

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

Form #4

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OFFICE OF THE
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NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: West Virginia Board of Optometry TITLE NUMBER: 14

CITE AUTHORITY: 30-8-1, et. al.

AMENDMENT TO AN EXISTING RULE: YES NO

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 PROPOSED LEGISLATIVE RULES, FOLLOWING REVIEW BY THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE, IS HEREBY MODIFIED AS A RESULT OF REVIEW AND COMMENT BY THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE. THE ATTACHED MODIFICATIONS ARE FILED WITH THE SECRETARY OF STATE.



Authorized Signature

FILED

TITLE 14
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF OPTOMETRY

2010 DEC 23 PM 12: 00

SERIES 11
INJECTABLE PHARMACEUTICAL AGENTS CERTIFICATE

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

§14-1-1. General.

1.1. Scope. -- This rule establishes the requirements, procedures and standards for the certification of a licensee ~~with the authority 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 §30-8-1 et. seq. ~~§30-8-6 and 30-8-15~~

1.3. Filing Date. -- .

1.4. Effective Date. -- .

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. ~~rather than the underlying medical condition.~~

§14-11-23. Requirements: Certification Generally.

23.1. The 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.

23.12. The A licensee shall have

~~obtained therapeutic and~~ obtain oral prescriptive licensure certification prior to application for certification to administer pharmaceutical injections.

~~2.2. The licensee shall comply with all application requirements listed in this rule.~~

~~2.3. The licensee shall meet all educational and reporting requirements listed in this rule.~~

~~2.4. The licensee shall maintain current certification in basic life support from the American Red Cross or the American Heart Association or their successor organizations.~~

23.53. Any applicant for licensure by examination, by endorsement, reciprocity, or by reinstatement after March 1, 2011 shall only be granted licensure if the applicant ~~has meet~~ meets the requirements for injection certification.

~~2.6. The licensee shall meet all continuing education requirements listed in this rule.~~

§14-11-4. Application Certification Requirements.

To be certified the licensee shall:

4.1. ~~The licensee shall e~~Complete the required application form;

4.2. Submit proof of oral pharmaceutical certification;

4.23. ~~The licensee shall s~~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;

~~4.34. The licensee shall sSubmit proof of current certification from the American Red Cross or the American Heart Association or their successor organizations in basic life support; Maintenance of this certification as current shall be a requirement for all certificate holders. Such certification must be kept current throughout the current and subsequent licensing renewal periods; and proof of such shall be submitted as a part of the license renewal process.~~

~~4.45. The licensee shall sSubmit the injectable pharmaceutical agents certificate fee Pharmaceuticals By Injection Certificate Fee as listed in the Board's rule, 14CSR.5 W. Va. Code of Rules, §14-5.~~

§14-11-35. Education and Training.

~~3.1. All licensees who wish to administer agents by injection must satisfactorily complete a certification process which follows the educational criteria listed in this section.~~

~~35.1. The Board shall accept any 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 certifying that the optometrist is competent in providing the administration of pharmaceuticals by injection. provided, the course includes the criteria listed in subsections 5.2.1 through 5.2.3.~~

~~35.32. 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:~~

~~35.32.1. Each course shall include indications, contra-indications, medications, techniques, risks, benefits and sharps management;~~

~~35.32.2. Each course shall contain~~

appropriate follow up and management of any adverse reactions caused by an injection;

~~35.32.3. Each course shall teach the procedures of injection on human subjects in a closely supervised environment with a proficiency assessment examination.~~

~~35.43. A list of approved courses for injection administration instruction will be maintained by the Board for public inspection.~~

~~35.54. The A licensee shall obtain current certification from the American Red Cross or the American Heart Association or their successor organizations in basic life support. Maintenance of this certification as current shall be a requirement for all certificate holders.~~

~~35.5. Any The license granted to an applicant who graduated from an accredited school or college of optometry and who passed Part III 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 this section listed in section 4 5.~~

§14-11-4. Application.

~~4.1. The licensee shall complete the required application.~~

~~4.2. The licensee shall 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.~~

~~4.3. The licensee shall submit current certification from the American Red Cross or the American Heart Association or their successor organizations in basic life support. Maintenance of this certification as current shall be a requirement for all certificate holders. Such certification must be kept current throughout the current and subsequent licensing renewal periods and proof of such shall be submitted as a part of the license renewal process.~~

~~4.4. The licensee shall submit the injectable pharmaceutical agents certificate fee as listed in the Board's rule, 14CSR.5.~~

§14-11-56. Certification.

~~5.1. A certificate to administer pharmaceuticals by injection may be issued by the Board upon the licensee's completion of all of the requirements of the provisions of §§14-11-2 through 14-11-4.~~

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.

~~56.2. Upon issuance of the certificate, the licensee's license number shall be changed. The license number will be followed by a dash and the initials "I" for injectable pharmaceuticals; "OD" for oral prescriptive authority; and "D" for therapeutic prescriptive privileges.~~

14-11-67. Treatment Guidelines.

~~67.1. A licensee certificate holder who has an Injectable Pharmaceutical Agents Certificate may administer injections which are considered rational to the diagnosis and treatment of the human eye or its appendages.~~

~~67.2. 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.~~

~~67.3. The licensee certificate holder shall follow all applicable Occupational Safety and Health Administration (OSHA) and Centers for Disease Control (CDC) guidelines pertaining to administration of injections.~~

~~67.4. The licensee certificate holder shall adhere to generally accepted standards of care and follow established clinical guidelines for administering injections. The licensee certificate holder shall monitor the patient response for an adverse reaction and provide appropriate follow up care for patients treated by injections.~~

~~67.5. 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 licensee certificate holder shall only administer agents through injection that are for the treatment and management of abnormalities of the eye or its appendages.~~

~~67.6. In no event may a licensee certificate holder be granted an Injectable Pharmaceutical Agents Certificate administer a pharmaceutical agent by injection directly in the globe of the eye.~~

§14-11-7. Continuing Education.

~~7.1. The licensee holding an Injectable Pharmaceutical Agents Certificate must maintain current certification in basic life support as listed in subsection 4.3.~~

~~7.2. The licensee who holds an Injectable Pharmaceutical Agents Certificate must obtain 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 14CSR10-2.3(d).~~

§14-11-8. Reporting.

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

~~8.2. Any reporting that may contain 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.~~

8.34. The licensee certificate holder 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~~ shall be made by fax, documented phone call or standard U.S. mail, ~~or the licensee 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.~~

8.34.1. 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.

~~8.34.12.~~ 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~~ 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.

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

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

8.45.2. A statement indicating the purpose of the injection;

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

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

8.45.5. The name and certification or licensure level of any persons working in

conjunction with the licensee to administer pharmaceutical agents through injections;

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

8.56. 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.

8.67. The Board may ~~request~~ require the a licensee 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 licensee's certificate holder's full records to ensure compliance with injection certificate requirements.

8.78. If a patient has an adverse event reaction related to the administration of any agent through injection, the licensee certificate holder ~~must~~ shall provide the Board with an incident report listing the details of the adverse event reaction and the measures used to correct that event reaction. This report must be received by the Board within 5 business days of the resolution of the adverse event 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 14CSR10-2.3(d)-W. Va. Code of Rules, §14-10, Continuing Education.

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

§14-11-~~910~~. Delegation.

~~910~~.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.

§14-11-~~1011~~. Restrictions.

~~1011~~.1. Nothing within this rule or the W.Va. Code prohibits the administration of pharmaceuticals by injection to a patient by a ~~certified licensee-~~ certificate holder for a reasonable charge provided, there is no mark up on the cost of the pharmaceutical agents provided in the injection. Nothing in this rule shall prohibit ~~the optometrist~~ a certificate holder from charging a usual and customary fee for performing the injection.