TO: Professional Practice Committee

FROM: David H. Hamilton

SUBJECT: Proposed Amendment of Sections 66.5 and 66.6 of the Regulations of the Commissioner of Education Relating to the Use of Therapeutic Pharmaceutical Agents and Continuing Education Requirements for Licensed Optometrists Certified to Prescribe and Use Therapeutic Pharmaceutical Agents

DATE: February 27, 2025

AUTHORIZATION(S):

SUMMARY

Issue for Decision

Should the Board of Regents amend sections 66.5 and 66.6 of the Regulations of the Commissioner of Education relating to the use of therapeutic pharmaceutical agents and continuing education requirements for licensed optometrists certified to prescribe and use therapeutic pharmaceutical agents?

Reason for Consideration

Required by State statute (Section 1 of Chapter 516 of the Laws of 2024).

Proposed Handling

The proposed rule is presented to the Professional Practice Committee for discussion and recommendation to the Full Board for adoption as an emergency rule at the March 2025 meeting of the Board of Regents. A copy of the proposed rule (Attachment A) and a statement of facts and circumstances justifying emergency action (Attachment B) are attached.

Procedural History

A Notice of Emergency Adoption and Proposed Rulemaking will be published in the State Register on March 26, 2025, for a 60-day public comment period. Supporting materials are available upon request from the Secretary to the Board of Regents.

Background Information

Currently, only ophthalmologists are authorized to prescribe a nasal spray for the treatment of dry eye disease. There are also several New York counties that do not have ophthalmologists available; thus, patients in those counties rely on optometrists for their eye care and treatment of vision problems. The optometric scope of practice statute currently limits prescriptive authority for dry eye disease to "direct to the eye" medications, such as eye drops or topical medications. This precludes patients with dry eye disease who see an optometrist for their eye care from using newer FDA approved topical treatments, including one that is administered through a nasal spray.

To address these issues, Section 1 of Chapter 516 of the Laws of 2024 (Chapter 516), effective November 22, 2024, amended subdivision (1) of section 7101-a of the Education Law to add nasal sprays to the list of topical therapeutic pharmaceutical agents that optometrists are authorized to use for the treatment of dry eye disease.

Proposed Amendment

The proposed amendment implements Chapter 516 by amending section 66.5 of the Commissioner's regulations by adding nasal sprays as topical therapeutic pharmaceutical agents that can be used by licensed and certified optometrists to treat dry eye disease.

The proposed amendment also:

- establishes certification requirements, which include clinical training, coursework, and examination requirements for optometrists seeking to use nasal sprays as topical therapeutic pharmaceutical agents for the treatment of dry eye disease;

- establishes reporting requirements for licensed optometrists, who are certified to use nasal sprays to treat dry eye disease.

Additionally, the proposed amendment implements Chapter 516 by amending section 66.6 of the Commissioner's regulations to require licensed optometrists certified to use nasal sprays as topical therapeutic pharmaceutical agents to treat dry eye disease to comply with the continuing education requirements for licensed optometrists certified to use certain therapeutic pharmaceutical agents.

Related Regents Items

Not applicable.

Recommendation

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

VOTED: that sections 66.5 and 66.6 of the Regulations of the Commissioner of Education be added, as submitted, effective March 11, 2025, 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 the provisions of section 1 of Chapter 516 of the Laws of 2024, which became effective November 22, 2024.

Timetable for Implementation

If adopted at the March 2025 meeting, the emergency rule will take effect on March 11, 2025. It is anticipated that the proposed amendment will be presented to the Board of Regents for permanent adoption at the July 2025 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 July 2025 meeting, it is anticipated that an additional emergency action will be presented for adoption at the May 2025 meeting. If adopted at the July meeting, the proposed rule will become effective as a permanent rule on July 30, 2025.

Attachment A

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6506, 6507, 7101-a of the Education Law and Section (1) of Chapter 516 of the Laws of 2024.

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) 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[.] or nasal sprays for the treatment of dry eye disease identified in subparagraph (iii) of paragraph (f) of section 7101-a of the Education Law.

(2) …

(i) …

(3) …

(4) …

(5) …

(6) …

(b) Certification requirements.

(1) Topical therapeutic pharmaceutical agents and nasal sprays as topical therapeutic pharmaceutical agents for the treatment dry eye disease. To receive a certificate issued by the department to use topical therapeutic pharmaceutical agents and nasal sprays as topical therapeutic pharmaceutical agents for the treatment dry eye

disease, 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 topical therapeutic pharmaceutical agents and nasal sprays as topical therapeutic pharmaceutical agents for the treatment dry eye disease, shall be used in accordance with the provisions of Article 143 of the Education Law.

(2) …

(3) …

(c) Clinical training and course requirements for certification.

(1) To meet the clinical training requirements for certification in the use of topical therapeutic pharmaceutical agents[,] and nasal sprays as topical therapeutic pharmaceutical agents for the treatment dry eye disease, the applicant shall present satisfactory evidence of any of the following:

(i) …

(ii) …

(iii) certification to use topical therapeutic pharmaceutical agents and nasal sprays as topical therapeutic pharmaceutical agents for the treatment dry eye disease in another jurisdiction, provided that such optometrist has been certified for at least five years to use topical therapeutic pharmaceutical agents and nasal sprays as topical therapeutic pharmaceutical agents for the treatment dry eye disease 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 topical therapeutic pharmaceutical agents and nasal sprays as topical therapeutic pharmaceutical agents for the treatment dry eye disease without consultation with a licensed physician.

(2) …

(i) …

(ii) …

(iii) …

(3) …

(i) …

(ii) …

(4) …

(d) Examination.

(1) To meet the examination requirement for either certification in the use of topical therapeutic pharmaceutical agents and nasal sprays as topical therapeutic pharmaceutical agents for the treatment dry eye disease or certification in the use of topical therapeutic pharmaceutical agents for the treatment of glaucoma and ocular hypertension the applicant shall present evidence of passing of:

(a) …

(b) …

(2) …

(e) …

2. Section 66.6 of the Regulations of the Commissioner of Education is amended to read as follows:

§66.6 Continuing education for licensed optometrists certified to use certain therapeutic pharmaceutical agents.

(a) …

(b) Applicability of requirements.

(1) Each optometrist, required under article 143 of the Education Law to register with the department to practice in New York State and certified to use topical therapeutic pharmaceutical agents and nasal sprays as topical therapeutic pharmaceutical agents, and/or oral therapeutic pharmaceutical agents, shall comply with the mandatory continuing education requirements as prescribed in subdivision (c) of this section, except those licensees exempt from the requirement or who obtain an adjustment to the requirement pursuant to paragraph (2) of this subdivision or who are subject to a different requirement pursuant to this section.

(2) …

(i) …

(ii) …

Mandatory continuing education requirements.

(1) General requirements.

(i) During each triennial registration period, meaning a registration period of three years' duration, an optometrist certified to use topical therapeutic pharmaceutical agents and nasal sprays as topical therapeutic pharmaceutical agents for the treatment of dry eye disease and/or therapeutic pharmaceutical agents for the treatment of glaucoma and ocular hypertension, seeking to apply for registration shall complete at least 36 hours of continuing education, acceptable to the department, as prescribed in paragraph (3) of this subdivision.

(ii) …

(2) Proration.

(i) …

(ii) During each registration or certification period of less than three years duration, an applicant shall complete acceptable continuing education, as prescribed in

paragraph (3) of this subdivision, on a prorated basis at the rate of one hour of continuing education per month for those certified to administer topical therapeutic pharmaceutical agents and nasal sprays as topical therapeutic pharmaceutical agents for the treatment of dry eye disease and/or therapeutic pharmaceutical agents for the treatment of glaucoma and ocular hypertension and, for those certified to administer oral therapeutic pharmaceutical agents, on a prorated basis at the rate of one and one-half hour of continuing education per month for such registration or certification period.

(3) Acceptable formal continuing education. To be acceptable to the department, continuing education shall meet the requirements of this paragraph. Such continuing education must be in subjects prescribed in subparagraph (i) of this paragraph and be the types of learning activities prescribed in subparagraph (ii) of this paragraph and subject to the prohibition contained in subparagraph (iii) of this paragraph.

(i) Subjects.

(a) Acceptable continuing education of a licensee certified to use topical therapeutic pharmaceutical agents and nasal sprays as topical therapeutic pharmaceutical agents for the treatment of dry eye disease and/or therapeutic pharmaceutical agents for the treatment of glaucoma and ocular hypertension shall be in the area of ocular disease and pharmacology and may include both didactic and clinical components.

(b) …

(ii)(a) Types of learning activities. Acceptable continuing education shall be the types of learning activities prescribed in this subparagraph and shall be subject to the limitations prescribed in this subparagraph and subparagraph (iii) of this paragraph.

(1) For optometrists certified for topical therapeutic pharmaceutical agents and nasal sprays as topical therapeutic pharmaceutical agents for the treatment of dry eye

disease and/or therapeutic pharmaceutical agents for the treatment of glaucoma and ocular hypertension, at least 27 hours of continuing education in a registration period shall consist of live instruction in a formal course of study offered by a sponsor approved by the department pursuant to subdivision (i) of this section, during which the student must be able to communicate and interact with the instructor and other students. Up to nine hours of such continuing education in a registration period may be completed through a self-study program, meaning structured study, provided by a sponsor approved pursuant to subdivision (i) of this section, that is based on audio, audio-visual, written, on-line, and other media, and does not include live instruction, transmitted in person or otherwise, during which the student may communicate and interact with the instructor and other students.

(2) …

(iii) …

(4) …

(d) …

(1) …

(2) …

(3) …

(e) Requirement for lapse in practice.

(1) A licensee returning to the practice of optometry after a lapse in practice, as evidenced by not being registered to practice in New York State, whose first registration date after such lapse in practice occurs less than three years from January 1, 2023 shall be required to complete:

(i) at least one hour of acceptable continuing education for each month that the licensee was not registered to practice for a licensee certified to use topical therapeutic

pharmaceutical agents and nasal sprays as topical therapeutic pharmaceutical agents for the treatment of dry eye disease and/or therapeutic pharmaceutical agents for the treatment of glaucoma and ocular hypertension or at least one and one-half hours of acceptable continuing education for each month that a licensee was not registered to practice for a licensee certified to use oral therapeutic pharmaceutical agents from January 1, 2023 until the beginning of the new registration period.

(a) …

(b) …

(ii)(a) for a licensee who has not lawfully practiced as a licensed optometrist continuously in another jurisdiction throughout such lapse period, at least 12 hours of acceptable continuing education in each successive 12-month period of the new registration period for a licensee certified to use topical therapeutic pharmaceutical agents and nasal sprays as topical therapeutic pharmaceutical agents for the treatment of dry eye disease and/or therapeutic pharmaceutical agents for the treatment of glaucoma and ocular hypertension or at least 18 hours of acceptable continuing education for a licensee certified to use oral therapeutic pharmaceutical agents; or

(b) …

(2) Except as prescribed in paragraph (1) of this subdivision for registrations therein specified, a licensee who returns to practice as a licensed optometrist after a lapse in practice in which the licensee was not registered to practice in New York State and did not lawfully practice continuously in another jurisdiction throughout the lapse period, shall be required to complete:

(i) …

(ii) at least one hour of acceptable continuing education for each month of lapsed registration up to a maximum 36 hours if certified to use topical therapeutic

pharmaceutical agents and nasal sprays as topical therapeutic pharmaceutical agents for the treatment of dry eye disease and/or therapeutic pharmaceutical agents for the treatment of glaucoma and ocular hypertension or a maximum of 54 hours if certified to use oral therapeutic pharmaceutical agents. Such continuing education shall be completed in the 12 months before the beginning of the new registration period; and

(iii) at least 12 hours of acceptable continuing education in each succeeding 12-month period if certified to use topical therapeutic pharmaceutical agents and nasal sprays as topical therapeutic pharmaceutical agents for the treatment of dry eye disease and/or therapeutic pharmaceutical agents for the treatment of glaucoma and ocular hypertension or 18 hours if certified to use oral therapeutic pharmaceutical agents, after such registration is reissued, until the next registration date.

(3) Except as prescribed in paragraph (1) of this subdivision for registrations therein specified, a licensee who returns to the practice of optometry after a lapse in practice in which the licensee was not registered to practice in New York State but did lawfully practice optometry continuously in another jurisdiction throughout the lapse period, shall be required to complete:

(i) …

(ii) at least one hour of acceptable continuing education if certified to use topical therapeutic pharmaceutical agents and nasal sprays as topical therapeutic pharmaceutical agents for the treatment of dry eye disease and/or therapeutic pharmaceutical agents for the treatment of glaucoma and ocular hypertension and one-and-one-half hours if certified to use oral therapeutic pharmaceutical agents for each month of lapsed registration up to a maximum of 36 hours. Such continuing education shall be completed in the new registration period or, at the option of the licensee, in the

period beginning 36 months before the commencement of the new registration period and ending at the conclusion of the new registration period; and

(iii) …

(f) …

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Attachment B

8 NYCRR §§66.5 and 66.6

STATEMENT OF FACTS AND CIRCUMSTANCES WHICH NECESSITATE EMERGENCY ACTION

To address the nasal sprays for the treatment of dry eye disease access issue for patients, section 1 of Chapter 516 of the Laws of 2024 (Chapter 516), effective November 22, 2024, amended subdivision (1) of section 7101-a of the Education Law to add nasal sprays to the list of topical therapeutic pharmaceutical agents that optometrists are authorized to use for the treatment of dry eye disease. Allowing optometrists, in addition to ophthalmologists, to use nasal sprays to treat dry disease will improve patients' access to this treatment because there are several New York counties that do not have ophthalmologists available; as such, patients in those counties rely on optometrists for their eye care and treatment of vision problems.

Since the Board of Regents meets at fixed intervals, the earliest the proposed amendment could be adopted by regular (nonemergency) action after the expiration of the 60-day public comment period provided for in the State Administrative Procedure Act (SAPA) sections 201(1) and (5) would be the July 2025 Regents meeting. Furthermore, pursuant to SAPA 203(1), the earliest effective date of the proposed rule, if adopted at the July 2025 meeting, would be July 30, 2025, the date the Notice of Adoption would be published in the State Register.

Therefore, emergency action is necessary at the March 2025 meeting, effective March 11, 2025, for the public health and preservation of the general welfare in order to immediately implement Chapter 516, which became effective November 22, 2024.

It is anticipated that the proposed rule will be presented to the Board of Regents for adoption as a permanent rule at the July 2025 meeting, which is the first scheduled meeting after the 60-day public comment period mandated by SAPA for state agency rulemaking. However, since the emergency action will expire before the July Regents meeting, it is anticipated that an additional emergency action will be presented for adoption at the April 2025 Regents meeting.