

mortgage bankers, mortgage brokers or exempt organizations. Additionally, in the case of servicers that operate in rural areas and are not otherwise exempted, the Superintendent has the authority to reduce, waive or modify the financial responsibility requirements for individuals that do a de minimis amount of servicing.

Rural Area Participation: Industry representatives have participated in outreach programs regarding regulation of servicers. The Department also maintains continuous contact with large segments of the servicing industry through its regulation of mortgage bankers and brokers. The Department likewise maintains close contact with a variety of consumer groups through its community outreach programs and foreclosure mitigation programs. In response to comments received regarding earlier versions of this regulation, the Department has modified the financial responsibility requirements. The revised requirements should generally be less burdensome for mortgage loan servicers, particularly smaller servicers and those located in rural areas.

#### Job Impact Statement

Article 12-D of the Banking Law, as amended by the Subprime Lending Reform Law (Ch. 472, Laws of 2008), requires persons and entities which engage in the business of servicing mortgage loans to be registered with the Superintendent of Financial Services (formerly the Superintendent of Banks). This emergency regulation sets forth the application, exemption and approval procedures for registration as a Mortgage Loan servicer (MLS), as well as financial responsibility requirements for applicants, registrants and exempted persons. The regulation also establishes requirements with respect to changes of officers, directors and/or control of MLSs and provisions with respect to suspension, revocation, termination, expiration and surrender of MLS registrations.

The requirement to comply with the emergency regulations is not expected to have a significant adverse effect on jobs or employment activities within the mortgage loan servicing industry. Many of the larger entities engaged in the mortgage loan servicing business are already subject to oversight by the Department of Financial Services (formerly the Banking Department) and exempt from the new registration requirement. Additionally, the regulations give the Superintendent the authority to reduce, waive or modify the financial responsibility requirements for entities that do a de minimis amount of servicing.

The registration process itself should not have an adverse effect on employment. The regulations require the use of the internet-based National Mortgage Licensing System and Registry, developed by the Conference of State Bank Supervisors and the American Association of Residential Mortgage Regulators. This system uses a common on-line application for servicer registration in New York and other participating states. It is believed that any remaining adverse impact would be due primarily to the nature and purpose of the statutory registration requirement rather than the provisions of the emergency regulations.

## New York State Gaming Commission

### PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

#### Per Se Thresholds and Related Rule Amendments for Cobalt, Ketoprofen, Isoflupredone and Albuterol

I.D. No. SGC-48-15-00006-P

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

**Proposed Action:** Amendment of sections 4043.2(i), 4043.3 and 4120.3 of Title 9 NYCRR.

**Statutory authority:** Racing, Pari-Mutuel Wagering and Breeding Law, sections 103(2), 104(1), (19), 301(1), (2) and 902(1)

**Subject:** Per Se thresholds and related rule amendments for cobalt, ketoprofen, isoflupredone and albuterol.

**Purpose:** To preserve the integrity of pari-mutuel racing while generating reasonable revenue for the support of government.

**Text of proposed rule:** Subdivision (i) of section 4043.2 of 9 NYCRR would be amended as follows:

§ 4043.2. Restricted use of drugs, medication and other substances.

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

\* \* \*

(i) In addition, a horse may not race for the following periods of time:  
(1) for at least five days following a systemic administration of a prednisolone or dexamethasone;

(2) for at least seven days following a joint injection of a corticosteroid; and the following corticosteroids may be administered only by means of a joint injection: betamethasone, *isoflupredone*, any formulation of methylprednisolone and any formulation of triamcinolone;

(3) for at least 14 days following an administration of clenbuterol or *firocoxib*.

\* \* \*

Section 4043.3 of 9 NYCRR would be amended as follows:

§ 4043.3. 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) *Albuterol*: 1 ng/ml in urine;

[(2)] (3) Betamethasone: 10 pg/ml in plasma;

[(3)] (4) Butorphanol:

(i) 300 ng/ml of total butorphanol in urine; or

(ii) 2 ng/ml of free butorphanol in plasma;

[(4)] (5) Clenbuterol:

(i) 140 pg/ml in urine; or

(ii) any clenbuterol in plasma;

(6) *Cobalt*: 50 ng/ml in plasma;

[(5)] (7) Dantrolene: 100 pg/ml of 5-hydroxydantrolene in plasma;

[(6)] (8) Detomidine:

(i) 1 ng/ml of any metabolite of detomidine in urine; or

(ii) any detomidine in plasma;

[(7)] (9) Dexamethasone: 5 pg/ml in plasma;

[(8)] (10) Diclofenac: 5 ng/ml in plasma;

[(9)] (11) DMSO: 10 mcg/ml in plasma;

[(10)] (12) *Firocoxib*: 20 ng/ml in plasma;

[(11)] (13) Flunixin: 20 ng/ml in plasma;

[(12)] (14) Furosemide: 100 ng/ml in plasma and a specific gravity of urine less than 1.010;

[(13)] (15) Glycopyrrolate: 3 pg/ml in plasma;

[(14)] (16) *Isoflupredone*: 100 pg/ml in plasma;

[(15)] (17) Ketoprofen: [10] 2 ng/ml in plasma;

[(16)] (18) Lidocaine: 20 pg/ml of total 3-hydroxylidocaine in plasma;

[(17)] (19) Mepivacaine:

(i) 10 ng/ml of total hydroxymepivacaine in urine; or

(ii) any hydroxymepivacaine in plasma;

[(18)] (20) Methocarbamol: 1 ng/ml in plasma;

[(19)] (21) Methylprednisolone: 100 pg/ml in plasma;

[(20)] (22) Omeprazole: 1 ng/ml of omeprazole sulfide in urine;

[(21)] (23) Phenylbutazone: 2 mcg/ml in plasma;

[(22)] (24) Prednisolone: 1 ng/ml in plasma;

[(23)] (25) Procaine penicillin: 25 ng/ml of procaine in plasma;

[(24)] (26) Triamcinolone acetonide: 100 pg/ml in plasma; and

[(25)] (27) 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.

(c) *Special provisions.*

(1) *Cobalt.* A person who is found responsible for a violation of this section for the substance cobalt, when the detected concentration of cobalt exceeds 300 ng/ml in plasma, shall incur the same penalty described in paragraph (2) of subdivision (b) of section 4043.12 of this Part.

(2) *Corticosteroid joint injection.* It shall not be a violation of this section for the drug betamethasone, isoflupredone or triamcinolone acetonide when:

(i) the laboratory positive resulted from an administration that was recorded in the contemporaneous veterinary records of the horse, reported to the commission in compliance with subdivision (b) of section 4043.4 of this Part before the horse raced, and administered to the horse in compliance with subdivision (i) of section 4043.2 of this Part at least seven days before the race; and

(ii) the commission had not previously issued a warning to the trainer that the commission laboratory reported finding such substance, in a urine or blood sample collected from any horse trained by such trainer, at a concentration in excess of the threshold set forth in subdivision (a) of this section.

Section 4120.3 of 9 NYCRR would be amended 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.

- (1) Acepromazine: 10 ng/ml HEPS in urine;
- (2) *Albuterol*: 1 ng/ml in urine;
- [(2)] (3) Butorphanol:
  - (i) 300 ng/ml of total butorphanol in urine; or
  - (ii) 2 ng/ml of free butorphanol in plasma;
- (4) *Cobalt*: 50 ng/ml in plasma;
- [(3)] (5) Dantrolene: 100 pg/ml of 5-hydroxydantrolene in plasma;
- [(4)] (6) Detomidine:
  - (i) 1 ng/ml of any metabolite of detomidine in urine; or
  - (ii) any detomidine in plasma;
- [(5)] (7) Diclofenac: 5 ng/ml in plasma;
- [(6)] (8) DMSO: 10 mcg/ml in plasma;
- [(7)] (9) Firocoxib: 20 ng/ml in plasma;
- [(8)] (10) Flunixin: 20 ng/ml in plasma;
- [(9)] (11) Furosemide: 100 ng/ml in plasma and a specific gravity of urine less than 1.010;
- [(10)] (12) Glycopyrrolate: 3 pg/ml in plasma;
- [(11)] (13) Ketoprofen: [10] 2 ng/ml in plasma;
- [(12)] (14) Lidocaine: 20 pg/ml of total 3-hydroxylidocaine in plasma;
- [(13)] (15) Mepivacaine:
  - (i) 10 ng/ml of total hydroxymepivacaine in urine; or
  - (ii) any hydroxymepivacaine in plasma;
- [(14)] (16) Methocarbamol: 1 ng/ml in plasma;
- [(15)] (17) Methylprednisolone: 100 pg/ml in plasma;
- [(16)] (18) Omeprazole: 1 ng/ml of omeprazole sulfide in urine;
- [(17)] (19) Phenylbutazone: 2 mcg/ml in plasma;
- [(18)] (20) Procaine penicillin: 25 ng/ml of procaine in plasma; and
- [(19)] (21) 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.

(c) *A person who is found responsible for a violation of this section for the substance cobalt, when the detected concentration of cobalt exceeds 300 ng/ml in plasma, shall incur the same penalty described in paragraph (2) of subdivision (d) of section 4120.17 of this Part.*

**Text of proposed rule and any required statements and analyses may be obtained from:** Kristen M. Buckley, New York State Gaming Commission, 1 Broadway Center, PO Box 7500, Schenectady, New York 12301, (518) 388-3407, email: gamingrules@gaming.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**

1. Statutory authority: The New York State Gaming Commission (“Commission”) is authorized to promulgate these rules pursuant to Racing Pari-Mutuel Wagering and Breeding Law (“Racing Law”) Sections 103(2), 104(1, 19), 301(1, 2) and 902(1). Under Section 103(2), the Commission is responsible for supervising, regulating and administering all horse racing and pari-mutuel wagering activities in the State. Subdivision (1) of Section 104 confers upon the Commission general jurisdiction over all such gaming activities within the State and over the corporations, associations and persons engaged in such activities. Subdivision (19) of Section 104 authorizes the Commission to promulgate any rules and regulations that it deems necessary to carry out its responsibilities. Under Section 301, which applies to only harness racing, the Commission is authorized to supervise generally all harness race meetings and to adopt rules to prevent the circumvention or evasion of its regulatory purposes and provisions and is directed to adopt rules to prevent horses from racing under the influence of substances affecting their speed. Section 902(1) authorizes the Commission to promulgate rules and regulations for an equine drug testing program that assures the public’s confidence and continues the high degree of integrity in pari-mutuel racing and to impose administrative penalties for racing a drugged horse.

2. Legislative objectives: To enable the Commission to preserve the integrity of pari-mutuel racing while generating reasonable revenue for the support of government.

3. Needs and benefits: This rule making is necessary to align the Commission’s laboratory “per se” thresholds for controlled therapeutic medi-

cations with the latest ones approved by the Association of Racing Commissioners International, Inc. (“ARCI”) and to ensure that the restricted time periods for equine drug use are consistent with such thresholds.

The proposal would amend sections 4043.3 (Thoroughbred) and 4120.3 (harness) of 9 NYCRR to add two more thresholds and to modify an existing threshold. ARCI recommends adding a threshold for albuterol, a bronchodilator, and lowering the existing threshold for ketoprofen, an approved non-steroidal anti-inflammatory drug (“NSAID”). Both recommendations are consistent with the Commission’s existing time restrictions for albuterol (96 hours) and NSAIDs (48 hours) that ensure a horseperson will not inadvertently commit threshold violations.

ARCI also recommends adding a Thoroughbred threshold for isoflupredone, a corticosteroid that is used in corticosteroid joint injections. The proposal would make various amendments corresponding to the Commission’s thoroughbred regulations for such corticosteroids: requiring their use be reported to the Commission before racing, under section 4043.4(b), and restricting use to only joint injections and permitting no administrations within seven days of a race, under section 4043.2(i). The Commission does not have similar regulations for harness racing.

In addition, the proposal would establish a requirement that the Commission first warn a Thoroughbred trainer whose horse tests in excess of corticosteroid thresholds when the corticosteroid joint injection causing the threshold violation is shown in documentary evidence (pre-race report to Commission, veterinary records) to have been administered safely in compliance with the Commission’s seven-day restricted time period for Thoroughbred racehorses. The purpose of this provision is to avoid having a restricted time period that fails to assure a regulated party that compliance will result in no threshold violation. This provision would be added in a new subdivision (c) for sections 4043.3 and 4120.3.

The proposal would also increase the Commission’s regulation of cobalt. ARCI’s Scientific Advisory Committee recommends adopting two thresholds for cobalt, a dietary element: one (50 ng/ml) detects the intentional overuse of cobalt, a practice that has no valid purpose and cannot occur without using refined products, and another (300 ng/ml) imposes a blood-doping level of penalty when the violation has occurred undeniably. Cobalt is reportedly misused in a manner that causes serious central nervous system distress and blood-doping to a horse. The proposal would amend subdivision (a) of section 4043.3 to create the lower threshold, and a new subdivision (c) of section 4043.3 would establish the consequences of a violation of the higher threshold.

4. Costs:

(a) Costs to regulated parties for the implementation of and continuing compliance with the rule: These amendments will not add any new mandated costs to the existing rules.

(b) Costs to the agency, the state and local governments for the implementation and continuation of the rule: None. The amendments will not add any new costs. There will be no costs to local government because the Commission is the only governmental entity authorized to regulate pari-mutuel harness racing.

(c) The information, including the source(s) of such information and the methodology upon which the cost analysis is based: N/A.

5. Local government mandates: None. The Commission is the only governmental entity authorized to regulate pari-mutuel thoroughbred racing activities.

6. Paperwork: There will be no additional paperwork.

7. Duplication: No relevant rules or other legal requirements of the state and/or federal government exist that duplicate, overlap or conflict with this rule.

8. Alternatives: The Commission considered the adoption of a third cobalt threshold (25 ng/ml) that would disqualify the horse from its race and prevent the horse from racing until testing below such threshold. In such cases, however, the Commission believes it is necessary to investigate whether a lawful vitamin administration was the cause, making a mandatory threshold inappropriate. In addition, the reported misuses of cobalt typically involve administrations that result in a higher concentration for several weeks.

9. Federal standards: There are no minimum standards of the Federal government for this or a similar subject area.

10. Compliance schedule: The Commission believes that regulated persons will be able to achieve compliance with the rule upon adoption of this rule.

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

A regulatory flexibility analysis for small business and local governments, a rural area flexibility analysis, and a job impact statement are not required for this rule making proposal because it will not adversely affect small businesses, local governments, rural areas, or jobs.

The proposal revises the Commission’s horse racing rules that regulate the use of certain substances with per se thresholds and restricted time periods to conform to recent national recommendations. Trainers have

been meeting these thresholds for many years in New York by complying with the Commission's longstanding restricted time period rules that restrict how long a horse must not race after being treated with various equine drugs and other substances. All horsepersons will be able to comply with these rules and competitors will not be able to violate the thresholds to the detriment of others. The thresholds are common with those in other states, making it easier to prepare a horse to race in multiple states. Special provisions will protect trainers and veterinarians who rely on the corticosteroid joint-injection restricted time periods, which assist a horseperson to comply with the national thresholds, and impose a serious penalty in undeniable cases of mistreating a horse with extremely large cobalt administrations.

The rule amendments serve to enhance the integrity of racing, the health and safety of racehorses and the drivers and jockeys. This rule will not impose an adverse economic impact or reporting, record keeping, or other compliance requirements on small businesses in rural or urban areas or on employment opportunities. No local government activities are involved.

This proposal will not adversely impact small businesses, local governments, jobs, or rural areas. It does not require a Regulatory Flexibility Analysis (for Small Businesses and Local Governments), Rural Area Flexibility Analysis, or Job Impact Statement.

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## Department of Health

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### EMERGENCY RULE MAKING

#### Protection Against Legionella

**I.D. No.** HLT-48-15-00004-E

**Filing No.** 973

**Filing Date:** 2015-11-13

**Effective Date:** 2015-11-13

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

**Action taken:** Addition of Part 4 to Title 10 NYCRR.

**Statutory authority:** Public Health Law, section 225(5)(a)

**Finding of necessity for emergency rule:** Preservation of public health, public safety and general welfare.

**Specific reasons underlying the finding of necessity:** Improper maintenance of cooling towers can contribute to the growth and dissemination of Legionella bacteria, the causative agent of legionellosis. Legionellosis causes cough, shortness of breath, high fever, muscle aches, headaches and can result in pneumonia. Hospitalization is often required, and between 5-30% of cases are fatal. People at highest risk are those 50 years of age or older, current or former smokers, those with chronic lung diseases, those with weakened immune systems from diseases like cancer, diabetes, or kidney failure, and those who take drugs to suppress the immune system during chemotherapy or after an organ transplant. The number of cases of legionellosis reported in New York State between 2005-2014 increased 323% when compared to those reported in the previous ten year period.

Outbreaks of legionellosis have been associated with cooling towers. A cooling tower is an evaporative device that is part of a recirculated water system incorporated into a building's cooling, industrial process, refrigeration, or energy production system. Because water is part of the process of removing heat from a building, these devices require biocides—chemicals that kill or inhibit bacteria (including Legionella)—as means of controlling bacterial overgrowth. Overgrowth may result in the normal mists ejected from the tower having droplets containing Legionella.

For example, in 2005, a cooling tower located at ground level adjacent to a hospital in New Rochelle, Westchester County resulted in a cluster of 19 cases of legionellosis and multiple fatalities. Most of the individuals were dialysis patients or companions escorting the patients to their dialysis session. One fatality was in the local neighborhood. The cooling tower was found to have insufficient chemical treatment. The entire tower was ultimately replaced by the manufacturer in order to maintain cooling for the hospital and to protect public health. In June and July of 2008, 12 cases of legionellosis including one fatality were attributed to a small evaporative condenser on Onondaga Hill in Syracuse, Onondaga County. An investigation found that the unit was not operating properly and this resulted in the growth of microorganisms in the unit. Emergency biocide treatment was initiated and proper treatment was maintained. No new cases were then detected thereafter.

Recent work has shown that sporadic cases of community legionellosis are often associated with extended periods of wet weather with overcast skies. A study conducted by the New York State Department of Health that included data from 13 states and one United States municipality noted a dramatic increase in sporadic, community acquired legionellosis cases in May through August 2013. Large municipal sites such as Buffalo, Erie County reported 2- to 3-fold increases in cases without identifying common exposures normally associated with legionellosis. All sites in the study except one had a significant correlation, with some time lag, between legionellosis case onset and one or more weather parameters. It was concluded that large municipalities produce significant mist (droplet) output from hundreds of cooling towers during the summer months. Periods of sustained precipitation, high humidity, cloud cover, and high dew point may lead to an "urban cooling tower" effect. The "urban cooling tower" effect is when a metropolitan area with hundreds of cooling towers acts as one large cooling tower producing a large output of drift, which is entrapped by humid air and overcast skies.

More recently, 133 cases of legionellosis, which included 16 fatalities, occurred in Bronx, NY (July-September, 2015). This event was preceded by an outbreak in Co-Op City in the Bronx, from December 2014 to January 2015, which involved 8 persons and no fatalities. Both of these outbreaks have been attributed to cooling towers, and emergency disinfection of compromised towers helped curtail these outbreaks. These events highlight the need for proper maintenance of cooling towers.

The heating, ventilation, and air-conditioning (HVAC) industry has issued guidelines on how to seasonally start a cooling tower; treat it with biocides and other chemicals needed to protect the components from scale and corrosion; and set cycles of operations that determine when fresh water is needed; and how to shut down the tower at the end of the cooling season. The American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) has recently released a new Standard entitled Legionellosis: Risk Management for Building Water Systems (ANSI/ASHRAE Standard 188-2015). Section 7.2 of that document outlines components of the operations and management plan for cooling towers. The industry also relies on other guidance for specific treatment chemicals, emergency disinfection or decontamination procedures and other requirement.

However, none of the guidance is obligatory. Consequently, poor practice in operation and management can result in bacterial overgrowth, increases in legionellae, and mist emissions that contain a significant dose of pathogenic legionellae. This regulation requires that all owners of cooling towers ensure proper maintenance of the cooling towers, to protect the public and address this public health threat.

Further, these regulations require all general hospitals and residential health care facilities (i.e., nursing homes) to develop a sampling plan, report the results, and take necessary actions to protect the safety of their patients or residents. The details of each facility's sampling plan and remedial measures will depend on the risk factors for acquiring Legionnaires' disease in the population served by the hospital or nursing home.

Most people in nursing homes should be considered at risk, as residents are typically over 50 years of age. In general hospitals, persons at risk include those over 50 years of age, as well as those receiving chemotherapy, those undergoing transplants, and other persons housed on healthcare units that require special precautions. Additional persons who might be at increased risk for acquiring Legionnaires' disease include persons on high-dose steroid therapy and persons with chronic lung disease. Certain facilities with higher risk populations, such as those with hematopoietic stem-cell transplant (HSCT) and solid organ transplant units, require more protective measures.

An environmental assessment involves reviewing facility characteristics, hot and cold water supplies, cooling and air handling systems and any chemical treatment systems. The purpose of the assessment is to discover any vulnerabilities that would allow for amplification of Legionella spp. and to determine appropriate response actions in advance of any environmental sampling for Legionella. Initial and ongoing assessment should be conducted by a multidisciplinary team that represents the expertise, knowledge and functions related to the facility's operation and service. A team should include, at a minimum, representatives from the following groups: Infection Control; Physical Facilities Management; Engineering; Clinicians; Laboratory; and Hospital Management.

These regulations, which originally became effective on August 17, 2015, implemented important requirements that protect the public from the threat posed by Legionella. To ensure that protection is maintained, the Commissioner of Health and the Public Health and Health Planning Council have determined it necessary to file these regulations on an emergency basis. Public Health Law § 225, in conjunction with State Administrative Procedure Act § 202(6) empowers the Council and the Commissioner to adopt emergency regulations when necessary for the preservation of the public health, safety or general welfare and that compliance with routine administrative procedures would be contrary to the public interest.