WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #3

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Aug 18 3 25 PM '00

OFFICE OF WEST VIRGINIA SECRETARY OF STATE

NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

CITE AUTHORITY: 30-5-1, 60A-1-101

AMENDMENT TO AN EXISTING RULE: YES x NO ____

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 2

TITLE OF RULE BEING AMENDED: Rules and Regulations of the Board of Pharmacy for the Uniform Controlled Substances Act

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: ____

TITLE OF RULE BEING PROPOSED: ____

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

William T. Douglass Jr.

Authorized Signature

William T. Douglass, Jr.
558-0558

4/15.98

SUMMARY OF PROPOSED RULE

TITLE 15

LEGISLATIVE RULES

SERIES 2

RULES AND REGULATIONS OF THE BOARD OF PHARMACY FOR THE UNIFORM CONTROLLED SUBSTANCES ACT

This rule repeals and replaces existing series 2 which has not been amended since 1982 and removes antiquated language and brings the rule into compliance with federal regulations. The rule clarifies the requirements for controlled substance permits, establishes security requirements regarding the storage and handling of controlled substances, establishes labeling and packaging requirements for controlled substances, establishes the requirement for maintenance of records and inventories, establishes manner of issuance of prescriptions, the form of prescriptions, and time limitations on controlled substance prescriptions.

STATEMENT OF CIRCUMSTANCES

TITLE 15

LEGISLATIVE RULES

SERIES 2

RULES AND REGULATIONS OF THE BOARD OF PHARMACY FOR THE UNIFORM CONTROLLED SUBSTANCES ACT

This rule repeals and replaces existing series 2 which has not been amended since 1982 and removes antiquated language and brings the rule into compliance with federal regulations. Many changes have occurred in the past 18 years in relation to the dispensing of controlled substances and it is necessary to address those changes by amending these rules at this time.

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: August 18, 2000

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM:(*Agency Name, Address & Phone No.*) West Virginia Board of Pharmacy
232 Capitol Street
Charleston, WV 25301 Phone: 558-0558

LEGISLATIVE RULE TITLE: Rules and Regulations of the Board of Pharmacy for the Uniform Controlled Substances Act

1. Authorizing statute(s) citation 30-5-1, 60A-1-101

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:

July 3, 2000

b. What other notice, including advertising, did you give of the hearing?

Sent public notice to each pharmacy in state which was posted in public view informing patients of proposed rules and providing address and phone number of Board to request rules or send written comments.

c. Date of Public Hearing(s) ***or*** Public Comment Period ended:

Comment period ended 8/4/2000. Public meeting held 8/7/2000 to review commen

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached x No comments received _____

e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

August 18, 2000

f. **Name, title, address and <u>phone/fax/e-mail numbers</u>** of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

William T. Douglass, Jr., Executive Director

232 Capitol Street

Charleston, WV 25301

Phone: 558-0558 Fax: 558-0572

g. **<u>IF DIFFERENT</u> FROM ITEM 'f'**, please give **Name, title, address and phone number(s)** of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

N/A

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

N/A

b. Date of hearing or comment period:

N/A

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

N/A

d. Attach findings and determinations and reasons:

Attached N/A

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Rules and Regulations of the Board of Pharmacy for the Uniform Controlled Subs

Type of Rule: x Legislative ____ Interpretive ____ Procedural

Agency: West Virginia Board of Pharmacy

Address: 232 Capitol Street

Charleston, WV 25301

1. Effect of Proposed rule:

	ANNUAL		FISCAL YEAR		
	INCREASE	DECREASE	CURRENT	NEXT	THEREAFTER
ESTIMATED TOTAL COST	N/A	N/A	N/A	N/A	N/A
PERSONAL SERVICES	N/A	N/A	N/A	N/A	N/A
CURRENT EXPENSE	N/A	N/A	N/A	N/A	N/A
REPAIRS & ALTERATIONS	N/A	N/A	N/A	N/A	N/A
EQUIPMENT	N/A	N/A	N/A	N/A	N/A
OTHER	N/A	N/A	N/A	N/A	N/A

2. Explanation of Above Estimates:
Rule would not have nay fiscal impact upon state government or citizens of state.

3. Objectives of These Rules:
Update and amend controlled substance regulations.

Rule Title: Rules and Regulations of the Board of Pharmacy for the Uniform Controlled Sub

4. Explanation of Overall Economic Impact of Proposed Rule:

   A. Economic Impact on State Government:
   N/A

   B. Economic Impact on Political Subdivisions; Specific Industries; Specific Groups of Citizens: N/A

   C. Economic Impact on Citizens/Public at Large.
   N/A

Date: 8-18-2000

Signature of Agency Head or Authorized Representative:

William T. Doughss

William T. Doughss Jr.
558-0558

TITLE 15
LEGISLATIVE RULE
BOARD OF PHARMACY

SERIES 2
RULES AND REGULATIONS OF THE BOARD OF PHARMACY
FOR THE UNIFORM CONTROLLED SUBSTANCES ACT

§15-2-1. General.

1.1. Scope. -- The West Virginia Code, section nineteen, article five, chapter thirty et seq. mandates that the Board of Pharmacy shall make such Rules and Regulations, not inconsistent with law, as necessary, to carry out the purposes and enforce the provisions of this article.

1.2. Authority. -- W. Va. Code §60A.

1.3. Filing Date. -- _____

1.4. Effective Date. -- _____

1.5. Repeal of Former Rule. -- This legislative rule repeals and replaces WV 15CSR2 "Rules and Regulations of the Board of Pharmacy for the Uniform Controlled Substances Act" filed December 28, 1982 and effective December 28, 1982.

§15-2-2. Adoption of federal law.

2.1. The requirements of the federal regulations, Drug Enforcement Administration, Department of Justice, 21 CFR Parts 1300-1316, are adopted by the West Virginia Board of Pharmacy and licensed pharmacies shall comply with them. Any changes to the federal Controlled Substances Act and applicable federal regulations regarding controlled substances shall be incorporated by reference within this rule.

§15-2-3 Controlled Substance Permits

3.1. Persons required to register.

3.1.1 Every person who manufactures, distributes or dispenses any controlled substance or who proposes to engage in the manufacture, distribution or dispensing of any controlled substance shall obtain annually a controlled substance permit unless exempted by law or pursuant to Section 3.2 of these rules. Only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration). "Registrant" means a person who has obtained a controlled substance permit from the West Virginia Board of Pharmacy.

3.2. The West Virginia Board of Pharmacy shall exempt from payment of a fee for a controlled substance permit the following persons:

3.2.1. Any official or agency of the United States Army, Navy, Marine Corps, Air Force, Coast Guard, Veterans' Administration or Public Health Service who is authorized to procure or purchase controlled substances for official use; and

3.2.2. Any official, employee or other civil officer or agency of the United States, of any state or any political subdivision or agency thereof, who is authorized to purchase controlled substances, to obtain such substances from official stocks, to dispense or administer such substances, to conduct research, instructional activities, or chemical analysis with such substances, or any

combination thereof, in the course of his official duties or employment.

3.3. In order to claim exemption from payment of a fee, the applicant shall have completed the certification on the appropriate application form, wherein the registrant's superior certifies to the status and address of the registrant and to the authority of the registrant to acquire, possess or handle controlled substances.

3.4. Exemption from payment of a fee does not relieve the registrant of any other requirements or duties prescribed by law.

3.5. Each application shall include all information called for in the form, unless the item is not applicable, in which case this fact shall be indicated.

3.6. Each application, attachment, or other document filed as part of an application, shall be signed by the applicant, if an individual; by a partner of the applicant if a partnership; or by an officer of the applicant, if a corporation, corporate, corporate division, association, trust or other entity. Another person may be authorized to sign for the applicant, if proof of authority (e.g., general power of attorney) accompanies the application.

3.7. If the applicant is a pharmacy, , it shall be necessary for the pharmacist in charge of the pharmacy to sign the application; and where the owner of such pharmacy is a person, other than the practicing pharmacist, it shall be necessary for such other person, partnership or corporation, corporate division, association, trust or other entity, to sign the application form as provided in section 3.6 in addition to any other persons required to sign said application.

3.8 If the applicant is a rest home, nursing home, hospital, orphanage, clinic, home for the aged, governmental agency or institution or other place requiring the use of pharmacist consultants or coordinators of pharmaceutical services, it shall be necessary for such consultant or coordinator to sign the application in addition to any other persons required to sign the application.

3.9. Filing of application; joint filings.

3.9.1 All applications for registration shall be submitted for filing to the office of the the Board of Pharmacy.

3.9.2 Any person required to obtain more than one (1) registration may submit all applications in one (1) package. Each application must be complete and should not refer to accompanying application for required information.

3.10. Acceptance for filing; defective applications.

3.10.1 Applications submitted for filing are dated upon receipt. If found to be complete, the application will be accepted for filing. Application failing to comply with the requirements of this Part will not generally be accepted for filing. In the case of minor defects as to completeness the West Virginia Board of Pharmacy may accept the application for filing with a request to the applicant for additional information. A defective application will be returned to the applicant within ten (10) days following its receipt with a statement of the reason for not accepting the application for filing. A defective application may be corrected and resubmitted for filing at any time; the West Virginia Board of Pharmacy shall accept for filing any application upon resubmission by the applicant, whether complete or not.

3.10.2 Accepting an application for filing does not preclude any subsequent request for additional information pursuant to Section 3.20 of these rules and has no bearing on whether the application will be granted.

3.11. Additional information.

3.11.1 The West Virginia Board of Pharmacy may require an applicant to submit such documents or written statements of fact relevant to the application as it deems necessary to

determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the West Virginia Board of Pharmacy in granting or denying the application.

3.12. Amendments to and withdrawal of applications.

3.12.1 An application may be amended or withdrawn without permission of the West Virginia Board of Pharmacy at any time before the date on which the applicant receives an order to show cause pursuant to Section 3.29 of these rules, or before the date on which a notice of hearing on the application is published pursuant to section three hundred five, article three, chapter sixty-a of the West Virginia Code, whichever is sooner. An application may be amended or withdrawn with permission of the West Virginia Board of Pharmacy at any time where good cause is shown by the applicant or where the amendment or withdrawal is in the public interest.

3.12.2 After an application has been accepted for filing the request by the applicant that it be returned or the failure of the applicant to respond to official correspondence regarding the application, when sent by registered or certified mail, return receipt requested, shall be deemed to be a withdrawal of the application.

3.13. Administrative review generally.

3.13.1 The West Virginia Board of Pharmacy may inspect, or cause to be inspected, the establishment of an applicant or registrant, pursuant to article five of the Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code). The West Virginia Board of Pharmacy shall review the application for registration and other information gathered by the West Virginia Board of Pharmacy regarding an applicant in order to determine whether the applicable standards of section three hundred three of the Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code), have been met by the applicant.

3.14. Applications for research in Schedule I substances.

3.14.1 In the case of an application for registration to conduct research with controlled substances in Schedule I, the West Virginia Board of Pharmacy shall determine the qualifications and competency of the applicant as well as the merits of the research protocol. The Board, in determining the merits of a research protocol, shall confer as to effective procedures to safeguard adequately against diversion of such controlled substances from legitimate medical or scientific use. If the Board finds the applicant qualified and competent and the research protocol meritorious and adequately safeguarded, it shall register the applicant unless it finds registration should be denied for reasons set forth in section three hundred three, article three of the Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code).

3.14.2 If the Board is unable to find the applicant qualified or the Board finds that grounds exist for the denial of the application, it shall issue an order to show cause and, if requested by the applicant, shall hold a hearing on the application.

3.15 The controlled substance permit shall contain the name, address and registration number of the registrant, the activity authorized by the registration, the schedules of the controlled substances which the registrant is authorized to handle, the amount of fee paid (or exemption) and the expiration date of the registration. The registrant shall prominently display the controlled substance permit at the registered location.

3.16 No registration or any authority conferred thereby shall be assigned or otherwise

transferred except upon such conditions as the West Virginia Board of Pharmacy may specifically designate and then only pursuant to its written consent.

§15-2-4. Security Requirements.

4.1. Security requirements.

4.2. Security requirements generally.

4.2.1 All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the West Virginia Board of Pharmacy shall evaluate the overall security system and needs of the applicant or registrant.

4.2.2 Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operations. If a controlled substance is transferred to a different schedule or a noncontrolled substance is listed on any schedule, or the quantity of controlled substances in the possession of the registrant in normal business operations significantly increases, physical security controls shall be expanded and extended accordingly.

4.2.3 All registrants who receive or transfer substantial quantities of controlled substances in normal business operations shall employ security procedures to guard against in-transit losses.

4.3 Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Board or with the appropriate state controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.

4.4. The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Office of the West Virginia Board of Pharmacy of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

4.5. The registrant shall notify the Office of the West Virginia Board of Pharmacy of any theft or significant loss of any controlled substances upon discovery of such theft or loss. The registrant shall also complete the form provided by the Secretary regarding such theft or loss.

4.6.. Physical security controls

4.6.1. When a pharmacy is closed, controlled substances listed in Schedule II shall be stored in a securely locked narcotic cabinet made of 20 gauge metal or better or may be dispersed throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substance. Any other method of storage of controlled substances listed in Schedule II is not allowed unless specifically approved by the Board for that particular pharmacy. Only pharmacists practicing at the pharmacy and authorized by the pharmacist-in-charge may possess any keys or combinations to the narcotic cabinet. Controlled substances listed in Schedule III, IV, or V may be stored in the narcotic cabinet or may be dispersed throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substance. A secure automated distribution system, approved by the Board, may contain controlled substances within an institutional setting in lieu of a narcotic cabinet.

4.6.2. The registrant shall not employ as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration denied, or has had his registration revoked.

§15-2-5. Labeling And Packaging Requirements For Controlled Substances.

5.1. Labeling and packaging requirements for controlled substances.

5.2. Scope of article.

Requirements governing the labeling and packaging of controlled substances pursuant to section three hundred five of the Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code) are set forth generally by that section and specifically by the sections of this Part.

5.3. Definitions.

5.3.1. As used in this Part, the following terms shall have the meanings specified:

(a) The term "Commercial Container" means any bottle, jar, tube, ampule, or other receptacle in which a substance is held for distribution or dispensing to an ultimate user, and in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term "Commercial Container" does not include any package liner, package insert or other material kept with or within a commercial container, nor any carton, crate, drug, or other package in which commercial containers are stored or are used for shipment of controlled substances.

(b) The term "Label" means any display of written, printed, or graphic matter placed upon the commercial container of any controlled substance by any manufacturer of such substance.

(c) The term "Labeling" means all labels and other written, printed or graphic matter (1) upon any controlled substance or any of its commercial containers or wrappers, or (2) accompanying such controlled substance.

(d) The term "Manufacture" means the producing, preparation, propagation, compounding or processing of a drug or other substance or the packaging or repackaging of such substance, or the labeling or relabeling of the commercial container of such substance, but does not include the activities of a practitioner who, as an incident to his administration or dispensing such substance in the course of his professional practice, prepares, compounds, packages or labels such substance. The term "Manufacture" means a person who manufactures a drug or other substance, whether under a registration as a manufacturer or under authority of registration as a researcher or chemical analyst.

(e) Any term not defined in this section shall have the definition set forth in section one hundred one of the Uniform Controlled Substances Act, West Virginia Code Chapter sixty-a.

5.4. Symbol required; exceptions.

5.4.1. Each commercial container of a controlled substance except for a controlled substance accepted by the West Virginia Board of Pharmacy pursuant to section three hundred eight of this chapter, shall have printed on the label the symbol designating the schedule in which such controlled substance is listed. Each such commercial container, if it otherwise has no label, must bear a label complying with the requirement of this Part.

5.4.2 Each manufacturer shall print upon the labeling of each controlled substance distributed by him the symbol designating the schedule in which such controlled substance is listed.

5.4.3. The following symbols shall designate the schedule corresponding thereto:

Schedule I ..... CI or C-I. Schedule II ..... CII or C-II. Schedule III ..... CIII or C-III. Schedule IV ..... CIV or C-IV. Schedule V

..... CV or C-V.

The word "Schedule" need not be used. No distinction need be made between narcotic and nonnarcotic substances.

5.4.4 The symbol is not required on a carton or wrapper in which a commercial container is held if the symbol is easily legible through such carton or wrapper.

5.4.5. The symbol is not required on a commercial container too small or otherwise unable to accommodate a label, if the symbol is printed on the box or package from which the commercial container is removed upon dispensing to an ultimate user.

5.4.6. The symbol is not required on a commercial container containing, or on the labeling of, a controlled substance being utilized in clinical research involving blind and double blind studies.

5.4.7. The symbol is not required on a commercial container containing, or on the labeling, of a controlled substance intended for export from the United States.

5.5. Location and size of symbol on label.

5.5.1 The symbol shall be prominently located on the right upper corner of the principal panel of the label of the commercial container and/or the panel of the commercial container normally displayed to dispensers of any controlled substance listed in Schedule I through V. The symbol must be at least two (2) times as large as the largest type otherwise printed on the label.

5.5.2. In lieu of locating the symbol in the corner of the label, as prescribed in Paragraph (a) of this section, the symbol may be overprinted on the label, in which case the symbol must be printed at least one half (½) the height of the label and in a contrasting color providing clear visibility against the background color of the label.

5.5.3 In all cases, the symbol shall be clear and large enough to afford easy identification of the schedule of the controlled substance upon inspection without removal from the dispenser's shelf.

5.6. Location and size of symbol on labeling.

5.6.1 The symbol shall be prominently located on all labeling other than labels covered by Section 5.5 of these rules. In all cases the symbol shall be clear and large enough to afford prompt identification of the controlled substance upon inspection of the labeling.

5.7. Effective dates of labeling requirements.

5.7.1 All labels on commercial containers of, and all labeling of, a controlled substance which is listed in any schedule on June 15, 1971, and which is packaged after December 1, 1971, shall comply with the requirements of Section 5.4 of these rules.

5.7.2. All labels on commercial containers of, and all labeling of, a controlled substance which either is listed in any schedule on June 15, 1971, and thereafter transferred to another schedule or is added to any schedule after June 15, 1971, and which is packaged more than one hundred eighty (180) days following the date on which the transfer or addition becomes effective, shall comply with the requirements of Section 5.4 of these rules.

5.7.3. The West Virginia Board of Pharmacy may, in the case of any controlled substance, require compliance with the requirements of Section 5.4 of these rules, within a period of time shorter than required by this section if it finds that public health or safety necessitate an earlier effective date.

5.7.4. Until compliance is required under this section, the label on commercial container containing, and the labeling of, any controlled substance shall comply with any requirements under Federal Law as to labels of such containers and as to labeling of such

substances existing prior to the effective date prescribed in this section.

5.8. Sealing of controlled substances.

5.8.1. On each bottle, multiple dose, vial or other commercial container of any controlled substance listed in Schedules I and/or II, and of any narcotic controlled substance listed in Schedule III or IV, there shall be securely affixed to the stopper, cap, lid, covering or wrapper or such container a seal to disclose upon inspection any tampering or opening of the container.

5.8.2. Any seal accepted for use under Federal Law prior to May 1, 1971, shall be deemed acceptable for use under this section.

§15-2-6. Records And Reports Of Registrants.

6.1. All records required to be kept must be readily retrievable. "Readily Retrievable" means that certain records are kept by automatic data processing systems or other electronic or mechanized record keeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, red-lined or in some other manner visually identifiable apart from other items appearing on the records.

6.2 Maintenance of records and inventories.

6.2.1. Every inventory and other record required to be kept under the Act shall be kept by the registrant and be available, for at least five (5) years from the date of such inventory or record, for inspecting and copying by authorized employees of the West Virginia Board of Pharmacy.

6.2.2. Each registered manufacturer, distributor, importer, and exporter shall maintain inventories and records of controlled substances as follows:

(a) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and

(b) Inventories and records of controlled substances listed in Schedules III, IV and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.

6.2.3. Each registered individual practitioner required to keep records and institutional practitioner shall maintain inventories and records of controlled substances in the manner prescribed in Paragraph (b) of this section.

6.2.4 Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(a) Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file; and

(b) Inventories and records of controlled substances listed in Schedules III, IV and V shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy, and prescriptions for such substances shall be maintained either in separate prescription file for controlled substances listed in Schedules III, IV and V only, or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than 1 inch high and filed either in the

prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for noncontrolled substances. However, if a pharmacy employs an automated data processing system or other electronic record-keeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

6.3. General requirements for inventories.

6.3.1. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken. Controlled substances shall be deemed to be "On Hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, substances ordered by a customer but not yet invoiced, substances stored in a warehouse on behalf of the registrant and substances in the possession of employees of the registrant and intended for distribution as complimentary samples.

6.3.2. A separate inventory shall be made by a registrant for each registered location. In the event controlled substances in the possession or under the control of the registrant at a location for which he is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. Each inventory for a registered location shall be kept at the registered location.

6.3.3. A separate inventory shall be made by a registrant for each independent activity for which he is registered, except as provided in Section 7.14 of these rules.

6.3.4. A registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date. The registrant shall indicate on the inventory records whether the inventory is taken as of the opening or as of the close of business and the date the inventory is taken.

6.3.5. An inventory must be maintained in a written, typewritten or printed form. An inventory taken by use of an oral recording device must be promptly transcribed.

6.4. Initial inventory date.

6.4.1. Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he or she first engages in the manufacture, distribution or dispensing of controlled substances, in accordance with Sections 6.4 through 6.7 of these rules, as applicable. In the event a person commences business with no controlled substances on hand, he or she shall record this fact as the initial inventory.

6.5. Biennial inventory date.

6.5.1. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

6.6. Inventory date for new controlled substances.

6.6.1 On the effective date of a rule or statutory change by the West Virginia Board of Pharmacy or the DEA adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who is manufacturing, distributing or dispensing that substance shall take an inventory of all stocks of the substance on hand. Thereafter such substance shall be included in each inventory made by the registrant pursuant to Section 6.4 of these rules.

6.7. Inventories of manufacturers.

6.7.1. Each registered manufacturer shall include the following information in his inventory:

(a) For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or noncontrolled substances in finished form:

(1) The name of the substance; and

(2) The total quantity of the substance to the nearest metric unit weight consistent with unit size (except that for inventories made in 1971, avoirdupois weights may be utilized where metric weights are not readily available).

(b) For each controlled substance in the process of manufacture on the inventory date:

(1) The name of the substance;

(2) The quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number; and

(3) The physical form which the substance is to take upon completion of the manufacturing process (e.g. granulations, tablets, capsules or solutions), identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance (e.g. ten (10) milligram tablet or ten (10) milligram concentration per fluid ounce of milliliter) and the number or volume thereof.

(c) For each controlled substance in finished form:

(1) The name of the substance;

(2) Each finished form of the substance (e.g., ten (10) milligram tablet or ten (10) milligram concentration per fluid ounce or milliliter);

(3) The number of units or volume of each finished form in each commercial container (e.g., one hundred (100) tablet bottles or six (6) three (3) milliliter vials); and

(4) The total quantity of the substance in all forms to the nearest metric unit weight.

(d) For each controlled substance not included in Paragraphs (a), (b) or (c) of this section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings):

(1) The name of the substance;

(2) The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and

(3) The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

6.8. Inventories of distributors.

6.8.1. Each registered distributor shall include in his inventory the same information required of manufacturers pursuant to Section 6.8.1 (c) and (d) of these rules.

6.9. Inventories of dispensers and researchers.

6.9.1. Each person registered to dispense or conduct research with controlled substances and required to keep records pursuant to Section 6.4 of these rules, shall include in his inventory the same information required of manufacturers pursuant to Section 6.8.1. (c) and (d) of these rules. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser shall do as follows:

(a) If the substance is listed in Schedule I or II, he shall make an exact count or measure of the content; and

(b) If the substance is listed in Schedule III, IV or V, he shall make an estimated count or measure of the contents, unless the container holds more than one thousand (1,000) tablets or capsules in which case he must make an exact count of the contents.

6.10.. Inventories of importers and exporters.

6.10.1. Each registered importer or exporter shall include in his inventory the same information required of manufacturers pursuant to Section 6.7.1 (a), (c) and (d) of these rules. Each registered importer and exporter who is also registered as a manufacturer or as a distributor shall include in his inventory as an importer or exporter only those stocks of controlled substances that are actually separated from his stocks as a manufacturer or as a distributor (e.g., in transit or in storage for shipment).

6.11. Inventories for chemical analysts.

6.11.1 Each analytical laboratory registered to conduct chemical analysis with controlled substances shall include in its inventory the same information required of manufacturers pursuant to Section 6.8.1 (a), (c) and (d) of these rules, as to substances which have been manufactured, imported or received by the laboratory conducting the inventory, if less than one (1) kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in Schedule I), or less than twenty (20) grams of a hallucinogenic substance listed in Schedule I, (other than lysergic acid diethylamide), or less than five tenths (0.5) gram of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory. Laboratories of the West Virginia Board of Pharmacy may possess up to one hundred fifty (150) grams of any hallucinogenic substance in Schedule I without regard to a need for an inventory of those substances.

6.12. General requirements for continuing records.

6.12.1 On and after June 15, 1971, every registrant required to keep records pursuant to Section 6.3 of these rules, shall maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported or otherwise disposed of by him.

6.12.2. Separate records shall be maintained by a registrant for each registered location. In the event controlled substances are in the possession or under the control of a registrant at a location for which he is not registered, the substances shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.

6.12.3. Separate records shall be maintained by a registrant for each independent activity for which he is registered.

6.12.4. In recording dates of receipt, importation, distribution, exportation or other transfer, the date on which the controlled substances are actually received, imported, distributed, exported or otherwise transferred shall be used as the date of receipt or distribution of any documents of transfer (e.g., invoices or packing slips).

6.13. Records of manufacturers.

6.13.1.Each registered manufacturer shall maintain records with the following information:

(a) For each controlled substance in bulk form to be used, or capable of use in, or being used in, the manufacture of the same or other controlled or noncontrolled substances in finished form:

(1) The name of the substance;

(2) The quantity manufactured in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch manufactured;

(3) The quantity received from other

persons, including the date and quantity of each receipt and the name, address and registration number of the other person from whom the substance was received;

(4) The quantity imported directly by the registrant (under a registration as an importer) for use in manufacture by him, including the date, quantity and import permit or declaration number for each importation;

(5) The quantity used to manufacture the same substance in finished form, including:

A) The date and batch or other identifying number of each manufacture;

B) The quantity used in the manufacture;

C) The finished form (e.g., ten (10) milligram tablets or ten (10) milligram concentration per fluid ounce or milliliter);

D) The number of units of finished form manufactured;

E) The quantity used in quality control;

F) The quantity lost during manufacturing and the causes therefore, if known;

G) The total quantity of the substance

contained in the finished form;

H) The theoretical and actual yields; and

I) Such other information as is necessary

to account for all controlled substances used in the manufacturing process.

(6) The quantity used to manufacture other controlled and noncontrolled substances, including the name of each substance manufactured and the information required in Subparagraph (5) of this paragraph;

(7) The quantity distributed in bulk form to other persons, including the date and quantity of each distribution and the name, address and registration number of each person to whom a distribution was made;

(8) The quantity exported directly by the registrant (under a registration as an exporter), including the date, quantity and export permit or declaration number of each exportation;

(9) The quantity distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address and registration number of the person to whom distributed and the quantity distributed or disposed.

(b) For each controlled substance in finished form.

(1) The name of the substance;

(2) Each finished form (e.g., ten (10) milligram tablet or ten (10) milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., one hundred (100) tablet bottle or three (3) milliliter vial);

(3) The number of containers of each such commercial finished form manufactured from bulk form by the registrant, including the information required pursuant to Subparagraph (5) of Paragraph (a) of this section;

(4) The number of units of finished forms and/or commercial containers received from other persons, including the date of and number of units and/or commercial containers in each receipt and the name, address and registration number of the person from whom the units were received;

(5) The number of units of finished forms and/or commercial containers imported directly by the registrant (under a registration as an importer), including the date of and the number of units and for commercial containers in each

importation;

(6) The number of units and/or commercial containers manufactured by the registrant from units in finished form received from others or imported, including:

A) The date and batch or other identifying number of each manufacture;

B) The operation performed (e.g., repackaging or relabeling);

C) The number of units of finished form used in the manufacture, the number manufactured and the number lost during manufacture, with the causes therefore, if known; and

D) Such other information as is necessary to account for all controlled substances used in the manufacturing process.

(7) The number of commercial containers distributed to other persons, including the date of and number of containers in each distribution, and the name, address and registration number of the person to whom the containers were distributed;

(8) The number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers and export permit or declaration number for each exportation; and

(9) The number of units of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address and registration number of the person to whom distributed and the quantity in finished form distributed or disposed.

6.14. Records for distributors.

6.14.1 Each registered distributor shall maintain records with the following information for each controlled substance:

(a) The name of the substance;

(b) Each finished form (e.g., ten (10) milligram tablet or ten (10) milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., one hundred (100) tablet bottle or three (3) milliliter vial);

(c) The number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address and registration number of the person from whom the containers were received;

(d) The number of commercial containers of each such finished form imported directly by the registrant (under a registration as an importer), including the date of and the number of containers in each importation;

(e) The number of commercial containers of each such finished form distributed to other persons, including the date of and number of containers in each distribution and the name, address and registration number of the person to whom the containers were distributed;

(f) The number of commercial containers of such finished form exported directly by the registrant (under a registration as an exporter), including the date of and the number of containers in each exportation; and

(g) The number of units or volume of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (e.g., by distribution as complimentary samples), including the date and manner of distribution or disposal, the name, address and registration number of the person to whom distributed and the quantity of the substance in finished form distributed or disposed.

6.15. Records for dispensers and researchers.

6.15.1. Each person registered to dispense or conduct research with controlled substances and required to keep records pursuant to Section 6.3 of these rules, shall maintain records with the following information for each controlled substance:

(a) The name of the substance;

(b) Each finished form (e.g., ten (10) milligram tablet or ten (10) milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., one hundred (100) bottle or three (3) milliliter vial);

(c) The number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address and registration number of the person from whom the containers were received;

(d) The number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser; and

(e) The number of units or volume of such finished forms and/or commercial containers disposed of in any other manner by the registrant, including the date and manner of disposal and the quantity of the substance in finished form disposed.

6.16. Records for importers.

6.16.1 Each registered importer shall maintain records with the following information for each controlled substance:

(a) The name of the substance;

(b) The quantity (or number of units or volume in finished form) imported, including the date, quantity (or number of units or volume) and import permit or declaration number for each importation;

(c) The quantity (or number of units or volume in finished form) distributed to other persons, including the date and quantity (or number of units or volume) of each distribution and the name, address and registration number of each person to whom a distribution was made;

(d) The quantity disposed of in any other manner by the registrant (except quantities used in manufacturing by an importer under a registration as a manufacturer, which quantities are to be recorded pursuant to Section 7.18 (a) (4) or (b) (5) of these rules, including the date and manner of disposal and the quantity disposed.

6.17. Records for chemical analysis.

6.17.1. Each person registered to conduct chemical analysis with controlled substances shall maintain records with the following information (to the extent known and reasonably ascertainable by him) for each controlled substance:

(a) The name of the substance;

(b) The form or forms in which the substance is received, imported or manufactured by the registrant (e.g., powder, granulation, tablet, capsule or solution) and the concentration of the substance in such form (e.g., C.P., U.S.P., N.F., ten (10) milligram tablet or ten (10) milligram concentration per milliliter);

(c) The total number of the forms received, imported or manufactured (e.g., one hundred (100) tablets, thirty (30) one (1) milliliter vial, or ten (10) grams of powder), including the date and quantity of each receipt, importation or manufacture and the name, address and registration number, if any, of the person from whom the substance was received;

(d) The quantity distributed, exported or destroyed in any manner by the registrant (except quantities used in chemical analysis or

other laboratory work), including the date, the manner of distribution, exportation or destruction and the name, address and registration number, if any, of each person to whom the substance was distributed or exported.

6.17.2. Order forms, import and export permits, import invoices and export declarations relating to controlled substances shall be maintained separately from all other records of the registrant.

6.17.3. Records of controlled substances used in chemical analysis are not required.

6.17.4. Records relating to known or suspected controlled substances received as samples for analysis are not required under this section.

§15-2-7. Prescriptions.

7.1. Rules governing the issuance, filling and filing of prescriptions are set forth generally in West Virginia Code §60A-3-308.

7.2.. Definitions.

7.2.1. As used in this Part, the following terms shall have the meanings specified:

(a) The term "Act" means the Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code).

(b) The term "Individual Practitioner" means a physician, dentist, veterinarian or other individual licensed, registered or otherwise permitted, by the state jurisdiction in which he practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy or an institutional practitioner.

(c) The term "Institutional Practitioner" means a hospital or other person (other than an individual) licensed, registered or otherwise permitted, by the state jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

(d) The term "Pharmacist" means any pharmacist licensed by a state to dispense controlled substances and shall include a pharmacist intern authorized by a state to dispense controlled substances under the supervision of a pharmacist licensed by such state.

(e) The term "Prescription" means an order for medication which is dispensed to or for an ultimate user but does not include the immediate administration to the ultimate user.

(f) Any term not defined in this section shall have the definition set forth in section one hundred one, article one of the Act (chapter sixty-a, West Virginia Code).

7.3.. Persons entitled to issue prescriptions.

7.3.1. A prescription for a controlled substance may be issued only by an individual practitioner who is authorized to prescribe controlled substances in the jurisdiction in which he or she practices.

7.3.2. A prescription issued by an individual practitioner except for Schedule II controlled substance, may be communicated to a pharmacist by an employee or agent of the individual practitioner.

7.4.. Purpose of issue of prescription.

7.4.1. A prescription for a controlled substance to be effective must be issued for a legitimate purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the

usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section three hundred eight, article three of the Act and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

7.4.2. A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients; i.e. office use.

7.4.3. A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his dependence upon such drugs, except in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program.

7.5. Manner of issuance of prescriptions.

7.5.1. All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, and name, address and registration number of the practitioner. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (e.g. J.H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or a typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by a secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed in these regulations.

7.6. Form of controlled substance prescription.

7.6.1.. Each controlled substance prescription shall be written on a separate blank and no non-controlled substance can be ordered on a blank with a controlled substance; provided that this rule does not apply to prescriptions written for patients of an institutional facility. "Institutional facility" means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services, including but not limited to a hospital, convalescent home, nursing home, extended care facility, mental health facility, rehabilitation center, psychiatric center, developmental disability center, drug abuse treatment center, family planning clinic, penal institution, hospice, public health facility, or athletic facility. No more than one controlled substance can be written per prescription blank. A controlled substance prescription issued by a practitioner located outside the state of West Virginia that does not comply with this section may be accepted by the pharmacist if it is issued pursuant to the laws in the state in which the practitioner resides.

7.6.2. If a pharmacist receives a prescription with more then one controlled substance on the blank or a non-controlled substance on a blank with a controlled substance, then the pharmacist shall refuse to fill the prescription; Provided, that if the pharmacist in his or her professional judgement determines the immediate necessity for the patient to receive their medication, then the prescriptions may be dispensed and the pharmacist must document in a log the prescription numbers and drugs dispensed. This log must be kept in the pharmacy and be available for inspection. The pharmacist shall contact the prescriber as soon as possible to inform them that the prescription was not written according this rule. If the pharmacist continues to receive prescriptions from the same practitioner that do not comply with this rule, then the pharmacist shall inform the West Virginia Board of Pharmacy.

7.6.3. .Every controlled substance prescription shall have the name of the

practitioner stamped, typed, or printed legibly on the face of the prescription, as well as the signature of the practitioner. Institutional prescription blanks shall include the DEA number of the hospital or other institution and the special internal code number (suffix) assigned to him or her by the hospital or other institution, in lieu of the individual DEA number of the practitioner. If multiple practitioners are listed on a prescription blank, then the specific name of the prescriber must be clearly distinguished upon the prescription. If a pharmacist receives a prescription that does not comply with this section, then the pharmacist shall refuse to fill the prescription; Provided, that if the pharmacist in his or her professional judgement determines the immediate necessity for the patient to receive their medication, then the prescriptions may be dispensed and the pharmacist must document in a log the date, patient name, practitioner name, prescription numbers, and drugs dispensed. This log must be kept in the pharmacy and be available for inspection. The pharmacist shall contact the prescriber as soon as possible to inform them that the prescription was not written according this rule. If the pharmacist continues to receive prescriptions from the same practitioner that do not comply with this rule, then the pharmacist shall inform the West Virginia Board of Pharmacy.

7.7. Persons entitled to fill prescriptions.

7.7.1. A prescription for controlled substances may only be filled by a pharmacist acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy or registered institutional practitioner (e.g., a hospital, nursing home, home for the aged, clinic, orphanage, governmental agency or institution or other place of similar character which dispenses controlled substances).

7.8. Dispensing of narcotic drugs for maintenance purposes.

7.8.1 The administering or dispensing directly (but not prescribing) of narcotic drugs listed in any schedule to a narcotic drug dependent person for "detoxification treatment" or "maintenance treatment" shall be deemed to be within the meaning of the term "in the course of his professional practice or research.": Provided, that the practitioner is separately registered with the U.S. Attorney General as required by section 303(g) of the federal Controlled Substances Act (21 U.S.C. 823(g)) and then thereafter complies with the regulatory standards imposed relative to treatment qualification, security, records and unsupervised use of drugs pursuant to the Act.

7.8.2 Nothing in this section shall prohibit a physician who is not specifically registered to conduct a narcotic treatment program from administering (but not prescribing) narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three days and may not be renewed or extended.

7.8.3 This section is not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

7.9. Controlled substances listed in Schedule II.

7.9.1.. Requirement of prescription.

(a) A pharmacist may dispense a controlled substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug and Cosmetic Act, only pursuant to a written prescription signed by the prescribing individual practitioner, except as provided in Rule 7.9.2 of this section. A

confirms to the pharmacist that he or she still wants the prescription filled and the pharmacist documents upon the prescription that such confirmation was obtained.

(b) An individual practitioner may administer or dispense a controlled substance listed in Schedule II in the course of his professional practice without a prescription, subject to Section 9.8 of these rules.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

7.9.2. In the case of an emergency situation, a prescription for a Schedule II controlled substance may be communicated by the practitioner orally or by way of electronic transmission, provided that if the prescribing practitioner is not known to the pharmacist, he or she shall make a reasonable effort to determine that the oral authorization came from a registered practitioner, which may include a callback to the practitioner using the practitioner's phone number as listed in the telephone directory and other good faith efforts to insure his identity; and:

a. the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing practitioner);

b. the orally communicated prescription is immediately reduced to writing by the pharmacist, or, if necessary, the prescription communicated by way of electronic transmission is immediately reduced to a hard copy;

c. within seven (7) days after authorizing an emergency oral prescription, the practitioner has a written prescription for the emergency quantity prescribed delivered to the dispensing pharmacist. The prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the orally or electronically transmitted prescription. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the seven (7) day period. Upon receipt, the dispensing pharmacist shall attach this written prescription to the emergency oral prescription which had earlier been reduced to writing or to the hard copy of the electronically transmitted prescription. The pharmacist shall notify the nearest office of the U.S. Drug Enforcement Administration and the West Virginia Board of Pharmacy if the prescribing practitioner fails to deliver a written prescription.

7.10.. Refilling Schedule II prescriptions.

7.10.1 The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.

7.11.. Partial filling of Schedule II prescriptions.

7.11.1. The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within seventy-two (72) hours of the first partial filling, however, if the remaining portion is not or cannot be filled within the seventy-two (72) hour period, the pharmacist shall so notify prescribing individual practitioner. No further quantity may be supplied beyond seventy-two (72) hours without a new prescription.

7.12.. Labeling of Schedule II prescriptions.

7.12.1. The pharmacist filling a written or emergency oral prescription for a controlled

substance listed in Schedule II shall affix to the package a label showing date of filling, the pharmacy name and address, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner and directions for use and cautionary statements, if any, contained in such prescription or required by law.

7.13.. Filing of prescriptions.

7.13.1. All written prescriptions and written records of emergency oral prescriptions shall be kept in accordance with requirements of this chapter.

7.14.. Controlled substances listed in Schedules III , IV, and V.

7.14.1.. Requirement of prescription.

(a) A pharmacist may dispense a controlled substance listed in Schedule III, IV, or V, which is a prescription drug as determined under the Federal Food, Drug and Cosmetic Act, only pursuant to either a written prescription signed by a prescribing individual practitioner and/or an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist containing all information required in these rules, except for the signature of the prescribing individual practitioner.

(b) An individual practitioner may administer or dispense a controlled substance listed in Schedule III, IV, or V in the course of his professional practice without a prescription, subject to the provisions of Section 7.8 of these rules.

(c) An institutional practitioner, as described in Section 7.2 of these rules, may administer or dispense directly (but not prescribe) a controlled substance listed in Schedules III, IV, or V pursuant to a written prescription signed by a prescribing individual practitioner, or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in Section 7.5 of these rules, except for the signature of the prescribing individual practitioner), or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user, subject to Section 7.8 of these rules.

7.15. Refilling of Schedule III or IV prescriptions.

7.15.1. No prescription for a controlled substance listed in Schedule III or IV shall be filled or refilled more than six (6) months after the date on which such prescription was issued and no such prescription authorized to be refilled may be refilled more than five (5) times. Each refilling of a prescription shall be entered on the back of the prescription (or on another uniformly maintained appropriate record, such as medication records, which indicate prescription refills), initialed, and dated by the pharmacist as of the date of dispensing, and shall state the amount dispensed. If the pharmacist merely initials and dates the back of the prescription, he shall be deemed to have dispensed a refill for the full face amount of the prescription. Additional quantities of controlled substances listed in Schedule III or IV may only be authorized by a prescribing practitioner through issuance of a new prescription as provided in Section 7.14 of these rules, which shall be a new and separate prescription. The number of partial fills may be more than five times as long as the total quantity prescribed is not exceeded.

7.16. Partial Filling of Schedule III, IV, or V prescriptions.

7.16.1. The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible provided that:

(a) Each partial filling is recorded in the same manner as a refilling,

(b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and

(c) No dispensing occurs after 6 months

after the date on which the prescription was issued.

7.17.. Labeling of Schedule III, IV, or V prescriptions.

7.17.1. The pharmacist filling a prescription for a controlled substance listed in Schedule III, IV, or V shall affix to the package a label showing the pharmacy name and address, the serial number and date of initial filling the name of the patient, the name of the practitioner issuing the prescription, and directions for use and cautionary statements, if any, contained in such prescription as required by law.

7.18.. Filing of Schedule III, IV, or V prescriptions.

7.18.1. All prescriptions for controlled substances listed in Schedules III, IV, or V shall be kept in accordance with Section 6.3.4 of this rule.

7.19.. Dispensing without prescription.

7.19.1. A controlled substance listed in Schedules II, III, IV, or V which is not a prescription drug as determined by the Federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail: Provided, That

(a) Such dispensing is made only by a pharmacist and not by a nonpharmacist employee even if under the direct supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in this section, the actual cash, credit transaction or delivery, may be completed by a nonpharmacist);

(b) Not more than 240 cc. (8 ounces) of any such controlled substance containing opium, nor more than 120 cc. (4 ounces) of any other such controlled substance mor more than 48 dosage units of any such controlled substance containing opium, nor more than 24 dosage units of any other such controlled substance may be dispensed at retail to the same purchaser in any given forty eight (48) hour period;

(c) The purchaser is at least eighteen (18) years of age;

(d) The pharmacist requires every purchaser of a controlled substance under this section not known to him to furnish suitable identification (including proof of age where appropriate);

(e) A bound record book for distributions of controlled substances under this section (other than by prescription) is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase and the name or initials of the pharmacist who dispensed the substance to the purchaser (the book shall be maintained in accordance with the record keeping requirement of Section 7.5 of these rules); and

(f) A prescription is not required for distribution or dispensing of the substance pursuant to any other federal, state or local law.

§15-2-8. Miscellaneous.

8.1. Distribution upon discontinuance or transfer of business.

8.1.1. Any registrant desiring to discontinue or transfer business activities altogether or with respect to controlled substances shall notify the Board of Pharmacy immediately and on such notification shall submit a complete and detailed closing inventory of all controlled substances in the registrant's possession.

8.2. Disposal of controlled substances.

8.2.1. Compliance with federal law and regulations shall be deemed in compliance with this section. A registrant shall document the

altogether or with respect to controlled substances shall notify the Board of Pharmacy immediately and on such notification shall submit a complete and detailed closing inventory of all controlled substances in the registrant's possession.

8.2. Disposal of controlled substances.

8.2.1. Compliance with federal law and regulations shall be deemed in compliance with this section. A registrant shall document the destruction or disposal of all controlled substances on the appropriate form approved by the Board. The disposal of excessive amounts of residual and wasted controlled substances accrued by extemporaneous compounding in an institutional setting may be completed by two (2) registered or licensed health care professionals with a record of the destruction indicating the two witnesses with their signatures.

8.3. Reporting theft of drugs.

8.3.1. In the event of any controlled substances being stolen, it shall be the duty of the registrant to immediately submit a report of drug theft with the Board of Pharmacy.

8.4 Ordering of Controlled Substances.

8.4.1. An order form (DEA Form 222) is required for each transfer of a Schedule II controlled substance to another registrant without a prescription.

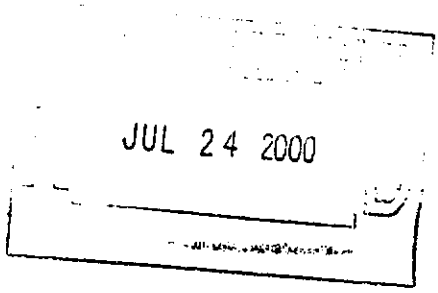
8.4.2. A pharmacist shall verify the receipt within the pharmacy of all controlled substances listed in Schedule II-V by reviewing and countersigning the invoices or packing documents.

WRITTEN PUBLIC COMMENTS RECEIVED WITH AGENCY'S RESPONSE

THE BIG FOUR DRUG STORE, INC.
HILTON, WEST VIRGINIA 25951

July 18, 2000

W. Va. Board of Pharmacy
232 Capitol Street
Charleston, WV 25301



Gentlemen:

Thank you for your recent letter with regard to proposed new rules about controlled substances.

I have two comments. First, the extension from 3 to 30 days for a Schedule II prescription to be filled is good idea. Second, the requirement to have each controlled substance written on a separate blank is not a good idea. This will cause needless inconvenience to the doctor, pharmacist, and especially the patient. Patient care may be compromised in some situations when the doctor is unavailable during after office hours.

Sincerely yours.

John Mark Ellison, RPh 3501

State of West Virginia
Board of Pharmacy

Phone (304) 558-0558
Fax (304) 558-0572

Office
232 Capitol Street
Charleston, West Virginia 25301

August 10, 2000

John Mark Ellison
HC 76 Box 6
Nimitz, WV 25978

Dear Mr. Ellison :

The Board reviewed your written comments on the proposed new legislative rules regarding controlled substances at its meeting on August 7, 2000. Based upon comments received, the Board made the following amendments to the rules:

1. The time period that a prescription for a Schedule II controlled substance is valid was changed from 30 days to 90 days from the date issued.

2. The rule requiring each controlled substance prescription be written on a separate blank and no non-controlled substance be ordered on a blank with a controlled substance is being written so that it applies only to outpatient prescriptions. The rule will also exempt prescriptions written for patients of an institutional facility. Institutional facility is defined in §15-1-2.1.19. (p. 63 of pharmacy law book) and includes hospital, convalescent home, nursing home, extended care facility, mental health facility, hospice, etc.

Some people stated their concerns that the requirement of separate blanks for each controlled substance would allow "drug seekers" to only have the controlled drug filled and not obtain the other drugs such as antibiotics. The Board understood the concern but feels that the benefits of reduction in errors outweigh the problems posed by non-compliant patients. In addition, physicians with such a concern about their patients can write notations upon the prescription like "1 of 2", "2 of 2", etc. to indicate to the pharmacist that a prescription in addition to the controlled prescription was issued on that same date.

Some people stated their concerns about the pharmacist having to police the physicians that do not comply with the regulations and affecting patient care by having to refuse to fill a prescription not issued correctly. Patient care does not have to suffer because the pharmacist can go ahead and fill the prescription and then must document this information. The pharmacist is to contact the prescriber about the prescriptions not written according to the rule; this is a means to correct the problem at an informal level. If the problems continue, then the pharmacist is to contact the Board of Pharmacy, who will then get involved by either corresponding with the prescriber or filing a formal complaint with the appropriate licensing board. Once this rule is passed, it is very important that physicians by educated about the new requirements and the Board of Pharmacy will attempt to work with the medical licensing boards to accomplish this.

The Board appreciates your input and attempted to take into consideration all points of view to come up with regulations that meet the Board's duty to protect the public and enforce the controlled substances act.

Sincerely,

William T. Douglass, Jr.
Executive Director and
General Counsel

West Virginia Board of Pharmacy
Charleston, WV 25301

35 Willingham Rd.
Charles Town, WV. 25414
July 11,2000

JUL 21 2000

Dear Board Members,

I am writing in regard to the proposed changes in the regulations concerning controlled substances. I serve as Consultant Pharmacist for our local Hospice organization. We are currently able to partially fill prescriptions for schedule II narcotics for a period of sixty days for our Hospice patients. The proposed changes include a provision for limiting the dispensing time for schedule II prescriptions to 30 days after date of prescribing. It would be in keeping with Hospice/Long-Term care procedures to extend this time period to sixty days or to make an exception for these patients- as long as the condition for which the prescription was written still applied.

I think requiring physicians to write one drug per prescription blank is long overdue. This change will greatly facilitate filing prescriptions properly.

One of our greatest challenges has been to decipher physician signatures, especially for controlled drug prescriptions. I am glad that the Board is addressing this issue. What provisions will be made to educate the prescribers if and when these changes are made? This problem occurs most frequently in large, teaching facilities where it is difficult to track down the unit from which the prescription originated and then the actual prescriber. Perhaps we could suggest a sample prescription blank for these institutions to use that would comply with regulations and facilitate dispensing for out-of-town pharmacies.

Thank you for consideration of my comments.

Regards,

Linda D. Bowers R.Ph.

Linda D. Bowers, R.Ph.
Jefferson Pharmacy
304-725-6533

State of West Virginia
Board of Pharmacy

Phone (304) 558-0558
Fax (304) 558-0572

Office
232 Capitol Street
Charleston, West Virginia 25301

August 10, 2000

Linda D. Bowers
35 Willingham Road
Charles Town, WV 25414

Dear Ms. Bowers :

The Board reviewed your written comments on the proposed new legislative rules regarding controlled substances at its meeting on August 7, 2000. Based upon comments received, the Board made the following amendments to the rules:

1. The time period that a prescription for a Schedule II controlled substance is valid was changed from 30 days to 90 days from the date issued.

2. The rule requiring each controlled substance prescription be written on a separate blank and no non-controlled substance be ordered on a blank with a controlled substance is being written so that it applies only to outpatient prescriptions. The rule will also exempt prescriptions written for patients of an institutional facility. Institutional facility is defined in §15-1-2.1.19. (p. 63 of pharmacy law book) and includes hospital, convalescent home, nursing home, extended care facility, mental health facility, hospice, etc.

Some people stated their concerns that the requirement of separate blanks for each controlled substance would allow "drug seekers" to only have the controlled drug filled and not obtain the other drugs such as antibiotics. The Board understood the concern but feels that the benefits of reduction in errors outweigh the problems posed by non-compliant patients. In addition, physicians with such a concern about their patients can write notations upon the prescription like "1 of 2", "2 of 2", etc. to indicate to the pharmacist that a prescription in addition to the controlled prescription was issued on that same date.

Some people stated their concerns about the pharmacist having to police the physicians that do not comply with the regulations and affecting patient care by having to refuse to fill a prescription not issued correctly. Patient care does not have to suffer because the pharmacist can go ahead and fill the prescription and then must document this information. The pharmacist is to contact the prescriber about the prescriptions not written according to the rule; this is a means to correct the problem at an informal level. If the problems continue, then the pharmacist is to contact the Board of Pharmacy, who will then get involved by either corresponding with the prescriber or filing a formal complaint with the appropriate licensing board. Once this rule is passed, it is very important that physicians by educated about the new requirements and the Board of Pharmacy will attempt to work with the medical licensing boards to accomplish this.

The Board appreciates your input and attempted to take into consideration all points of view to come up with regulations that meet the Board's duty to protect the public and enforce the controlled substances act.

Sincerely,

William T. Douglass, Jr.
Executive Director and
General Counsel

MEDICAL CENTER PHARMACY
Allied Health Services

Memorandum

To: Mr. William T. Douglass, Jr.

From: Kenneth A. Ferretti, PharmD, RPh

Date: 07/17/00

Re: Proposed rules – C Substances

Mr. Douglass,

I am the Director of Ambulatory Pharmacy Services at West Virginia University Hospitals. I have only two comments re: the proposed regulations dealing with controlled substances.

1. We have recently renovated our pharmacy and have two cabinets used for CIIs. Our pharmacy is within the Physician Office Center with 24-hour surveillance of the building. The pharmacy is protected by a security system (doors are alarmed and motion detectors within pharmacy) and it is also under camera surveillance. Furthermore, the cabinets have separate locks with a separate alarm, which has to be deactivated. Consequently, I am asking for a variance from the new regulation or at least asking that the board will be flexible enough to see that we have meant the intent and spirit of the law.

2. As regards point number 6 (Rxs for CIIs good for 30 days) while I understand the need to limit the window that a CII is valid there are many of our Pain Clinic patients that only need to be seen every 60 to 90 days. In that case the MD writes "Do not fill before July 18 (for example)" and this keeps the patient on schedule. They will often give them Rxs for 3 months at a time. I know that our pain clinic closely monitors their patients and has them sign narcotic contracts and to require patients to return every 30 days would unnecessarily burden both patient and overwhelm an already packed MD schedule. I would suggest that Rxs be valid for 90 –100 days from date of issue to help both MDs and patients while still accomplishing your desired goal of closing the open-ended nature of current CII Rxs.

Thank you for considering my input and keep up the fine work you do with the Board.

1 Stadium Drive • PO Box 732 • Morgantown, WV 26507-0782 • Telephone (304) 598-4848 • Fax (304) 598-4849

State of West Virginia
Board of Pharmacy

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Office
232 Capitol Street
Charleston, West Virginia 25301

August 10, 2000

Kenneth A. Ferretti
1 Stadium Drive
P.O. Box 782
Morgantown, WV 26507-0782

Dear Mr. Ferretti :

The Board reviewed your written comments on the proposed new legislative rules regarding controlled substances at its meeting on August 7, 2000. Based upon comments received, the Board made the following amendments to the rules:

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You asked for a variance from the regulation about the required controlled substance security but such a request is premature until the regulation would actually pass the legislature and become effective. The Board appreciates your input and attempted to take into consideration all points of view to come up with regulations that meet the Board's duty to protect the public and enforce the controlled substances act.

Sincerely,

William T. Douglass, Jr.
Executive Director and
General Counsel

Memorandum

To: William T. Douglas Jr., Executive Director, WV Board of Pharmacy

From: Virginia R. Blosser, RPh #4697, PIC VBlosser
Plateau Medical Center
430 Main Street
Oak Hill, WV 25901
304-465-1782

Re: **Notice of Proposed Rules, Controlled Substances**

Date: July 26, 2000

I am currently PIC in a hospital pharmacy that does not do any outpatient dispensing. However, my question is how these proposed amendments will effect how a physician writes C2 medication orders in the hospital/Operating room setting.

Amendment #3-In the hospital setting multiple drugs are written on the physician order form and in the hospital setting this is what pharmacy uses to fill medication orders for the patient in essence it is our prescription. I feel that it would cause many problems effecting patient care if the C2 drug order had to be written on a separate order sheet.

Amendment #4-Current hospital procedure does not require the practitioner to stamp, type or print legibly when ordering a medication. In general, they sign their name in cursive. Does this regulation apply to hospital C2 medications? We also have verbal or telephone orders written and you would also have the nursing or pharmacist signature on the order in addition to the physician.

Amendment #6-In the hospital or Skilled nursing facility setting, I am assuming that a C2 medication order must be reordered at least every 30 days or does this amendment only effect outpatient written prescriptions?

In the hospital setting, the original physician order sheet is kept in the patient's chart. Our pharmacy is computerized and we also have Pyxis, we currently keep all Pyxis narcotic transactions and we print a monthly narcotic transaction report. Is this sufficient to meet controlled substance requirements in the hospital setting? We currently shred our copy of the patient's physician order sheet when we have put the orders into the computer and if any question comes up we go to the patient's chart to review the orders or medication administration record.

State of West Virginia
Board of Pharmacy

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Office
232 Capitol Street
Charleston, West Virginia 25301

August 10, 2000

Virginia Blosser
Plateau Medical Center
430 Main Street
Oak Hill, WV 25901

Dear Ms. Blosser :

The Board reviewed your written comments on the proposed new legislative rules regarding controlled substances at its meeting on August 7, 2000. Based upon comments received, the Board made the following amendments to the rules:

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The Board appreciates your input and attempted to take into consideration all points of view to come up with regulations that meet the Board's duty to protect the public and enforce the controlled substances act.

Sincerely,

William T. Douglass, Jr.
Executive Director and
General Counsel

Home Care Pharmacy, Inc.

4200 First Avenue
Suite 200
Nitro, West Virginia 25143
304-755-8460
800-847-2649

AUG -2 2000

West Virginia Board of Pharmacy
William T. Douglass, Jr., Executive Director
232 Capital Street
Charleston, WV 25301

This letter is in response to your bulletin from July, 2000 concerning new legislative rules.

Home Care Pharmacy is more of an institutional pharmacy serving long-term care, personal care and MR communities. We would like to voice our comments and concerns as follows:

Proposed Rule #2

We currently have a metal cabinet in which all Schedule II medications are stored. (Checking on the gauge) In addition to this, the cabinet is locked in a room with a regular and dead-bolt lock. We are open for inspection and possibly an exemption from the 20 gauge requirement, if possible.

Proposed Rule #3 & #4

We receive about 90-95% of our orders by fax, usually multiple orders on each page. We also receive hospital discharge summaries in many cases and, these too, have multiple orders including controlled substances. We see no possible way to comply with these rules since our orders come from hospitals and nursing homes. We are open for suggestion. We currently make a copy of all controlled substance items on these pages since all our controlled substances are stored and filled in a separate room. These orders are also filed separately for easy inspection.

We make every effort to comply with the regulations and do everything possible to prevent diversion. Our drivers sign out for each controlled substance they are delivering and are responsible to return a signed delivery receipt to the pharmacy. We will work with the board in any way possible, but we believe that the proposed legislation is geared more to retail than the institutional pharmacy.

Thank you for your attention to our responses to the new legislative rules. I can be contacted at (304) 755-8460.

Cordially,

John J. Stock
Group Director of WV

State of West Virginia
Board of Pharmacy

Phone (304) 558-0558
Fax (304) 558-0572

Office
232 Capitol Street
Charleston, West Virginia 25301

August 10, 2000

John Stock
4200 First Avenue
Suite 200
Nitro, WV 25143

Dear Mr. Stock :

The Board reviewed your written comments on the proposed new legislative rules regarding controlled substances at its meeting on August 7, 2000. Based upon comments received, the Board made the following amendments to the rules:

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Sincerely,

William T. Douglass, Jr.
Executive Director and
General Counsel

NACDS

National Association of Chain Drug Stores

M E M O R A N D U M

August 3, 2000

TO: The West Virginia Board of Pharmacy

FROM: Diane Darvey, Pharm.D., JD

SUBJECT: West Virginia Controlled Substances Act Revisions

DISCUSSION: On behalf of our members operating in West Virginia, the National Association of Chain Drug Stores (NACDS) appreciates the opportunity to provide comments on the following Board proposed rule changes.

Rule 7.6.2 would require that pharmacists refuse to fill prescriptions:

- With more than one controlled substance on the blank
- With a non-controlled substance on a blank with a controlled substance
- Unless the pharmacist determines with his or her professional judgment that the immediate necessity for the patient to receive their medication

Rule 7.6.3 would require the pharmacist to refuse to fill prescriptions that do not meet the following requirements.

- Every controlled substance prescription to have the name of the practitioner stamped, typed, or printed legibly on the face of the prescription
- Institutional prescription blanks to include the DEA number of the hospital or institution and the internal code number assigned by the hospital or institution (in lieu of the individual DEA number of the practitioner), and
- that the specific name of the prescriber be clearly distinguished on the prescription if multiple practitioners are listed on a prescription blank
- Unless the pharmacist determines in his or her professional judgment the immediate necessity for the patient to receive their medication and the pharmacist documents in a log the date, patient name, practitioner name, prescription numbers, and drugs dispensed.
- If the pharmacist continues to receive prescriptions from the same practitioner that do not comply with this rule, the pharmacist must inform the West Virginia Board of Pharmacy.

COMMENTS:

NACDS believes that these proposed regulations are problematic for a number of reasons, and that other approaches would provide better solutions.

- These regulations force the pharmacist into the role of policing physicians on technicalities such as the number of prescriptions on a blank and what is required to be stamped on a prescription blank. . and mandate that the pharmacist refuse to fill prescriptions lacking such technicalities unless there is an emergency.
- The patient would suffer unnecessary delays in obtaining their prescriptions. The pharmacist would either be forced to send the patient back to the physician to get another prescription or prescriptions or the patient would have to wait or return to the pharmacy at another time while the pharmacist contacts the physician to change the prescriptions.
- The regulations require the pharmacist to tell the physician that they have not complied with these Board of Pharmacy regulation when it should be the applicable medical licensing board's role to do so. The potential for detrimental effects on pharmacist-physician relationships exists.
- The time spent by pharmacists on the activities required by these proposed regulations would take valuable time away from duties such as patient counseling and pharmaceutical care. In this time of increasing prescriptions, workload and pharmacist shortages, NACDS believes that means other than these regulations should be explored and used.

NACDS recommends that a preferable solution is for the Board to work with the applicable medical licensing boards to apprise them of the problems the Board is seeking to cure and solicit their assistance. The applicable medical Boards are the proper regulatory bodies to inform prescribers of the problems and enforce compliance with regulations.

State of West Virginia
Board of Pharmacy

Phone (304) 558-0558
Fax (304) 558-0572

Office
232 Capitol Street
Charleston, West Virginia 25301

August 10, 2000

Diane Darvey
National Association of Chain Drug Stores
413 North Lee Street
P.O. Box 1417-D49
Alexandria, VA 22313-1480

Dear Ms. Darvey :

The Board reviewed your written comments on the proposed new legislative rules regarding controlled substances at its meeting on August 7, 2000. Based upon comments received, the Board made the following amendments to the rules:

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prescription like "1 of 2", "2 of 2", etc. to indicate to the pharmacist that a prescription in addition to the controlled prescription was issued on that same date.

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The Board appreciates your input and attempted to take into consideration all points of view to come up with regulations that meet the Board's duty to protect the public and enforce the controlled substances act.

Sincerely,

William T. Douglass, Jr.
Executive Director and
General Counsel

AUG - 2 2000

1 August 2000

MEMORANDUM FOR: West Virginia Board of Pharmacy ; 232 Capitol Street, Charleston, West Virginia, 25301

SUBJECT: Proposed Legislative Rules

1. Several of the proposed legislative rule changes are of concern to me and could have a major impact on the practice of pharmacy in the state. I feel that in particular southern West Virginia there is currently a problem with abuse and diversion of controlled substances. The proposed rule changes could potentially compound the problem and forces pharmacists into the role of monitoring/policing physician prescription writing practices.

2. The proposed rule change requiring controlled substance prescriptions be on a separate prescription form and only one controlled substance per prescription for would compound the existing problem in southern West Virginia via the only prescription presented to the pharmacy would be the one for the controlled substance. On several occasions I have had patients bring in prescriptions for an antibiotic and a controlled substance to treat an abscessed tooth and the only medication they want is the controlled substance. There are several physicians in my area the writing for controlled substances and other medications with guidance to the pharmacist that the pharmacist to fill all medications or none unless an exception to policy is granted by the physician or his agent. The proposed rule change could put me in a position of potentially filling a prescription without the authorization of the physician if the only prescriptions that are presented for filling are the controlled substance prescriptions and increase the potential for diversion of controlled substances.

3. The rule requiring physicians to have their name stamped, typed, or printed legibly on the face of the prescription will not work. It is impossible to get the physicians to put their DEA number on the prescription the majority of the time. The pharmacist is responsible and held accountably to insure the DEA number is on the prescription along with the address of the patient are on a controlled substance prescription so a lot of pharmacists have to fill in the information so they will not be in violation of the law. This will only serve to increase the amount of information the pharmacist has to add to the prescription.

4. The rule requiring pharmacists to refuse to fill a prescription that does not comply with the rules only serves to punish the patient and the pharmacist for laziness on behalf of the physician. The patient is inconvenienced by being forced to return the prescription to the physician or the pharmacist for having to fill out the information for the physician. If the

pharmacist refuses to fill the prescription he or she opens themselves up to verbal abuse by the patient and if they work for a chain pharmacy to complaints to their corporate headquarters particularly if this occurred after the physicians regular office hours. The end result could also be loss of business for any pharmacy abiding by the rules. I know it would have an impact on my business because I abide the rules. The requirement to contact the physician would require an audit trail verifying the pharmacist did in fact contact the physician. I have called physicians regarding the absence of their printed name or DEA number on a schedule II prescription to verify if I have guessed correctly as to who wrote the prescription and remind them of their legal requirements and they do not care or are rude in their response. The requirement to contact the Board of Pharmacy is appropriate and prudent but only would have an impact on pharmacists. If the Board of Pharmacy had the ability to fine a physician for prescription violations then the legislative rule would have some impact on the prescribing physician. Though the Board of Pharmacy has a good track record of overseeing the practice of pharmacy in the state, I feel considering the current situation regarding controlled substances in southern West Virginia the Board of Medicine may not hold a similar view. This legislative rule would increase the work load of pharmacists and the Board of Pharmacy inspectors with no impact on non compliant physicians. The majority of the physicians in my area of the state are highly competent professionals and would try to comply with the new rules but some would be non compliant. The only ones that could be held accountable and punishable would be pharmacists. I feel the main reason Pharmacy is the most trusted profession is that it is the most regulated profession. At times, that is not necessarily a bad thing.

5. Thank you for the opportunity to add my input to the proposed legislative rules. If you have any questions of me feel free to call me at 304-589-3315.

James D. Bellamy; RPH
521 Jesse James Drive
Rock, WV 24747

State of West Virginia
Board of Pharmacy

Phone (304) 558-0558
Fax (304) 558-0572

Office
232 Capitol Street
Charleston, West Virginia 25301

August 10, 2000

James Bellamy
521 Jesse James Drive
Rock, WV 24747

Dear Mr. Bellamy :

The Board reviewed your written comments on the proposed new legislative rules regarding controlled substances at its meeting on August 7, 2000. Based upon comments received, the Board made the following amendments to the rules:

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Sincerely,

William T. Douglass, Jr.
Executive Director and
General Counsel

Raleigh Psychiatric Services, Inc.

P.O. Box 1025
Beckley, West Virginia 25802
Phone 252-8409
Fax 252-0022

M. KHALID HASAN, M.D., F.A.P.A.
M.R.C. Psych. (UK), F.R.C.P. (C)

Diplomate American Board of Psychiatry & Neurology
Fellow, American Psychiatric Association
Diplomate, Geriatric Psychiatry
Diplomate, Addiction Psychiatry
Diplomate, Managed Care
Diplomate, Forensic Psychiatry

NADEEM AHMED, M.D.
Psychiatrist

John H. Johnson, Jr., M.S.W., B.C.D., C.A.C.
Licensed Independent Clinical Social Worker

Dreama G. Baker, M.A.
Licensed Psychologist

Roger P. Mooney, M.A., Ed. D., N.C.C., L.P.C.
Licensed Psychologist

Debra R. Mooney, M.S.N., R.N., C.S.
Certified Family Nurse Practitioner

Francie E. Anderson, M.A., L.P.C.
Licensed Professional Counselor

July 31, 2000

WV Board of Pharmacy
232 Capitol Street
Charleston, West Virginia 25301

RE: Proposed Pharmacy Changes:

Dear Sirs:

This letter is concerning the proposed pharmacy changes with the comment period of July 2000. The Board Review, Volume 1, No. 1 July 2000, listed several proposed changes. The one that is most disturbing and not practical or acceptable is No. 3, in which each controlled substance must be written on a separate blank and no non-controlled substance can be ordered on a blank with a controlled substance. The reasons I am protesting are as follows:

1. Compliance will become a real issue, as patients with a controlled substance and antidepressant will only get the controlled substance filled and not the antidepressant; and neither the pharmacist nor I will be aware whether it has been filled or not. This has been our experience with patients with substance abuse.

2. This will be an enormous waste of resources and time when two or three substances can be written on the same prescription. At the same time the clients can be monitored.

I feel this is a poor choice of dealing with prescriptions and would ask that this not be enacted. Thank you.

Sincerely,

M. Khalid Hasan, M.D., F.A.P.A.
Diplomate,
American Board of Psychiatry and Neurology

Nadeem Ahmed, M.D.

Debra R. Mooney, MSN, RN, CS
Certified Family Nurse Practitioner
Certified Clinical Nurse Specialist

MKH:TETC01

State of West Virginia
Board of Pharmacy

Phone (304) 558-0558
Fax (304) 558-0572

Office
232 Capitol Street
Charleston, West Virginia 25301

August 10, 2000

M. Khalid Hasan, M.D.
Raleigh Psychiatric Services, Inc.
P.O. Box 1025
Beckley, WV 25802

Dear Dr. Hasan :

The Board reviewed your written comments on the proposed new legislative rules regarding controlled substances at its meeting on August 7, 2000. Based upon comments received, the Board made the following amendments to the rules:

1. The time period that a prescription for a Schedule II controlled substance is valid was changed from 30 days to 90 days from the date issued.

2. The rule requiring each controlled substance prescription be written on a separate blank and no non-controlled substance be ordered on a blank with a controlled substance is being written so that it applies only to outpatient prescriptions. The rule will also exempt prescriptions written for patients of an institutional facility. Institutional facility is defined in §15-1-2.1.19. (p. 63 of pharmacy law book) and includes hospital, convalescent home, nursing home, extended care facility, mental health facility, hospice, etc.

Some people stated their concerns that the requirement of separate blanks for each controlled substance would allow "drug seekers" to only have the controlled drug filled and not obtain the other drugs such as antibiotics. The Board understood the concern but feels that the benefits of reduction in errors outweigh the problems posed by non-compliant patients. In addition, physicians with such a concern about their patients can write notations upon the prescription like "1 of 2", "2 of 2", etc. to indicate to the pharmacist that a prescription in addition to the controlled prescription was issued on that same date.

Some people stated their concerns about the pharmacist having to police the physicians that do not comply with the regulations and affecting patient care by having to refuse to fill a prescription not issued correctly. Patient care does not have to suffer because the pharmacist can go ahead and fill the prescription and then must document this information. The pharmacist is to contact the prescriber about the prescriptions not written according to the rule; this is a means to correct the problem at an informal level. If the problems continue, then the pharmacist is to contact the Board of Pharmacy, who will then get involved by either corresponding with the prescriber or filing a formal complaint with the appropriate licensing board. Once this rule is passed, it is very important that physicians by educated about the new requirements and the Board of Pharmacy will attempt to work with the medical licensing boards to accomplish this.

The Board appreciates your input and attempted to take into consideration all points of view to come up with regulations that meet the Board's duty to protect the public and enforce the controlled substances act.

Sincerely,

William T. Douglass, Jr.
Executive Director and
General Counsel

STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Cecil H. Underwood
Governor

Bureau for Medical Services
Policy Units
350 Capitol Street, Room 251
Charleston, West Virginia 25301-3707
Telephone: (304) 558-1753 - Fax: (304) 558-1542

Joan E. Ohl
Secretary

August 4, 2000

William T. Douglas, Jr.
Executive Director and General Counsel
West Virginia State Board of Pharmacy
232 Capitol Street
Charleston, West Virginia 25301

Dear Mr. Douglas:

This letter responds to the proposed Rules and Regulations of the Board of Pharmacy for the Uniform Controlled Substances Act.

As Pharmacy Coordinator for the State of West Virginia's Medicaid agency, I would like to recommend that prescribers be required to supply diagnosis or diagnosis code information on all controlled substance prescriptions. Because federal statute requires pharmacists to offer counseling to Medicaid patients concerning the proper use of medications, and pharmacists are often required to supply diagnosis information for prior authorization purposes, it is imperative that pharmacists have this information available to them. Knowing the intended use for prescribed medications will decrease calls to physicians' offices and give pharmacists valuable information to more effectively offer their services to improve patient outcomes.

Thank you for the opportunity to comment on the proposed regulations. Please let me know if you have any questions or if I can be of any help to the Board.

Sincerely,

Peggy A. King

Peggy A. King, R.Ph.
Pharmacy Coordinator

State of West Virginia
Board of Pharmacy

Phone (304) 558-0558
Fax (304) 558-0572

Office
232 Capitol Street
Charleston, West Virginia 25301

August 10, 2000

Peggy King, Pharmacy Coordinator
Bureau for Medical Services Policy Units
350 Capitol Street, Room 251
Charleston, WV 25301-3707

Dear Peggy :

The Board reviewed your written comments on the proposed new legislative rules regarding controlled substances at its meeting on August 7, 2000. Based upon comments received, the Board made the following amendments to the rules:

1. The time period that a prescription for a Schedule II controlled substance is valid was changed from 30 days to 90 days from the date issued.

2. The rule requiring each controlled substance prescription be written on a separate blank and no non-controlled substance be ordered on a blank with a controlled substance is being written so that it applies only to outpatient prescriptions. The rule will also exempt prescriptions written for patients of an institutional facility. Institutional facility is defined in §15-1-2.1.19. (p. 63 of pharmacy law book) and includes hospital, convalescent home, nursing home, extended care facility, mental health facility, hospice, etc.

The Board agreed with your suggestion that it would be quite beneficial to require the diagnosis or diagnosis codes upon controlled substance prescriptions. However, the Board felt that this requirement should be sought through a separate statutory change so as not to jeopardize this set of regulations due to the expected opposition by the medical community to such a change.

Some people stated their concerns that the requirement of separate blanks for each controlled substance would allow "drug seekers" to only have the controlled drug filled and not obtain the other drugs such as antibiotics. The Board understood the concern but feels that the benefits of reduction in errors outweigh the problems posed by non-compliant patients. In addition, physicians with such a concern about their patients can write notations upon the prescription like "1 of 2", "2 of 2", etc. to indicate to the pharmacist that a prescription in addition to the controlled prescription was issued on that same date.

Some people stated their concerns about the pharmacist having to police the physicians that do not comply with the regulations and affecting patient care by having to refuse to fill a prescription not issued correctly. Patient care does not have to suffer because the pharmacist can go ahead and fill the prescription and then must document this information. The pharmacist is to contact the prescriber about the prescriptions not written according to the rule; this is a means to correct the problem at an informal level. If the problems continue, then the pharmacist is to contact the Board of Pharmacy, who will then get involved by either corresponding with the prescriber or filing a formal complaint with the appropriate licensing board. Once this rule is passed, it is very important that physicians by educated about the new requirements and the Board of Pharmacy will attempt to work with the medical licensing boards to accomplish this.

The Board appreciates your input and attempted to take into consideration all points of view to come up with regulations that meet the Board's duty to protect the public and enforce the controlled substances act.

Sincerely,

William T. Douglass, Jr.
Executive Director and
General Counsel

Date: August 4, 2000

To: WV Board of Pharmacy

From: Stephen Small, RPh, MS
1006 Brettwald Drive
Morgantown, WV 26508

RE: Comments on Proposed Uniform Controlled Substances Act

To Whom It May Concern:

Section 7.5.1. Line 10-11. "Electronic Printer" should be added to the section which states how a prescription can be written.

Section 7.6.3

As we know the Board of Pharmacy's purpose is to protect the public. Therefore I would like to request that the proposed legislation be amended to add the requirement that the diagnosis for the use of the medication be stated on the face of the prescription. This could be done either in script or by using an approved code for the disease state.

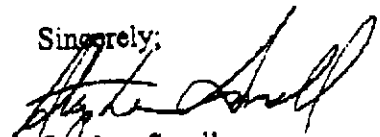
In Section 7.4.1 it is stated that the dispensing pharmacist holds a corresponding responsibility for the proper prescribing and dispensing of controlled substances. My question of this law is: How can the pharmacist be held legally responsible for the proper prescribing without knowing for what purpose the prescriber is using the medication?

As you also know, a professional role of a pharmacist is to counsel the patient on the proper use and expected outcomes of the medication. The Board of Pharmacy, for the public's safety, should ensure that the pharmacist has the proper information from the prescriber to enhance this counseling role of the pharmacist.

Another issue involved in requiring the diagnosis on the prescription is "Medication Errors". It has been determined in many studies that a greater proportion of medication errors can be averted when the patient's diagnosis is presented to the dispensing pharmacist. This provides another avenue by which the Board of Pharmacy can protect the public's safety.

On the "Medication Error" issue, I very strongly feel that the Board of Pharmacy should require the diagnosis be documented on **all** prescriptions, not just controlled substances. The issue of patient confidentially has been the caveat for not writing the diagnosis on the prescription, but in my opinion all health care providers, including the professional pharmacist, must have the appropriate information to guarantee the appropriate and safe clinical outcome of the patient.

Sincerely;



Stephen Small

State of West Virginia
Board of Pharmacy

Phone (304) 558-0558
Fax (304) 558-0572

Office
232 Capitol Street
Charleston, West Virginia 25301

August 10, 2000

Stephen Small
1006 Brettwald Drive
Morgantown, WV 26508

Dear Stephen :

The Board reviewed your written comments on the proposed new legislative rules regarding controlled substances at its meeting on August 7, 2000. Based upon comments received, the Board made the following amendments to the rules:

1. The time period that a prescription for a Schedule II controlled substance is valid was changed from 30 days to 90 days from the date issued.

2. The rule requiring each controlled substance prescription be written on a separate blank and no non-controlled substance be ordered on a blank with a controlled substance is being written so that it applies only to outpatient prescriptions. The rule will also exempt prescriptions written for patients of an institutional facility. Institutional facility is defined in §15-1-2.1.19. (p. 63 of pharmacy law book) and includes hospital, convalescent home, nursing home, extended care facility, mental health facility, hospice, etc.

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obtain the other drugs such as antibiotics. The Board understood the concern but feels that the benefits of reduction in errors outweigh the problems posed by non-compliant patients. In addition, physicians with such a concern about their patients can write notations upon the prescription like "1 of 2", "2 of 2", etc. to indicate to the pharmacist that a prescription in addition to the controlled prescription was issued on that same date.

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The Board appreciates your input and attempted to take into consideration all points of view to come up with regulations that meet the Board's duty to protect the public and enforce the controlled substances act.

Sincerely,

William T. Douglass, Jr.
Executive Director and
General Counsel

Keith Foster, R.Ph.

COLONY DRUG

Patty Johnston, R.Ph.

2801 Robert C. Byrd Drive
Beckley, WV 25801
(304) 252-5305
FAX (304) 253-4281

August 3, 2000

Mr. Robert Davis
West Virginia Board of Pharmacy
White Sulphur Springs, WV

Dear Mr. Davis:

This is in response to the Board of Pharmacy's request for comment on the proposed new controlled substance rules.

We are in strong agreement that CII prescriptions should be written one drug on one blank. However, we would propose that CIII-V drugs could be written more than one RX per blank. We have several physicians who require patients to have all RXs on the blank filled or none at all, preventing them from picking and choosing controlled substances over other maintenance medications.

The Board's proposal to reduce the time limit for a schedule II RX to be valid to 30 days is a good idea. Most CII medications are of a timely nature and if not needed within 30 days would necessitate the patient being re-evaluated by the prescriber.

Another issue we would like to see the Board address is that of large teaching hospitals with prescibers who fail to write legibly, indicate DEA numbers, and phone numbers on their RX blanks. This creates a great burden on the pharmacist who must track down the prescriber to verify or clarify the patient's prescription. A case in point, prescription blanks from Charleston Area Medical Center do not have phone numbers on them or indicate the division from which they originated.

We hope these comments will help you as you discuss these new proposals.

Sincerely,

Patty Johnston, R.Ph. PIC

Keith Foster, R.Ph.

State of West Virginia
Board of Pharmacy

Phone (304) 558-0558
Fax (304) 558-0572

Office
232 Capitol Street
Charleston, West Virginia 25301

August 10, 2000

Patty Johnston
Colony Drug
2801 Robert C. Byrd Drive
Beckley, WV 25801

Dear Ms. Johnston:

The Board reviewed your written comments on the proposed new legislative rules regarding controlled substances at its meeting on August 7, 2000. Based upon comments received, the Board made the following amendments to the rules:

1. The time period that a prescription for a Schedule II controlled substance is valid was changed from 30 days to 90 days from the date issued.

2. The rule requiring each controlled substance prescription be written on a separate blank and no non-controlled substance be ordered on a blank with a controlled substance is being written so that it applies only to outpatient prescriptions. The rule will also exempt prescriptions written for patients of an institutional facility. Institutional facility is defined in §15-1-2.1.19. (p. 63 of pharmacy law book) and includes hospital, convalescent home, nursing home, extended care facility, mental health facility, hospice, etc.

Some people stated their concerns that the requirement of separate blanks for each controlled substance would allow "drug seekers" to only have the controlled drug filled and not obtain the other drugs such as antibiotics. The Board understood the concern but feels that the benefits of reduction in errors outweigh the problems posed by non-compliant patients. In addition, physicians with such a concern about their patients can write notations upon the prescription like "1 of 2", "2 of 2", etc. to indicate to the pharmacist that a prescription in addition to the controlled prescription was issued on that same date.

Some people stated their concerns about the pharmacist having to police the physicians that do not comply with the regulations and affecting patient care by having to refuse to fill a prescription not issued correctly. Patient care does not have to suffer because the pharmacist can go ahead and fill the prescription and then must document this information. The pharmacist is to contact the prescriber about the prescriptions not written according to the rule; this is a means to correct the problem at an informal level. If the problems continue, then the pharmacist is to contact the Board of Pharmacy, who will then get involved by either corresponding with the prescriber or filing a formal complaint with the appropriate licensing board. Once this rule is passed, it is very important that physicians by educated about the new requirements and the Board of Pharmacy will attempt to work with the medical licensing boards to accomplish this.

The Board appreciates your input and attempted to take into consideration all points of view to come up with regulations that meet the Board's duty to protect the public and enforce the controlled substances act.

Sincerely,

William T. Douglass, Jr.
Executive Director and
General Counsel

CONTACT MEDICAL CENTER

CONTACT PHARMACY

2233 S. KANAWHA ST., BECKLEY, WV 25801

To: Robert Davis, Board of Pharmacy Inspector
From: Karen Reed, R.Ph.
RE: Proposed Changes to Controlled Substances Rules/Regs

As you know, I prefer my Schedule II inventory dispersed among other inventory. I hope if a break-in occurs, the time to find the drugs would match the police call time of the alarm system. If a cabinet is used, it should be impossible to remove or break into prior to police response.

I was pleased with the idea that controlled substances would be written on separate blanks. For me, it gives more security and legitamacy to the prescription if a question arises if it is in the doctor's own handwriting and DATED. Some pharmacists are concerned that other prescriptions (i.e. antibiotics, inhalers, muscle relaxants) will not be filled since they are on separate blanks: that happens now. We are forced to write off the narcotic and that brings us back to the issue I mentioned above. Another concern is that patients won't be able to keep up with ALL those prescriptions. Its better to put 7 or 8 drugs on 1 blank. Patients have to accept some responsibility. Multiple prescriptions on one blank lead to errors and jeopordize patient safety.

The rules will take time to learn. I would not refuse prescriptions at first but, send a letter reminding them of changes and asking their help in complying. I see this as a great help in preventing a schedule II and another controlled or non-controlled drug on the same blank. How do you properly file those?

I am also in favor of the practitioner's name being stamped, typed, or printed on the prescription. How much patient/pharmacist time

is spent trying to find out who wrote the prescription? Often residents have moved to another training facility before a prescription is filled and we have to locate them in another WV town. It is much easier to find someone if we know their name.

In my practice, a 30 day time limit on Schedule II drugs is more than generous. These drugs are intended for acute use or chronic pain management with close monitoring and restrictions. These prescriptions therefore should be filled in a timely manner. You mentioned hospice patients needing a longer time frame. My feeling (maybe lack of understanding) is hospice patients should be reevaluated for pain management at least every 30 days. Perhaps I need to understand that practice better, but the hospice patients I have had experience varying degrees of pain and require adjustments regularly. Unfortunately, I have had other family members try to obtain prescriptions for loved ones for their own personal or illegal use or assisted suicide.

New rules always bring about some adjustment periods. I appreciate your attention to these controlled substance issues.I continue to be concerned by the increased hydrocodone use/abuse and the practitioners prescribing outside their realm of practice (i.e. podiatrists, osteopaths and their pain management techniques).

Please do not hesitate to contact me if I can be of any assistance to you or anyone else on the Board.

State of West Virginia
Board of Pharmacy

Phone (304) 558-0558
Fax (304) 558-0572

Office
232 Capitol Street
Charleston, West Virginia 25301

August 10, 2000

Karen Reed
Contact Pharmacy
2233 S. Kanawha St.
Beckley, WV 25801

Dear Ms. Reed:

The Board reviewed your written comments on the proposed new legislative rules regarding controlled substances at its meeting on August 7, 2000. Based upon comments received, the Board made the following amendments to the rules:

1. The time period that a prescription for a Schedule II controlled substance is valid was changed from 30 days to 90 days from the date issued.

2. The rule requiring each controlled substance prescription be written on a separate blank and no non-controlled substance be ordered on a blank with a controlled substance is being written so that it applies only to outpatient prescriptions. The rule will also exempt prescriptions written for patients of an institutional facility. Institutional facility is defined in §15-1-2.1.19. (p. 63 of pharmacy law book) and includes hospital, convalescent home, nursing home, extended care facility, mental health facility, hospice, etc.

Some people stated their concerns that the requirement of separate blanks for each controlled substance would allow "drug seekers" to only have the controlled drug filled and not obtain the other drugs such as antibiotics. The Board understood the concern but feels that the benefits of reduction in errors outweigh the problems posed by non-compliant patients. In addition, physicians with such a concern about their patients can write notations upon the prescription like "1 of 2", "2 of 2", etc. to indicate to the pharmacist that a prescription in addition to the controlled prescription was issued on that same date.

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The Board appreciates your input and attempted to take into consideration all points of view to come up with regulations that meet the Board's duty to protect the public and enforce the controlled substances act.

Sincerely,

William T. Douglass, Jr.
Executive Director and
General Counsel

APPALACHIAN REGIONAL HEALTHCARE

SERVING THE CENTRAL APPALACHIAN COMMUNITIES OF KENTUCKY, VIRGINIA & WEST VIRGINIA

August 4, 2000

Robert G. Davis
PO Box 247
White Sulphur Springs, WV 24986

Dear Mr. Davis:

As requested, our staff (outpatient, institutional, clinical, and administrative) compiled comments and questions regarding the new legislative rules about controlled substances as proposed by the Board. They are as follows:

1. *Rule automatically adopts any changes to the federal rules about controlled substances.* This will eliminate the need to determine the more strict rule which will reduce confusion. How will this impact current discrepancies such as medications scheduled by WV which are not federally controlled (e.g. Soma, Stadol, etc.)? Will this rule only apply to future changes?

2. *Storage of schedule II drugs.* The ability to disperse stock in lieu of storage in the metal cabinet is appreciated. In institutional settings where controlled substances are kept in various areas, approval of the Board will be required for such items as medication carts, anesthesia boxes, and crash carts which may not meet the 20 gauge requirement.

3. *Each controlled substance prescription must be written on a separate blank.* We have no opinion here. Physician compliance is a concern. We assume that this does not refer to medication orders within the institutional setting.

4. *Every controlled substance prescription must have the name of the practitioner stamped, typed, or printed legibly on the face of the prescription.* This is necessary and appreciated. We see this as mainly impacting group and hospital practices in which an "institutional blank" is used.

306 Stanaford Road
Beckley, West Virginia 25801
(304) 253-8000

5. *If a pharmacist receives a prescription that does not conform to the rule, then the pharmacist must refuse to fill it.* Some pharmacists are uncomfortable "enforcing" this rule. The time that will inevitably be required to inform non-compliant physicians will be significant. Substantial physician education is recommended.

6. *A prescription for a Schedule II controlled substance is valid for 30 days from the date issued.* Thank you.

If additional information is required, please do not hesitate to call.

Sincerely,

C-V-st

Chris Vaught, R.Ph.
Director, Pharmacy Services

State of West Virginia
Board of Pharmacy

Phone (304) 558-0558
Fax (304) 558-0572

Office
232 Capitol Street
Charleston, West Virginia 25301

August 10, 2000

Chris Vaught
36 Avocet Way
Beckley, WV 25801

Dear Mr. Vaught:

The Board reviewed your written comments on the proposed new legislative rules regarding controlled substances at its meeting on August 7, 2000. Based upon comments received, the Board made the following amendments to the rules:

1. The time period that a prescription for a Schedule II controlled substance is valid was changed from 30 days to 90 days from the date issued.

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The Board appreciates your input and attempted to take into consideration all points of view to come up with regulations that meet the Board's duty to protect the public and enforce the controlled substances act.

Sincerely,

William T. Douglass, Jr.
Executive Director and
General Counsel

Woods Pharmacy Inc.
400 Virginia Street
Oak Hill, WV 25901
304-469-2923

5 August 2008

Re: Davis...

Dan and I discussed the proposed legislative rules. Our opinion and concern follow.

1. Adopt changes to federal law – Good

2. Storage requirements – Good

3. Separate blanks – Great idea – May be hard to control, especially for out of state physicians and for physicians already in the habit of writing multiples.

4. Physician name stamped or printed – Please, yes!

5. This gives us a way to put the patients name, which is important. It allows for filling an Rx that does not conform to the rule proposed in #3 above. As far as having to contact the physician, this is not always practical or possible. Example – Resident physician from Duke University or out of town specialist in a large group practice. Much time to track them down & the expense of a prolonged long distance call are unacceptable to me.

6. Fill time limit – Would rather it be 60 or 90 days

Susan Thorn

State of West Virginia
Board of Pharmacy

Phone (304) 558-0558
Fax (304) 558-0572

Office
232 Capitol Street
Charleston, West Virginia 25301

August 10, 2000

Susan Woods
Woods Pharmacy, Inc.
400 Virginia Street
Oak Hill, WV 25901

Dear Ms. Woods:

The Board reviewed your written comments on the proposed new legislative rules regarding controlled substances at its meeting on August 7, 2000. Based upon comments received, the Board made the following amendments to the rules:

1. The time period that a prescription for a Schedule II controlled substance is valid was changed from 30 days to 90 days from the date issued.

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Sincerely,

William T. Douglass, Jr.
Executive Director and
General Counsel

ALDERMAN'S PHARMACY
RT. 92 N, P.O. BOX 371
WHITE SULPHUR SPRINGS, WV 24986

PHONE 304-536-2454

Mr. Bob Davis,

My opinions on some of the topics we discussed are included for this letter.

I believe that pharmacies should be allowed to distribute controlled substances throughout the regular inventory. I believe that it would take a robber more time to find the controlled drugs if he has to search for them in the regular inventory. By taking more time it increases the possibility of him getting caught.

On the topic of multiple prescriptions on one blank especially (II)'s written with non controlled drugs, I believe that only one prescription per blank should be allowed. Transcribing errors will be reduced. Errors in interpreting the prescription will also be reduced. Most all of us have seen prescriptions where the physicians has written 3, 4, or 5 Drugs on one blank and know how hard that is to read. This rule should not be enforced by the pharmacist, it should be up to the Board of Medicine to enforce and

ALDERMAN'S PHARMACY
RT. 92 N, P.O. BOX 371
WHITE SULPHUR SPRINGS, WV 24986

PHONE 304-536-2454

educate the physicians.

I believe lunch breaks are a good idea. Right now I am considering implementing this policy in my pharmacy. It is a matter of educating the physicians and patients about our new policy. There is no reason why we as professionals should not be allowed a break. We need a rule concerning breaks. The store would have to close the pharmacy for a specific period of time. If a pharmacy has 2 or more pharmacists working at the same time (How many pharmacies do these days?) there would have to be a ruling on that. Personally I believe the pharmacy should be closed for a break no matter how many pharmacists on duty. This would show the public and other professionals that the rule is mandated by the Board of Pharmacy and there is no confusion on why one pharmacy is open and the other is closed.

Thank you.
Pharmacist Alderman, R.Ph.

ALDERMAN'S PHARMACY
RT. 92 N, P.O. BOX 371
WHITE SULPHUR SPRINGS, WV 24986

PHONE 304-536-2454

Mr. Bob Evans,

My opinion on the Time limit for CII prescriptions is that it should be 60 days.

I believe that a requirement for a physician to print or stamp name on the blanks is good. If the physician prints his name it should be printed legibility.

Thank you,
Bruce Alderman, RPh.

State of West Virginia
Board of Pharmacy

Phone (304) 558-0558
Fax (304) 558-0572

Office
232 Capitol Street
Charleston, West Virginia 25301

August 10, 2000

Bruce Alderman
Alderman's Pharmacy
Rt. 92 N, P.O. Box 371
White Sulphur Springs, WV 24986

Dear Mr. Alderman:

The Board reviewed your written comments on the proposed new legislative rules regarding controlled substances at its meeting on August 7, 2000. Based upon comments received, the Board made the following amendments to the rules:

1. The time period that a prescription for a Schedule II controlled substance is valid was changed from 30 days to 90 days from the date issued.

2. The rule requiring each controlled substance prescription be written on a separate blank and no non-controlled substance be ordered on a blank with a controlled substance is being written so that it applies only to outpatient prescriptions. The rule will also exempt prescriptions written for patients of an institutional facility. Institutional facility is defined in §15-1-2.1.19. (p. 63 of pharmacy law book) and includes hospital, convalescent home, nursing home, extended care facility, mental health facility, hospice, etc.

The Board appreciated your comments regarding the need for lunch breaks and agrees that it is an issue to address through possible legislation but that concept was not included with these proposed regulations which deal with controlled substances. If that subject is addressed at another time your suggestions will be duly considered.

Some people stated their concerns that the requirement of separate blanks for each controlled substance would allow "drug seekers" to only have the controlled drug filled and not

obtain the other drugs such as antibiotics. The Board understood the concern but feels that the benefits of reduction in errors outweigh the problems posed by non-compliant patients. In addition, physicians with such a concern about their patients can write notations upon the prescription like "1 of 2", "2 of 2", etc. to indicate to the pharmacist that a prescription in addition to the controlled prescription was issued on that same date.

Some people stated their concerns about the pharmacist having to police the physicians that do not comply with the regulations and affecting patient care by having to refuse to fill a prescription not issued correctly. Patient care does not have to suffer because the pharmacist can go ahead and fill the prescription and then must document this information. The pharmacist is to contact the prescriber about the prescriptions not written according to the rule; this is a means to correct the problem at an informal level. If the problems continue, then the pharmacist is to contact the Board of Pharmacy, who will then get involved by either corresponding with the prescriber or filing a formal complaint with the appropriate licensing board. Once this rule is passed, it is very important that physicians by educated about the new requirements and the Board of Pharmacy will attempt to work with the medical licensing boards to accomplish this.

The Board appreciates your input and attempted to take into consideration all points of view to come up with regulations that meet the Board's duty to protect the public and enforce the controlled substances act.

Sincerely,

William T. Douglass, Jr.
Executive Director and
General Counsel

The Pill Box Pharmacy and Gift Shoppe, Inc.
P O BOX 308, MAIN STREET
FRANKLIN WEST VIRGINIA 26807
TELEPHONE [illegible]

8/5/00

Mr Bob Davis:

Below are my opinions on the issues you called about on Thurs.

(1) I have no problem with the Board ruling on the specifications for a locked box for Class II drug storage as long as we still have the option to disperse them among our stock To me dispersal is still the best means to use in the event of a robbery.

(2) I feel the Board does need to rule on physicians writing multiple scripts on one prescription blank especially when controls & non-controls are mixed. It is difficult enough to read some of their writing much less when they write smaller to crowd more on the prescription blank. Since many of us file Class 3, 4, C5's separately it forces us to remove the non-controls & deal with them separately. Not many mds do list multiple Rx's but Dr. Sharp in Marlington is really bad for this. The big question is how do you get it enforced??

The Pill Box Pharmacy and Gift Shoppe, Inc.
P.O. BOX 908, MAIN STREET
FRANKLIN, WEST VIRGINIA 26807
TELEPHONE 304-358-2867

(3) I HAVE NO PROBLEM WITH A TIME LIMIT TO FILL CLASS II SCRIPTS BECAUSE I WOULD NOT FILL SUCH A SCRIPT IF IT WERE MORE THAN 30 DAYS OLD WITHOUT CONSULTING THE MD TO DETERMINE IF IT WAS STILL NEEDED.

(4) ON THE ISSUE OF DESIGNATED LUNCH TIME FOR PHARMACISTS, YOU KNOW I AM A BELIEVER AS IN ALL THE 32 YEARS I HAVE BEEN HERE I HAVE ALWAYS CLOSED FOR LUNCH FOR 45 MINUTES. PEOPLE LEARN TO ADAPT TO YOUR HOURS & NO ONE EVER QUESTIONS WHY I DO BUT RITE AID DOESN'T WE ARE PROFESSIONALS - DO OTHE PROFESSIONALS TAKE A LUNCH BREAK. EVEN UNION WORKERS DO.

THE TERM LUNCH BREAK DESIGNATES TWO THINGS FIRST THAT LUNCH IS AN ENJOYABLE EXPERIENCE AND NOT SOMETHING THAT YOU GOBBLE DOWN BETWEEN SCRIPTS OR EAT COLD BECAUSE YOU COULDN'T GET TO IT IN TIME. WHEN YOU LOOK BACK ON YOUR CAREER AT RETIREMENT WAS THE INGESTION WORTH FILLING EVERYONE'S WISHES AT THAT MOMENT.

SECOND IS THE WORD BREAK. PHARMACISTS

The Pill Box Pharmacy and Gift Shoppe, Inc.
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FRANKLIN, WEST VIRGINIA 26807
TELEPHONE [illegible]

HAVE SO MANY ADDED RESPONSIBILITIES TO CONCENTRATE ON NOW VERSUS WHEN I FIRST STARTED. SIGNATURE LOGS - 3RD PARTY EDITS - SPECIAL AUTHORIZATIONS - FORMULARY CONSIDERATIONS BOARD MANDATED DOCUMENTATION ALL REQUIRE OUR UTMOST CONCENTRATION. IN A BUSY STORE IF YOU ARE THE ONLY PHARMACIST, HOW CAN YOU BE EXPECTED TO ZERO-IN ALL DAY. TO ME THAT IS A PRIME SOURCE FOR ERROR. MY LUNCH BREAK ALLOWS ME TO GET AWAY & GET MY MIND ON OTHER THINGS WHICH I THINK MAKES ME A BETTER, LESS FRAZZLED PHARMACIST FOR THE REMAINDER OF THE DAY.

WE AS PHARMACISTS HAVE SOLD OURSELVES OUT WHEN WE HAVE CATERED TO THE PUBLIC TO THE POINT THAT WE DON'T TREAT OURSELVES TO THE BASIC RIGHT OF A QUIET, UNINTERRUPTED LUNCH.

LARRY REXRODE, RPh

State of West Virginia
Board of Pharmacy

Phone (304) 558-0558
Fax (304) 558-0572

Office
232 Capitol Street
Charleston, West Virginia 25301

August 10, 2000

Larry Rexrode
Pill Box Pharmacy
P.O. Box 908, Main St.
Franklin, WV 26807

Dear Mr. Rexrode:

The Board reviewed your written comments on the proposed new legislative rules regarding controlled substances at its meeting on August 7, 2000. Based upon comments received, the Board made the following amendments to the rules:

1. The time period that a prescription for a Schedule II controlled substance is valid was changed from 30 days to 90 days from the date issued.

2. The rule requiring each controlled substance prescription be written on a separate blank and no non-controlled substance be ordered on a blank with a controlled substance is being written so that it applies only to outpatient prescriptions. The rule will also exempt prescriptions written for patients of an institutional facility. Institutional facility is defined in §15-1-2.1.19. (p. 63 of pharmacy law book) and includes hospital, convalescent home, nursing home, extended care facility, mental health facility, hospice, etc.

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obtain the other drugs such as antibiotics. The Board understood the concern but feels that the benefits of reduction in errors outweigh the problems posed by non-compliant patients. In addition, physicians with such a concern about their patients can write notations upon the prescription like "1 of 2", "2 of 2", etc. to indicate to the pharmacist that a prescription in addition to the controlled prescription was issued on that same date.

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The Board appreciates your input and attempted to take into consideration all points of view to come up with regulations that meet the Board's duty to protect the public and enforce the controlled substances act.

Sincerely,

William T. Douglass, Jr.
Executive Director and
General Counsel

State of West Virginia
Board of Pharmacy

Phone (304) 558-0558
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Office
232 Capitol Street
Charleston, West Virginia 25301

Unable to respond to two written comments received:

1. **Joe Anderson- no return address and cannot locate licensed pharmacist by that name.**
2. **Anonymous written comment- no name or return address**

Mr. Douglas,

I shake my head in wonderment each time I see a new proposed legislative rule from the board of pharmacy. The new rule concerning controlled substances is, by far, the most ignorant piece of legislation I've read. I do not believe there is any purpose to this legislation other than to save auditors a few minutes in their "search" of pharmacy records. The only thing this piece of legislation will guarantee is many incredulous, irritated physician phone calls not to the board of pharmacy, but to already overworked pharmacists. We already spend hours on the phone each day dealing with petty things, this new rule would just add to that problem. The board of pharmacy should be concerned about pertinent issues to the "practice" of pharmacy such as workplace conditions, third-party insurance dicatorships, and decreasing margins. Don't create new rules for the sake of showing the public the board is "doing something." Concentrate on the real issues that are destroying pharmacy and decreasing the number of young people who won't even consider becoming a pharmacist.

A concerned pharmacist

To whom it may concern:

This is in regard to the proposed new rule that was sent out to retail pharmacies. Rule #3 states that each controlled Rx must be written on separate blank. My concerns are that the "drug-seekers" will benefit more than anyone from this possible new rule. If a patient goes to a DDS for example and gets an antibiotic along with pain meds....more than likely the pain med will be the only Rx that we ever see. That is just one example that comes to mind that makes it impossible for us to stop these "seekers" from abusing the system. On the other hand, it would be a good rule to create some uniformity in physician prescribing habits plus record keeping on our behalf. If their were a way to compromise the two sides of the issue I feel it would be better served. Thanks for your time!

Joe Anderson