding following an administration of the drug in a regimen that is consistent with accepted veterinary practice, e.g., the administration of a clinical dose. The new threshold for methylprednisolone requires, in order for the use restriction for such drug to provide such an assurance, that the administration of any formulation of methylprednisolone results in the horse being ineligible to race until the horse tests below the threshold and is released to race by the presiding judge. A clinical dose of this

drug may result in a positive test for more than 50 days after some joint injections, yet a small clinical dose in a different joint may result in a concentration in the horse's plasma below the threshold value within seven days. As a result, a single restricted time period may be unreasonable for this drug. The Commission also lacks sufficient scientific data to formulate a reasonably precise restricted time period that can protect regulated parties in all circumstances; there are too many unknown variables to adopt a specific time period for this drug. The use of this drug is particularly harmful to the potential long-term health of a horse, and the prohibition of the use of this drug is one reasonable alternative. Rather than prohibit all together the use of this drug, whose use might be the best therapeutic option in some circumstances, a use restriction that the horse must test negative and be released to race by the presiding judge will limit the use of this drug to such circumstances and will provide the Commission and regulated parties with a use restriction that is reasonable to apply.

NOTICE OF ADOPTION

Per Se Regulatory Standardbred Threshold and Restricted Time Period for Flunixin

I.D. No. SGC-49-13-00015-A
Filing No. 1110
Filing Date: 2014-12-31
Effective Date: 2015-04-01

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Repeal of section 4120.2(d); amendment of section 4120.2(e); and addition of section 4120.3(a)(8) to Title 9 NYCRR.

Statutory authority: Racing, Pari-Mutual Wagering and Breeding Law, sections 103(2), 104(1), (19) and 122

Subject: Per Se regulatory standardbred threshold and restricted time period for flunixin.

Purpose: To enhance the integrity and safety of standardbred horse racing with new flunixin drug rules.

Text of final rule: A new Section 4120.3 would be added to read as follows:

§ 4120.3. Equine drug thresholds; per se

(a) A horse shall have raced in violation of this section if any of the following substances is found, by the laboratory conducting tests for the commission, to be present in a race-day urine or blood sample taken from such horse at a concentration in excess of a threshold listed below. The test result of such laboratory shall include an assessment of the measurement uncertainty and imprecision of the quantitative threshold for the substance.

(8) Flunixin: 20 ng/ml in plasma;

Subdivision (d) of Section 4120.2 of 9 NYCRR would be repealed.

The final unnumbered paragraph of subdivision (e) of Section 4120.2 of 9 NYCRR would be amended as follows:

None of these substances may be administered within 48 hours of the scheduled post time of the race in which the horse is to compete[, except that flunixin may be used in accordance with the specific authorization set forth in subdivision (d) of this section]. In this regard, substances ingested by a horse shall be deemed administered at the time of eating and drinking. It shall be part of the trainer's responsibility to prevent such ingestion within such 48 hours.

Final rule as compared with last published rule: Nonsubstantive changes were made in section 4120.3(a).

Text of rule and any required statements and analyses may be obtained from: Kristen Buckley, Acting Secretary, New York State Gaming Commission, 1 Broadway Center, PO Box 7500, Schenectady, NY 12305-7500, (518) 388-3407, email: gamingrules@gaming.ny.gov

Revised Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

The changes made to the rulemaking proposal do not require a revised RIS, RFA, RAFA or JIS as they are non-substantive in nature; therefore, the impact on small businesses, local governments, jobs, or rural areas remains the same as presented in the rule as originally proposed in the State Register on December 4, 2013.

The non-substantive changes were to renumber the proposed Section 4120.3(a)(24) as 4120.3(a)(8) and to reword the technical description of laboratory test results (e.g., changing the word "evaluation" to "assessment") in Section 4120.3(a).

Initial Review of Rule

As a rule that does not require a RFA, RAFA or JIS, this rule will be initially reviewed in the calendar year 2019, which is no later than the 5th year after the year in which this rule is being adopted.

Assessment of Public Comment

The Commission received public comments that are included in the record of its duly noticed legislative rulemaking public hearing held on January 21, 2014, in support of coordinating its restricted time period for standardbred race horses with the Commission's proposed laboratory threshold for flunixin. One standardbred industry representative said that the 24 hour restricted time period needed to be lengthened or the proposed threshold would create a large number of inadvertent rule violations. The executive director of the Racing Medication and Testing Consortium ("RMTC") testified that RMTC recommended the proposed flunixin threshold but decided further research was necessary on the subject of its 24-hour withdrawal guideline, and counseled it was "very important" to administer a specific dose based on the horse's weight in order to avoid a threshold violation. RMTC was further concerned about flunixin's very short half-life, meaning that a horse testing just below the flunixin threshold in post-race samples will have a relatively high concentration of this drug at the time of the horse's pre-race examination earlier in the day, causing a greater risk that the examining veterinarian might not detect lameness that should prevent a horse from being allowed to race, in comparison to a common alternative nonsteroidal anti-inflammatory drug ("NSAID"), phenylbutazone.

After the public hearing, the New York Thoroughbred Horsemen's Association issued a press release urging thoroughbred horsepersons not to administer the specified dose any closer than 32 hours before a horse's next race, and RMTC revised its withdrawal guideline to 32 hours.

The Commission's restricted time periods complement its proposed per se thresholds and perform the essential function of providing a simple instruction for trainers to follow for when to stop the administration of various drugs before a horse's next race. The per se threshold rule for flunixin is intended to ensure that flunixin will not be used in a manner that could endanger a horse and driver or manipulate the outcome of pari-mutuel horse races. It will simplify the administrative adjudication of equine rule violations by making it an automatic rule violation to exceed this threshold. The adoption of this threshold nationally will also make it easier for trainers to race in New York and elsewhere. Although trainers who participate in other states are explicitly not assured that the recommended withdrawal time of RMTC for flunixin will prevent the occurrence of a positive post-race test, trainers may rely on the Commission's restricted time period, when following accepted veterinary practices (e.g., clinical doses), to ensure their compliance with the national flunixin threshold in all states.

A further assessment of the public comments is provided in the following official Fact Findings in regard to this legislative rulemaking proposal that the Commission, based on decades of institutional knowledge and close supervision of standardbred horse racing in New York, the veterinary expertise of Equine Medical Director Scott Palmer, D.V.M., and consultation with internationally-renowned equine pharmacologist, toxicologist, and equine practices scientific consultant George A. Maylin, D.V.M., M.S., Ph.D, made on December 22, 2014.

The Commission made the following rulemaking fact findings with regard to this rulemaking:

Agency Finding D:

A horse will not incur a positive laboratory finding in excess of the following threshold, following an administration of flunixin in which the drug regimen is consistent with accepted veterinary practice, e.g., the administration of a clinical dose, provided that the drug is not administered within the Commission's restricted time periods (including as adopted on December 22, 2014):

8. Flunixin [48 hours]: 20 ng/ml in plasma

Agency Finding E:

If there is a positive laboratory finding in excess of the foregoing threshold, then the administration of flunixin had the potential to affect the race performance of such horse.

Agency Finding F:

If there is a positive laboratory finding in excess of the foregoing threshold, assuming an administration of flunixin in which the drug regimen is consistent with accepted veterinary practice, then a violation of the Commission's restricted time period for such drug occurred.

Agency Finding G:

The Commission finds that it is necessary and proper to repeal the previous permission to inject a standardbred horse with flunixin until 24 hours before its next race and to restore our historic restricted time period of administration by any means until 48 hours before a horse's next race. For 34 years, from 1971 to 2005, the latter was the restricted time period in New York and there were no complaints and few positives. The shorter restricted time period has resulted in a large number of rule violations and is inappropriate because of a number of factors, e.g., (1) flunixin is often obtained from a compounding pharmacy which cannot provide an accurate and reliable concentration of the drug as well as a pharmaceutical company and the Commission does not want regulated parties who comply with its

restricted time periods to incur a threshold violation; (2) many regulated persons (e.g., trainers) have incurred a drug positive after having confused the limited route of administration (IV only) permitted since 2005 and given flunixin as an oral paste that has a longer clearance and detection time of the drug; (3) a 48-hour restricted time period for all permitted nonsteroidal anti-inflammatory drugs ("NSAID") eliminates the artificial incentive for a regulated party to choose flunixin for treating a horse close to its next race when there are other permitted NSAIDs that are more efficient and predictable (a longer half-life); (4) a 48-hour restricted time period for all NSAIDs prevents administrations of multiple NSAIDs ("stacking") for a period of 48 hours before a horse's next race; (5) a restricted time period of 48 hours does not permit any NSAID administrations the day before a horse races and this enhances the ability of the Commission to regulate drug use in the stables; (6) the Commission expects, based on the available research data, that regulated parties would have inadvertent positives were the Commission to adopt a restricted time period for flunixin of 32 hours; (7) the Commission would introduce complexity and confusion with a 32-hour restricted time period rather than our standard multiples of 24 hours (e.g., 24, 48, 72, 96 hours) before race day; (8) a 48-hour restricted time period ensures that a person who complies with the restricted time period will not incur a drug positive with a clinical dose, the assurance described in Agency Finding D; (9) a restricted time period of 48 hours minimizes how much a pre-race flunixin administration can interfere with an examining veterinarian's detection of lameness in the hours immediately preceding a race.

NOTICE OF ADOPTION

Restricted Time Period for Standardbred Firocoxib Use

I.D. No. SGC-49-13-00017-A
Filing No. 1111
Filing Date: 2014-12-31
Effective Date: 2015-04-01

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Addition of section 4120.2(h) to Title 9 NYCRR.

Statutory authority: Racing, Pari-Mutual Wagering and Breeding Law, sections 103(2), 104(1), (19) and 122

Subject: Restricted time period for standardbred firocoxib use.

Purpose: To enhance the integrity and safety of standardbred horse racing with a firocoxib equine drug rule.

Text of final rule: A new Subdivision (h) would be added to Section 4120.2 as follows [former 4120.2(h) has been renumbered as 4120.2(n), in I.D. No. SGC-49-13-00011-P]:

(h) A horse may not race for at least 14 days following an administration of firocoxib.

Final rule as compared with last published rule: Nonsubstantive changes were made in section 4120.2(m).

Text of rule and any required statements and analyses may be obtained from: Kristen Buckley, Acting Secretary, New York State Gaming Commission, 1 Broadway Center, PO Box 7500, Schenectady, NY 12305-7500, (518) 388-3407, email: gamingrules@gaming.ny.gov

Revised Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

The changes made to the rulemaking proposal do not require a revised RIS, RFA, RAFA or JIS as they are non-substantive in nature; therefore, the impact on small businesses, local governments, jobs, or rural areas remains the same as presented in the rule as originally proposed in the State Register on December 4, 2013.

The non-substantive change was to renumber the proposed section 4120.2(m) as 4120.2(h).

Initial Review of Rule

As a rule that does not require a RFA, RAFA or JIS, this rule will be initially reviewed in the calendar year 2019, which is no later than the 5th year after the year in which this rule is being adopted.

Assessment of Public Comment

The agency received no public comment.

NOTICE OF ADOPTION

Per Se Regulatory Standardbred Threshold and Restricted Time Period for DMSO

I.D. No. SGC-49-13-00018-A
Filing No. 1112
Filing Date: 2014-12-31
Effective Date: 2015-04-01

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of section 4120.2(a)(1); and addition of sections 4120.2(e)(20) and 4120.3(a)(6) to Title 9 NYCRR.

Statutory authority: Racing, Pari-Mutual Wagering and Breeding Law, sections 103(2), 104(1), (19) and 122

Subject: Per Se regulatory standardbred threshold and restricted time period for DMSO.

Purpose: To enhance the integrity and safety of standardbred horse racing with new DMSO equine drug rules.

Text of final rule: A new section 4120.3 would be added to read as follows:

§ 4120.3. Equine drug thresholds; per se

(a) A horse shall have raced in violation of this section if any of the following substances is found, by the laboratory conducting tests for the commission, to be present in a race-day urine or blood sample taken from such horse at a concentration in excess of a threshold listed below. The test result of such laboratory shall include an assessment of the measurement uncertainty and imprecision of the quantitative threshold for the substance.

(6) DMSO: 10 mcg/ml in plasma.

Paragraph 1 of subdivision (a) of section 4120.2 would be amended to read as follows:

§ 4120.2 Restricted use of drugs, medication and other substances.

Drugs and medications are permitted to be used only in accordance with the following provisions:

(a) The following substances are permitted to be used at any time up to race time:

(1) topical applications (such as antiseptics, ointments, salves, [DMSO,] leg rubs, leg paints and liniments) [which] *that* may contain antibiotics but do not contain benzocaine, *DMSO,* steroids or other drugs; and

A new paragraph 20 would be added to subdivision (e) of section 4120.2 as follows:

(e) The following substances are permitted to be administered by any means until 48 hours before the scheduled post time of the race in which the horse is to compete:

***

(20) dimethyl sulfoxide (i.e., DMSO).

Final rule as compared with last published rule: Nonsubstantive changes were made in sections 4120.2(e)(21) and 4120.3(a).

Text of rule and any required statements and analyses may be obtained from: Kristen Buckley, Acting Secretary, New York State Gaming Commission, 1 Broadway Center, PO Box 7500, Schenectady, NY 12305-7500, (518) 388-3407, email: gamingrules@gaming.ny.gov

Revised Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

The changes made to the rulemaking proposal do not require a revised RIS, RFA, RAFA or JIS as they are non-substantive in nature; therefore, the impact on small businesses, local governments, jobs, or rural areas remains the same as presented in the rule as originally proposed in the State Register on December 4, 2013.

The non-substantive changes were to renumber the proposed section 4120.2(e)(21) as 4120.2(e)(20) and the proposed section 4120.3(a)(23) as 4120.3(a)(6), and to reword the technical description of laboratory test results (e.g., changing the word "evaluation" to "assessment") in section 4120.3(a).

Initial Review of Rule

As a rule that does not require a RFA, RAFA or JIS, this rule will be initially reviewed in the calendar year 2019, which is no later than the 5th year after the year in which this rule is being adopted.

Assessment of Public Comment

The Commission received public comments that are included in the record of its duly noticed legislative rulemaking public hearing held on January 21, 2014, in support of coordinating its restricted time period for standardbred race horses with the Commission's proposed laboratory

threshold. The executive director of the Racing Medication and Testing Consortium ("RMTC") testified that RMTC recommended the proposed threshold for dimethyl sulfoxide ("DMSO"), and indicated that its withdrawal guidelines give sufficient warning provided RMTC's dose and route of administration specifications are followed. Representatives of the standardbred industry were concerned about discrepancies between typical racetrack use of drugs and the regimens studied by RMTC to provide information for avoiding an inadvertent threshold violation.

The Commission's restricted time periods complement its proposed per se thresholds and perform the essential function of providing a simple instruction for trainers to follow for when to stop the administration of various drugs before a horse's next race. The per se threshold rule for DMSO is intended to ensure that DMSO will not be used in a manner that could endanger a horse and driver or manipulate the outcome of pari-mutuel horse races. It will simplify the administrative adjudication of equine rule violations by making it an automatic rule violation to exceed this threshold. The adoption of this threshold nationally will also make it easier for trainers to race in New York and elsewhere. Although trainers who participate in other states are explicitly not assured that the recommended withdrawal time of RMTC for DMSO will prevent the occurrence of a positive post-race test, trainers may rely on the Commission's restricted time period, when following accepted veterinary practices (e.g., clinical doses), to ensure their compliance with the national DMSO threshold in all states.

A further assessment of the public comments is provided in the following official Fact Findings in regard to this legislative rulemaking proposal that the Commission, based on decades of institutional knowledge and close supervision of standardbred horse racing in New York, the veterinary expertise of Equine Medical Director Scott Palmer, D.V.M., and consultation with internationally-renowned equine pharmacologist, toxicologist, and equine practices scientific consultant, George A. Maylin, D.V.M., M.S., Ph.D, made on December 22, 2014.

The Commission made the following rulemaking fact findings with regard to this rulemaking:

Agency Finding H:

A horse will not incur a positive laboratory finding in excess of the following threshold, following an administration of dimethyl sulfoxide ("DMSO") in which the drug regimen is consistent with accepted veterinary practice, e.g., the administration of a clinical dose, provided that the drug is not administered within the Commission's restricted time periods (including as adopted on December 22, 2014):

6. DMSO [48 hours]: 10 mcg/ml in plasma

Agency Finding I:

If there is a positive laboratory finding in excess of the foregoing threshold, then the administration of DMSO had the potential to affect the race performance of such horse.

Agency Finding J:

If there is a positive laboratory finding in excess of the foregoing threshold, assuming an administration of DMSO in which the drug regimen is consistent with accepted veterinary practice, then a violation of the Commission's restricted time period for such drug occurred.

NOTICE OF ADOPTION

Restricted Time Periods for the Use of Clenbuterol in Standardbred Racing

I.D. No. SGC-37-14-00005-A

Filing No. 1106

Filing Date: 2014-12-31

Effective Date: 2015-04-01

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Addition of section 4120.2(l) to Title 9 NYCRR.

Statutory authority: Racing, Pari-Mutual Wagering and Breeding Law, sections 103(2), 104(1), (19) and 122

Subject: Restricted time periods for the use of clenbuterol in standardbred racing.

Purpose: To enhance the integrity and safety of standardbred horse racing.

Text of final rule: A new subdivision (l) would be added to Section 4120.2 as follows:

(l) Clenbuterol shall be administered only under the general supervision of a treating veterinarian and in a manner not exceeding its use for treating respiratory disorders.

Final rule as compared with last published rule: Nonsubstantive changes were made in section 4120.2(p).

Text of rule and any required statements and analyses may be obtained from: Kristen Buckley, Acting Secretary, New York State Gaming Commission, 1 Broadway Center, PO Box 7500, Schenectady, NY 12305-7500, (518) 388-3407, email: gamingrules@gaming.ny.gov

Revised Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

The changes made to the rulemaking proposal do not require a revised RIS, RFA, RAFA or JIS as they are non-substantive in nature; therefore, the impact on small businesses, local governments, jobs, or rural areas remains the same as presented in the rule as originally proposed in the State Register on September 17, 2014.

The non-substantive change was to renumber the proposed Section 4120.2(p) as 4120.2(l).

Initial Review of Rule

As a rule that does not require a RFA, RAFA or JIS, this rule will be initially reviewed in the calendar year 2019, which is no later than the 5th year after the year in which this rule is being adopted.

Assessment of Public Comment

The agency received no public comment.

NOTICE OF ADOPTION

Reporting of Standardbred Corticosteroid Joint Injections to the Commission

I.D. No. SGC-37-14-00007-A

Filing No. 1107

Filing Date: 2014-12-31

Effective Date: 2015-04-01

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of section 4120.4 of Title 9 NYCRR.

Statutory authority: Racing, Pari-Mutual Wagering and Breeding Law, sections 103(2), 104(1), (19) and 122

Subject: Reporting of standardbred corticosteroid joint injections to the Commission.

Purpose: To enhance the integrity and safety of standardbred horse racing.

Text or summary was published in the September 17, 2014 issue of the Register, I.D. No. SGC-37-14-00007-P.

Final rule as compared with last published rule: No changes.

Text of rule and any required statements and analyses may be obtained from: Kristen Buckley, Acting Secretary, New York State Gaming Commission, 1 Broadway Center, PO Box 7500, Schenectady, NY 12305-7500, (518) 388-3407, email: gamingrules@gaming.ny.gov

Initial Review of Rule

As a rule that does not require a RFA, RAFA or JIS, this rule will be initially reviewed in the calendar year 2019, which is no later than the 5th year after the year in which this rule is being adopted.

Assessment of Public Comment

The agency received no public comment.

Public Service Commission

PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED

Waiver of Tariff Provisions Related to SC 14 Non-Core Transportation Services for Electric Generation

I.D. No. PSC-03-15-00002-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed Action: The Commission is considering a petition by the Village of Freeport seeking a waiver of certain tariff provisions of KeySpan Gas East Corporation d/b/a National Grid.

Statutory authority: Public Service Law, sections 65 and 66

Subject: Waiver of tariff provisions related to SC 14 Non-Core Transportation Services for Electric Generation.

Purpose: To determine whether a waiver is warranted.

Substance of proposed rule: On November 26, 2014, the Village of Freeport (Freeport), submitted a petition requesting that the Commission order waive a penalty provision included in a tariff of KeySpan Gas East Corporation d/b/a National Grid (KEDLI) concerning back up fuel requirements for Service Classification No. 14 — Non-Core Transportation Services for Electric Generation (SC 14). The Commission is considering Freeport's petition and can grant, deny or modify, in whole or in part, the requested relief.

Text of proposed rule and any required statements and analyses may be obtained by filing a Document Request Form (F-96) located on our website http://www.dps.ny.gov/f96dir.htm. For questions, contact: Elaine Agresta, Public Service Commission, 3 Empire State Plaza, Albany, New York 12223-1350, (518) 486-2660, email: Elaine.Agresta@dps.ny.gov

Data, views or arguments may be submitted to: Kathleen H. Burgess, Secretary, Public Service Commission, 3 Empire State Plaza, Albany, New York 12223-1350, (518) 474-6530, email: secretary@dps.ny.gov

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

Statements and analyses are not submitted with this notice because the proposed rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act.

(14-G-0513SP1)

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

To Allow Residential Customers to Opt Out of AMR Metering for Gas and Make Other Tariff Changes Related to Gas Metering

I.D. No. PSC-03-15-00003-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed Action: The Commission is considering a petition by Consolidated Edison Company of New York, Inc. to make various changes to P.S.C. No. 9 to allow for customers to opt-out of the use of Automated Meter Reading for gas service and to address other meter issues.

Statutory authority: Public Service Law, section 66(1) and (12)(b)

Subject: To allow residential customers to opt out of AMR metering for gas and make other tariff changes related to gas metering.

Purpose: To allow residential customers to opt out of AMR metering for gas and make other tariff changes related to gas metering.

Substance of proposed rule: The Commission is considering whether to approve, modify or reject, in whole or in part, a tariff filing by Consolidated Edison Company of New York, Inc. (the Company) to make revisions to its gas tariff schedule, P.S.C. No. 9, related to Automated Meter Reading (AMR) and Advanced Metering Infrastructure (AMI). The Company is proposing a new General Information Section III.8 – Metering and Billing - AMR/AMI Meter Opt-Out. This new provision would allow residential customers in one or two family homes that have AMR or AMI meters installed by the Company the option of a one-time election to opt-out of AMR/AMI metering and thereby, have their meters read manually. Customers who choose to opt out would have to: 1) complete an AMR/AMI opt-out application; 2) pay a monthly charge of $19 per account per visit for onsite cycle meter readings; and 3) if a meter was previously installed, pay for the removal of such meter and for the installation of a solid-state non-communicating meter at the costs specified in General Information Section IV.2, unless the Company did not notify the customer in writing in advance of the AMR/AMI meter installation, in which case there will be no charge. Customers who opt out of AMR/AMI metering and have two months of estimated bills in a 12-month period due to no access to the meter will be required to furnish, install and maintain the facilities necessary to accept outdoor meter(s) or provide access to the Company to install, or re-install, as applicable, AMR/AMI metering. Customers who opt out of AMR/AMI metering may elect to participate in AMR/AMI metering at a later date. The amendments have an effective date of April 1, 2015.

In addition, the Company proposed to modify the Gas Tariff's Table of Contents to extend General Information III.8, "Metering and Billing" to Leaf No. 76.2. The Company is also modifying General Information Section III.8.D, "Meter Reading and Billing Period," which indicates that the Company shall attempt an actual meter reading for each scheduled meter reading by a visit to the Customer's premises: the Company shall attempt an actual reading either remotely or by a visit to the premises. Additionally, the Company is eliminating reference to the installation of remote registers in General Information III.5.A. (Leaf 41) and III.8.I, because remote registers are no longer being installed.

Text of proposed rule and any required statements and analyses may be obtained by filing a Document Request Form (F-96) located on our website http://www.dps.ny.gov/f96dir.htm. For questions, contact: Elaine Agresta, Public Service Commission, 3 Empire State Plaza, Albany, New York 12223-1350, (518) 486-2660, email: elaine.agresta@dps.ny.gov

Data, views or arguments may be submitted to: Kathleen H. Burgess, Secretary, Public Service Commission, 3 Empire State Plaza, Albany, New York 12223-1350, (518) 474-4535, email: secretary@dps.ny.gov

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

Statements and analyses are not submitted with this notice because the proposed rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act.

(14-G-0571SP1)

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

To Allow Residential Customers a One Time Election to Opt Out of AMR Metering and Make Other Tariff Changes Related to Metering

I.D. No. PSC-03-15-00004-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed Action: The Commission is considering a petition by Consolidated Edison Company of New York, Inc. to make various changes to P.S.C. No. 10 to allow for customers to opt-out of the use of Automated Meter Reading and to address other meter issues.

Statutory authority: Public Service Law, section 66(1) and (12)

Subject: To allow residential customers a one time election to opt out of AMR metering and make other tariff changes related to metering.

Purpose: To allow residential customers a one time election to opt out of AMR metering and make other changes related to metering.

Substance of proposed rule: The Commission is considering whether to approve, modify or reject, in whole or in part, a tariff filing by Consolidated Edison Company of New York, Inc. (the Company) to make revisions to its electric tariff schedule, P.S.C. No. 10. The Company is proposing a new General Rule 6.10 - AMR/AMI (Automated Meter Reading/Advanced Metering Infrastructure) Meter Opt-Out. This new rule would allow one or two family residential customers in one or two family homes that have AMR or AMI meters installed by the Company the option of a one-time election to opt-out of AMR/AMI metering and thereby, have their meters read manually. Customers who choose to opt out would have to: 1) complete an AMR/AMI opt-out application; 2) pay a monthly charge of $19 per account per visit for onsite cycle meter readings; and 3) if a meter was previously installed, pay for the removal of such meter and for the installation of a solid-state non-communicating meter at the costs specified in General Rule 17.6.1, unless the Company did not notify the customer in writing in advance of the AMR/AMI meter installation, in which case there will be no charge. Customers who opt out of AMR/AMI metering and have two months of estimated bills in a 12-month period due to no access to the meter will be required to furnish, install and maintain the facilities necessary to accept outdoor meter(s) or provide access to the Company to install, or re-install, as applicable, AMR/AMI metering. Customers who opt out of AMR/AMI metering may elect to participate in AMR/AMI metering at a later date. The amendments have an effective date of April 1, 2015. In addition, the Company is adding new General Rule 6.10 to the Electric Tariff's Table of Contents. It is also modifying General Rule 10.3, "Meter Reading and Billing Period," which indicates that the Company shall attempt an actual meter reading for each scheduled meter reading by a visit to the Customer's premises: the Company shall attempt an actual reading either remotely or by a visit to the premises. Additionally, the Company is eliminating reference to the installation of remote registers in General Rule 13.3.4, because remote registers are no longer being installed.

Text of proposed rule and any required statements and analyses may be obtained by filing a Document Request Form (F-96) located on our website http://www.dps.ny.gov/f96dir.htm. For questions, contact: Elaine Agresta, Public Service Commission, 3 Empire State Plaza, Albany, New York 12223-1350, (518) 486-2660, email: elaine.agresta@dps.ny.gov

Data, views or arguments may be submitted to: Kathleen H. Burgess, Secretary, Public Service Commission, 3 Empire State Plaza, Albany, New York 12223-1350, (518) 474-6530, email: secretary@dps.ny.gov

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

Statements and analyses are not submitted with this notice because the proposed rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act.

(14-E-0570SP1)

PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED

Minor Electric Rate Filing

I.D. No. PSC-03-15-00005-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed Action: The Public Service Commission is considering whether to approve or reject, in whole or in part, a proposal filed by Fishers Island Electric Corp. to make various changes to the rates, charges, rules and regulations contained in P.S.C. No. 2 — Electricity.

Statutory authority: Public Service Law, section 66(12)(b)

Subject: Minor electric rate filing.

Purpose: For approval to increase annual revenues by about $300,000 or 17.96%.

Substance of proposed rule: The Public Service Commission is considering whether to approve, modify or reject, in whole or in part, a tariff filing by Fishers Island Electric Corporation to increase their electric revenues by about $300,000 or 17.96%. The proposed amendments have an effective date of May 1, 2015.

Text of proposed rule and any required statements and analyses may be obtained by filing a Document Request Form (F-96) located on our website http://www.dps.ny.gov/f96dir.htm. For questions, contact: Elaine Agresta, Public Service Commission, 3 Empire State Plaza, Albany, New York 12223-1350, (518) 486-2660, email: Elaine.Agresta@dps.ny.gov

Data, views or arguments may be submitted to: Kathleen H. Burgess, Secretary, Public Service Commission, 3 Empire State Plaza, Albany, New York 12223-1350, (518) 474-6530, email: secretary@dps.ny.gov

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

Statements and analyses are not submitted with this notice because the proposed rule is within the definition contained in section 102(2)(a)(ii) of the State Administrative Procedure Act.

(14-E-0569SP1)