

<h1>Regulatory Analysis Form</h1> <p>(Completed by Promulgating Agency)</p> <p><i>(All Comments submitted on this regulation will appear on IRRC's website)</i></p>		<p><b>INDEPENDENT REGULATORY REVIEW COMMISSION</b></p> <p><b>RECEIVED</b></p>	
<p>(1) Agency <b>Department of State, Bureau of Professional and Occupational Affairs</b></p>		<p>FEB 15 2019</p> <p>Independent Regulatory Review Commission</p>	
<p>(2) Agency Number: <b>16A</b></p> <p>Identification Number: <b>16A-5213</b></p>		<p>IRRC Number: <b>3223</b></p>	
<p>(3) PA Code Cite:</p> <p><b>49 Pa. Code §§ 23.1, 23.21, 23.82, 23.86, 23.87, 23.90 and 23.91.</b></p>			
<p>(4) Short Title:</p> <p><b>General Revisions</b></p>			
<p>(5) Agency Contacts (List Telephone Number and Email Address):</p> <p>Primary Contact: <b>Jacqueline A. Wolfgang, Counsel, State Board of Optometry, P.O. Box 69523, Harrisburg, PA 17106-5923 (phone 717-783-7200) (fax 787-0251) <a href="mailto:jawolfgang@pa.gov">jawolfgang@pa.gov</a>.</b></p> <p>Secondary Contact: <b>Cynthia Montgomery, Deputy Chief Counsel, Department of State, P.O. Box 69523, Harrisburg, PA 17106-9523 (phone 717-783-7200) (fax 787-0251) <a href="mailto:cymontgome@pa.gov">cymontgome@pa.gov</a>.</b></p>			
<p>(6) Type of Rulemaking (check applicable box):</p> <p><input checked="" type="checkbox"/> <b>PROPOSED REGULATION</b></p> <p><input type="checkbox"/> Final Regulation</p> <p><input type="checkbox"/> Final Omitted Regulation</p>		<p><input type="checkbox"/> Emergency Certification Regulation;</p> <p><input type="checkbox"/> Certification by the Governor</p> <p><input type="checkbox"/> Certification by the Attorney General</p>	
<p>(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)</p> <p><b>The proposed regulations define contact lenses to include lenses that correct vision conditions, act as a diagnostic or therapeutic device, or provide a cosmetic or decorative effect. Additionally, the Board proposes changes to its continuing education (CE) regulations and proposes amendments to the reciprocity regulations.</b></p>			
<p>(8) State the statutory authority for the regulation. Include <u>specific</u> statutory citation.</p> <p><b>The amendments are authorized under section 3(b)(14) of the Optometric Practice and Licensure Act (act) (63 P.S. § 244.3(b)(14)). Under section 3(b)(12) of the act, the Board is authorized to establish and approve by rule and regulation courses of continuing professional optometric education.</b></p>			

(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

**This regulation is not mandated by any Federal or State law, court order or Federal regulation. However, to comply with Federal laws and regulations as well as State law, the Board would add a definition of contact lens at § 23.1 (relating to definitions). Under section 6(h)(2) of the act (63 P.S. § 244.6(h)(2)) a prescription of a licensed physician (ophthalmologist) or optometrist is required for the fitting of a contact lens.**

**Under Federal law, decorative or cosmetic contact lenses, including non-corrective plano lenses, are considered “medical devices” under section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §§ 321(h) and 360j(n)(1)). As medical devices, decorative contact lenses are subject to premarket approval by the Federal Food and Drug Administration (FDA) before they can be legally marketed under section 510(k) of the Food, Drug and Cosmetic Act (21 U.S.C. § 360(k)). All currently approved or cleared decorative contact lenses are legally marketed as prescription devices. Therefore, a prescription is required. Furthermore, medical devices without premarket authorization by the FDA are considered adulterated or misbranded under the Food, Drug and Cosmetic Act (21 U.S.C. §§ 351(f)(1)(B) and 352(o)).**

(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

**The Board believes the contact lens definition will clarify that contact lenses are medical devices, which require a prescription, and include plano, zero-powered, cosmetic, and decorative lenses. The Board believes this regulation will help reduce damages to individuals’ eyes, especially among young people during holidays such as Halloween and Christmas.**

**The Board would make four changes to its regulations on continuing education (CE) by: (1) addressing reporting, auditing and enforcement; (2) establishing current providers of CE, describing how additional organizations may provide CE, providing more precise details for licensees to obtain retroactive approval of CE, setting forth the maximum credits available for a variety of options for licensees to obtain CE, thereby indirectly encouraging licensees to take more courses in a greater variety of subjects; (3) allowing licensees to report CE electronically if they so desire; and (4) set forth guidance for licensees and providers of CE to avoid conflicts of interest and establish standards for commercial support. The Board would also establish a new fee structure for CE providers and licensees seeking CE credit retroactively. Course providers could benefit by being able to apply for provider-approval at a fee of \$135, instead of paying a \$45 fee for approval of each course. By making these changes to the CE that optometrists must take, this regulation will improve the education and training of licensed optometrists, thereby benefiting public health and safety.**

(11) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

**The regulations do not provide standards that are more stringent than Federal laws or regulations.**

(12) How does this regulation compare with those of the other states? How will this affect Pennsylvania's ability to compete with other states?

**This regulation will not adversely affect Pennsylvania's ability to compete with other states. There are other surrounding states that also have laws and regulations dealing with continuing education (CE).**

**In Delaware, all non-therapeutically-licensed optometrists must obtain 12 hours of CE during each biennial licensure period in which a maximum of 2 hours may be fulfilled by self-reported study. All therapeutically-licensed optometrists must obtain 24 hours of CE during each biennial licensure period, in which a maximum of 4 hours may be fulfilled by self-reported study. Twelve of those 24 hours must include education in the areas of therapeutics and management of ocular disease. All therapeutically-licensed optometrists must also maintain current CPR certifications for both children and adults throughout the licensure period. Any new licensee is required to complete CE equivalent to one hour for each month between the date of licensure and the biennial renewal date. The first twelve 12 hours of pro-rated CE must be in the treatment and management of ocular disease. Licensees must maintain all proof of CE for at least two licensure periods. CE credit is awarded for courses through pre-approved providers listed in the regulations. In the alternative, course providers may submit an application and fee (\$40) for course approvals; however, there is no fee when licensees submit applications for course approval. There is no indication that retroactive course approval is permitted or prohibited. There is no mechanism to become a board-approved provider.**

**In Maryland, the CE required by the Board must be in courses approved by the Board. The Board requires non-therapeutically certified optometrists to attend no more than 50 hours in any biennial licensing period. The Board requires therapeutically certified optometrists to attend at least 50 hours of CE in a licensing period. In each licensing period, a therapeutically certified optometrist shall attend 30 hours of CE on the use and management of therapeutic pharmaceutical agents. The 30 hours of CE required must be counted toward the total number of required hours of CE in a licensing period. At the time a licensee applies for license renewal, the licensee must submit a certification that the licensee has attended the required courses to the Board. CE credit is awarded for courses through pre-approved providers listed in the regulations. Course providers may submit applications for approval of continuing education. The Board does not have a fee for this application. There is no indication that retroactive course approval is permitted or prohibited. There is no mechanism to become a board-approved provider.**

**In New Jersey, an applicant for an active registration renewal certificate must complete, during the preceding biennial period, a minimum of 50 credits of continuing professional optometric education. At least 30 of the 50 credits shall consist of courses or programs classified as therapeutic pharmaceutical agent credits and shall be primarily devoted to the diagnosis, treatment and management of ocular disease, ocular pathology or the ocular manifestation of systemic disease. Of the credits, 10 of the 30 continuing professional optometric education credits shall be in oral**

therapeutic pharmaceutical agents (TPA) credits. The remaining 20 general continuing professional optometric education credits must be in content areas set forth in the regulations. An applicant who initially obtains a certificate within the first year of a biennial period shall complete at least 25 of the minimum required credits of continuing professional optometric education. At least 15 of the 25 credits shall consist of courses or programs classified as TPA credits. An applicant who initially obtains a certificate within the second year of a biennial period shall be exempt from completing continuing professional optometric credits for that biennial renewal period. A licensee who completes more than the required 50 credits in any biennial period may carry up to 20 credits into any succeeding biennial period. Any credits to be carried over must be earned in the last one year of the biennial renewal period and shall be applied to the general continuing professional optometric education requirements and not to the therapeutic pharmaceutical agent requirements. CE credit is awarded for courses through pre-approved providers listed in the regulations. In the alternative, course providers may submit an application for course approvals at no cost. Retroactive course approval is not permitted; however, upon an audit, if a course is not pre-approved, the board may grant CE credit if the board determines that the course has appropriate content. There is no mechanism to become a board-approved provider.

In New York, during each triennial registration period an applicant for registration must complete at least 36 hours of formal CE. At least 3/4 of the CE in a registration period should consist of live in-person instruction in a formal course of study. Up to 1/4 of such CE in a registration period may consist of live instruction in a formal course of study offered through audio, audio-visual, written, on-line, and other media, during which the student must be able to communicate and interact with the instructor. During each registration or certification period of less than 3 years, an applicant shall complete acceptable CE on a prorated basis at the rate of 1 hour of CE per month for the registration period. Acceptable education for CE must be in the area of ocular disease and pharmacology and may include both didactic and clinical components. CE credit is awarded for courses through pre-approved providers listed in the regulations. In the alternative, course providers may submit an application for course approvals at no cost. There is no indication that retroactive course approval is permitted or prohibited. There is no mechanism to become a board-approved provider.

In Ohio, each year all licensed optometrists, as a prerequisite for license renewal, must file proof of attendance for 25 clock hours to the Board. Those clock hours must include 10 clock hours of instruction in pharmacology of board approved CE during the study compliance year. The study compliance year shall extend from October 1 through September 30 for the subsequent license renewal year beginning January 1 and ending December 31. Credit will be allowed only for the study compliance year in which the educational course was actually attended. CE credit is awarded for courses through pre-approved providers listed in the regulations. In the alternative, course providers may submit an application for course approvals at no cost. There is no indication that retroactive course approval is permitted or prohibited. There is no mechanism to become a board-approved provider.

In Virginia, as a prerequisite to renewal of a license or reinstatement of a license, each optometrist is required to take annual courses relating to optometry as approved by the Board. The courses may include, but need not be limited to, the utilization and application of new techniques, scientific and clinical advances and new achievements of research. The Board shall prescribe criteria for approval of courses of study and credit hour requirements. However, the required number of credit hours shall not exceed 16 in any one calendar year. The Board may approve alternative courses upon timely application of any licensee. Fulfillment of education requirements shall be certified to the

**Board and must be submitted by each licensed optometrist at the time they apply to the Board for the renewal of their license. CE credit is awarded for courses through pre-approved providers listed in the regulations. The board does not approve courses and does not have a mechanism to become a board-approved provider; therefore, there are no correlating fees.**

**In West Virginia, it is the responsibility of a licensed optometrist to maintain evidence of meeting the CE requirements for each license renewal to the Board. A licensee must complete a minimum of 43 hours of CE for each even numbered, 2-year cycle. Of the required 43 hours, the licensee must complete a minimum of 12 hours of study in pharmacology or therapeutics courses, a maximum of 6 hours of study in practice management, and a maximum of 10 hours of optometric study may be taken by correspondence, or via the Internet. Of the required 43 hours, a licensee who holds an oral pharmaceutical certificate shall complete at least 12 hours of instruction in ocular pathology and therapeutic pharmacological agents. Of the required 43 hours, a licensee who holds an Injectable Pharmaceutical Agents Certificate shall complete 2 hours of instruction in administering pharmaceutical agents by injection. CE credit is awarded for courses through pre-approved providers listed in the regulations. In the alternative, course providers may submit an application and fee (\$50) for course approvals. West Virginia prohibits retroactive approval of courses. There is no mechanism to become a board-approved provider.**

**Based on these regulations from other States, this regulation will not place Pennsylvania at a competitive disadvantage. Because the proposed regulation would set forth the maximum credits for a variety of CE options for Pennsylvania optometrists, the Board hopes it will indirectly encourage licensees to take more courses in a greater variety of CE methodologies.**

**The Board's retroactive application fee provides additional opportunity for those individuals who failed to request CE credit before taking courses or engaging in other creditable activities. The cost of the retroactive application is the same as the Board's prospective application. Similarly, prospective course approval fees in Delaware (\$40) and West Virginia (\$50) are comparable to the Board's proposed fee for retroactive approval (\$45). Therefore, the retroactive application fee will not place Pennsylvania at a competitive disadvantage. Regarding the Board's proposed board-approved provider fees, none of the above states allow for board-approved providers. In this regard, the Board's proposed regulation may make Pennsylvania more competitive because providers will have an opportunity to become approved providers in Pennsylvania. As a board-approved provider, the provider will not have to submit applications for every course, but rather, will only have to submit one application and one fee per biennium. Although some states do not charge for CE approval proposed in this regulation, Pennsylvania has a low biennial renewal fee (\$135) as compared to other states. For example, Maryland's biennial fee is \$600 and New Jersey's biennial fee is \$250. Charging a fee for approval of CE courses and providers is preferable over charging licensees higher biennial fees because it allocates the fee to the specific service instead of raising the biennial fee for all licensees. Thus, the Board does not believe the board-approved provider fee or the retroactive fee will impact Pennsylvania's ability to compete with other states.**

**(13) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.**

**The proposed regulation will have no effect on other regulations of the Board or other state agencies.**

(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses, and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. ("Small business" is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)

**The Board discussed this regulation package at public Board meetings. Representatives of the Pennsylvania Optometric Association (POA) and the Pennsylvania Academy of Ophthalmology (PAO) regularly attend these meetings. In addition, the Board released an "exposure draft" of the proposal to stakeholders and interested parties and received comments from both the POA and PAO. The Board considered stakeholder comments in finalizing its proposed rulemaking.**

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

**There are approximately 2,812 individuals in this Commonwealth with current licenses. According to the Pennsylvania Department of Labor and Industry (L&I) in 2016, almost half of the optometrists (49.33%) work in offices of other health practitioners. 15.32% of optometrists are self-employed, and (6.72%) work in health and personal care stores. A few optometrists work in medical equipment and supplies manufacturing, department stores and other general merchandise stores, colleges and universities, offices of physicians, outpatient care centers, and other hospitals.**

**For the business entities listed above, small businesses are defined in Section 3 of Act 76 of 2012, which provides that a small business is defined by the U.S. Small Business Administration's (SBA) Small Business Size Regulations under 13 CFR Ch. 1 Part 121. Specifically, the SBA has established these size standards at 13 CFR § 121.201 for types of businesses under the North American Industry Classification System (NAICS). In applying the NAICS standards to the types of businesses where optometrists work, a small business in the categories of offices of optometrists, offices of all other miscellaneous health practitioners, and all other health and personal care stores are ones with \$7.5 million or less in average annual receipts. Also in the NAICS category of health and personal care stores, small businesses in pharmacies and drug stores have \$27.5 million or less in average annual receipts.**

**Other businesses in the NAICS small business category of health and personal care stores include optical goods stores with annual receipts of \$20.5 million or less and food (health) supplement stores with annual receipts of \$15 million or less. A small business for department stores is one with \$32.5 million or less in average annual receipts. For colleges, universities and professional schools, the annual threshold is \$27.5 million or less. The NAICS thresholds for offices of physicians is \$11 million or less annually. Small businesses in outpatient care centers are \$20.5 million or less annually. Finally, the threshold for small businesses in general medical and surgical hospitals is \$38.5 million.**

**In considering all of these small business thresholds set by NAICS for the businesses in which optometrists work, it is probable that most of the licensed optometrists work in small businesses. Optometrists are provided greater clarity regarding these requirements by the rulemaking. The only fiscal impact on optometrists would be the fee for retroactive approval of continuing education activities, courses, and programs that were not provided by a pre-approved provider. However, this cost could be avoided simply by taking only those courses offered by a pre-approved provider.**

**(16) List the persons, groups or entities, including small businesses, that will be required to comply with the regulation. Approximate the number that will be required to comply.**

**All 2,812 currently licensed optometrists will be required to comply with the regulations, as will all continuing education providers who wish to offer approved courses to licensees.**

**The Board proposes four changes to its regulations on continuing education (CE) by: (1) addressing reporting, auditing and enforcement; (2) establishing current providers of CE, describing how additional organizations may provide CE, providing more precise details for licensees to obtain CE retroactively, setting forth the maximum credits available for a variety of options for licensees to obtain CE; (3) allowing licensees to report CE electronically if they so desire; and (4) setting forth guidance for licensees and providers of CE to avoid conflicts of interest and establishing standards for commercial support.**

**The Board would also establish new fees for CE providers and licensees seeking CE credit retroactively. Approximately 15 to 20 organizations listed under § 23.86(b) (relating to sources of continuing education hours) currently sponsor CE programs at a cost of \$45 for each course sponsored. The Board's administrative staff process approximately 50 to 60 CE applications per year. During the past year, the Board received only 1 request for applications to obtain CE retroactively.**

**(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.**

**As noted in the answer to questions 7 and 10, the Board would define contact lenses to include decorative or cosmetic contact lenses because eye injuries have occurred when individuals wear contact lenses that are made for "one size fits all." This change would have no financial, economic or social impact in that it is simply a definition. The Board hopes that the new definition will provide notice that even cosmetic or decorative contact lenses are available by prescription only and may reduce damages to individuals' eyes, especially among young people during holidays such as Halloween and Christmas.**

**The only provision relating to CE that would have a fiscal impact is the new fee structure for CE providers and licensees seeking retroactive CE course approval. CE providers could actually benefit from the new fee structure in that they could simply apply for provider approval at a fee of \$135, rather than applying for approval of each individual course at \$45 each. Licensees could avoid the fee for retroactive approval of a CE course by simply taking pre-approved courses.**

**(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.**

**As noted in the answer to questions 7 and 10, the Board would define contact lenses to include decorative or cosmetic contact lenses because eye injuries have occurred when individuals wear contact lenses that are made for "one size fits all." The Board hopes that the new definition will reduce damages to individuals' eyes, especially among young people during holidays such as Halloween and Christmas. There are no costs associated with this change.**

**The Board would make four changes to its regulations on continuing education (CE) by: (1) addressing reporting, auditing and enforcement; (2) establishing current providers of CE, describing how additional organizations may provide CE, providing more precise details for licensees to obtain retroactive approval of CE already completed, setting forth the maximum credits available for a variety of options for licensees to obtain CE; (3) allowing licensees to report CE electronically if they so desire; and (4) set forth guidance for licensees and providers of CE to avoid conflicts of interest and establish standards for commercial support. These changes have no fiscal impact, yet they provide greater clarity to the regulated community.**

**The Board would also establish new fees for CE providers and licensees seeking approval of CE retroactively. These fees are needed to cover the costs associated with processing applications for approval. The Board's licensees should not bear these costs. CE providers could actually benefit from the new fee structure in that they could simply apply for provider approval at a fee of \$135, rather than applying for approval of each individual course they offer at \$45 each. Licensees could avoid the fees for retroactive approval of a CE course by simply taking pre-approved courses. However, this process provides the possibility of obtaining credit for relevant courses that would otherwise meet the Board's regulations, but for the fact that the CE provider failed obtain pre-approval.**

**(19) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.**

**The only definitive cost to licensees associated with compliance with the regulation is a \$45 fee at § 23.91 (relating to fees) for an application for licensees seeking approval of CE retroactively under § 23.86(e) or (h) (relating to sources of continuing education hours). During the past calendar year, the Board has received only 1 such application. If 1 licensee seeks approval retroactively after this regulation is promulgated, the total cost would be \$45 per year.**

**If licensees take advantage of electronic tracking of the CE credits by using such programs as OE tracker as provided at § 23.87(b) (relating to reporting of continuing education hours), they will incur costs. For example, with regard to ARBO's OE Tracker, licensees pay \$20 annually for this voluntary program. Licensees may be willing to pay this fee in order to save time in retaining their own CE records. Because OE tracker or other electronic databases are voluntary, there are no required costs to licensees.**

**CE providers who are not pre-approved would now have the option of obtaining provider approval at a cost of \$135, or of obtaining course approval at \$45 per course (which is the current fee). If a provider offers more than three courses per biennium, it would be advantageous to seek provider approval.**

**(20) Provide a specific estimate of the costs and/or savings to the local governments associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.**

**There will be no costs or savings to local governments associated with this rulemaking.**

(21) Provide a specific estimate of the costs and/or savings to the state government associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

**This rulemaking should have no fiscal impact on State government. Only minor paperwork requirements are imposed for the Board to develop a form for approval of providers of continuing education under § 23.86(b)(1) and a biennial renewal form for continuing education providers. The costs associated with processing this paperwork would be covered by the revised fee structure in § 23.91.**

(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

**Only minor paperwork requirements are imposed for the Board to develop a form for approval of providers of continuing education under § 23.86(b)(1) and a biennial renewal form for continuing education providers.**

(22a) Are forms required for implementation of the regulation? **Yes.**

(22b) If forms are required for implementation of the regulation, attach copies of the forms here. If your agency uses electronic forms, provide links to each form or a detailed description of the information required to be reported. Failure to attach forms, provide links, or provide a detailed description of the information to be reported will constitute a faulty delivery of the regulation.

**The Board has attached the forms required for implementation of the regulation. (See Attachment A) including: the Application for Continuing Education Provider Approval, the Biennial Renewal Application for Continuing Education Provider Approval, the Optometrist Request for Continuing Education Approval, and the Application for Continuing Education Course/Program Approval.**

(23) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY 18-19	FY +1 19-20	FY +2 20-21	FY +3 21-22	FY +4 22-23	FY +5 23-24
<b>SAVINGS:</b>	\$	\$	\$	\$	\$	\$
<b>Regulated Community</b>						

<b>Local Government</b>						
<b>State Government</b>						
<b>Total Savings</b>						
<b>COSTS:</b>						
<b>Regulated Community</b>	<b>0</b>	<b>\$45</b>	<b>\$45</b>	<b>\$45</b>	<b>\$45</b>	<b>\$45</b>
<b>Local Government</b>						
<b>State Government</b>						
<b>Total Costs</b>	<b>0</b>	<b>\$45</b>	<b>\$45</b>	<b>\$45</b>	<b>\$45</b>	<b>\$45</b>
<b>REVENUE LOSSES:</b>						
<b>Regulated Community</b>						
<b>Local Government</b>						
<b>State Government</b>						
<b>Total Revenue Losses</b>						

(23a) Provide the past three-year expenditure history for programs affected by the regulation.

<b>Program</b>	<b>FY -3 15-16</b>	<b>FY -2 16-17</b>	<b>FY -1 16-17 (Projected)</b>	<b>Current FY 17-18 (Budgeted)</b>
<b>State Board of Optometry</b>	\$177,952.28	\$177,570.27	\$171,000.00	\$176,000.00

(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:

- (a) An identification and estimate of the number of small businesses subject to the regulation.
  - (b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.
  - (c) A statement of probable effect on impacted small businesses.
  - (d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.
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- (a) As noted above, this regulation will not have an adverse impact on small businesses. To the extent that small businesses may be impacted, as many as 2,812 small businesses could be subject to these regulations.
  - (b) The only paperwork associated with the proposed rulemaking are the applications for continuing education approval. No special skills are needed to complete these applications.
  - (c) The probable effect on small businesses would be the costs associated with obtaining approval as continuing education providers (\$135) and biennial renewal of that approval

**(\$45) or those costs associated with licensees obtaining retroactive approval of continuing education activities that were not otherwise pre-approved (\$45 per course or activity). However, the \$45 fee to licensees can be avoided merely by completing all continuing education by pre-approved providers or Board-approved providers.**

- (d) The Board could discern no less intrusive or less costly method of achieving the purpose of the proposed regulation. The proposed fees are required to cover the costs associated with processing the applications for approval of continuing education course/providers.**

**(25) List any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, the elderly, small businesses, and farmers.**

**The Board has not identified a particular group for which special provisions are needed.**

**(26) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.**

**No alternative regulatory provisions were considered.**

**(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:**

- a) The establishment of less stringent compliance or reporting requirements for small businesses;
- b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
- c) The consolidation or simplification of compliance or reporting requirements for small businesses;
- d) The establishment of performing standards for small businesses to replace design or operational standards required in the regulation; and
- e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

**(a) The Board did not consider less stringent compliance or reporting requirements for small businesses.**

**(b) The Board did not consider less stringent schedules or deadlines for compliance or reporting requirements for small businesses.**

**(c) There are no compliance or reporting requirements that could be consolidated for small businesses.**

**(d) There are no design or operational standards that could be replaced with performing standards in the regulation.**

**(e) The Board did not consider exempting small businesses from all or any part of the requirements contained in the regulation. All continuing education providers must either apply for provider approval or for course approval. To exempt a small business from the fee associated with processing the application would be inconsistent with the Board's mandate to be self-funded. The fee must cover the costs of processing the application, regardless of the size of the business making application.**

(28) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

**The proposed rulemaking is not based on any data, studies, or references.**

(29) Include a schedule for review of the regulation including:

- |   |  |
|---|--|
| A. The length of the public comment period:   | <b>30 days after publication</b>   |
| B. The date or dates on which public meetings or hearings will be held:                       | <b>Public meetings will be held after publication of the proposed regulation to discuss any public comments.</b> |
| C. The expected date of delivery of the final-form regulation:                                | <b>Spring 2019</b>   |
| D. The expected effective date of the final-form regulation:                                  | <b>Final promulgation</b>  |
| E. The date by which compliance with the final-form regulation will be required:              | <b>Effective date</b>  |
| F. The expected date by which required permits, licenses or other approvals must be obtained: | <b>Effective date</b>  |

(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.

**The Board continually reviews the efficacy of its regulations, as part of their annual process pursuant to Executive Order 1996-1. The Board generally meets quarterly. During 2018, the Board will meet on the following remaining dates: August 16, and November 1, 2018. More information can be found on the Board's website ([www.dos.state.pa.us/opt](http://www.dos.state.pa.us/opt)).**

# ATTACHMENT “A”

1. Application for Continuing Education Provider Approval
2. Biennial Renewal Application for Continuing Education Provider Approval
3. Optometrist Request for Continuing Education Approval
4. Application for Continuing Education Course/Program Approval.



STATE BOARD OF OPTOMETRY  
P.O. Box 2649  
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Telephone: (717) 783-7155  
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Website: [www.dos.pa.gov/opt](http://www.dos.pa.gov/opt)  
E-Mail: [st-optometry@pa.gov](mailto:st-optometry@pa.gov)

Courier Address:  
2601 North Third Street  
Harrisburg, PA 17110

## APPLICATION FOR CONTINUING EDUCATION PROVIDER APPROVAL

### INFORMATION:

Preapproved providers listed in the Board's regulations at 49 Pa. Code § 23.86 are not required to complete this application.

#### **Title 49. Professional and Vocational Standards**

#### **Part I. Department of State**

#### **Subpart A. Professional and Occupational Affairs**

#### **Chapter 23. State Board of Optometry**

#### **§ 23.83. Continuing education subject matter.**

(a) Acceptable courses of study are limited to those pertaining to the use of means or methods for examination, diagnosis and treatment of conditions of the human visual system and may include examination for and adapting and fitting of all types of lenses. The Board will not accept courses of study which do not relate to the actual practice of optometry such as studies in office management and financial procedures.

(b) Courses that will meet the requirements for certification in the prescription and administration of pharmaceutical agents for therapeutic purposes in accordance with section 4.1 of the act (63 P. S. § 244.4a) shall concern the treatment and management of ocular or oculo-systemic disease.

(c) Courses that will meet the requirements for certification to treat glaucoma in accordance with § 4.2 of the act (63 P.S. § 244.4(b) shall concern the treatment and management of primary open angle glaucoma, exfoliation glaucoma and pigmentary glaucoma.

### INSTRUCTIONS:

- a. Applications cannot be considered unless all questions on the application are answered.
- b. Submit \$135.00 application fee. Make check or money order payable to "Commonwealth of PA." **Application fees are not refundable.** If you do not receive the Board's approval within one year from the date the application is received, you will be required to submit another application fee. A processing fee of \$20.00 will be charged for any check or money order returned unpaid by your bank, regardless of the reason for non-payment.
- c. Applications for provider approvals must be submitted to this Board at least 90 days in advance of the date the initial course is given.

- d. Providers may not offer any course for credit until the Board grants its approval as an approved provider.
- e. Please review the Board's continuing education regulations at 49 Pa. Code § 23.82-23.90, which can be accessed on the Board's website.
- f. Provider approval is valid for the 2-year biennial period, from the date the provider is approved. All Pennsylvania provider approvals expire November 30 of each even numbered year.
- g. If you wish to continue as a provider, the provider approval must be renewed each biennium.
- h. This form must be printed or typed only.

**PLEASE NOTE: It is your responsibility to maintain a copy of this application and all documents submitted to, or received from the Board for your future reference.**

---

**STATE BOARD OPTOMETRY**

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---

**APPLICATION FOR CONTINUING EDUCATION PROVIDER APPROVAL**

1. **Provider name:** \_\_\_\_\_

2. **Telephone number:** (     ) \_\_\_\_\_

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3. **Address:** \_\_\_\_\_

4. **Email address:** \_\_\_\_\_

5. **Professional Qualifications of Provider:** \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

6. **Background Information about Provider, including experience in optometric education:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

7. **Describe the method to be used to monitor attendance and satisfactory completion of programs:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**8. Methods of instruction (lecture, group dynamics, audiovisual aids, etc.):**

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**9. Methods of evaluation (indicate methods to be used and how you will use evaluation findings. Attach copy of evaluation form, if available):**

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**10. What means will be used to publicize or otherwise announce availability of programs to assure open attendance?**

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**11. Describe the criteria for selecting and evaluating faculty instructors, subject matter, and instructional materials.**

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**12. Describe the mechanism for measuring the quality of programs being offered.**

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**13. Describe the criteria for evaluating programs to determine effectiveness.**

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**14. Certificate of Attendance:** Attach a sample of the Certificate of Attendance that will be given to each attendee. It must include the name of the sponsor, name of the licensee, title of the course, date of the course, number of credit hours, PA Board approval number, and signature of person authenticating attendance.

**CERTIFICATION**

I verify that the statements in this application are true and correct to the best of my knowledge, information, and belief. I understand that false statements are made subject to the penalties of 18 Pa. C.S. § 4904 relating to unsworn falsification to authorities and may result in the suspension or revocation of my approval. I verify that this form is in the original format as supplied by the Department of State and has not been altered or otherwise modified in any way. I am aware of the criminal penalties for tampering with public records or information pursuant to 18 Pa.C.S. § 4911.

Signature of provider \_\_\_\_\_

Date \_\_\_\_\_

**OFFICIAL BOARD USE ONLY**

Provider Number \_\_\_\_\_

Board member reviewing \_\_\_\_\_

Date approved \_\_\_\_\_

Date disapproved and reason \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_



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Harrisburg, PA 17110

## **BIENNIAL RENEWAL APPLICATION FOR CONTINUING EDUCATION PROVIDER APPROVAL**

### **INFORMATION:**

Preapproved providers listed in the Board's regulations at 49 Pa. Code § 23.86 are not required to complete this application.

**Title 49. Professional and Vocational Standards**  
**Part I. Department of State**  
**Subpart A. Professional and Occupational Affairs**  
**Chapter 23. State Board of Optometry**

### **§ 23.83. Continuing education subject matter.**

(a) Acceptable courses of study are limited to those pertaining to the use of means or methods for examination, diagnosis and treatment of conditions of the human visual system and may include examination for and adapting and fitting of all types of lenses. The Board will not accept courses of study which do not relate to the actual practice of optometry such as studies in office management and financial procedures.

(b) Courses that will meet the requirements for certification in the prescription and administration of pharmaceutical agents for therapeutic purposes in accordance with section 4.1 of the act (63 P. S. § 244.4a) shall concern the treatment and management of ocular or oculo-systemic disease.

(c) Courses that will meet the requirements for certification to treat glaucoma in accordance with § 4.2 of the act (63 P.S. § 244.4(b)) shall concern the treatment and management of primary open angle glaucoma, exfoliation glaucoma and pigmentary glaucoma.

### **INSTRUCTIONS:**

- a. Applications cannot be considered unless all questions on the application are answered.
- b. Submit \$45.00 application fee. Make check or money order payable to "Commonwealth of PA." **Application fees are not refundable.** If you do not receive the Board's approval within one year from the date the application is received, you will be required to submit another application fee. A processing fee of \$20.00 will be charged for any check or money order returned unpaid by your bank, regardless of the reason for non-payment.

- c. Providers may not offer any course for credit until the Board grants its approval as an approved provider.
- d. Please review the Board's continuing education regulations at 49 Pa. Code § 23.82-23.90, which can be accessed on the Board's website.
- e. Provider approval is valid for the 2-year biennial period, from the date the provider is approved. All Pennsylvania provider approvals expire November 30 of each even numbered year.
- f. If you wish to continue as a provider, the provider approval must be renewed each biennium.
- g. This form must be printed or typed only.

**PLEASE NOTE: It is your responsibility to maintain a copy of this application and all documents submitted to, or received from the Board for your future reference.**

---

**STATE BOARD OPTOMETRY**

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**BIENNIAL RENEWAL APPLICATION FOR CONTINUING EDUCATION PROVIDER APPROVAL**

1. **Provider name:** \_\_\_\_\_

2. **Telephone number:** (\_\_\_\_) \_\_\_\_\_

3. **Address:**  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

4. **Email address:** \_\_\_\_\_

5. **Professional Qualifications of Provider:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

6. **Background Information about Provider, including experience in optometric education:**  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

7. **Describe the method to be used to monitor attendance and satisfactory completion of programs:**  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**8. Methods of instruction (lecture, group dynamics, audiovisual aids, etc.):**

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**9. Methods of evaluation (indicate methods to be used and how you will use evaluation findings. Attach copy of evaluation form, if available):**

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**10. What means will be used to publicize or otherwise announce availability of programs to assure open attendance?**

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**11. Describe the criteria for selecting and evaluating faculty instructors, subject matter, and instructional materials.**

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**12. Describe the mechanism for measuring the quality of programs being offered.**

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**13. Describe the criteria for evaluating programs to determine effectiveness.**

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**14. Certificate of Attendance:** Attach a sample of the Certificate of Attendance that will be given to each attendee. It must include the name of the sponsor, name of the licensee, title of the course, date of the course, number of credit hours, PA Board approval number, and signature of person authenticating attendance.

**CERTIFICATION**

I verify that the statements in this application are true and correct to the best of my knowledge, information, and belief. I understand that false statements are made subject to the penalties of 18 Pa. C.S. § 4904 relating to unsworn falsification to authorities and may result in the suspension or revocation of my approval. I verify that this form is in the original format as supplied by the Department of State and has not been altered or otherwise modified in any way. I am aware of the criminal penalties for tampering with public records or information pursuant to 18 Pa.C.S. § 4911.

Signature of provider \_\_\_\_\_ Date \_\_\_\_\_

**OFFICIAL BOARD USE ONLY**

Provider Number \_\_\_\_\_

Board member reviewing \_\_\_\_\_

Date approved \_\_\_\_\_

Date disapproved and reason \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

VERSION: May 2017



STATE BOARD OF OPTOMETRY  
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2601 North Third Street  
Harrisburg, PA 17110

## -----OPTOMETRIST REQUEST FOR CONTINUING EDUCATION APPROVAL-----

### INSTRUCTIONS:

- a. NO practice management courses will be considered (please see regulation referenced below for acceptable courses of study).
- b. Submit one application for each continuing education activity. Please print or type.
- c. Applications cannot be considered unless all questions are answered.
- d. Submit \$45.00 application fee. Make check or money order payable to "Commonwealth of PA." **Application fees are not refundable.** If you do not receive the Board's approval of the continuing education activity within one year from the date the application is received, you will be required to submit another application fee. A processing fee of \$20.00 will be charged for any check or money order returned unpaid by your bank, regardless of the reason for non-payment.
- e. *Application deadline:* Please submit completed application to the Board at least 60 days in advance for prior approval.
- f. *Retroactive approval:* Applicants may seek retroactive approval on an individual basis for attendance at programs; however, licensees will only receive CE credit if the Board finds the course to be in compliance with Board regulations. Applicants for retroactive approval must submit a \$45.00 application fee and must submit application within 60 days of attending the program.
- g. Please review the Board's continuing education regulations at 49 Pa. Code § 23.82-23.90, which can be accessed on the Board's website.
- h. For information regarding continuing education subject matter, review 49 Pa. Code § 23.83. For information regarding acceptable sources of continuing education hours, please review 49 Pa. Code § 23.86.

**PLEASE NOTE:** It is your responsibility to maintain a copy of this application and all documents submitted to, or received from the Board for your future reference.

VERSION: May 2017

## STATE BOARD OF OPTOMETRY

**Mailing Address:**

P.O. Box 2649  
Harrisburg, PA 17105-2649  
Telephone: (717) 783-7155  
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### OPTOMETRIST REQUEST FOR CONTINUING EDUCATION APPROVAL

Requesting approval for (check one). Please indicate number of continuing education hours requested.

- Program  
Credit hours requested: \_\_\_\_\_
- Teacher, preceptor, lecturer or speaker  
Credit hours requested: \_\_\_\_\_
- Publications, articles, books, or research relating to the practice of optometry  
Credit hours requested: \_\_\_\_\_
- Other \_\_\_\_\_  
Credit hours requested: \_\_\_\_\_

1. Licensee's Name: \_\_\_\_\_

2. License number: \_\_\_\_\_ 3. Telephone number: (\_\_\_\_) \_\_\_\_\_

4. Address: \_\_\_\_\_

5. E-Mail address: \_\_\_\_\_

6. Title of program, publication, article, book or research: \_\_\_\_\_

7. Location of program: \_\_\_\_\_

8. Date of program/date of publication: \_\_\_\_\_

9. Program Application – attach the following:
- Detailed time schedule of program
  - Outline of faculty
  - Outline of subject
  - Certificate of attendance

Program sponsor: \_\_\_\_\_

Program sponsor address: \_\_\_\_\_

10. Teacher, preceptor, lecturer or speaker – attach the following:

- Detailed time schedule of program
- Outline of subject
- Letter from the sponsor verifying date of service as a teacher, preceptor, lecturer, or speaker.

11. Publications, articles, books, or research – attach one of the following:

- Copy of publication with publication date
- Copy of article with publication date
- Copy of title page of the book, the table of contents, and the date of publication
- Copy of research abstract, paper or other documentation verifying research.

VERSION: *May 2017*

The Board's Continuing Education Committee will review your application. If the request is approved, you will receive an approval letter from the Board. Retain this approval letter as your certificate.

**Verification**

I verify that the statements in this application are true and correct to the best of my knowledge, information and belief. I understand that false statements are made subject to the penalties of 18 Pa. C.S. §4904 relating to unsworn falsification to authorities and may result in the suspension or revocation of my approval. I verify that this form is in the original format as supplied by the Department of State and has not been altered or otherwise modified in any way. I am aware of the criminal penalties for tampering with public records or information pursuant to 18 Pa. C.S. § 4911.

Signature of licensee: \_\_\_\_\_ Date: \_\_\_\_\_



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## APPLICATION FOR CONTINUING EDUCATION COURSE/PROGRAM APPROVAL

### INSTRUCTIONS:

- a. NO practice management courses will be considered (please see regulation referenced below for acceptable courses of study).
- b. Submit one application for each continuing education program. Please print or type.
- c. Applications cannot be considered unless all questions are answered.
- d. Submit \$45.00 application fee. Make check or money order payable to "Commonwealth of PA." **Application fees are not refundable.** If you do not receive the Board's approval of the continuing education program within one year from the date the application is received, you will be required to submit another application fee. A processing fee of \$20.00 will be charged for any check or money order returned unpaid by your bank, regardless of the reason for non-payment.
- e. Attach a Faculty/Presenter Information Form for each presenter.
- f. Program Schedule: Attach detailed time schedule, hour by hour, of subject matter.
- g. Certificate of Attendance: Attach a sample of the Certificate of Attendance that will be given to each attendee. It must include the name of the sponsor, name of the licensee, title of the course, date of the course, number of credit hours, PA Board approval number, and signature of person authenticating attendance.
- h. Applications for approval of programs must be submitted to this Board 30 days in advance of presentation.
- i. The Continuing Education Committee will review your application for continuing education approval. If the program is approved, please note the continuing education approval number and the number of approved credit hours when you receive your approval letter. The approval number and the number of approved credit hours must be listed on certificates of attendance given to attendees of your program.

**PLEASE NOTE:** It is your responsibility to maintain a copy of this application and all documents submitted to, or received from the Board for your future reference.

**Title 49. Professional and Vocational Standards**  
**Part I. Department of State**  
**Subpart A. Professional and Occupational Affairs**  
**Chapter 23. State Board of Examiners of Optometry**

**§ 23.83. Continuing education subject matter.**

(a) Acceptable courses of study are limited to those pertaining to the use of means or methods for examination, diagnosis and treatment of conditions of the human visual system and may include examination for and adapting and fitting of all types of lenses. The Board will not accept courses of study which do not relate to the actual practice of optometry such as studies in office management and financial procedures.

(b) Courses that will meet the requirements for certification in the prescription and administration of pharmaceutical agents for therapeutic purposes in accordance with § 4.1 of the act (63 P. S. § 244.4a) shall concern the treatment and management of ocular or oculo-systemic disease.

(c) Courses that will meet the requirements for certification to treat glaucoma in accordance with § 4.2 of the act (63 P. S. § 244.4b) shall concern the treatment and management of primary open angle glaucoma, exfoliation glaucoma and pigmentary glaucoma.

**STATE BOARD OF EXAMINERS OF OPTOMETRY**

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Fax: (717) 787-7769

---

**APPLICATION FOR CONTINUING EDUCATION PROGRAM APPROVAL**

1. Provider name: \_\_\_\_\_
2. Telephone number: \_\_\_\_\_ (      )
3. Address: \_\_\_\_\_
4. Program Coordinator: \_\_\_\_\_
5. Program Coordinator's E-Mail Address: \_\_\_\_\_
6. Program title: \_\_\_\_\_
7. Date(s) program will be offered: \_\_\_\_\_
8. Program location(s): \_\_\_\_\_
9. Attach a Faculty/Presenter Information Form for each of the following presenters:

Name	Title	Major Field of Interest

10. Program Schedule: Attach detailed time schedule, hour by hour, of subject matter.
11. Total credit hours requested: \_\_\_\_\_  
Breakdown of requested hours: Core: \_\_\_\_\_ Therapeutics: \_\_\_\_\_ Glaucoma: \_\_\_\_\_
12. Describe the method to be used to monitor attendance and satisfactory completion of program: \_\_\_\_\_  
\_\_\_\_\_
13. Objectives and Outline of program: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
14. Describe admission requirements: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**VERSION: September 2016**

15. Identify core subjects of the program: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

16. Methods of instruction (lecture, group dynamics, audiovisual aids, etc.): \_\_\_\_\_  
\_\_\_\_\_

17. Methods of evaluation (indicate methods to be used and how you will use evaluation findings. Attach copy of evaluation form, if available): \_\_\_\_\_  
\_\_\_\_\_

18. What means will be used to publicize or otherwise announce availability of program to assure open attendance?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

19. Certificate of Attendance: Attach a sample of the Certificate of Attendance that will be given to each attendee. It must include the name of the sponsor, name of the licensee, title of the course, date of the course, number of credit hours, PA Board approval number, and signature of person authenticating attendance.

**Verification**

I verify that the statements in this application are true and correct to the best of my knowledge, information and belief. I understand that false statements are made subject to the penalties of 18 Pa. C.S. § 4904 relating to unsworn falsification to authorities and may result in the suspension or revocation of my approval. I verify that this form is in the original format as supplied by the Department of State and has not been altered or otherwise modified in any way. I am aware of the criminal penalties for tampering with public records or information pursuant to 18 Pa. C.S. § 4911.

Signature of Program Coordinator: \_\_\_\_\_ Date: \_\_\_\_\_

## State Board of Optometry Faculty/Presenter Information Form

**Instructions:**

*\*To be submitted with application*

*\*To be printed or types only.*

*\*Provide complete background and expertise of presenter.*

1. Name of Faculty/Presenter: \_\_\_\_\_

2. Address: \_\_\_\_\_

\_\_\_\_\_

3. Telephone Number: \_\_\_\_\_

4. Education: \_\_\_\_\_

\_\_\_\_\_

5. Specify professional qualifications: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

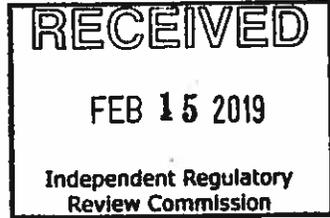
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\_\_\_\_\_

\_\_\_\_\_



FACE SHEET FOR FILING DOCUMENTS WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General

Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:

Copy below is approved as to form and legality. Executive or Independent Agencies.

BY: [Signature] (DEPUTY ATTORNEY GENERAL)

State Board of Optometry (AGENCY)

BY: [Signature]

DOCUMENT/FISCAL NOTE NO. 16A-5213

DEC 03 2018 DATE OF APPROVAL

DATE OF ADOPTION: BY: [Signature] Carl J. Urbanski, O.D.

NOV 08 2018 DATE OF APPROVAL

TITLE: Chairperson (EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

Deputy General Counsel, Chief Counsel, Independent Agency (Strike inapplicable title)

- Check if applicable Copy not approved. Objections attached. Check if applicable. No Attorney General approval or objection within 30 day after submission.

PROPOSED RULEMAKING COMMONWEALTH OF PENNSYLVANIA DEPARTMENT OF STATE BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS STATE BOARD OF OPTOMETRY

49 PA. CODE, §§ 23.1, 23.21, 23.82, 23.86, 23.87, 23.90 and 23.91

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 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*

The proposed rulemaking would amend § 23.1 (relating to definitions) by adding a definition of "contact lens." Although both 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 cornea and 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.

The 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 the 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) through (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 (ACOE) 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’s) 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 website. 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) through (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 (OE) 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 CE 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 a new § 23.90 (relating to standards for commercial support), 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 (SCS) and standards developed by the Pharmaceutical Research and Manufacturers of America (PhRMA).

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*

The 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 the 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 or by email to [RA-STRegulatoryCounsel@pa.gov](mailto:RA-STRegulatoryCounsel@pa.gov), within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Please reference No. 16A-5213 Optometry Board General Revisions, when submitting comments.

Carl J. Urbanski, O.D., Chair  
State Board of Optometry

**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:

\* \* \* \* \*

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.

\* \* \* \* \*

**LICENSE BY RECIPROCITY AND INTERSTATE CERTIFICATION**

**§ 23.21. Reciprocal application.**

\* \* \* \* \*

(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 that meet the requirements of § 23.83(a) (relating to continuing education subject matter). [; accordingly,] Accordingly, the following providers [have program approval in all allowable areas for continuing education] are preapproved sources for continuing optometric education courses:

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

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

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

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

(5) [the] 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)[,].

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

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

(9) [the] 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 website 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 30<sup>th</sup> 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) (relating to sources of continuing education hours). 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.

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**§ 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:

\* \* \* \* \*

(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.

\* \* \* \* \*

**§ 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.

### FEEES

#### § 23.91. Fees.

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

\* \* \* \* \*

Application for continuing education <u>course or program approval</u> .....	\$ 45
<u>Application for continuing education provider initial approval for providers under § 23.86(b) (relating to sources of continuing education hours)</u> .....	\$135
<u>Biennial renewal fee for providers approved under § 23.86(b)</u> .....	\$ 45
<u>Application for licensees seeking continuing education credit retroactively under § 23.86(e) or (h)</u> .....	\$ 45
Application for certification to treat glaucoma.....	\$ 25

\* \* \* \* \*



COMMONWEALTH OF PENNSYLVANIA  
DEPARTMENT OF STATE  
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS  
STATE BOARD OF OPTOMETRY  
Post Office Box 2649  
Harrisburg, Pennsylvania 17105-2649  
(717) 783-7155

February 15, 2019

The Honorable George D. Bedwick, Chairman  
INDEPENDENT REGULATORY REVIEW COMMISSION  
14<sup>th</sup> Floor, Harristown 2, 333 Market Street  
Harrisburg, Pennsylvania 17101

Re: Proposed Regulation  
State Board of Optometry  
16A-5213: General Revisions

Dear Chairman Bedwick:

Enclosed is a copy of a proposed rulemaking package of the State Board of Optometry pertaining to General Revisions.

The Board will be pleased to provide whatever information the Commission may require during the course of its review of the rulemaking.

Sincerely,

A handwritten signature in black ink, appearing to read "Carl J. Urbanski".

Carl J. Urbanski, O.D., Chairperson  
State Board of Optometry

JAW:bmz

Enclosure

cc: Ian J. Harlow, Commissioner of  
Professional and Occupational Affairs  
Kalonji Johnson, Director of Policy, Department of State  
Cynthia K. Montgomery, Deputy Chief Counsel  
Department of State  
Jacqueline A. Wolfgang, Counsel  
State Board of Optometry  
State Board of Optometry

**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE  
REGULATORY REVIEW ACT**

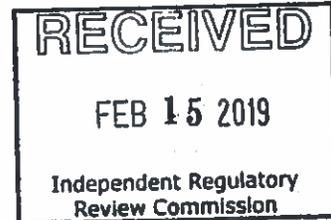
**I.D. NUMBER:** 16A-5213

**SUBJECT:** General Revisions

**AGENCY:** DEPARTMENT OF STATE  
Bureau of Professional and Occupational Affairs  
State Board of Optometry

**TYPE OF REGULATION**

- X Proposed Regulation
- Final Regulation
- Final Regulation with Notice of Proposed Rulemaking Omitted
- 120-day Emergency Certification of the Attorney General
- 120-day Emergency Certification of the Governor
- Delivery of Disapproved Regulation
  - a. With Revisions
  - b. Without Revisions



**FILING OF REGULATION**

<u>DATE</u>	<u>SIGNATURE</u>	<u>DESIGNATION</u>
<i>HOUSE COMMITTEE ON PROFESSIONAL LICENSURE</i>		
2/15/19	Cathy O'Donnell	MAJORITY CHAIR Rep. David Hinkernell
2/15/19	Juan Fergu	MINORITY CHAIR Rep. Harry A. Readshaw
<i>SENATE COMMITTEE ON CONSUMER PROTECTION &amp; PROFESSIONAL LICENSURE</i>		
2/15/19	Tom Blauch	MAJORITY CHAIR Sen. Robert M. Tomlinson
2/15/19	D. Toomey	MINORITY CHAIR Sen. Lisa M. Boscola
<i>INDEPENDENT REGULATORY REVIEW COMMISSION</i>		
<i>ATTORNEY GENERAL (for Final Omitted only)</i>		
2/15/19	Cassine Inaut	<i>LEGISLATIVE REFERENCE BUREAU (for Proposed only)</i>