



**WEST VIRGINIA
SECRETARY OF STATE**

NATALIE E. TENNANT

ADMINISTRATIVE LAW DIVISION

eFILED

12/19/2016 11:15:32 AM

OFFICE OF
WEST VIRGINIA SECRETARY OF STATE

FORM 4 -- NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

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 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.

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS 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: 33159



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FORM 11 -- FISCAL NOTE FOR PROPOSED RULES (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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SUMMARIZE IN A CLEAR AND CONCISE MANNER WHAT IMPACT THIS MEASURE WILL HAVE ON COSTS AND REVENUES OF STATE GOVERNMENT.

The modifications will not have any impact on the prior fiscal notes filed.

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FORM 11 -- FISCAL NOTE FOR PROPOSED RULES (Page 2)

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**

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

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



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FORM 11 -- FISCAL NOTE FOR PROPOSED RULES (Page 3)

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**

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

The modifications will not have any impact on the prior fiscal notes filed.

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



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FORM 11 -- FISCAL NOTE FOR PROPOSED RULES (Page 4)

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**

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.

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



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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 legislative rule shall terminate 10 years from its effective date unless renewed prior to that 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 a 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 a place within this state where drugs are dispensed and pharmacist care is provided and a 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 shall 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. 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~~ 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~~ prescription 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.