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House of Representatives
COMMONWEALTH OF PENNSYLVANIA
HARRISBURG

(11)

CHAIRMAN
PROFESSIONAL LICENSURE COMMITTEE

November 16, 2004

Honorable Basil L. Merenda
Commissioner, Bureau of
Professional and Occupational Affairs
Pennsylvania Department of State
Penn Center
2601 North Third Street
Harrisburg, Pennsylvania 17110

Re: Regulation 16A-528, final rulemaking of the State Board of Optometry relating to general revisions

Dear Commissioner Merenda:

Per your request, we are sending this letter to outline our concerns regarding this regulation. We hope this information will be helpful to you, and we stand ready to assist you. We wish to sincerely thank you for your leadership.

Legal backdrop

Before stating our concerns, it is important to review the legal backdrop against which Regulation 16A-528 was promulgated. The starting point, of course, is the Optometric Practice and Licensure Act ("the act"). The act defines the term "practice of optometry" as follows:

(1) The use of any and all means or methods for the examination, diagnosis and treatment of conditions of the human visual system and shall include the examination for, and adapting and fitting of, any and all kinds and types of lenses including contact lenses.

(2) The administration and prescription of legend and nonlegend drugs as approved by the Secretary of Health as provided in section 4.3 for treatment of the eye, the eyelids, the lacrimal system and the conjunctiva and the removal of superficial foreign bodies from the ocular surface and adnexa so long as treatment of diseases or conditions of the visual system, other than glaucoma, as authorized under this paragraph shall not continue beyond six weeks from the initiation of treatment unless the prescribing optometrist documents consultation with a licensed physician. As used in this paragraph, the initiation of treatment may, but need not, include the prescription or administration of pharmaceutical agents for therapeutic purposes.

(3) The term shall not include:
   (i) surgery, including, but not limited to, laser surgery; the use of lasers for therapeutic purposes; and the use of injections in the treatment of ocular disease;
   (ii) the use of Schedule I and Schedule II controlled substances;
   (iii)treatment of systemic disease; and
   (iv)treatment of glaucoma, except that optometrists may use all topical pharmaceutical agents in the treatment of primary open angle glaucoma, exfoliation glaucoma and pigmentary glaucoma.

Section 2 of the act.

The staring point, then, is the plain meaning of the act. The key language is "any and all means or methods for the examination, diagnosis and treatment of conditions of the human visual system."

However, this broad grant of authority is limited by the language found in paragraphs (2) and (3) of the term "practice of optometry." The language of paragraph (2) states that an optometrist may only prescribe drugs approved by the Secretary of Health for treatment of the eye, the eyelids, the lacrimal system, and the conjunctiva as long as treatment by the optometrist does not continue beyond six weeks. In order for an optometrist to treat such conditions with drugs for a longer period, the optometrist must consult with a licensed physician.

Similarly, the language of paragraph (3) states that the practice of optometry does not include surgery. The term "surgery" includes laser surgery or the use of lasers for therapeutic purposes or the use of injections. Further under paragraph (3), the practice of optometry does not include the use of Schedule I or II controlled substances, the treatment of systemic disease, or the treatment of glaucoma, except the use of pharmaceutical agents to treat primary angle, exfoliation or pigmentary glaucoma.

As with any regulation of a licensed professional, the practice act sets out specific parameters, but does not set out the only parameters. The Optometric Practice and Licensure Act does not exist in a vacuum and must be seen within the broader context and limits of the other practice acts. Optometrists, just like any other licensed health care professional, are not permitted to practice chiropractic, podiatry, or medicine, for example, unless specifically licensed to do so.

Most importantly, the provisions of the Optometric Practice and Licensure Act must be viewed through the prism of protecting and promoting public health and safety.

<u>Areas of concern</u>

Following is a list of our areas of concern. For certain provisions, we offer a specific recommendation with respect to the treatment of the language in the final regulation. For others, we do not. With all of the areas of concern - - even where we offer a recommendation - - we leave it to the board and to you to determine the language which will finally be delivered to the House Professional Licensure Committee for approval or disapproval.

(1) Definition of "visual rehabilitation." (Page 3 of the annex, Section 23.1)

The term "visual rehabilitation" means diagnosis of visual impairment, prescription of lenses, prisms, filters, and the design of treatment plans to compensate for visual defects.

Our concern is that this language may not permit occupational therapists and those working in schools to continue to provide low vision therapeutic services.

We have no specific recommendation, but ask that the language be reviewed to ensure that those non-optometrists who currently provide low vision therapeutic services be permitted to continue to do so.

(2) Means and method for the examination, diagnosis and treatment of conditions of the visual system. (Page 3 of the annex, Section 23.3)

This section sets forth the specific means and methods an optometrist may use to examine, diagnose and treat conditions of the visual system. The language which we have concerns about includes that having to do with: (1) testing for glaucoma and electrodiagnostic testing, (2) treatment of the lacrimal system, (3) ultrasound examination of the eye and orbit including A-scans, with or without intraocular lens calculations, and B-scans, (4) ordering of radiographs, CAT scans, MRIs, and laboratory work, and (5) ordering, interpreting and reporting of angiographic studies of blood flow, but excluding the administration of intravenous materials.

Before turning to specific language, we want to re-state that our paramount concern is the health and safety of Pennsylvanians. We want to offer our thoughts in that light and ask that the board continue to act first and foremost with the health of Pennsylvanians in mind.

A. Testing for glaucoma and electrodiagnostic testing:

Glaucoma - - The preamble states that the board wanted to remove provactive testing for glaucoma. The language "testing for glaucoma and electrodiagnostic testing," however, does not provide any limitation on the kinds of tests permitted with respect to glaucoma. Simply put, it may be the board's intention to prohibit provactive testing, but the language of Section 23.3(a)(5) does not accomplish this. Rather, this language would permit all kinds of glaucoma testing, including provactive tests.

We recommend that the board add language to effectuate its intent to prohibit provocative testing.

B. Treatment of the lacrimal system:

As set forth in the preamble, the board did not intend to allow treatment of the lacrimal system to include probing the tear duct, or incision or excision, as such would constitute surgery. However, the language "treatment of the lacrimal system including the use of

punctual plugs, dilation of the punctum and irrigation of the lacrimal system" does not limit the use of probes or prevent incision or excision. Under statutory construction principles, the word "including" means "including but not limited to." Hence, this language can be used as justification to use probes and to perform surgery on the lacrimal system.

We recommend that the board add language to effectuate its intent to limit treatment of the lacrimal system to those means and methods that would not constitute surgery.

C. Ultrasound examination of the eye and orbit including A-scans, with or without intraocular lens calculations, and B-scans

Intraocular lens calculations - - Our understanding is that intraocular calculations are needed in order to perform cataract surgery. The question then arises whether an optometrist can properly make these calculations when the optometrist cannot perform the surgery. Additionally, we question whether, because the optometrist cannot perform surgery, the patient will need to undergo another exam/testing if an opthamologist decides to perform his own calculations. Hence, we are also concerned about the patient's having to undergo multiple exams/procedures, as well as driving up the cost of health care unnecessarily.

We have no specific recommendations, but ask the board to consider whether some type of limitation is appropriate. For example, perhaps the calculations can be made after consultation with or under the direction of a physician.

Ultrasound examinations - - As with intraocular lens calculations, we are concerned that patients may have to undergo the procedure more than once if they are later seen by a physician.

Again, while we have no specific recommendation, we ask the board to consider whether some type of limitation is appropriate, such as ordering these tests after consultation with or at the direction of a physician.

D. Ordering of radiographs, CAT scans, MRIs, and laboratory work

Again, we echo the concerns raised in the section pertaining to intraocular lens calculations and ultrasound examinations. We are concerned about the risk to patients when ordering these tests, and we ask whether optometrists have sufficient training to properly analyze such tests or know if such tests are in fact indicated. For example, if an optometrist orders a CAT scan to rule out a condition of the eye, and he is able to rule out a specific problem because the problem he is looking for does not appear, we ask whether the review and interpretation of the results are consistent with an optometrist's training and education. Similarly, with respect to radiographs and laboratory work, we question whether an optometrist will be able to "rule something in" from the results even if the problem he is looking for is ruled out. For example, if an optometrist orders a test of a patient's urine for diabetes, and is able to rule out

diabetes from the results, could the optometrist miss another condition that could be revealed from such a test.

While we have no specific recommendation, we ask the board to consider whether there should be some limitation placed on ordering radiographs, MRIs, CAT scans, and laboratory work. Perhaps these should be ordered upon the direction of a physician.

E. Ordering, interpretation and reporting of angiographic studies of ocular vasculature and blood flow, but excluding the administration of intravenous materials

It is our understanding that angiographic studies involve injecting dye into a patient. Our further understanding is that the language, "but excluding the administration of intravenous materials," is intended by the board to ensure that the optometrist does not actually inject the dye.

We have a concern with respect to the risk to the patient. Our understanding is that these tests can be contraindicated for certain patients and that it is not uncommon for some patients to have adverse reactions to the dye. We question whether an optometrist can make a judgment about the risk to a specific patient given that an optometrist's training is largely limited to the visual system.

(3) The practice of optometry may include all levels of evaluation and management services (Page 5 of the annex, Section 23.3(b))

The wording of this subsection is," The practice of optometry may include all levels of evaluation and management services and also includes, for those optometrists who hold therapeutic or glaucoma certification, the administration and prescription of approved legend and nonlegend drugs."

It is our understanding that the first part of the sentence, "The practice of optometry may include all levels of evaluation and management services..." is directed at insurance companies in order to provide for reimbursement. It is our further understanding that the board included this provision because the Department of State can no longer issue advisory opinions regarding whether a service that would be billed to an insurance company would fall under the definition of "practice of optometry," thereby necessitating payment.

We have strong reservations about this language for the following reasons. First, the words, "The practice of optometry may include all levels of evaluation and management services" does not coincide with the statutory definition of "practice of optometry." Under the act, the practice of optometry is the use of any and all means and methods for the examination, diagnosis and treatment of conditions of the human visual system, excluding surgery, and including limitations placed on prescriptive authority.

The words "all levels of evaluation and management services" cannot be reconciled with the statutory definition. Further, "management services" would, in a fair reading, include billing,

hiring of personnel, management of the optometric office and practice, paying state and federal taxes and the like. This clearly is not what the General Assembly had in mind with respect to the term "practice of optometry."

Second, we seriously question the attempt by the board to regulate insurance companies. The Department of Insurance regulates insurance companies in the Commonwealth. While the board may not have intended such a result, the language essentially allows the board to regulate the practice of insurance companies, something it has no statutory authority to do.

Third, insurance reimbursement is governed by contract between the provider and the insurance company. The provider and the insurance company are in privity with one another, and are overseen by the Department of Insurance. There simply is no role for the board to play here.

Our recommendation is that the board strike subsection (b) from the regulation.

(4) Professional conduct (Page 9 of the annex, Section 23.64(c))

This language allows an optometrist to terminate the care of a patient who, in the professional opinion of the optometrist, is not adhering to appropriate regimens of care and follow-up. The subsection goes onto state that the optometrist must notify the patient in writing and the reasons for the termination. In addition, the optometrist must make a copy of the patient's records available and may charge a reasonable fee.

We have concerns about this language. To begin, a review of the regulations of the State Board of Medicine and the State Board of Dentistry do not include a similar provision. With respect to those two boards, the regulations contain language which prohibits abandonment of patients. Abandonment subjects the dentist or physician to disciplinary action.

With respect to dentists, 49 Pa. Code 33.221 Unprofessional Conduct provides that unprofessional conduct includes withdrawing dental services after a dentist-patient relationship has been established so that the patient is unable to obtain necessary dental care in a timely manner.

Similarly, 49 Pa. Code 16.61(a)(17) Unprofessional and Immoral Conduct provides that unprofessional conduct includes abandoning a patient. Abandonment occurs when a physician withdraws his services after a physician-patient relationship has been established, by failing to give notice of the physician's intention to withdraw in sufficient time to allow the patient to obtain medical care.

Our concern with the regulation is that withdrawal can easily become abandonment.

We recommend that the provision be written from the same perspective as that of the dental and medical professions. The provision should set out the steps an optometrist must take to withdraw his services, and also state that failure to conform to the provision shall constitute abandonment and subjects the optometrist to disciplinary action.

Further, the provision should state a reasonable time for continued care by the optometrist, 60 or 90 days, as an example. The provision should require written notice, sent by mail, return receipt requested, with that notice being written in plain English, clearly stating the reasons for withdrawal. The provision must impose upon the optometrist a duty to help the patient find alternate care. The provision must require that the optometrist provide a copy of records and that the cost of such records cannot exceed the statutory limited provided in 42 PaCS 6152(a)(2)(i).

Commissioner Merenda, we wish to thank you once again for your efforts to resolve the outstanding issues associated with this regulation.

Please feel free to call upon us again if we can be of assistance.

Very truly yours,

Thomas P. Gannon
Majority Chairman

William W. Reiger
Minority Chairman

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