

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

Form #2

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2010 JUN 24 PM 4:07

OFFICE WEST VIRGINIA  
SECRETARY OF STATE

**NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE**

AGENCY: West Virginia Board of Optometry TITLE NUMBER: 14-11

RULE TYPE: Legislative CITE AUTHORITY: W. Va. Code 30-8

AMENDMENT TO AN EXISTING RULE: YES  NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: \_\_\_\_\_

TITLE OF RULE BEING AMENDED: Rules of the West Virginia Board of Optometry

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

TITLE OF RULE BEING PROPOSED: Injectable Pharmaceutical Agents Certificate

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON July 23, 2010 AT 5:00 p.m. ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

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

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.

  
Authorized Signature

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

WEST VIRGINIA BOARD OF OPTOMETRY

14CSR11

**Injectable Pharmaceutical Agents Certificate**

Summary

The amendment brings §14-11 into compliance with the passage of Senate Bill 230, W. Va. Code §30-8 during the 2010 Legislative Session.

- The amendment establishes requirements for a certificate to administer injectable pharmaceuticals in compliance with Senate Bill 230.
- It establishes education and training requirements.
- The amendment set up an application procedure.
- It also sets up treatment guidelines.
- Reporting requirements are outlined in compliance with Senate Bill 230.

WEST VIRGINIA BOARD OF OPTOMETRY

**14CSR11**

**Injectable Pharmaceutical Agents Certificate**

Circumstances

The amendment is written in order to comply with the requirements of Senate Bill 230 passed during the 2010 Legislative Session rewriting the Board's enabling statute, W. Va. Code §30-8.

**FISCAL NOTE FOR PROPOSED RULES**

Rule Title: Injectable Pharmaceutical Agents Certificate

Type of Rule:  Legislative  Interpretive  Procedural

Agency: West Virginia Board of Optometry

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

Phone Number: 304-558-5901 Email: wbdopt@verizon.net

**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 228 licensees will apply for injection privileges. It will take approximately 3 hours to process the applications and set up systems for the record keeping portion of the rule. There will be 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	0.00	16,204.00	16,204.00
Personal Services	0.00	12,496.00	12,496.00
Current Expenses	0.00	2,728.00	2,728.00
Repairs & Alterations	0.00	200.00	200.00
Assets	0.00	700.00	700.00
Other	0.00	0.00	0.00
2. Estimated Total Revenues	0.00	16,204.00	16,204.00

Rule Title: Injectable Pharmaceutical Agents Certificate

Rule Title:

Injectable Pharmaceutical Agents 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 three hours to process the application and set up the reporting and tracking components for each certificate. 228 licensees are eligible for this certificate. Therefore personnel costs would be \$12496 ( $\$18.27 \times 3 \times 228$ ). Current expenses include \$1.00 each for printing and filing materials  $228 \times \$1.00 = \$228$ . Improvements to the web site will cost approximately \$2500. The Board will require a new filing cabinet to house certificate and reporting information.

**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: \_\_\_\_\_

Signature of Agency Head or Authorized Representative

A handwritten signature in black ink, appearing to read "L. J. Jones", is written over a horizontal line.

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2010 JUN 24 PM 4:07

OFFICE WEST VIRGINIA  
SECRETARY OF STATE

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 with the authority to administer and dispense injectable pharmaceutical agents. This rule excludes the administration of epinephrine to treat emergency cases of anaphylaxis or anaphylactic shock.

1.2. Authority. -- W. Va. Code §30-8-1 et. seq.

1.3. Filing Date. -- .

1.4. Effective Date. -- .

3.1. An applicant for a certificate to administer injectable pharmaceutical agents shall complete and successfully pass an approved course in the administration of pharmaceuticals by injection.

3.2. The Board shall accept any course for injection 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.

3.3. The Board may, at its discretion, 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, provided those courses provide the same level of training as required by the accredited schools or colleges of optometry to maintain accreditation.

3.4. Any license granted to an applicant who graduated from an accredited school or college of optometry in 2011 or thereafter and who passed Part III of the National Board Examination in 2011 which includes injection testing or thereafter shall be deemed to have met the criteria listed in this section.

**§14-11-2. Requirements.**

2.1. Any applicant for licensure by examination, by endorsement, or by reinstatement after March 1, 2011 shall only be granted licensure if the applicant has met the requirements for injection certification.

2.2. The licensee shall have obtained therapeutic and oral prescriptive licensure prior to application for certification to administer pharmaceutical injections.

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

2.4. The licensee shall comply with all education and reporting requirements listed in this rule.

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

**§14-11-4. Application.**

4.1. The licensee shall complete the prescribed application.

4.2. The licensee shall ensure that proof of attendance and the successful passage of the required course in injection administration shall be sent directly from the course provider to the

**§14-11-3. Education and Training.**

Board.

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. This certification shall 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.

#### **§14-11-5. 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.

5.2. 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, "O" for oral prescriptive authority and "D" for therapeutic prescriptive privileges.

#### **14-11-6. Treatment Guidelines.**

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

6.2. The licensee shall adhere to generally accepted standards of care and follow established clinical guidelines for administering injections. The licensee shall monitor patient response and provide appropriate follow up care for patients treated by injections.

6.3. 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 shall only

administer agents through injection that are for the treatment and management of abnormalities of the eye and its adnexa.

#### **§14-11-7. Reporting.**

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

7.1.1. Any reporting that may contain patient Protected Health Information (PHI), shall be done in accordance with the Health Insurance Portability and Accountability Act (HIPAA) patient privacy requirements.

7.1.2. In instances where the patient requests that a report be provided to his or her primary care physician, the licensee shall provide a clinical report to the patient's primary care physician of record when providing treatment by injection.

7.1.3. In instances where a licensee provides treatment by injection without complication, there is no reporting requirement other than the requirements listed in this section.

7.1.4. In the event that the treatment by injection has observed implications, interactions, or impact with regard to any other diagnosis or condition a patient may have or any other treatment the patient may be receiving, or an unanticipated outcome or unexpected side effect occurs as a result of treatment by injection, the licensee shall be required to provide a report of such treatment and its clinical outcome to the patient's primary care physician of record.

7.1.4.a. 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, 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.

7.1.5. In any instance where treatment by injection results in an unanticipated response,

an allergic or idiosyncratic reaction, or an unexpected outcome, the licensee shall, on a timely basis, notify the Board of any and all such cases.

7.1.6. A licensee who has become certified to provide treatment by injection may work in conjunction with any certified or licensed clinician to administer agents through injection. However, nothing in this rule shall permit a licensee to delegate to a non certified or non licensed clinician the privilege to administer pharmaceutical agents through injection.