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ADMINISTRATIVE LAW DIVISION

Form #2

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NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

RULE TYPE: Legislative CITE AUTHORITY: WV Code Section 30-5-1 (SB 722)

AMENDMENT TO AN EXISTING RULE: YES X NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED:

TITLE OF RULE BEING AMENDED:

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

TITLE OF RULE BEING PROPOSED: Regulation of Charitable Clinic Pharmacies

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON August 29, 2008 AT 3:00 p.m. ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

West Virginia Board of Pharmacy
Attn: David Potters
232 Capitol Street
Charleston, West Virginia 25301

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.

David E. Potters
Authorized Signature

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

4.00

**BRIEF SUMMARY OF AND STATEMENT OF CIRCUMSTANCES WHICH REQUIRE
THE PROPOSED LEGISLATIVE RULE**

Regulation of Charitable Clinic Pharmacies

15 CSR 1

Summary and Statement of Circumstances: SB 722, passed during the Regular Session, 2008, and duly enacted into law, provides that the Board of Pharmacy has jurisdiction over pharmacies in charitable (or free) clinics in this State, and provides for those pharmacies to be regulated in a new, special class called “charitable clinic pharmacies”. SB 722 contains a directive to the West Virginia Board of Pharmacy to promulgate rules to provide for the regulation of such pharmacies, allowing the charitable clinic pharmacies to continue operating without any licensure until such rules are enacted to implement and enforce the provisions of SB 722. Therefore, in accordance with the directive set forth by the Legislature, the purpose of this rule is to revise existing rules governing requirements of a pharmacist in charge and operation of pharmacies when the pharmacy falls within the classification of a charitable clinic pharmacy, to provide guidance and regulation as to the receipt of sample drugs by such pharmacies, and to otherwise provide for the regulation of these pharmacies in this new category, all in order to protect the public health, safety, and welfare with regard to prescriptions filled and dispensed to patients of the charitable clinic pharmacies.

For Further Information: Copies of the proposed rule may be obtained from the website of the West Virginia Secretary of State at www.wvsos.com, or interested parties may call the Administrative Law Division of the Office of the Secretary of State at (304) 558-6000.

Further information may be obtained by contacting the West Virginia Board of Pharmacy, David E. Potters, Executive Director and General Counsel, 232 Capitol Street, Charleston, West Virginia, 25301, telephone (304) 558-0558.

Note: Strike-throughs in the proposed rule indicate language that would be stricken from the present law, and underscoring indicates new language that would be added.

FISCAL NOTE FOR PROPOSED RULES

Rule Title: 15-13-1, et seq: Regulation of Charitable Clinic Pharmacies

Type of Rule: Legislative Interpretive Procedural

Agency: West Virginia Board of Pharmacy

Address: 232 Capitol Street, Charleston, West Virginia 25301

Phone Number: (304) 558-0558 Email: dpotters@wvbop.com

Fiscal Note Summary

Summarize in a clear and concise manner what impact this measure will have on costs and revenues of state government.

The Board of Pharmacy will have to process and issue licenses for Charitable Clinic Pharmacies, and will have to expend time and costs to conduct regular required inspections. However, the Board shall not charge any fee for the licensure of these charitable clinic pharmacies. Thus, this will have a negative impact on the Board's budget. Nonetheless, this is a very important issue for the protection of patients of these pharmacies, and to assist these pharmacies in providing services to their patients.

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.

FISCAL YEAR			
Effect of Proposal	Current Increase/Decrease (use "-")	Next Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	4,500.00	4,500.00	4,500.00
Personal Services			
Current Expenses			
Repairs & Alterations			
Assets			
Other			
2. Estimated Total Revenues	4,500.00	4,500.00	4,500.00

Rule Title: _____

Rule Title: 15-13-1. et seq: Regulation of Charitable Clinic Pharmacies

3. Explanation of above estimates (including long-range effect):

Please include any increase or decrease in fees in your estimated total revenues.

The Board estimates that there are approximately 15 to 20 readily identifiable charitable clinic pharmacies in the State that will desire to continue to operate as pharmacies. Ten of those are members of the West Virginia Free Clinic Association. There are numerous others around the State that are not members of the Association. The Board of Pharmacy will have to process and issue licenses for pharmacies to continue to operate, including future renewals. This includes costs of providing applications (in other than electronic format), time for Board employees to process applications, costs of producing and mailing certificates, and costs of producing and mailing notices for renewals. SB 722 prohibits the Board from charging any licensing fee of the charitable clinic pharmacies, due to the relatively tight budgets on which they operate and the "indigent" patients they serve at no charge. Thus, while the Board of Pharmacy will realize costs, it will also be providing for the minimum patient health safety and welfare standards of these pharmacies, much the same as is required of any other pharmacy in this State.

MEMORANDUM

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.

Date: July 31, 2008

Signature of Agency Head or Authorized Representative

David E. Potters

[Amend and modify:]

§ 15-1.2.1.38. "Pharmacist-in-charge" means a pharmacist currently licensed in this state who:

a. Accepts responsibility for the operation of a pharmacy in conformance with all state and federal laws and rules pertinent to the practice of pharmacy and the distribution of drugs;

b. has the responsibility for the practice of pharmacy, as defined in this rule, at the pharmacy for which he or she is pharmacist-in-charge. The pharmacy permit holder has responsibility for all other functions, administrative and operational, of the pharmacy. The pharmacist-in-charge may advise the pharmacy permit holder on administrative and operational matters but following such advice shall not be legally required responsible; ~~and~~

c. works at least 30 hours a per week with the pharmacist-in-charge working at least three days per week in that pharmacy, including the use of any accrued annual or sick leave; Provided that, in any pharmacy which is open on average less than 40 hours per week in a calendar year, he or she must work in the pharmacy a majority of the hours that the pharmacy is open (e.g., if open 20 hours per week, the pharmacist-in-charge must work 11 hours per week within the pharmacy); and

d. Notwithstanding the requirements of subsection c. above, with regard to a pharmacist-in-charge in a Charitable Clinic Pharmacy, if the pharmacy is open an average of more than 40 hours per week, the pharmacist-in-charge must work at least 8 hours per calendar month; if the charitable clinic pharmacy is open on average at least 30 and up to 40 hours per week, the pharmacist-in-charge must work in the charitable clinic pharmacy at least 6 hours per calendar month; if the charitable clinic pharmacy is open on average at least 15 and up to 30 hours per week, the pharmacist-in-charge must work in the charitable clinic pharmacy at least 4 hours per calendar month; if the charitable clinic pharmacy is open on average at least 5 and up to 15 hours per week, the pharmacist-in-charge must work 2 hours per calendar month; and, if the charitable clinic pharmacy is open less than 5 hours per week, the pharmacist-in-charge must work in the charitable clinic pharmacy the lesser of 2 hours per month or 50% of the hours the charitable clinic pharmacy is open.

Charitable Clinic Pharmacy hours per week	Hours required by PIC per month
More than 40	8
30 to 40	6
15 to 30	4
5 to 15	2
Less than 5	The lesser of 2 or 50% of hours open

[Amend and modify:]

§ 15-1-20.1. A pharmacy may not operate without a pharmacist-in-charge (hereinafter "PIC"), who shall be designated on the application for a pharmacy license, and in each license renewal. A pharmacist may not serve as PIC unless he or she is physically present in the pharmacy a sufficient amount of time to provide supervision and control. A pharmacist may not serve as PIC for more than one pharmacy at any one time. Provided that, he or she may volunteer as the pharmacist-in-charge at a charitable clinic pharmacy while serving as a PIC in another pharmacy.

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[Add the following new series to Title 15 at 15-13-1, et seq.]

Series 13 Charitable Clinic Pharmacies

§15-13-1. General.

1.1. Scope. -- To establish rules 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 Senate Bill 722 passed during the 2008 Regular Legislative Session and enacted into law, which amended certain sections of the West Virginia Code, at §30-5-1, et seq., providing for oversight and regulation of Charitable Clinic Pharmacies..

1.3. Filing Date. -- July 30, 2008.

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, unless the context otherwise requires:

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 indigent patients. A charitable clinic pharmacy shall meet the minimum standards for a pharmacy as set forth in this article and by legislative rule promulgated by the Board of Pharmacy, 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.

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" means an unopened package of a manufacturer's 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 indigent 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.

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. As such, a charitable clinic pharmacy permit shall be required for a charitable organization to operate a pharmacy in this State to dispense prescription drugs to qualified indigent patients in this State. No fee shall be required to apply for or obtain the permit.

3.2. Permits obtained pursuant to this section shall 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 Title.

§15-13-4. Controlled Substances Restricted; Prescriptions to qualified indigent 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 indigent 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 the prescribing practitioner prior to being dispensed.

4.2.2. Any other rule notwithstanding, the prescribing practitioner may access the charitable clinic pharmacy to fill, check, or dispense prescriptions written by him or her when no pharmacist is present, provided a pharmacist technician is present and insures proper documentation of the dispensing.

4.2.3. Any other rule notwithstanding, if there is no pharmacist present for up to two hours during the charitable clinic pharmacy's regular hours of operation, pharmacy technicians may continue to process and fill prescriptions during that period of time 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 shall not charge any fee for the dispensing of prescription drug samples or prescription legend drugs to qualified indigent patients of the charitable clinic pharmacy.

4.4. Strict screening guidelines based on needs assessment shall be developed by the charitable clinic pharmacy to determine who is eligible as a qualified indigent patient. This may be accomplished in conjunction with the clinic itself, and documented through

a patient medical record shared between the charitable clinic pharmacy and the clinic itself.

4.5. All screening guidelines, needs assessments, and revisions shall be submitted to the Board upon request.

4.6. 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. However, a charitable clinic pharmacy shall only receive, possess, and dispense prescription drug samples if the following conditions are satisfied:

- (a) The samples are dispensed at no charge to qualified indigent 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. A charitable clinic pharmacy shall not sell, purchase, or trade prescription drug samples.

5.3. Dispensing A Sample Drug By A Charitable Clinic Pharmacy 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 to the patient free of charge.

5.3.4. 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, pursuant to rule 4729-9-02 of the Administrative Code, clearly states that the drug dispensed is a sample drug.

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

6.1. The pharmacist-in-charge at the charitable clinic pharmacy shall be 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 are destroyed, or did not have the identifying drug information on them as required; and
- (e) manifests for donated drugs that are dispensed or destroyed are created or maintained at the charitable clinic pharmacy for two (2) years from the date of destruction.
- (f) Dispensing errors are documented and reported monthly to the Board.

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

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

5.3 A Charitable Clinic Pharmacy shall not accept lost identity or unknown drugs.

5.4 No misbranded drugs shall be accepted by the Charitable Clinic Pharmacy.

5.5 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

7.1. 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 shall create and implement the use of 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 and established by S.B. 722.

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 measures.