Original: 2323

May 17, 2004

Steven J. Reto, Chair
State Board of Optometry
PO Box 2649
Harrisburg, PA 17105-2649

Dear Chair Reto:

I am writing to thank you for referencing the Fairness to Contact Lens Consumers Act (Public Law No: 108-164) in the state Board of Optometry's Final Form Regulation 16A-528 and to ask that you consider some changes to the regulation. Also, I continue to respectfully request that the Board wait to act on these final form regulations until the Federal Trade Commission (FTC) prescribes rules pursuant to Public Law No: 108-164.

Otherwise, we request the following changes to the regulation:

First, *Section 23.72 Prescriptions* of the regulation states that a "contact lens prescriptions shall specify the lens type, all 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."

1-800 Contacts fears that the "number of refills" language may allow eye doctors to intentionally limit the number of contacts lenses that may be purchased from a seller of contact lenses. For example, the standard practice is for individuals to buy contacts in a 6 month or one year supply. If the eye doctor chooses to limit refills to a lesser amount of time, consumers may be forced to re-visit their eye care professional for the sole purpose of having to purchase contact lenses.

Second, *Section 23.72 Prescriptions* also says, "but in no case shall the expiration date be greater than one year."

Clearly, this language would allow eye doctors to write a contact lens prescription for less than one year. As you know, according to the Fairness to Contact Lens Consumers Act, a contact lens prescription shall expire (1) on the date specified by the law of the State in which the prescription was written if that date is **one year or more after the issue date of the prescription; (2) not less than one year after the issue date of the prescription if such State law specifies no date** (which is the case in Pennsylvania) **or a date that is less than one year after the issue date of the prescription;** or (3) notwithstanding paragraphs (1) and (2), on the date specified by the prescriber, if that date is based on the medical judgment of prescriber with respect to the ocular health of the patient.

1 800 CONTACTS 66 East Wadsworth Park Drive | 3rd Floor | Draper, Utah 84020 | T 801 924 9800 | F 801 924 9905

It is the position of 1-800 Contacts that the words: "but in no case shall the expiration date be greater than one year" in the regulation should be changed to: "**not less than one year unless otherwise specified by the patients medical record.**" Obviously, this language would more closely reflect federal law.

Finally, according to the Federal Law, a prescriber shall now provide to the patient a copy of the contact lens prescription, whether requested by the patient, and shall, as directed by any person designated to act on behalf of the patient, provide or verify the contact lens prescription be electronic or other means.

Thank you again for recognizing the Fairness to Contact Lens Consumers Act in Regulation number 16A-528. I appreciate your attention in the matter of pending FTC rulings and ask that you recognize my sincere concern with particular language in the Regulation.

If you have any questions concerning this letter, please do not hesitate to contact me at 801-924-9876.

Sincerely,

Jay Magure
Director, Government Relations
1-800 Contacts

cc: Secretary Pedro A. Cortés, Department of State
Senator Robert M. Tomlinson, Majority Chairman, Consumer Protection and Professional Licensure Committee
Senator Lisa M. Boscola, Minority Chairwoman, Consumer Protection and Professional Licensure Committee
Representative Thomas P. Gannon, Majority Chairman, Professional Licensure Committee
Representative William W. Rieger, Minority Chairman, Professional Licensure Committee
John R. McGinley, Jr., Esq., Chairman, Independent Regulatory Review Commission
Gerald J. Pappert, Attorney General
Richard J. Gmerek, Esq.

Original: 2323

March 9, 2004

Steven J. Reto, Chairman
State Board of Optometry
Po Box 2649
Harrisburg, PA 17105-2649

Dear Chairman Reto:

As the Director of Government Relations for 1-800 Contacts Inc., I am writing today to request that the proposed Final Form Regulations for regulation number 16A-528 reflect current Federal Public Law No: 108-164. Also, I respectfully request that the Board wait to release final form regulations until the Federal Trade Commission (FTC) prescribes rules pursuant to Public Law No: 108-164. It is my understanding that the Pennsylvania State Board of Optometry posted an intent to issue the final form regulations in Spring of 2004 in the February 7, 2004 Pennsylvania Bulletin, Volume 34. It is also my understanding that the Board intends to meet on March 11, 2004.

As you may know, H.R. 3140 was signed into law by the President on December 6, 2003. The law provides that when a prescriber completes a contact lens fitting, the prescriber shall provide to the patient a copy of the contact lens prescription, whether or not requested by the patient, and shall, as directed by any person designated to act on behalf of the patient, provide or verify the contact lens prescription be electronic or other means.

Our reasons for requesting changes to regulation number 16A-528 are as follows:

First, prior to federal law, the Pennsylvania State Board of Optometry proposed regulation number 16A-528 in March 2003 to provide for contact lens prescriptions to be released at the discretion of the licensee. Specifically, the Board recommended the following changes to amend Section 23.71 (c) of the Pennsylvania Code 49, Chapter 23: "Requests for spectacle prescriptions from examinations over 2 years prior to the request **[, or for contact lens prescriptions,]** may be complied with at the discretion of the optometrist. **Requests for contact lens prescriptions may be complied with at the discretion of the optometrist.** Please see the attached copy of the Proposed Rulemaking from the Pennsylvania Bulletin as it relates to contact lens prescription release, pages 4, 5, 9 and 10.

DSG:4663.1/ONE053-900083

It is the position of 1-800 Contact Inc. that this proposed Rulemaking must be changed to reflect current Public Law No: 108-164.

Second, The Independent Regulatory Review Commission (IRRC) issued comments that appear to reflect our concerns on State Board of Optometry Regulation No. 16A-528 (General Revisions) on April 30, 2003. In the comments, under point number 4., Section 23.71 Patient records.- Clarity; Reasonableness; Protection of the public health., the Independent Regulatory Review Commission made the following comments, "We have two concerns with Subsection (b). First, this Subsection states that requests for contact lens prescriptions may be given at the discretion of the optometrist. If an optometrists provides a contact lens prescription to a patient, Subsection (c) requires that certain factors be considered before that prescription is provided. The preamble states that these factors were included to protect the optometrist from liability. Since these protections were included in the regulation, why is a patient's request for contact lens prescription "at the discretion of the optometrist"?". Please see the attached IRRC comments.

Third, under Public Law No. 108-164 a prescriber may not require purchase of contact lenses from the prescriber or from another person as a condition of providing a copy of a prescription under subsection (a) (1) or (a) (2) or verification of a prescription under subsection (a) (2).

The prescriber may not require payment in addition to, or as part of, the fee for an eye examination, fitting and evaluation as a condition of providing a copy of a prescription under subsection (a) (1) or (a) (2) or verification of a prescription under subsection (a) (2) ; or require the patient to sign a waiver or release as a condition of verifying or releasing a prescription.

Fourth, a seller (1-800 Contacts) may sell contact lenses only in accordance with a contact lens prescription for the patient that is presented to the seller by the patient or prescriber directly or by facsimile; or verify by direct communication. A prescription is verified under Public Law No: 108-164 only if one of the following occurs:

1. The prescriber confirms the prescription is accurate by direct communication with the seller.

2. The prescriber informs the seller that the prescription is inaccurate and provides the accurate prescription.

3. The prescriber fails to communicate with the seller within 8 business hours, or a similar time as defined by the Federal Trade Commission, after receiving from the seller the information described in subsection (c).

Fifth, a contact lens prescription shall expire under the law on the date specified by the law of the State in which the prescription was written if that date is one year or more after the issue date of the prescription; not less than one year after the issue date of the prescription if such State law specifies no date or a date that is less than one year after the issue date of the prescription; or notwithstanding paragraphs (1) and (2), on the date specified by the prescriber, if that date is

based on the medical judgment of prescriber with respect to the ocular health of the patient. Please see the attached copy of Public Law No: 108-164.

Sixth, the Federal Trade Commission shall prescribe rules pursuant to section 18 of the Federal Trade Commission Act (15 U.S.C. 57a) to carry out the Act no later than 180 days after the effective date of the Act.

Again, I respectfully urge the Board to wait to release final form regulations until the Federal Trade Commission (FTC) prescribes rules pursuant to Section 18 of the Federal Trade Commission Act pertaining to Public Law No: 108-164. As stated above, the FTC must make rules within 180 days after the effective date of Public Law No: 108-164.

Finally, in light of the comments made by the Independent Regulatory Review Commission and Public Law No: 108-164, I respectfully request that any Final Form regulations in reference to contact lens prescriptions issued by the PA Board of Optometry reflect federal law.

If you have any questions concerning this matter, please do not hesitate to contact me at

Sincerely,

Jay Magure
Director, Government Relations
1-800 Contacts

cc: Secretary Pedro A. Cortés, Department of State
Senator Robert M. Tomlinson, Majority Chairman, Consumer Protection and Professional Licensure Committee
Senator Lisa M. Boscola, Minority Chairwoman, Consumer Protection and Professional Licensure Committee
Representative Thomas P. Gannon, Majority Chairman, Professional Licensure Committee
Representative William W. Rieger, Minority Chairman, Professional Licensure Committee
John R. McGinley, Jr., Esq., Chairman, Independent Regulatory Review Commission
Gerald J. Pappert, Attorney General

DSG:4663.1/ONE053-900083

Original: 2323

PROPOSED RULEMAKING

[49 PA. CODE CH. 23]

General Revisions

[33 Pa.B. 1120]

The State Board of Optometry (Board) proposes to amend §§ 23.1, 23.33--23.35, 23.42, 23.64 and 23.71 and to add § 23.72 to read as set forth in Annex A. The proposed rulemaking would generally update the Board's regulations to reflect current practices in the profession and to simplify the formation of professional corporations.

Effective Date

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

Statutory Authority

Section 3(a)(2.1) of the Optometric Practice and Licensure Act (act) (63 P. S. § 244.3(a)(2.1)) added by the act of October 30, 1996 (P. L. 721, No. 130) (Act 130) 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."

Background and Need for the Proposed Amendments

The Board's current regulations were promulgated prior to the amendments made by Act 130 and do not address the means and methods for the examination, diagnosis and treatment of conditions of the visual system. Act 130 placed additional duties on the Board. In addition, the Board routinely receives numerous requests for information regarding whether optometrists are permitted to perform specific procedures. Act 130 defines the practice of optometry very broadly. Act 130 specifies that the Board has the duty to address the more specific means and methods that optometrists may employ. This proposed rulemaking addresses both public inquiry and the amendments made by Act 130.

The Board's current regulations are outdated in that they do not set minimum requirements that optometrists shall follow in writing prescriptions and do not require

optometrists to record the pharmaceutical agents used in a patient's medical record (optometrists were granted use of limited pharmaceutical agents by Act 130). In addition, the Board's regulations do not reflect the Board's current recordkeeping system. These proposed amendments are necessary to bring the Board's regulations into compliance with the amendments made in Act 130.

Following numerous meetings of the Board's regulations committee and consideration by the entire Board, an exposure draft was sent to the Pennsylvania Optometric Association (Association), the Pennsylvania College of Optometry (College) and the Pennsylvania Academy of Ophthalmology (Academy). Following this solicitation of input from stakeholders, the Board placed notices of a public hearing in major newspapers of this Commonwealth inviting the general public to a public hearing on July 12, 2001. The Association, College and Academy sent representatives to the public hearing. No members of the general public attended the meeting. After considering the input received, the Board now proposes the amendments as set forth in Annex A.

Description of the Proposed Amendments

§ 23.1 (relating to definitions)

In accordance with the mandate of Act 130, the Board proposes to amend § 23.1 to define "means and methods for the examination, diagnosis and treatment of condifitions of the visual system." In formulating the provisions of the proposal, the Board considered extensive comments from the College, Academy and Association at its public hearing held on July 12, 2001. The Board's proposal includes diagnostic and treatment procedures that have been performed by optometrists for up to 25 years as well as newer technologies that have only become a standard part of optometric practice in the past few years.

The proposed amendment provides that optometrists may employ the following diagnostic techniques: the use of any computerized or automatic refracting device, visual field testing, ophthalmoscopy, anterior and posterior segment photography, provocative tests, electrodiagnostic tests, the use of lasers for diagnostic purposes, ultrasound examination of the eye and orbit and diagnostic tests to determine the patency of the lacrimal system. In addition, the proposed amendments provide that optometrists may order radiographs, computer assisted tomography scans, magnetic resonance imaging scans and laboratory work. Finally, the proposed amendments provide that optometrists may order, interpret and report on angiographic studies. The proposed amendments also address means and methods of treatment. The amendments provide that optometrists may employ vision therapy or orthoptics, low vision rehabilitation, epilation of lashes and may treat the lacrimal system including using punctal plugs. The specific procedures are authorized by Act 130 and are consistent with the practice of optometry in all states surrounding this Commonwealth.

§ 23.33 (relating to practice)

The Board proposes to amend § 23.33 to conform to current practice in the field of optometry. Subsection (a) of the current regulation restricts an optometrist to practice in a room used exclusively for the practice of optometry. The Board proposes to amend subsection (a) to clarify that this restriction applies only when the optometrist is practicing in his own office. The reality of today's practice is that optometrists practice in health care facilities as well as their offices and cannot, therefore, always practice in a room used

exclusively for the practice of optometry.

The Board also proposes to amend subsection (b) to further define the practice of an optometrist in a licensed health care facility. The proposed amendment merely reflects the current state of practice of the profession, defining "licensed health care facility" to include "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."

Finally, the Board proposes to amend § 23.33 by adding a subsection (e) to permit optometrists to provide visual screenings at any location, public or private, within this Commonwealth. Optometrists are frequently asked to perform simple visual screenings, which do not require the facilities of the optometric office or health care facility, at various events and locations. The amendment would permit optometrists to perform these screenings. The provision of vision screening services is a great benefit to the citizens of this Commonwealth.

§§ 23.34 and 23.35 (relating to professional corporations; and fictitious names)

The Board proposes to amend §§ 23.34 and 23.35 to reflect current optometric practice and to reflect the current recordkeeping procedures of the Board administrative office and the Department of State Corporation Bureau (Bureau). The Board proposes to amend § 23.34(a) to permit optometrists to incorporate with other health care professionals if authorized by the Commonwealth's laws pertaining to incorporation. The Board proposes to amend §§ 23.34 and 23.35 by deleting the requirements that optometrists file articles of incorporation or fictitious name registrations with the Board for approval prior to filing with the Bureau. Departmental practice is for the Bureau to send copies of all optometric filings to the Board for review. Because the Bureau is essentially a filing office and is not staffed to ensure compliance with the current §§ 23.34 and 23.35, there is no way to enforce the current provisions. In addition, the Board has found no public benefit to the current requirements of these sections.

§ 23.42 (relating to equipment)

The Board proposes to amend § 23.42 first by clarifying that the equipment listed in the section is the minimum required for performing a basic, rather than "complete" optometric examination. In addition, the Board proposes to replace the equipment ophthalmometer with the equipment keratometer. This change reflects current practice.

§ 23.64 (relating to professional conduct)

The Board proposes to add subsection (c) to § 23.64. Subsection (c) would allow an optometrist to terminate his care of a patient who is not adhering to appropriate regimens of care and follow-up. The proposed subsection would require the optometrist to notify the patient in writing and explain why the optometrist was terminating his care of the patient. Finally, the proposed subsection would require the optometrist to copy the patient's record and give the record either to the patient or to the subsequent treating optometrist.

§ 23.71 (relating to patient records)

The Board proposes to amend § 23.71 to reflect current practice. The changes reflect the

current terms used ("uncorrected" vision instead of "naked" vision) and refer to the use of perimtery, which is the standard in visual field testing. In addition, the Board proposes to amend § 23.71 by adding subsection (a)(19) which requires the optometrist to record in the patient's medical record any pharmaceutical agents used or prescribed, including strength, dosage, number of refills and adverse reaction, if applicable. The information updates the regulations in compliance with Act 130's grant of authority to use pharmaceutical agents and reflects proper medical practice in recordkeeping.

Finally, the Board proposes to amend § 23.71(c) by setting forth requirements for optometrists who provide a patient with a contact lens prescription. The current section provides that the optometrist has the discretion to determine whether to provide a patient with a contact lens prescription rather than dispensing the lens to the patient. Some optometrists have been reluctant to provide patients with a contact lens prescription, even when the patient requested the prescription, for fear of liability if the dispenser provides the patient with incorrect lenses. The proposed subsection (c)(1) requires the optometrist to determine all requirements for a satisfactory fit prior to providing a contact lens prescription. This provision protects the optometrist by clarifying the optometrist's responsibility in determining fit requirements for contact lenses. The proposed subsection (c)(2) provides that an optometrist shall consider all contact lenses used in determining the contact lens prescription to be diagnostic lenses. This provision protects the optometrist by clarifying that the optometrist has not determined the final prescription until the optometrist writes the prescription, because any trial lenses used are merely diagnostic.

§ 23.72 (relating to prescriptions)

The Board proposes to amend its regulations by adding requirements for prescriptions in § 23.72. Act 130 expanded the scope of practice of optometry to include "[t]he administration and prescription of legend and nonlegend drugs as approved by the Secretary of Health. . ." 63 P. S. § 244.2. Prior to 1996, optometrists only wrote prescriptions for contact lenses and spectacles, and the Board's regulations did not set requirements for these prescriptions. To standardize practice in this Commonwealth and ensure that all optometrists in this Commonwealth include information important to the patient on any prescription written, the Board proposes requirements on optometric prescriptions generally and proposes to set specific requirements for contact lens, spectacle and pharmaceutical prescriptions.

Proposed § 23.72 would require that all optometric prescriptions bear the name, address and license number of the optometrist, the name of the patient, date the prescription is issued and expiration date. Contact lens prescriptions would have to specify the lens type, all 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 in no case greater than 1 year. These requirements are consistent with the generally accepted standard of optometric practice and ensure that the contact lens dispenser will dispense the proper lenses for the patient as determined by the optometrist. In addition, the maximum of 1 year expiration date ensures that contact lens wearing patients will be rechecked by the optometrist at least yearly, the maximum time period recommended by medical professionals. For spectacles, the maximum time period recommended for reexamination is 2 years. This time period is reflected in § 23.71(b).

Fiscal Impact and Paperwork Requirements

The proposed amendments should have no fiscal impact on licensees, the Board, the private sector, the general public or any political subdivisions. The proposed amendments 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 this proposed rulemaking to the Independent Regulatory Review Commission (IRRC), the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) and the House Professional Licensure Committee (HPLC). In addition to submitting the proposed rulemaking, the Board has provided IRRC, SCP/PLC and HPLC with a copy of a detailed Regulatory Analysis Form prepared by the Board. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act (71 P. S. § 745.5(g)), if IRRC has objections to any portion of the proposed rulemaking, it will notify the Board within 30 days of the close of the public comment period. The notification shall specify the regulatory review criteria which have not been met. The Regulatory Review Act specifies detailed procedures for review of objections by the Board, the General Assembly and the Governor prior to publication of the regulations.

Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding this proposed rulemaking to Deborah Smith, Board Administrator, P. O. Box 2649, Harrisburg, PA 17105-2649, www.dos.state.pa.us, within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*.

STEVEN J. RETO, O.D.,
Chairperson

Fiscal Note: 16A-528. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 23. STATE BOARD OF OPTOMETRY

GENERAL PROVISIONS

§ 23.1. Definitions.

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

* * * * *

Means and methods for the examination, diagnosis and treatment of conditions of the visual system--

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

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

(B) Visual field testing such as manual or automated perimetry.

(C) Ophthalmoscopy, 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, any condensing lenses, gonioscopy lenses and fundus contact lenses.

(D) Anterior and posterior segment photography.

(E) Provocative tests for glaucoma and electrodiagnostic testing.

(F) The use of lasers for diagnostic purposes.

(G) The employment of vision therapy or orthoptics.

(H) Low vision rehabilitation.

(I) Treatment of the lacrimal system including the use of punctal plugs and diagnostic procedures to determine the patency of the lacrimal system.

(J) Epilation of lashes.

(K) Ultrasound examination of the eye and orbit, including A-scans with or without Intraocular Lens calculations and B-scans.

(L) Ordering of radiographs, computer assisted tomography scans ("CAT" scans), magnetic resonance imaging scans ("MRI" scans) and laboratory work.

(M) Ordering, interpretation and reporting of angiographic studies of ocular vasculature and blood flow.

(ii) The practice of optometry includes all levels of evaluation and management services and also includes, for those optometrists who are therapeutically certified, the administration and prescription of approved legend and nonlegend drugs.

* * * * *

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 his 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**.

* * * * *

(e) **An optometrist may provide visual screenings at any location, public or private, within this Commonwealth.**

(f) * * *

§ 23.34. Professional corporations.

(a) An optometrist licensed by the Board may professionally incorporate with other optometrists, medical doctors, doctors of osteopathy, dentists, psychologists, podiatrists **[and],** chiropractors**[,] and other health care professionals** if this incorporation is authorized by Chapter 5, 17, 25, 29, 33 or 41.

(b) **[The articles of incorporation and registry statement of the proposed corporation shall be filed with the Board for review and approval, prior to submission to the Corporation Bureau.**

(c) The name of a professional corporation will be approved by the Board.] If a name is chosen **for the professional corporation** which does not contain the names of all the licensed professionals with an ownership interest in the practice, the Board shall be supplied with a list of these persons. **[The Board will notify the optometrist of its approval, or disapproval, and this notice shall be submitted to the Corporation Bureau, together with the documents and fees required by that agency for filing articles of incorporation.**

(d)] An optometrist **[incorporating] practicing** under the terms of this section shall notify the Board of a change in the name or ownership of the **[corporation, and shall seek Board approval of these changes prior to practicing under a new name or ownership structure] business**.

§ 23.35. Fictitious names.

* * * * *

(b) **[A fictitious name registration shall be filed with the Board for approval, prior to submission to the Corporation Bureau.**

(c) A fictitious name will be approved by the Board.] A list of the optometrists with an ownership interest in the practice shall be submitted to the Board concurrently with the fictitious name registration. **[The Board will notify the optometrist of its approval, or disapproval, and this notice shall be submitted to the Corporation Bureau, together with the documents and fees required by that agency for filing a fictitious name registration.**

(d)] An optometrist practicing under the terms of this section shall notify the Board of changes in the name or ownership of the business**[, and shall seek Board approval of these changes prior to practicing under a new name or ownership structure]**.

OFFICE OF OPTOMETRIST

§ 23.42. Equipment

An office maintained for the practice of optometry shall be fully equipped for the making of a **[complete] basic** optometrical examination including**[, but not limited to,]** the following:

(1) **[Ophthalmometer] Keratometer.**

* * * * *

UNLAWFUL PRACTICES

§ 23.64. Professional conduct.

* * * * *

(c) An optometrist may terminate his or her 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) 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 reasonable fee for copying the record.

[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 5 years after the last consultation with a patient. Records shall indicate when a referral has been made to a physician. An examination may include**[, but is not limited to,]** the following:

* * * * *

(2) **[Naked] Uncorrected** visual acuity.

* * * * *

(14) Visual fields **[, central (after age 40)] including manual or automated perimetry.**

* * * * *

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

(b) An optometrist shall comply with a patient request for a copy of the patient's spectacle prescription, within 2 years of the patient's last eye examination. Requests for spectacle prescriptions from examinations over 2 years prior to the request**[, or for contact lens prescriptions,]** may be complied with at the discretion of the optometrist. **Requests for contact lens prescriptions may be complied with at the discretion of the optometrist.**

(c) **[An optometrist's license number shall appear on each prescription written by that optometrist.] An optometrist who, in his discretion, provides a contact lens prescription, shall comply with the following:**

(1) The optometrist shall determine the requirements for a satisfactory fit of a contact lens prior to providing a contact lens prescription.

(2) The optometrist shall consider the contact lenses used in determining the contact lens prescription to be diagnostic lenses.

§ 23.72. Prescriptions.

(a) Optometric prescriptions shall bear:

(1) The name, address 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 in no case shall the expiration date be greater than 1 year. The prescription may include a statement of caution or a disclaimer if the statement or disclaimer 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.

[Pa.B. Doc. No. 03-351. Filed for public inspection February 28, 2003, 9:00 a.m.]

Original: 2323

Comments of the Independent Regulatory Review Commission

on

State Board of Optometry Regulation No. 16A-528

General Revisions

April 30, 2003

We submit for your consideration the following Comments that include references to the criteria in the Regulatory Review Act (71 P.S. § 745.5b) which have not been met. The State Board of Optometry (Board) must respond to these Comments when it submits the final-form regulation. If the final-form regulation is not delivered within two years of the close of the public comment period, the regulation will be deemed withdrawn.

1. Section 23.1. Definitions. - Protection of the public health; Need; Clarity.

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

Examination, diagnosis and treatment

The House Professional Licensure Committee (House Committee) commented requesting "a detailed explanation of the training of optometrists in order to perform the 14 services listed in the proposed regulations, as well as an explanation as to how long each service has been part of optometric practice. Additionally, the Committee requests information as to the extent these services are considered to be within the scope of optometric practice in other states." The House Committee also listed the following specific concerns:

- Subsection (i)(C) appears to authorize optometric offices as facilities in which anesthesia may be administered.
- The House Committee noted the comments submitted by the Pennsylvania Medical Society (PMS) on Subsection (i)(F) requesting that the use of lasers be limited to diagnostic imaging purposes.
- Subsection (i)(H) would appear to limit low vision rehabilitation exclusively to the practice of optometry. The Committee fears this would have a negative impact on unlicensed individuals who are appropriately engaged in the practice of low vision rehabilitation.
- The House Committee noted the PMS comment that recommends deleting or modifying Subsection (i)(I) relating to diagnostic and non-surgical treatment of the lacrimal system.

- The House Committee questions why Subsection (ii) includes all levels of evaluation and management services, and not just those levels of evaluation and management services pertaining to the visual system.

We agree with the House Committee concerns and requests for additional supporting information regarding the scope of optometric practice.

Additionally, the public submitted comments questioning the list of procedures included in this definition as follows:

- Commentators believe Subsection (i)(E) should not allow optometrists to provoke attacks of glaucoma which they believe is outside the scope of the practice of optometry.

- Commentators believe that under Subsection (i)(K), an optometrist should not be allowed to order or calculate the lens implant power which they also believe is outside the scope of the practice of optometry.

- Commentators believe that under Subsection (i)(L), the ordering of computer assisted tomography (CAT) and magnetic resonance imaging (MRI) scans is the practice of medicine and is outside the scope of the practice of optometry.

- Under Subsection (i)(M), commentators believe that the ordering, interpretation and reporting of angiography studies is outside the scope of practice of optometry.

The Board should evaluate each comment and provide either an explanation of why each provision is appropriately within an optometrist's scope of practice under the Optometric Practice and Licensure Act, amend the provision to address the concern raised, or delete the provision.

Placement within the definition section

We have two concerns with the placement of this provision within the definitions section.

- Some of the provisions appear to be substantive, such as Subsection (i)(C). Substantive provisions within a definition are not enforceable. Therefore, it is not clear how this definition would be applied.

- We only found this term used once within the regulation in Section 23.83 *Continuing education subject matter*. We question the need to define this term rather than explain it where it is used in the regulation.

For these reasons, the Board should move the provisions in the proposed definition to a section in the body of the regulation under the title "Scope of practice."

2. Section 23.33. Practice. - Clarity.

Subsection (a) includes the phrase, "when practicing in *his* office." (Emphasis added.) The use of words that show gender distinction should only be used in a regulation that specifically applies to one sex. The Board should amend this phrase to be gender neutral.

Subsection (b) states, in part, the following, "...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." We have two concerns.

First, the phrase, "or any facility" is very broad. Is the intention of this Subsection to allow optometrists to provide services in facilities other than licensed health care service facilities? Where would an optometrist be precluded from providing services?

Second, the phrase "optometric services" is vague. Would an optometrist be permitted to perform all of the services described in the definition of "means and methods for the examination, diagnosis and treatment of conditions of the visual system?" Would an optometrist be required to comply with § 23.21, relating to display of license and § 23.42, relating to equipment? The Board should specify what services are allowed.

Under Subsection (e), the phrase "visual screening" is used. However, this phrase is not defined. How does a visual screening differ from "optometric services" noted in Subsection (b)? The final-form regulation should include a definition of the phrase "visual screening."

3. Section 23.34. Professional corporations. - Clarity.

Subsection (a) states, in part, the following, "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*...." (Emphasis added.) Besides the specific professions listed in this Subsection, what other "health care professionals" may professionally incorporate with a licensed optometrist? The regulation should clearly state or cross reference who specifically the Board considers to be a "health care professional."

4. Section 23.71. Patient records. - Clarity; Reasonableness; Protection of the public health.

We have two concerns with Subsection (b). First, this Subsection states that requests for contact lens prescriptions may be given at the discretion of the optometrist. If an optometrist provides a contact lens prescription to a patient, Subsection (c) requires that certain factors be considered before that prescription is provided. The Preamble states that these factors were included to protect the optometrist from liability. Since these protections were included in the regulation, why is a patient's request for contact lens prescriptions "at the discretion of the optometrist"?

Second, this Subsection states that a patient's request for a spectacle prescription shall be complied with if the request was made within two years of the patient's last eye examination. In

order to protect the public health, should a similar requirement be placed on contact lens prescription requests?

Subsection (c) includes the phrase, "in *his* discretion." (Emphasis added.) The Board should amend this phrase to be gender neutral.

5. Section 23.72. Prescriptions. - Clarity.

Subsection (a) describes the information that must be included in an optometric prescription. A phone number would allow the person filling the prescription to easily verify a prescription if a question arises. The Board should consider adding this requirement.

Subsection (b) addresses information that must be included in a contact lens prescription. It states, in part, the following, "...but in no case shall the expiration date be greater than 1 year." Does the one-year expiration date refer to the date of the contact lens examination or the date when the optometrist wrote the prescription? The final-form regulation should address this concern.

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Bill 1 of 50

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Fairness to Contact Lens Consumers Act (Received in Senate from House)

HR 3140 RDS

108th CONGRESS

1st Session

H. R. 3140

IN THE SENATE OF THE UNITED STATES

November 20, 2003

Received

AN ACT

To provide for availability of contact lens prescriptions to patients, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the `Fairness to Contact Lens Consumers Act'.

SEC. 2. AVAILABILITY OF CONTACT LENS PRESCRIPTIONS TO PATIENTS.

(a) IN GENERAL- When a prescriber completes a contact lens fitting, the prescriber--

(1) whether or not requested by the patient, shall provide to the patient a copy of the contact lens prescription; and

(2) shall, as directed by any person designated to act on behalf of the patient, provide or verify the contact lens prescription by electronic or other means.

(b) LIMITATIONS- A prescriber may not--

(1) require purchase of contact lenses from the prescriber or from another person as a condition of providing a copy of a prescription under subsection (a)(1) or (a)(2) or verification of a prescription under subsection (a)(2);

(2) require payment in addition to, or as part of, the fee for an eye examination, fitting, and evaluation as a condition of providing a copy of a prescription under subsection (a)(1) or (a)(2) or verification of a prescription under subsection (a)(2); or

(3) require the patient to sign a waiver or release as a condition of verifying or releasing a prescription.

SEC. 3. IMMEDIATE PAYMENT OF FEES IN LIMITED CIRCUMSTANCES.

A prescriber may require payment of fees for an eye examination, fitting, and evaluation before the release of a contact lens prescription, but only if the prescriber requires immediate payment in the case of an examination that reveals no requirement for ophthalmic goods. For purposes of the preceding sentence, presentation of proof of insurance coverage for that service shall be deemed to be a payment.

SEC. 4. PRESCRIBER VERIFICATION.

(a) PRESCRIPTION REQUIREMENT- A seller may sell contact lenses only in accordance with a contact lens prescription for the patient that is--

(1) presented to the seller by the patient or prescriber directly or by facsimile; or

(2) verified by direct communication.

(b) RECORD REQUIREMENT- A seller shall maintain a record of all direct communications referred to in subsection (a).

(c) INFORMATION- When seeking verification of a contact lens prescription, a seller shall provide the prescriber with the following information:

(1) Patient's full name and address.

(2) Contact lens power, manufacturer, base curve or appropriate designation, and diameter when appropriate.

(3) Quantity of lenses ordered.

(4) Date of patient request.

(5) Date and time of verification request.

(6) Name of contact person at seller's company, including facsimile and telephone number.

(d) VERIFICATION EVENTS- A prescription is verified under this Act only if one of the following occurs:

(1) The prescriber confirms the prescription is accurate by direct communication with the seller.

(2) The prescriber informs the seller that the prescription is inaccurate and provides the accurate prescription.

(3) The prescriber fails to communicate with the seller within 8 business hours, or a similar time as defined by the Federal Trade Commission, after receiving from the seller the information described in subsection (c).

(e) INVALID PRESCRIPTION- If a prescriber informs a seller before the deadline under subsection (d)(3) that the contact lens prescription is inaccurate, expired, or otherwise invalid, the seller shall not fill the prescription. The prescriber shall specify the basis for the inaccuracy or invalidity of the prescription. If the prescription communicated by the seller to the prescriber is inaccurate, the prescriber shall correct it.

(f) NO ALTERATION- A seller may not alter a contact lens prescription. Notwithstanding the preceding sentence, if the same contact lens is manufactured by the same company and sold under multiple labels to individual providers, the seller may fill the prescription with a contact lens manufactured by that company under another label.

(g) DIRECT COMMUNICATION- As used in this section, the term `direct communication' includes communication by telephone, facsimile, or electronic mail.

SEC. 5. EXPIRATION OF CONTACT LENS PRESCRIPTIONS.

(a) IN GENERAL- A contact lens prescription shall expire--

(1) on the date specified by the law of the State in which the prescription was written, if that date is one year or more after the issue date of the prescription;

(2) not less than one year after the issue date of the prescription if such State law specifies no date or a date that is less than one year after the issue date of the prescription; or

(3) notwithstanding paragraphs (1) and (2), on the date specified by the prescriber, if that date is based on the medical judgment of the prescriber with respect to the ocular health of the patient.

(b) Special Rules for Prescriptions of Less Than 1 Year- If a prescription expires in less than 1 year, the reasons for the judgment referred to in subsection (a)(3) shall be documented in the patient's medical record. In no circumstance shall the prescription expiration date be less than the period of time recommended by the prescriber for a reexamination of the patient that is medically necessary.

(c) DEFINITION- As used in this section, the term `issue date' means the date on which the

patient receives a copy of the prescription.

SEC. 6. CONTENT OF ADVERTISEMENTS AND OTHER REPRESENTATIONS.

Any person that engages in the manufacture, processing, assembly, sale, offering for sale, or distribution of contact lenses may not represent, by advertisement, sales presentation, or otherwise, that contact lenses may be obtained without a prescription.

SEC. 7. PROHIBITION OF CERTAIN WAIVERS.

A prescriber may not place on the prescription, or require the patient to sign, or deliver to the patient a form or notice waiving or disclaiming the liability or responsibility of the prescriber for the accuracy of the eye examination. The preceding sentence does not impose liability on a prescriber for the ophthalmic goods and services dispensed by another seller pursuant to the prescriber's correctly verified prescription.

SEC. 8. RULEMAKING BY FEDERAL TRADE COMMISSION.

The Federal Trade Commission shall prescribe rules pursuant to section 18 of the Federal Trade Commission Act (15 U.S.C. 57a) to carry out this Act. Rules so prescribed shall be exempt from the requirements of the Magnuson-Moss Warranty--Federal Trade Commission Improvement Act (15 U.S.C. 2301 et seq.). Any such regulations shall be issued in accordance with section 553 of title 5, United States Code. The first rules under this section shall take effect not later than 180 days after the effective date of this Act.

SEC. 9. VIOLATIONS.

(a) IN GENERAL- Any violation of this Act or the rules required under section 8 shall be treated as a violation of a rule under section 18 of the Federal Trade Commission Act (15 U.S.C. 57a) regarding unfair or deceptive acts or practices.

(b) ACTIONS BY THE COMMISSION- The Federal Trade Commission shall enforce this Act in the same manner, by the same means, and with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) were incorporated into and made a part of this Act.

SEC. 10. STUDY AND REPORT.

(a) STUDY- The Federal Trade Commission shall undertake a study to examine the strength of competition in the sale of prescription contact lenses. The study shall include an examination of the following issues:

(1) Incidence of exclusive relationships between prescribers or sellers and contact lens manufacturers and the impact of such relationships on competition.

(2) Difference between online and offline sellers of contact lenses, including price, access, and availability.

(3) Incidence, if any, of contact lens prescriptions that specify brand name or custom

labeled contact lenses, the reasons for the incidence, and the effect on consumers and competition.

(4) The impact of the Federal Trade Commission eyeglasses rule (16 CFR 456 et seq.) on competition, the nature of the enforcement of the rule, and how such enforcement has impacted competition.

(5) Any other issue that has an impact on competition in the sale of prescription contact lenses.

(b) REPORT- Not later than 12 months after the effective date of this Act, the Chairman of the Federal Trade Commission shall submit to the Congress a report of the study required by subsection (a).

SEC. 11. DEFINITIONS.

As used in this Act:

(1) CONTACT LENS FITTING- The term `contact lens fitting' means the process that begins after the initial eye examination and ends when a successful fit has been achieved or, in the case of a renewal prescription, ends when the prescriber determines that no change in prescription is required, and such term may include--

(A) an examination to determine lens specifications;

(B) except in the case of a renewal of a prescription, an initial evaluation of the fit of the lens on the eye; and

(C) medically necessary follow up examinations.

(2) PRESCRIBER- The term `prescriber' means, with respect to contact lens prescriptions, an ophthalmologist, optometrist, or other person permitted under State law to issue prescriptions for contact lenses in compliance with any applicable requirements established by the Food and Drug Administration.

(3) CONTACT LENS PRESCRIPTION- The term `contact lens prescription' means a prescription, issued in accordance with State and Federal law, that contains sufficient information for the complete and accurate filling of a prescription, including the following:

(A) Name of the patient.

(B) Date of examination.

(C) Issue date and expiration date of prescription.

(D) Name, postal address, telephone number, and facsimile telephone number of prescriber.

(E) Power, material or manufacturer or both.

(F) Base curve or appropriate designation.

(G) Diameter, when appropriate.

(H) In the case of a private label contact lens , name of manufacturer, trade name of private label brand, and, if applicable, trade name of equivalent brand name.

SEC. 12. EFFECTIVE DATE.

This Act shall take effect 60 days after the date of the enactment of this Act.

Passed the House of Representatives November 19, 2003.

Attest:

JEFF TRANDAHL,

Clerk.

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COMMONWEALTH OF PENNSYLVANIA
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April 25, 2003

Honorable Steven J. Reto, O.D., Chairman
State Board of Optometry
PO Box 2649
Harrisburg, PA 17105-2649

Subject: Regulation 16A-528, General Revisions

Dear Dr. Reto:

At its April 22, 2003, meeting the State Board of Medicine had the opportunity to review proposed regulation 16A-528 of the State Board of Optometry, which would revise definitions affecting the scope of practice of optometry. Respectfully, the State Board of Medicine is concerned that the proposed regulation appears to expand the practice of optometry into the medical field in a manner that creates unacceptable risks to patients and into areas in which optometrists have no independent need to provide services. Indeed, your proposal would permit optometrists to perform and/or order procedures that should be provided by or under the supervision of physicians.

Under section 23.1(3) the proposed regulation would allow optometrists to perform examinations under anesthesia. There is no optometric need for an examination to be performed under anesthesia. Such examinations are performed only to determine whether visual problems are related to underlying medical conditions that may warrant medical treatment. Additionally, patients who undergo anesthesia are always placed at some risk, which can include death. The determination that an examination under anesthesia is necessary is a determination that must be made taking into consideration the entire medical condition and history of the patient and is thus inherently a medical determination. Accordingly, the decision to subject a patient to such risks must be made by a physician.

Section 23.1(5) authorizes provocative glaucoma and electrodiagnostic testing. Such tests induce eye pressure, and will in some percentage of patients result in an acute glaucoma attack, which can result in permanent blindness within hours. If such an attack occurs the patient requires immediate medical intervention that is beyond the scope of optometric care. Further, the

treatment of acute glaucoma is beyond the scope of optometric care, therefore there is no reason for an optometrist to perform such tests.

Section 23.1(6) authorizes the use of lasers for diagnostic purposes. The use of lasers is inherently dangerous and even in diagnostic applications has been known to cause anatomical changes to the eye. Moreover, optometrists are not trained to address the complications, such as retinal detachment and cataracts, that can result from the use of lasers.

Section 23.1(9) authorizes the probing of the lacrimal system. This surgical procedure always presents the potential scarring of the duct. Further, if not performed carefully, the metal probe can penetrate the brain. Moreover, the patients who are most often in need of such a procedure are infants. Section 23.1(10) authorizes the epilation of lashes. No matter how simple this procedures may seem, it is a surgical procedure that can create serious risk of infection and other harm to the patients. Furthermore, the performance of these procedures without a medical examination may delay the proper diagnoses of medical conditions underlying the presenting symptomology of the patient.

Sections 23.1(11) and (12) authorize the performance of diagnostic scans that are not only complex, but also involve systems of the human anatomy beyond the visual system, such as brain function. The purpose of such examinations is to determine whether there is a need for surgical intervention (such as in the case of retinal detachment) or to determine lens implant power, and for other surgical purposes. 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.

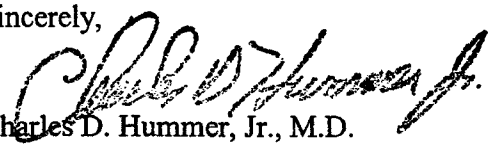
Section 23.1(13) authorizes angiographic studies that involve intravenous introduction of dyes. Some percentage of patients will have an adverse effect from the intravenous dyes, including anaphylaxic shock that can lead to the death of the patient. Even in the field of ophthalmology these are specialized tests that are usually performed by retinal specialists who maintain adequate emergency response measures.

Section 23.1(14) suggests the broad use of drugs by optometrists. We believe the regulation should clearly state that the use of drugs is limited to those approved for optometric care. Because of drug interaction and drug side effects it is imperative that the patient's physician, especially in the case of the elderly, be involved with decisions to prescribe medications.

We understand that some optometrists may with the appropriate involvement of physicians, as contemplated by sections 17 and 21 of the Medical Practice Act, perform functions in support of the overall care of our joint patients. However, we are greatly concerned that the proposed regulation as it stands invites optometrists to practice independently in areas beyond that which are appropriate or safe.

Thank you for considering these comments. We understand that the comment period has ended. We trust that you will appreciate that because we meet on a monthly basis, as do you, this was the first opportunity we have had to develop meaningful comments to your proposal.

Sincerely,



Charles D. Hummer, Jr., M.D.
Chairman

c. Hon. Kenneth A. Rapp,
Deputy Secretary for Regulatory Programs
John R. McGinley, Jr., Chairman
Independent Regulatory Review Commission
Hon. Mario J. Civera, Jr., Chairman
Professional Licensure Committee
Hon. Robert M. Tomlinson, Chairman
Consumer Protection and Professional Licensure Committee
Scott Messing, Deputy Commissioner
Bureau of Professional and Occupational Affairs
Andrew Sislo, Chief Counsel
Department of State

Pennsylvania Academy of Ophthalmology

"Preserving the Integrity of Ophthalmology"

EYE MDs

Ms. Deborah Smith
Board Administrator
State Board of Optometry
P.O. Box 2649
Harrisburg, PA. 17105-2649

Re: Pennsylvania Bulletin, March 1, 2003; State Board of Optometry Regulations Proposed General Revisions (16A-528)

As President of the Pennsylvania Academy of Ophthalmology, I am writing to comment on the proposed rulemaking by the State Board of Optometry submitted on February 12, 2003 pertaining to general revisions.

Within the preamble of the proposed general revisions, it was stated that the State Board of Optometry (Board) sent a draft of the revisions to the Pennsylvania Academy of Ophthalmology (Academy) soliciting input for consideration. The Academy strongly opposed these revisions and requested Mark C. Maria, M.D. provide testimony on their behalf at the July 12, 2001 public hearing. Although the Board indicates that they had considered the input received, they failed to recognize any of the recommendations made by Dr. Maria on behalf of the Academy. The Academy's continued position is summarized below.

General Provisions – 23.1 Definitions

#3 - The revisions within this section would allow optometrists to order the administration of intravenous and inhalational anesthetic agents to allow examinations under anesthesia. Optometrists cannot order or administer these agents and are specifically forbidden to delegate this authority under the Medical Practice Act. The risks of general anesthesia include death and the need to subject a patient to a potentially fatal anesthetic procedure is solely the purview of the physician; not the optometrist.

#5 - The revisions within this section would allow optometrists to provoke attacks of glaucoma. Acute attacks of glaucoma can cause permanent blindness within hours. Optometrists are specifically forbidden from treating acute glaucoma and logically should not be permitted to provoke such attacks.

#9 - Treatment of the nasolacrimal system as proposed requires the use of surgical procedures. For instance, the proposed revisions 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. This is a surgical maneuver with the potential for permanent scarring of the tear duct or passage of the probe into the brain. Also, placement of punctal plugs is a surgical procedure under the CPT manual, which is the bible of medical and surgical insurance coding. Surgery is forbidden by the optometric practice act and, for the above reasons, this revision should not be allowed.

#11 – In reference to ultrasound examinations, the selection of the implant power for cataract surgery is the responsibility of the surgeon. While optometrists and technicians may perform the ultrasound scans, only the surgeon can analyze the data and order the lens implant. Errors in lens power can cause disabling double vision and the need for re-operation to correct the mistake.

#12 - The ordering of CT and MRI scans is the practice of medicine. These tests generally require the administration of intravenous contrast agents with the potential to cause kidney failure and death. Ordering of tests with the need for intravenous agents is specifically outside of the scope of practice of optometry. Some of these tests expose patients to the risks of radiation, which is a more significant concern in children.

#13 - A similar argument is valid for the ordering of angiography procedures. Optometrists are requesting the ability to order a nurse to administer intravenous contrast agents. Again, optometrists cannot order or administer intravenous agents and cannot delegate this authority. The revision would also allow the ordering of arteriograms of the carotid arteries, which carry the risks of stroke and death. Non-physicians should not be given such authority.

#14 - The final revision that we would like to oppose is the use of all levels of evaluation and management codes by optometry. The highest levels of these codes require physical examination of the entire body along with a comprehensive medical history. These physical examination skills and the ability to perform a comprehensive medical history are taught in medical school and are not the domain of the optometrist. However, we have no objection to use of the low to intermediate level codes or the ophthalmic codes by optometry.

Thank you for allowing our Academy's comments. We hope that you will deny passage of these revisions in order to protect the safety of the citizens of our Commonwealth. We remain available for any further input that you or your committee may require.

Sincerely,

John C. Maher, M.D.
President

Cc: Chair, Senate Consumer Protection and Professional Licensure Committee
Chair, House Professional Licensure Committee
Chair, Independent Regulatory Review Commission
Chair, State Board of Optometry
Chair, State Board of Medicine
Physician-General, Department of Health
Acting Deputy Commissioner, Bureau of Professional and Occupational Affairs
Chief Counsel, Department of State

Pennsylvania Academy of Ophthalmology

"Preserving the Integrity of Ophthalmology"

EYE MDs

Ms. Deborah Smith
Board Administrator
State Board of Optometry
P.O. Box 2649
Harrisburg, PA. 17105-2649 Original: 2323

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Sincerely,

John C. Maher, M.D.
President

Cc: Chair, Senate Consumer Protection and Professional Licensure Committee
Chair, House Professional Licensure Committee
Chair, Independent Regulatory Review Commission
Chair, State Board of Optometry
Chair, State Board of Medicine
Physician-General, Department of Health
Acting Deputy Commissioner, Bureau of Professional and Occupational Affairs
Chief Counsel, Department of State

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EYE PHYSICIANS AND SURGEONS, LTD.

Christ A. Balouris, M.D. - John C. Maher, M.D. - Gana R. Nadiga, M.D.
Laurie A. Roba, M.D. - John C. Stuart, M.D.

4-14-03

Dear Ms. Smith.

It is with surprise and regret that your board has ignored and rejected the testemony of Dr Maria concerning the Board of Optometry regulation changes. (Title 16 of the PA code) Instead of updating the code to reflect New legislation concerning glaucoma, you have taken this as an opportunity to increase the scope of practice of optometry. The following are problems that I feel exist in the current language. These are the same issue that were given in testemony by Dr Maria over 14 yrs ago!

1) "The practice of optometry includes all levels of evaluation and Management services. (Line 14)

This is not possible. Optometry does not practice or teach physical diagnosis. To use the Level 4 or 5 E and M codes requires a complete Review of Systems - An evaluation Well beyond any Optometrist. Even level 3 requires a focused Review of systems. By this statement, your board is stating that optometry teaches physical diagnosis of the entire patient! This is obviously inaccurate. To have an Optometrist use this code boarders on fraud.

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Laurie A. Roba, M.D. - John C. Stuart, M.D.

(2) Line 11

Ultrasound examination of the eye and orbit, including A scan with or without intraocular lens calculation and B-scan.

Because, at this time, Optometry does not do Cataract surgery, and the only reason to do A-scans are for IOL calculation, there is no justification for this. The optometric practice act excludes surgery and the Ascan is part of the pre op evaluation of the patient and an integral part of the surgical process. This would increase the cost of patient care by needless duplication of services in an area not germain to optometry.

(3) Line 12

Ordering of radiographs, computer assisted tomography scans, magnetic resonance imaging scans and laboratory work.

The purpose of ordering these scans are to evaluate significant medical issues or in the possible planning of surgery. The optometric practice act does not allows Optometrists to practice medicine or do surgery. These test also envolve injection of contrast, and the ordering of such injections is not allowed by Optometry. This provision will expose patients to possibly unnecessary tests and miss diagnosis. The jobs of interpritation of these tests are not only the responsibility of the radiologist but the physician that orders them. Optometrists have no qualification to do this

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(4) Line 12. Ordering, interpretation, and reporting of angiographic studies of ocular vasculature and blood flow.

On two levels this should be removed. One is that since this test requires an intravenous injection of contrast, and optometrists are not allowed to inject medications or dyes, they therefore are not allowed to order others to do it.

Two, it is not clear that this does not exclude Angiography of the orbit, which is part of the ocular vasculature. Arteriography carries a 10% mortality rate, and a person with limited medical knowledge both of patients in general or of individuals should never be allowed to order such a test.

This will lead to costly, dangerous, and misleading diagnosis.

(5) (Line 5) provocative tests for glaucoma and electrodiagnostic testing.

The fact that provocative testing is still asked for reflects a lack of current knowledge of the practice of glaucoma therapy. This almost never done because of the risk of acutely precipitating glaucoma surgery. Optometrists are not allowed to do surgery, and should not be doing tests that can cause the need for emergency surgery.

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(6) Line (3)

Ophthalmoscopy, 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;

Again, optometrist do not have the training to deal with the anesthitized patient. They are trained to work in the operating room environment. Even though you have another person, an M.D., giving the anesthesia, the surgeon is the Captain of the ship. He is the final responsible person. He is the one who placed the patient at risk.

Because a majority of patient who require exams under anesthesia are infants, children, or mentally retarded patient, I find it beyond comprehension how an Optometric education would grant this level of decision making.

Under the medical practice act, the OD is also not allowed to order i.v. treatment which is required by anesthesia.

(7) Line 9

Treatment of the lacrimal system including the use of punctal plugs and diagnostic procedures to determine the patency of the lacrimal system.

(5)

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Again this line overstep the training and law concerning the practice of optometry. Both punctal plugs and lacrimal probing and irrigation are considered surgical procedures by Medicare. OD's are not permitted to do surgery.

Probing of the lacrimal system is dangerous and is done under general anesthesia in children. An infants it can result in a metal probe being passed into the brain. Probing is surgery which manipulates tissue. Optometrists are not trained surgeons.

The obvious lack of understanding of the medical practice act, the laws governing optometry and any understanding of the consequences of these actions is truely frightening. The risk to patients is obvious. It leads one to be concerned the boards main objective is to increase the scope of billable procedures and not the safe practice of optometry.

I look forward to your response to my comments

Sincerely yours.

John C Maher MD

PENNSYLVANIA OPTOMETRIC ASSOCIATION

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AFFILIATED WITH THE AMERICAN OPTOMETRIC ASSOCIATION

March 19, 2003

Original: 2323

Ms. Deborah Smith, Board Administrator
State Board of Optometry
P.O. Box 2649
Harrisburg, PA 17105

RE: Comments of the Pennsylvania Optometric Association regarding the proposed rulemaking under 49 Pa. Code Chapter 23, General Revisions.

Dear Ms. Smith:

The Pennsylvania Optometric Association (POA) received notice that the State Board of Optometry proposes to amend sections 23.1, 23.33-23.35, 23.42, 23.64, and 23.71, updating the Board's regulations to reflect current practices in the profession and to simplify the formation of professional corporations. The POA is in full support of the amended language defining "means and methods for the examination, diagnosis and treatment of conditions of the visual system." (§23.1). We also support the amendment that clarifies the restriction that an optometrist practice in a room used exclusively for the practice of optometry to apply only when the optometrist is practicing in his/her own office. The POA supports §23.33 which permits optometrists to provide visual screenings at any location, public or private, within the Commonwealth.

The amendment relating to professional corporations and fictitious names, §23.34 and §23.35, is supported by the POA. We also support the amendment to §23.42 which clarifies that the equipment listed in the section is the minimum required for performing a basic, rather than "complete" optometric examination. In addition, the POA supports the amendment to §23.64 and §23.71, relating to termination of care of a patient who is not adhering to appropriate regimens of care and follow-up and recording a patients used or prescribed pharmaceutical agents.

The POA is in full support of Section 23.72, proposing requirements on optometric prescriptions generally and the specific requirements for contact lens, spectacle and pharmaceutical prescriptions.

We request that the final form regulation and comment and response documents are forwarded to us, and that we continue to be kept apprised of all future correspondence relating to this matter.

Thank you for your continued support.

Sincerely,

PENNSYLVANIA OPTOMETRIC ASSOCIATION

Gregory L. Bittner, O.D.,
President

GB/alz

Pennsylvania
MEDICAL SOCIETY®

April 8, 2003 Original: 2323

Ms. Deborah Smith
Board Administrator
State Board of Optometry
P.O. Box 2649
Harrisburg, PA. 17105-2649

Re: Pennsylvania Bulletin, March 1, 2003; State Board of Optometry Regulations Proposed General Revisions (16A-528)

Dear Ms. Smith:

I am writing as President of the Pennsylvania Medical Society to comment on the proposed revisions to the regulations governing the practice of optometry in the Commonwealth.

Under section **23.1 Definitions**. There are three methods for the examination, diagnosis, and treatment listed that we believe are outside the practice of optometry. The first is item (6) the use of lasers for diagnostic purposes. As you know, the Optometric Practice Act specifically excludes the use of lasers for surgery and therapeutic treatment. We are aware of the use of a laser for diagnostic imaging of the optic nerve in the diagnosis of glaucoma. In an effort to clarify the diagnostic use of lasers, we would recommend the addition of the word "imaging" so that item (6) would read the use of lasers for diagnostic imaging purposes. The second item is (9) treatment of the lacrimal system including the use of punctual plugs and diagnostic procedures to determine the patency of the lacrimal system. The majority of procedures listed in the Current Procedural Terminology (CPT) Manual for the treatment of the lacrimal system involve incision, excision, repair, probing, and/or related procedures. Many of the procedures require the administration of anesthesia, and include post-operative follow-up of up to 90 days. Since all of these terms relate to the performance of surgery, and since the Optometric Practice Act specifically excludes the performance of surgery, the section should be deleted or at least modified to include only diagnostic and non-surgical treatment of the lacrimal system.

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The third issue is (14) which defines the practice of optometry as including all levels of evaluation and management services. Evaluation and management services are divided into levels with increasing complexity of diagnostic decision-making and time involvement. Services performed during the visit range from a problem focused history and examination and straightforward decision making to a comprehensive history and examination and medical decision making of high complexity. The higher levels of E & M visits include examination of more than the eye and related systems and require the knowledge an experience to recognize how other body systems affect and are affected by the visual system. This evaluation and treatment process is beyond the scope of practice permitted by the Optometric Practice Act and therefore should either be deleted or modified the limit performance of E & M services to those based on focused problems related to the visual system.

Another area of concern is under section **23.33. Practice**. Subsection (b) adds language expanding areas where optometrists may provide services to include in-patient and out-patient hospitals, emergency rooms, and long term facilities and nursing homes. The Health Care Facilities Act which regulates the facilities mentioned in this newly inserted language outlines who may be assigned clinical privileges or duties in those facilities and describes the process by which those privileges/duties are assigned. Reference should be made to the Health Care Facilities Act to distinguish between the scope of practice delineated by the Optometric Practice Act and the right to practice in a facility regulated by the Facilities Act.

On behalf of the Pennsylvania Medical Society, I appreciate the opportunity to comment on these proposed regulations.

Sincerely,

Edward H. Dench, Jr., MD
President

Cc: Chair, Senate Consumer Protection and Professional Licensure Committee
Chair, House Professional Licensure Committee
Chair, Independent Regulatory Review Commission
Chair, State Board of Optometry
Chair, State Board of Medicine
Physician-General, Department of Health
Acting Deputy Commissioner, Bureau of Professional and Occupational Affairs
Chief Counsel, Department of State