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WEST VIRGINIA LEGISLATURE
Legislative Rule-Making Review Committee

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December 10, 2012

NOTICE OF ACTION TAKEN BY THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

TO: Natalie E. Tennant, Secretary of State, State Register

TO: Pamela Carper, Executive Director
WV Board of Optometry
179 Summers Street
Suite 231
Charleston, WV 25301

FROM: Legislative Rule-Making Review Committee

Proposed Rule: Expanded Therapeutic Procedures Certificate, 14CSR12

The Legislative Rule-Making Review Committee Recommends that the West Virginia Legislature:

1. Authorize the agency to promulgate the Legislative rule:
 - (A) as originally filed _____
 - (B) as modified by the agency _____
2. Authorize the agency to promulgate part of the Legislative rule; a statement of reasons for such recommendation is attached. _____
3. Authorize the agency to promulgate the Legislative rule with certain amendments; amendments and a statement of reasons for such recommendation is attached. _____ *φ*
4. Authorize the agency to promulgate the Legislative rule as modified with certain amendments; amendments and a statement of reasons for such recommendation is attached. _____
5. Recommends that the Legislature rule be withdrawn; a statement of reasons for such recommendation is attached. _____

West Virginia Board of Optometry
Expanded Therapeutic Procedures Certificates
14CSR12

Statement of Reason

The legislative rule-making committee amended the rule to clarify the rule by specifying a procedure the board should follow when proposing a scope a practice expansion. Also, in order to comply with §30-1A-2 of W.Va. Code the committee required the board to submit the scope of practice expansion to the Performance Evaluation and Review Division for a sunrise scope of practice expansion review.

West Virginia Board of Optometry
Expanded Therapeutic Procedures Certificates
14CSR12

Amendments

The Legislative Rule-making Committee moves to amend the rule on page 1, by striking everything and inserting in lieu thereof the following:

"§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. --

1.5. Purpose - This rule establishes the process for any future legislative rule wherein any proposed expanded or revised scope of practice, through each specific expanded therapeutic procedure, would be reviewed and approved for compliance on an application for a sunrise review by the Performance Evaluation Division of the Legislative Auditor's Office, in conformance with §30-1A-2 of W.Va. Code, before it is submitted to the Legislative Rule Making Review Committee.

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, §30-8-6(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. Application to Add an Expanded Therapeutic Procedure.

3.1. The Board may accept an application from any interested party to add a therapeutic procedure or class of procedures for certification of licensees. The application shall include:

3.1.1. the applicant or group's name, title, and form of licensure if applicable,

3.1.2. the address, telephone number, address and e-mail address of the applicant or group,

3.1.3. the name and telephone number of a contact person to discuss the application,

3.1.4. the name of the procedure or class of procedures that is being requested for addition to therapeutic practice,

3.1.5. a statement of support for the procedure or class of procedures proposed for regulation which has been signed by at least ten residents or citizens of the State of West Virginia who are licensed optometrists,

3.1.6. the estimated number of licensees who are represented by the requesting person or group if applicable,

3.1.7. a list of accredited optometry schools that are teaching such expanded therapeutic procedure or class of procedures and written documentation from each accredited school on the list to the effect that each school is teaching such expanded therapeutic procedure or class of procedures.

3.1.8. the names and contact information for the Dean of Academic Affairs or his or her designee of each school the applicant lists as teaching such expanded therapeutic procedure or class of procedures.

3.1.9. a definition of the problem which requires the

expansion of scope through the procedure or class of procedures requested and the extent to which consumers need and will benefit from licensees who are certified to practice the proposed therapeutic procedure or class of procedures.

§14-12-4. The Board Education Committee.

4.1. The application to approve a procedure or class of procedures shall be referred to the Board Education Committee.

4.2. The Board Education Committee shall consist of at least three Board members.

4.3. The Education Committee may include additional ex-officio members who may not be members of the Board to act as consultants to the Board.

§14-12-5. Board Education Committee Data Request.

5.1. The Education Committee shall communicate in writing with each optometry school accredited by the American Council on Optometric Education or its successor approved by the U.S. Department of Education who teach the proposed procedure or class of procedures as cited in the application. The request may be sent to each optometry school's Dean of Academic Affairs or his or her designee. The Education Committee may enlist the assistance of accrediting bodies or professional associations to obtain this information. The request by the Board Education Committee shall include:

5.1.1. If the procedure or class of procedures is or are taught by the optometry school,

5.1.2. Additional information as the Board deems necessary which may include, but not be limited to:

5.1.2.1. The methods of instruction used to teach the requested procedure or class of procedures, and

5.1.2.2. The clinical experience of each student or the methods used to provide instruction for the proposed procedure or class of procedures in a closely supervised environment.

§14-12-6. Board Education Committee Report.

6.1. The Board Education Committee shall evaluate the responses from accredited optometry schools and confirm that 50% of all accredited optometry schools teach the proposed therapeutic procedure or class of procedures. If the Board Education Committee determines that less than fifty percent (50%) of the accredited optometry schools teach the expanded therapeutic procedure or class

of procedures, the proposed procedure shall be rejected.

6.2. The Board Education Committee shall prepare a list of schools that teach the proposed procedure or class of procedures and make it available to the public for inspection. The Board Education Committee may make the list available to the public including, but not limited to, publication through the Board's web site.

6.3. The Board Education Committee may gather additional information and make a recommendation to the Board for approval or disapproval of the procedure or class of procedures. Based on the sole determination as to whether the expanded therapeutic procedure or class of procedures are taught at fifty (50%) or more of all accredited optometry schools and the sufficiency of the supported documentation submitted by the applicant and gathered by the Education Committee. The recommendation shall include:

6.3.1. Proposed guidelines for training to ensure the proficiency of optometrists certified in the procedure or class of procedures. The recommendation may include the appropriate hours of instruction required,

6.3.2. Treatment guidelines for the proposed procedure or class of procedures,

6.3.3. Methods of testing to be used to ensure that optometrists certified to perform the requested procedure or class of procedures are proficient in using the procedure or class of procedures.

6.3.4. The Board shall hold a public hearing regarding the recommendation of the Education Committee if the Education Committee recommends that the proposed therapeutic procedure or class of procedures be approved. The purpose of such public hearing is to determine whether the documentation reviewed and gathered by the Education Committee is sufficient to prove that the expanded therapeutic procedure is currently being taught at fifty percent or more of all accredited optometry schools. The Board shall allow those members of the public who wish to speak solely to the sufficiency of the documentation submitted by the applicant and evidence gathered by the Education Committee. If, after the public hearing and review of the recommendation, the Board determines that the documentation and evidence is sufficient to demonstrate that fifty percent (50%) or more of all accredited optometry schools currently teach the expanded therapeutic procedure, the Board shall approve the application. If the Board determines that the documentation and evidence is not sufficient to demonstrate that fifty percent (50%) or more of all accredited optometry schools currently teach the expanded therapeutic procedure, the board shall

reject the application.

6.3.5. The Board Education Committee shall review the list of expanded therapeutic procedures or class of procedures that have been approved pursuant to this process not less than once every two years. In such review, the Board shall verify that each expanded therapeutic procedure or class of procedures are still taught at fifty percent (50%) or more of all accredited optometry schools. If, upon such review, the Board finds that any expanded therapeutic procedure or class of procedures is not taught at fifty percent (50%) or more of all accredited optometry schools, the Board shall remove such expanded therapeutic procedure or class of procedures from the list of approved expanded therapeutic procedures.

§14-12-7. Public Access and Board Accountability.

7.1. The Board shall document and maintain a list for public inspection of each approved expanded therapeutic procedure for each approved licensee. The list will contain clinical educational and treatment guidelines and the minimum number of clinical procedures performed for each such procedure by each licensee as approved by the Board.

§14-12-8. Certification Generally.

8.1. 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.

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

§14-12-9. Certification Requirements.

To be certified the licensee shall:

- 9.1. Complete the required application form;
- 9.2. Submit proof of injectable pharmaceutical agents certification;
- 9.3. Submit proof of attendance and satisfactory completion of the required clinical education and treatment training in expanded therapeutic procedures. The Board shall verify successful completion of the approved clinical educational and treatment training directly with the provider accredited school of optometry;
- 9.4. Submit the Expanded Therapeutic Procedures Fee as listed in the Board's rule, W. Va. Code of Rules, §14-5.

§14-12-10. Clinical Education and Training.

10.1. The Board shall accept clinical education and treatment 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.

10.2. The Board shall submit any expanded therapeutic procedure on an application for a sunrise review by the Performance Evaluation Division of the Legislative Auditor's Office, in conformance with §30-1A-2 of W.Va. Code, before it is filed with the Legislative Rule Making Review Committee. The Board shall confirm that each therapeutic procedure is actually performed as taught through clinical educational and treatment training by optometry students in at least fifty percent (50%) of all optometry schools accredited by the Accreditation Council on Optometric Education or its successor organization.

10.3. The Board may accept expanded therapeutic procedure clinical educational and treatment 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 for each procedure to the clinical educational and treatment training required by this state, and that each such procedure is documented to be currently taught through clinical educational and treatment training in at least 50% of all accredited optometry schools.

10.4. Additional clinical education and treatment training requirements shall be required by the Board and approved by rule, that includes the minimum number of specific procedures that must be performed by each applicant for each expanded therapeutic procedure, prior to certification. A complete log of each such procedure performed must be kept and submitted to the Board with documentation that the applicant was supervised by an individual licensed to perform each such procedure.

§14-12-11. Certification.

11.1. Upon the licensee's successful completion of the requirements listed in sections 9 through 10 and approval by the Board an expanded therapeutic procedures certificate may be issued.

11.2. 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.

§14-12-12. Treatment Guidelines.

12.1. 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.

12.2. 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;

12.3. 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.

12.4. 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. Any adverse outcome shall be reported to the board by the certificate holder.

§14-12-13. Recertification.

A certificate holder shall meet the following requirements for recertification:

13.1. 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.

13.2. The certificate holder shall submit proof of a minimum of 2 hours of continuing clinical education instruction in performing each expanded therapeutic procedures per two year continuing education cycle as listed in W.Va. Code of Rules §14-10 Continuing Education.

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

§14-12-14. Compliance with W. Va. Code §30-1A-2.

14.1 This rule requires the Board of Optometry to follow all provisions of §30-1A-2 of the West Virginia Code."