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OFFICE OF WEST VIRGINIA
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Form #6

NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE

AGENCY: West Virginia Board of Optometry TITLE NUMBER: 30-8

AMENDMENT TO AN EXISTING RULE: YES ____ NO X

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

_____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 14-11

TITLE OF RULE BEING PROPOSED: Injectable Pharmaceutical Agents Certificate

_____

THE ABOVE RULE HAS BEEN AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE.

AUTHORIZATION IS CITED IN (house or senate bill number) HB 2639

SECTION 64-9-8(h), PASSED ON _____

THIS RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON THE FOLLOWING DATE: November 1, 2011

Matthew Beard

Authorized Signature

TITLE 14
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF OPTOMETRY

SERIES 11
INJECTABLE PHARMACEUTICAL AGENTS CERTIFICATE

§14-1-1. General.

1.1. Scope. -- This rule establishes the requirements, procedures and standards for the certification of a licensee to administer injectable pharmaceutical agents which are considered rational to the diagnosis and treatment of the human eye and its appendages. The provisions of this rule excludes the administration of epinephrine to treat emergency cases of anaphylaxis or anaphylactic shock which is permitted through W. Va. Code §30-8-15(a).

1.2. Authority. -- W. Va. Code §30-8-6 and 30-8-15.

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

1.4. Effective Date. -- November 1, 2011.

14-11-2. Definitions.

2.1. "Certificate Holder" means a licensee who has met the requirements of this rule and has been issued an Injectable Pharmaceutical Agents Certificate by the Board.

2.2. "Adverse Reaction" For the purposes of this rule, an adverse reaction shall be defined as any reaction that causes injury to a patient as the result of the medical intervention by injection.

§14-11-3. Certification Generally.

3.1. A licensee shall complete an application and meet all requirements as listed in this rule in order to be certified to administer injectable pharmaceutical agents.

3.2. A licensee shall obtain oral prescriptive certification prior to application for certification to administer pharmaceutical injections.

3.3. An applicant for licensure by examination, by reciprocity, or by reinstatement after March 1, 2011 shall only be granted licensure if the applicant meets the requirements for injection certification.

§14-11-4. Certification Requirements.

To be certified the licensee shall:

4.1. Complete the required application form;

4.2. Submit proof of oral pharmaceutical certification;

4.3. Submit proof of attendance and satisfactory completion of the required course in injection administration. The Board shall verify successful completion of the cited course directly with the provider;

4.4. Submit proof of current certification from the American Red Cross or the American Heart Association or their successor organizations in basic life support;

4.5. Submit the Pharmaceuticals By Injection Certificate Fee as listed in the Board's rule, W. Va. Code of Rules, §14-5.

§14-11-5. Education and Training.

5. 1. The Board shall accept a 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 provided, the

course includes the criteria listed in subsections 5.2.1 through 5.2.3.

5.2. 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:

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

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

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

5.3. A list of approved courses for injection administration instruction will be maintained by the Board for public inspection.

5.4. A licensee shall obtain current certification from the American Red Cross or the American Heart Association or their successor organizations in basic life support.

5.5. The license granted to an applicant who graduated from an accredited school or college of optometry and who passed the Injection Portion of the National Board Examination in 2011 or thereafter shall be deemed to have met the education and training criteria listed in listed in section 5.

§14-11-6. Certification.

6.1. Upon the licensee's successful completion of the requirements and application listed in sections 3 through 5 and approval by the Board or its designee an injectable pharmaceutical agents certificate may be issued.

6.2. 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 "I" for injectable pharmaceuticals.

14-11-7. Treatment Guidelines.

7.1. A certificate holder may administer injections which are considered rational to the diagnosis and treatment of the human eye or its appendages.

7.2. The Board will maintain a list of approved sites and agents for the administration of pharmaceuticals by injection for public inspection. The list will contain treatment guidelines for each agent approved by the Board for injection.

7.3. The certificate holder shall follow all applicable Occupational Safety and Health Administration (OSHA) and Centers for Disease Control (CDC) guidelines pertaining to administration of injections.

7.4. The certificate holder shall adhere to generally accepted standards of care and follow established clinical guidelines for administering injections. The certificate holder shall monitor the patient for an adverse reaction and provide appropriate follow up care for patients treated by injections.

7.5. 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 certificate holder shall only administer agents through injection that are for the treatment and management of abnormalities of the eye or its appendages.

7.6. In no event may a certificate holder administer a pharmaceutical agent by injection directly in the globe of the eye.

§14-11-8. Reporting.

8.1. A certificate holder shall comply with the following reporting requirements.

8.2. Reporting that contains 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 certificate holder shall notify the primary care physician or other health care provider as identified by the person receiving the pharmaceutical agent(s) by injection. Such notification shall include the diagnosis, treatment and expected results of the injection.

8.4. The certificate holder shall document in the patient's record that the patient's primary care provider was notified of an injection given to the patient for record documentation. This notification shall be made by fax, documented phone call or standard U.S. mail.

8.4.1. If the patient does not have a primary care provider or refuses to provide written permission to report the injection(s) to his or her primary care provider the certificate holder may provide a written statement to the patient regarding the injection(s) administered with instruction to the patient to give the listed injection information to his or her current primary care provider or any primary care provider they would choose to see in the future.

8.4.2. 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 reaction, 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.

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

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

8.5.2. A statement indicating the purpose of the injection;

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

8.5.4. The treatment guidelines followed which must be compliant with the guidelines approved by the Board which are on file at the Board Office.

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

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

8.6. 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.

8.7. The Board may require a certificate holder 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 certificate holder's full records to ensure compliance with injection certificate requirements.

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

§14-11-9. Recertification.

A certificate holder shall meet the following requirements for recertification:

9.1. The certificate holder shall submit proof of current certification in basic life support from the American Red Cross or American Heart Association or their successors.

9.2. The certificate holder shall submit proof of a minimum of two (2) hours of continuing education instruction in administering pharmaceutical agents by injection per two year continuing education cycle as listed in W. Va. Code of Rules, §14-10, Continuing Education.

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

§14-11-10. Delegation.

10.1. Nothing in this rule or W. Va. Code shall permit a licensee who has been certified to administer injections of pharmaceutical agents by the Board to delegate to any individual the administration of pharmaceutical agents through injection.

§14-11-11. Restrictions

11.1. A certificate holder may not establish a pharmacy in an optometric office or sell injectable pharmaceutical agents prescribed in treatment unless there is a licensed pharmacist on staff or present when the prescription is filled. Nothing in this rule shall prohibit the optometrist from charging a usual and customary fee for performing the injection.

11.2. Retrobulbar and Peribulbar injections are prohibited.

11.3 The board shall establish a formulary of pharmaceutical agents to be administered by injection.

11.3.1. The injection formulary shall be created from those agents that certificate holders have been authorized previously to administer or prescribe as topical agents or oral medication categories listed in the oral formulary of the Board in the W. Va. Code of State Rules, §14-2-7.2a through §14-2-7.2.g.

11.3.2. New drugs or drug indications may be added to the formulary by a decision of the Board based on any of the following criteria:

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

11.3.2.2. 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.