



**WEST VIRGINIA
SECRETARY OF STATE**

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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OFFICE OF
WEST VIRGINIA SECRETARY OF STATE

**FORM 1 -- NOTICE OF A PUBLIC HEARING OR COMMENT PERIOD ON A PROPOSED RULE
(Page 1)**

AGENCY **Pharmacy**
RULE TYPE **Legislative** AMENDMENT TO EXISTING RULE No TITLE-SERIES **15-14**
RULE NAME **Centralized Prescription Processing**

CITE AUTHORITY **30-5-7**

COMMENTS LIMITED TO
Written

DATE OF PUBLIC HEARING

LOCATION OF PUBLIC HEARING

DATE WRITTEN COMMENT PERIOD ENDS
Monday, July 17, 2017 4:00 PM

WRITTEN COMMENTS MAY BE MAILED TO
**West Virginia Board of Pharmacy
Series 14 Comments
2310 Kanawha Boulevard East
Charleston, West Virginia 25311**

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: 15-14



Rule Id: 16500



Document: 49451



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**FORM 1 -- NOTICE OF A PUBLIC HEARING OR COMMENT PERIOD ON A PROPOSED RULE
(Page 2)**

AGENCY **Pharmacy**
RULE TYPE **Legislative** AMENDMENT TO EXISTING RULE No TITLE-SERIES **15-14**
RULE NAME **Centralized Prescription Processing**

CITE AUTHORITY **30-5-7**

PROVIDE A BRIEF SUMMARY OF YOUR PROPOSAL

Central filling and processing of prescriptions has become commonplace around the United States. Currently, West Virginia has rules in current Section 15-1-28 that allow for some remote data entry and remote order review, which was the Boards first step towards allowing some parts of central prescription processing. This rule would allow for central filling and processing of prescriptions by pharmacies licensed by the state, which would include non-resident pharmacies, and would move portions of 15-1-28 on remote data entry and remote order review to this series.

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.



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FORM 11 -- FISCAL NOTE FOR PROPOSED RULES (Page 1)

AGENCY **Pharmacy**
RULE TYPE **Legislative** AMENDMENT TO EXISTING RULE No TITLE-SERIES **15-14**
RULE NAME **Centralized Prescription Processing**

CITE AUTHORITY **30-5-7**

PRIMARY CONTACT

David E. Potters
2310 Kanawha Boulevard East

Charleston, West Virginia 25311

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FORM 11 -- FISCAL NOTE FOR PROPOSED RULES (Page 1)

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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 Board does not anticipate any impact on costs or revenues. Some pharmacies may decide to participate in this activity, and it will become part of the Board's regular inspections.

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

AGENCY **Pharmacy**
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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

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

AGENCY **Pharmacy**
RULE TYPE **Legislative** **AMENDMENT TO EXISTING RULE** **No** **TITLE-SERIES** **15-14**
RULE NAME **Centralized Prescription Processing**

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 Board does not anticipate any increases or decreases in licensure as a result of this activity, or increased costs in terms of inspections. Over time, a pharmacy chain or group of pharmacies may choose to open a central fill pharmacy, but any such additions would be part of the regular cycle of new pharmacy openings and closures such that the Board does not anticipate any upswing in registrations from this rule.

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

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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.

N/A

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)

AGENCY **Pharmacy**
RULE TYPE **Legislative** AMENDMENT TO EXISTING RULE No TITLE-SERIES **15-14**
RULE NAME **Centralized Prescription Processing**

CITE AUTHORITY **30-5-7**

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

Central filling and processing of prescriptions has become commonplace around the United States. Currently, West Virginia has rules in current Section 15-1-28 that allow for some remote data entry and remote order review, which was the Boards first step towards allowing some parts of Central prescription processing. Several years ago, the Board granted a local pharmacy chain a waiver to do a pilot central filling and processing operation, which has been successful. This rule would allow for central filling and processing of prescriptions by pharmacies licensed by the state, which would include non-resident pharmacies, and would move portions of 15-1-28 on remote data entry and remote order review to this series.

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.



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TITLE 15

LEGISLATIVE RULE, WEST VIRGINIA BOARD OF PHARMACY

SERIES 14

CENTRALIZED PRESCRIPTION PROCESSING

§15-14-1. General.

1.1. Scope -- To establish standards for central prescription processing.

1.2. Authority -- W. Va. Code § 30-5-7.

1.3. Filing date -- _____.

1.4. Effective date -- _____.

1.5. Sunset Date -- This rule shall terminate and have no further force or effect upon the expiration of 5 years from its effective date.

§15-14-2. Definitions.

2.1. The following words and phrases as used in this Rule have the following meanings:

2.1.a. "Central fill pharmacy" means a pharmacy or central filling operation registered as a pharmacy by the Board acting as an agent of or under contract with the originating pharmacy to fill or refill a prescription.

2.1.b. "Central prescription filling" means filling of a new or refilling of a prescription drug order by a central fill pharmacy at the request of an originating pharmacy for delivery to the patient or patient's agent pursuant to the lawful order of a practitioner.

2.1.c. "Originating pharmacy" means a pharmacy registered with the Board that uses a central fill pharmacy to fill or refill a prescription order received by or transferred to that pharmacy by the patient, the patient's agent, or the patient's prescriber.

§15-14-3. General Requirements.

3.1. Any other rule notwithstanding, a pharmacy may outsource a prescription drug order filling to another pharmacy via central prescription filling provided the pharmacies:

3.1.a. Have the same owner; or

3.1.b. Have entered into a written contract or agreement which outlines the services to be provided and responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations, and include confidentiality of patient information; and

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3.1.c. Share a common electronic file or have appropriate technology or interface to allow secure access to sufficient information necessary or required to fill or process a prescription drug order.

3.2. The pharmacist in charge of the central fill pharmacy shall assure that:

3.2.a. The pharmacy maintains and uses adequate storage or shipment containers and shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of appropriate packaging material and/or devices to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication through the delivery process; and

3.2.b. The filled prescriptions are shipped in containers which are sealed in a manner as to show evidence of opening or tampering.

3.3. The filling, processing and delivery of a drug order by a central fill pharmacy for an originating pharmacy pursuant to this Series shall not be considered a drug order transfer or a wholesale distribution.

3.4. Any filled prescription which was not picked up by or actually delivered to the patient must be put into the originating pharmacy's inventory.

3.5. Prior to outsourcing the filling of a prescription to a central fill pharmacy, the originating pharmacy must notify patients that their prescription may be outsourced to a central fill pharmacy, and provide the name and address of the central fill pharmacy. Such notice may be provided through a one-time written notice to the patient or through the use of a sign in the pharmacy.

3.6. The originating pharmacy, as the delivering pharmacy, is responsible for making the offer to counsel to the patient or patient's agent picking up the prescription on behalf of the patient.

3.7. Pharmacies that perform central prescription filling shall create operating policies and procedures. The policies and procedures must include:

3.7.a. an audit trail that records and documents the central prescription filling process and the individuals accountable at each step in the process for complying with Federal and State laws and regulations including recordkeeping; and

3.7.b. provisions for dispensing prescription drug orders when the filled order is not received from the central fill pharmacy, or the patient or patient's representative comes in to the originating pharmacy before the order is received from the central fill pharmacy. The standard of care must not be altered by the pharmacies' central fill program. Ultimately the patient's therapy cannot be unreasonably delayed.

3.8. The prescription label of a centrally filled prescription shall display the name and address of the originating pharmacy and may include the name of the central fill pharmacy, as well as all other information required by Rule § 15-1-22.

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3.9. Each pharmacy engaging in central prescription filling shall be jointly responsible for:

3.9.a. Maintaining manual or electronic records that identify, individually for each drug order processed, the name, initials, or other unique identifier of each pharmacist, intern or pharmacy technician who took part in the central prescription filling functions performed at that pharmacy;

3.9.b. Maintaining manual or electronic records that identify, individually for each drug order filled or dispensed, the name, initials, or other unique identifier of each pharmacist, pharmacy intern, pharmacy technician, and pharmacy technician trainee who took part in the filling and dispensing functions performed at that pharmacy;

3.9.c. Maintaining a mechanism for tracking the drug order during each step of the processing and filling procedures performed at the pharmacy. The central fill pharmacy must keep a record of the date the filled prescription was delivered to the originating pharmacy and the method of delivery (i.e., private, common or contract carrier). The originating pharmacy must keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (i.e. private, common or contract carrier) and the name of the originating pharmacy employee accepting delivery;

3.9.d. Providing for adequate security to protect the confidentiality and integrity of patient information; and

3.9.e. Providing for inspection of any required record or information within 72 hours of any request by the Board or its designee.

15-14-4. Remote Order Entry and Remote Order Review

4.1. Remote-order-entry or remote-order-review of prescription orders for prescriptions received at a pharmacy registered by this state is permitted to be performed by another pharmacy registered by the state, Provided that:

4.1.a. for purposes of data entry, the data entry must be performed by a licensed pharmacist, licensed pharmacy intern, or registered pharmacy technician or pharmacy technician trainee who is located at the other pharmacy registered by the state which shares a common automated data processing system, and such system creates an audit trail of which pharmacist, pharmacy intern, or pharmacy technician or pharmacy technician trainee entered the data; and

4.1.b. for purpose of drug regimen review, the review must be performed by a licensed pharmacist or licensed pharmacy intern who is located at the other pharmacy registered by the state which shares a common automated data processing system, and such system creates an audit trail of which pharmacist or pharmacy intern provided the drug regimen review.