

**WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION**

Form #4

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OFFICE WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

CITE AUTHORITY: WV Code Sections 30-5-14, and 30-5-19.

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: Series 13

TITLE OF RULE BEING PROPOSED: Board of Pharmacy Rules Regarding Charitable Clinic Pharmacies

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.

David E. Potters
Authorized Signature



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OFFICE WEST VIRGINIA
SECRETARY OF STATE

Board of Pharmacy

Office
232 Capitol Street
Charleston, West Virginia 25301

Phone (304) 558-0558
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APPROVAL OF FILING OF REGULATIONS

BE IT HEREBY KNOWN that the West Virginia Board of Pharmacy approves the filing of the following modified rules with the Secretary of State and the Legislative Rulemaking and Review Committee:

- (1) Series 1 regarding with modification regarding electronic prescribing (per SB 1001, 2007 1st Special Session) and regulation of charitable clinic pharmacies (per SB 722, 2008 Regular Session);
- (2) Pharmacist Administration of Immunizations (per HB 3056, 2008 Regular Session); and
- (3) Regulation of Charitable Clinic Pharmacies (per SB 722, 2008 Regular Session).

Signed this 20th day of February, 2009,

BY: George Karos
George Karos, President



Board of Pharmacy

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Signed this 20th day of February, 2009,

BY:


Charles Woolcock, Secretary

**TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY**

**SERIES 13
Board of Pharmacy Rules Regarding
Charitable Clinic Pharmacies**

§15-13-1. General.

1.1. Scope. -- This rule establishes the requirements for charitable clinic pharmacies to operate in West Virginia to prepare and dispense prescriptions to patients of the clinics in this State.

1.2. Authority. -- These regulations are promulgated in accordance with the authority granted by West Virginia Code §§ 30-5-14 and 30-5-19.

1.3. Filing Date. -- _____.

1.4. Effective Date. -- _____.

1.5 PREAMBLE: The West Virginia Board of Pharmacy exists to protect the public health, safety, and welfare through, among other things, the regulation of pharmacies, pharmacists, technicians, drug distributors, and places that stock controlled substances. The Board also enforces requirements established by the FDA, USP, DEA, EPA, and the CPSC for the storage, delivery, dispensing, and destruction of drugs and construction of sterile preparation areas and nuclear pharmacy facilities within this State.

Under the auspices of the West Virginia Department of Health and Human Resources, the West Virginia Legislature created a system of Basic Public Health Services as defined and set forth in W.Va. Code § 16-1-1 et seq. Pursuant to its commitment to the citizens of its state, the West Virginia Legislature, acting through of WV Department of Health and Human Resources, created the Primary Care Support Program pursuant to W.Va. Code § 16-2-H-1 et seq. The Primary Care Support Program has been and continues to be instrumental in providing basic medical and dental services to West Virginia residents that do not have sufficient access. As such, there are numerous facilities in West Virginia which operate tax exempt free clinics and free clinic pharmacies to provide free medical care and drug therapies to their clients. The Board of Pharmacy requirements for the practice of pharmacy, including, but not limited to, sanitary practices, proper storage and handling of drugs, counseling, and providing correct treatment as prescribed are essential to ensure proper therapeutic outcomes which involve pharmaceutical care. These requirements can only be accomplished by the presence of a properly licensed and trained pharmacist to oversee the delivery of the pharmaceutical care provided. After receiving the direct input and advice of the West Virginia Department of Health and Human Resources and the West Virginia Board of Pharmacy, the West Virginia Legislature determined that the role of the nonprofit, community-based free health and dental clinics of providing no cost drug therapies

to its patients, needed to be formally recognized and made part of the regulatory framework of the State of West Virginia. Accordingly, the West Virginia Legislature created a new designation within the regulatory framework already existing for pharmacies, the "Charitable Clinic Pharmacies", to continue the delivery of drug therapies to those citizens who meet the requirements of the Primary Care Support Program and to receive free medical and dental services under guidelines established and enforced by the West Virginia Department of Health and Human Resources. Such Charitable Clinic Pharmacies were created pursuant the enactment of Senate Bill No. 722, which passed the West Virginia Legislature on March 8, 2008.

It is in the interest of both the charitable clinic pharmacies and their clients to provide those clients the same minimum protection afforded all other citizens of West Virginia as required by the statutes and regulations applicable to the practice of pharmacy in this State. The Board of Pharmacy recognizes that the charitable clinics and their pharmacies operate on limited grant funding along with donations from many professionals and suppliers of materials, time, and monetary support. Therefore, necessarily, they operate on tightly controlled and limited budgets.

As such, given the unique nature of the free clinics and the valuable service they provide to the community, these regulations applicable to charitable clinic pharmacies are designed to protect the health, safety, and welfare of the public while relieving the clinics from, due to the limited nature of their practice of pharmacy, certain unnecessary regulatory burdens. Providing these limited exemptions, the Board of Pharmacy believes, will not infringe on safe-guarding the pharmaceutical care provided to the clients of the free clinics, and will allow the clinics the necessary leeway to provide safe and effective care on their limited resources.

§15-13-2. Definitions.

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

2.1.1. "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 West Virginia 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.

2.1.2. "Charitable organization" means an organization which operates a clinic or facility organized as a not-for-profit corporation which is qualified as a charitable organization pursuant to Section 501(c)(3) of the Internal Revenue Code, or its successor.

2.1.3. "Legend drug sample" for purposes of this Series means an unopened package of a manufacturers legend drug product that has been distributed to either a practitioner or the charitable clinic pharmacy in accordance with the provisions of the Prescription Drug Marketing Act of 1987, 21 U.S.C. §301 et seq, or its successor.

2.1.4. "Qualified patient" means a patient of the charitable clinic pharmacy that has been screened and approved by the charitable organization as meeting the organization's mission of providing pharmaceutical care to those who are without sufficient funds to obtain needed legend

drugs. The requirements and screening process employed by the charitable organization must be in accordance with the "Guidelines" and other program requirements developed by the West Virginia Department of Health and Human Resources, Office of Community Health Systems, Division of Primary Care, for eligibility to receive funding as a "Free Clinic" for "Uncompensated Care and Equipment and Capital Costs Funding".

Section §15-13-3. Charitable Clinic Pharmacy Permit Required.

3.1. A charitable clinic pharmacy is considered to be a pharmacy and must follow all federal and state laws, rules, and regulations that pertain to pharmacies and the practice of pharmacy, except as otherwise provided specifically herein. A charitable clinic pharmacy permit is required for a charitable organization to operate a pharmacy in this State to dispense prescription drugs to qualified patients. No fee is required to apply for or obtain the permit.

3.2. Permits obtained pursuant to this section expire on June 30 of each calendar year. Renewal will be conducted in accordance with the laws and rules for renewing pharmacy permits as outlined in this rule.

3.3. Charitable Clinic Pharmacies may petition the Board for exemptions from portions of the requirements set forth in this rule which are not addressed here on a case by case basis, including, but not limited to, such things as the requirement for weights and measures if no compounding is to be done, the requirement for separate security features and alarms if they are available on the clinic building as a whole, and other such requirements.

§15-13-4. Controlled Substances Restricted; Prescriptions to qualified patients.

4.1. A charitable clinic pharmacy shall not purchase, possess, trade, distribute, or dispense controlled substances.

4.2. Patient Dispensing. Prescriptions filled in a charitable clinic pharmacy may only be dispensed to qualified patients of that pharmacy on lawful orders or prescriptions of practitioners authorized by law to prescribe or administer said drugs.

4.2.1. All prescriptions filled by the charitable clinic pharmacy must be checked by a pharmacist or a prescribing practitioner licensed as such in the State of West Virginia prior to being dispensed; Provided That any prescribing practitioner licensed in this State may access the charitable clinic pharmacy to fill, check, or dispense prescriptions when no pharmacist is present, provided that he or she insures proper labeling and documentation of the dispensing.

4.2.2. Any other rule notwithstanding, in the absence of a pharmacist, a prescribing practitioner who is licensed in the State of West Virginia may also supervise the work of pharmacy technicians within the pharmacy, so that they may continue to work during that period of time.

4.2.3. Any other rule notwithstanding, if there is no pharmacist or prescribing practitioner who is licensed in the State of West Virginia present to supervise the pharmacy technicians, the pharmacy technicians may continue to process and fill prescriptions, and perform all other duties which may be performed by a pharmacy technician, for up to two hours during the charitable clinic pharmacy's regular hours of operation provided that no actual dispensing may occur until the prescriptions filled are checked in accordance with subsection 4.2.1 above.

4.3. The charitable clinic pharmacy may not charge any fee for dispensing prescription drug samples or prescription legend drugs to qualified patients of the charitable clinic pharmacy. However, this rule does not prevent a charitable clinic or charitable clinic pharmacy from requesting voluntary donations from its patients who receive prescriptions, provided that a sign is posted in a conspicuous location where it can be seen by all patients stating that a donation is not required to receive prescription drugs.

4.4 Any other rule notwithstanding, a charitable clinic pharmacy may allow completed prescription orders to be dispensed to its patients by permitting a pharmacy technician or other licensed health care provider working on behalf of the charitable clinic to transport the completed prescription to another remote clinic operated by the charitable clinic, Provided That:

a. the completed prescriptions are kept in a locked tote or other such storage container and remain in the possession of the licensed health care provider until such time as they are actually dispensed directly to the patient or someone picking up on behalf of the patient;

b. the completed prescriptions are accompanied by a manifest indicating the contents of the tote at the time they leave the pharmacy;

c. the patient or person picking up the prescription on behalf of the patient signs for receipt of the prescription; and

d. any prescriptions which are not dispensed at the remote clinic site are returned in the locked tote to the charitable clinic pharmacy, along with the manifest, by a licensed health care provider working on behalf of the charitable clinic, and are reconciled by the pharmacy.

4.5. Charitable clinic pharmacies are exempt from the restrictions in Section 15-1.19.10 insofar as the charitable clinic pharmacy may provide prescription blanks imprinted with its name for prescribers working in the clinic to write prescriptions to be filled at the charitable clinic pharmacy.

§15-13-5. Prescription Drug Samples.

5.1. Except insofar as it may conflict with federal law, charitable clinic pharmacies are exempt from any State law or rule which restricts who may receive sample drugs from a manufacturer. Specifically, unless it conflicts with federal law, a charitable clinic pharmacy may accept donated prescription drugs in their unbroken original packaging from pharmacies, licensed prescribers, wholesalers, or manufacturers provided appropriate records of transfer, donation, and receipt are maintained: Provided That the samples have been stored under the proper conditions required by the manufacturer and applicable law to prevent deterioration or contamination. However, a charitable clinic pharmacy may only receive, possess, and dispense prescription drug samples if the following conditions are satisfied:

(a) The samples are dispensed at no charge to qualified patients of that charitable clinic pharmacy;

(b) The samples are possessed in compliance with the Federal Prescription Drug Marketing Act of 1987, 21 U.S.C. §301 et seq, or its successor;

(c) The samples are in the original container in which they were placed by the manufacturer and the container is clearly marked sample;

(d) Prior to being furnished or dispensed, the samples have been stored under the proper conditions to prevent deterioration or contamination;

(e) The samples are clearly marked with an expiration date and lot number;

(f) The samples are not expired; and

(g) The samples are not a controlled substance.

5.2 If donated samples are received which do not comply with Section 15-13-5.1, then they must be refused, returned, or properly disposed of by the charitable clinic pharmacy.

5.3. A charitable clinic pharmacy may not sell, purchase, or trade prescription drug samples.

5.4. A Charitable Clinic Pharmacy dispensing a sample drug shall comply with the following:

5.3.1. A pharmacist in a charitable clinic pharmacy must have a valid prescription prior to dispensing a sample drug to a patient.

5.3.2. The charitable clinic pharmacy must determine the eligibility requirements for a patient to receive a sample drug.

5.3.3. The sample drug is dispensed:

(a) In the original container in which it was placed by its manufacturer where the container is clearly marked as sample; or

(b) By removing the sample drug from the original container only if the prescription label on the appropriate container clearly states that the drug dispensed is a sample drug.

5.3.4. Nothing in this rule shall restrict a prescribing practitioner from providing samples in their original container from being given to the practitioner's patients in accordance with federal law.

§15-13-6. Pharmacist-In-Charge Responsibilities.

6.1. The pharmacist-in-charge at the charitable clinic pharmacy is responsible for implementing policies and procedures and a quality assurance program for operation of the charitable clinic pharmacy.

6.2. The pharmacist-in-charge at the charitable clinic pharmacy shall ensure through implementation of policies and procedures that the following occurs at the charitable clinic pharmacy:

(a) donated drugs dispensed from pharmacy are properly labeled;

(b) donated drugs that are expired, adulterated, misbranded, recalled, deteriorated, not kept under proper conditions, or did not have the identifying drug information on them as required are not dispensed to patients;

(c) donated drugs are inspected prior to dispensing to determine that the donated drugs meet all federal and state requirements for product integrity;

(d) donated drugs that are expired, adulterated, misbranded, recalled, deteriorated, not kept under proper conditions, or did not have the identifying drug information on them as required are destroyed; and

(e) manifests for donated drugs that are dispensed pursuant to prescriptions from the charitable clinic pharmacy are created and maintained at the charitable clinic pharmacy as required for all prescription records.

(e) dispensing errors are documented and reported monthly to the Board.

§15-13-7. Limitations of Charitable Clinic Pharmacies.

Charitable Clinic Pharmacies shall comply with the following:

7.1 All drug therapies and prescriptions shall be prescribed on an individual basis.

7.2 A Charitable Clinic Pharmacy may not accept lost identity or unknown drugs.

7.3 Misbranded drugs may not be accepted by the Charitable Clinic Pharmacy.

7.4 A Charitable Pharmacy may accept donated and unadulterated prescription drugs in their unbroken original manufacturer packaging from pharmacies, licensed prescribers, wholesalers or manufacturers, the State of West Virginia, the Board of Pharmacy or by other means, provided appropriate records of receipt are maintained.

§15-13-8. Continuing Education Credits for Volunteering in Charitable Clinic Pharmacy.

A pharmacist who volunteers as a pharmacist-in-charge or a staff pharmacist in a charitable clinic pharmacy may earn up to a maximum of six live continuing education credits for such activities. For every eight hours worked in a charitable clinic pharmacy as the PIC, the PIC may earn one hour of live continuing education credit. For every ten hours worked in a charitable clinic pharmacy as a staff pharmacist, the pharmacist may earn one hour of live continuing education credit.

15-13-9 Inspection and Investigation of Charitable Clinic Pharmacies.

9.1 The Board of Pharmacy will use an Inspection Form which is consistent with the requirements under which a Charitable Clinic Pharmacy shall operate as contemplated by W.Va. Code § 30-5-1b.

9.2 Upon receipt of the completed inspection form, the Board of Pharmacy and any appointed Quality Control Committee or other such body of the Charitable Clinic Pharmacy may meet and confer to address and resolve issues which may impact the health and safety of the pharmacy's patients. To the extent necessary, corrective plans may result from such meeting(s) with timeframes established by the Board of Pharmacy for the resolution of Quality control issues.