

**California State Athletic Commission
Department of Consumer Affairs
Initial Statement of Reasons**

HEARING DATE: December 15, 2014

SUBJECT MATTER OF PROPOSED REGULATIONS:

Therapeutic Use Exemption

SECTIONS AFFECTED:

Adopt Section 424 of Article 14 of Division 2 of Title 4 of the California Code of Regulations

PROBLEM STATEMENT

Rule 303, Administration or Use of Drugs was originally drafted as one of strict liability. Any athlete who tested positive for any of the substances listed, or its derivatives is subject to loss of license and/or fines, with the exception of other Beta-2 agonists or asthma medications. However, there may in fact be instances, albeit extraordinarily rare, in which an athlete may need an exemption for competition.

Under its current construct, were Rule 303 to be strictly followed, it would be excessively prohibitive. Rule 303 could prevent an otherwise qualified athlete from participating in a sport of his or her choice simply because they have an illness which requires them to take a medication which may contain a portion of a prohibited substance, even though it does not enhance their performance as an athlete. These guidelines do not reflect the current standards of the medical or sports community.

BENEFITS

It is anticipated that this regulation will protect the health and safety of athletes, prevent discrimination against those athletes with legitimate medical conditions and promote fairness and social equity by allowing eligible legitimate contenders an equal opportunity to enter the ring. The amendment will allow athletes taking a very common but effective medication to continue the use of such medication, in specific doses proven not to provide an unfair advantage, prior to and during competition. Currently, athletes with prescribed medications often discontinue taking their medication, thereby risking their health, in order to fight in California.

PURPOSE

Adopt Section 424 (a) and (b): To allow athletes (foreign and domestic) a method to request for permission from the commission to use a prohibited substance, when proven necessary and that does not provide an unfair advantage. This regulation also

establishes the process for an athlete to obtain an exemption for a therapeutic medical use by requesting permission from the Commission by completing a form, named "Therapeutic Use Exemption Application" form (Rev 1/2014, this form is incorporated by reference).

The "Therapeutic Use Exemption Application" form (Rev 1/2014) requests the following information and the purpose for each:

1. **Name, Address, Telephone Number, Email, Gender and DOB** - This is requested so the Commission can identify and correspond with the applicant for TUE.
2. **Medical Information & Diagnosis/ Medication Details** - This information is requested and required in order to evaluate the TUE request in the context of possible anti-doping rule violations. This information is necessary because the commission must have enough medical documentation to come to the same diagnosis and treatment plan without ever seeing the patient.
3. **Authorization to Release Information** - this is required on all of the commission's application forms - established pursuant to Sections 18640, 18642 and 18643 of the Business and Professions Code.
4. **Applicant Declaration** - this is required on all of the commission's application forms (penalty of perjury statement).
5. **Authorization to Use and Disclose Protected Health Information** - this is required on all of the commission's application forms - HIPAA disclosure.
6. **Examining Physician Declaration** - Name, Medical License Number, Medical Specialty, Address, Telephone Number, email and signature of the physician is requested to determine the treatment is medically appropriate and that the use of the alternative medications not on the prohibited list would be unsatisfactory for the condition. The Commission also needs to identify and correspond with the licensed physician.

Adopt Section 424 (c) and (d): To define "Prohibited substance" as those substances specified in the Prohibited List of the World Anti-Doping Code, as promulgated by the World Anti-Doping Agency (WADA).

Adopt Section 424 (e): Gives a timeframe in which an athlete shall apply for a TUE to the Commission.

Adopt Section 424 (f): Gives exceptions to applying within the specified timeframe in subsection (e).

Adopt Section 424 (g): Lists the documentation necessary and shall accompany the application for TUE.

Adopt Section 424 (h): To allow the commission to request from athletes applying for a TUE to undergo any additional medical examination and testing at the sole discretion of the commission.

Adopt Section 424 (i): Specifies that the commission shall determine based upon the facts and circumstances of the case there is no reasonable suspicion to the satisfaction of the commission the applicant used the substance for the purpose of enhancing his or her athletic performance.

Adopt Section 424 (j): Specifies that If the athlete intends to compete further in any event or competition that may subject the athlete to drug testing by the commission, the athlete must apply for a separate TUE for any prohibited substance in advance of such event or competition in accordance with the provisions of this section.

NECESSITY

These regulations are designed to protect the health and safety of athletes, prevent discrimination against those athletes with legitimate medical conditions and promote fairness and social equity by allowing eligible legitimate contenders an equal opportunity to compete. This regulation also establishes the process for an athlete to obtain an exemption for a therapeutic medical use by requesting permission from the Commission by completing a form, named "Therapeutic Use Exemption Application" form (Rev 1/2014, this form is incorporated by reference).

Rule 303(a) provides that the administration or use of any drugs, alcohol, stimulants, or injections is prohibited. However, a small number of athletes who have a medical condition that requires prescribed medications should be permitted to compete, if they are otherwise healthy and would not have an unfair advantage.

UNDERLYING DATA:

1. 2014 Wada Prohibited List of Substances.
2. IOC Anti-Doping Rules, Applicable to the XXX Olympiad.
3. IOC Anti-Doping Rules, Applicable to the XXII Winter Olympics in Sochi.
4. IOC Summary on TUE Applicable to the XXX Olympiad.
5. IOC Summary on TUE Applicable to the 2010 Youth Olympics.
6. IOC Medical and Scientific Application form 2012 and 2014.
7. USOC Anti-Doping Policies.
8. USOC and USDA TUE policy.
9. USOC and USDA TUE application form.
10. WADA Medical Information to Support TUE for Adrenal Insufficiency.
11. WADA Medical Information to Support TUE for Anaphylaxis.
12. WADA Medical Information to Support TUE for Androgen Deficiency/Male Hypogonadism.
13. WADA Medical Information to Support TUE for Arterial Hypertension.
14. WADA Medical Information to Support TUE for Asthma.

15. WADA Medical Information to Support TUE for Diabetes Mellitus.
16. WADA Medical Information to Support TUE for Growth Hormone Deficiency.
17. WADA Medical Information to Support TUE for Post Infectious Cough.
18. WADA Medical Information to Support TUE for Musculoskeletal Injuries.

ECONOMIC IMPACT ANALYSIS/ASSESSMENT:

The Creation or Elimination of Jobs Within the State of California

The regulations are designed to bring California's combat sports into compliance with the standard of practice in the medical, international and national sports communities, which is to grant exemptions only in the most extraordinary of circumstances, particularly with testosterone exemption applications. The regulations will only affect licensees who have a legitimate medical need and afford them the opportunity to apply for a therapeutic use exemption. Records indicate that there have been no exemptions given in the United States for testosterone use for boxers between 2008 and 2013. In California, the commission didn't receive a single application for exemption from a boxer. However, in the sport of mixed martial arts, there were 15 exemptions given by athletic commissions and the Ultimate Fighter Championship (UFC). Therefore, the commission has determined that this regulatory proposal will not have an impact on the creation or elimination of jobs in the State of California.

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

The regulations are designed to bring California's combat sports into compliance with the standard of practice in the medical, international and national sports communities, which is to grant exemptions only in the most extraordinary of circumstances, particularly with testosterone exemption applications. The regulations will only affect licensees who have a legitimate medical need and afford them the opportunity to apply for a therapeutic use exemption. A company cannot be required to apply for a therapeutic use exemption; only an individual licensee can be required to do so, making the adoption of section 424 not relevant to the creation or elimination of businesses in California. Therefore, the commission has determined that this regulatory proposal will not have a significant impact on the creation of new businesses or the elimination of existing businesses in the State of California.

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

The regulations are designed to bring California's combat sports into compliance with the standard of practice in the medical, international and national sports communities, which is to grant therapeutic use exemptions only in the most extraordinary of circumstances, particularly with testosterone exemption applications. The regulations will only affect licensees who have a legitimate medical need and afford them the opportunity to apply for a therapeutic use exemption. A company cannot be required to apply for a therapeutic use exemption; only an individual licensee can be required to do so, making the adoption of section 424 not relevant to the expansion of businesses in California. Therefore, the commission has determined that this regulatory proposal will not have a significant impact on the expansion of businesses within the State of California.

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

The anticipated benefits to this regulation are increased consumer protections through industry compliance with rules and regulations; clarity for licensees in applying for a therapeutic use exemption; and following international standards for granting exemptions.

BUSINESS IMPACT:

This policy should have minor impact on businesses. In the case of athletes legitimately seeking exemptions, and should they be granted under the specifications of this proposal, then business may benefit by allowing that particular athlete to be licensed and participate in the state. Since the Commission anticipates an extremely small number of athletes that can actually meet the requirements to be granted a TUE, the impact on business is negligible. Therefore the Commission made a determination that this proposal will not have a significant statewide adverse economic impact directly affecting businesses including the ability to compete with other businesses in California.

FISCAL IMPACT ANALYSIS:

Applicants not granted a TUE as specified by this policy would suffer financially by not being allowed to compete. Promoters may also suffer by not being able to promote and showcase an athlete who would qualify and apply for a TUE.

REQUIREMENTS FOR SPECIFIC TECHNOLOGIES OR EQUIPMENT:

The proposed regulation would not mandate the use of technologies or equipment or other prescriptive standards.

DESCRIPTION OF ALTERNATIVES:

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific.

The Commission could simply not grant a TUE and maintain the status quo. Under this alternative, any athlete with a medical condition requiring a banned substance would not be allowed to compete. This would include but not be limited to athletes with asthma requiring inhalers, athletes that have suffered testicular or ovarian cancer, transgender athletes seeking licensure, and any other rare case. This would disallow a very small number of athletes from competing because of a medical condition requiring treatment to safely compete.

The Commission could grant a TUE using the proposed regulation. Because the standards for receiving this exemption are very difficult to meet, the public could be assured that only athletes who must have a TUE are granted one.

Another alternative would be to allow any athlete to fight while under the influence of a prohibited substance. This would require a change in statute and regulation and the Commission would not be supportive of this alternative.