DRAFT
BOARD OF OPTOMETRY
BOARD MEETING AND PUBLIC HEARING
OCTOBER 6, 2004

TIME AND PLACE:	The meetings were held at the Department of Health Professions, 6603 West Broad Street, Room 3, at 8:40 a.m.
CHAIRMAN:	David H. Hettler, O.D., Chair
MEMBERS PRESENT:	Paula H. Boone, O.D. Gregory P. Jellenek, O.D. W. Ernest Schlabach, Jr., O.D. William T. Tillar, O.D.
MEMBERS NOT PRESENT:	Cathleen Burk, Citizen Member
STAFF PRESENT:	Elizabeth A. Carter, Ph.D. Emily Wingfield, Assistant Attorney General, Board Counsel Elaine Yeatts, Senior Research Analyst Carol Stamey, Administrative Assistant
OTHERS PRESENT:	Pat Jackson, VOA Bruce Keeney, VOA Cal Whitehead, VA Society of Opthalmology
BOARD MEMBER TRAINING:	The board member training on conflict of interest statute amendments began at 8:40 a.m. and ended at 9:10 a.m. The board member training resumed after completion of board business.
PUBLIC HEARING:	The board meeting was called to order at 9:12 a.m. beginning with the public hearing to receive public comment on the proposed amendments to the TPA formulary and treatment guidelines. Mr. Cal Whitehead, VA Society of Ophthalmology, presented written comment and it is incorporated into the minutes as Attachment 1. Mr. Bruce Keeney, VA Optometric Association, presented written comment, and it is incorporated into the minutes as Attachment 2.

The Board reviewed the written comments of Jeetandra M. Athelli, O.D., representing the Northern Virginia Optometric Society. The written comments are incorporated into the minutes as Attachment 3.

With no further comment, the hearing concluded at 9:20 a.m.

BOARD BUSINESS:

General Public Comment

Mr. Keeney requested that electronic licensure renewal registration require optometrists to list all principal office locations and phone numbers.

Ms. Yeatts indicated that the current regulations do not require this information so renewing licensees could not be compelled to provide this information.

Agenda

Dr. Hettler added an additional item under new business, 2005 calendar.

◈**Action -** On properly seconded motion by Dr. Schlabach, the Board voted unanimously to approve the minutes of the August 23, 2004 meeting as amended.

Adoption of TPA Formulary and Treatment Guidelines

◈**Action –** On properly seconded motion by Dr. Boone, the Board voted unanimously to accept the treatment guidelines as amended and the amendments are incorporated into the minutes as Attachment 4.

The amendments to TPA formulary and treatment guidelines will be sent out for public comment on November 1, 2004. The board will meet in early December to review and receive any additional public comment and adopt final regulations.

Adoption of guidance document and proposed regulations for delegation of informal fact-finding to an agency subordinate

◈**Action –** On properly seconded motion by Dr. Tillar, the board voted unanimously to adopt the guidance document and proposed regulations for delegation of informal fact-finding to an agency

subordinate.

EXECUTIVE DIRECTOR'S REPORT:

Dr. Carter noted that information on the new statutory "Duty to Report Adult Abuse, Neglect or Exploitation" had been posted to the agency's website. She reported that optometrists had been included in the list of mandated reporters and are required to report incidents of suspected abuse to the Department of Social Services.

Dr. Carter informed the Board that ARBO had developed a database to track and maintain individual continuing education. She indicated that more information on this would be forthcoming shortly.

With regard to statistics, Dr. Carter reported the following:
Licensee count - 1390 total licensees (892 in VA and 498 outside VA)
TPA licensees - 1069 (792 in VA and 277 outside of VA)
Professional designations – 130
Case load – 32
Case standards – 63%

Dr. Carter informed the Board that the licensees will not be notified of CE audit through the licensure renewal process but conducted by the Enforcement Division via certified letters. Dr. Carter requested that the Board determine the percentage of licensees audited.

◈**<u>Action</u> –** On properly seconded motion by Dr. Jellenek, the Board voted unanimously that the Enforcement Division will audit five (5) percent of the licensees and include the addition of licensees with disciplinary action within the last year and exclude licensees audited the previous year.

BOARD MEMBER TRAINING:

The board members and staff resumed the required conflict of interest training.

PRESIDENT'S REPORT:

<u>Report on Board of Health Professions</u>
Dr. Hettler apprised the Board that the Board of Health Professions was conducting a study on the need to regulate assisted living directors. Also, Dr.

Hettler updated the Board on the sanction reference study and its implementation across the various boards.

Dr. Carter noted that the Board of Medicine had posted its sanction reference manual to their website page under guidance documents for review and reference.

COMMITTEE REPORTS:

Credentials
Dr. Boone reported that the Committee had approved four (4) endorsement applications and approved two (2) reinstatement applications.

Continuing Education (CE)
The Committee had no information to report.

CPT
The Committee had no information to report. Dr. Schlabach noted that he would be attending the St. Louis ARBO meeting and would request comment from the American Optometric Association regarding its angle closure CPT code descriptions verses that of the American Medical Association.

Professional Designation
Dr. Boone reported that the Committee had approved eight (8) applications for the use of professional designation titles.

Legislative/Regulatory Review
The Committee had no additional information to report.

Newsletter
The Committee requested that a newsletter be published in mid December with inclusion of the following topics:

Mandatory reporting
CE – ARBO update and retention of CE verification
TPA legislation
Website and on-line license renewal
License lookup

Dr. Carter reported that the agency website will be

undergoing revisions to include a search tool and should be completed by January/February. Also, Dr. Carter requested that any additional newsletter articles be submitted to her via e-mail.

NEW BUSINESS:

The Board set December 7, 2004 as its next Board meeting date to review and adopt the amendments to the TPA formulary and treatment guidelines.

2005 Calendar
The 2005 calendar was set as follows:

- March 8, 2005
- June 8, 2005
- September 15, 2005
- December 9, 2005

◈**Action –** On properly seconded motion by Dr. Jellenek, the Board voted unanimously that the TPA Formulary Committee meet once a year. Specifically, the Committee is scheduled to meet June 8, 2005.

ADJOURNMENT:

The meeting adjourned at 11:55 a.m.

____
David H. Hettler, O.D., President

____
Elizabeth A. Carter, Ph.D., Executive Director

October 1, 2004

Elizabeth A. Carter PhD Executive Director
Board of Optometry
6603 West Broad St., 5th Fl. Richmond, VA 23230-1712

Re: Proposed Amendments to 18 V AC 105-20 Regulating the Practice of Optometry

Dear Dr. Carter:

The Virginia Society of Ophthalmology (VSO) appreciates the opportunity to submit public comments regarding the proposed amended regulations governing Therapeutic Pharmaceutical Agent (TPA) certification, the TPA formulary, and treatment guidelines. The VSO stron
regulations and we object to the Board of Optometry selectiv
recommendations, especially when many of the recommenda e
Committee.

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Web Address: www.vaeyemd.org

The process that has led to the development of these proposed regulations has not met the General Assembly"s legislative intent set forth in Chapter 744. The VSO argues that the TPA Formular

Attachment 1

inclusive list of *specific* medications which are appropriate for optometrists to use based on their education and training. The medications on the Formulary should only be appropriate for the treatment of diseases and conditions of the eye and its adnexa under the practice of optometry, not ophthalmology.

The role of the TPA Committee should be ongoing as a multi-disciplinary body to review, amend, and change the Formulary using consensus and based on advancements in medical technology and optometrists' education and experience. Instead, the Board considers the TPA Committees' work complete and is prepared to implement a TPA Drug List that is broad and vague. Board members, staff, and policymakers should be troubled that this TPA Drug List is based on divided recommendations, many of which carne forward on 3-3 votes with ties being broken by the Chairnan Dr. *Tillar.* The dissenting votes each time were the Committee's two physicians and pharmacologist.

We recommend the following:

I. That "decongestants" be excluded from the *list* of medications that can be prescribed and administered by optometrists.

2. That "anterior" be re-inserted in B. 4 before "uveitis".

President - Richard W. Morton. MD President-EJect - Joy Robinson. MD Secretary- - Kurt Guelzow, MD,
Treasurer - Kenneth Karlin. MD. AAO Councilor – Ira R. Lcderman. MD A1ternare Councilor - Kevin R. Scott, MD
Directors: Paul Bullock. MD; W. David Kiser. MD; Barry Mandell, MD; P. Wesley Mullen. MD;
Barry Roper. MD; Garth Stevens,.Jr, MD

3. That "jmmunosuppressive agents"; be excluded from the list of medications that can be prescribed and administered by optometrists, as recommended by a majority of the TPA Committee.

The VSO urges the Board of Optometry to adopt these recommendations. Please contact me if I can answer questions or provide additional information.

Sincerely,

Richard Morton. MD

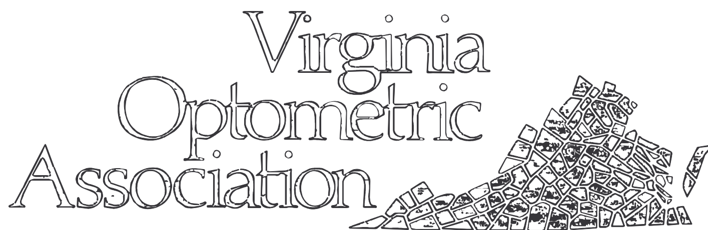
President

Cc: The Honorable Jerry Kilgore Attorney General of Virginia

The Honorable Jane Woods Secretary of Health and Human

The Honorable S. Chris Jones Delegate. 76th District Patron HB 856 *(2004)*

Ralph Small, RPh
Member, TPA Formulary Committee



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Richmond, VA 23219-2305
Phone 804-643-0309
Fax 804-643-0311

Attachment 2

September 30, 2004

Virginia Board of Optometry
6603 West Broad Street, 5th Floor
Richmond, VA 23230

Re: Public Comments on Proposed Amendments of Regulations 18V ACIO5-20-46 (Treatment Guidelines for TPA Certification) and18V ACIO5-20-47 (Therapeutic Pharmaceutical Agents)

The Virginia Optometric Association (VOA), representing approxjmately 80% of Virginia's actively practicing doctors of optometry, appreciates the opportunity to provide comments to the Virginia Board of Optometry (Board) related to proposed amendments to regulations regarding Treatment Guidelines for TP A Certification and also for Therapeutic Pharmaceutical Agents (TPAs).

For the record and as a preamble to our comments, the VOA notes that Virginia TPA certified optometrists have a superb record in the safe and proper administration and prescribing of pharmaceutical agents to treat abnormal and diseased conditions of the human eye and its adnexa. Additionally, we note that virtually every TPA certified doctor of optometry has successfully completed extensive didactic and clinical training in the diagnosis and treatment of abnormal and diseased conditions of the eye and its adnexa. In fact, an optometrist's training in these areas is comparable to and most often greater than that obtained by an ophthalmologist (when excluding surgical training undertaken by an ophthalmologist.) We further note that such training undertaken by optometrists includes didactic and clinical training provided and supervised by ophthalmologists, pharmacists, Ph.D. pharmacologists, and optometrists specializing in the diagnosis and treatment of eye conditions.

In considering regulations governing the practice of optometry, it is important to recognize the diverse settings in which Virginia licensed optometrists practice. It is not uncommon for an optometrist in rural areas of the Commonwealth to be the only eye care provider. Optometrists now practice in hospital settings, including care delivered in hospital emergency rooms. We also have optometrists serving as faculty in medical schools within the Commonwealth, providing not only instruction to physicians in ophthalmology residency programs, but delivery of care to patients of medical schools and their affiliated facilities. Additionally, optometrists practice in Veterans Administration Hospitals, military clinics, staff model HMOs, etc. and serve as the primary eye care provider in those facilities. We mention these varied practice locations in that

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any regulations governing the use of pharmaceutical agents by optometrists must appreciate that doctors of optometry are sometimes the sole provider of health care providing services to prevent loss of sight due to abnormal or diseased conditions. It is clearly in the public's best interest to provide TP A certified optometrists with the proper pharmaceutical agents to serve the eye and vision care needs of these patients.

The VOA fully supports the Board's suggested regulations related to ***"Therapeutic Pharmaceutical Agents" (18 VAC 105-20-47.)***

1. *We support the use of classifications of agents* rather than attempts to create an extensive laundry list of agents. Use of classifications rather than a laundry list will reduce the need for frequent meetings of the Advisory Formulary Committee and revisions of regulations, all of which reduce costs to the Board and thus, indirectly to its licensees.

   (A) Use of classifications provides the TPA certified optometrist greater flexibility in prescribing agents, giving them greater flexibility to prescribe a TP A which may be lower in cost for the patient. It would be contrary to public interest if a formulary failed to include a TPA which may be appropriate for treatment of a specific condition and was less expensive than a comparable agent incorporated in a list. With the high cost of prescription drugs, doctors should have the flexibility to prescribe the most appropriate agent and additionally consider cost to the patient.

   (B) Use of classifications reflects a system under which an optometrist has been trained as well as reference texts referred to by TP A certified optometrists. By use of classifications, the optometrist is encouraged to consider a variety of agents to assist in the most appropriate agent for treatment of a particular condition. Such enhances the patient having prescribed the most medically appropriate agent.

2. Certain opponents of optometrists prescribing any TPA erroneously suggest that the proposed regulations may allow an optometrist to treat conditions other than abnormal or diseased conditions of the human eye and its adnexa. Both the enabling statute and Board's proposed amendments to the regulations clearly and appropriately limit the use of TPAs by stating:

   (A) the TPA certified optometrist is restricted to "acting within (an optometrist's) the scope of his practice"; and

   (B) limits the use of TPAs "to treat disease and abnormal conditions of the human eye and its adnexa."

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3. We note that the Board of Optometry added *"immunosuppressive agents"* to the formulary, contrary to the recommendation (by a contested vote) of the Advisory Formulary Committee. The *VOA supports inclusion of this class of agents,* recognizing that optometrists in rural areas, hospital settings, and/or specialized clinical facilities may be the only eye care provider available. Those on the Advisory Formulary Committee objected to inclusion *of* this class of drugs in that its inclusion necessitated more specific standards of care... and that such was beyond the charge of the Advisory Committee. These standards of care have been incorporated in the Board's proposed Treatment Guidelines, thus negating any concern previously raised. Finally and of interest is that TP A certified optometrists have received training in this class of agents.

The VOA generally supports the Board's suggested regulations related to ***"Treatment Guidelines for TP A Certification" (18V ACI 05-20-46)*** but *suggests certain critically* important *and necessary~ revisions.*

1. Generally, revisions suggested simply reflect changes in statute and are both necessary and appropriate.

2. The VOA suggests a minor but important revision to the first paragraph (A) in the Treatment Guidelines, **specifically clarifying that treatment is to be "medicallv appropriate."** With this revision, the paragraph would read:

> "A. TPA-certified optometrist may treat diseases and abnormal conditions of the following structures of the human eye and its adnexa which may be ~~appropriately~~ treated *as medically appropriate* with pharmaceutical agents as referenced in 18 VAC 105-20-47:"

This would revise Section A so that it ensures TPAs used are "medically appropriate" rather than simply "appropriate." We recognize the addition of the word "medically" may be construed as being more restrictive upon the TPA certified optometrist. However, revising the term to reflect "as medically appropriate" serves to alleviate concerns, though arguably unfounded, that a TPA certified optometrist may treat conditions outside the restrictions of "human eye and its adnexa." As an example, ophthalmologists serving on the Advisory Formulary Committee voiced concerns that an optometrist would be allowed to prescribe Viagra, noting that no ophthalmologist would ever write a prescription for erectile dysfunction. The VOA dismissed those concerns as unfounded in that Viagra is clearly not medically appropriate to treat a condition of the eye and its adnexa. But to

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address those types of questions and concerns, the VOA believes "as medically appropriate" is a necessary clarification. Additionally, review of various statutes governing the delivery of health care indicates common use of the term "as medically appropriate" rather than simply "appropriate." Clearly use of the term "as medically appropriate" refers to an accepted standard of care whereas the simple term "appropriate" may be subject to interpretation. In that Board regulations are to be clear and concise, the VOA strongly encourages this revision.

3. The VOA specifically **objects to and opposes the Board's "protocol for treatment of angle closure"** in that, as presented, the regulations create confusion and are subject to misinterpretation by the Board's licensees. Additionally, failure to clarify protocol for treatment of angle closure glaucoma provisions unfairly places the optometrist in the position of unintentionally violating the regulations.

   The statute states "Treatment of angle closure glaucoma shall be limited to initiation of immediate emergency care." Yet the statute fails to define "angle closure glaucoma." When a term is used in statute which may be subject to interpretation, it is necessary, appropriate and required for a Board to properly define such in its regulations, especially in that all regulations are to be clear and concise.

   The VOA has attached for reference a copy of the ICD 9 CM listing of codes for diagnosis of various types of glaucoma. Health care providers, including optometrists, are required to use this code system for use in submitting third party insurance. Consequently, such coding is incorporated in patient records to indicate patient conditions and diagnosis. Review of the ICD 9 CM codes show "angle closure glaucoma" as sharing the exact same code as "narrow angle glaucoma," though clearly narrow angle is medically recognized as distinctly different from angle closure. And by statute, for over 10 years and no change reflected with enactment of2004legislation, optometrists have been and are legally authorized to fully treat (excluding surgery) all types of glaucoma other than "angle closure" (and infantile and congenital).

   In general, "angle closure glaucoma" is limited to initiating immediate emergency treatment whereas treatment of ' 'narrow angle" glaucoma has no statutory, regulatory or historical restrictions for treatment by a TP A certified optometrist. Though the two types of glaucoma are distinctly different, they share the same ICD 9 CM (diagnosis code). A **specific definition of "angle closure glaucoma" is thus imperative** so that an optometrist is not falsely accused of violating statute and Board regulations. Ljkewise, a specific definition of "angle closure glaucoma" will aide the Board in its enforcement of

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statute should a TPA certified optometrist provide treatment for "angle closure glaucoma" beyond that allowed by statute. We note that inclusion of a specific definition of "angle closure glaucoma" is additionally important in that optometrists often use a diagnosis code as the sole indicator of the patient's diagnosis.

The Board has a legal and ethical responsibility to promulgate regulations which are clear and concise. Additionally, to protect the public, the Board has the responsibility of clarifying, when necessary, terms used in statute, to ensure proper understanding of those terms.

For all of these reasons, the **VOA urges the Board to add a definition** of "angle **closure glaucoma."** We would suggest retaining section C and subsections CI through C4, and **simply add a new subsection C.5. as follows:**

C. 5. *Angle closure glaucoma shall mean:*
A. Closed angle in the involved eye;
B. Significantly increased intraocular pressure; and
C. *Corneal Microcystic edema.*

This suggested definition of "angle closure glaucoma" should be without controversy in that it reflects the definition of angle closure glaucoma as set forth in the "Wills Eye Manual," a textbook reference used by optometry and medical schools, and by ophthalmology residency programs, in the training of treatment of glaucoma.

4. Under Section A of the Treatment Guidelines, we **suggest the following revision:**

- under the main section A. we suggest deletion of the words "following structures of the human eye" so that the revised sentence reads "... abnormal conditions of the human eye and its adnexa..."
- we then further suggest deletion of subsections Al through A 5 in their entirety.

We agree the regulations should restate statutory provisions and thus support the regulations clearly stating a TP A certified optometrist may treat diseases and abnormal conditions of the human eye and its adnexa. However, we see no reason for a delineation of structures.

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Should the Board disagree with our recommendation and believe it necessary to have a delineation of structures which may be treated, we urge the following corrections and/or revisions:

- after "A. 1. Lids and adnexa" add in parentheses *"(including eyebrows and eyelashes)"* which is simply clarifying in nature;
- add the following new and additional subsections under "A." as follows:
  6. *Sclera*
  7. Uvea
  8. *Ocular muscles associated with ocular movement.*

Addition of sclera .is a necessary correction to an oversight of previous regulations and simply places into regulations a structure long recognized and accepted as one in which an optometrist can treat applicable conditions.

Addition of uvea is clarification since it is authorized under section B (and should thus be also listed in section A which includes structures.)

Addition of "ocular muscles associated with ocular movement" corrects an oversight of previous regulations and places into regulations a structure long recognized and accepted as one in which an optometrist can treat applicable conditions. (Note, this suggestion would not allow surgical treatment of ocular muscle related conditions.)

In summation, the VOA suggests and encourages the following:

1. Treatment Guidelines should include a specific stated standard of care (as suggested in the draft) related to use and prescribing of immunosuppressive agents.

2. Treatment Guidelines must include a specific definition of "angle closure glaucoma" with such definition that which is widely recognized by the medical and optometric community.

3. Treatment Guidelines should clearly state that use of TPAs shall be that which is "as medically appropriate".

4. Treatment Guidelines should not delineate structures which may be treated. However, if such is utilized, the list should include clarification related to eyebrows and eyelashes, and addition of sclera, uvea and ocular muscles associated with ocular movement.

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We respectfully offer these recommendations and encourage the Board to adopt such for the reasons stated.

Respectfully,

M. E. "Pat" Jackson, O.D. President
Virginia Optometric Association

MEJ/sjr

enclosure (copy of applicable ICD 9 CM code references)

Northern Virginia Optometric Society
C/O Jeetandra M. Athelli, O.D., President
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NORTHERN VIRGINIA OPTOMETRIC SOCIETY

Attachment 3

10/04/2004

Virginia Board of Optometry
Elizabeth A. Carter, Ph.D.
Executive Director of the Board of Optometry
6603 West Broad Street
Richmond, Virginia 23230

Re: Amendment to my comments on Optometry regulations submitted on 10/02/04.

Dear Dr. Carter and Virginia Board of Optometry Members,

It has come to my attention that some references have the diagnosis code for narrow angle glaucoma and (primary) angle closure glaucoma as being the same. This leaves room for confusion, so I suggest, for clarification, regardless of what the current or future diagnosis code is or will become, that the regulations include a definition for angle closure glaucoma. Below is a suggest definition.

Angle closure glaucoma is defined as:

a) Closed angle in the involved eye; with
b) Significantly elevated intraocular pressure; and
c) Corneal microcystic edema

Thank you for your time and consideration.

Respectfully Submitted,

Jeetandra M. Athelli, O.D.
President, N.V.O.S.

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C/O Jeetandra M. Athelli, O.D., President (703) 631-0014
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NORTHERN VIRGINIA OPTOMETRIC SOCIETY

10/02/04

Virginia Board of Optometry
Elizabeth A. Carter, Ph.D.,
Executive Director of the Board of Optometry
6603 West Broad Street
Richmond, Virginia 23230

Re: Public Comment for proposed amended regulations

Dear Dr. Carter and Virginia Board of Optometry Members,

I am the president of the Northern Virginia Optometric Society, but I can not claim to represent anyone but myself. I am in the process of distributing my comments and suggestions not only to the Board of Optometry, but also to our local society regarding the proposed regulatory revisions, 18VAC 105-20-46 Treatment Guidelines for TPA Certification and 18VAC 105-20-47 Therapeutic Pharmaceutical Agents.

I suggest that the proposed regulatory revisions to 18VAC 105-20-46 be replaced in its entirety by the revisions that I have proposed, including the title of this section back to “Treatment guidelines” from the section it is replacing, 18VAC 105-30-60.

I have read the comments and suggestions of the Virginia Optometric Association, and I agree that using the term “medically” appropriate is more accurate, but I also suggest that “as well as provide related post-operative care in cooperation with a patient’s surgeon” be added at the end of the statement in order to be complete with the TPA-certified optometrist’s treatment guideline in subpart A.

I think it will be helpful not only to optometrists, but to all, to have clear and referenced definitions of the “human eye and its adnexa”. The comprehensive definition of the “Human eye” is referenced from the sixteenth edition of *Taber’s Cyclopedic Medical Dictionary*, and the definition of “Adnexa” is referenced from *Webster’s New Collegiate Dictionary*.

I think it would also be more clear and concise, to all, to replace subparts B, C, and D with a single subpart B, titled “Treatment limitations”. I am basically not changing anything in the substance of the regulation, but simply placing it in a more logical format and fine tuning the wording, so that to me, it will be straight forward and concise for both optometrists and non-optometrists alike.

Furthermore, I think it is inappropriate and unnecessary to list specific treatment options for any condition, like is being done with angle closure glaucoma. Virginia Code permits the initiation of treatment for the immediate emergency care of angle closure glaucoma. Angle closure is actually general terminology. Angle closure has different etiologies and different levels of severity, therefore treatment must not be potentially limited by regulations. I feel the purpose of regulations is to give guidance such as the requirement of referring the patient to an ophthalmologist after initiating emergency care, not guidance in specific treatment options. Additionally, the comments from the Virginia Optometric Association express the need to define angle closure glaucoma, because it shares the same diagnosis code as narrow angle glaucoma. That is an incorrect statement. The diagnosis code (ICD-9-CM) for narrow angle glaucoma is 365.02 and the diagnosis code for (primary) angle closure glaucoma is 365.20.

With the current Code of Virginia for optometry, it does not make any sense to me to list ocular trauma and uveitis separate from subpart A. It is redundant and may add confusion. With oral Schedule VI immunosuppressive agents, I suggest some minor changes to the wording for clarification, not wanting to leave any doubt as to the usage of these agents.

The only change to 18VAC 105-20-47 is a typo. The subpart “A” needs another “A.” at the beginning. I have just a quick comment about the usage of classifications of agents rather then an extensive list of agents. Using classifications of agents rather than a list will give TPA-certified optometrists timely access to the most updated / current formulary, providing prescription choices which may result in safer and more effective treatment and in the some cases, like combination medications, result in less cumbersome and less costly treatment for the patient, and I believe the whole point of these laws and regulations is to better serve the public.

I feel strongly about my suggestions and comments, but again, I can only speak for myself for now.

Respectfully Submitted,

Jeetandra M. Athelli, O.D., N.V.O.S. President

Enc: Rewritten proposed regulations, pages 3 and 4.

PROPOSED AMENDED REGULATIONS

Promulgated under § 54.1-3223 of the Code of Virginia

(Public Comment received until 10/6/04)

18VAC105-20-46. Treatment guidelines.

A. TPA-certified optometrists may treat, including medically appropriate treatment with pharmaceutical agents as referenced in 18VAC105-20-47, diseases and abnormal conditions of the human eye and its adnexa as well as provide related post-operative care in cooperation with a patient's surgeon:

1. Human eye: Anatomically composed of three coats. From inside the eye out they are retina, sensory for light; uvea (choroid, ciliary body, and iris); sclera and cornea, serving as protection for the delicate retina. These layers enclose two cavities, the more anterior or ocular chamber being the space lying in front the lens. It is divided by the iris into an anterior chamber and a posterior chamber, both of which are filled with a watery aqueous humor. The cavity behind the lens is much larger and filled with a jellylike vitreous body. The lens is suspended behind the iris by the ciliary zonule. Anteriorly, the sclera is covered by the conjunctiva, which continues and forms the inner layer of the eyelids. Movements of the eyeball are brought about by six muscles: the superior, inferior, medial and external or lateral rectus muscles, and the superior and inferior oblique muscles.

2. Adnexa: Conjoined, subordinate, or associated anatomic parts of the human eye as defined in 18VAC105-20-46(A)(1).

B. Treatment limitations:

1. Treatment of angle closure glaucoma shall be limited to initiation of immediate emergency care. When the diagnosis of angle closure glaucoma has been established by the optometrist and immediate emergency care has been initiated, the ophthalmologist, to whom the patient will be referred, shall be contacted.

2. Treatment of congenital and infantile glaucoma shall be prohibited.

3. Treatment through surgery or other invasive modalities shall not be permitted, except for treatment of emergency cases of anaphylactic shock with intramuscular epinephrine. The foregoing shall not restrict the authority of any licensed or certified optometrist, as defined in Chapter 32 of the Code of Virginia, from removing superficial foreign bodies from the human eye and its adnexa.

4. Oral Schedule VI immunosuppressive agents shall only be used when 1) the disease or abnormal condition of the human eye and/or adnexa fails to respond to any other treatment regimen; 2) such agents are prescribed in consultation with the appropriate physician(s); and 3) treatment with such agents include monitoring of systemic effects.

18VAC105-20-47. Therapeutic pharmaceutical agents.

A. A TPA-certified optometrist, acting within the scope of his practice, may procure, administer and prescribe therapeutic pharmaceutical agents (or any therapeutically appropriate combination thereof) to treat diseases and abnormal conditions of the human eye and its adnexa within the following categories:

1. Oral analgesics - Schedule III, IV and VI narcotic and non-narcotic agents.

2. Topically administered Schedule VI agents:

a. Alpha-adrenergic blocking agents;

b. Anesthetic (including esters and amides);

c. Anti-allergy (including antihistamines and mast cell stabilizers);

d. Anti-fungal;

e. Anti-glaucoma (including carbonic anhydrase inhibitors and hyperosmotics);

f. Anti-infective (including antibiotics and antivirals);

g. Anti-inflammatory;

h. Cycloplegics and mydiratics;

i. Decongestants; and

j. Immunosuppressive agents.

3. Orally administered Schedule VI agents:

a. Aminocaproic acids (including antifibrinolytic agents);

b. Anti-allergy (including antihistamines and leukotriene inhibitors);

c. Anti-fungal;

d. Anti-glaucoma (including carbonic anhydrase inhibitors and hyperosmotics);

e. Anti-infective (including antibiotics and antivirals);

f. Anti-inflammatory (including steroidal and non-steroidal);

g. Decongestants; and

h. Immunosuppressive agents.

B. Schedule I, II and V drugs are excluded from the list of therapeutic pharmaceutical agents.

C. Over-the-counter topical and oral medications for the treatment of the eye and its adnexa may be procured for administration, administered, prescribed or dispensed.

Attachment 4

PROPOSED AMENDED REGULATIONS

Promulgated under § 54.1-3223 of the Code of Virginia

(Changes in the proposed regulations that were adopted by the Board of Optometry on 10/6/04 are bracketed and highlighted. Comment on the proposed changes may be received until December 1, 2004.)

18VAC105-20-46. Treatment guidelines for TPA[~~certification~~ certified optometrists].

A. TPA-certified optometrists may treat diseases and abnormal conditions of the [~~following structures of the~~] human eye and its adnexa which may be [~~appropriately~~] treated with [medically appropriate]pharmaceutical agents as referenced in 18VAC105-20-47. [The adnexa is defined as conjoined, subordinate or immediately associated anatomic parts of the human eye, including eyelids and eyebrows.]

[~~1. Lids and adnexa;~~

~~2. Lacrimal system;~~

~~3. Cornea;~~

~~4. Conjunctiva; and~~

~~5. Episclera.~~]

B. In addition, the following may be treated:

1. Glaucoma (excluding the treatment of congenital and infantile glaucoma). Treatment of angle closure shall follow the [definition and] protocol prescribed in subsection C of this section.

2. Ocular-related post-operative care in cooperation with patient's surgeon.

3. Ocular trauma to the above tissues as in subsection A of this section.

4. Uveitis.

5. Anaphylactic shock (limited to the administration of intramuscular epinephrine).

C. The [definition and] protocol for treatment of angle closure glaucoma shall be as follows:

1. As used in this chapter, angle closure glaucoma shall mean a closed angle in the involved eye with significantly increased intraocular pressure, and corneal microcystic edema.

2. Treatment shall be limited to the initiation of immediate emergency care with appropriate pharmaceutical agents as prescribed by this chapter;

3. Once the diagnosis of [~~acute~~] angle closure glaucoma has been established by the optometrist, the ophthalmologist to whom the patient is to be referred should be contacted immediately;

4. If there are no medical contraindications, an oral osmotic agent may be administered as well as an oral carbonic anhydrase inhibitor and any other medically accepted, Schedule III, IV or VI, oral antiglaucomic agent as may become available; and

5. Proper topical medications as appropriate may also be administered by the optometrist.

D. An oral Schedule VI immunosuppressive agent shall only be used when 1) the condition fails to appropriately respond to any other treatment regimen; 2) such agent is prescribed in consultation with a physician; and 3) treatment with such agent includes monitoring of systemic effects.

18VAC105-20-47. Therapeutic pharmaceutical agents.

A. A TPA-certified optometrist, acting within the scope of his practice, may procure, administer and prescribe [medically appropriate] therapeutic pharmaceutical agents (or any therapeutically appropriate combination thereof) to treat diseases and abnormal conditions of the human eye and its adnexa within the following categories:

1. Oral analgesics - Schedule III, IV and VI narcotic and non-narcotic agents.

2. Topically administered Schedule VI agents:

a. Alpha-adrenergic blocking agents;

b. Anesthetic (including esters and amides);

c. Anti-allergy (including antihistamines and mast cell stabilizers);

d. Anti-fungal;

e. Anti-glaucoma (including carbonic anhydrase inhibitors and hyperosmotics);

f. Anti-infective (including antibiotics and antivirals);

g. Anti-inflammatory;

h. Cycloplegics and mydriatics;

i. Decongestants; and

j. Immunosuppressive agents.

3. Orally administered Schedule VI agents:

a. Aminocaproic acids (including antifibrinolytic agents);

b. Anti-allergy (including antihistamines and leukotriene inhibitors);

c. Anti-fungal;

d. Anti-glaucoma (including carbonic anhydrase inhibitors and hyperosmotics);

e. Anti-infective (including antibiotics and antivirals);

f. Anti-inflammatory (including steroidal and non-steroidal);

g. Decongestants; and

h. Immunosuppressive agents.

B. Schedule I, II and V drugs are excluded from the list of therapeutic pharmaceutical agents.

C. Over-the-counter topical and oral medications for the treatment of the eye and its adnexa may be procured for administration, administered, prescribed or dispensed.