RULES AND REGULATIONS

Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

STATE BOARD OF OPTOMETRY

[49 PA. CODE CH. 23]

General Revisions

The State Board of Optometry (Board) amends §§ 23.1, 23.33—23.35, 23.42, 23.64 and 23.71 and adds §§ 23.3 and 23.72 (relating to means and methods for the examination, diagnosis and treatment of conditions of the visual system; and prescriptions) to read as set forth in Annex A.

Response to Comments

Notice of proposed rulemaking was published at 33 Pa.B. 1120 (March 1, 2003). Following publication, the Board received public comments from the Pennsylvania Optometric Association (POA), the Pennsylvania Medical Society (PMS), the Pennsylvania Academy of Ophthalmology (Academy), and John C. Maher, M.D. Additionally the State Board of Medicine (Medical Board) sent comments to the Board. On April 1, 2003, the House Professional Licensure Committee (HPLC) submitted comments. On April 30, 2003, the Independent Regulatory Review Commission (IRRC) submitted comments. The majority of the comments submitted related to the definition of the means and methods for the examination, diagnosis and treatment of conditions of the visual system that may be employed by optometrists.

The POA noted its full support for the proposed rulemaking regarding the means and methods for the examination, diagnosis and treatment of conditions of the visual system that may be employed by optometrists. The POA also approved of the proposed rulemaking regarding practice in an office used exclusively for the practice of optometry, professional corporations and fictitious names, the equipment required for a basic ophthalmic examination, termination of patient care, recordkeeping and contact lens, spectacle and pharmaceutical prescriptions.

The Academy wrote to the Board on April 14, 2003, and asserted that the proposed rulemaking "would allow optometrists to order the administration of intravenous and inhalation anesthetic agents to allow examinations under anesthesia," "would allow optometrists to provoke attacks of glaucoma" and "would allow an optometrist to pass a steel probe through the tear duct opening in the eyelid of a six-month old, down the entire length of the tear duct, perforating fleshy tissue on the way into the nose." In addition, the Academy opined that ordering computer assisted tomography (CAT) and magnetic resonance imaging (MRI) scans and angiography procedures are the practice of medicine. The Academy opined that "[w]hile optometrists and technicians may perform the ultrasound scans" the selection of lens implant power is the surgeon's responsibility. Finally, the Academy questioned the paragraph regarding insurance billing codes. Dr. Maher, who wrote the response for the Academy, submitted comments that were essentially identical to the Academy's comments.

On April 8, 2003, the PMS provided comments on the proposed rulemaking. The PMS asked that the Board clarify that optometrists could use only diagnostic lasers. The PMS opined that treatment of the lacrimal system was surgical and involved incision, excision, repair or probing, and asked that the Board modify the section referencing treatment of the lacrimal system. The PMS also questioned the need to include language regarding billing codes. Finally, the PMS pointed out that the ability of an optometrist to provide optometric services might be limited by the Health Care Facilities Act (35 P. S. §§ 448.101—448.901).

In addition to drafting suggestions, the HPLC asked the Board to provide a detailed explanation of the training of optometrists in order to perform the services listed in § 23.3, as well as an explanation of how long each service has been a part of optometric practice. Additionally, the Committee requested information as to the extent these services are considered to be within the scope of optometric practice in other states.

IRRC suggested that the delineation of the means and methods for the examination, diagnosis and treatment of conditions of the visual system was a substantive provision that had been improperly placed in the regulation's definition section. IRRC suggested the provisions be relocated under the title "scope of practice." The Board has relocated the section by adding § 23.3 under the topic "General Provisions." The Board has retained the title "means and methods for the examination, diagnosis and treatment of conditions of the visual system" to correlate with section 3(a)(2.1) of the Optometric Practice and Licensure Act (act) (63 P. S. § 244.3(a)(2.1)).

The final-form rulemaking was delivered to the HPLC, the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) and IRRC on October 1, 2004. The HPLC requested additional information and the Board withdrew the final-form rulemaking on October 15, 2004, to further answer the HPLC's questions. At the request of the Commissioner of the Bureau of Professional and Occupational Affairs (Bureau) and representatives from the POA, the PMS and the Academy were invited to meet with the Commissioner and Chairperson of the Board to further discuss the rulemaking. The Board has made various amendments to the rulemaking in response to the concerns expressed, which are reflected in Annex A. Remaining points of disagreement are specifically noted in the following discussion.

Use of computerized or automatic refracting devices

Refraction is the process by which an optometrist determines the correct lens correction for a visual deficiency. Since the advent of optometry in the 1800s, optometrists have performed refractions. In the past, optometrists performed refractions by simply holding different lenses in front of the patient's eyes and asking the patient which lens provided the patient with the clearest vision. Advances in technology have created automatic and computerized refracting devices, which enable optometrists to determine the correct refractions with greater accuracy. Automatic and computerized refracting devices have been in use since 1970 and all states consider refraction part of the practice of optometry. Optometrists are taught to perform refractions using computerized and automated devices in their first year of optometry school, and refractions are a standard part of students' practice during their internship years. The

Academy and the PMS agree that the use of computerized or automatic refracting devices are routine to the practice of optometry.

Visual field testing such as manual or automatic perimetry

Optometrists have performed visual field testing on patients since 1920. Visual field testing is used to test a patient's peripheral vision and is an early diagnostic tool for glaucoma. The first automated perimeters came onto the market in the 1970s. In 2001, the journal of the Indiana School of Optometry published an article indicating that, in the last decade or so, automated perimetry had become the "gold standard" in visual field assessment. *Demirel, Shaban, Recent Advances in Automated Perimetry*, Ind. J. of Optometry, vol. 4, no. 1, p. 3. Visual field testing is taught in the classroom and clinics at optometry schools, with students having about 1,000 encounters with the procedure as part of their optometric education. Visual field testing is a standard part of the practice of optometry in all states. The Academy and the PMS agree that the employment of visual field testing such as manual or automatic perimetry is routine to the practice of optometry.

Ophthalmoscopy and gonioscopy

Ophthalmoscopy is the term used to describe viewing the interior portions of the eye by looking through the patient's iris. An indirect ophthalmoscope is a binocular, stereoscopic instrument that allows the optometrist to gain a wide-field view of the vitreous and retina. A light source from the indirect ophthalmoscope is directed into the patient's eye by an adjustable mirror and a condensing lens gathers the reflected light to form a virtual inverted image of the retina. Gonioscopy is the term used for ophthalmoscopy where the lens utilized is a gonio lens rather than a condensing lens. The angle of the eye, where the cornea meets the iris, can only be examined with a specialized lens such as a gonio lens. The gonio lens is applied to the surface of the cornea under topical anesthesia to evaluate the anatomy of the angle. This is a diagnostic procedure essential to the evaluation and management of patients with glaucoma. Optometrists have performed direct ophthalmoscopy since 1920 and have performed indirect ophthalmoscopy and gonioscopy since 1973. The procedure is taught throughout the optometric curriculum, with students having about 2,000 contacts with direct ophthalmoscopy, 2,000 contacts with indirect ophthalmoscopy and 100 contacts with gonioscopy. Ophthalmoscopy and gonioscopy are utilized in all states.

Several comments related to proposed subparagraph (i)(C) in § 23.1 (relating to definitions), which provides for "[o]phthalmoscopy, including ophthalmoscopy of a patient who has been anesthetized by a practitioner authorized to provide anesthesia services and in accordance with applicable law and regulation governing the anesthesia provider and facility, and with or without the use of diagnostic lenses, including, but not limited to, any and all condensing lenses, gonioscopy lenses, and fundus contact lenses." The Academy commented that it believed the subparagraph would allow optometrists to order the administration of intravenous and inhalation anesthetic agents. The Medical Board commented that there "is no optometric need for an examination to be performed under anesthesia." Dr. Maher commented optometrists do not have the training to deal with the anesthetized patient. The HPLC and IRRC commented that the subparagraph appeared to authorize optometric offices as facilities in which anesthesia may be administered.

The Board does not agree that the proposed definition would have authorized optometrists to order or administer anesthesia or that the subsection would have authorized the administration of anesthesia in optometric offices. The Board did not intend either to authorize optometrists to order intravenous or inhalation anesthetic agents or to provide for the administration of anesthesia in optometric offices. The reference to an anesthetized patient was included to encompass the practice of optometrists who work in a hospital setting and who may be asked to perform ophthalmoscopy on a patient who has been anesthetized under the order of, and under the care of, a physician. Because of the confusion generated by this subparagraph, the Board has determined that the subsection should be amended to eliminate any reference to anesthesia.

The Board amended the definition to refer to ophthalmoscopy and gonioscopy in renumbered § 23.3(3). The Academy and the PMS agree that ophthalmoscopy and gonioscopy are standard optometric practices.

Testing for glaucoma

Optometrists have been testing patients to detect glaucoma since 1920. In the early years, imprecise tests such as provocative testing were employed. Provocative testing has not been used for many years, as technology has advanced and optometrists have employed more sophisticated tests for glaucoma. Glaucoma diagnosis and treatment is taught throughout the optometry school curriculum, and students have approximately 2,000 contacts with glaucoma patients throughout their education. Section 2 of the act (63 P. S. § 244.2) specifically authorizes optometrists to perform diagnostic tests for glaucoma and to use topical pharmaceutical agents to treat primary open angle glaucoma, exfoliation glaucoma and pigmentary glaucoma. Testing for and treatment of glaucoma is part of optometric practice in all states.

Several commentators addressed subparagraph (i)(E) of the proposed rulemaking, which mentioned provocative tests for glaucoma. The Academy, the Medical Board and Dr. Maher commented that because optometrists were not authorized to treat acute glaucoma, they should not be authorized to provoke acute glaucoma attacks. IRRC asked the Board to address these comments. The Board agrees with the comments that provocative tests for glaucoma are not currently utilized and would be inappropriate for a provider to perform as newer, more accurate testing methods have been available for many years. Therefore, the Board has deleted the language referring to provocative tests. The Board retained the general language regarding testing for glaucoma in renumbered § 23.3(5). The Academy and the PMS agree that testing for glaucoma is part of standard optometric practice.

Electrodiagnostic testing

Clear vision depends on optimal function of each component of the eye's sensory mechanisms. In response to visual stimuli, the eye's photoreceptors create electrical impulse, which are then transmitted by means of the optic nerve into the visual cortex of the brain. When visual function becomes impaired, electrodiagnostic tests can help pinpoint the source of the malfunction. Optometrist have performed electrodiagnostic testing since 1970, and the testing is taught in multiple courses and clinics in schools of optometry.

There are several types of electrodiagnostic tests utilized for the diagnosis of various conditions of the visual system. One example is the electro-oculogram (EOG) test

that evaluates the retinal pigment epithelium (RPE) and the photoreceptors. The RPE is affected quite early in many hereditary degenerative visual disorders. Electrodes are placed on the skin on either side of the eye. The patient is asked to fixate on target lights that alternately illuminated causing a 30° excursion of the eyes horizontally. The developed potential between the electrodes induces a current that is amplified and displayed on recording equipment. The EOG is valuable particularly in the evaluation of patients suspected of having disorders that affect the RPE, such as retinitis pigmentosa.

Another type of electrodiagnostic testing is the electroretinogram that measures the mass retinal response to a stimulus of light using a corneal electrode and neutral electrodes placed on the skin around the eye. The corneal electrode is placed gently behind the lower lid and contracts the cornea. A topical anesthetic is employed in adult patients. A flash of light is shown to the patient and the electrodes record the retinal potentials that develop as a response to the flash. This diagnostic procedure is useful in diagnosing hereditary eye diseases and in distinguishing between a variety of retinal disorders such as cone dystrophy and retinal pigmentosa.

Electrodiagnostic testing became widespread in the late 1990s and is utilized in all states. The Academy and the PMS agree that electrodiagnostic testing is part of standard optometric practice.

Use of lasers for diagnostic purposes

Several comments were submitted on proposed subparagraph (i)(F), which related to the use of lasers for diagnostic purposes. Diagnostic lasers have been in use since 1978 in all states and, because of the variety of diagnostic devices with integrated diagnostic lasers, their use is taught throughout the optometric curriculum. The PMS suggested the subparagraph would be clarified by being rewritten "the use of lasers for diagnostic imaging purpose." The Medical Board commented that the use of lasers is inherently dangerous and even in diagnostic applications has been known to cause anatomical changes to the eye. The HPLC noted the PMS's comment.

The Board considered the comments and amended the language of proposed § 23.1(i)(F). The Board cannot adopt the language suggested by the PMS because not all diagnostic tests commonly employed by optometrists and that utilize lasers produce images, for example, laser interferometry. Laser interferometry is used on children with a "lazy eye" diagnosis to determine the potential best vision after vision therapy. However, to clarify, the Board added the adjective "diagnostic" to "lasers" and, at the suggestion of the HPLC staff, referenced section 2 of the act, which prohibits optometrists from performing surgery, including laser surgery, in new § 23.3(a)(6). The Academy and the PMS agree that the Board's amended language addresses their concerns and have no further issues with optometrists utilizing diagnostic lasers for diagnostic purposes.

Employment of vision therapy and visual rehabilitation

The Academy and the PMS agree that optometric practice includes vision therapy and visual rehabilitation. The HPLC expressed concern that the Board's rulemaking might restrict the practice of educators who work with the visually impaired. The Pennsylvania College of Optometry (College) offers master's degree programs in vision impairment, low vision rehabilitation, orientation and mobility, rehabilitation teaching and education of children and youth with visual and multiple impairments. The Board consulted with the College in the development of this final-form rulemaking, and the College did not express any concerns that educators of the visually impaired would be restricted in any way by the final-form rulemaking. Individuals who are not optometrists but who hold one of these specialized master's degrees implement, rather than design, treatment plans, and use, rather than prescribe, devices. In addition, these master's educated nonoptometrists do not diagnose visual impairments or use orthoptics. Similarly, occupational therapists licensed by the Bureau, implement treatment plans designed by an optometrist or physician. An occupational therapist may not prescribe devices or diagnose a visual impairment. The Board has concluded that the final-form rulemaking will not interfere with the practice of nonoptometrists. Former subparagraph (i)(G) and (H) was renumbered as § 23.3(8) and (9), respectively, and definitions of "vision therapy" and "visual rehabilitation" were added to § 23.1 (relating to definitions).

Treatment of the lacrimal system

Section 2 of the act authorizes optometrists to employ any and all means for the examination and diagnosis of conditions of the human visual system, which includes the lacrimal system. Section 2 of the act also specifically authorizes optometrists to treat the lacrimal system by nonsurgical means. Optometrists have been diagnosing and treating conditions of the lacrimal system through nonsurgical dilation and irrigation since 1978. Optometrists have used punctal plugs for over 20 years. The diagnosis and treatment of the lacrimal system are taught in multiple courses, including clinical courses in optometry schools, and are part of the practice of optometry in all states.

The Academy commented that "the bible of medical and surgical insurance coding" lists the placement of punctual plugs as a surgical procedure. Dr. Maher echoed the comments of the PMS. The use of punctual plugs is not a surgical procedure. Optometrists have been using punctual plugs and obtaining insurance reimbursement for the use of punctual plugs for approximately 20 years. Following the Commissioner's meeting in late 2004, the Academy and the PMS agreed that the use of punctual plugs was part of the practice of optometry.

Regarding the more general language in subparagraph (i)(I), the PMS stated that the majority of the procedures for the treatment of the lacrimal system involve incision, excision, repair and probing, many of which require the administration of anesthesia. The PMS suggested that subparagraph (i)(I) be deleted or modified to include only diagnostic and nonsurgical treatment of the lacrimal system. The Academy commented that treatment of the lacrimal system requires the use of surgical procedures and suggested that subparagraph (i)(I) "would allow optometrists to pass a steel probe through the tear duct opening in the eyelid of a six-month old, down the entire length of the tear duct, perforating fleshy tissue on the way into the nose." The Medical Board commented that subparagraph (i)(I) authorized probing of the lacrimal system and noted that lacrimal probing was a surgical procedure that, if not performed carefully, could result in the metal probe penetrating the brain.

The Board agrees that treatments involving incision, excision, surgical repair and probing the entire length of the tear duct would constitute surgery prohibited by section 2 of the act, and agrees that optometrists do not now, and do not wish to, perform these procedures. The Board has amended subparagraph (i)(I), renumbered as § 23.3(10), to clarify that the means and methods for the examination, diagnosis and treatment of conditions of the visual system that may be employed by a licensed

optometrist include only "diagnosis and treatment of the lacrimal system through the use of punctual plugs, dilation of the punctum and irrigation of the lacrimal system." Through their omission in § 23.3(10), incision, excision, surgical repair and probing the entire length of the tear duct are prohibited.

Following the Board's suggested amendment of subparagraph (i)(I) to address the concerns raised by the Academy and the PMS, the Academy, at the meeting of the parties in late 2004, opposed the provision which would allow an optometrist to perform irrigation of the lacrimal system. At the meeting, the Academy representatives were asked to share any professional literature that suggested that dilation and irrigation of the lacrimal system by optometrists was problematic. The Academy did not provide the Board with any professional literature suggesting a problem with optometrists performing this procedure. The Board asked the research librarian at the College to search all medical, ophthalmological and optometric journals to find any reported injuries caused by optometrists performing this procedure. No journal references were found to suggest that the performance of this procedure is a risk to the public. The Board's research shows that optometrists have performed dilation and irrigation since 1978 without any reported incidents of injury to the public. In addition, in accordance with its statutory mandate, the Board determined that optometrists are educated and clinically trained to diagnose and treat conditions of the lacrimal system, including dilation and irrigation. The Board therefore retained this language in the final-form rulemaking.

Epilation of lashes

The Medical Board commented on subparagraph (i)(J), regarding epilation, or plucking, of eyelashes, stating that no matter how simple this procedure may seem "it is a surgical procedure that can create serious risk of infection and other harm to the patients." In addition, the Medical Board expressed concern that plucking an eyelash without a medical examination may delay the proper diagnoses of medical conditions underlying the presenting symptomology of the patient. The Board disagrees. Epilation is a nonsurgical treatment that has long been a part of the practice of optometric practice. The Academy had no objection to this procedure being included on the list of the means and methods employed by optometrists. The section was renumbered as § 23.3(10).

Ultrasound examination of the eye and orbit

The Academy commented that although optometrists and technicians may perform ultrasound scans, only a surgeon can analyze data from an ultrasound scan to order a lens implant. In addition, the Medical Board stated that the purpose of the examinations is to determine whether there is a need for surgical intervention and "because the surgeon is ultimately responsible for the surgical results, it is imperative that the responsibility for the measurements of the eye and the calculation of the implant power be vested in the surgeon." Dr. Maher objected to subparagraph (i)(K) because, he stated, "A scans are used to determine intraocular lenses and is pre-surgical." Dr. Maher reasoned that if optometrists are prohibited from performing surgery, they would also be prohibited from performing presurgical testing.

The Board agrees with the Academy that optometrists, and even technicians, may perform ultrasound examinations of the eye. The Board also acknowledges that A-scans are currently used to calculate lens implant power prior to cataract surgery. However, A-scans are also used to measure anterior chamber depth for diagnostic purposes in managing certain glaucoma patients whom optometrists are authorized to treat.

At their meeting in December 2004, the Academy agreed that ultrasound examination of the eye and orbit, including both A-scans and B-scans, should be included within the repertoire of diagnostic tests used by optometrists. The Academy suggested that intraocular lens calculations should be addressed separately, as this is a measurement taken in anticipation of surgery. The Board agreed that this calculation would only be performed by an optometrist who was working with an ophthalmologist, in anticipation of surgery by the ophthalmologist. The Board and the Academy agreed that the current language, which allows optometrists to perform all types of ultrasound examination of the eye and orbit, but limits the performance of intraocular lens calculations and lens implant power, is consistent with the role of the optometrist. The section was renumbered as § 23.3(11).

Diagnostic radiology

Comments were also submitted on subparagraph (i)(K)—(M). The Academy stated that the ordering of CAT and MRI scans is the practice of medicine. Dr. Maher commented that the purpose of ordering radiographs, MRIs or CAT scans was to evaluate medical issues or in the possible planning of surgery. Dr. Maher again reasoned that since the act does not allow optometrists to practice medicine or perform surgery, optometrists should not order diagnostic tests that may reveal a condition that would require medical intervention or surgery. The Medical Board commented that the performance of diagnostic scans is complex and involves systems of the human anatomy beyond the visual system. IRRC asked the Board to respond to the previous comments.

At the December 2004, meeting, the Board suggested that its rulemaking be amended to permit optometrists to recommend diagnostic radiology to a patient's physician. The Board believed that this amendment would be consistent with the education and training of optometrists who have studied diagnostic radiology in their clinical medicine and neuro-ophthalmic disease courses since 1980. The Academy objected to this language because it feared "it may give a false impression of expertise to the physician." The Academy recommended that the language related to diagnostic radiology be stricken entirely. Given the difficulty in finding language that accurately reflects an optometrist's role in discussing diagnostic radiology with a patient's physician, the Board determined that the Academy's suggestion was a good suggestion, and has removed the references to diagnostic radiology in the final-form rulemaking.

Laboratory work

The Academy, the PMS and Dr. Maher had no comments on subparagraph (i)(L), regarding laboratory work. Similarly, neither the HPLC nor IRRC commented on this subparagraph. Nevertheless, in its January 3, 2005, letter, the Academy opined that it opposed "the ordering of any and all laboratory work by optometrists." The Board strongly disagrees.

Ordering and, when properly equipped, performing, laboratory tests are integral to the safe and effective practice of optometry. An optometrist may order a laboratory test to determine the type of conjunctivitis (eye infection) in a patient, as bacterial, viral and gonococcal infections are appropriately treated with different drugs. An optometrist may order and perform a scrape and culture of a corneal ulcer as different medications are

required to treat different types of corneal ulcers. Similarly, there are many types of uveitis that require laboratory testing for rheumatoid factor to properly diagnose and treat. Optometrists diagnose and treat many different conditions of the visual system; to expect optometrists to practice safely and effectively without the aid of simple diagnostic laboratory tests is absurd and would be a great disservice to the public.

Angiographic studies

The Board received numerous comments regarding ordering and interpretation of angiographic studies, subparagraph (i)(M) of the proposed rulemaking. The standard of practice in this Commonwealth requires an optometrist to utilize an angiographic specialist or physician to perform an angiography. For this reason, the Board did not anticipate that it would receive comments regarding an optometrist performing angiography.

The Academy commented that optometrists cannot administer intravenous injections and, therefore, should not be authorized to "order a nurse to administer intravenous contrast agents." The Academy suggested that subparagraph (i)(M) would allow an optometrist to order arteriograms of the carotid arteries. As optometrists are limited to diagnosing and treating the visual system, the Board does not agree that proposed subparagraph (i)(M) would have authorized optometrists to order arteriograms of the carotid arteries.

Regarding angiographic studies, Dr. Maher also reasoned that because optometrists cannot perform injections, they could not order others to perform injections. The Board notes that the act does not prohibit optometrists from performing injections for diagnostic purposes. The act provides that optometrists may not "use injections in the treatment of ocular disease." In addition, Dr. Maher noted that "it is not clear that this does not exclude angiography of the orbit," which is part of the ocular vasculature. According to Dr. Maher, arteriography carries a 10% mortality rate and optometrists do not have sufficient education and training to order arteriograms. Regarding angiography, the Medical Board noted that these studies involve intravenous introduction of dyes and that some percentage of patients will have an adverse effect that can lead to death. The Medical Board stated that these are specialized tests that are usually performed by retinal specialists who maintain adequate emergency response measures.

Based on the comments, and with the approval of the Academy and the PMS, the Board has amended its final-form rulemaking to refer only to interpreting and reporting on angiographic studies at the request of an ophthalmologist. This amended provision is consistent with the practice of optometry in this Commonwealth and is also consistent with the education and training optometrists have received since 1978.

Levels of management and practice

Several comments were submitted on subparagraph (ii), regarding levels of management and practice. After considering the comments, the Board determined that the subparagraph was inappropriate in a Board regulation and has deleted the provision.

Other comments

IRRC commented that § 23.33(a) (relating to practice) should be amended to make the subsection gender neutral. In drafting the final-form rulemaking, the Board conformed to § 6.10(b) (relating to gender) of the *Pennsylvania Code and Bulletin Style Manual*.

Regarding § 23.33(b), IRRC asked if the Board intended to allow optometrists to provide services in facilities other than licensed health care facilities. The Board intended to provide for the practice of optometry in all facilities in which there is a need for optometric services. The most common facilities that are not licensed health care facilities where optometrists are asked to provide optometric services, particularly visual screening, are schools, prisons, fire halls and township buildings. Some optometrists operate mobile practices. IRRC also commented that the phrase "optometric services" was vague and asked if an optometrist could provide the full range of optometric services in other facilities. The Board intended to allow optometrists to perform the full range of optometric practice. Just as some ophthalmologists perform laser surgery by transporting equipment in a mobile van, an optometrist can transport diagnostic equipment and perform any testing enabled by that equipment. IRRC also asked the Board to define "visual screening" as used in § 23.33(e). The Board has added the definition to § 23.1. Regarding § 23.34 (relating to professional corporations), IRRC questioned with what other health care professionals an optometrist could incorporate. The section allows incorporation with other optometrists, medical doctors, doctors of osteopathy, dentists, psychologists, podiatrists, chiropractors and other health care professionals if the incorporation is authorized by the practice acts of the respective professions and 15 Pa.C.S. §§ 2901—2907 (relating to preliminary provisions).

IRRC commented on § 23.71(b) (relating to patient records). IRRC asked why a patient's request for a contact lens prescription was at the discretion of the optometrist. The Board's regulations currently provide that a patient's request for a contact lens prescription is at the discretion of the patient's optometrist. The Board's intent had been to maintain this provision, which was, at the time, consistent with Federal law. However, the United States Congress recently enacted the Fairness to Contact Lens Consumers Act (15 U.S.C.A. §§ 7601—7610) which became effective in early February 2004. The Board has amended its final-form rulemaking to conform to the new Federal statute. The Board also amended the requirement regarding release of a spectacle prescription to conform to the Federal Trade Commission Ophthalmic Practice Rules (16 CFR 456.1—456.4).

IRRC also commented that § 23.71(c) included the phrase "in his discretion" and stated that the Board should amend this phrase to make it gender neutral. On final-form rulemaking, the Board deleted § 23.71(c).

IRRC commented on § 23.72 and suggested that an optometric prescription include the optometrist's telephone number in § 23.72(a). To conform to the new Federal law, the Board has added both the telephone number and facsimile number to the final-form rulemaking.

Finally, regarding § 23.72(b), IRRC asked if the 1-year expiration date referred to the date of the patient's examination or the date when the optometrist wrote the prescription. The Fairness to Contact Lens Consumers Act provides that an optometrist must provide a patient with a copy of the patient's contact lens prescription when the contact lens fitting is complete. The 1-year expiration date would run from the date the prescription is issued.

Other amendments to proposed rulemaking

Following delivery of the final-form rulemaking on October 1, 2004, the HPLC commented that § 23.64(c)(1) (relating to professional conduct) should include a provi-

sion requiring an optometrist to give a patient time and assistance in securing alternate care. The Board has made this amendment. In addition, the HPLC commented that the Board should refer to statutorily set fees for medical records in § 23.64(c)(2). The Board make this amendment. In addition, § 23.64(c) was renumbered as § 23.64(d), and § 23.64(c) was added to provide that an optometrist will be subject to discipline under section 7 of the act for violating standards of professional care, including those in § 23.3(12) and (14).

Statutory Authority

Section 3(a)(2.1) of the act provides that the Board shall have the duty "[t]o determine, in accordance with optometric education, training, professional competence and skill, the means and methods for examination, diagnosis and treatment of conditions of the visual system." Section 3(a)(3) of the act requires the Board "[t]o record all licenses in its office." Section 3(b)(9) of the act authorizes the Board "[t]o establish and administer a records system which records shall be open to public inspection during the regular business hours of the Board." Finally, section 3(b)(14) of the act authorizes the Board "[t]o promulgate all rules and regulations necessary to carry out the purposes of this act."

Fiscal Impact and Paperwork Requirements

The final-form rulemaking should have no fiscal impact on licensees, the Board, the private sector, the general public or any political subdivisions. The regulations should not create additional paperwork for the Board or the private sector.

Sunset Date

The Board continuously monitors 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 12, 2003, the Board submitted a copy of the notice of proposed rulemaking, published at 33 Pa.B. 1120, to IRRC and the Chairpersons of the HPLC and the SCP/PLC for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC, the HPLC and the SCP/PLC were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Department has considered all comments from IRRC, the HPLC and the SCP/PLC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on April 12, 2005, the final-form rulemaking was approved by the HPLC. On April 27, 2005, the final-form rulemaking was deemed approved by the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on April 28, 2005, and approved the final-form rulemaking.

Additional Information

Persons who would like additional information regarding this final-form rulemaking should contact Deborah Smith, Board Administrator, P. O. Box 2649, Harrisburg, PA 17105-2649, www.dos.state.pa.us.

Findings

The Board finds that:

(1) Public notice of intention to adopt these amendments has been given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202) and the regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law and all comments were considered.

(3) This final-form rulemaking is necessary and appropriate for the administration of the act.

(4) Amendments to this final-form rulemaking do not enlarge the original purpose of the proposed rulemaking published at 33 Pa. B. 1120.

Order

The Board therefore orders that:

(a) The regulations of the Board, 49 Pa. Code Chapter 23, are amended by amending §§ 23.1, 23.33—23.35, 23.42, 23.64 and 23.71 and by adding §§ 23.3 and 23.72 to read as set forth in Annex A.

(b) The Board shall submit this order and a copy of Annex A to the Office of Attorney General and the Office of General Counsel for approval as required by law.

(c) The Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(d) This order shall take effect upon publication in the *Pennsylvania Bulletin*.

STEVEN J. RETO, O.D.,
Chairperson

(*Editor's Note:* For the text of the order of the Independent Regulatory Review Commission, relating to this document, see 35 Pa.B. 2972 (May 14, 2005).)

Fiscal Note: Fiscal Note 16A-528 remains valid for the final adoption of the subject regulations.

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 otherwise:

Act—The Optometric Practice and Licensure Act (63 P. S. § § 244.1—244.12).

Board—The State Board of Optometry of the Commonwealth.

Child abuse—A term meaning any of the following:

(i) A recent act or failure to act by a perpetrator which causes nonaccidental serious physical injury to a child under 18 years of age.

(ii) An act or failure to act by a perpetrator which causes nonaccidental serious mental injury to or sexual abuse or sexual exploitation of a child under 18 years of age.

(iii) A recent act, failure to act or series of acts or failures to act by a perpetrator which creates an imminent risk of serious physical injury to or sexual abuse or sexual exploitation of a child under 18 years of age.

(iv) Serious physical neglect by a perpetrator constituting prolonged or repeated lack of supervision or the failure to provide the essentials of life, including adequate medical care, which endangers a child's life or development or impairs the child's functioning.

ChildLine—An organizational unit of the Department of Public Welfare which operates a 24-hour a day Statewide toll free telephone system for receiving reports of suspected child abuse, referring reports for investigation and maintaining the reports in the appropriate file.

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.

Continuing education hour—Fifty minutes of continuing education.

Continuing education program—A group, self-study, correspondence or other program approved by the Board for which continuing education hours are given.

Inactive status—The status of not having one's license currently registered.

Individual residing in the same home as the child—An individual who is 14 years of age or older and who resides in the same home as the child.

NBEO—The National Board of Examiners in Optometry.

National Board Examination—A written academic examination developed, prepared, administered and scored by the NBEO, which the Board adopts as the National uniform written examination for licensure.

Perpetrator—A person who has committed child abuse and is a parent of the child, a person responsible for the welfare of a child, an individual residing in the same home as a child or a paramour of a child's parent.

Person responsible for the child's welfare—A person who provides permanent or temporary care, supervision, mental health diagnosis or treatment, training or control of a child in lieu of parental care, supervision and control. The term does not include a person who is employed by or provides services or programs in a public or private school, intermediate unit or area vocational-technical school.

Recent acts or omissions—Acts or omissions committed within 2 years of the date of the report to the Department of Public Welfare or county agency.

Retired practitioner—One who is no longer engaged in the practice of optometry as defined in section 2 of the act (63 P. S. § 244.2; see the definition of "practice of optometry").

Serious mental injury—A psychological condition, as diagnosed by a physician or licensed psychologist, including the refusal of appropriate treatment, that does one or more of the following:

(i) Renders a child chronically and severely anxious, agitated, depressed, socially withdrawn, psychotic or in reasonable fear that the child's life or safety is threatened.

(ii) Seriously interferes with a child's ability to accomplish age-appropriate developmental and social tasks.

Serious physical injury—An injury that causes a child severe pain or significantly impairs a child's physical functioning, either temporarily or permanently.

Sexual abuse or exploitation—The employment, use, persuasion, inducement, enticement or coercion of a child to engage in or assist another person to engage in sexually explicit conduct or a simulation of sexually explicit conduct for the purpose of producing a visual depiction, including photographing, videotaping, computer depicting or filming, of sexually explicit conduct or the rape, sexual assault, involuntary deviate sexual intercourse, aggravated indecent assault, molestation, incest, indecent exposure, prostitution, statutory sexual assault or other form of sexual exploitation of children.

TMOD—Treatment and Management of Ocular Disease Examination—An examination developed, prepared, administered and scored by the NBEO, which the Board adopts as the examination for certification in pharmaceutical agents for therapeutic purposes.

Vision therapy—A term meaning any of the following:

(i) Design of treatment plans for problems of eye teaming, focusing, tracking, sensory adaptation and visual information processing.

(ii) Prescription of devices and procedures that modify the oculomotor and sensory aspects of the visual process.

(iii) Orthoptics.

Visual rehabilitation—A term meaning any of the following:

(i) Diagnosis of a visual impairment.

(ii) Prescription of lenses, prisms, filters, occluders mirrors, and optical and electrooptical magnification and minification.

(iii) Design of treatment plans to compensate for central and peripheral visual field defects.

Vision screening—The limited process of surveying an individual for problem areas such as visual acuity, eye muscle coordination and refractive error.

§ 23.3. Means and methods for the examination, diagnosis and treatment of conditions of the visual system.

The means and methods for the examination, diagnosis and treatment of conditions of the visual system that may be employed by licensed optometrists include:

(1) The use of any computerized or automatic refracting device.

(2) Visual field testing such as manual or automatic perimetry.

(3) Ophthalmoscopy and gonioscopy.

(4) Anterior and posterior segment photography.

(5) Testing for glaucoma.

(6) Electrodiagnostic testing.

(7) The use of diagnostic lasers for diagnostic purposes consistent with section 2 of the act (63 P. S. § 244.2), which excludes the use of therapeutic lasers and laser surgery.

(8) The employment of vision therapy.

(9) Visual rehabilitation.

(10) Diagnosis and treatment of the lacrimal system through the use of therapeutic agents, punctal plugs, dilation of the punctum and irrigation of the lacrimal system.

(11) Epilation of lashes.

(12) Ultrasound examination of the eye and orbit. An optometrist may perform intraocular lens calculations upon the written order of an ophthalmologist. The ophthalmologist shall make final selection of lens implant power.

(13) Ordering laboratory work.

(14) At the request of an ophthalmologist, interpreting and reporting of angiographic studies of ocular vasculature and blood flow.

BUSINESS PRACTICES

§ 23.33. Practice.

(a) An optometrist engaged in the active practice of optometry shall practice in a room used exclusively for the practice of optometry when practicing in the optometrist's office. A change in this address, or the addition of places of practice, shall comply with §§ 23.43 and 23.44 (relating to offices; and additional practice locations).

(b) In compliance with § 23.36 (relating to consultant, advisor, staff or employe optometry), an optometrist may arrange the professional practice to include service to a licensed health care service facility, including in-patient or out-patient hospitals and emergency rooms, nursing homes and long-term care facilities, or any facility with the need for optometric services.

(c) An optometrist may, as a professional courtesy, accept a request to attend the patients of another optometrist in the office of the other optometrist, during a temporary absence from practice, if consistent with other duties.

(d) An optometrist may provide services to a patient who is physically incapable of coming to the optometrist's office, at that patient's residence or location.

(e) An optometrist may provide vision screening at any location, public or private, within this Commonwealth.

(f) An optometrist shall carry his wallet renewal card on his person as proof of current licensure, for presentation on demand, whenever rendering optometric services outside of his regular practice location.

§ 23.34. Professional corporations.

An optometrist licensed by the Board may professionally incorporate with other optometrists, medical doctors, doctors of osteopathy, dentists, psychologists, podiatrists, chiropractors and other health care professionals if this incorporation is authorized by the practice acts of the relevant professions.

§ 23.35. Fictitious names.

An optometrist practicing as a sole proprietor, in association with other optometrists, or in a business form other than a professional corporation, may do business under a fictitious name.

OFFICE OF OPTOMETRIST

§ 23.42. Equipment

An office maintained for the practice of optometry shall be fully equipped for the making of a basic optometrical examination including the following:

(1) Keratometer.

(2) Ophthalmoscope and retinoscope.

(3) Trial case and its accessories or a phoropter.

(4) Visual acuity charts.

(5) Ophthalmic chair.

(6) Field testing equipment.

(7) Slitlamp—Biomicroscope.

(8) Tonometer.

UNLAWFUL PRACTICES

§ 23.64. Professional conduct.

(a) Registered optometrists shall adhere to the standards of professional conduct which are generally accepted by the profession of optometry of this Commonwealth.

(b) The standards of professional conduct for registered optometrists are higher than, and may not partake of the standards and practices of the market place.

(c) Failure of an optometrist to conform to the standards of professional conduct, including those in § 23.3(12) and (14) (relating to means and methods for the examination, diagnosis and treatment of conditions of the visual system) may subject the optometrist to disciplinary action under section 7 of the act (63 P. S. § 244.7).

(d) An optometrist may terminate the optometric care of a patient who, in the professional opinion of the optometrist, is not adhering to appropriate regimens of care and follow-up.

(1) The optometrist shall notify the patient, in writing, that the optometrist is terminating the professional relationship and the reasons for the termination.

(2) The optometrist shall provide the patient with at least 60 days of continued care after the notice of termination is sent and provide reasonable assistance to the patient to find alternative care.

(3) In addition, the optometrist shall make a copy of the patient's medical record available to the patient or successor eye care provider designated by the patient, and may charge a fee for copying the record consistent with the fees in 42 Pa.C.S. § 6152(a)(2)(i) (relating to subpoena of records).

PROFESSIONAL PRACTICE

§ 23.71. Patient records.

(a) An optometrist shall use professional judgment to determine what services are to be provided to his patients. Records of the actual services rendered shall be maintained for a minimum of 7 years after the last consultation with a patient. Records must indicate when a referral has been made to a physician. An examination may include the following:

(1) Complete history.

(2) Uncorrected visual acuity.

(3) Detailed report of the external findings.

(4) Ophthalmoscopic examination (media, fundus, blood vessels, disc).

(5) Corneal curvature measurements (dioptral).

(6) Static retinoscopy.

(7) Amplitude of convergence and accommodation.

(8) Ocular muscle balance.

(9) Subjective refraction test.

(10) Fusion.

(11) Stereopsis.

(12) Color vision.

(13) Visual fields (confrontation).

(14) Visual fields including manual or automated perimetry.

(15) Prescription given and visual acuity obtained.

(16) Biomicroscopy (slit lamp).

(17) Tonometry.

(18) Prognosis, stable or unstable.

(19) Pharmaceutical agents used or prescribed, including strength, dosage, number of refills and adverse reaction, if applicable.

(b) An optometrist shall provide a patient with a copy of the patient's contact lens prescription in accordance with the Fairness to Contact Lens Consumers Act (15 U.S.C.A. §§ 7601—7610). An optometrist shall provide a patient with a copy of the patient's spectacle prescription in accordance with the Federal Trade Commission Ophthalmic Practice Rules (16 CFR 456.1—456.4).

§ 23.72. Prescriptions.

(a) Optometric prescriptions shall bear:

(1) The name, address, telephone number, facsimile telephone number and license number of the optometrist.

(2) The name of the patient.

(3) The date the prescription is issued by the licensed practitioner.

(4) The expiration date.

(b) Contact lens prescriptions shall specify the lens type, the specifications necessary for the ordering and fabrication of the lenses, number of refills and expiration date consistent with the type and modality of use of the contact lens being prescribed, but the expiration date may not be greater than 1 year. The prescription may include a statement of caution if the statement is supported by appropriate findings and documented in the patient's medical record.

(c) Pharmaceutical prescriptions shall specify the name of the drug prescribed, quantity and potency prescribed, expiration date, number of refills allowed, instructions for use and any indicated precautionary statements.

(d) Spectacle prescriptions shall specify any information that would be relevant to manufacturing glasses including the dioptic value of the sphere, astigmatism, prism, slab off, add power and axis or orientation of the astigmatism correction. The expiration date of a spectacle prescription may not be greater than 2 years.

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