

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

Form #3

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SECRETARY OF STATE
STATE OF WEST VIRGINIA

**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE
AND
FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE**

AGENCY: WV Board of Optometry TITLE NUMBER: 14CSR9

CITE AUTHORITY: §30-8-1, et. seq.

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: 14CSR9

TITLE OF RULE BEING PROPOSED: Contact Lenses That Contain and Deliver Pharmaceutical Agents
Certificate

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.



Authorized Signature

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: July 30, 2010

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency Name, Address & Phone No.) WV Board of Optometry, 179 Summers Street, Charleston,
WV 25301, 304-558-5901

LEGISLATIVE RULE TITLE: ~~14CSR9 Contact Lenses That Contain and Deliver~~
Pharmaceutical Agents Certificate

1. Authorizing statute(s) citation ~~§30-8-1, et seq~~

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:
June 25, 2010

b. What other notice, including advertising, did you give of the hearing?
A memo was mailed to all licensees directing them to our web site, www.wvbo.org, where the proposed rules were posted. Notice was given by phone and hand delivery of the rules to the West Virginia Optometric Association, and notice was given by phone contact, and an e-mail was sent to the West Virginia Academy of Ophthalmologists informing them of the posting on the web site.

c. Date of Public Hearing(s) *or* Public Comment Period ended:
July 26, 2010 at noon

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached xx No comments received _____

- e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

July 30, 2010 at 2:00 p.m.

- f. Name, title, address and phone/fax/e-mail numbers of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

Pamela Carper, 179 Summers Street, Suite 231, Charleston, WV 25301, 304-558-5901 The cell phone number is 304-546-2907.

- g. **IF DIFFERENT FROM ITEM 'f'**, please give Name, title, address and phone number(s) of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

Gregory Moore, O.D., President, WV Board of Optometry, 179 Summers Street, Suite 231, Charleston, WV 25301, 304-558-5901 or 304-768-7902 or contact Pam Carper listed above.

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

- a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

n/a

b. Date of hearing or comment period:

n/a

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

n/a

d. Attach findings and determinations and reasons:

Attached n/a

WEST VIRGINIA BOARD OF OPTOMETRY

14CSR9

Contact Lenses That Contain and Deliver Pharmaceutical Agents Certificate

Summary

This new rule brings the Board's rules into compliance with the passage of Senate Bill 230, W. Va. Code §30-8, passed during the 2010 Legislative Session.

- The rule sets up requirements and an application process to obtain a certificate to prescribe and dispense contact lenses that contain and deliver pharmaceutical agents approved by the FDA as a drug.
- The rule also makes it clear that the licensee may dispense these contact lenses for his or her optometric office.
- The licensee may charge reasonable and customary fees for the dispensation of contact lenses that contain and deliver pharmaceutical agents approved by the FDA as a drug.

WEST VIRGINIA BOARD OF OPTOMETRY

14CSR9

Contact Lenses That Contain and Deliver 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.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Contact Lenses That Contain and Deliver Pharmaceutical Agents Certificate, §14-9

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: wvbdopt@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.

This new rule establishes the Contact Lenses That Contain and Deliver Pharmaceutical Agents Certificate in compliance with Senate Bill 230 passed during the 2010 Legislative Session.

It will take staff one hour per certificate to prepare them. There are 290 licensees eligible to apply for the certificate costing \$5298.30 (\$18.27 x 290 licensees = \$5298.30). There will be additional staff time developing the program, designing the certificates and database accomodation (16 hrs x \$18.27/hr = \$291.00). The Board estimates that there will be a 13% demand on current expenses at \$5080 (\$39076 x 13% = \$5080). There will be a \$1500 web master charge to re-design the database and web site. The Board estimates \$700 for a new filing cabinet and filing supplies. §14-5, Schedule of Fees sets up a fee of \$50 per licensee raising \$14500.

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 | 12,869.00 | 12,869.00 |
| Personal Services | 0.00 | 7,089.00 | 7,089.00 |
| Current Expenses | 0.00 | 5,080.00 | 5,080.00 |
| Repairs & Alterations | 0.00 | 0.00 | 0.00 |
| Assets | 0.00 | 700.00 | 700.00 |
| Other | 0.00 | 0.00 | 0.00 |
| 2. Estimated Total Revenues | 0.00 | 14,500.00 | 14,500.00 |

Rule Title: Contact Lenses That Contain and Deliver Pharmaceutical Agents Certificate, §14-9

Rule Title:

Contact Lenses That Contain and Deliver Pharmaceutical Agents Certificate, §14-9

3. Explanation of above estimates (including long-range effect):

Please include any increase or decrease in fees in your estimated total revenues.

This new rule establishes the Contact Lenses That Contain and Deliver Pharmaceutical Agents Certificate in compliance with Senate Bill 230 passed during the 2010 Legislative Session.

It will take staff one hour per certificate to prepare them. There are 290 licensees eligible to apply for the certificate costing \$5298.30 ($\18.27×290 licensees = \$5298.30). There will be additional staff time developing the program, designing the certificates and database accomodation ($16 \text{ hrs} \times \$18.27/\text{hr} = \291.00). The Board estimates that there will be a 13% demand on current expenses at \$5080 ($\$39076 \times 13\% = \5080). There will be a \$1500 web master charge to re-designing the database and web site. The Board estimates \$700 for a new filing cabinet and filing supplies. §14-5, Schedule of Fees sets up a fee of \$50 per licensee raising \$14500.

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: 7/20/10

Signature of Agency Head or Authorized Representative



**TITLE 14
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF OPTOMETRY**

**SERIES 9
CONTACT LENSES THAT CONTAIN AND DELIVER PHARMACEUTICAL AGENTS
CERTIFICATE**

§14-9-1. General.

1.1. Scope. -- This rule establishes the requirements, procedures and standards for the certification of a licensee with the authority to prescribe and dispense contact lenses that contain and deliver pharmaceutical agents and that have been approved by the Food and Drug Administration as a drug.

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

1.3. Filing Date. -- .

1.4. Effective Date. -- .

§14-9-2. Requirement.

2.1. In order to qualify for certification, a licensee shall have previously attained topical therapeutic certification.

§14-9-3. Application.

3.1. The licensee shall submit the Board's prescribed certificate application form to the Board;

3.2. The licensee shall attach a copy of his or her topical therapeutic license as proof of his or her topical therapeutic certification; and

3.3. Shall pay the fee listed in the Board's rule, Schedule of Fees, 14CSR5.

§14-9-4. Dispensation.

4.1. A licensee with certification under the provisions of this rule may dispense contact lenses that deliver pharmaceutical agents approved by the Food and Drug Administration as a drug from his or her optometric office.

4.2. The licensee shall be permitted to charge reasonable and customary fees for the dispensation of contact lenses that contain and deliver pharmaceutical agents approved by the Food and Drug Administration as a drug.

4.3. Nothing in this rule shall permit a licensee to dispense contact lenses that deliver pharmaceutical agents based on an outside prescription.