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: 15-19

RULE TYPE: Legislative

Amendment to Existing Rule: No

RULE NAME: Inspections

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:

N/A

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:

The legislature has directed us to file this emergency rule to place our inspection procedures in administrative rule.

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:

NA

B. ECONOMIC INPACT ON SPECIAL REVENUE ACCOUNTS:

NA

C. ECONOMIC IMPACT ON THE STATE OR ITS RESIDENTS:

NA

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2022 Increase/Decrease (use "-")	2023 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):

NA

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

Yes

Ryan L Hatfield--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 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 19
INSPECTIONS

§15-19-1. General.

1.1. Scope. -- Inspection process for the West Virginia Board of Pharmacy.

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

1.3. Filing date --

1.4. Effective date --

1.5. Sunset Provision-- This rule will terminate and have no further force or effect on August 1, 2027.

§15-19-2. Definitions.

2.1. The following words and phrases as used in this Rule mean:

2.1.1. "Board" means the West Virginia Board of Pharmacy.

2.1.2. "Charitable Clinic Pharmacy" means a clinic or facility organized as a not-for-profit corporation that offers pharmaceutical care and dispenses prescriptions free of charge to appropriately screened and qualified patients. A charitable clinic pharmacy shall meet the minimum standards for a pharmacy as set forth in W. Va. Code §30-5-1, et seq., and by this rule, but may not be charged any applicable licensing fees. A charitable clinic pharmacy may have pharmacists-in-charge, as that term is defined in this section, who volunteers his or her services. A charitable clinic may also receive donated drugs. It is not the intent of this rule to affect any organizations which are merely operating a prescribing practitioner's or clinic's free sample drug room.

2.1.3. "Controlled Substance Permit" means the permit require to be obtained by the Board, unless otherwise exempt, for every person who manufactures, distributes, including reverse distributing, or dispenses any controlled substances or who proposes to engage in the manufacture, distribution or dispensing of any controlled substance within this state.

2.1.4. "Inspection" means the process by which the Board verifies certain information of Board licenses.

2.1.5. "Inspector" means a person employed by the Board to perform inspections.

2.1.6. "Institutional Pharmacy" means that physical portion of an institutional facility that is engaged in the compounding, dispensing, and distribution of drugs, devices, and other materials used in the diagnosis and treatment of injury, illness, and disease and which holds a pharmacy license from the Board.

2.1.7. "Non-compliance report" means a report created noting a deficiency discovered during an inspection.

2.1.8. "Non-Sterile Compounding" means the process of combining, admixing, diluting, pooling,

reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug or bulk drug substance to create a non-sterile preparation.

2.1.9. "Nuclear pharmacy" means a place where radioactive drugs are prepared and dispensed and which operates under specialized rules.

2.1.10. "Outpatient pharmacy" means any pharmacy, apothecary, or place within this state where drugs are dispensed and sold at retail or displayed for sale at retail and where the practice of pharmacy is conducted and pharmacist care is provided; and any place outside of this state where drugs are dispensed and the practice of pharmacy and pharmacist care is provided to residents of this state.

2.1.11. "Pop-In Inspection" means an unannounced Inspection.

2.1.12. "Sterile Compounding" means compounding or mixing prescription orders for sterile solutions or suspensions to be administered parenterally, enterally, by irrigation or ophthalmic drops.

2.1.13. "Wholesaler" means any person within this state or another state, other than a manufacturer, who sells, transfers or in any manner furnishes a drug product to any other person in this state for the purpose of being resold.

§15-19-3. Inspector Qualifications.

3.1. In order to qualify for the position of Inspector, a candidate must have at least ten (10) years of pharmacy practice experience.

3.2. Upon being hired, each Inspector shall complete a training program in accordance with the Board's training manual, complete the National Investigator and Inspector Training Basic Course, and complete the National Association of Boards of Pharmacy Certification for inspecting Sterile Compounding facilities.

§15-19-4. Regions.

4.1 The Board shall establish regions within the state. Each region shall have approximately the same amount of licensed facilities.

4.2. Each Inspector shall be assigned a region.

§15-19-5. Scheduling of Inspections.

5.1. Inspections shall be conducted within ninety days of the regularly scheduled inspection frequency, unless circumstances make compliance with this timeframe unattainable.

5.2. Inspectors shall schedule Inspections by notifying the facility to be inspected at least one week in advance of the Inspection.

5.3. Pop-In Inspections shall be conducted by each Inspector on an annual basis for an amount of inspections not to exceed 10% of the facilities within the Inspector's region.

§15-19-6. Conducting Inspections.

6.1. The Board shall establish policies and procedures for conducting Inspections.

6.2. At a minimum, the methods established by the Board for conducting inspections shall include the following:

6.2.1. presentation of credentials;

6.2.2. copies of the inspection forms to be used;

6.2.3. details on the use of electronic inspection forms;

6.2.4. a listing of documents to be reviewed; and

6.2.5. listing of staff that may be interviewed.

6.3. Completed hard copy inspections shall be submitted to the Board office in a timely manner.

6.4. Completed hard copy inspections shall be recorded in the Board database.

6.5. Electronic inspection shall be automatically entered into the Board database.

6.6. Copies of the completed inspection form shall be provided to the facility inspected.

6.7. Non-compliance reports shall be completed and entered into the Board database.

6.8. Completed inspections shall be reviewed by the Chief Compliance Officer within ninety days. This review shall be documented in the Board database.

6.9. Non-compliance reports shall be logged in a manner which allows for the systematic monitoring of facility's actions toward correcting areas of significant deficiencies.

6.10. Facilities not meeting the expected corrections within the timeframe established by the inspector shall be referred to the Complaint Committee of the Board.

6.11. All records, documents, communications, and images shall be maintained in the Board database for a period of five years.

§15-19-7. Inspection Forms.

7.1. The Board shall create inspection forms for each type of facility inspected. The inspection forms shall contain citations to relevant laws and regulations.

7.2. The inspection forms used by the Board shall be made available to the public on the Board's website.

§15-19-8. Inspection Frequency.

8.1. The following facility types shall be inspected annually:

8.1.1. outpatient pharmacies;

8.1.2. institutional pharmacies;

8.1.3. charitable clinic pharmacies;

8.1.4. nuclear pharmacies;

8.1.5. hazardous drug handling permit;

8.1.6. sterile compounding facilities;

8.1.7. non-sterile compounding facilities.

8.2. Facilities that only hold a controlled substance permit and no other Board permit or license shall be inspected biennially.