WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION

Form #3

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SECRETARY OF STATE
STATE OF WEST VIRGINIA

NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

AGENCY: WV Board of Optometry TITLE NUMBER: 14CSR2

CITE AUTHORITY: §30-8-1, et. seq.

AMENDMENT TO AN EXISTING RULE: YES xx NO ____

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 14CSR2

TITLE OF RULE BEING AMENDED: Expanded Prescriptive Authority

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: ____

TITLE OF RULE BEING PROPOSED: ____

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

Authorized Signature

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: July 30, 2010

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM:(*Agency Name, Address & Phone No.*) WV Board of Optometry, 179 Summers Street, Charleston, WV 25301, 304-558-5901

LEGISLATIVE RULE TITLE: §14CSR2 Oral Pharmaceutical Certificate

1. Authorizing statute(s) citation §30-8-1, et seq

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:

June 25, 2010

b. What other notice, including advertising, did you give of the hearing?

A memo was mailed to all licensees directing them to our web site, www.wvbo.org, where the proposed rules were posted. Notice was given by phone and hand delivery of the rules to the West Virginia Optometric Association, and notice was given by phone contact and an e-mail was sent to the West Virginia Academy of Ophthalmologists informing them of the posting on the web site.

c. Date of Public Hearing(s) ***or*** Public Comment Period ended:

July 26, 2010 at noon

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached xx No comments received _____

e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

July 30, 2010 at 2:00 p.m.

f. **Name, title, address and <u>phone/fax/e-mail numbers</u>** of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

Pamela Carper, 179 Summers Street, Suite 231, Charleston, WV 25301, 304-558-5901 The cell phone number is 304-546-2907.

g. **<u>IF DIFFERENT</u> FROM ITEM 'f'**, please give **Name, title, address and phone number(s)** of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

Gregory Moore, O.D., President, WV Board of Optometry, 179 Summers Street, Suite 231, Charleston, WV 25301, 304-558-5901 or 304-768-7902 or contact Pam Carper listed above.

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

~~n/a~~

b. Date of hearing or comment period:

n/a

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

n/a

d. Attach findings and determinations and reasons:

Attached n/a

WEST VIRGINIA BOARD OF OPTOMETRY

14CSR2

Amendment to Expanded Prescriptive Authority

Summary

The amendment brings §14-2 to into compliance with the passage of Senate Bill 230, W. Va. Code §30-8, passed during the 2010 Legislative Session.

- The amendment clarifies the application process for an oral pharmaceutical certificate.
- It increases the amount of liability insurance required form $1,000,000 to $1,000,000 per occurrence and $3,000,000 aggregate coverage.
- It includes oral nonsteroidal anti-inflammatory drugs and oral carbonic anhydrase inhibitors in the formulary as listed in Senate Bill 230.
- It adds new drugs or drug indications to the formulary from Schedules III, IV and V of the Uniform Controlled Substances Act, regardless of their listed categories, which have been shown to be effective in the treatment and management of abnormalities of the aye or its appendages which may be approved by the Board as listed in §§30-8-9 and 30-8-14 as part of Senate Bill 230.

WEST VIRGINIA BOARD OF OPTOMETRY

14CSR2
Expanded Prescriptive Authority

Circumstances

The amendment is written in order to comply with the requirements of Senate Bill 230 passed during the 2010 Legislative Session rewriting the Board's enabling statute, W. Va. Code §30-8.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Expanded Prescriptive Authority

Type of Rule: [X] Legislative [ ] Interpretive [ ] Procedural

Agency: West Virginia Board of Optometry

Address: 179 Summers Street, Suite 231

Charleston, WV 25301

Phone Number: 304-558-5901 Email: wvbdopt@verizon.net

Fiscal Note Summary

Summarize in a clear and concise manner what impact this measure will have on costs and revenues of state government.

The bill has a neutral effect on revenue and expenditures. It only adds requirements for the licensee and no new costs for the Board. The certificte takes about 2% of the Board's resources. 2% of the Board's revenues equals the expense.

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

FISCAL YEAR			
Effect of Proposal	Current Increase/Decrease (use "-")	Next Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	2,340.00	0.00	2,340.00
Personal Services	760.00	0.00	760.00
Current Expenses	782.00	0.00	782.00
Repairs & Alterations	8.40	0.00	0.00
Assets	0.00	0.00	0.00
Other	0.00	0.00	0.00
2. Estimated Total Revenues	2,340.00	0.00	2,340.00

Rule Title: §14-2 Expanded Prescriptive Authority

Rule Title: Expanded Prescriptive Authority

3. Explanation of above estimates (including long-range effect):
Please include any increase or decrease in fees in your estimated total revenues.

The bill has a neutral effect on revenue and expenditures. It only adds requirements for the licensee and no new costs for the Board. The certificte takes about 2% of the Board's resources. 2% of the Board's revenues equals the expense.

MEMORANDUM

Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

Date: 7/30/10

Signature of Agency Head or Authorized Representative

TITLE 14
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF OPTOMETRY

SERIES 2
~~EXPANDED PRESCRIPTIVE AUTHORITY~~ ORAL PHARMACEUTICAL CERTIFICATE

§14-2-1. General.

1.1. Scope. -- This legislative rule establishes the requirements, procedures and standards for the certification and re-certification of individual optometrists with ~~expanded prescriptive~~ oral pharmaceutical prescriptive ~~drug formulary~~ authority, by the West Virginia Board of Examiners in Optometry, regarding prescriptive authority and expanded oral pharmaceutical prescriptive authority, as defined in W. Va. Code ~~§§30-8-2a. and 30-8-2b~~ §§30-8-6, 30-8-9 and 30-8-14.

1.2. Authority. -- W. Va. Code ~~§§30-8-2a and 30-8-2b~~ §§30-8-1 et. seq.

1.3. Filing Date. -- .

1.4. Effective Date. -- .

§14-2-2. ~~Certification~~ Requirements For Oral Pharmaceutical Certificate.

2.1. In order to be permitted to prescribe oral drugs under the provisions of W. Va. Code ~~§§30-8-2a and 30-8-2b~~ §§30-8-9 and 30-8-14, a ~~registered optometrist~~ licensee shall apply to the Board for certification. In order to qualify for certification, ~~an optometrist~~ a licensee:

2.1.a. Shall have previously attained topical therapeutic certification;

2.1.b. Shall satisfactorily complete~~, and pass an examination in,~~ a course in clinical pharmacology as applied to optometry. This course shall have particular emphasis on the administration of oral pharmaceutical agents for the ~~purpose of examination of the human eye, and analysis of ocular functions~~ diagnosis and treatment of visual defects or abnormal conditions of the human eye and its ~~adnexa~~ appendages. In addition, the course shall include instruction on the clinical use of Schedule III, IV, and V agents. This course shall consist of a minimum of thirty (30) hours in clinical systemic pharmacology. The course shall be taught by:

2.1.b.1.~~(1)~~ a school or college of optometry or a medical school, accredited by a regional or professional accreditation organization which is recognized or approved by the council on postsecondary accreditation or by the United States Department of Education;~~;~~

2.1.b.2.~~(2)~~ a federally sponsored health education center; or

2.1.b.3.~~(3)~~ other non-profit continuing education agencies in cooperation with appropriate optometry or medical school faculty. All courses of instruction shall be approved by the Board; and

2.1.c. Shall pass an examination relating to the treatment and management of ocular disease, which is prepared, administered, and graded by the West Virginia Board of Optometry or its designee through the National Board of Examiners in Optometry or other nationally recognized optometric organization as approved by the board.

§14-2-3. Certificate Application.

3.1. The licensee shall complete the prescribed oral pharmaceutical certificate application form.

3.2. The licensee shall ensure that a certificate of successful completion by the licensee for the course listed in 2.1.b. of this rule will be submitted by the course provider directly to the Board.

3.3. The licensee shall ensure that the

passing score report for the exam listed in 2.1.c of this rule will be submitted by the examiner directly to the Board.

3.4. The licensee shall submit a copy of a liability insurance certificate in an amount of not less than One Million Dollars ($1,000,000) per occurrence and Three Million ($3,000,000) aggregate coverage.

3.5. The licensee shall submit the fee listed in the Board's rule, Schedule of Fees, 14CSR5.

§14-2-~~3~~4. Re-certification.

~~3~~4.1. Each ~~optometrist~~ licensee applying for re-certification shall have available for the Board, satisfactory evidence that he or she has acquired the continuing education hours required under the ~~Board of Optometry Rule~~, Rules of the West Virginia Board of Optometry, 14CSR10 and this rule, to renew his or her ~~biennial~~ annual ~~registration~~ license. Of those required hours, an optometrist certified under the provisions of this rule shall furnish the Board satisfactory evidence that at least six (6) hours of the required hours were acquired in educational optometric programs in ocular pathology or therapeutic pharmacological agents.

§14-2-~~4~~5. Insurance.

~~4~~5.1. All ~~optometrists~~ licensees certified under this rule shall carry liability insurance coverage in an amount of not less than One Million Dollars ($1,000,000) per occurrence and Three Million Dollars ($3,000,000) aggregate coverage. No ~~optometrist~~ licensee shall practice under the provisions of this rule unless and until he or she has submitted to the board evidence of the liability insurance coverage in an amount not less than One Million Dollars ($1,000,000) per occurrence and Three Million Dollars ($3,000,000) aggregate coverage.

~~4~~.5.2. It is the responsibility of each ~~individual optometrist~~ licensee to furnish proof of current liability insurance coverage to the Board upon application for certification and re-certification.

~~**§14-2-5. Procedures for Certification.**~~

~~5.1. The educational and training requirements for certification by the Board shall be from taught by a college or university accredited by a regional or professional accreditation organization which is recognized or approved by the council on postsecondary accreditation or by the United States Department of Education.~~

~~**§14-2-6. Fees.**~~

~~6.1. The administrative fee for the certification of an individual optometrist for an expanded scope of practice prescriptive authority is $200.~~

§14-2-~~7~~6. Drug Formulary.

~~7~~6.1. ~~Optometrists~~ Licensees certified under the provisions of this rule may prescribe the drugs set forth in W. Va. Code ~~§30-8-2a~~ §§30-8-9, 30-8-14 and this section.

~~7~~6.2. W. Va. Code ~~§30-8-2b~~ §30-8-6, authorizes the Board to develop a formulary of categories of oral drugs to be considered rational to the diagnosis and treatment of visual defects or abnormal conditions of the human eye and its appendages from Schedules III, IV and V of the Uniform Controlled Substances Act. The categories include:

6.2.a. Oral Antibiotics;

6.2.b. Oral Nonsteroidal Anti-inflamatory Drugs;

6.2.c. Oral Carbonic Anhydrase Inhibitors;

~~7~~6.2.~~a~~ d. Antihistamines;

~~7~~6.2.~~b~~ e. Oral Corticosteroids, may be prescribed for a duration of no more than six days;

~~7~~.6.2.~~ef~~. Analgesics, provided that no oral narcotic analgesic may be prescribed for a duration of more than three days; and

~~7~~6.2.~~d~~g. Nutritional Supplements.

6.2.~~e~~ h.New drugs or new drug indications from Schedules III, IV and V of the Uniform Controlled Substances Act~~, regardless of their listed categories,~~ which, regardless of their listed classification, have been shown to be effective in the treatment and management of the eye or its appendages may be approved by the Board according to the provisions of W. Va. Code §§30-8-9 and 30-8-14.

6.2.i. A list of approved new drugs and new drug indications proven to be shown to be effective in the treatment of the eye and its appendages will be maintained by the Board for public inspection.

6.2.j. The approval of Schedule I and Schedule II narcotics is prohibited.

§14-2-7. New Drug Approval.

7.1. The addition of new drugs or drug indications by the Board as cited in subsection 6.2 of this rule may be based on any of the following criteria:

7.1.a. A new or existing drug has been approved by the Food and Drug Administration for the treatment of the eye or its appendages.

7.1.b. A new drug or new drug indication has gained accepted use in the eye care field. Such acceptance may be indicated by its inclusion in the curriculum of an optometry school accredited by the Accreditation Council on Optometric Education or its successor approved by the U.S. Department of Education or approved post-graduate continuing education, through peer-reviewed, evidence-based research and professional journal articles, or by inclusion in established standards of practice and care published by professional organizations.

§14-2-8. Education and Training on the Use of New Drugs and New Drug Indications.

8.1. Additional education and training may be required by the Board as it deems appropriate when it adds new drugs or new drug indications.

8.2. This training may be provided through an accredited optometry school or approved post-graduate training.

8.3. A list of Board required training for new drugs or new drug indications will be maintained by the Board for public inspection.

§14-2-~~8~~9. Restrictions.

~~8~~9.1. ~~An optometrist~~ A licensee may not establish a pharmacy in an optometric office or sell oral or topical pharmaceutical agents prescribed in treatment unless there is a licensed pharmacist on staff and present when the prescriptions are filled.

9.1.a. ~~However, n~~Nothing in this section or in any other provision of law prohibits ~~an optometrist~~ a licensee who is properly certified under the provisions of this rule from administering or supplying oral or topical pharmaceutical agents to a patient in his or her office ~~without charge for the pharmaceutical agents,~~ to initiate appropriate treatment. An optometrist may also pass on to the patient a charge for any medications provided to initiate treatment which reflects only the actual amount paid by the optometrist for the agents. In no event shall an optometrist increase the cost of the pharmaceutical agent beyond the wholesale cost of that medication.

~~8~~9.2. Any ~~optometrist~~ licensee practicing under the authority of this rule shall be held to the same standards of care as that of other health care practitioners providing similar services.

~~8~~9.3. No ~~optometrist~~ licensee shall practice under the provisions of this rule unless and until he or she submits to the board evidence of satisfactory completion of all of the education and examination requirements of sub-divisions 2.1.a., 2.1.b. and 2.1.c. of this rule and has been certified by the board as educationally qualified.

WEST VIRGINIA BOARD OF OPTOMETRY

179 Summers Street, Suite 231
Charleston, WV 25301
Phone: (304) 558-5901 Fax: (304) 558-5908
e-mail: wvbdopt@verizon.net

MEMORANDUM

TO: All Licensees

FROM: Gregory Moore, O.D., President

DATE: June 28, 2010

RE: Board Rules Filed For Comment Last Week

The Board has been working on rule amendments and two new rules to comply with Senate Bill 230 which passed during the 2010 Legislative Session. The bill completely re-wrote the Board's enabling statute, W. Va. Code, §30-8.

New provisions needed to be written to implement the privileges gained. We have made amendments to the Board's existing rules, §14-1 through §14-8. The Board is also proposing three new rules, §14-9, §14-10 and §14-11. These rules outline the certificate procedure to prescribe contacts lenses that contain and deliver pharmaceutical agents required by SB 230, separate the continuing education provisions currently listed in §14-1 with some modernization of the rule and a new specific procedure for course pre-approval, and a rule outlining the procedures required to obtain the privilege to use injections for substances other than epinephrine as required by SB 230. These provisions are listed in §30-8-15 of SB 230.

The proposed rules are posted on our web site, www.wvbo.org in two places. The first is just under the Board's mission statement beside the Annual Report and Education and Training of Optometrists. The second posting is under "Laws and Regulations Governing Optometry" under proposed rules. We have also posted the full text of SB 230 so you may refer to the requirements listed requiring the changes to the rules. The language to be eliminated is struck through and the new language is underlined. There are no underlines or strike throughs in §14-9 through §14-11 because they are new rules.

The Board welcomes and values your opinion. Please review the proposed rules and let us know of your recommendations or concerns. Please send your written comments to the Board by e-mail to wvbdopt@verizon.net, by postal mail at 179 Summers Street, Suite 231, Charleston, WV 25301, or by fax at 304-558-5908. The Board office phone number is 304-558-5901 if you have any questions.

Once again, we value your opinion. Please review these proposals and give us your input. **The last date we can receive your comments for §14-11, Injection Certificate, is Friday, July 23, at 5:00 p.m. The last day we may receive comments for the rest of the rules is noon on Monday, July 26.** Thank you for your time and attention.

Laws

- Senate Bill 230 Chapter 30-8
- Chapter 30 - Article 8 Optometrists
- 14-1 Rules Of The West Virginia Board of Optometry
- 14-2 Expanded Prescriptive Authority Procedures for Optometrists
- 14-3 Contested Case Hearing Procedure
- 14-4 Disciplinary and Complaint Procedures for Optometrists
- 14-5 Schedule of Fees
- 14-6 Examination and Scoring Policy
- 14-7 Administration and Board Meeting
- 14-8 Licensure by Endorsement

Proposed Rules

- Senate Bill 230 Chapter 30-8
- 14-1 Rules of the West Virginia Board of Optometry
- 14-2 Oral Pharmaceuticals
- 14.3 Contested Case Hearing Procedures
- 14.4 Disciplinary and Complaint Procedures
- 14.5 Schedule of Fees
- 14.6 Examination and Scoring Policy
- 14.7 Administration and Board Meetings
- 14.8 Licensure by Endorsement
- 14.9 Contact Lenses that Contain and Deliver Pharmaceutical Agents Certificate
- 14.10 Continuing Education
- 14.11 Injectable Pharmaceutical Agents Certificate

Optometrist List
Click here to start, or call the board office for more information

West Virginia Board of Optometry
179 Summers Street, Suite 231
Charleston, WV 25301
Phone: (304) 558-5901
Fax: (304) 558-5908
Email: wvbdopt@frontier.com

Click here to log in to the
Member Account Manager

Website design by Dream Catcher, LLC

To view PDF's you will need the free Adobe Acrobat Reader

Adobe Reader
download

West Virginia Board of Optometry

From: West Virginia Board of Optometry [wvbdopt@verizon.net]

Sent: Thursday, June 24, 2010 6:12 PM

To: Nancy Tonkin (nancy.tonkin@wvtmg.com)

Subject: Rules

Attachments: 14-11 Proposed Rule Injections 062410.doc

The injection rule was filed today. All of the rules were sent to our web master to be posted on our web site. Guess which one has a broken link? I have sent an email to Dream Catcher to correct it. They are usually pretty fast. It should be up by tomorrow. Here is a copy until then.

Have a good evening,

Pamela Carper
West Virginia Board of Optometry
179 Summers Street, Suite 231
Charleston, WV 25301
Phone: 304-558-5901
Fax: 304-558-5908
E-mail: wvbdopt@verizon.net
Web Site: www.wvbo.org

TO: CHAIRMAN MINARD AND CHARIMAN BROWN
THE LEGISLATIVE RULE-MAKING COMMITTEE

FROM: THE WEST VIRGINIA BOARD OF OPTOMETRY

SUBJECT: LIST OF COMMENTERS FOR PROPOSED RULES

DATE: 7/29/2010

COMMENT PERIOD ON PROPOSED RULES ENDING July 26, 2010

Please note that a complete response, including amendments, and the reasons for the amendments is enclosed in this packet. It is a memo dated July 29, 2010, Response to Public Comments.

LIST OF COMMENTER BY RULE

14CSR 1 RULES OF THE WEST VIRGINIA BOARD OF OPTOMETRY

David W. Harshberger, O.D. by e-mail, dwharshberger @verizon.net

14CSR2 ORAL PHARMACEUTICAL CERTIFICATE

Edgar Gamponia, President, West Virginia Academy of Ophthalmologists, 2110 Kanawha Boulevard, East, Suite 220, Charleston, WV 25311

Sidney B. Jackson, M.D., President, WV Academy of Family Physicians, P.O. Box 1090 Hurricane, WV 25526

Carlos C. Jiminez, M.D., President, WV Medical Association, 4307 MacCorkle Avenue, SE, Charleston, WV 25364

Randolph L. Johnston M.D., President and Cynthia A. Bradford, M.D., Senior Secretary for Advocacy, Academy of Ophthalmology, P.O. Box 7424, San Francisco, CA 94120

Michael D. Maves, M.D., MBA, Executive Vice President, American Medical Association, 515 N. State Street, Chicago, IL 60654

Robert C. Knittle, Executive Director, WV Board of Medicine, 101 Dee Drive, Suite 103, Charleston, WV 25311

Michael F. McGuire, M.D., President, American Society of Plastic Surgeons, 444 East Algonquin Road, Arlington Heights, IL 60005

David R. Neilsen, M.D., Executive Vice President and CEO, American Academy of Otolaryngology – Head and Neck Surgery

William D. James, M.D. F.A.A.D., President, American Academy of Dermatology Association

Joseph L. LoCasscio, III, M.D., F.A.C.S., 5170 U.S. Rt. 60, East, Huntington, WV 25702

Stephen R Powell, M.D.

David B. Hoyt, M.D. FACS, Executive Director, American College of Surgeons, 633 N Saint Clair Street, Chicago, IL 60611

Laurance M. Minardi, M.D., 500 Donnally Street, Charleston, WV 25301

Christoforo R. Larzo, M.D., P.O. Box 9193, Morgantown, WV 26506-9193

14CSR5 SCHEDULE OF FEES

David W. Harshberger, O.D., by e-mail, dwharshberger@verizon.net

14CSR10 CONTINUING EDUCATION

David W. Harshberger, O.D., by e-mail, dwharshberger@verizon.net

14CSR11 INJECTABLE PHARMACEUTICAL AGENTS CERTIFICATE

Edgar Gamponia, President, West Virginia Academy of Ophthalmologists, 2110 Kanawha Boulevard, East/Suite 220, Charleston, WV 25311

Sidney B. Jackson, M.D., President, WV Academy of Family Physicians, P.O. Box 1090 Hurricane, WV 25526

Carlos C. Jiminez, M.D., President, WV Medical Association, 4307 MacCorkle Avenue, SE, Charleston, WV 25364

Randolph L. Johnston M.D., President and Cynthia A. Bradford, M.D., Senior Secretary for Advocacy, Academy of Ophthalmology, P.O. Box 7424, San Francisco, CA 94120

Michael D. Maves, M.D., MBA, Executive Vice President, American Medical Association, 515 N. State Street, Chicago, IL 60654

TO: CHAIRMAN MINARD AND CHAIRMAN BROWN
THE LEGISLATIVE RULE-MAKING COMMITTEE

FROM: THE WEST VIRGINIA BOARD OF OPTOMETRY

SUBJECT: RESPONSE TO PUBLIC COMMENTS

DATE: 7/29/2010

On May 27 and 28, 2010, the West Virginia Board of Optometry (hereinafter "Board") filed proposed legislative rules with the Secretary of State's office. In accordance with appropriate laws, the Board held a public comment period for each of the proposed rules which concluded on July 26, 2010 at noon. The Board has carefully considered all comments received and prepared the following response which will address the comments by rule. Some comments may be paraphrased as many were redundant; however, copies of all received comments are included in this packet as required by law.

14CSR1 RULES OF THE WEST VIRGINIA BOARD OF OPTOMETRY

COMMENT: WHY IS THE BOARD USING ANNUAL RENEWAL?

The Board has opted to change to annual renewal because doing so eases compliance with W. Va. Code §30-1-10.

14CSR2 ORAL PHARMACEUTICAL CERTIFICATE

COMMENT(S): THE LEGISLATURE DID NOT INTEND FOR THE EXPANSION OF THE ORAL FORMULARY.

The Board received sixteen (16) comments suggesting that 14CSR2, as proposed, goes beyond legislative intent when passing Senate Bill 230. It is the Board's position that such an assertion is incorrect and that the legislative intent was expressed in Enrolled Senate Bill 230, subsequently signed into law by the Governor. West Virginia Code §30-8-9(a)(3) states, in pertinent part, that the scope of practice of an optometrist includes the ability to:

> "(A) Administer or prescribe any drug from the drug formulary, as established by the board pursuant to section six of this article, for use in the examination, diagnosis or treatment of diseases and conditions of the

human eye and its appendages: *Provided,* That the licensee has first obtained a certificate;
(B) New drugs and new drug indications may be added to the drug formulary by approval of the board[.]"

West Virginia Code §30-8-14(a) further provides that:

> (a) A licensee may prescribe: (1) topical pharmaceutical agents, (2) oral pharmaceutical agents that are included in the drug formulary established by the board pursuant to section six of this article or new drugs or new drug indications added by a decision of the board, and (3) contact lenses that contain and deliver pharmaceutical agents that have been approved by the Food and Drug Administration as a drug.

It is for those reasons that the Board respectfully submits that 14CSR2 as proposed is within the legislative intent of West Virginia Code §30-8-1 *et seq.*

COMMENT(S): WHAT IS THE DEFINITION OF "APPENDAGES?"

The term "appendages" was defined by the legislature in West Virginia Code §30-8-3(a).

COMMENT(S): PLEASE CLARIFY THE LANGUAGE IN 14CSR2-6.6.2H THE NEW DRUGS AND NEW DRUG INDICATIONS SECTION.

In reviewing this comment, the Board has amended the proposed rule to clarify the language in 14CSR2-6.6.2.h. The language previously submitted stated:

> *6.2.h. New drugs or new drug indications from Schedules III, IV and V of the Uniform Controlled Substances Act, regardless of their listed categories, which have been shown to effective in the treatment and management of abnormalities of the eye or its appendages may be approved by the Board according to the provisions of W. Va. Code §§30-8-9 and 30-8-14.*

This language has been amended and additional language has been added which now states:

> *6.2.h. New drugs or new drug indications from Schedules III, IV and V of the Uniform Controlled Substances Act which, regardless of their listed classification, have been shown to be effective in the treatment and management of the eye or its appendages may be approved by the Board according to the provisions of W. Va. Code §§30-8-9 and 30-8-14.*

6.2.i. A list of approved new drugs and new drug indications proven to be shown to be effective in the treatment of the eye and its appendages will be maintained by the Board for public inspection.

6.2.j. The approval of Schedule I and Schedule II narcotics is prohibited.

In addition to that language, the Board has proposed two additional sections to further clarify this process, which read as follows:

§14-2-7. New Drug Approval.

7.1. The addition of new drugs or drug indications by the Board as cited in subsection 6.2 of this rule may be based on any of the following criteria:

7.1.a. A new or existing drug has been approved by the Food and Drug Administration for the treatment of the eye or its appendages.

7.1.b. A new drug or new drug indication has gained accepted use in the eye care field. Such acceptance may be indicated by its inclusion in the curriculum of an optometry school accredited by the Accreditation Council on Optometric Education or its successor approved by the U.S. Department of Education or approved post-graduate continuing education, through peer-reviewed, evidence-based research and professional journal articles, or by inclusion in established standards of practice and care published by professional organizations.

COMMENT(S): DID THE BOARD MEAN THAT OPTOMETRISTS COULD SELL DRUGS FOR INJECTION AT RETAIL?

The Board did not intend for any pharmaceuticals, oral, topical or injection, to be sold at retail with the language proposed in 14CSR2.7.1.a & b. An amendment to that proposed rule has been made to better clarify this issue. 14CSR2.7.1.a & b as submitted for public comment provided that:

7.1.a. Nothing in this section or in any other provision of law prohibits a licensee who is certified under the provisions of this rule from administering or supplying oral or topical pharmaceutical agents to a patient, without charge for the pharmaceutical agents, to initiate appropriate treatment.

7.1.b. Nothing within this rule or the W. Va. Code prohibits the direct sale to the patient of pharmaceuticals by injection or contact lenses that deliver pharmaceutical agents that have been approved by the Food and Drug Administration as a drug.

The amended language, located in what is now 14CSR2-9.1.a & b, and provides that:

> *9.1.a. Nothing in this section or in any other provision of law prohibits a licensee who is properly certified under the provisions of this rule from administering or supplying oral or topical pharmaceutical agents to a patient, to initiate appropriate treatment. An optometrist may also pass on to the patient a charge for any medications provided to initiate treatment which reflects only the actual amount paid by the optometrist for the agents. In no event shall an optometrist increase the cost of the pharmaceutical agent beyond the wholesale cost of that medication.*
>
> *9.1.b. Nothing within this rule or the W. Va. Code prohibits the administration of pharmaceuticals by injection to a patient by a certified licensee for a reasonable charge or the dispensing of contact lenses that deliver pharmaceutical agents, provided, there is no mark up on the cost of the pharmaceutical agents provided in the injection or in the contact lenses that deliver pharmaceutical agents. Nothing in this rule shall prohibit a properly certified optometrist from charging a usual and customary fee for performing the injection or fitting the contact lenses that deliver pharmaceutical agents.*

The Board is confident that these changes adequately clarifies its intention to permit properly certified licensees to utilize appropriate oral, topical and injection medications, and medicated contact lenses and to have the ability to be compensated for the wholesale cost of any medications and, in the case of injections and medicated contact lenses, be compensated a customary fee for services rendered.

COMMENT(S): THE W. VA. CODE §30-8-15 DOES NOT AUTHORIZE THE DISPENSATION OF PHARMACEUTICALS BY INJECTION, ONLY THE ADMINISTRATION OF PHARMACEUTICALS BY INJECTION.

The Board has submitted amendments addressing this comment, please see previous response.

COMMENT: WILL THE BOARD PUT LIMITS ON LENGTH OF USE OF THE NEW DRUGS ADDED BY THE BOARD?

As addressed above, the Board has amended the language 14CSR2-6.2.i requiring the Board to maintain a list at the board office of any new drug or new drug application that has been shown to be effective in the treatment of the eye or its appendages. By law those drugs will be limited for that purpose and the dosing and duration will be subject to those limitations.

COMMENT(S): WHERE WILL OPTOMETRISTS GET ADDITIONAL TRAINING FOR THE NEW DRUGS ADDED TO THE FORMULARY BY THE BOARD?

The Board has amended 14CSR2 to include language regarding the training for new drugs and/or new drug indications that are approved by the Board. This language states:

> ***§14-2-8. Education and Training on the Use of New Drugs and New Drug Indications.***
>
> *8.1. Additional education and training may be required by the Board as it deems appropriate when it adds new drugs or new drug indications.*
>
> *8.2 This training may be provided through an accredited optometry school or approved post-graduate training.*
>
> *8.3 A list of Board required training for new drugs or new drug indications will be maintained by the Board for public inspection.*

COMMENT(S): WILL THE BOARD REQUIRE COLLABORATION OR CONSULTATION WITH THE PATIENT'S PRIMARY CARE PHYSICIAN BEFORE PRESCRIBING ORAL MEDICATIONS?

There is no requirement contained within state law requiring collaboration or consultation with a patient's primary care physician before prescribing oral medications; however, optometrists certified to prescribe oral medications are well versed in the systemic interactions of medications used for the eye and its appendages and, when appropriate, co-manage patients with other providers.

COMMENT(S): THE ORAL FORMULARY IS ILLEGAL BECAUSE THE OPTOMETRIST CANNOT PRESCRIBE SYSTEMIC AGENTS THAT HAVE SYSTEMIC EFFECTS SUCH AS ORAL ANTIBIOTICS AND NONSTEROIDAL ANT-INFLAMMATORY DRUGS.

Optometrists have had the ability, through legislation, to prescribe oral antibiotics and non-steroidal anti-inflammatory drugs since 1997.

14CSR5 FEE SCHEDULE

COMMENT: THE BOARD HAS MADE A LARGE INCREASE IN YEARLY LICENSE FEES.

After reviewing this comment, the Board is of the opinion that the commenter had misread the fee schedule citing one time certificate fees as annual fees. The increase in the license renewal fee is $75 per year. This is a 23% increase. The Board currently administers licensure, monitoring and investigation of complaints received, disciplinary action, and compliance with all state regulations and financial requirements of a state

agency. The Board has governed four forms of licensure and permit. Senate Bill 230 authorized four new scope programs and three new types of permits.

14CSR10 CONTINUING EDUCATION

COMMENT: CAN THE CONTINUING EDUCATION REQUIREMENT CONTINUE TO BE FULFILLED EVERY TWO YEARS?

The Board has taken this concern under consideration and has made an amendment to 14CSR1 and 14CSR10. The original language in 14CSR10-2.3 in the proposed rule stated that:

> *The evidence shall show his or her attendance or time teaching continuing education as a Board approved instructor for a minimum of twenty (20) hours during the preceding year at educational optometric programs covering one or more of the subjects approved by the Board including the following requirements:*
>
> *(a) a minimum of six (6) hours of study in pharmacology or therapeutics courses;*
>
> *(b) a maximum of three (3) hours of study in practice management;*
>
> *(c) a maximum of five (5) hours of optometric study may be taken by correspondence, or via the internet;*

This language has been amended and now reads as follows:

> *The evidence shall show his or her attendance or time teaching continuing education as a Board approved instructor for a minimum of forty (40) hours for each two (2) year cycle beginning with the dates July 1, 2008 to June 30, 2010 at educational optometric programs covering one or more of the subjects approved by the Board including the following requirements:*
>
> *(a) a minimum of twelve (12) hours of study in pharmacology or therapeutics courses;*
>
> *(b) a maximum of six (6) hours of study in practice management;*
>
> *(c) a maximum of ten (10) hours of optometric study may be taken by correspondence, or via the internet;*

COMMENT: 14CSR10-2.3(E) ON BASIC LIFE SUPPORT DOES NOT COMPLY WITH THE W.VA. CODE

The Board has taken this comment under consideration and has made an amendment to comply with §30-8-15(b)(3). The proposed amendment to14CSR10-2.3(e) states:

In addition to the above listed continuing education requirements, any licensee who has been granted an Injectable Pharmaceutical Agents Certificate shall obtain and maintain current certification from the American Red Cross, American Heart Association or their successor organizations in basic life support.

The Board submits the amended language is in compliance with the newly enacted provisions of West Virginia Code § 30-8-1 *et seq.*

14CSR11 Injectable Pharmaceutical Agents Certificate

Comment(s): 14CSR11 violates the intent of the Legislature. It only intended epinephrine.

The intent and will of the Legislature is expressed in Enrolled Senate Bill 230 signed into law by the Governor. Senate Bill 230 §30-8-15(b) says,

> "(b) Additional pharmaceutical agents by injection may be included in the rules for legislative approval in accordance with the provisions of article three, chapter twenty-nine-a of this code. These rules shall provide, at a minimum, for the following:"

Comment(s): There is no formulary for pharmaceuticals by injection.

In response to the comment, the Board submits that West Virginia Code §30-8-15 does not require a formulary for pharmaceuticals administered by injection. The fact that the legislature refused to add a formulary for topical medications warrants mention. The legislature entrusted the Board with the sole authority to add to the oral formulary demonstrating a confidence in this Board's ability to regulate the practice of optometry, including the utilization of pharmaceutical agents effective in the treatment and management of the eye and its appendages, regardless of route of administration, as mandated by law.

Comment(s): 14CSR11-7.1.6 says that nothing shall permit a licensee to delegate to a non-certified or non-licensed clinician. This may be interpreted that an optometrist may delegate to a licensed clinician such as a registered nurse.

The intent of this proposed rule was to permit an optometrist properly certified to prescribe and administer injections, the ability to write orders for injections which a properly credentialed nurse may administer. This rule was not proposed to permit non-certified optometrists to prescribe an injection and delegate the administration of injections to someone who is certified to give injections. The Board submits the following language to as clarification of this issue:

§14-11-9. Delegation.

9.1. Nothing in this rule or W. Va. Code shall permit a licensee who has not been certified to administer injections of pharmaceutical agents by the Board to delegate to any individual the administration of pharmaceutical agents through injection.

COMMENT(S): 14CSR11 DOES NOT INCLUDE THE STATUTORY PROVISION RESTRICTING OPTOMETRISTS FROM INJECTING INTO THE GLOBE OF THE EYE.

Although the Board deems the restriction found in West Virginia Code §30-8-15 prohibiting optometrists from injecting into the globe of the eye as sufficient, the Board has taken this concern into consideration and has amended 14CSR11 to include the prohibition of injections into the globe in the rule.

COMMENT(S): 14CSR11 DOES NOT PROVIDE SPECIFICS.

While overly broad, the Board has considered this concern and has made amendments to the rule as it deemed appropriate. *See Agency Approved Rule for full proposed language.*

COMMENT(S): INJECTION LOCATIONS AND TYPES ARE NOT LISTED.

The Board has examined the rule and amended the bill include that use of pharmaceuticals by injection by licensees are those which are to be considered rational to the diagnosis and treatment of the human eye and its appendages as defined in West Virginia Code § 30-8-3(a). As with oral medications a list will be kept on file in the board office available for viewing by the public upon request listing and site or agent for which optometrists are certified to provide through accredited schools and colleges of optometry.

COMMENT(S): THE REPORTING REQUIREMENTS ARE INADEQUATE.

The Board has taken this concern under consideration and has made amendments to the bill to deal with this concern. Specifically the language of 14CSR11-6 states:

§14-11-8. Reporting.

8.1. Each licensee who possesses a certificate to administer pharmaceutical agents by injection shall comply with the following reporting requirements.

8.2. Any reporting that may contain patient Protected Health Information (PHI), shall be done in accordance with the Health

Insurance Portability and Accountability Act (HIPAA) patient privacy requirements.

8.3. The licensee shall document in the patient's record that the patient's primary care provider was notified of any injection given to the patient for record documentation. This notification may be made by fax, documented phone call, standard U.S. mail or the licensee may provide a written statement to the patient regarding the injection(s) with instruction to the patient to the listed injection information to his or her current primary care provider.

8.3.1. The above reporting procedure serves to inform the patient's primary care physician as to the rationale and outcome of a licensee's treatment, report any adverse outcomes, and assist in collaborative care of common patients. In no event shall such reporting be construed as permission or approval of an order for treatment by injection.

8.4. A log book of all injections given shall be maintained including:

8.4.1. The patient's initials, age, gender and race;

8.4.2. A statement indicating the purpose of the injection;

8.4.3. The name of the medication administered and the type and location of the injection;

8.4.4. The treatment guidelines followed which must be compliant with the guidelines approved by the Board.

8.4.5 The name and certification or licensure level of any persons working in conjunction with the licensee to administer agents through injections;

8.4.6 How the primary care provider was notified that the patient had been given an injection.

8.5. A copy of the injection log book shall be submitted to the Board upon request. This log book may be requested at any time by the Board with or without cause.

8.6. The Board may request the licensee to supply the complete medical record for any of the patients listed in the log book for review.

The Board may also request an audit of the licensee's full records to ensure compliance with injection certificate requirements.

8.7. If a patient has an adverse event related to the administration of any agent through injection, the licensee must provide the Board with an incident report listing the details of the adverse event and the measures used to correct that event. This report must be received by the Board within 5 business days of the resolution of the adverse event.

COMMENT(S): W. VA. CODE §30-8-15 AUTHORIZES THE ADMINISTRATION OF PHARMACEUTICALS BY INJECTION, NOT THE DISPENSATION OF THOSE AGENTS.

As previously discussed in the aforementioned response to the dispensing of oral and topical medications, the Board has considered this comment and has made an amendment to the rule to address this issue. The amended proposed language provides that:

9.1.b. Nothing within this rule or the W. Va. Code prohibits the administration of pharmaceuticals by injection to a patient by a certified licensee for a reasonable charge or the dispensing of contact lenses that deliver pharmaceutical agents, provided, there is no mark up on the cost of the pharmaceutical agents provided in the injection or in the contact lenses that deliver pharmaceutical agents. Nothing in this rule shall prohibit a properly certified optometrist from charging a usual and customary fee for administering the injection or fitting the contact lenses that delivers pharmaceutical agents.

COMMENT: THERE IS NO PROVISION FOR A LIST OF COURSES APPROVED BY THE BOARD FOR INJECTION.

The Board has examined this concern and has amended 14CSR11 to address this issue. Specifically the Board has amended language of 14CSR11-3.3 states:

3.2 The Board shall accept any course for certification that is provided by or through a school or college of optometry accredited by the Accreditation Council on Optometric Education or its successor organization certifying that the optometrist is competent in providing the administration of pharmaceuticals by injection.

3.3 The Board, at its discretion, may approve courses provided through organizations other than accredited schools or colleges of optometry certifying that the optometrist is competent in providing the administration of pharmaceuticals by injection if, and only if, the course meets the following minimum criteria:

3.3.1. Each course shall include indications, contra-indications, medications, techniques, risks, benefits and sharps management;

3.3.2. Each course shall contain appropriate follow up and management of any adverse reactions caused by an injection;

3.3.3. Each course shall teach the procedures of injection on human subjects in a closely supervised environment with a proficiency assessment examination.

The Board is of the opinion that this language is responsive to the comment.

COMMENT: 14CSR11-3.4 ALLOWS GRADUATES POST 2011 TO BE CERTIFIED IN INJECTIONS WITHOUT CHECKING THEIR COURSES TAKEN.

This provision has two conditions: (1) graduation from an accredited school or college of optometry and (2) passage of Part III of the National Board of Examiners in 2011 or later. One hundred percent (100%) of accredited schools and colleges of optometry must provide this in the curriculum for students graduating in 2011. Those students will sit for the National Board of Examiners in Optometry Examination Part III, Clinical Skills, which will include testing of injection techniques on human subjects.

COMMENT(S): 14CSR11 INCLUDES CONTINUING EDUCATION IN BASIC LIFE SUPPORT AS LISTED IN W. VA. CODE §30-8-15(3) BUT HAS NOT INCLUDED CONTINUING EDUCATION IN INJECTIONS AS LISTED IN W. VA. CODE §30-8-15(4).

The Board has examined this comment and determined that the appropriate action is to make an amendment to 14CSR10-2.3.d. Therefore that proposed rule has been amended to the requiring:

[A] minimum of two (2) hours of instruction in administering pharmaceutical agents by injection for those licensees who hold an Injectable Pharmaceutical Agents Certificate.

In making this amendment, the Board has mandated a specific number of hours per reporting period for all licensees with the certification to administer injections.

COMMENT(S): THE TREATMENT GUIDELINES LISTED IN 14CSR11 ARE VAGUE AND NOT DEFINITIVE AS REQUIRED IN W. VA. CODE 30-8-15(B)(2).

The Board has examined this concern and has amended the rule to address this concern. *See Agency Approved Rule for full proposed language.*

COMMENT: THE AMA CONSIDERS INJECTIONS TO BE SURGERY, AND W. VA. CODE PROHIBITS SURGERY BY OPTOMETRISTS.

In considering this comment, the Board directs the commenter to West Virginia Code § 30-8-9(a)(7)(A-G) which states in pertinent part that a licensee may:

> (A) [r]emove a foreign body from the ocular surface and adnexa utilizing a non-intrusive method; (B) [r]emove a foreign body, external eye, conjunctive, superficial, using topical anesthesia; (C) [r]emove embedded foreign bodies or concretions from conjunctiva, using topical anesthesia, not involving sclera; (D) [r]emove corneal foreign body not through to the second layer of the cornea using topical anesthesia; (E) [e]pilation of lashes by forceps; (F) [c]losure of punctum by plug; and (G) [d]ilation of the lacrimal puncta with or without irrigation.

That code section describes seven procedures optometrists are permitted to perform which are coded as surgical procedures. Further, West Virginia Code §30-8-9(a)(11) also states "those procedures permitted by the board prior to January 1, 2010 shall be permitted." Finally, West Virginia Code §30-8-9(b)(1) provides that a licensee may not "[p]erform surgery except as provided in this article or by legislative rule." Additionally, while the AMA is a highly respected organization, the Legislature has authorized properly certified optometrists to administer injections under certain conditions. Further, it appears that this comment is an attempt to undermine the Legislature's directive to the Board to make its rules congruent with the newly enacted changes to the laws governing the practice of optometry.

COMMENT: HOW MANY CLINICALLY SUPERVISED INJECTIONS MUST LICENSEES PERFORM?

In reviewing this comment, the Board has amended its proposed rule to clearly require this training to be through an accredited school or college or optometry. *See above response regarding 14CSR11-3.3.* The Board deems it prudent to note that specifics of such training will undoubtedly change with the advent of new science and technology. Requiring this training and certification to be done through an accredited school or college of optometry ensures the board and the legislature that the training is appropriate.

COMMENT: WILL LICENSEES WITH AN INJECTION CERTIFICATE BE INJECTING CHILDREN?

A licensee who is properly certified through the Board to administer injections will only administer injections to children if trained to do so through accredited schools and colleges of optometry.

COMMENT: WILL THE LICENSEE WITH AN INJECTIONS CERTIFICATE BE PERFORMING FLOURESCEIN ANGIOGRAMS?

A licensee who is properly certified through the Board to administer injections are only permitted to administer those injections taught and certified for through an accredited school or college of optometry.

COMMENT: WILL THE BOARD REQUIRE A DISPENSING LICENSE TO DISPENSE PHARMACEUTICALS BY INJECTION?

As discussed above, the Board has amended 14CSR9 to address the issue of optometrists "dispensing" pharmaceuticals. *See above response regarding 14CSR9-1.a & b.*

COMMENT: ADVERSE REACTION TRAINING IS PROHIBITED BY LAW SINCE THAT IS A WHOLE BODY SYSTEMIC PROCEDURE.

Throughout the process of enacting changes to West Virginia Code §30-8-1 *et seq.*, not only did the Legislature authorize the administration of injections by certified optometrists, it mandated that the Board determine the appropriate education and training to grant such certification. For the Board to permit licensees to hold certifications to administer injections, it is prudent for the Board to require adverse reaction training for those determined qualified for this certification. Any suggestion that training in recognizing and/or responding to an adverse reaction is, or should be, prohibited by law is irresponsible and rejected by this Board. Further, the Legislature provided in West Virginia Code §30-8-9(a)(4) that a licensee may "[a]dminister epinephrine by injection to treat emergency cases of anaphylaxis or anaphylactic shock[,]" which is an example of a whole body systemic procedure. This Board understands that the ability to administer injections is nothing to be taken lightly, and, in maintaining congruency with its legislative mandate to protect the public, will require any optometrist who seeks certification to inject pharmaceuticals to have such training.

COMMENT(S): THERE IS NO NATIONAL STANDARD FOR TEACHING INJECTIONS IN ACCREDITED OPTOMETRY SCHOOLS. HOW WILL THE BOARD ENSURE PROPER INSTRUCTION?

The legislature has clearly shown confidence in the accrediting bodies which oversee educational institutions as it requires that training be from institutions which are accredited, be it medical, dental, or optometry schools. By requiring training through accredited schools and colleges of optometry, the legislature, through the oversight of the board, is ensuring that the candidates are receiving the appropriate training.

West Virginia
Academy Of
Ophthalmology

Gregory S. Moore, OD
President
West Virginia Board of Optometry
179 Summers Street, Suite 231
Charleston, WV 25301

July 21, 2010

Dear Dr. Moore,

As President of the West Virginia Academy of Ophthalmology I am providing comments and asking for clarifications with specific questions surrounding Title 14 Series 2 and Title 14 Series 11 rules that have been submitted to the Secretary of State's office. The medical community is extremely concerned with patient safety issues which are evident in these rules.

Title 14
Legislative Rule
West Virginia Board of Optometry
Series 2

§ 14-2-2 ~~Certification~~ Requirements for Oral Pharmaceutical Certificate.

2.1.b "Shall satisfactorily complete a course in clinical pharmacology as applied to optometry. This course shall have particular emphasis on the administration of oral pharmaceutical agents for ~~the purpose of examination of the human eye and analysis of ocular functions~~ diagnosis and treatment of the visual defects or abnormal conditions of the human eye and its ~~adnexa~~ appendages."

Comment:

The primary concern with this deals with defining appendages. It is assumed that the Board will follow the definition that is in state law. However, it is necessary to identify what the Board considers within the realm of the practice of optometry.

Questions:

1. Does the Board of Optometry consider the brain an appendage of the eye?
2. Does the Board of Optometry consider the skin of the face appendages of the eye?

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3. Does the Board of Optometry consider muscles of the face appendages of the eye?
4. Does the Board of Optometry consider the sinuses appendages of the eye?

§ 14-2-6 Drug Formulary

6.2.h "New drugs or new drug indications from Schedules III, IV, and V of the uniform Controlled Substances Act, regardless of their listed categories, which have been shown to be effective in the treatment and management of abnormalities of the eye or its appendages may be approved by the Board according to the provisions of W. Va. Code §§ 30-8-9 and 30-8-14."

Comments

There is a serious concern regarding the expansion of oral medications as these drugs circulate throughout the body, not just targeting the eye, but targeting all organs and affecting bodily functions. As has been expressed in the past, there are patient safety issues when an individual prescribing medications that affect the whole body has not had training and management of systemic diseases. Systemic medications do often cause an adverse systemic reaction of one or more organ systems. Specific questions regarding the statement: "which have been shown to be effective in the treatment and management of abnormalities of the eye or its appendages may be approved by the Board" include:

Questions:

1. Does the Board mean that they will approve only drugs that have specific indications for use as determined by the pharmaceutical company and the FDA?
2. What educational clinical supervised training will be required for optometrists to use new drugs that are not on the formulary?
3. Where will optometrists get the additional supervised training in using new systemic drugs?
4. What are the criteria for the Board defining "which have been shown to be effective in the treatment and management of abnormalities of the eye or its appendages"
5. What does the Board mean by "regardless of their listed categories"?
6. Why is there not a mandatory collaboration with the patient's primary care physician, or other physician to give protections for systemic drug interaction and other adverse organ consequences?

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§ 14-2-7 Restrictions

7.1.b "Nothing within this rule or the W. Va. Code prohibits the direct sale to the patient of pharmaceuticals by injection or contact lenses that deliver pharmaceutical agents that have been approved by the Food and Drug Administration as a drug."

Comments:

This section is very disturbing to think that the Board of Optometry could approve optometrists to sell and dispense drugs for injections. It is interesting that the Board prohibits the sale of topical and oral medications, yet drugs which have a significantly greater chance of reaction (injectables) could be sold by optometrists in their office. This is egregious. Serious concerns regarding injectables will be addressed in the review of Rule 14-11.

Title 14
Legislative Rule
West Virginia Board of Optometry
Series 11
Injectable Pharmaceutical Agents Certificate

This Rule has some very dangerous provisions in it that would place citizens of our state at significant risk if the rule were to pass. It exceeds any such provision of any state in our Nation and would open our citizens up to potential harm. It is not necessary and the following analysis and comments will identify these high risk areas for our citizens. Additionally, the intent of the Board is very unclear and can only be understood by answering specific questions.

I will identify specific areas of concern followed by comments and specific questions.

§ 14-11-1. General.

1.1 Scope. -- This rule establishes the requirements, procedures and standards for the certification of a licensee with the authority to administer and dispense injectable pharmaceutical agents.

Comments:

Administering and dispensing injectable agents should be done by individuals qualified to deal with acute reactions or acute organ failure. A reaction to injections can require immediate medical treatment to include the use of other injectable drugs and

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performing life support measures. It should be done in a controlled environment where physicians or medical personnel who have had supervised clinical training can deal with a severe reaction.

Questions:

1. What injectable medications does the Board of Optometry intend to allow to be injected by optometrists?
2. Does the Board intend to allow optometrists to sell injectable medications?
3. What are the supervisory requirements of optometrists giving injections?
4. What is the required supervised clinical training required before an optometrist can give injections?

§ 14-11-3 Education and Training

3.1. An applicant for a certificate to administer injectable pharmaceutical agents shall complete and successfully pass an approved course in the administration of pharmaceuticals by injection.

3.2. The Board shall accept any course for injection certification that is provided by or through a school or college of optometry accredited by the Accreditation Council on Optometric Education or its successor organization certifying that the optometrist is competent in providing the administration of pharmaceuticals by injection.

3.3. The Board may, at its discretion, approve courses provided through organizations other than accredited schools or colleges of optometry certifying that the optometrist is competent in providing the administration of pharmaceuticals by injection, provided those course provide the same level of training as required by the accredited schools or colleges of optometry to maintain accreditation.

3.4. Any license granted to an applicant who graduated from an accredited school or college of optometry in 2011 or thereafter and who passed Part III of the National Board Examination in 2011 which includes injection testing or thereafter shall be deemed to have met the criteria listed in this section.

Comments:

There are many open ended assumptions regarding the education and training as defined in § 14-11-3. It appears that there is a very big discrepancy in what other disciplines consider appropriate education and training and what the Board of Optometry has described. For instance, during training in dental school, podiatry residencies, and medical residencies (osteopathic and allopathic), clinical training and supervision plays the ultimate educational role in learning clinical skills. Most optometry schools are in states that do not permit injections and therefore students do not get

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supervised in performing injections. Even more importantly, they do not have experience in dealing with adverse reactions

Questions:

1. Sections 3.1 thru 3.4 does not refer to obtaining any clinical supervised experience. What will be the minimum clinical supervised experience required for each type of injection for optometrists in the state of West Virginia?
2. What is the injectable drug formulary that the Board is considering?
3. Will the Board require more than a demonstration on an artificial vein or limb to be certified to inject West Virginia residents?
4. How will the Board handle the different educational experience if there are no minimum requirements for injection privileges in the optometry schools?
5. If there are no national minimum requirements for injections in schools of optometry, does that mean that practicing optometrists are also not required to undergo supervision to give different types of injections?
6. If injections are given by the optometrist, where will the optometrist learn to deal with the emergent complications (heart failure, seizure, paralysis, kidney failure, anaphylactic shock, respiratory arrest, etc) that accompany some injections?

§ 14-11-6. Treatment Guidelines

6.2. The licensee shall adhere to generally accepted standards of care and follow established clinical guidelines for administering injections. The licensee shall monitor patient response and provide appropriate follow up care for patients treated by injections.

Comments:

Optometrists do not have clinical training in dealing with systemic disease. Scope of practice restricts the treatment of disease to those of the eye and appendages with restrictions as defined in law.

Questions:

1. What actual clinical training will be required of optometrists to deal with abnormal responses to injections?
2. Will a physician be required to be present in case of an adverse reaction?
3. How can the optometrists provide "appropriate follow up care" when there is a serious reaction if there has been no supervised clinical training of the optometrist?
4. What happens if there is an unrecognized reaction or the reaction occurs after the patient has left the office?

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5. Would optometrists be required to have a dispensing license to sell drugs by injection as is required by the Board of Medicine for physicians?

§ 14-11-6. Treatment Guidelines

6.3 Unless requested through an emergency rule of the West Virginia legislature or the Federal Government through the Department of Homeland Security or its successor organizations, a licensee shall only administer agents through injection that are for the treatment and management of abnormalities of the eye and its adnexa.

Comments:

Serious reactions to injectable agents are not uncommon. Many such reactions require immediate and urgent attention. Optometrists do not have the supervised clinical training to address these serious reactions. These reactions involve organ systems outside of the eye and adnexa that optometrists have not had supervised training in treating.

Questions:

1. Optometrists are restricted by law to the treatment and management of abnormalites of the eye and its adnexa with specific scope of practice restrictions. If a patient has an adverse urgent reaction optometrists have not had the training to deal with, and, in fact are prohibited by law to treat other organ systems. How does the Board rectify this discrepancy?
2. Basic Life support does not provide enough support to patients who have a serious drug induced (injection) reaction. Physicians have had extensive clinical training in adverse drug reactions from injections. Physicians that perform invasive injections have crash carts with intravenous drugs and airway devices to be used. Will optometrists meet the same standard of care? If so, how will they learn to use life saving drugs in the crash carts?

§ 14-11-7. Reporting

7.1.4 In the event that the treatment by injection has observed implications, interactions, or impact with regard to any other diagnosis or condition a patient may have or any other treatment the patient be receiving, or an unanticipated outcome or unexpected side effect occurs as a result of treatment by injection, the licensee shall be required to provide a report of such treatment and its clinical outcome to the patient's primary care physician of record.

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Comments:

This statement implies that the optometrist has had clinical training in the ramifications of giving serious intravenous and intramuscular injections that can affect other organ systems. It also implies that optometrists are trained to handle other organ systems in the event of an adverse reaction. Scope of practice specifically limits optometrists to the treatment and management of abnormalities of the eye and adnexa within state law. Section 7.1.4 ignores this and allows optometrists to administer injections that affect other organs and in fact interfere with medications that patient may be on. This is dangerous and section 7.1.4.a even allows optometrists to give injections without approval by the primary care physician. The safety of the patient must be more important than the Board permitting optometrists to randomly give injections without involvement of the primary care physician.

Questions:

1. All injections can have serious ramifications. Physicians should be on site in case of an adverse event. Is it true that the Board is not requiring the optometrist to get approval from the primary care physician to help decrease the risk of giving such injections?
2. What is the supervised clinical training that an optometrist must complete in order to recognize and identify adverse reactions of other organ systems?

§ 14-11-7. Reporting

7.1.5 A licensee who has become certified to provide treatment by injection may work in conjunction with any certified or licensed clinician to administer agents through injection. However, nothing in this rule shall permit a licensee to delegate to a non certified or non licensed clinician the privilege to administer pharmaceutical agents through injection.

Comments:

This has potentially serious ramifications. What this is indicating is that an optometrist can give an order to a nurse or other practitioner to give injections under their supervision. An optometrist who has had no supervised clinical training dealing with systemic diseases would be permitted, by rule, to now supervise medical personnel giving the injections. Medical personnel would now be assuming liability and the individual supervising would not have had supervised medical training to deal with the complications.

Questions:

1. What injections do the Board of Optometry feel can be delegated to medical personnel?

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2. Who does the Board consider to have appropriate certification?
3. What licensed clinicians are the Board referring to?

General Observations

1. This rule is very vague and open ended allowing the Board of Optometry to approve every type of injection (injections into the eye are prohibited by law).
2. Title 14, Series 2 has a definitive formulary identifying drugs that are approved for use by optometrists. Title 14, Series 11 on the other hand is completely open ended without mention of a formulary.
3. Injections can have immediate and potentially fatal complications. Yet, the Board has not submitted a formulary so that discussion of the risks could be debated. Instead, they simply want to approve all intramuscular, intravenous, skin and injections on the surface of the eye and face.
4. The cost of having an OSHA compliant office is totally ignored. If an optometrist wanted to be OSHA compliant with the handling of needles, there are significant expenses. They would have to plan on doing enough volume to cover the costs of proper disposal and protection of employees.
5. There is virtually no supervised clinical training required to learning how to give injections and, more importantly, how to deal with complications. Didactic, classroom introduction to injections does not meet the strict educational criteria that clinical (hands on) medical training involves.

Thank you for your attention to these issues.

Sincerely,

Edgar Gamponia, MD

Edgar Gamponia, MD
President
West Virginia Academy of Ophthalmology

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WEST VIRGINIA ACADEMY OF
FAMILY PHYSICIANS
STRONG MEDICINE FOR WEST VIRGINIA

July 23, 2010

Gregory S. Moore, O.D., President
West Virginia Board of Optometry
179 Summers Street, Suite 231
Charleston, WV 25301

Dear Dr. Moore:

The West Virginia Academy of Family Physicians is the largest state medical specialty society in West Virginia. On behalf of our 850 practicing family physician members, we hereby express serious concerns over the rules by the Board of Optometry as filed with the Secretary of State. We do not believe these proposals are appropriate to maintain patient protections for prescription medications and injections to patients of our state.

Our particular concerns are addressed to proposed Rules 14-2 and 14-11:

Proposed Rule: 14-2

The title of this section is "ORAL PHARMACEUTICAL CERTIFICATE" and the scope section 14-2-1.1 pertains to "oral pharmaceutical prescriptive authority; however, section 14.2.7.b allows optometrists to provide the "direct sale to the patient of pharmaceuticals by injection" if approved by the FDA. This is clearly inappropriate to this section for oral drugs and also is of concern as optometrists are not allowed to sell other drugs to patients, and licensed physicians and surgeons are required to obtain a special license to sell any prescription drug to a patient.

While section 14-2-6.2 authorizes the Board of Optometry to develop by rule a formulary of categories of oral drugs, there is no approved drug formulary provided for new drugs or new drug category indications as contained in section 14-2-6.2e. This is a severe lack of patient protection to have an unrestricted use of all new drugs or drug categories without a drug formulary specifically contained in this rule.

Optometrists are not clinically trained in the systemic use of prescription medications and it is important for the medical care of patients to carefully evaluate how any prescribed medication affects not only in and around the eye, but more importantly, the rest of the body. It is also important for any prescriber to have the knowledge of all other medications used by the patient to measure adverse systemic medical affects and contraindications, which optometrists

are not clinically trained to do. It seems only appropriate that the provisions of the proposed rule must require consultation or approval with the patient's family physician before these prescription medications are allowed.
For these reasons, this rule should be modified to prohibit the direct sale by optometrists of any drug by injections to patients, create and include a total drug formulary for legislative approval, and require consultation or approval by a primary care physician (PCP) for any medications prescribed by an optometrist.

Proposed Rule: 14-11
While the provisions of SB 230 allows the Board of Optometry to propose a rule relating to permissive use of injections under certain circumstances by optometrists, the rule fails to provide any specifics and is violative of the statutory authorization.

The legislature was very cautious about allowing optometrists to administer injections, and for good cause. The proposed rule fails to provide the need for optometrists to give injections, the circumstances of the injection, the types of injections allowed, the medications to be injected, the allowable age of the patient receiving injections, or the body location of the injections.

The proposed rule purports to say that reporting procedures in the rule "serves to inform the patient's PCP as to the rationale and outcome of treatment by an optometrist," but the rule actually fails to do this in all cases when an injection would be given, and we strongly disagree that it does not provide that communication to the PCP or safety protection for the patient.

Of critical concern to family physicians is the lack of required consultation or approval of injections for an optometrist by the primary care physician, which endangers patient care. In fact, most injections, if any, should not be legislatively approved by rule for administration by an optometrist, particularly to pediatric patients, and in other cases on-site availability of a primary care physician should be required to handle emergency treatment for adverse patient reactions.

For these reasons, this rule should be withdrawn.

It is the position of the West Virginia Academy of Family Physicians that 14-2 and 14-11 of the proposed rules by the Board of Optometry, actually lowers the standard of medical care and pharmaceutical treatment for West Virginians, while failing to provide any demonstrated need, any cost savings, or any lack of accessibility and availability of quality eye care.

Sincerely,

Sidney B. Jackson, MD
WVAFP President

WEST VIRGINIA State Medical Association

July 23, 2010

Mr. Gregory S. Moore, OD
President
WV Board of Optometry
79 Summers Street, Suite 231
Charleston, WV 25301

Re: 14 CSR 2, Expanded Prescriptive Authority

Dear Dr. Moore,

On Behalf of the West Virginia State Medical Association (WVSMA) I am writing to share comment regarding the West Virginia Board of Optometry's (Board) **Rule 14 CSR 2 Expanded Prescriptive Authority**. In our review of this rule we have identified the following questions and concerns:

West Virginia code §30-8-6(9) directs the Board to draft a rule containing a prescription drug formulary classifying categories of oral drugs from Schedules III, IV and V which are "rational to the diagnosis and treatment of visual defects or abnormal conditions of the human eye and its appendages". The Board, instead of establishing a formulary, simply suggests that such controlled substances "regardless of their listed categories" may be approved by the Board. This language is vague and leaves to question what drugs are approved. No formulary is established in the rule as is required by statute. The WVSMA is uncertain as to the full impact of this section of the rule since it has been left vague. It is the opinion of the WVSMA that the intent of the statute is to establish such a specific formulary in the rule and requests that the Board modify its rule to include such specific information. The WVSMA is interested in understanding how the Board plans to approve new drugs or drug indications if this is left incomplete.

Under section §14-2-7.1.b of the rule the Board clarifies that nothing in the rule or code "prohibits the direct sale to the patient of pharmaceuticals by injection...". However, in 7.1 the Board specifically clarifies that such sale of pharmaceuticals, if they are to be oral or topical, is in fact prohibited. This is clearly an awkward conflict between the two sections and calls to question what the Board considers to be the differing factor between the two. Additionally, it is the understanding of the WVSMA that no one other than a licensed pharmacist may sell at retail legend drugs. This would include injectable pharmaceutical agents. The WVSMA questions the intent of this section and requests from the board a clarification on what type of drug sale was envisioned to occur in West

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Virginia's optometric offices and why the Board believes that optometric offices are afforded the ability to sell pharmaceuticals when other providers are not.

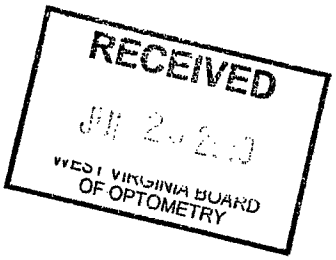
In summary the WVSMA is concerned about the imprecision and deficiencies of this rule. We believe the rule need to be substantially enhanced with clarifying language on virtually all points.

We thank you for the opportunity to comment on this proposed rule and hope that the Board will take into serious consideration the questions and concerns raised in this letter. If you have any questions please do not hesitate to contact us.

Sincerely,

Carlos C. Jimenez, MD
President

AMERICAN ACADEMY OF OPHTHALMOLOGY
The Eye M.D. Association



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July 23, 2010

Gregory S. Moore, O.D.
President
West Virginia Board of Optometry
179 Summers Street, Suite 231
Charleston, West Virginia 25301

Dear Dr. Moore:

On behalf of the American Academy of Ophthalmology, we are writing to state our concern on the series of proposed regulations filed with the West Virginia Secretary of State by the Board of Optometry in response to Senate Bill 230 passed by the West Virginia State Legislature and signed by Governor Manchin this spring. As medical doctors and doctors of osteopathy who care deeply for the welfare of our patients, we want to ensure the highest quality eye care for West Virginia residents.

As we understand it, the Board's role is to interpret Senate Bill 230 by issuing regulations to clarify the scope of practice of optometrists in West Virginia in preparation for the new law going into effect. However, we have grave concerns with the Board's proposed regulations. These proposed regulations would significantly expand the optometric scope of practice well beyond the very clear legislative intent of Senate Bill 230. In particular, proposed Regulations 14-11 and 14-2 are significant departures from Senate Bill 230.

Proposed Regulation 14-11

Proposed Regulation 14-11 would expand the optometric scope of practice far beyond what the legislature intended in Senate Bill 230 by issuing open-ended, blank check authority to the Board to determine certification standards for when an optometrist may administer and dispense injectable pharmaceutical agents. The legislature extensively debated and specifically rejected virtually identical language giving open-ended authority to the Board of Optometry to determine which injectable pharmaceutical agents optometrist would be allowed to administer. As you are fully aware, the House-Senate Conference Committee removed the similar language and amended SB 230 to specifically limit injections to the administration of epinephrine by injection to treat emergency cases of anaphylaxis or anaphylactic shock. To now propose a regulation that would give the Board authority to determine certification standards to allow optometrists to administer and dispense any injectable medication defiantly and glaringly violates the intent of the West Virginia Legislature. In fact, these injection provisions were drafted with such blatant disregard of the intent of the state legislature that although this language would allow optometrists to "work in conjunction with any certified or licensed clinician to administer agents through injection," SB 230 specifically prohibits optometrists from delegating the authority to administer injections <u>to any other person</u>. Moreover, the introduction of the term "dispense" would appear to allow optometrist to also sell injectable medications, an entirely new provision that was never included in any version of Senate Bill 230. In fact, as you know, the West Virginia Legislature in SB 230 only authorized optometrists to dispense contact lenses that contain and deliver pharmaceutical agents and that have been approved by the Food and Drug Administration as a drug.

AMERICAN ACADEMY OF OPHTHALMOLOGY
The Eye M.D. Association

Proposed Regulation 14-2
The proposed language in 14-2 would allow the Board of Optometry to authorize optometrists to sell drugs for injections. This practice is not even allowed for topical and oral medications.

This legislation was debated for two years in the legislature and gained a good deal of national attention, because, as originally introduced, SB 230 would have given West Virginia optometrists one of the most expansive scopes of practice in the United States. After hours of debate, numerous hearings and several iterations of the bill, the West Virginia legislature passed a much scaled-down version of what had been originally introduced in the bill.

These proposed regulations appear to be an attempt to use the regulatory process to pass a substantial number of provisions that had been introduced in the original version of Senate Bill 230 but were later removed or amended at the legislature's direction for passage of the bill. To pass these provisions now as regulations would be to deliberately undermine what the legislature saw fit to make law after careful consideration over what is best for West Virginia residents. Even more alarming is the detrimental effect these regulations could have on the safe, quality care West Virginia patients deserve.

Thus, in the interest of patient safety, we respectfully request that the Board of Optometry retract proposed regulations 14-2 and 14-11 and any other language that does not ensure the delivery of the highest quality eye care in West Virginia. We further encourage you to work with the dedicated community of medical doctors and doctors of osteopathy in West Virginia to develop regulations that do not expand optometric scope beyond the provisions enacted by the West Virginia legislature in Senate Bill 230.

Thank you for your consideration.

Sincerely,

Randolph L. Johnston, MD
President

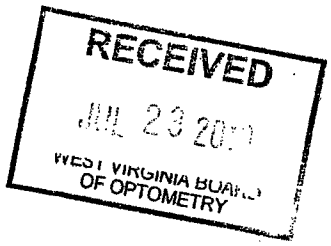
Cynthia A. Bradford, MD
Senior Secretary for Advocacy

Cc: West Virginia Academy of Ophthalmology
West Virginia State Medical Association

AMA
AMERICAN
MEDICAL
ASSOCIATION

Michael D. Maves, MD, MBA, Executive Vice President, CEO

July 23, 2010



Gregory S. Moore, OD
President
West Virginia Board of Optometry
179 Summers Street, Suite 231
Charleston, WV 25301

Dear Dr. Moore:

On behalf of the medical student and physician members of the American Medical Association (AMA), I am writing to highlight our concerns regarding Proposed Regulations 14-2 and 14-11. The AMA appreciates the opportunity to provide comment regarding these regulations, which – as currently proposed – raise significant patient safety issues that we believe must be addressed to ensure high quality eye and medical care for West Virginia's patients.

Specific comments are below that outline our top-level concerns, but the AMA believes a more appropriate course of action is for the West Virginia Board of Optometry (WVBO) to retract the proposed regulations until such time that the WVBO and the physician community in West Virginia can mutually agree how to best ensure the safety of West Virginia's patients.

West Virginia law clearly limits optometric prescriptive authority to the human eye and prohibits optometric authority to treat systemic disease

- Pursuant to the definition of the "practice of optometry,"[1] the West Virginia legislature clearly intended to limit optometric scope of practice to the human eye. Furthermore, the West Virginia legislature also clearly intended to limit optometric administration and prescription to a limited range of pharmaceuticals for treatment focused solely on the eye.[2]

- Proposed Regulations §14-2-2, §14-2-6 and §14-2-7, however, have the potential to greatly expand optometric scope of practice to pharmaceuticals that have whole-body systemic effects – clearly beyond the intent of the West Virginia Legislature and in violation of West Virginia law.

- West Virginia Code §30-8-9 clearly states that "a licensee may not treat systemic disease."[3] However, Proposed Regulation §14-2-6 creates a vast formulary for pharmaceuticals that have unquestionable systemic effects, including oral antibiotics, oral nonsteroidal anti-inflammatory drugs, antihistamines, analgesics and more. Incredibly, the only guidance that the WVBO provides to guide optometrists is that the prescription be "rational." Without physician supervision, patient safety is put at risk.

[1] W.V. Code §30-8-3(l) "Practice of optometry" means the examining, diagnosing and treating of any visual defect or abnormal condition of the human eye or its appendages within the scope established in this article or associated rules.
[2] *See generally,* W.V. Code §30-8-9 and §30-8-14.
[3] W.V. Code §30-8-9(b)(3)

- Without much greater specificity and thorough revision, Proposed Regulations §14-2-2 and §14-2-6 would place patients in dangerous situations beyond an optometrist's education and training. The AMA does not dispute that optometrists provide valuable eye-care services. However, the West Virginia legislature specifically prohibits the WVBO from authorizing prescriptive authority for drugs that have systemic effects. As such, the AMA strongly urges the WVBO to go back to the drawing board and work with the medical community to satisfy and follow the will of the West Virginia legislature.

West Virginia law clearly limits optometric authority for injections only in emergency situations

- The AMA considers the injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system to be surgery. Patient safety can only be assured when surgical procedures are done by a physician. The West Virginia legislature takes the same approach in having clearly prohibited optometrists from performing surgery.[4]

- In direct contravention of West Virginia law, however, Proposed Regulation §14-2-7.1.b purports to allow the injection of pharmaceuticals. What makes the proposed regulation even more concerning is that it does not specify where the injections are to occur: in the human eye? In the central nervous system? In an artery? Therefore, not only does Proposed Regulation §14-2-7.1.b violate West Virginia's prohibition against performing surgery, it also violates West Virginia law (as described above) that prohibits optometrists from using treatments that have systemic effects.

Proposed educational requirements raise troubling patient safety concerns

- Proposed Regulation §14-2 suggests that by virtue of taking "***a*** course in clinical pharmacology as applied to optometry," that consists of a mere "***30 hours in clinical systemic pharmacology***," (emphasis added) optometrists will somehow gain the requisite education and training to safely prescribe any Schedule III-V pharmaceutical by any route, whether topical, oral or by injection. There are numerous patient safety concerns that this proposed regulation raises.

- As explained above, pharmaceutical agents, such as those proposed by the WVBO, undeniably have broad systemic effects. To suggest that they are limited only as applied to optometry demonstrates the false presumption and emphasizes the great patient safety concerns raised by physicians in West Virginia. The reason that ophthalmologists and other physicians safely prescribe pharmaceuticals is because they have the specific education, training and understanding of how pharmaceuticals affect the entire person.

- Proposed Regulation §14-11-3 not only violates West Virginia's law prohibiting optometrists from performing surgery, but its educational requirements are severely vague and deficient. Specifically, upon whom will the optometric students practice injections, and who will supervise for potential adverse reactions? The proposed regulation makes no mention of any minimum standards other than stating that the WVBO "shall accept ***any*** course for injection certification" (emphasis added) from an optometric-accrediting institution.

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[4] *See* W.V. Code §30-8-9(b)(1).

The proposed treatment guidelines and other patient protections are severely lacking

- Proposed Regulation §14-11-6 appears to try and put forward patient protections, but the vague requirement for a prescribing optometrist to follow "generally accepted standards of care" does not specify what standards those may be. Are they standards for medical care that go beyond the legal scope of practice for optometrists? Or are they optometric prescribing standards of care that are not defined in statute or regulation? This troubling lack of specificity must be addressed before the WVBO moves forward with this proposed rule.

- The only protection apparently afforded by proposed regulation is an after-the-fact reporting requirement of Proposed Regulation §14-11-7. Optometrists only are required to report "observed" adverse reactions. Many adverse reactions, however, may not manifest until after the patient leaves the office.

- Furthermore, without a thorough understanding of system effects and whole-body diagnosis, an optometrist would be woefully unprepared to assist a patient who has an adverse reaction either in the office or after the injection. While the AMA supports the reporting requirement of adverse reactions and "unexpected side effect(s)," the AMA believes a safer approach would be to do everything possible to avoid those potentially dangerous situations altogether. The AMA believes Proposed Regulation §14-11-7 puts the patient directly in harm's way.

The AMA appreciates the opportunity to provide these comments, and we strongly urge the WVBO to retract the proposed regulations until such time that the numerous patient safety issues are specifically addressed to the mutual satisfaction of West Virginia's physician and optometric communities. The AMA did not support Senate Bill 230 because we believe that it exposes patients to unnecessary risk, and we are even more concerned by the proposed regulations, which put patients in even greater danger.

Thank you for your consideration.

Sincerely,

Michael D. Maves, MD, MBA

cc: Evan Jenkins
David Parke, MD

State of West Virginia
Board of Medicine

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July 16, 2010

Gregory S. Moore, O.D., President
West Virginia Board of Optometry
179 Summers Street, Suite 231
Charleston, West Virginia 25301

Re: Proposed 14 CSR 2

Dear Dr. Moore:

On behalf of the West Virginia Board of Medicine, I am submitting the following comment on 7.1.b of the above proposed rule. The way 7.1.b is written currently does not take into account an important case decided by our Supreme Court in 1979. The case is Ye Olde Apothecary v. G.O. McClellan, 163 W.Va. 19, 253 S.E. 2d 545, and I enclose a copy for your review.

Our General Counsel is of the opinion that this case would be equally applicable to any health care provider other than a pharmacist selling drugs from his or her office. Our dispensing rule, 11 CSR 5, contains a provision taking into account the ruling in Ye Olde Apothecary v. G.O. McClellan, that is at 11-5-5.1 specifying that the sale at retail of legend drugs by dispensing physicians is prohibited.

I suggest that proposed 14 CSR 2 7.1.b be re-written so that it conforms with the law and clarifies that patients of the optometrists may receive injectables for a reasonable charge. This shouldn't be difficult.

With respect to the entire rule, the rule in no respect should exceed the authority given by Senate Bill 230. On behalf of the Board of Medicine, I suggest you give this aspect increased scrutiny before filing the Agency Approved Rule.

Thank you for your time and attention.

Sincerely,

Robert C. Knittle

lab
enclosure

C
Ye Olde Apothecary v. McClellan
W.Va., 1979.

Supreme Court of Appeals of West Virginia.
YE OLDE APOTHECARY
v.
G. O. McCLELLAN.
No. 13907.

April 10, 1979.

Retail druggist sought injunction against sales of medications by physician to people not his patients who had prescriptions from other sources. The Circuit Court, Lincoln County, Jerry W. Cook, J., granted injunction against physician, and he appealed. The Supreme Court of Appeals, Harshbarger, J., held that statute governing dispensing of drugs by physicians authorizes physicians to supply drugs to their own patients but not to fill prescriptions written by other physicians, nor to sell at retail such drugs as they supply to their own patients; they may make reasonable charges for their services, including any medications they supply, and may dispense such amounts of drugs as they deem sufficient to patient's course of treatment.

Affirmed, as modified.
West Headnotes
Health 198H ⇐192

198H Health
198HI Regulation in General
198HI(B) Professionals
198Hk191 Regulation of Professional Conduct; Boards and Officers
198Hk192 k. In General. Most Cited Cases
(Formerly 138k11 Drugs and Narcotics)

Health 198H ⇐947

198H Health
198HVII Compensation
198Hk947 k. Amount. Most Cited Cases
(Formerly 299k23 Physicians and Surgeons)
Statute governing dispensing of drugs by physicians authorizes physicians to supply drugs to their own patients but not to fill prescriptions written by other physicians, nor to sell at retail such drugs as they supply to their own patients; they may make reasonable charges for their services, including any medications they supply, and may dispense such amounts of drugs as they deem sufficient to patient's course of treatment. Code, 30-5-21.
*****545 Syllabus by the Court***
***19** W.Va.Code, 30-5-21, authorizes physicians to supply drugs to their own patients but not fill prescriptions written by other physicians; nor sell at retail such drugs as they supply to their own patients. They may make reasonable charges for their services, including any medications they supply, and may dispense amounts of drugs as they deem sufficient to the patient's course of treatment.

Jackson, Kelly, Holt & O'Farrell, Robert L. Elkins, W. Henry Jernigan, Jr., Charleston, for appellant.
Greene, Ketchum & Mills, Menis E. Ketchum, Lawrence J. Tweel, Huntington, for appellee.
****546 *20** HARSHBARGER, Justice:
G. O. McClellan is a Lincoln County physician who not only supplies medications that ordinarily would require prescriptions to his patients, but sells drugs to people not his patients who have prescriptions from other sources. Ye Olde Apothecary obtained an injunction against his drug sales, from which he appeals.

Chapter 30, Article 5 of our Code is titled " Pharmacists, Assistant Pharmacists and Drugstores." Its Section 18 prohibits Retail sale of poisonous, deleterious, or habit-forming drugs by any person other than a registered pharmacist. Its Section 3, among other things, prohibits any person not a registered pharmacist to conduct a pharmacy for the purpose of "retailing, compounding or dispensing

medicines, poisons or narcotic drugs . . . ." Section 1 has definitions, among which is subsection (5): " The term 'pharmacy' or 'drugstore' or 'apothecary ' shall be held to mean and include every store or shop or other place (a) where drugs are dispensed, or Sold at retail, or displayed for Sale at retail ; or (b) where physicians' prescriptions are compounded . . . ." (Our emphasis)

Code, 30-5-21 excludes from the prohibitions of the article ". . . any legally qualified practitioner of medicine, . . . in the compounding of his own prescriptions, or to prevent him from supplying to his patients such medicines as he may deem proper, if such supply is not made as a Sale." (Our emphasis)

A state board of pharmacy is established with authority to regulate the pharmacist profession, Code, 30-5-2, 5, 6, 7, Et seq. It has volunteered to define "sale" in its rules to be "(T)he supplying of drugs and medicines for any consideration whether charged separately or incorporated with other charges for professional services. Further, the providing of patients with quantities of drugs and medicines beyond those amounts required for immediate administration shall be deemed a sale." Article 1, Section 1, Rules and Regulations of the West Virginia Board of Pharmacy.

*21 We believe the board of pharmacy overreached when it incorporated in its regulations this sale definition. A more contorted definition of "sale" could hardly be imagined.[FN1] This rule if literally applied would require a physician to prescribe, but not dispense, every pill or potion provided to a patient that was not to be taken immediately.

FN1. Even a gift of medicines beyond those required for immediate use enough to be taken every four hours, say, until vibrant health returned would be by the board of pharmacy's definition converted to a sale.

One wonders if a physician, who by statute and custom can compound his medications, could only mix one teaspoon of cough medicine, for example. Presumably, he might mix, and press, only one dosage of his favorite pill. The patient then, if mobile, according to the board of pharmacy, must shuffle, aching and feverish, to his pharmacist for whatever further doses the physician might prescribe, to complete his recovery.

We must try to reconcile the Chapter 30 provisions; and the sensible way to do so is simply to set aside the pharmacy board's definition of a sale and look for the legislature's intention.

A key to the act's application to physicians is the word "supply": a physician is authorized to supply " . . . to his patients such medicines as he may deem proper, if such supply is not made as a sale." Code, 30-5-21.

To supply is to furnish, and the dictionaries indicate that some volume or number of things is contemplated.[FN2] The fact that the supplying should not be made as a sale really confuses the matter. If it is not made as a sale, *22 must it be a gift? Must it **547 be, as appellees contend, a supply of free samples? The statutory permission to physicians to supply patients with medicines, but not sell them, would seem to be nonsense because physicians, as the pharmacists argue, could only provide patients with supplies of free sample medicines. We doubt this to be the legislative intent.

FN2. Funk & Wagnalls New Standard Dictionary, (1973):
"Supply . . . 1. To furnish with what is needed or desired; provide with adequate material or store . . . as, to supply an army with ammunition. 2. To give, as something needful or desirable; furnish an adequate quantity or number of . . . ."

Our reconciliation would lead us to conclude that the legislature intended that sale in this context means Retail sale. The act guarantees those to pharmacists, and a physician cannot sell at retail.

We are cited to Miners in General Group v. Hix, 123 W.Va. 637, 17 S.E.2d 810 (1941); State v.

Cole, W.Va., 238 S.E.2d 849 (1977), and Wooddell v. Dailey, W.Va., 230 S.E.2d 466 (1977), that bind us to give undefined words and terms used in legislation, such as "sale," their common, ordinary and accepted meanings. But we must interpret statutes to give practical effect to all their clauses, if possible. Carolina Lumber Company v. Cunningham, 156 W.Va. 272, 192 S.E.2d 722 (1972).

Also, the pharmacists enjoin us to give "great deference" to the definition they give through the pharmacy board, to "sale." Detch v. Board of Education of the County of Greenbrier, 145 W.Va. 722, 117 S.E.2d 138 (1960). [FN3] This definition is so deficient that deference is undeserved.

FN3. The pharmacists also urge that we read Chapter 30, Article 5 with Chapter 60A, referring us to Fruehauf Corp. v. Huntington Moving & Storage Co., W.Va., 217 S.E.2d 907 (1975). We need not do so because 60A, the Uniform Controlled Substances Act, gives us no help in defining "sale," as the word appears in Code, 30-5-21.

Appellant's brief cites only two cases, both for his contention that the circuit court's order enjoining him from "sale" of drugs, was unclear. Lichtenstein v. Lichtenstein, 425 F.2d 1111 (3d Cir. 1970); H. K. Porter Company, Inc., v. National Friction Products Corp., 568 F.2d 24 (7th Cir. 1978) . We have here eliminated whatever uncertainty there was in the trial court's order.

***23** Neither party directs us to cases which have dealt with similar statutes. But we found a few. One decided at the beginning of this century is on point. In Commonwealth v. Hovious, 112 Ky. 491, 66 S.W. 3 (1902), a statute prohibited sale or compounding drugs except by a registered pharmacist but provided that "(n)othing in this act shall apply to, or in any manner interfere with the business of any licensed practicing physician, or prevent him from supplying to his patients such articles as may seem to him proper, or with his compounding his own prescriptions." The court held that the physician might sell drugs to his own patients but not fill prescriptions sent to him by others. See, 74 A.L.R. 1086.

We are led by the Kentucky court's interpretation of the similar wording in its statute, and by our reading of the clause in ours that purports to allow a physician to supply his patients with drugs but not sell them to the patients, to hold that physicians may supply drugs to their own patients but not fill prescriptions written by other physicians; nor sell at retail such drugs as they supply to their own patients. They may make reasonable charges for their services, including any medications they supply, and may dispense amounts of drugs as they deem sufficient to the patient's course of treatment.

The injunction is continued, as modified.

Rx: Utri suus daretur.

Affirmed, as modified.

W.Va., 1979.
Ye Olde Apothecary v. McClellan
163 W.Va. 19, 253 S.E.2d 545

END OF DOCUMENT

AMERICAN SOCIETY OF PLASTIC SURGEONS
PLASTIC SURGERY EDUCATIONAL FOUNDATION

Executive Office
444 East Algonquin Road • Arlington Heights, IL 60005-4664
847-228-9900 • Fax: 847-228-9131 • www.plasticsurgery.org

July 23, 2010

Gregory S. Moore, O.D.
President
West Virginia Board of Optometry
179 Summers Street, Suite 231
Charleston, W.V. 25301

Dear Dr. Moore,

On behalf of the American Society of Plastic Surgeons (ASPS), I am writing to express serious concerns with the West Virginia Board of Optometry's (the Board's) current proposed regulations (14-2 and 14-11). We believe these proposals, which were drafted in response to the recent passage of Senate Bill 230, raise considerable patient safety concerns for the citizens of West Virginia . ASPS appreciates the opportunity to provide comment regarding this issue.

ASPS shares the concerns of the American Academy of Ophthalmology, the American College of Surgeons, and the American Medical Association—specifically, with the Board's effort to codify language allowing an optometrist to administer and dispense injectable pharmaceutical agents. In its consideration of SB 230, the West Virginia legislature earlier this year explicitly rejected nearly identical language after extensive study and hearing lengthy debate on all sides. While very useful when used and managed appropriately in the therapeutic setting, complex pharmaceuticals can have potentially dangerous complications. Only physicians have the clinical and educational background to best protect patients in the rare instance when an allergic reaction or some other life-threatening complication arises when these drugs are administered orally or via injection. The proposed regulation (14-11) patently ignores the intent of the bill in giving authority to the Board to decide and control which injectable pharmaceutical agents optometrists are allowed to administer.

Proposed regulations 14-2 and 14-11 would allow optometrists to perform procedures that fall well within the practice of medicine and outside the bounds of West Virginia law which governs optometric scope of practice. We believe this is a direct affront to patient safety.

Thank you again for the opportunity to register comment and for your consideration.

Sincerely,

Michael F. McGuire, MD
President
American Society of Plastic Surgeons

AMERICAN SOCIETY OF PLASTIC SURGEONS
PLASTIC SURGERY EDUCATIONAL FOUNDATION

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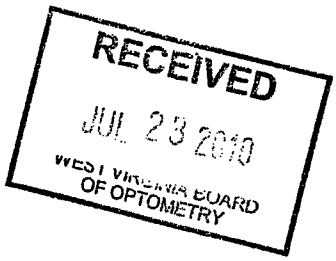
July 23, 2010



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Sincerely,

Michael F. McGuire, MD
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American Society of Plastic Surgeons

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July 23, 2010

Gregory S. Moore, O.D.
President
West Virginia Board of Optometry
179 Summers Street, Suite 231
Charleston, W.V. 25301

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Thank you again for the opportunity to register comment and for your consideration.

Sincerely,

Michael F. McGuire, MD
President
American Society of Plastic Surgeons

AMERICAN ACADEMY OF
OTOLARYNGOLOGY–
HEAD AND NECK SURGERY

July 23, 2010

Gregory S. Moore, OD, President
West Virginia Board of Optometry
179 Summers Street, Suite 231
Charleston, WV 25301

Re: Amended Series Number 14-2, Expanded Prescriptive Authority, and Proposed Series Number 14-11, Injectable Pharmaceutical Agents Certificate

Dear Dr. Moore:

The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) appreciates the opportunity to comment on amended Series Number 14-2 and proposed Series Number 14-11, both released as a result of the passage of Senate Bill 230 earlier this year. Patient safety and quality of care are of the utmost importance to the AAO-HNS; therefore, we wanted to express several concerns with the proposed rules, as written.

Specifically, with regards to Series Number 14-2, which sets forth guidelines for Expanded Prescriptive Authority, we are specifically concerned that the language appears to enable optometrists to sell injectable pharmaceuticals to patients. This dangerous provision would place patients at risk of myriad harmful and potentially life-threatening outcomes.

Series Number 14-11 is also problematic as written, as it inappropriately undermines the intention of the Legislature, which sought to provide certain optometrists the authority to administer injections of epinephrine for the purpose of treating emergency cases of anaphylaxis or anaphylactic shock. In addition, the Legislature intended injections to be administered only by certificate holders. However, this rule would enable the Board of Optometry to permit certificate holders to administer other injectables, which are not even clarified in the proposed rule. In addition, this rule would permit optometrists, who are not themselves adequately trained to respond to the potential adverse outcomes of the administration of injectables, to delegate and supervise the administration of any injectable by any certified or licensed clinician. Not only does this proposed rule disregard the language of the enrolled Senate Bill 230, but it would place patients at risk of undergoing procedures for which those administering or supervising the injections are not adequately trained to respond should a complication or adverse reaction occur.

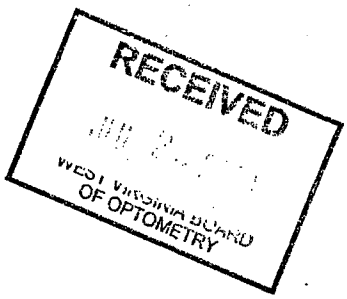
In the interest of patient safety and ensuring quality of care, the AAO-HNS strongly urges the Board of Optometry to revise amended Series Number 14-2 and proposed Series Number 14-11 to address these concerns. With questions, you may contact Jenna Kappel, Director of Health Policy, at 1-703-535-3724 or jkappel@entnet.org. Thank you for your consideration.

Sincerely,

David R. Nielsen MD

David R. Nielsen, MD
Executive Vice President and CEO

July 22, 2010



Gregory S. Moore, O.D.
President
West Virginia Board of Optometry
179 Summers Street, Suite 231
Charleston, West Virginia 25301

Dear Dr. Moore,

On behalf of the more than 12,000 U.S. members of the American Academy of Dermatology Association (AADA), and its 37 members in West Virginia, **I am writing to share concerns on proposed regulations (Title Number 14-2 and 14-11) pursuant to Senate Bill 230 (2010).** As medical doctors, we strongly believe these regulations endanger patient safety and jeopardize quality care, as we believe they disregard adequate and appropriate medical training, particularly with regard to injections.

Although we understand it is the role of the Board of Optometry to interpret SB 230, the proposed regulations radically expand optometric scope of practice well beyond the very clear legislative intent of the final legislation.

Our utmost concern, in all states, is to ensure that medical and surgical procedures are performed by licensed physicians or by appropriate providers under the direct, onsite supervision of a licensed physician. The practice of dermatology includes, but is not limited to, performing any act or procedure that can alter or cause biologic change or damage to the skin and subcutaneous tissue. The AADA maintains a steadfast position that these procedures should be performed only by an appropriately trained physician or non-physician personnel under the direct, on-site supervision of an appropriately trained physician.

The Proposed Regulations Endanger Patient Safety

> §14-1-1.1. Scope. -- This rule establishes the requirements, procedures and standards for the certification of a licensee with the authority to administer and dispense injectable pharmaceutical agents.
>
> §14-11-6.2. The licensee shall adhere to generally accepted standards of care and follow established clinical guidelines for administering injections.
>
> §14-11-6.3. ...a licensee shall only administer agents through injection that are for the treatment and management of abnormalities of the eye and its adnexa.

American Academy of Dermatology Association
Excellence in Dermatology™

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Web site: www.aad.org

Proposed regulation 14-11, in total, would expand the scope of practice for optometrists by issuing open-ended authority to the Board to determine the certification standards for when an optometrist may administer and dispense injectable pharmaceutical agents.

As you are fully aware, the legislature extensively debated and specifically rejected virtually identical language that would have given open-ended authority to the Board of Optometry to determine which injectable pharmaceutical agents optometrists would be allowed to administer. Furthermore, the House-Senate Conference Committee removed the similar language contained in 14-11 and amended SB 230 to specifically limit injections to the administration of epinephrine by injection to treat emergency cases of anaphylaxis or anaphylactic shock. **The proposed regulations blatantly disregard the legislature's decision regarding the administration of injectable products.**

Moreover, the proposed regulations do not adequately define the adnexa or appendages of the eye in which an optometrist may administer injections, nor do the regulations address the types of pharmaceutical agents which would be approved for use by licensed optometrists. These omissions provide open-ended authority to optometrists to make decisions on their own behalf of what is included in the adnexa of the eye or qualifies as an appendage. For example, these provisions would allow optometrists to administer botulinum toxin to the forehead or a collagen filler device to the nasolabial folds of the face, if independently deemed an "appendage" of the eye.

> §14-11-3.1. An applicant for a certificate to administer injectable pharmaceutical agents shall complete and successfully pass an approved course in the administration of pharmaceuticals by injection.

The short-term training course proposed in regulations 14-11-3.1 is in no way equivalent to a physician's training and understanding of a medical procedure and its implications for each patient. Ultimately, patient safety and quality of care could be seriously compromised.

Complications from procedures such as injections may include unexpected bleeding, scars, allergic reactions, and infection, among other concerns. Physicians performing these procedures have years of formal training in residencies to quickly recognize and address complications. Complications can occur in the best of hands, but they occur too often when injected by professionals who are inadequately trained. For example, when an individual decides to undergo facial augmentation with injectables, the purpose is generally to improve appearance; therefore, any sequelae that actually worsens the patient's appearance is a significant complication.

To pass these provisions now as regulations would be to deliberately undermine the legislative intent and debate on SB 230. These regulations are not in the best interest of West Virginians and could result in adverse events.

We respectfully urge you to reconsider the provisions of these regulations to be aligned with the legislative intent of SB 230. The AADA appreciates the opportunity to comment on this important issue. For further information, please contact Kathryn Chandra, Assistant Director of State Policy for the AADA, at (kchandra@aad.org) or (202) 712-2615.

Sincerely,

William D. James MD

William D. James, MD, FAAD
President, American Academy of Dermatology Association
WDJ/kgc

Outstanding Physicians.
HMG
Extraordinary Care.

5170 US RT#60 EAST HUNTINGTON, WV 25702 PH: 304-528-4600

July 21, 2010

Gregory S. Moore, O.D.
President, WV Board of Optometry
179 Summer Street, Suite 231
Charleston, WV 25301

Dear Dr. Moore:

I write with interest to your request for rule changes expanding optometric scope of practice. Many of your requests, I found so vague, that I could not be sure what you would do or would not do. It was clear from the legislature in 2009, in the summer interim sessions of 2009, and this legislature of 2010, that optometrists are not to be considered physicians and are not entitled to the same rights and privileges of individuals who have gone to medical school, and the four years of post graduate training at nationally certified programs, and then pass two national board examinations, one after medical school and another after residency with over 12,000 hours of additional training beyond "school". The proposed rules and regulations do not give patients the guarantee that the provider who performs what you propose, has the same level of qualification, expertise, fund of knowledge, and clinical experience as M.D./D.O's. Please answer, why should a new, lesser level of provider than an M.D./D.O. that increases the number and types of procedures, increasing health care costs be allowed, when there is no access problems especially for elective procedures such as cosmetic and Botox procedures, which would seem to be allowed under this proposed rule and regulation change?

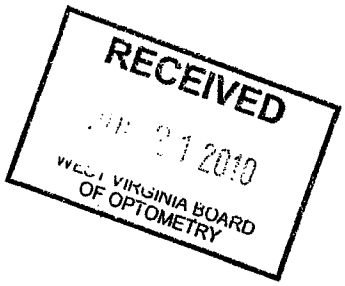
Please also answer fully and completely the questions posed by the WV Academy of Ophthalmology in their letter to you.

Sincerely yours,

MD, FACS

Joseph A. LoCascio, III, M.D., F.A.C.S.
JAL/lw2 7-21-2010

7/20/2010



Gregory S. Moore, OD
President
West Virginia Board of Optometry
179 Summers Street, Suite 231
Charleston, WV 25301

Dear Dr. Moore:

As you and members of the Board know, I was asked to be involved at many levels in addressing concerns of SB 230. I am contacting the Board of Optometry to state serious patient safety concerns regarding proposed regulations 14-2 and 14-11. I have discussed the proposed rules with a number of my colleagues who were disturbed by the patient safety concerns raised. I have incorporated many of these discussions and serious questions in this letter.

I also believe that there needs to be extensive clarification on these rules as there is grossly deficient information regarding clinical exposure for education and handling of emergencies from injections. The proposed rules are far reaching, clearly beyond the intent of the legislature in passing SB 230. Patient safety has clearly been ignored in favor of expanding scope of practice beyond the intent of the legislature. Rule 14-11 is so onerous, it should be withdrawn.

Of particular concern is the fact that injections affect the whole body and not just the eye. Clearly giving intravenous, intramuscular, and periocular injections have far reaching affects, beyond the structures of the eye. It is imperative that the individual giving these injections have supervised training in treating the organ systems that could be affected. Children, and adults that are immunocompromised or have heart, kidney or lung disease are particularly prone to reactions to injections.

There is also no mention of the intent of the Board with regards to what drugs might be injected, why they would be injected, or where they would be injected. This is completely open-ended. This was not the intent of the Legislature and that is why Rules were to be promulgated to insure patient safety.

Another serious concern is that the Board of Optometry is composed of optometrists and lay people who have never given injections or dealt with the complications of injections. The Board is however willing to set "standards" that are far below the rigorous supervised clinical training that doctors of medicine and doctors of osteopathy are required to complete before administering medications that can have significant morbidity and possible mortality.

Section 14-11-7 goes so far as to say that the optometrist is not required to get approval or even report injections given to the patient to their primary care

physician. Not only should this be required, a medical doctor should be on site to handle any emergencies from injections. Optometrists do not have the required clinical supervised training to deal with other organ failures as a direct result of intravenous, intramuscular, and injections around and on the eye.

There are many questions regarding Rule 14-11 that must be addressed. A partial list of these questions is as follows:

1. If the Board is setting the educational standards regarding injections, where did the Board learn to do injections?

2. How many of each type of injections have Board members done under supervision?
    a. Intramuscular?
    b. Intravenous?
    c. Subcutaneous?
    d. Subconjunctival?
    e. Periocular?
    f. Retrobulbar?
    g. Other?

3. How many of each type of injection will be required of an optometrist to do under supervision before being "certified" ?
    a. Intramuscular?
    b. Intravenous?
    c. Subcutaneous?
    d. Subconjunctival?
    e. Periocular?
    f. Retrobulbar?
    g. Other?

4. What areas of the face does the Board plan on allowing optometrists to inject and for what purpose?
    a. The surface of the eye?
        i. For what purpose?
    b. Around the globe/eye?
        i. For what purpose?
    c. Behind the globe/eye?
        i. For what purpose?
    d. The muscles of the eye?
        i. For what purpose?
    e. The muscles around the eye?
        i. For what purpose?
    f. The skin of the face?
        i. Eyelids?
            1. For what purpose?
        ii. Eyebrows?
            1. For what purpose?

iii. Forehead?
1. For what purpose?
iv. Central Face?
1. For what purpose?
v. Nose?
1. For what purpose?

g. Does the Board plan to permit injections of these types into children?

5. What drugs does the Board plan on permitting for injections into the vein?
   a. Fluorescein?
      i. For what purpose?
   b. Antibiotics?
      i. For what purpose?
   c. Immunosuppressives?
      i. For what purpose?
   d. Steroids?
      i. For what purpose?
   e. Anti-anxiety drugs?
      i. For what purpose?
   f. Controlled substances?
      i. For what purpose?
   g. Chemotherapy agents?
      i. For what purpose?
   h. Insulin?
      i. For what purpose?
   i. Tensilon?
      i. For what purpose?
   j. Does the Board plan to permit injections of these types into children?

6. What drugs do optometrists plan to inject into the facial muscles or eyelids/eyebrows?
   a. Botulism toxin?
      i. For what purpose?
   b. Permanent Derm fillers (Polyacrylamide, polyalkylamide)?
      i. For what purpose?
   c. Non-permanent Derm fillers (Restylane, Radiesse)?
      i. For what purpose?
   d. Anesthetics?
      i. For what purpose?
   e. Steriods
      i. For what purpose?
   f. Does the Board plan to permit injections of these types into children?

7. What Intravenous and Intramuscular drugs do optometrists plan on dispensing from their office?

8. How does the Board plan on handling the fact that there are no national minimum requirements for injections in schools of optometry and that most optometry schools are in states where state law prohibits optometrists from giving injections?

9. Why does the Board not require that a physician be on-site for an injection in case there is an emergency? Should a physician be on site if an optometrists injects a child?

10. Most general ophthalmologists do not give intravenous and intramuscular injections. Retinal specialists perform Fluorescein angiograms with the primary purpose of directing intraocular or surgical intervention, rarely to make a diagnosis. New non-invasive technology, available to optometrists, has essentially eliminated the need to give intravenous fluorescein. What is the need for optometrists to give these injections?

11. If optometrists have not had clinical training in systemic diseases of other organ systems, how will they recognize the cause of an adverse reaction? How can they report what they do not recognize? What about the adverse reaction that occurs after the patient leaves the office? What about adverse reactions in children?

12. Do optometrists plan on admitting patients to the hospitals to give injections? If so, are hospitals willing to assume the liability?

13. The costs associated with OSHA protocols and the costs of expensive equipment required to perform Fluorescein Angiograms are cost prohibitive. The volume of injections needed to pay for such equipment is significant. The costs to society are significant. How is it that an optometrist could afford to be OSHA compliant and afford expensive cameras and digital equipment if the volume of such testing is extremely low?

14. If an optometrist were to do an angiogram, and send the patient to a retina specialist, the study would almost certainly need repeated. Does the Board understand that charging twice for services will result in expense to the patients?

15. Optometrists have extremely limited training in interpreting fluorescein angiograms, far less than medical doctors practicing ophthalmology. Why should optometrists perform this rare test when they have had little training in interpreting the tests? This adds to the cost of health care without any benefit.

There are some serious concerns regarding Rule 14-2.

If a new drug comes out with a specific indication for treatment of eye disease, it will also affect other organ systems.

1. Will the Board put restrictions on length of use of new oral drugs such as is the case with steroids and narcotic analgesics?

2. Why does the Board not require direct collaboration with a patient's primary care physician to use a new drug that comes to market?
    a. Is the Board aware that there can be serious organ effects from medications, other than on the eye?
    b. Is the Board aware that there can be serious interactions with other medications that treat diseases such as diabetes, hypertension, heart failure, liver disease, neurological diseases?

3. If the Board does realize this, then wouldn't it make sense to require the optometrist using new drugs to work with the primary care physician who understands the interactions and potential whole body side effects?

4. Does the Board of Optometry plan on allowing new drugs to be used on children?

With all of these questions raised, Rule 14-11 should be withdrawn. This rule creates serious patient safety issues and does nothing positive for citizens of our state. In fact, this Rule is so vague that virtually everything is open-ended with injections, including dispensing them from the office.

Rule 14-2 should be amended to include patient safety protections that the optometrist would work with the primary care physician, or other physician responsible for the care of the patient. By doing this, optometrists will have access to new systemic drugs and patients will be protected with the involvement of the primary care or other physician who knows there medical status and medication interaction potential.

Thank you for your consideration.

Stephen R. Powell, MD

West Virginia Board of Optometry

From: AMacias@facs.org
Sent: Wednesday, July 21, 2010 12:26 PM
To: wvbdopt@frontier.com
Subject: ACS Comments on Proposed Regulations 14-11, 14-2

Attachments: West Virginia Optometry Board Comments July 2010.pdf

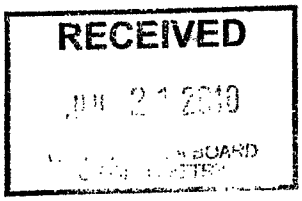
West Virginia Optometry Board ...

Dear Dr. Moore,

Attached please find comments to be submitted to the West Virginia Board of Optometry opposing proposed regulations 14-11, 14-2 on behalf of the American College of Surgeons. Please feel free to contact me with any questions.

Thank you,

Alexis Walters Macias
Regional State Affairs Associate
American College of Surgeons
633 N Saint Clair Street Chicago, IL 60611
P: 312-202-5446
F: 312-202-5023



American College of Surgeons

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ACS Web site: www.facs.org

July 16, 2010

Gregory S. Moore, O.D.
President, West Virginia Board of Optometry
179 Summers Street, Suite 231
Charleston, VW 25301

Dear Dr. Moore:

On behalf of the American College of Surgeons (ACS), representing over 77,000 surgeons of which over 340 are in West Virginia, I am writing to state our concerns of proposed regulations, 14-11 and 14-2, filed with the West Virginia Secretary of State by the Board of Optometry in response to S.B. 230. The proposed regulations would significantly expand the scope of practice of optometry into the practice of medicine/surgery, raising considerable patient safety concerns.

The ACS has a strong history of addressing matters relating to patient care and safety, and we are concerned that the proposed regulations would allow optometrists to practice medicine without the oversight and education requirements imposed on medical doctors. Practicing outside of their scope of practice and without proper supervision by a medical doctor may open up West Virginia citizens to unsafe practice environments and procedures.

The ACS shares the many concerns expressed by the American Academy of Ophthalmology (AAO). As stated by AAO, the proposed regulations would expand the scope of practice for optometrists far beyond what the legislature intended in passing S.B. 230. One area of major concern shared by both organizations is found in proposed regulation 14-11 which would allow an optometrist to administer and dispense injectable pharmaceutical agents. The West Virginia legislature rejected virtually identical language giving open-ended authority to the Board of Optometry to determine which injectable pharmaceutical agents optometrists would be allowed to administer. To propose a regulation that would give the Board authority to determine certification standards to allow optometrists to administer and dispense any injectable medication violates the intent of the legislature.

In the interest of patient safety, the American College of Surgeons believes that the types of procedures proposed by the Board should only be performed by a licensed Medical Doctor or Doctor of Osteopathic Medicine. Simply knowing how to perform a procedure does not make one capable of handling the possible complications affecting other organ systems, placing patients at high risk of disability or death. As such, the ACS strongly urges the Board to protect patient safety for West Virginia citizens and reject proposed regulation 14-11 and 14-2.

Sincerely,

David B. Hoyt

David B. Hoyt, MD, FACS
Executive Director

MINARDI EYE CENTER
"BETTER TECHNIQUES FOR BETTER VISION"

July 20, 2010

West Virginia Board of Optometry
179 Summers Street, Suite 231
Charleston, WV 25301

I am writing in regards to the amendment to the rule 14-2.
The new rules raise several concerns:

1) Does the Board of Optometry consider the brain an appendage of the eye?
2) Does the Board of Optometry consider the skin of the face appendages of the eye?
3) Does the Board of Optometry consider muscles of the face appendages of the eye?
4) Does the Board of Optometry consider the sinuses appendages of the eye?
5) How does the Board of Optometry define the word "appendages" as it applies to the eye?
6) Does the Board mean that they will approve only drugs that have specific indications for use as determined by the pharmaceutical company and the FDA?
7) What educational clinical supervised training will be required for optometrist to use new drugs that are not on the formulary?
8) Where will optometrists get the additional supervised training in using new systemic drugs?
9) What are the criteria for the defining "which have been shown to be effective in the treatment and management of abnormalities of the eye or its appendages"

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10) What does the Board mean by "regardless of their listed categories"?
11) Members of the Board of Optometry have never given injections, how are they qualified to set educational standards for those injections?
12) What are the specific drugs by injection that the Board of Optometry feels that optometrists are qualified to sell?
    a. Intravenous antibiotics?
    b. Intravenous steroids?
    c. Intramuscular vaccines?
    d. Intramuscular botulism toxin?
    e. Intramuscular anesthetics?
    f. Epi-pens for anaphylaxis
    g. Injections around the eye?

13) Where will the Board approve optometrists to inject these drugs?
    a. Intravenous?
    b. Intramuscular
        i. In the arm?
        ii. In the leg?
        iii. Around the eye?
    c. In the skin?
    d. Into the outside layers of the eye?
    e. Around, beside or behind the eye?
    f. Into the face?

14) Has the Board of Optometry developed a list of drugs by injection that optometrists would be able to sell to patients?
15) Would optometrists be required to have a dispensing license to sell drugs by injection?
16) Are these drugs that will be sold to patients, to be injected by the patients or by the optometrist?
    a. If by the optometrist, where is the supervised clinical

exposure to injecting patients going to be obtained?

b. If by the optometrist, where will the optometrist learn to deal with the emergent complications (heart failure, seizure, paralysis, kidney failure, etc) that accompany some injections?

c. Will there be a requirement to have a supervising physician attend the injection in case of emergency?

17) How can the optometrists provide "appropriate follow up care" when there is a serious reaction if there has been no supervised clinical training of the optometrist?

18) Optometrists are restricted by law to the treatment and management of abnormalities of the eye and its adnexa with specific scope of practice restrictions. If a patient has an adverse urgent reaction optometrists have not had the training to deal with, and, in fact are prohibited by law to treat other organ systems. How does the board rectify discrepancy?

19) Basic life support does not provide enough support to patients who have a serious drug induced (injection) reaction. Physicians have had extensive clinical training in adverse drug reactions from injections. Physicians that perform invasive injections have crash carts with intravenous drugs and airway devices to be used. Will optometrists meet the same standard of care?

20) Will the Board require more than a demonstration on an artificial vein or limb to be certified to inject West Virginia residents?

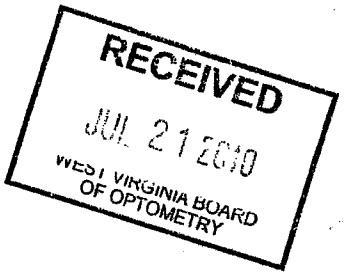
21) How will the Board handle the different educational experience if there are no minimum requirements for injection privileges in the optometry schools?

22) If there are no national minimum requirements for injections in schools of optometry, does that mean that practicing optometrists are also not required to undergo supervision to give different types of injections?

The above questions that I have addressed are serious concerns of mine, please respond.

Lawrence M. Minardi, M.D.
500 Donnally Street
Charleston, WV 25301
(304)343-6219

July 19, 2010



Gregory S. Moore, O.D.
President
West Virginia Board of Optometry
179 Summers Street, Suite 231
Charleston,WV 25301

Dear Dr. Moore:

I am writing in response to proposed regulations filed with the West Virginia Secretary of State by the Board of Optometry in response to Senate Bill 230 passed by the West Virginia State Legislature and signed by Governor Manchin this spring. I have specific questions regarding the ability of West Virginia's optometrists being allowed to inject medications around the eye and its "appendages." If you're familiar with allopathic or osteopathic medical terminology, you will find that this term is not used with frequency in the literature. If you mean specifically the ocular adnexa could you please clarify that in the proposed regulations? Furthermore, after the extensive debate and press coverage this issue gained during the legislative session why would these regulations be appended now to this bill when they were struck down or removed from the bill earlier this year? As a physician I still wonder why the scope of optometrists needs to be expanded to include these issues. Your last arguments of providing access to medical care did not fall on deaf ears. No one opposed removing superficial foreign bodies from the cornea since this may save the patient a trip to another town or city to an ophthalmologist's office. No one opposed the use of an Epi-pen in the event a patient was having a life-threatening emergency that may require your intervention. But can you tell me which specific injections an optometrist would need to perform around the eye or it's "appendages" that are not readily available at a ophthalmologist's, dermatologist's or plastic surgeon's clinic?

Additionally, the proposal gives optometrists the ability to sell pharmaceuticals directly the patient? I'm not familiar with any medical clinics that do this so can you give some specific examples of medications

that are crucial to the practice of optometry that you need to sell in your office.

The regulations also allow oral pharmaceutical use for eye conditions? Would optometrists be required to do rotations on the renal dialysis unit as MDs and DOs are so they may fully understand the effects that oral medications like Acyclovir have on renal function? Will they be required to rotate in a dermatologist's office to identify a drug reaction from Diamox that can be life-threatening? Will they be required to rotate in the ICU to understand the effects on the adrenal glands from orally administered steroids? These are all things that physicians have done and make us able to prescribe these medications without endangering our patient.

Please consider these questions carefully and ask yourself if these regulations need to be passed in order for an optometrist to have a meaningful career. Or is it another attempt to gain privileges through legislative efforts instead of education?

Thank you

Cristoforo R. Larzo MD
Vitreoretinal surgeon
PO Box 9193, Stadium Drive
Morgantown WV 26506-9193

WEST VIRGINIA State Medical Association

July 23, 2010

Mr. Gregory S. Moore, OD
President
WV Board of Optometry
79 Summers Street, Suite 231
Charleston, WV 25301

Re: 14 CSR 11, Injectable Pharmaceutical Agents Certificate

Dear Dr. Moore,

On Behalf of the West Virginia State Medical Association (WVSMA) I am writing to share comment regarding the West Virginia Board of Optometry's (Board) **Rule 14 CSR 11 Injectable Pharmaceutical Agents Certificate**. In our review of this rule we have identified the following questions and concerns:

First, under §14-1-1 General, 1.1 Scope, the Board establishes the scope of the rule to allow certification of a licensee with the authority to "administer and dispense" injectable pharmaceutical agents. It is the opinion of the WVSMA that the *dispensing* of any injectable pharmaceutical agents is not permitted in state code and it appears the Board has gone beyond their statutory authority to grant such an allowance. West Virginia Code section §30-8-15 Administration of Injectable Pharmaceutical Agents, which grants the authority to the Board to draft this rule, only speaks to the administration of injectables not the dispensing. It is unclear to the WVSMA what the Board was specifically considering when it included this language in the scope of the rule. The WVSMA requests that the term "dispense" be deleted from the rule.

Additionally, surprisingly nowhere in the rule does the Board specify what injectable pharmaceutical agents may be used by licensees and in what locations on the body. It would seem that this is the basic premise of the intent for the drafting of such a rule and that strict specificity should be given to those agents permitted *and* prohibited from administration. Additionally, there is a firm prohibition in the statute from licensees injecting into the globe of the eye, however this is not clarified in the rule. Understandably, it is virtually impossible to ascertain the true scope of this rule and its implications on the public if there is no clarity on the injectable pharmaceutical agents allowed for administration (and dispensing) by licensees. The WVSMA has serious concern regarding this obvious omission and requests that the Board clarify with specificity the agents contemplated.

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West Virginia statute §30-8-15(1) requires the Board to "establish a course, or provide a list of approved courses, in administration of pharmaceutical agents by injection". The rule, under 14-11-3, leaves this area very vague and does not delve into the specifics that the statute aims to require. The Board seems to simply intend to allow any "course" offered by a school or college of optometry or potentially any continuing education training offered by another organization. The WVSMA is aware that in your separate rule currently out for public comment **14 CSR 10 Continuing Education** there is reference to the statutory requirement for those licensees with a certificate to administer injectables to obtain and maintain certification in basic life support. Though this does meet the statutory requirement for basic life support, the Legislature also evidently intended for there to be additional continuing education credits specifically targeted toward injectable pharmaceutical agents.

Additionally, the board is granting carte blanche to all future graduates the ability to administer injectables without a review of the courses they have taken. Clearly the Legislature intended for there to be more specificity in regard to the educational requirements of the licensees to perform injections. In addition, the statute under §30-8-15 (4) requires continuing education for this area of practice, however, nowhere in the rule is this contemplated. The WVSMA believes this is potentially a serious concern to the public safety and requests that the Board follow the requirement set by the Legislature and set out proper parameters for the approved courses and lists of courses as well as continuing education.

West Virginia statute §30-8-15 (2) requires the Board to establish "definitive treatment guidelines" that "shall include, but not be limited to, appropriate observation for an adverse reaction of an individual following the administration of a pharmaceutical agent by injection". Though the rule makes vague reference to OSHA and CDC guidelines and generally accepted standards of care, it appears that this requirement has not satisfactorily been met. Clearly the Legislature contemplated more substance and clarity to be attached to the establishment of the treatment guidelines since the statute requires them to be "definitive". The WVSMA requests that the board greatly enhance this area of the rule.

West Virginia statute §30-8-15 (5) requires the Board to establish reporting requirements to the patient's primary care physician. The rule clearly states under 7.1.3 that the only instance when there would be any reporting requirement is when a complication is observed. It is the opinion of the WVSMA that this lack of coordination with the patient's treating physician poses significant risk to the public.

In summary the WVSMA is gravely concerned about the imprecision and deficiencies of this rule. We believe the rule need to be substantially enhanced with clarifying language on virtually all points.

We thank you for the opportunity to comment on this proposed rule and hope that the Board will take into serious consideration the questions and concerns raised in this letter. If you have any questions please do not hesitate to contact us.

Sincerely,

Carlos C. Jimenez, MD