

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

TO: The Professional Practice Committee

FROM: Sarah S. Benson Laul d. 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: February 3, 2022

AUTHORIZATION(S): Sully Com-

SUMMARY

Issue for Discussion

Should the Board of Regents amend subdivision (a) of section 66.5 of the Commissioner's regulations relating to optometrists certified to use therapeutic pharmaceutical agents?

Reason(s) for Consideration

Review of policy.

Proposed Handling

The proposed amendment will be presented to the Professional Practice Committee for discussion at the February 2022 meeting of the Board of Regents. A copy of the proposed amendment is attached (Attachment A).

Procedural History

A Notice of Proposed Rule Making will be published in the State Register on March 2, 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 TEC¹ 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.²

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. 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

^T The TEC is no longer in existence.

² Stuart, Annie et al. Eyenet Magazine, Sept. 2018: 27-29.

this regulatory change will be an important tool in the management and treatment of glaucoma.

Related Regents Items

Not applicable.

Recommendation

Not applicable.

<u>Timetable for Implementation</u>

It is anticipated that the proposed amendment will be presented for adoption at the June 2022 Regents meeting, after publication of the proposed amendment in the State Register and expiration of the 60-day public comment period required under the State Administrative Procedure Act. 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, <u>Rho kinase inhibitors</u>, and prostaglandin analogs. Such drugs shall be limited to topical application to the surface of the eye for therapeutic purposes.