

James Campbell
Authorized Signat

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: 8/31/12

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency Name, Address & Phone No.) West Virginia Board of Optometry

LEGISLATIVE RULE TITLE: Expanded Therapeutic Procedures Certificate

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

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

July 19, 2012

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

Personal phone call and e-mail to the Executive Director, West Virginia Academy

of Eye Physicians and Surgeons, letter of notification to all licensees, personal phone call and e-mail to the Executive Director of the West Virginia Association of Optometric Physicians, posted proposed rule on our web site, www.wvbo.org.

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

August 20, 2012

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)

August 31, 2012

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

Pamela Carper, Executive Director, West Virginia Board of Optometry

179 Summers Street, Suite 231, Charleston, WV 25301, phone: 304-558-5901

fax: 304-558-5908, e-mail: wvbdopt@frontier.com

- g. **IF DIFFERENT 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)

Glenn Bailey, O.D., Rules Officer and Secretary-Treasurer, West Virginia Board of

Optometry, 179 Summers Street, Suite 231, Charleston, WV 25301, phone:

304-558-5901, fax: 304-558-5908, e-mail: wvbdopt@frontier.com

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.

b. Date of hearing or comment period:

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

d. Attach findings and determinations and reasons:

Attached

WEST VIRGINIA BOARD OF OPTOMETRY

Agency Approved Rule §14-12 Expanded Therapeutic Procedures Certificate

List of Those Persons Who Commented on the Rule

Mr. Robert Knittle, Esq, Executive Director, West Virginia Board of Medicine

Ronald L. Hopping, O.D., M.P.H., President, the American Optometric Association

Charity Hix, M.D., President, West Virginia Academy of Eye Physicians and Surgeons

Geoff Bradford, M.S., M.D., Professor of Ophthalmology, Residency Program Director

Chad D. Robinson, Executive Director, West Virginia Association of Optometric Physicians

Mary Ann Cater, D.O., President, West Virginia State Medical Association

Gerry D. Stover, M.S., Executive Vice President – West Virginia Academy of Family Physicians

WEST VIRGINIA BOARD OF OPTOMETRY

14CSR12

Expanded Therapeutic Procedures Certificate

Summary

The rule is written to define that process by which new techniques, procedures and treatments are taught and approved as they are developed through research and regular developments in the field. These new techniques, procedures and treatments must be taught in 50% of all accredited optometry schools as required in the West Virginia Optometric Practice Act, §30-8-6(14).

- The rule establishes requirements for a certificate to perform expanded therapeutic procedures.
- It establishes education and training requirements. It also outlines a method for the Board to add additional training requirements as new techniques are developed and approved. The procedures must be taught in 50% of all accredited optometry schools.
- The rule sets up an application procedure.
- The rule sets up how the Board will be accountable to the public.
- It also sets up treatment guidelines.

WEST VIRGINIA BOARD OF OPTOMETRY

14CSR12

Expanded Therapeutic Procedures Certificate

Circumstances

The rule is written to define that process by which new techniques, procedures and treatments are taught and approved as they are developed through research and regular developments in the field. These new techniques, procedures and treatments must be taught in 50% of all schools accredited by the American Council on Optometric Education recognized by the U.S. Department of Education as required in West Virginia Code, §30-8-6(14).

§30-8-6. Rulemaking.

(a) The board shall propose rules for legislative approval, in accordance with the provisions of article three, chapter twenty- nine-a of this code, to implement the provisions of this article, including:

(14) Requirements for an expanded scope of practice for those procedures that are taught at 50% of all accredited optometry schools; and

APPENDIX B
FISCAL NOTE FOR PROPOSED RULES

Rule Title: Expanded Therapeutic Procedures Certificate

Type of Rule: ☒ Legislative ☐ Interpretive ☐ Procedural

Agency: WV Board of Optometry

Address: 179 Summers Street, Suite 231
Charleston, WV 25301

Phone Number: 304-558-5901 Email: wvbdopt@frontier.com

Fiscal Note Summary

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

The Board estimates that approximately 100 licensees will apply for an Expanded Therapeutic Procedures Certificate. It will take approximately 6 hours per applicant to set up policies, procedures, forms, process the applications, verify training, and set up systems for the record keeping portion of the rule. There will associated current expense costs involved as well.

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	4,250.00	4,250.00	8,500.00
Personal Services	2,625.00	2,625.00	5,250.00
Current Expenses	1,625.00	1,625.00	3,250.00
Repairs & Alterations	0.00	0.00	0.00
Assets	0.00	0.00	0.00
Other	0.00	0.00	0.00
2. Estimated Total Revenues	5,000.00	5,000.00	10,000.00

Rule Title: Expanded Therapeutic Procedures 

Rule Title:

Expanded Therapeutic Procedures Certificate

3. Explanation of above estimates (including long-range effect):

Please include any increase or decrease in fees in your estimated total revenues.

It would take staff approximately 6 hours per applicant in personnel costs to set up policies, procedures, process each application and set up reporting and tracking components. Current expenses include \$40 for printing, certificates and filing materials for each applicant. Improvements to the web site would cost about \$2500.

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: August 30, 2012

Signature of Agency Head or Authorized Representative



TITLE 14
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF OPTOMETRY

FILED

2012 AUG 31 AM 11:15

SERIES 12

EXPANDED THERAPEUTIC PROCEDURES CERTIFICATE

§14-12-1. General.

1.1. Scope. -- This rule establishes the requirements, procedures and standards for the certification of a licensee to perform expanded therapeutic procedures which are considered rational to the diagnosis and treatment of the human eye and its appendages.

1.2. Authority. -- W. Va. Code §30-8-6 and §30-8-9.

1.3. Filing Date. --

1.4. Effective Date. --

14-12-2. Definitions.

2.1. "Accredited Optometry School" means an optometry school accredited by the Accreditation Council on Optometric Education or its successor organization recognized by the U.S. Department of Education.

2.2. "Appendages" means the eyelids, the eyebrows, the conjunctiva and the lacrimal apparatus.

2.3. "Board" means the West Virginia Board of Optometry.

2.4. "Certificate Holder" means a licensee who has met the requirements of this rule and has been issued an Expanded Therapeutic Procedures Certificate by the Board.

2.5. "Procedures," "Therapeutic Procedures" "Expanded Therapeutic Procedures" or "Approved Procedures" are procedures approved by the West Virginia Board of Optometry that meet the criteria of this rule. All expanded therapeutic procedures must meet the criteria listed in W.Va. Code, §30-8-1, et seq. §30-8-6(14) which states that all expanded therapeutic procedures shall be taught in at least fifty percent (50%) of all optometry schools

accredited by the Accreditation Council on Optometric Education or its successor organization recognized by the U.S. Department of Education.

§14-12-3. Public Access and Board Accountability.

3.1. The Board shall maintain a list of approved expanded therapeutic procedures for public inspection. The list will contain treatment guidelines for the procedures approved by the Board.

§14-12-3. §14-12-4. Certification Generally.

3.1.4.1. A licensee shall complete a Board approved application and meet all requirements as listed in this rule in order to be certified to perform expanded therapeutic procedures.

3.2.4.2. A licensee shall obtain injectable pharmaceutical agents certification prior to application for certification to perform expanded therapeutic procedures.

3.3.4.3. An applicant for licensure by examination, by reciprocity, or by reinstatement after a date to be determined by the Board shall only be granted licensure if the applicant meets the requirements for expanded therapeutic procedures.

§14-12-4. §14-12-5. Certification Requirements.

To be certified the licensee shall:

4.1.5.1. Complete the required application form;

4.2.5.2. Submit proof of injectable pharmaceutical agents certification;

4.3.5.3. Submit proof of attendance and

satisfactory completion of the required training in expanded therapeutic procedures. The Board shall verify successful completion of the approved training directly with the provider;

4.5.5.4. Submit the Expanded Therapeutic Procedures Fee as listed in the Board's rule, W. Va. Code of Rules, §14-5.

14-12-5. §14-12-6. Education and Training.

5.1.6.1. The Board shall accept training for certification in expanded therapeutic procedures that is provided by or through a school or college of optometry accredited by the Accreditation Council on Optometric Education or its successor organization.

5.2.6.2. The Board, at its discretion, may approve courses provided through organizations or individuals other than accredited schools or colleges of optometry, Provided, that the training meets the criteria established by the Board for training provided by accredited schools of optometry.

5.3.6.3. The Board may accept expanded therapeutic procedures training used to obtain licensure for expanded therapeutic procedures from another state or states: Provided, that the other state or states have requirements that are substantially equivalent to the training required by this state.

6.4. Additional education and training may be required by the Board as it deems appropriate when it adds new approved procedures or requirements.

§14-12-6. §14-12-7. Certification.

6.1.7.1. Upon the licensee's successful completion of the requirements listed in sections 34 through 56 and approval by the Board or its designee an expanded therapeutic procedures certificate may be issued.

6.2.7.2. Upon issuance of the certificate, the licensee's license number shall be changed. The license number will be followed by a dash and the initial "E" for expanded therapeutic procedures.

§14-12-7. §14-12-8. Treatment Guidelines.

7.1.8.1. A certificate holder may perform Board approved expanded therapeutic procedures which are considered rational to the diagnosis and treatment of the human eye or its appendages.

7.2.8.2. Any pharmaceutical agent which may be administered while performing approved procedures shall be selected from the agents the certificate holder is authorized to prescribe or administer under his or her topical, oral or injectable pharmaceutical agents certification granted by W.Va. Code, §30-8-1, et. Seq. and the provisions of W.Va. Code of Rules, §14-2, Oral Pharmaceutical Certificate, and W.Va. Code of Rules, §14-11 Injectable Pharmaceutical Agents Certificate;

7.3.8.3. The certificate holder shall follow all applicable Occupational Safety and Health Administration (OSHA) and Centers for Disease Control (CDC) guidelines pertaining to performance of expanded therapeutic procedures.

7.4.8.4. The certificate holder shall adhere to generally accepted standards of care and follow established clinical guidelines for approved procedures. The certificate holder shall monitor the patient for an adverse outcome and provide appropriate follow up care for patients treated by expanded therapeutic procedures.

§14-12-8. §14-12-9. Recertification.

A certificate holder shall meet the following requirements for recertification:

8.1.9.1. The certificate holder shall submit proof of current certification in life support for the professional rescuer or for medical providers from the American Red Cross or American Heart Association or their successors.

8.2.9.2. The certificate holder shall submit proof of a minimum of two (2) hours of continuing education instruction in performing

expanded therapeutic procedures per two year continuing education cycle as listed in W. Va. Code of Rules, §14-10, Continuing Education.

~~8-3.9.3.~~ The certificate holder shall submit the ~~recertification~~ Annual Renewal fee as listed in the W. Va. Code of Rules, §14-5.



State of West Virginia *Board of Medicine*

REV. O. RICHARD BOWYER
PRESIDENT

MARIAN SWINKER, MD, MPH
SECRETARY

101 Dee Drive, Suite 103
Charleston, WV 25311
Telephone 304.558.2921
Fax 304.558.2084
www.wvbom.wv.gov

MICHAEL L. FERREBEE, MD
VICE PRESIDENT

ROBERT C. KNITTLE
EXECUTIVE DIRECTOR

August 15, 2012

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

Re: Proposed Rule 14 CSR 12, Expanded Therapeutic Procedures Certificate

Ladies and Gentlemen:

The above proposed rule must be withdrawn as it violates applicable law. The reasons follow.

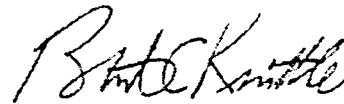
1. It appears that this proposed rule filing circumvents all the provisions of West Virginia Code § 30-1A-1 et seq.: Procedure for Regulation of Occupations and Professions. West Virginia Code § 30-1A-2 has been amended to mandate that any revision or expansion of the scope of practice of a regulated profession requires the submission of an application to the Joint Standing Committee on Government Organization. Neither this required procedure nor any of the subsequent procedures required by West Virginia Code § 30-1A-1 et seq. have been followed. This is a fatal flaw to the proposed rule, inasmuch as optometry is a regulated profession in West Virginia and the proposed rule's title clearly declares that the proposed rule relates to "expanded therapeutic procedures." (emphasis added)
2. In addition, at 14 CSR 12 2.5, the definition of "Procedures", "Therapeutic Procedures", "Expanded Procedures", and "Approved Procedures" is improperly mysterious, useless, and dangerous, as it puts no one on notice of what such procedures are, which is the purpose of a definition. A person reading this rule should be able to find within the four corners of the rule all the information needed to assess what the terms described mean. The Board of Medicine understands this concept to be a central focal point of law in the United States of America. Please, tell us in the proposed rule at 2.5. precisely what the Board of Optometry is contemplating as a "therapeutic procedure" and an "expanded procedure". That is why rules are supposed to be

promulgated. See West Virginia Code § 29A-1-2(i), where "Rule" is defined in pertinent part as "affecting private rights, privileges or interests, or the procedures available to the public, adopted by an agency to implement, extend, apply, interpret or make specific the law enforced or administered by it or to govern its organization or procedure..." In the Board of Medicine's opinion, this definition in 2.5. does not remotely qualify as a real "Rule".

3. The last sentence in 2.5. is entirely unhelpful to all parties involved. "All expanded therapeutic procedures must meet the criteria listed in W.Va. Code, § 30-8-1, et seq." To what specific criteria are you referring among the twenty-two (22) sections of Article 8, Chapter 30? As it stands, the proposed rule leaves any citizen of West Virginia, whoever it may be, completely confused and unclear. Rather than erecting a smokescreen, an accurate statement of what "criteria" in Article 8, Chapter 30 the Board of Optometry is thinking of would be appropriate and beneficial to everyone.

Thank you for your consideration of the comments of the West Virginia Board of Medicine.

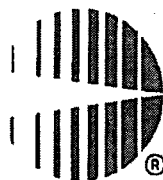
For the Board,

A handwritten signature in black ink, appearing to read "Robert C. Knittle". The signature is fluid and cursive, with the first name "Robert" and last name "Knittle" clearly distinguishable.

Robert C. Knittle

pc: O. Richard Bowyer, President

Ronald L. Hopping, OD, MPH
President

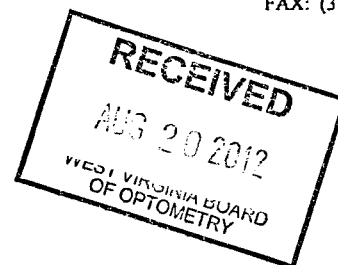


American Optometric Association

243 N. Lindbergh Blvd • St. Louis, MO 63141 Blvd • (314) 991-4100
FAX: (314) 991-4101

August 17, 2012

Dr. James Campbell, President
West Virginia Board of Optometry
179 Summers Street
Suite 231
Charleston, WV 25301



Dear Dr. Campbell:

The American Optometric Association (AOA) represents almost 35,000 Doctors of Optometry, optometry students, and paraoptometric assistants and technicians. Optometrists provide almost two-thirds of all primary eye care in the United States and West Virginia and we fully support the rule as proposed. We believe the proposed rule reflects the intent of W.Va. Code §30-8. With the implementation of this rule it protects the public as Senate Bill 230 was intended and also allows optometrists to provide much needed services in rural areas of West Virginia.

Optometrists are highly qualified, trained doctors who examine, diagnose, treat and manage diseases and disorders of the eye and adjacent structures. Optometry school consists of four years of graduate-level, doctoral study concentrating on both the eye and related systemic health. Passing these regulations will give optometrists in West Virginia the ability to add additional tools for providing that care while maintaining safety standards for patients.

Proposed rule 14CSR12 establishes the minimum education and training requirements, treatment guidelines and rules for acquiring the certification needed before applying these procedures in their practices. This protection was added during the legislative process and the AOA believes that the West Virginia Board of Optometry has taken every precaution necessary to protect the public through the proposed rule. Optometry is the only doctoral-level profession where continuing education is required for license renewal in every jurisdiction in the United States which shows the professions continuing dedication to providing the public with high quality health care close to their homes.

The AOA thanks the Board of Optometry for following the legislation as passed in preparing proposed rule 14CSR12. We know you have spent hundreds of hours deliberating in meetings, reviewing public comment and then finalizing this rule.

If you have any questions, please feel free to contact Sherry Cooper, Associate Director of State Government Relations at 314-938-4266, or via email at slcooper@aoa.org.

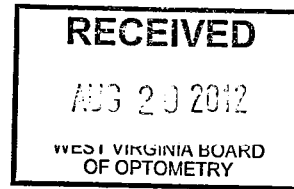
Sincerely,

Ronald L. Hopping, OD, MPH



August 19, 2012

Matthew Berardi, OD
President, WV Board of Optometry
179 Summers Street, Suite 231
Charleston, WV 25301



Dear Dr. Berardi:

The proposed Legislative Rule by the Board of Optometry in **Title 14, Series 12**, relating to "Expanded Therapeutic Procedures Certificate," should not be considered by the Legislature's Rule Making Review Committee and should be withdrawn. It exceeds the statutory authority of the WV Board of Optometry.

In the proposed rule it is clearly stated in **§14-12-1.1** that: "This rule establishes the requirements, procedures and standards for the certification of a licensee to perform *expanded* therapeutic procedures . . ."

These *expanded* procedures are the same as an *expanded* scope of practice. This rule is then in violation of **§30-1A-2 of the West Virginia Code** which clearly provides:

"(a) Any professional or occupational group or organization who proposes to substantially revise or expand the scope of practice of a regulated profession or occupation, shall submit an application to the Joint Standing Committee on Government Organization, as set out in this article."

However, there is no record of any application by the Board of Optometry for an *expanded* scope of practice for these procedures on file with the Joint Standing Committee on Government Organization.

It is also important to understand that **§30-8-9(a)(7) of the West Virginia Code** provides only seven procedures allowed to be performed in the scope of practice by optometrists under current law. So, the proposed rule in **§14-12.2.5** for *expanded* procedures and in **§14-12-5** for education and training, is fatally flawed and should not be considered for adoption. That is because the proposed rule clearly violates the provisions of **§30-8-6 of the West Virginia Code**, which dictates that under any permissible proposed rule for expanded procedures by the Board of Optometry, this provision must apply:



Page 2.

"(14) Requirements for an expanded scope of practice for those procedures that are taught at fifty percent of all accredited optometry schools;"

The proposed rule fails in every way to demonstrate that more than one-half of all accredited optometry schools have teaching programs for any *expanded* scope of practice for the proposed expanded procedures in West Virginia. In fact, the actual *expanded* procedures are not even defined or otherwise identified in the proposed rule.

In addition, the Board of Optometry actually proposes in the rule to ignore the statute by allowing it, at its own discretion, to approve educational courses for *expanded* therapeutic procedures as "provided through organizations or individuals other than accredited schools of optometry," clearly a violation of current law.

We regret that the Board of Optometry did not engage in any discussion of this proposed rule with physicians and surgeons, the Board of Medicine, the Board of Osteopathic Medicine, or the Medical Schools at West Virginia University and Marshall University, prior to offering of this rule for public comment. This discussion could have proved beneficial since there is no accredited optometry school in West Virginia.

Therefore, we respectfully request that the Board of Optometry withdraw proposed Legislative Rule **Title 14, Series 12**.

Please contact me if you would like further discuss our concerns or explore any alternatives.

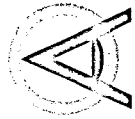
Sincerely yours,

Charity Hix, MD / NSR

Charity Hix, MD
President

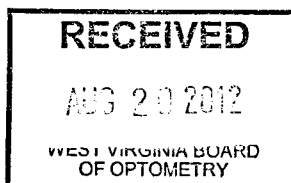
CC:

Honorable Joseph M. Minard, Co-chair, Legislative Rule Making Review Committee



Honorable Bonnie Brown, Co-chair, Legislative Rule Making Review Committee
Honorable Herb Snyder, Chair, Senate Government Organization Committee
Honorable Jim Morgan, Chair, Senate House Government Organization Committee
Honorable Ron Stollings, Chair, Senate Health Committee
Honorable Don Perdue, Chair, House Health Committee
Honorable Corey Palumbo, Chair, Senate Judiciary Committee
Honorable Tim Miley, Chair, House Judiciary Committee
Robert Knittle, Executive Director, West Virginia Board of Medicine
Diana Shepard, Executive Director, West Virginia Board of Osteopathic Medicine
Evan Jenkins, Executive Director, West Virginia State Medical Association
Gerry Stover, West Virginia Academy of Family Physicians
Michael Adelman, DO, WV School of Osteopathic Medicine
Bob Palmer, American Academy of Ophthalmology
West Virginia Dermatological Association
West Virginia University School of Medicine
West Virginia University Eye Institute, Department of Ophthalmology
Joseph I. Shapiro, MD, Dean, Joan C. Edwards School of Medicine at Marshall University

Matthew Berardi, OD, President
West Virginia Board of Optometry
179 Summer St., Ste 231
Charleston, WV 25301



August 19, 2012

Dear Berardi,

In reference to the ongoing deliberations regarding the scope of practice for the field of optometry, I would like to highlight the criteria for the medical and surgical training of ophthalmologists in West Virginia and throughout the United States. These uniformly high national standards are set and vigorously enforced by the Accreditation Council for Graduate Medical Education (www.acgme.org). The ACGME is the independent regulatory agency responsible for ensuring that this country consistently produces the highest quality physicians, who, upon graduation, then provide the most effective and safest medical and surgical care available.

The ACGME stipulates that training programs in ophthalmology provide a stable, well-coordinated and progressive educational experience in the entire spectrum of ophthalmic diseases and ocular surgery. Each trainee (resident) must develop diagnostic, therapeutic and manual skills, as well as sound judgment in the application of such skills. Each trainee must have major technical and patient care responsibilities in order to provide an adequate base for subsequent independent practice.

Training must be at least 36 months and can begin only after the successful completion of four years of medical school and at least one year of practice as an intern in an academic hospital accredited by the ACGME. The faculty physicians must have active state medical licenses and be Board-Certified by the American Board of Ophthalmology and must keep their time-limited certification updated regularly.

Each training program in the United States accepts only a small number of new doctors each year to begin their specialty training in ophthalmology. Our state's flagship program at WVU accepts only three doctors each year to be residents in ophthalmology. WVU has a total of 9 residents, each of whom trains for 36 months. WVU graduates three fully trained comprehensive ophthalmologists a year.

The ACGME stipulates that residents be substantially involved in the care of at least 3000 patients over three years. The residents at WVU care for about 9000 patients before they graduate. The vast majority of these patients have severe eye disease. Under one-on-one supervision with faculty, WVU residents also perform about 400 surgeries over three years. The ACGME requires 186. WVU residents also assist faculty in the surgery of an additional 350 patients. A minimum of 178 assistant cases are required by the ACGME.

I hope summary will provide you with an appreciation for the physically, emotionally, and intellectually demanding training inherent in producing quality ophthalmologists in both this state and in the country. This training, experience and emphasis on patient safety are unparalleled in any other allied health profession, including the field of optometry. We are fortunate to have many of WVU's graduates remain in our state for their careers to serve our citizens. Many have also achieved national and international prominence in their fields. West Virginians can rest assured that they have high quality medical and surgical eye care provided by their ophthalmologists.

Sincerely,

A handwritten signature in black ink, appearing to read "Geoff Bradford". The signature is fluid and cursive, with a large loop at the end.

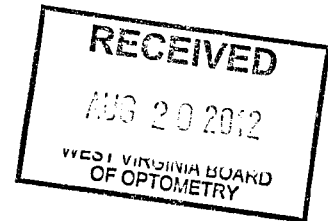
Geoff Bradford, MS, MD
Professor of Ophthalmology
Residency Program Director

WEST VIRGINIA ASSOCIATION OF OPTOMETRIC PHYSICIANS

2210 WASHINGTON STREET EAST • CHARLESTON, WV 25311
TELEPHONE 304.720.8262 • 866.205.5897 • FAX 304.343.4251 • WEBSITE www.wvaop.org

August 19, 2012

Dr. James Campbell, President
WV Board of Optometry
179 Summers Street
Suite 231
Charleston, WV 25301



Dear Dr. Campbell:

This letter is in reference to the WV Board of Optometry's proposed Rule 14CSR12, Expanded Therapeutic Procedures Certificate.

After thorough review by our membership please be advised the West Virginia Association of Optometric Physicians fully supports the rule as proposed. We believe the proposed rule reflects the intent of W.Va. Code §30-8. With the implementation of this rule it protects the public as Senate Bill 230 was intended and also allows our physicians the opportunity to provide much needed services in our less populated areas of our state.

Proposed rule 14CSR12 establishes the minimum education and training requirements, treatment guidelines and rules for acquiring the certification needed before applying these procedures in their practices. This protection was added through much discussion in past legislation and we believe the WV Board of Optometry has taken every precaution necessary to protect the public through the proposed rule.

Once again please share with the Board our appreciation for following the legislation as passed in preparing proposed rule 14CSR12. We know you have spent many of hours deliberating in meetings, reviewing public comment and then finalizing this rule.

Should you have any questions from me or members of our association, please do not hesitate to call.

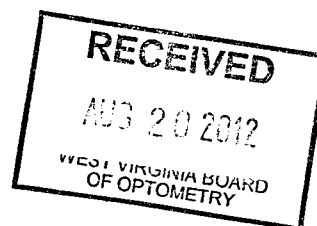
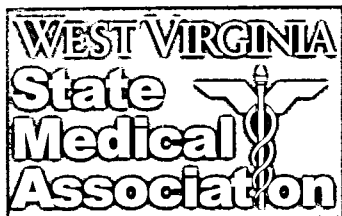
Sincerely,

A handwritten signature in black ink, appearing to read "Chad D. Robinson".

Chad D. Robinson
Executive Director
WV Association of Optometric Physicians



West Virginia Association of Optometric Physicians
Affiliated with American Optometric Association



August 20, 2012

Matthew Berardi, OD
President, WV Board of Optometry
179 Summers Street, Suite 231
Charleston, WV 25301

Dear Dr. Berardi:

I am writing on behalf of the WV State Medical Association regarding your Board's rule 14 CSR 12, "*Expanded Therapeutic Procedures Certificate*". This rule should be withdrawn as it directly conflicts with recently enacted legislation and exceeds the statutory authority of the WV Board of Optometry.

During the 2012 legislative session SB 214 was passed. This bill amended §30-1A-2 of the West Virginia Code specifying that a sunrise application must be submitted to the Joint Standing Committee on Government Organization if a profession "proposes to substantially revise or expand the scope of practice of a regulated profession or occupation". This rule, proposes to "establish requirements, procedures and standards for the certification of a licensee to perform *expanded therapeutic procedures . . .*", and as such appears to be in direct violation of the statute since the Board has not undergone the statutorily required application and review.

Additionally, the rule is flawed because as required under §30-8-6 of the West Virginia Code if the Board of Optometry proposes a rule for expanded therapeutic procedures the specific procedures in question must be "taught at fifty percent of all accredited optometry schools". The rule neither lists the specific therapeutic procedures contemplated nor any information regarding the schools that offer such training. It is impossible to determine whether the therapeutic procedures so contemplated would meet the statutory requirements since they are not defined or otherwise referenced in the rule.

Also disconcerting is that the Board of Optometry proposes in the rule to, at its own discretion, approve educational courses for *expanded* therapeutic procedures as "provided through organizations or individuals other than accredited schools of optometry,". This is clearly a violation of current statute that requires this be tied to the educational training offered at more than fifty percent of the accredited optometry schools.

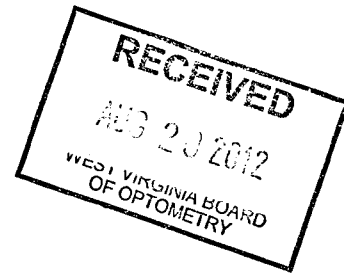
In light of the serious statutory conflicts with the rule and the absence of proper procedure being followed, we respectfully request that the Board of Optometry withdraw the proposed Legislative Rule 14 CSR 12.

If you have any questions regarding our comment please feel free to contact the Amy N. Tolliver, WVSMA Government relations Specialist at 304-925-0342.

Sincerely,

Mary Ann Cater, DO
President

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WEST VIRGINIA ACADEMY OF
FAMILY PHYSICIANS
STRONG MEDICINE FOR WEST VIRGINIA

August 20, 2012

James Campbell, OD
President, WV Board of Optometry
179 Summers Street, Suite 231
Charleston, WV 25301

Dear Dr. Campbell,

The purpose of this letter is to provide comment on the proposed Legislative Rule by the Board of Optometry.

The West Virginia Academy of Family Physicians is concerned with the contents of **Title 14, Series 12**, relating to "Expanded Therapeutic Procedures Certificate."

The proposed rule does not follow the proper procedures as enacted in Senate Bill 214 during the 2012 Regular Legislative Session.

The new law requires any proposed scope of practice expansion to follow the "Sunrise Application Process" through the Legislature's Joint Committee of Government Organization and the Legislative Auditor's Office.

The proposed rule should be withdrawn and should not be considered by the Legislature's Rule Making Review Committee.

In addition, the corresponding proposed Legislative Rule **Title 14, Series 5**, relating to "Schedule of Fees for Expanded Therapeutic Procedures Certificate," should also be withdrawn as unnecessary.

Respectfully Submitted,

Gerry D. Stover, MS

Executive Vice President – West Virginia Academy of Family Physicians

WEST VIRGINIA BOARD OF OPTOMETRY

**TO: Chairman Minard and Chairman Brown
Legislative Rule Making Review Committee**

FROM: The West Virginia Board of Optometry

SUBJECT: Response to Public Comments 14-12

Date: 8/31/12

On July 19, 2012 the West Virginia Board of Optometry (hereinafter "Board") filed proposed legislative rule, §14-12 Expanded Therapeutic Procedures. The comment period was concluded on August 19, 2012 at 4:00 p.m. Some comments may be paraphrased as a few were redundant; however, copies of all received comments are included in this packet as required by law.

The following statements represent the comments received by the Board:

1. An application for expansion of scope should have been made to the Joint Committee on Government Organization since the rule establishes expanded therapeutic procedures.
2. "In forming the rule the Board of Optometry actually proposes in the rule to ignore the statute to allow it, at its own discretion, approve educational courses for expanded therapeutic procedures as provided through organization or individuals other than accredited schools of optometry, clearly a violation of current law."
3. §14-12 is "fatally flawed" because it is not specific enough to inform the public of the Board's intentions regarding expanded therapeutic procedures.....

The Board thanks the public for its comments regarding §14-12 Expanded Therapeutic Procedures. Public comment is a valuable part of the rulemaking process, and all comments have been given careful consideration. The Board's response to comments follows, along with reference to modifications the Board has made to §14-12 in consideration of comments.

Senate Bill 230, the Optometric Practice Act, (West Virginia Code §30-8) was enacted during the 2010 Legislative Session and represented an historic update of the Optometric Practice statute. SB 230 clearly defined the Board of Optometry's role and affirmed its responsibility to regulate the profession. The statute also preserved the authority of the Board to promulgate rules to govern optometric practice. SB 230 defined optometric scope of practice and provided the mechanism for the Board to certify properly trained licensees to utilize new treatment agents and procedures as the profession's education evolves. Most importantly, SB-230 provided strong protections and safeguards to the public. The statute established the framework for the practice of optometry for many years to come. The provisions of Senate Bill 230, West Virginia Code 30-8, were followed strictly in developing §14-12.

West Virginia Code §30-8-3(l) states:

"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."

Rule §14-12 was formulated pursuant to the section of code allowing for an "expanded scope of practice for those procedures that are taught at 50% of all accredited optometry schools"(West Virginia Code §30-8-6(14)). It is evident that the legislative intent of SB 230 was for expanded procedures to become a part of the scope of optometric practice and that the Board was vested with the responsibility of establishing the agents and procedures optometrists would utilize in accordance with the provisions contained within the law, as well as to establish applicable educational requirements to utilize those agents and procedures.

In order for optometrists to be licensed to practice optometry in West Virginia, they must hold a degree from a school or college of optometry accredited by the Accreditation Council on Optometric Education. Before a licensee could be granted privileges for expanded therapeutic procedures, by statute those procedures must be taught in 50% of those institutions. While it is anticipated that newly graduated licensees would receive training for these procedures while in school, there must be a mechanism for existing licensees to obtain certification training through approved post-graduate training programs and continuing education.

Consequently, the Board would accept training from approved providers that are not necessarily a school or college of optometry. The Board has amended §14-12-6.3 with a proviso making it clear that alternate providers will have to adhere to the same standards as the accredited optometry schools. It reads:

"6.2. The Board, at its discretion, may approve courses provided through organizations or individuals other than accredited schools or colleges of optometry, *Provided, that the training meets the criteria established by the Board for training provided by accredited schools of optometry.*"

It is implicit that the Board would mandate the educational requirements that must be met before any licensee would be allowed to perform any specific additional procedures under the provisions of §14-12. Educational requirements are clearly established in the Optometric Practice Law and Rules, and properly referenced in proposed rule 14-12. Verification of educational requirements would be an administrative duty of the Board and need not be a part of the Rule. In consideration of the comments received, however, The Board has elected to add provisions that are parallel to those in the Board's Injectable Pharmaceutical Agents Certificate rule passed in the 2011 Legislative Session, §14-11-7.2, which requires the Board to maintain a list of approved procedures to be made available to the public, including treatment guidelines for each procedure.

"3.1. The Board shall maintain a list of approved expanded therapeutic procedures for public inspection. The list will contain treatment guidelines for the procedures approved by the Board."

In response to comments, to provide further clarification the Board has additionally added expanded language in the rule to directly cite West Virginia Code §30-8-6(14), which states that the Board may write rules listing "requirements for an expanded scope of practice for those procedures that are taught at 50% of all accredited optometry schools."

2.5. "Procedures," "Therapeutic Procedures" "Expanded Therapeutic Procedures" or "Approved Procedures" are procedures approved by the West Virginia Board of Optometry that meet the criteria of this rule. All expanded therapeutic procedures must meet the criteria listed in W.Va. Code, ~~§30-8-1, et seq.~~ §30-8-6(14) which states that all expanded therapeutic procedures shall be taught in at least fifty percent (50%) of all optometry schools accredited by the Accreditation Council on Optometric Education or its successor organization recognized by the U.S. Department of Education."

While it is understood that the Board would clearly delineate any authorized procedures as part of its administrative duties, and that as stated above the Board will add a provision to the rule to maintain a list of approved procedures available for public inspection, it is logistically impossible to provide a list of procedures to be included within the rule. Those procedures have yet to be determined, and specific procedures would be authorized only after methodically canvassing the optometry schools to determine which procedures are being taught, and that the 50% threshold is met. It is anticipated that there would be a relatively few procedures authorized initially, and that the list would grow slowly over time as new procedures are taught in schools and the 50% threshold is met.

With regard to comments received that proposed rule §14-2 be subject to the sunrise procedure for changing the scope of practice of a profession, it is the Board's opinion and position that the proposed rule does not invoke or trigger this process because the rule does not seek to change the scope of practice of optometry. This rule merely defines that process by which new techniques, procedures and treatments are taught and approved as they are developed through research and the regular developments in the field. Just as in any health care profession, new procedures and techniques become available and tested; then they are added to the arsenal of tools of the practitioner. The Board is not seeking to change the scope of practice as determined by the Optometric Practice Act; it is merely promulgating rules in accord within the scope of practice already provided for in the law.

West Virginia Board of Optometry
Agency Approved Rule §14-12 Expanded Therapeutic Procedures

Amendments

1. We added more specific language in the Definitions section in response to comments that the definition of expanded therapeutic procedures was not specific enough. We added language to §14-12-2.5 to read:

2.5. "Procedures," "Therapeutic Procedures" "Expanded Therapeutic Procedures" or "Approved Procedures" are procedures approved by the West Virginia Board of Optometry that meet the criteria of this rule. All expanded therapeutic procedures must meet the criteria listed in W.Va. Code, ~~§30-8-1, et seq.~~ §30-8-6(14) which states that all expanded therapeutic procedures shall be taught in at least fifty percent (50%) of all optometry schools accredited by the Accreditation Council on Optometric Education or its successor organization recognized by the U.S. Department Of Education."

2. We added a Public Access and Board Accountability Section in response to comments about the information on the Approved Procedures being unavailable to the public to read:

"§14-12-3. Public Access and Board Accountability.

3.1. The Board shall maintain a list of approved expanded therapeutic procedures for public inspection. The list will contain treatment guidelines for the procedures approved by the Board."

This language is adapted from language listed in our Injectable Pharmaceutical Agents Certificate rule, §14-11-7.2. The Injectable Pharmaceutical Agents Certificate rule passed in the 2011 Legislative Session.

3. We added a proviso to §14-12-6.2 in response to concerns to affirm that training from alternate providers must meet the same criteria as accredited schools of optometry. It reads:

~~"5-2-6.2.~~ The Board, at its discretion, may approve courses provided through organizations or individuals other than accredited schools or colleges of optometry, Provided, that the training meets the criteria established by the Board for training provided by accredited schools of optometry."

4. We added a provision to make the process more clear in response to comments requesting a more defined process. The nature of the process as dynamic, not static. We outlined that additional education and training may be required by the Board as it deems appropriate when it adds new approved procedures or requirements. §14-12-6.4 reads:

6.4. Additional education and training may be required by the Board as it deems appropriate when it adds new approved procedures or requirements.

5. We changed the recertification fee to the Annual Renewal Fee in response to a comment on our Schedule of Fees rule, §14-5. The commenter was concerned that it might not be clear that the Board did not intend to charge the \$200 certification fee repeatedly with each annual renewal period. The Board intended the \$200 fee to cover administrative costs to be charged only once. Only the Annual Renewal Fee will need to be paid upon recertification. It reads:

~~"8.3.9.3.~~ The certificate holder shall submit the ~~recertification~~ Annual Renewal fee as listed in the W. Va. Code of Rules, §14-5."