



TO: The Professional Practice Committee

FROM: Sarah Benson *Sarah A. Benson*

SUBJECT: Proposed Amendment of Section 66.5 to the Regulations of the Commissioner of Education Relating to Optometrist's Certification to Use Therapeutic Drugs

DATE: October 5, 2023

AUTHORIZATION(S): *Donna M. Bellizzi*

SUMMARY

Issue for Decision

Should the Board of Regents adopt the proposed amendment of section 66.5 of the Regulations of the Commissioner of Education relating to optometrists' certification to use therapeutic drugs?

Reason for Consideration

Required by State statute (Chapter 506 of the Laws of 2021).

Proposed Handling

The proposed amendment will be presented to the Professional Practice Committee for discussion and recommendation to the Full Board for adoption as an emergency rule at the October 2023 meeting. A copy of the proposed rule (Attachment A) and a statement of facts and circumstances justifying the emergency action (Attachment B) are attached.

Procedural History

A Notice of Emergency Adoption and Proposed Rule Making will be published in the State Register on November 1, 2023, for a 60-day public comment period. Supporting materials for the proposed amendment are available upon request from the Secretary to the Board of Regents.

Background Information

Since the enactment of Chapter 517 of the Laws of 1995 (Chapter 517), optometrists may obtain a specialty certification to use topically applied therapeutic

pharmaceutical agents for the treatment or prevention of ocular disease. Pursuant to Education Law §7101-a(2), certified optometrists are held to the same standard of care in the diagnosis and treatment of patients, including the use of pharmaceutical agents, as that degree of skill and proficiency commonly exercised by a physician in the same community. Since Chapter 517's enactment, New Yorkers have had more access to primary eye care services provided by optometrists who have obtained this specialty certification.

Chapter 506 of the Laws of 2021 (Chapter 506) builds upon the authority established in Chapter 517 by authorizing licensed and certified optometrists¹ to treat patients with additional topical and oral medications for certain ocular diseases. Chapter 506 aligns New York with the rest of the country, which already allow optometrists to prescribe and use a range of oral pharmaceutical agents for ocular diseases. It also establishes requirements that assist in ensuring that optometrists who obtain certification are prepared for the responsibilities relating to the use and prescribing of topical and oral medications for specified ocular diseases.

At its May 2023 meeting, the Board of Regents permanently added a new section 66.6 to the Commissioner's regulations to implement section 9 of Chapter 506, which became effective January 1, 2023. That provision relates to continuing education requirements for licensed optometrists certified to use certain pharmaceutical agents.

The remaining provisions of Chapter 506, effective October 25, 2023:

- amend Education Law §7101-a(1)(e) and (f) by replacing the phrases “phase one” and “phase two” with more descriptive terms related to the types of pharmaceutical agents that optometrists are authorized to use. i.e., “topical therapeutic pharmaceutical agents” and “therapeutic pharmaceutical agents for treatment of glaucoma and ocular hypertension”;
- adds immunosuppressive agents to the list of topical therapeutic pharmaceutical agents and prostaglandin analogs and carbonic anhydrase inhibitors to the list of therapeutic pharmaceutical agents for the treatment of glaucoma and ocular hypertension;
- adds a new paragraph (g) to Education Law §7101-a(1), which adds certain oral therapeutic pharmaceutical agents to the categories of drugs used and prescribed by optometrists for the treatment of diseases of the eye and adnexa;
- amends Education Law §7101-a(4) to require that licensed optometrists seeking to obtain and/or maintain their certification to use and prescribe oral therapeutic pharmaceutical agents: (1) be certified to prescribe pharmaceutical agents, topical therapeutic and therapeutic pharmaceutical agents for treatment of

¹ Certified optometrists are licensed optometrists who have met the certification requirements to prescribe and use topical therapeutic pharmaceutical agents for: (1) topical application to the surface of the eye for therapeutic purposes; (2) therapeutic pharmaceutical agents for topical application to the surface of the eye for treatment of glaucoma and ocular hypertension; and (3) oral therapeutic pharmaceutical agents for therapeutic purposes solely for the treatment of diseases of the eye and adnexa.

glaucoma and ocular hypertension; (2) complete an oral therapeutic pharmaceutical agent certification course;² and (3) pass an examination acceptable to the Department within five years³ of the Department's approval of the initial certification course; and

- amends Education Law §7104(8) to require a \$250 fee for the certification to use or prescribe oral therapeutic pharmaceutical agents.

Proposed Amendments

The proposed amendment of section 66.5 of the Commissioner's regulations implements the above provisions of Chapter 506 by:

- replacing the phrases "phase one" and "phase two" with "topical therapeutic pharmaceutical agents" and "therapeutic pharmaceutical agents for treatment of glaucoma and ocular hypertension;"
- adding a new category of drugs, "oral therapeutic pharmaceutical agents," that certified optometrists can prescribe for oral administration for therapeutic purposes solely for the treatment of diseases of the eye and adnexa; and
- establishing requirements for optometrists to obtain a certificate to administer oral therapeutic pharmaceutical agents.

Related Regents Items

May 2023: [Proposed Repeal of Section 66.6 and Addition of a New Section 66.6 to the Regulations of the Commissioner of Education Relating to the Continuing Education Requirements for Licensed Optometrists Certified to Prescribe and Use Therapeutic Pharmaceutical Agents](https://www.regents.nysed.gov/sites/regents/files/523brca10.pdf)

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Recommendation

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

VOTED: That section 66.5 of the Regulations of the Commissioner of Education be added, as submitted, effective October 25, 2023, as an emergency action, upon a finding that such action is necessary for the preservation of the public health and general welfare in order to timely implement certain provisions of Chapter 506 of the Laws of 2021, which become effective October 25, 2023.

² The requirement for the oral therapeutic pharmaceutical agent certification course and examination does not apply to optometrists who graduated from an accredited college of optometry after January 1, 2022 and have taken and successfully passed the National Board of Examiners in Optometry examination or an examination acceptable to the Department.

³ If an optometrist has commenced an oral therapeutic pharmaceutical agent certification course within the five-year time period has not yet passed the examination, they are permitted to take the examination and become certified after the five-year time period has ended.

Timetable for Implementation

If adopted at the October 2023 meeting, the emergency rule will take effect on October 17, 2023. It is anticipated that the proposed amendment will be presented to the Board of Regents for permanent adoption at the February 2024 meeting, after publication in the State Register for the 60-day public comment period required under the State Administrative Procedures Act. Because the emergency action will expire before the February 2024 meeting, it is anticipated that an additional emergency action will be presented for adoption at the December 2023 Regents meeting. If adopted at the February meeting, the proposed rule will become effective as a permanent rule on February 28, 2024.

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6506, 6507, 7101, 7101-a, of the Education Law and Chapter 506 of the Laws of 2021.

1. Section 66.5 of the Regulations of the Commissioner of Education is amended to read as follows:

§66.5 Use of therapeutic pharmaceutical agents.

(a) Definitions. As used in this section:

(1) [Phase one] Topical therapeutic pharmaceutical agents shall mean those drugs identified in paragraph (e) of subdivision (1) of section 7101-a of the Education Law, which shall be limited to topical application to the surface of the eye for therapeutic purposes.

(2) [Phase two] Topical therapeutic pharmaceutical agents for the treatment of glaucoma and ocular hypertension shall mean:

(i) those drugs identified in paragraph (f) of subdivision (1) of section 7101-a [(1)(f)] of the Education Law , and

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

(3) Oral therapeutic pharmaceutical agents solely for the treatment of diseases of the eye and adnexa shall mean those drugs identified in paragraph (g) of subdivision (1) of section 7101-a of the Education Law.

(4) Acceptable accrediting agency shall mean an organization accepted by the department as a reliable authority for the purpose of accrediting at the postsecondary level, applying its criteria for granting accreditation in a fair, consistent, and

nondiscriminatory manner, such as an agency recognized for these purposes by the United States Department of Education.

[(4)] (5) Education Review Committee shall mean that committee appointed by the commissioner in consultation with the chancellor of the State University of New York, pursuant to subdivision 9 of section 7101-a of the Education Law, whose function is to advise and assist the commissioner in evaluating acceptable clinical training.

[(5)] (6) Temporary Evaluation Committee shall mean that committee appointed by the commissioner of education to advise the commissioner in the evaluation of optometric use of therapeutic pharmaceutical agents, pursuant to section 3 of Chapter 517 of the Laws of 1995.

(b) Certification requirements.

(1) [Phase one] Topical therapeutic pharmaceutical agents. To receive a certificate issued by the department to use [phase one] topical therapeutic pharmaceutical agents, an optometrist shall be licensed in New York and meet the clinical training requirements set forth in paragraph (1) of subdivision (c) of this section and the examination requirements set forth in subdivision (d) of this section. After certification, such [phase one] topical therapeutic pharmaceutical agents shall be used in accordance with the provisions of Article 143 of the Education Law.

(2) [Phase two] Topical therapeutic pharmaceutical agents for the treatment of glaucoma and ocular hypertension. To receive a certificate issued by the department to use [phase two] topical therapeutic pharmaceutical agents for the treatment of glaucoma and ocular hypertension, an optometrist shall be licensed in New York and certified in the use of [phase one] topical therapeutic pharmaceutical agents, as set forth in paragraph (1) of this subdivision, and meet the clinical training requirements set forth

in paragraph (2) of subdivision (c) of this section and the examination requirements set forth in subdivision (d) of this section. After certification, such [phase two] topical therapeutic pharmaceutical agents for the treatment of glaucoma and ocular hypertension shall be used in accordance with the provisions of Article 143 of the Education Law.

(3) Oral therapeutic pharmaceutical agents solely for the treatment of diseases of the eye and adnexa. To receive a certificate issued by the Department to use oral therapeutic pharmaceutical agents, an optometrist shall be licensed in New York and certified in the use of diagnostic drugs as set forth in subdivision (b) of section 66.4 of this part, topical therapeutic pharmaceutical agents as set forth in paragraph (1) of this subdivision, and topical therapeutic pharmaceutical agents for the treatment of glaucoma and ocular hypertension as set forth in paragraph (2) of this subdivision, and meet the certification course requirements set forth in paragraph (3) of subdivision (c) of this section and the examination requirements set forth in subdivision (d) of this section. After certification, such oral therapeutic pharmaceutical agents shall be used in accordance with the provisions of Article 143 of the Education Law.

(c) Clinical training and course requirements for certification.

(1) To meet the clinical training requirements for certification in the use of [phase one] topical therapeutic pharmaceutical agents, the applicant shall present satisfactory evidence of [either] any of the following:

(i) graduation after January 1, 1993 from a professional program of study in optometry that is registered by the department pursuant to Part 52 of this Title, or is accredited by an acceptable accrediting agency, or determined by the department to be the equivalent of such a registered or accredited program; or

(ii) graduation on or before January 1, 1993 from a professional program of study in optometry that is registered by the department pursuant to Part 52 of this Title, or is accredited by an acceptable accrediting agency, or determined by the department to be the equivalent of such a registered or accredited program; and completion of at least 300 hours of acceptable clinical training, as prescribed in subdivision 4(a) and 9-a of section 7101-a of the Education Law; or

(iii) certification to use [phase one] topical therapeutic pharmaceutical agents in another jurisdiction, provided that such optometrist has been certified for at least five years to use [phase one] topical therapeutic pharmaceutical agents in another jurisdiction during which time such use was demonstrated in independently managed patients, meaning that the optometrist demonstrated that he or she has treated patients with [phase one] topical therapeutic pharmaceutical agents without consultation with a licensed physician.

(2) [to] To meet the clinical training requirements for certification in the use of [phase two] topical therapeutic pharmaceutical agents for the treatment of glaucoma and ocular hypertension, the applicant shall present satisfactory evidence of [either] any of the following:

(i) Graduation after January 1, 1993 from a professional program of study in optometry that is registered by the department pursuant to Part 52 of this Title, or is accredited by an acceptable accrediting agency, or determined by the department to be the equivalent of such a registered or accredited program; or

(ii) Graduation on or before January 1, 1993 from a professional program of study in optometry that is registered by the department pursuant to Part 52 of this Title, or is accredited by an acceptable accrediting agency, or determined by the department

to be the equivalent of such a registered or accredited program and completion of at least an additional 100 hours over that obtained for certification to use [phase one] topical therapeutic pharmaceutical agents of acceptable clinical training, as prescribed in subdivisions 4(b) and 9-a of section 7101-a of the Education Law; or

(iii) Certification to use [phase two] topical therapeutic pharmaceutical agents for the treatment of glaucoma and ocular hypertension in another jurisdiction, provided that such optometrist has been certified for at least five years to use [phase two] topical therapeutic agents for the treatment of glaucoma and ocular hypertension in another jurisdiction during which time such use was demonstrated in independently managed patients, meaning that the optometrist demonstrated that he or she has treated patients with [phase two] topical therapeutic pharmaceutical agents for the treatment of glaucoma and ocular hypertension without consultation with a licensed physician.

(3) To meet the course requirements for certification in the use of oral therapeutic pharmaceutical agents, the applicant shall present satisfactory evidence of either:

(i) graduation after January 1, 2022 from a professional program of study in optometry that is registered by the department pursuant to part 52 of this Title, or is accredited by an acceptable accrediting agency, or determined by the department to be the equivalent of such a registered or accredited program, and that the applicant has taken and successfully passed the National Board of Examiners in Optometry examination or an examination acceptable to the Department; or

(ii) graduation on or before January 1, 2022 from a professional program of study in optometry that is registered by the department pursuant to Part 52 of this Title, or is accredited by an acceptable accrediting agency, or determined by the department to be the equivalent of such a registered or accredited program, and that the applicant has

completed a course of at least 40 hours, as prescribed in paragraph (c) of subdivision 4 of section 7101-a of the Education Law.

(4) Applicants who meet the clinical training requirements for certification by complying with the requirements of subparagraph (ii) of paragraph (1) or subparagraph (ii) of paragraph (2) of this subdivision shall submit a written application to the department in a form approved by the department. The department shall submit each application to the education review committee for its review and recommendation, as prescribed in subdivisions 9 and 9-a of section 7101-a of the Education Law.

(d) Examination.

(1) To meet the examination requirement for either certification in the use of [phase one] topical therapeutic pharmaceutical agents or certification in the use of [phase two] topical therapeutic pharmaceutical agents for the treatment of glaucoma and ocular hypertension, the applicant shall present evidence of [successful completion] passing of:

[(1)] (a) the treatment and management of ocular diseases portion of the examination of the National Board of Examiners in Optometry; or

[(2)] (b) an examination determined by the State Board for Optometry to be equivalent in scope and content to the ocular diseases portion of the examination of the National Board of Examiners in Optometry.

(2) To meet the examination requirement for certification in the use of oral therapeutic pharmaceutical agents, the applicant shall present evidence of passing an examination as prescribed in paragraph (c) of subdivision 4 of section 7101-a of the Education Law, and which is acceptable to the Department. Provided, however, that pursuant to subparagraph (v) of paragraph (c) of subdivision 4 of section 7101-a of the

Education Law, such examination requirement shall not apply to applicants who meet the course requirements prescribed in subparagraph (i) or paragraph (3) of subdivision (c) of this section.

(e) Reporting requirement. An optometrist certified to use [phase two] topical therapeutic pharmaceutical agents for the treatment of glaucoma and ocular hypertension shall file with the temporary evaluation committee a [phase two] report for each patient treated with [phase two] topical therapeutic pharmaceutical agents for the treatment of glaucoma and ocular hypertension within seven days following the initial and each subsequent visit by the same patient. The report shall be in a form developed by the temporary evaluation committee and approved by the commissioner.

8 NYCRR § 66.5

STATEMENT OF FACTS AND CIRCUMSTANCES

WHICH NECESSITATE EMERGENCY ACTION

The proposed rule is necessary to implement Chapter 506 of the Laws of 2021 (Chapter 506), which, with the exception of section 9 of such Chapter which became effective January 1, 2023, becomes effective October 25, 2023. Chapter 506 authorizes licensed and certified optometrists to treat patients with additional topical and oral medications for certain ocular diseases and establish requirements that assist in ensuring that the optometrists who obtain certification are prepared for the responsibilities relating to the use and prescribing of such topical and oral medications for specified ocular diseases. At its May 2023 meeting the Board of Regents permanently added a new section 66.6 to the Commissioner's regulations to implement section 9 which relates to continuing education requirements for licensed optometrists certified to use certain pharmaceutical agents. This proposed rule conforms the Commissioner's regulation to the remaining provisions of Chapters 506.

Since the Board of Regents meets at fixed intervals, the earliest the proposed rule can be presented for adoption, after expiration of the required 60-day public comment period provided for in the State Administrative Procedure Act (SAPA) sections 202(1) and (5), would be the February 2024 Regents meeting. Furthermore, pursuant to SAPA section 203(1), the earliest effective date of the proposed amendment, if adopted at the February meeting, would be February 28, 2023, the date a Notice of Adoption would be published in the State Register.

Therefore, emergency action is necessary at the October 2023 meeting, effective October 25, 2023, for the preservation of the public health and the general welfare in order to timely implement certain provisions of Chapter 506, which become effective October 25, 2023.

It is anticipated that the proposed amendment will be presented for permanent adoption at the February 2024 Regents meeting, which is the first scheduled meeting after the expiration of the 60-day public comment period mandated by SAPA for state agency rule making. However, since the emergency action will expire before the February Regents meeting, it is anticipated that additional an emergency action will be presented for adoption at the December 2023 Regents meeting.