



THE STATE EDUCATION DEPARTMENT / THE UNIVERSITY OF THE STATE OF NEW YORK / ALBANY, NY 12234

**TO:** The Honorable Members of the Board of Regents

**FROM:** Sarah S. Benson *Sarah S. Benson*

**SUBJECT:** Proposed Amendment of Subdivision (a) of Section 66.5 of the Regulations of the Commissioner of Education Relating to the Use of Therapeutic Pharmaceutical Agents by Certified Optometrists

**DATE:** June 5, 2022

**AUTHORIZATION(S):**

*Don M. P.* *Bellotti*

**SUMMARY**

**Issue for Decision (Consent)**

Should the Board of Regents amend subdivision (a) of section 66.5 of the Regulations of the Commissioner of Education relating to the use of therapeutic pharmaceutical agents by certified optometrists?

**Reason(s) for Consideration**

Review of policy.

**Proposed Handling**

The proposed amendment will be presented to the Full Board for adoption at the June 2022 meeting of the Board of Regents. A copy of the proposed amendment is attached (Attachment A).

**Procedural History**

The proposed amendment was presented to the Professional Practice Committee for discussion at the February 2022 meeting of the Board of Regents. A Notice of Proposed Rule Making was published in the State Register on March 2, 2022. Following publication in the State Register, the Department received one supportive comment on the proposed amendment. An Assessment of Public Comment is included

as (Attachment B). No changes to the proposed amendment are recommended at this time. A Notice of Adoption will be published in the State Register on June 29, 2022. Supporting materials for the proposed amendment are available upon request from the Secretary of the Board of Regents.

### **Background Information**

Chapter 517 of the Laws of 1995 (Chapter 517) amended the Education Law to authorize optometrists to obtain a specialty certification so that they could use topically applied therapeutic pharmaceutical agents (TPAs) for the treatment or prevention of ocular disease. Section 7101-a of the Education Law, added by Chapter 517, separates TPAs into two phases, “phase one” and “phase two.” Optometrists may only receive certification to use phase two TPAs if they demonstrate specialized experience and training and have obtained phase one certification.

After the initial enactment of this law, optometrists certified to apply TPAs submitted reports to a Temporary Evaluation Committee (TEC) for a period of years (8 NYCRR 66.5 [e]). In 2004, the Department retained an independent research firm to assist the TEC<sup>1</sup> in evaluating these reports. After considering analyses by the TEC and firm, the Department determined that the continued use of TPAs by certified optometrists was safe and promoted public access to primary eye care services.

### **Proposed Amendment**

Pursuant to Education Law §7101-a(12), the Commissioner of Health may recommend to the Commissioner of Education additions or deletions to the Commissioner’s regulations relating to optometric use of drugs, except that such recommendations must be limited only to additions which have been determined to be equivalent to those drugs already authorized or deletions based upon a finding that the drugs are no longer appropriate for their current use or for other similar reasons.

Consistent with Education Law §7101-a(12), the Commissioner of Health has recommended to the Commissioner of Education that Rho kinase inhibitors be added to the list of drugs that phase two certified optometrists may use or prescribe. Rho kinase inhibitors are eye drops which are used to treat glaucoma. They are similar to a class of drugs which is already authorized for optometric use and can decrease the threat of irreversible vision loss from glaucoma in patients with open-angle glaucoma or ocular hypertension.<sup>2</sup>

The Department therefore proposes, in accordance with the Commissioner of Health’s recommendation, to amend subdivision (a) of section 66.5 of the Commissioner’s regulations to add a new class of drugs, Rho kinase inhibitors, to the list of drugs that an optometrist certified to use phase two TPAs may use and prescribe to treat patients.

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<sup>1</sup> The TEC is no longer in existence.

<sup>2</sup> Stuart, Annie et al. EyeNet Magazine, Sept. 2018: 27-29.

The proposed amendment permits such optometrists to use and prescribe Rho kinase inhibitors for topical application to the surface of the eye for therapeutic purposes only. This class of drugs has been approved by the United States Food and Drug Administration and is commercially available. The Department believes this regulatory change will be an important tool in the management and treatment of glaucoma.

### **Related Regents Items**

February 2022: [Proposed Amendment of Subdivision \(a\) of Section 66.5 of the Regulations of the Commissioner of Education Relating to the Use of Therapeutic Pharmaceutical Agents by Certified Optometrists](https://www.regents.nysed.gov/common/regents/files/222ppcd1.pdf)

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### **Recommendation**

It is recommended that the Board of Regents take the following action:

VOTED: That subdivision (a) of section 66.5 of the Regulations of the Commissioner of Education be amended, as submitted, effective June 29, 2022.

### **Timetable for Implementation**

If adopted at the June meeting, the proposed amendment will become effective on June 29, 2022.

**Attachment A**

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6507, 7101 and 7101-a of the Education Law.

Subparagraph (ii) of paragraph (2) of subdivision (a) of section 66.5 of the Regulations of the Commissioner of Education is amended, to read as follows:

(ii) carbonic anhydrase inhibitors, Rho kinase inhibitors, and prostaglandin analogs. Such drugs shall be limited to topical application to the surface of the eye for therapeutic purposes.

ASSESSMENT OF PUBLIC COMMENT

Since publication of the proposed rule in the State Register on March 2, 2022, the State Education Department (Department) received the following comment on the proposed rule:

The Department received a comment from a professional association in support of the proposed rule. The commenter supports the addition of a new class of drugs, Rho kinase inhibitors, to the list of drugs that a licensed optometrist certified to use phase two therapeutic pharmaceutical agents may use and prescribe to treat patients. The commenter states that the addition of this class of drug demonstrates equivalence to a class of drugs that optometrists certified to use phase two therapeutic pharmaceutical agents are already authorized to use for the treatment of patients. The commenter states that adding this class of drug to the authorized list will ensure that patients receive appropriate access to glaucoma treatment, noting that prior to the amendment of this regulation, patients would have to visit another practitioner authorized to prescribe this type of drug which is “neither appropriate nor efficient in the delivery of eye care in New York.” The commenter further states that optometrists are held to a common standard of care and this new drug has become the standard routine treatment for glaucoma.

DEPARTMENT RESPONSE:

The Department appreciates the supportive comment. Since the comment is supportive, no changes to the proposed rule are necessary.