

# PROPOSED RULEMAKING

## STATE BOARD OF OPTOMETRY

[ 49 PA. CODE CH. 23 ]

### General Revisions

The State Board of Optometry (Board) proposes to amend §§ 23.1, 23.21, 23.82, 23.86, 23.87 and 23.91, and to add § 23.90 (relating to standards for commercial support) to read as set forth in Annex A.

#### *Effective Date*

The amendments will be effective upon publication of the final-form rulemaking in the *Pennsylvania Bulletin*.

#### *Statutory Authority*

The amendments are authorized under section 3(b)(14) of the Optometric Practice and Licensure Act (act) (63 P.S. § 244.3(b)(14)).

#### *Background and Purpose*

Section 3(b)(14) of the act gives the Board the authority to promulgate all rules and regulations necessary to carry out the purposes of the act. Section 5(b) of the act provides the minimum requirements for continuing education of 30 hours in a biennial period for licensed optometrists. Because the Board is charged with ensuring the health, safety and welfare of the patients of optometrists, it strives to ensure that clear guidance is given to licensees in reporting continuing education and the standards for accepting commercial support from the providers of continuing education.

In compliance with Executive Order 1996-1, the Board extended invitations to comment on an exposure draft of this proposed rulemaking to parties who have indicated an interest in the Board's regulatory activities. The Board received comments from the Pennsylvania Optometric Association and the Pennsylvania Academy of Ophthalmology and considered their comments in drafting this proposal.

#### *Description of the Proposed Amendments*

This proposed rulemaking would amend § 23.1 (relating to definitions) by adding a definition of "contact lens." Although the act and the Board's regulations use the term "contact lens," neither provides a definition. The Board believes that this definition is necessary to provide guidance to optometrists and to the general public. Adding this definition will clarify that a contact lens includes any medical device or other item of any material, tissue or power (including plano or zero-powered) that is required to be dispensed by prescription and is placed directly on the cornea or the sclera to (1) correct vision conditions, (2) act as a diagnostic or therapeutic device or (3) provide a cosmetic or decorative effect. It is the Board's intent that this definition will provide clarification that all contact lenses, as the term is defined herein, are subject to both State and Federal regulations.

This proposed rulemaking would amend § 23.21 (relating to reciprocal application) to clarify that an applicant for licensure by reciprocity who is a graduate of an unaccredited school shall comply with the requirements of § 23.14 (relating to graduates of unaccredited schools).

Four sections of this proposed rulemaking would address continuing education. First, § 23.82 (relating to continuing education hour requirements) would be

amended to address reporting, audits and enforcement. Under § 23.82(a), the Board would add the word "immediately" to the phrase "during the 2 years preceding renewal or reactivation" to clarify when the continuing education hours must be taken in response to past questions from licensees. Likewise, in this subsection the Board would also propose an amendment to respond to questions that have arisen regarding the maximum number of continuing education hours in the treatment of glaucoma that may be applied to the 6 hours required to maintain certification for therapeutic purposes—no more than 4 hours. Under subsections (b)—(f), the Board would address the reporting, audits and making up deficiencies of continuing education requirements. All boards within the Bureau of Professional and Occupational Affairs require licensees to certify completion of their continuing education as a condition of renewal and conduct post-renewal audits to assure compliance. The Board is proposing these amendments to provide notice to licensees of the audit requirements and of the affirmative requirement, notwithstanding any disciplinary action that might be taken by the Board, to make up all deficiencies that are identified through the audit process.

Second, under § 23.86 (relating to sources of continuing education hours), the Board, for purposes of clarity, would set forth under subsection (a) the preapproved providers of continuing education in a numbered list, rather than in paragraph form. Also for clarity, the Board would provide that the schools and colleges of optometry that are accredited by the Accreditation Council of Optometric Education or its successor, are the ones that the Board deems approved. Where National or State organizations are listed, the Board would also clarify that the affiliated State or local entities are also included as preapproved providers. Under subsection (b), the Board would set forth the requirements for other providers of continuing education not listed in subsection (a) to obtain approved provider status. The Board would use the continuing education standards set by the Association of Regulatory Boards of Optometry's (ARBO) Council of Optometric Practitioner Education (COPE) to determine if a provider is competent to provide continuing education to optometrists. To inform licensees of new and existing providers of continuing education, the Board will maintain a list on its web site. Subsection (d) sets forth the process for individual course approval by providers who have not been approved under subsection (a) or (b). Subsection (e) would set forth the manner in which licensees may be awarded continuing education retroactively for attending programs that have not been previously approved. Finally, in subsections (f)—(i), the Board would provide guidance to its licensees on the maximum percentage of continuing education credits that a licensee may receive for specific types of continuing education.

Third, the Board, would add a new subsection (b) to § 23.87 (relating to reporting of continuing education credit hours) that would allow, but not require, a licensee to have the licensee's continuing education courses entered into an electronic database. One such electronic database developed by ARBO is the Optometric Education Tracker, which captures and stores continuing education data electronically for optometrists, thereby allowing licensees to track their continuing education compliance and allowing licensing boards to review and audit the continuing education credits earned by their licensees electronically. Costs are paid by licensees at \$20 per year.

In the final section pertaining to continuing education, the Board would add § 23.90, to address a new area regarding the type and amount of benefits that continuing education providers may give to licensees, including those who serve as course instructors or consultants rendering advisory services. In drafting its proposed regulations, the Board reviewed ARBO's COPE Standards for Commercial Support and standards developed by the Pharmaceutical Research and Manufacturers of America.

Finally, the Board would revise its fee structure under § 23.91 (relating to fees) to include applications for continuing education provider initial approval, renewal fees for approved providers and application fees for licensees seeking continuing education credit retroactively. Additionally, the Board clarified that the application for continuing education program approval includes continuing education courses.

*Fiscal Impact and Paperwork Requirements*

This proposed rulemaking should have no fiscal impact on the Commonwealth or its political subdivisions. Only minor paperwork requirements are imposed for the Board to develop forms for approval of providers of continuing education under § 23.86(b)(1). The only fiscal impact to the regulated community of optometrists would be associated with the \$45 fee for retroactive approval of continuing education courses. However, this cost could be avoided by simply taking all continuing education through pre-approved providers and courses. Providers of continuing education courses could benefit from the new fee structure in that they could apply for provider approval and pay a \$135 fee, rather than pay a \$45 fee for each course offered.

*Sunset Date*

The Board continually monitors the cost effectiveness of its regulations. Therefore, no sunset date has been assigned.

*Regulatory Review*

Under Section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on February 15, 2019, the Board submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the Senate Consumer Protection and Professional Licensure Committee and the House Professional Licensure Committee. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to this proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections shall specify the regulatory review criteria that have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Commissioner, the General Assembly and the Governor of comments, recommendations or objections raised.

*Public Comment*

Interested persons are invited to submit written comments, suggestions or objections regarding this proposed rulemaking to Jacqueline A. Wolfgang, Board Counsel, State Board of Optometry, 2601 North Third Street, P.O. Box 69523, Harrisburg, PA 17106-9523, RA-STRegulatoryCounsel@pa.gov, within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Reference No. 16A-5213 Optometry Board General Revisions, when submitting comments.

CARL J. URBANSKI, OD,  
Chair

**Fiscal Note:** 16A-5213. No fiscal impact; (8) recommends adoption.

ANNEX A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 23. STATE BOARD OF OPTOMETRY  
GENERAL PROVISIONS

§ 23.1. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly [ indicated ] indicates otherwise:

\* \* \* \* \*

*Clinical Skills Assessment Examination*—A clinical skills competency examination developed, prepared, administered and scored by the NBEO, which the Board adopts as the State clinical examination for licensure.

**Contact lens**—A medical device or any other item or device of any material, tissue or power, including plano or zero-powered, that is required to be dispensed by prescription, and is placed directly on the cornea or the cornea and sclera to do any of the following:

- (i) Correct vision conditions.
- (ii) Act as a diagnostic or therapeutic device.
- (iii) Provide a cosmetic or decorative effect.

*Continuing education hour*—Fifty minutes of continuing education.

\* \* \* \* \*

LICENSE BY RECIPROCITY AND INTERSTATE CERTIFICATION

§ 23.21. Reciprocal application.

(a) An applicant for licensure by reciprocity to practice optometry in this Commonwealth shall submit the following to the Board:

(1) A completed application which has been filed with the Board together with the fee required by § 23.91 (relating to fees), in the form of a check or money order, made payable to "Commonwealth of Pennsylvania—OE."

(2) A certificate of preprofessional education issued by the Department, showing that the preliminary education requirements are satisfied.

(3) A transcript of subjects and grades from the college or school of optometry from which the applicant has graduated.

(b) Any school or college of optometry from which the applicant for reciprocity has graduated shall be one approved by the Board at the time he was graduated.

**(c) An applicant for licensure by reciprocity who is a graduate of an unaccredited school shall comply with the requirements of § 23.14 (relating to graduates of unaccredited schools).**

CONTINUING EDUCATION

§ 23.82. Continuing education hour requirements; **continuing education reporting; audit and enforcement.**

(a) An applicant for biennial license renewal or reactivation of license is required to complete, during the 2

years **immediately** preceding renewal or reactivation, a minimum of 30 hours of continuing education. For licensees certified in accordance with section 4.1 of the act (63 P.S. § 244.4a), regarding certification to prescribe and administer pharmaceutical agents for therapeutic purposes, at least 6 of the required 30 hours shall concern the prescription and administration of pharmaceutical agents for therapeutic purposes. For licensees certified in accordance with section 4.2 of the act (63 P.S. § 244.4b), regarding additional requirements to prescribe and administer pharmaceutical agents for the treatment of certain types of glaucoma, at least 4 of the 30 hours shall concern the prescription and administration of pharmaceutical agents for the treatment of glaucoma. **[ The ] No more than** 4 hours taken in the treatment of glaucoma may be applied toward the 6 hours required to maintain therapeutic certification; however, all licensees shall complete at least 30 total hours. Completion of a Board-approved course described in section 4.1(a)(2) of the act or continuing education described in section 4.2 of the act shall satisfy the continuing education requirement for the biennial renewal period in which it is completed including the 6-hour requirement in therapeutics and the 4-hour requirement in glaucoma.

(b) **[ Persons failing to meet the continuing education requirements for any biennial renewal period will be disciplined in accordance with section 7(e) of the act (63 P.S. § 244.7(e)). ] Licensees shall certify completion of the required continuing education on the biennial renewal application. False certifications will be grounds for disciplinary action under section 7(a)(3) of the act (63 P.S. § 244.7(a)(3)).**

(c) **The Board may randomly audit licensees to ensure compliance with the continuing education requirements. A licensee selected for audit shall provide information to document the licensee's completion of required continuing education, which shall include the information at § 23.87(a) (relating to reporting of continuing education credit hours).**

(d) **A licensee who, as a result of an audit, is determined to be deficient in continuing education hours will be subject to formal disciplinary action under section 7(a)(8) of the act (63 P.S. § 244.7(a)(8)), or will be subject to the issuance of a citation under section 5(a) of the act of July 2, 1993 (P.L. 345, No. 48) (63 P.S. § 2205(a)) in accordance with § 43b.25 (relating to schedule of civil penalties—optometrists).**

(e) **Notwithstanding other disciplinary action taken as set forth in subsection (d), a licensee who is determined to be deficient in continuing education hours is required to make up all deficient hours of continuing education and submit documentation containing the information set forth in subsection (c) to the Board within 6 months from the issuance of a citation or the imposition of formal discipline. Hours of continuing education submitted to the Board to make up for a deficiency may not be used to satisfy the continuing education requirement for the current biennium.**

(f) **Failure to make up all deficiencies as set forth in subsection (e) will subject the licensee to further disciplinary action under section 7(a)(8) of the act.**

(g) **The Board may waive the requirements of continuing education in cases of certified illness or undue**

hardship. It is the duty of each licensee seeking waiver to notify the Board in writing and request the waiver prior to the end of the biennial renewal period for which the waiver is sought. The waiver will be granted, denied or granted in part.

#### **§ 23.86. Sources of continuing education hours.**

(a) **[ In addition to another provider which wishes to secure approval from the Board, the ] The Board finds that the [ following ] providers listed below have currently met the standards for provider approval for all acceptable courses of continuing education[ ; accordingly, ] that meet the requirements of § 23.83(a) (relating to continuing education subject matter). Accordingly, the following providers [ have program approval in all allowable areas for continuing education ] are preapproved sources for continuing optometric education courses:**

**[ the ] (1) The American Optometric Association, and its state affiliates.**

**[ the ] (2) The Pennsylvania Optometric Association, and its local societies.**

**[ all Board-accredited ] (3) All schools and colleges of optometry[ , ] accredited by the Accreditation Council on Optometric Education (ACOE) of the American Optometric Association, or its successor.**

**[ the ] (4) The College of Optometrists in Vision Development (COVD)[ , ].**

**[ the ] (5) The Council on Optometric Practitioner Education (COPE)[ , eye and vision-related continuing ]**

**(6) Continuing education courses offered by accredited medical colleges, as defined in section 2 of the Medical Practice Act of 1985 (63 P.S. § 422.2)[ , ].**

**[ the ] (7) The Optometric Extension Program[ , ].**

**[ the ] (8) The American Academy of Optometry and its state affiliates[ , ].**

**[ the ] (9) The American Academy of Ophthalmology and its state affiliates[ , and eye and vision-related courses offered by the ].**

**(10) The American Medical Association and its state affiliates.**

**(b) The Board may approve other providers of continuing education not listed in subsection (a). The Board will maintain on its web site a list of all approved providers.**

**(1) A provider seeking approved provider status shall:**

**(i) Apply to the Board, on forms supplied by the Board, at least 90 days in advance of the date the initial course is given. The provider may not offer any course for credit until the Board grants its approval as an approved provider.**

**(ii) Pay the required fees under § 23.91 (relating to fees).**

**(iii) Demonstrate that the provider is competent to provide continuing education to optometrists.**

(2) All provider approvals expire November 30th of each even-numbered year, regardless of the date of issuance, and must be renewed biennially.

(c) The approval given to [these] the providers approved in accordance with subsections (a) and (b) is subject to reevaluation. A rescission of provider or program approval will be made only in accordance with 1 Pa. Code Part II (relating to general rules of administrative practice and procedure).

[b] (d) Courses which are [provided] given by providers [not indicated in subsection (a)] who have not been approved in accordance with subsections (a) or (b) will count as continuing education hours provided that the [provider and subject matter are] course is approved by the Board prior to implementation of the course. The course provider shall submit an application for course approval on a form supplied by the Board and pay the fee required under § 23.91 at least 45 days in advance of the date the course is given. [In addition, credits may be obtained on an individual basis for attendance at programs which have not had prior approval of the Board so long as the individual submits proper application for program approval and supporting documentation and verification of attendance; however, in this instance, the licensee cannot guarantee himself proper credit from the Board unless the Board finds such course to be in compliance with the subject matter and the provider to be qualified.]

(e) Continuing education credit may be awarded retroactively for attending programs, to include lectures and college or university courses, which have not been previously approved. The attendee shall apply to the Board for approval on a form supplied by the Board, pay a fee under § 23.91, and document attendance within 60 days of attending the program. The attendee shall demonstrate to the Board's satisfaction that the program meets the requirements in § 23.83. A licensee may complete up to 50% of the licensee's required continuing education in programs approved under this subsection or subsections (f)—(h).

[(c)] (f) It shall be permissible to attend clinical conferences, clinical rounds, or training under a preceptor through clinical hospitals, medical centers, schools, and colleges which are acceptable at the rate of [one] 1 continuing education hour for every 50 minutes. If requested by the Board, a licensee shall provide documentation of completion. A licensee may complete up to 25% of the licensee's required continuing education from sources in this subsection and up to an additional 25% in required continuing education from any of the sources in subsections (e), (g) or (h).

[(d)] (g) Credit hours will be given for correspondence programs, taped study programs, online or webinar programs, journal courses, and other individual study programs at the rate of 1 continuing education hour for every 50 minutes. However, proper credit being given for such program is dependent upon the licensee proving, to the satisfaction of the Board, that the program meets the provisions of [§ 23.85 (relating to standards for providers)] subsections (a) or (b). A licensee may complete up to 50% of the licensee's required continuing education in individual study

in accordance with this subsection or in the continuing education from any of the sources in subsections (e), (f) or (h).

[(e)] (h) Credit hours will be credited for service as a teacher, preceptor, lecturer, or speaker and for publications, articles, books, and research relating to the practice of optometry. [Application should be made prior to the service to assure that approval will be given by the Board to the program.] At the request of the Board, a licensee shall provide documentation to the Board. Otherwise, the licensee will be required to secure retroactive approval as set forth in subsection [(b)] (e). One continuing education hour will be granted for every 50 minutes of initial instruction or research and 2 continuing education hours will be granted for the preparation of each hour of instruction. If a licensee prepares written materials to accompany the instruction, the continuing education credits for only the instruction will be doubled. Five continuing education hours will be granted for publication of a book, and 2 continuing education hours will be granted for publication of an article or a chapter in a book. A licensee may complete up to 25% of the licensee's required continuing education in accordance with this subsection and up to an additional 25% from any of the required continuing education sources in subsections (e), (f) and (g).

[(f) Each licensee is required to fulfill the continuing education hours using the following allocations:

(1) Subsections (a) and (b) count for a minimum of 50%. Continuing education hours may be completed from subsections (a) and (b).

(2) Subsections (c), (d) or (e) may be used up to a maximum of 25% of the required biennial credit hours. In no case may the combined total from these three subsections exceed 50% of the total biennial requirement of 30 hours.]

(i) Of the 30 hours of continuing education credit required at § 23.82 (relating to continuing education hour requirements), the following shall apply:

(1) Courses in jurisprudence or ethics shall count for no more than 2 hours of the total.

(2) Courses within the optometric curriculum offered by an accredited school of optometry or medicine in the United States or Canada shall count for no more than 25% of the required biennial credit hours. Two continuing education credit hours will be provided for each semester credit earned, including a course which the licensee audits.

§ 23.87. Reporting of continuing education credit hours.

(a) Applicants for a license or license renewal shall provide, at a time prescribed and on forms approved by the Board, a signed statement certifying that they have met the continuing education requirements set forth in section 5(b) of the act (63 P.S. § 244.5(b)) by providing information which shall include the following:

(1) Dates attended.

(2) Continuing education hours claimed.

(3) Title of course, including the course number assigned by the Board, if applicable, and description of

content. For those courses which are approved to meet the requirements for therapeutic or glaucoma certification, the licensee claiming credit shall ensure that the certificate of attendance includes the course number and number of hours that apply toward the requirement for therapeutic or glaucoma certification.

(4) School, clinical hospital, medical center, optometric center or organization sponsoring course, clinical conference, clinical rounds or preceptor training.

(5) Instructor.

(6) Name of licensee.

**(b) If a course provider does not use an electronic database such as the Association of Regulatory Boards of Optometry's (ARBO's) Optometric Education (OE) Tracker to report a continuing education course, the licensee may make arrangements to have the continuing education course entered into an electronic database for compliance purposes.**

*(Editor's Note: The following section is proposed to be added and is printed in regular text to enhance readability.)*

**§ 23.90. Standards for commercial support.**

(a) For a licensee to obtain continuing education credit, all continuing education must be free from the control of a commercial interest.

(1) There must be a clear separation of any type of product, service and instrument or device promotion with any continuing education courses. All commercial exhibits and advertisements must be physically separated from continuing education courses.

(2) Specific proprietary business interests or products may not be included in continuing education courses. Continuing education courses must give balanced coverage to treatment options.

(3) Financial relationships with commercial interests of any person in a position to impact or control the educational content must be disclosed to the licensees taking the course and to the Board.

(4) Course instructors shall assure that educational materials must not include any advertising or product group message. Instructors shall ensure balanced and transparent coverage of therapeutic and treatment options, and may disclose off-label or experimental information.

(b) A licensee's travel, lodging, honoraria or personal expenses (including social events and recreation) for attending a continuing education program may not be paid for or reimbursed by the provider of the continuing education. Licensees who are course instructors or consultants rendering advisory services to the continuing education provider may receive reasonable compensation for those services and reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing these services.

(c) A licensee may receive from the provider of continuing education food and refreshment of modest value according to local standards for attending the continuing education program.

**FEES**

**§ 23.91. Fees.**

The following is the schedule of fees for services charged by the Board:

\* \* \* \* \*

Application for continuing education **course or** program approval..... \$45

**Application for continuing education provider initial approval for providers under § 23.86(b) (relating to sources of continuing education hours)..... \$135**

**Biennial renewal fee for providers approved under § 23.86(b)..... \$45**

**Application for licensees seeking continuing education credit retroactively under § 23.86(e) or (h)..... \$45**

Application for certification to treat glaucoma . . . . \$25

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