



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

NOTICE OF AN EMERGENCY RULE

AGENCY: Pharmacy TITLE-SERIES: 15-14

RULE TYPE: Legislative Amendment to Existing Rule: Yes

RULE NAME: Centralized Prescription Processing

CITE STATUTORY AUTHORITY FOR PROMULGATING EMERGENCY RULE:

§30-5-7

IF THE EMERGENCY RULE WAS PROMULGATED TO COMPLY WITH A TIME LIMIT ESTABLISHED BY CODE OR FEDERAL STATUTE OR REGULATION, CITE THE CODE PROVISION, FEDERAL STATUTE OR REGULATION AND TIME LIMIT ESTABLISHED THEREIN:

PRIMARY CONTACT:

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THE ABOVE RULE IS BEING FILED AS AN EMERGENCY RULE TO BECOME EFFECTIVE AFTER APPROVAL BY THE SECRETARY OF STATE OR THE 42ND DAY AFTER FILING, WHICHEVER OCCURS FIRST. THE FACTS AND CIRCUMSTANCES CONSTITUTING THE EMERGENCY ARE AS FOLLOWS:

During COVID-19 pharmacies were permitted to perform prescription drug order processing functions from sites other than a licensed pharmacy. After the COVID-19 emergency waiver ended and the pharmacy industry has found itself without sufficient staff (pharmacists, interns and pharmacy technicians) to staff a pharmacy in the traditional manner. During COVID-19 schedules were modified for people to work remotely etc, but not pharmacies are closing several days a week leaving WVians without access to medications. This rule only permits the drug order processing functions and not the physical checking of the medication.

DOES THIS EMERGENCY RULE REPEAL A CURRENT RULE? No

HAS THE SAME OR SIMILAR EMERGENCY RULE PREVIOUSLY BEEN FILED AND OR EXPIRED? No

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED LEGISLATIVE RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

0

B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:

0

C. ECONOMIC IMPACT ON THE STATE OR ITS RESIDENTS:

0

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2023 Increase/Decrease (use "-")	2024 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. 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
2. Estimated Total Revenues	0	0	0

E. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

0

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

Krista Capehart--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.

15 CSR 14

TITLE 15

LEGISLATIVE RULE

WEST VIRGINIA BOARD OF PHARMACY

SERIES 14

BOARD OF PHARMACY RULES FOR 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 -- ~~April 9, 2020.~~

1.4. Effective date -- ~~April 9, 2020.~~

1.5. Sunset Date -- ~~This rule shall terminate and have no further force or effect on April 9, 2030.~~

§15-14-2. Definitions.

2.1. The following words and phrases 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 or delivering 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 or delivering 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, excluding prescription drug orders for Schedule II controlled substances listed in West Virginia Code § 60A-2-206, 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

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 delivering of a drug order by a central fill pharmacy for an originating or delivering pharmacy pursuant to this series is not to 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 or delivering pharmacy's inventory.

3.5. Prior to outsourcing the filling of a prescription to a central fill pharmacy, the originating or delivering 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 or 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 or delivering 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 or delivering pharmacy and may include the name of the central fill pharmacy, as well as all other information required by Rule § 15-1-22.

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 or delivering pharmacy and the method of delivery (i.e., private, common or contract carrier). The originating or delivering 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 or delivering 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 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.

4.1.c. Nothing in this Section shall prohibit an individual licensed pharmacist licensed in the state, who is an employee of or under contract with a licensed pharmacy, or a licensed pharmacy technician or pharmacy intern working under the supervision of the pharmacist, from accessing that pharmacy's electronic database from inside or outside the pharmacy and performing the prescription drug order processing functions permitted by the W.Va. Code §30-5 et seq., if both of the following conditions are met:

4.1.c.1. The pharmacy establishes controls to protect the confidentiality and integrity of Protected Health Information; and

4.1.c.2. No part of the database is duplicated, downloaded, or removed from the pharmacy's electronic database.