



**WEST VIRGINIA
SECRETARY OF STATE**

NATALIE E. TENNANT

ADMINISTRATIVE LAW DIVISION

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8/18/2016 1:00:51 PM

OFFICE OF
WEST VIRGINIA SECRETARY OF STATE

**FORM 3 -- NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE
LEGISLATIVE RULE-MAKING REVIEW COMMITTEE**

AGENCY **Pharmacy**
RULE TYPE **Legislative** AMENDMENT TO EXISTING RULE **Yes** TITLE-SERIES **15-06**
RULE NAME **Mail-Order and Non-Resident Pharmacies**

CITE AUTHORITY **30-5-7**

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.

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENTS ARE TRUE AND CORRECT.

Yes

David E Potters -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.



Title-Series: 15-06



Rule Id: 10212



Document: 28816



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FORM 10 -- LEGISLATIVE QUESTIONNAIRE (Page 1)

AGENCY Pharmacy
RULE TYPE Legislative AMENDMENT TO EXISTING RULE Yes TITLE-SERIES 15-06
RULE NAME Mail-Order and Non-Resident Pharmacies

CITE AUTHORITY 30-5-7

PRIMARY CONTACT

David E. Potters
2310 Kanawha Boulevard East

Charleston, STATE ZIP

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AUTHORIZING STATUTE(S) CITATION
West Virginia Code Section 30-5-7

DATE FILED IN STATE REGISTER WITH NOTICE OF HEARING OR PUBLIC COMMENT PERIOD
Friday, July 01, 2016

WHAT OTHER NOTICE, INCLUDING ADVERTISING, DID YOU GIVE OF THE HEARING?
None. Worked with stakeholders during the drafting of the rule.

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED
Thursday, August 04, 2016

David E Potters -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.



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FORM 10 -- LEGISLATIVE QUESTIONNAIRE (Page 2)

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ATTACH LIST OF PERSONS WHO APPEARED AT HEARING, COMMENTS RECEIVED,
AMENDMENTS, REASONS FOR AMENDMENTS.

No comments received

DATE YOU FILED IN STATE REGISTER THE AGENCY APPROVED PROPOSED LEGISLATIVE RULE
FOLLOWING PUBLIC HEARING: (BE EXACT)

Thursday, August 18, 2016

**David E Potters -- By my signature, I certify that I am the person authorized to file legislative rules, in
accordance with West Virginia Code §29A-3-11 and §39A-3-2.**



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IF THE STATUTE UNDER WHICH YOU PROMULGATED THE SUBMITTED RULES REQUIRES CERTAIN FINDINGS AND DETERMINATIONS TO BE MADE AS A CONDITION PRECEDENT TO THE PROMULGATION. 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.

David E Potters -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.



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FORM 10 -- LEGISLATIVE QUESTIONNAIRE (Page 4)

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CITE AUTHORITY **30-5-7**

DATE OF HEARING OR COMMENT PERIOD

ON WHAT DATE DID YOU FILE IN THE STATE REGISTER THE FINDINGS AND DETERMINATIONS
REQUIRED TOGETHER WITH THE REASONS THEREFOR?

ATTACH FINDINGS AND DETERMINATIONS AND REASONS
None

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENTS ARE TRUE AND CORRECT.

Yes
**David E Potters -- By my signature, I certify that I am the person authorized to file legislative rules, in
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FORM 11 -- FISCAL NOTE FOR PROPOSED RULES (Page 1)

AGENCY Pharmacy
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2310 Kanawha Boulevard East

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SUMMARIZE IN A CLEAR AND CONCISE MANNER WHAT IMPACT THIS MEASURE WILL HAVE ON COSTS AND REVENUES OF STATE GOVERNMENT.

None. The changes reflected are merely updates in language and definitions to match code and to reflect preexisting practices of the Board in licensing mail order and non-resident pharmacies. This will not have any effect on costs or revenue.

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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.

Effect Of Proposal	Current Increase/Decrease (use ' - ')	Next Increase/Decrease (use ' - ')	Fiscal Year (Upon Full Implementation)
ESTIMATED TOTAL COST	0	0	0
PERSONAL SERVICES	0	0	0
CURRENT EXPENSES	0	0	0
REPAIRS AND ALTERATIONS	0	0	0
ASSETS	0	0	0
OTHER	0	0	0
ESTIMATED TOTAL REVENUES	0	0	0

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3. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT). PLEASE INCLUDE ANY INCREASE OR DECREASE IN FEES IN YOUR ESTIMATED TOTAL REVENUES.

None

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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.

None

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENTS ARE TRUE AND CORRECT.

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FORM 12 -- BRIEF SUMMARY AND STATEMENT OF CIRCUMSTANCES (Page 1)

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SUMMARIZE IN A CLEAR AND CONCISE MANNER CONTENTS OF CHANGES IN RULE AND STATEMENT OF CIRCUMSTANCES REQUIRING THE RULE.

This rules series was last updated in 1992. In 2013, statutory changes to the Pharmacy Practice Act made some changes to terminology, continued to require that nonresident pharmacies must be registered to dispense into the state, and placed a new requirement that mail order pharmacies must have a pharmacist-in-charge (PIC) who is licensed to practice pharmacist care in West Virginia. These rules revisions, therefore, make some minor changes in terminology to reflect current language used in the industry, and then clarify that the PIC of the non-resident registration may be the PIC of the non-resident pharmacy or any other pharmacist at that pharmacy who is willing to get licensed to practice pharmacist care in this State and be the PIC of the West Virginia Mail Order registration for prescriptions mailed into this State, and does not place a burden on them of only having one pharmacist who is the PIC of their home-state pharmacy to have to get licensed in multiple states who have the same requirement as West Virginia. At the same time, it satisfies the directive of West Virginia law to have one person licensed here who is responsible for the registration. In addition, this is how the Board has implemented this since it was first passed in 2013.

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENTS ARE TRUE AND CORRECT.

Yes
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TITLE 15
LEGISLATIVE RULE
BOARD OF PHARMACY

SERIES 6
~~MAIL ORDER HOUSE~~MAIL-ORDER AND NON-RESIDENT PHARMACIES

§15-6-1. General.

- 1.1. Scope. -- To establish rules for the ~~Mail Order House~~Mail-order pharmacy and non-resident pharmacies.
- 1.2. Authority. -- W. Va. Code §30-5-~~6a~~7.
- 1.3. Filing Date. -- ~~April 9, 1992~~_____.
- 1.4. Effective Date. -- ~~April 9, 1992~~_____.
- 1.5. Sunset date -- This rule will Sunset effective 10 years from the effective date.

§15-6-2. Definitions.

- 2.1. ~~Mail Order House~~ “Mail-order pharmacy” means a pharmacy, regardless of its location, which dispenses greater than twenty-five percent prescription drugs or medicines through the United States via the mail or otherwise other delivery services.
- 2.2. ~~Mail Order Prescription means the drug or medicine prescribed by a practitioner on a prescription order as authorized under W. Va. Code §30-5-1(6) and §30-5-12(5)(6).~~ “Non-resident pharmacy” means any pharmacy outside of this state where drugs are dispensed and pharmacist care is provided to residents into this state.
- 2.3. ~~Board means the West Virginia Board of Pharmacy.~~ “Pharmacy” means any place within this state where drugs are dispensed and pharmacist care is provided and any place outside of this state where drugs are dispensed and pharmacist care is provided to residents of this state.
- 2.4. “Prescription or prescription drug order” means a lawful order from a practitioner for a drug or device for a specific patient, including orders derived from collaborative pharmacy practice, where a valid patient-practitioner relationship exists, that is communicated to a pharmacist in a pharmacy.

§15-6-3. ~~Permits Registrations for Mail Order Houses~~Mail-Order Pharmacies.

- 3.1. A ~~Mail Order House~~ mail-order pharmacy is required to apply for a ~~permit~~ registration for authorization to dispense prescription drugs or medicines in West Virginia. A non-resident pharmacy shall be registered in this state in the same manner as a mail-order pharmacy pursuant to this Series by issuance of a mail order registration.
- 3.2. A ~~Mail Order House~~ mail-order pharmacy or non-resident pharmacy shall submit the application for

the ~~permit~~ registration to the West Virginia Board of Pharmacy. The application shall contain the following information:

3.2.1a. The owner of the ~~Mail Order House~~ mail-order pharmacy or non-resident pharmacy, whether an individual, a partnership, or a corporation.

3.2.2b. The names and titles of all individual owners, partners or corporate officers.

3.2.3c. The pharmacy manager.

3.2.4d. The pharmacist-in-charge.

3.2.5e. The complete address, telephone number and fax number of the ~~Mail Order House~~ mail-order pharmacy or non-resident pharmacy.

3.3. The ~~Mail Order House~~ mail-order pharmacy or non-resident pharmacy shall obtain separate ~~permits~~ registrations if it operates more than one pharmacy.

3.4. The ~~Mail Order House~~ mail-order pharmacy or non-resident pharmacy shall maintain a permit, registration, or license as required by the state where located.

3.5. The ~~manager~~ pharmacist-in-charge shall certify that the ~~Mail Order House~~ mail-order pharmacy or non-resident pharmacy is in compliance with the standards of care relative to the dispensing of prescription drug orders as required by the state where located.

3.6. The pharmacist in charge shall submit the names of all pharmacists employed at the ~~Mail Order House~~ mail-order pharmacy or non-resident pharmacy.

§15-6-4. Prescription record and reporting.

The ~~Mail Order House~~ mail-order pharmacy or non-resident pharmacy shall maintain prescription records which are available for review if required by the Board. Further, the mail order pharmacy shall comply with the reporting requirements of the West Virginia Controlled Substances Monitoring Program as set forth in West Virginia Code § 60A-9-1 and the rules enacted in support thereof.

§15-6-5.

~~Mail Order Houses~~ Mail-order pharmacies or non-resident pharmacies shall have a toll free accessible telephone for consumers to obtain counseling with a licensed pharmacist during regular working hours and the telephone number shall be prominently identified on the prescription container or ~~one~~ on the prescription container label.

§15-6-6. Doing Business in West Virginia

~~Mail Order Houses~~ Mail-order pharmacies or non-resident pharmacies soliciting, receiving, and dispensing and delivering orders comprising legend drugs and scheduled controlled drug substances as defined in 21 UCS 1 et seq., and 21 CFR 1 et seq., ~~(1989)~~ and delivered to ultimate consumers in West Virginia constitutes doing business in West Virginia.

§15-6-7. Resident Agent

~~Mail Order Houses~~ Mail-order pharmacies or non-resident pharmacies doing business in West Virginia by dispensing and delivering prescription orders to West Virginia consumers shall designate a resident agent for purposes of service of process and notice.

§15-6-8. Pharmacist-In-Charge Licensure requirement

The pharmacist in charge or at least one designated pharmacist of the out-of-state mail order pharmacy or non-resident pharmacy shall be licensed to practice pharmacist care in West Virginia and act as the PIC of the registration, and any other pharmacist providing pharmacist care from the out-of-state mail order pharmacy or non-resident pharmacy shall be licensed in the state where the pharmacy is located.