

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:
 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:
 July 3, 2025

 AUTHORIZATION(S):
 July 3, 2025

 SUMMARY
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Issue for Decision (Consent)

Should the Board of Regents adopt the 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?

Reason for Consideration

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

Proposed Handling

The proposed amendment is submitted to the Full Board for adoption as a permanent rule at the July 2025 Regents meeting. A copy of the proposed rule (Attachment A) is attached.

Procedural History

The proposed amendment was presented to the Professional Practice Committee for discussion and recommendation to the Full Board for adoption as an emergency rule at its March 2025 meeting, effective March 11, 2025. A Notice of Emergency Adoption and Proposed Rule Making was published in the State Register on March 26, 2025, for a 60-day public comment period.

Because the March 2025 emergency action was set to expire on June 8, 2025, a second emergency action was necessary at the May 2025 meeting, effective June 9, 2025, to ensure that the emergency rule remained continuously in effect until it could be permanently adopted and take effect as a permanent rule. A Notice of Emergency Adoption was published in the State Register on June 25, 2025.

Following publication in the State Register, the Department received no comments on the proposed amendment. Therefore, an Assessment of Public Comment is not required and no changes to the proposed amendment are needed. If adopted at the July 2025 meeting, a Notice of Adoption will be published in the State Register on July 30, 2025. Supporting materials are available upon request to the Secretary of 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

March 2025: 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 (https://www.regents.nysed.gov/sites/regents/files/325ppca1.pdf)

May 2025: 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 (https://www.regents.nysed.gov/sites/regents/files/525brca15.pdf)

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 amended, as submitted, effective July 30, 2025.

Timetable for Implementation

If adopted at the July 2025 meeting, the proposed amendment 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[.] <u>or</u> <u>nasal sprays for the treatment of dry eye disease identified in subparagraph (iii) of</u> <u>paragraph (f) of section 7101-a of the Education Law.</u>

- (2) ...
- (i) ...
- (3) ...
- (4) ...
- (5) ...
- (6) ...

(b) Certification requirements.

(1) Topical therapeutic pharmaceutical agents <u>and nasal sprays as topical</u> <u>therapeutic pharmaceutical agents for the treatment of dry eye disease.</u> 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 of 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 <u>and nasal sprays as topical therapeutic</u> <u>pharmaceutical agents for the treatment of dry eye disease, shall be used in</u> 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[,] <u>and nasal sprays as topical therapeutic</u> <u>pharmaceutical agents for the treatment of dry eye disease</u>, the applicant shall present satisfactory evidence of any of the following:

(i) ...

(ii) ...

(iii) certification to use topical therapeutic pharmaceutical agents <u>and nasal</u> <u>sprays as topical therapeutic pharmaceutical agents for the treatment of dry eye</u> <u>disease</u> in another jurisdiction, provided that such optometrist has been certified for at least five years to use topical therapeutic pharmaceutical agents <u>and nasal sprays as</u> <u>topical therapeutic pharmaceutical agents for the treatment of dry eye disease</u> 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 <u>and nasal sprays as</u>

topical therapeutic pharmaceutical agents for the treatment of 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 <u>and nasal sprays as topical therapeutic</u> <u>pharmaceutical agents for the treatment of dry eye disease</u> 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 <u>and nasal sprays as topical therapeutic</u> <u>pharmaceutical agents</u>, 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 <u>and nasal sprays as topical therapeutic pharmaceutical agents for the treatment of dry</u> <u>eye disease</u> 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 <u>and nasal sprays as topical therapeutic pharmaceutical agents</u> <u>for the treatment of dry eye disease</u> 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 onehalf 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 pharmacelogy 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 <u>nasal sprays as topical therapeutic pharmaceutical agents for the treatment of dry eye</u> <u>disease</u> 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 12month period if certified to use topical therapeutic pharmaceutical agents <u>and nasal</u> <u>sprays as topical therapeutic pharmaceutical agents for the treatment of dry eye</u> <u>disease</u> 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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