

TITLE 14
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF OPTOMETRY

FILED

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SERIES 2
ORAL PHARMACEUTICAL CERTIFICATE

OFFICE OF THE CLERK
SECRETARY OF STATE

§14-2-1. General.

1.1. Scope. -- This legislative rule establishes the requirements, procedures and standards for the certification and re-certification of licensees to obtain an oral pharmaceutical certificate.

1.2. Authority. -- W. Va. §30-8-6, §30-8-9, and §30-8-14 .

1.3. Filing Date. -- August 12, 2011.

1.4. Effective Date. -- August 19, 2011.

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

2.1. To be permitted to prescribe oral drugs under the provisions of W. Va. Code §§30-8-9 and 30-8-14, a licensee shall apply to the Board for certification. To qualify for certification, a licensee:

2.1.a. 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 diagnosis and treatment of visual defects or abnormal conditions of the human eye and its 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.a.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.a.2. a federally sponsored health education center; or

2.1.a.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.b. Shall pass an examination relating to the treatment and management of ocular disease, which is prepared, administered, and graded by 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 submit a certificate of successful completion by the licensee for the course listed in section 2 of this rule. The Board or its designee shall verify successful completion of the course directly with the provider.

3.3. The licensee shall submit the passing score report for the examination listed in 2.1.b. of this rule. The Board or its designee shall verify passage of the examination directly with the provider.

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,

W. Va. Code of Rules, §14-5.

§14-2-4. Certification.

4.1. Upon the licensee's successful completion of the requirements and application listed in sections 2 and 3 and approval by the Board or its designee a certificate may be issued.

4.2. Upon issuance of the certificate, the licensee's license number shall be changed. The license number will be followed by a dash and "OD" for oral prescriptive authority.

§14-2-5. Re-certification.

5.1. The certificate holder 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 W. Va. Code of Rules, §14-10 and this rule, to renew his or her annual license. Of those required hours, an optometrist certified under the provisions of this rule shall furnish to 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.

5.2. The certificate holder 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.

5.3. The certificate holder shall submit the fee listed in the W. Va. State Code of Rules, §14-5, Schedule of Fees.

5.4. It is the responsibility of each licensee to furnish proof of current liability insurance coverage to the Board upon application for certification and re-certification.

§14-2-6. Insurance.

6.1. All 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

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.

§14-2-7. Drug Formulary.

7.1. Licensees certified under the provisions of this rule may prescribe the drugs set forth in W. Va. Code §§30-8-9, 30-8-14 and this section.

7.2. W. Va. Code §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, excluding Schedule I and Schedule II of the Uniform Controlled Substances Act. The categories include:

7.2.a. Oral Antibiotics;

7.2.b. Oral Nonsteroidal Anti-inflammatory Drugs;

7.2.c. Oral Carbonic Anhydrase Inhibitors;

7.2.d. Antihistamines;

7.2.e. Oral Corticosteroids, may be prescribed for a duration of no more than six days;

7.2.f. Analgesics, provided that no oral narcotic analgesic may be prescribed for a duration of more than three days; and

7.2.g. Nutritional Supplements.

7.2. h. New drugs or new drug indications from Schedules III, IV and V, excluding Schedule I and Schedule II of the Uniform Controlled Substances Act which, regardless of their listed classification, have been shown to be effective in the examination, diagnosis or treatment of diseases and conditions of the human eye and its appendages may be

approved by the Board according to the provisions of W. Va. Code §§30-8-9 and 30-8-14.

7.2.i. A list of approved new drugs and new drug indications proven to be effective in the examination, diagnosis or treatment of diseases and conditions of the human eye and its appendages will be maintained by the Board for public inspection.

7.2.j. The approval of Schedule I and Schedule II drugs is prohibited.

§14-2-8. New Drug Approval.

8.1. The addition of new drugs or drug indications by the Board as cited in subsection 7.2 of this rule may be based on any of the following criteria:

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

8.1.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.

§14-2-9. Education and Training on the Use of New Drugs and New Drug Indications.

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

9.2. This training may be provided through an optometry school accredited by the Accreditation Council on Optometric Education or its successor recognized by the U.S. Department of Education or approved post-graduate training.

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

§14-2-10. Restrictions.

10.1. A certificate holder may not establish a pharmacy in an optometric office or sell oral pharmaceutical agents prescribed in treatment unless there is a licensed pharmacist on staff and present when the prescriptions are filled.

10.1.a. The certificate holder 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.

10.2. The certificate holder 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.