WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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

AGENCY: Pharmacy TITLE-SERIES: 15-02

RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No

RULE NAME: 15-02 Uniform Controlled Substances Act

PRIMARY CONTACT

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CITE STATUTORY AUTHORITY: W. Va. Code §30-5-7

EXPLANATION OF THE STATUTORY AUTHORITY FOR THE LEGISLATIVE RULE, INCLUDING A DETAILED SUMMARY OF THE EFFECT OF EACH PROVISION OF THE LEGISLATIVE RULE WITH CITATION TO THE SPECIFIC STATUTORY PROVISION WHICH EMPOWERS THE AGENCY TO ENACT SUCH RULE PROVISION:

W. Va. Code §30-5-7(29)authorizes the Board to regulate wholesale drug distribution in this State. West Virginia Code of State Rules § 15-2-4.4 requires distributors of controlled substances, i.e., wholesale drug distributors, to design and operate systems to disclose suspicious orders of controlled substances, and to report those suspicious orders to the Board. The Board seeks to modify these provision to make the information received more meaningful, and add two categories of information to be reported, to proactively address these controlled substance orders.

DATE eFiled FOR NOTICE OF HEARING OR PUBLIC COMMENT PERIOD: 5/11/2017

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED: 6/12/2017

COMMENTS RECEIVED: Yes

(IF YES, PLEASE UPLOAD IN THE COMMENTS RECEIVED FIELD COMMENTS RECEIVED AND RESPONSES TO COMMENTS)

PUBLIC HEARING: No

(IF YES, PLEASE UPLOAD IN THE PUBLIC HEARING FIELD PERSONS WHO APPEARED AT THE HEARING(S) AND TRANSCRIPTS)

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

WHAT OTHER NOTICE, INCLUDING ADVERTISING, DID YOU GIVE OF THE HEARING?

None

SUMMARY OF THE CONTENT OF THE LEGISLATIVE RULE, AND A DETAILED DESCRIPTION OF THE RULE'S PURPOSE AND ALL PROPOSED CHANGES TO THE RULE:

DEA law at 21 CFR § 1301 requires distributors of controlled substances, i.e., wholesale drug distributors, to design and operate systems to disclose suspicious orders of controlled substances, and to report those suspicious orders to the DEA. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. West Virginia Code of State Rules § 15-2-4.4 contains a mirrored provision to the DEA law. The Board seeks to modify the provision to make the information received more meaningful, and add two categories of information to be reported: when a wholesale drug distributor determines to stop distributing controlled substances to a customer and when a wholesale drug distributor determines not to commence distribution to a potential customer due to a concern that the customer may be involved in dispensing those substances for other than a legitimate medical purpose. The revisions would also require zero reporting if a wholesale drug distributor realizes no suspicious orders in a calendar month.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

The Board seeks to modify the provision to make the information received more meaningful, and add two categories of information to be reported, so that we have sufficient information to proactively investigating these suspicious order reports, which are intended to alert our staff about concerning shipments of potentially dangerous drugs. These suspicious order reports, as well as the included zero reports, are essential tools that create accountability as to who is or is not submitting the reports, and provides the Board an invaluable tool for enforcement.

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

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

None

B. ECONOMIC IMPACT OF THE LEGISLATIVE RULE ON THE STATE OR ITS RESIDENTS:

None

C. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2017 Increase/Decrease (use "-")	2018 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services	0	0	0
Current Expenses	0	0	0
Repairs and Alterations	0	0	0
Assets	0	0	0
Other	0	0	0
2. Estimated Total Revenues	0	0	0

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

None

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENTS ARE TRUE AND CORRECT.

TITLE 15
LEGISLATIVE RULE
BOARD OF PHARMACY

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

§ 15-2-1. General.

1.1. Scope. -- W. Va. Code §60A-3-301 mandates that the Board of Pharmacy shall promulgate rules relating to the registration and control of the manufacture and distribution of controlled substances within this State.

1.2. Authority. -- W. Va. Code §60A-3-301.

1.3. Filing Date. -- ~~June 24, 2016~~_____.

1.4. Effective Date. -- ~~July 1, 2016~~_____.

1.5. Sunset Date -- This legislative rule shall terminate 10 years from its effective date unless renewed prior to that date.

§ 15-2-2. Adoption of Federal Law.

2.1. The requirements of the federal regulations, Drug Enforcement Administration, Department of Justice, 21 CFR Parts 1300-1321, and the federal Controlled Substances Act, 21 U.S.C. 801, as revised, are adopted by the West Virginia Board of Pharmacy (hereinafter, the "Board") and all licensed pharmacists and licensed pharmacies shall comply with them.

2.2. The federal regulations are available on the internet at http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR.

§ 15-2-3. Controlled Substance Permits.

3.1. Persons required to register.

3.1.1 Every person who manufactures, distributes, including reverse distributing, 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 this rule. Only persons actually engaged in these

activities are required to obtain a registration; related or affiliated persons who are not engaged in these 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. A person who has obtained a controlled substance permit from the Board is a "registrant".

3.2. The Board shall exempt from payment of a fee for a controlled substance permit the following registrants:

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 the substances from official stocks, to dispense or administer the substances, to conduct research, instructional activities, or chemical analysis with the substances, or any combination thereof, in the course of his or her official duties or employment.

3.2.3. In order to claim exemption from payment of a fee, the applicant shall complete the certification on the appropriate application form, in which 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.

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

3.3. An applicant shall include all information called for in the form, unless the item is not applicable, in which case this fact shall be indicated.

3.4. An individual applicant shall sign each application, attachment, or other document filed as part of an application; the partners shall sign the application if the applicant is a partnership; by a partner of the applicant if a partnership; the officers shall sign the application if the applicant is a corporation, 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.

3.5. If the applicant is a pharmacy, the pharmacist in charge of the pharmacy shall sign the application. If the owner of the pharmacy is a person, other than the practicing pharmacist, the other person, partnership, or corporation, corporate division, association, trust or other entity, shall sign the application form as provided in subsection 3.4 of this rule in addition to any other persons required to sign the application.

3.6. 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, the consultant or coordinator shall sign the application in addition to any other persons required to sign the application.

3.7. Filing of application; joint filings.

3.7.1 An applicant for registration shall submit the application to the office of the Board of Pharmacy for filing.

3.7.2. 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 an accompanying application for required information.

3.8. Acceptance for filing; defective applications.

3.8.1. Upon receipt, the Board shall date applications submitted for filing. If found to be complete, the Board will accept the application for filing. The Board will not accept any application failing to comply with the requirements of this rule. If an application has minor defects as to completeness, the Board may accept the application for filing with a request to the applicant for additional information. The Board shall return a defective application to the applicant within ten (10) days following its receipt with a statement of the reason for not accepting the application for filing. An applicant may correct a defective application and resubmit the application for filing at any time.

3.9. Additional information.

3.9.1. The Board may require an applicant to submit such documents or written statements of fact relevant to the application as it considers necessary to determine whether the application should be granted. The failure of the applicant to provide the documents or statements within a reasonable time after being requested to do so is considered a waiver by the applicant of an opportunity to present the documents or facts for consideration by the Board in granting or denying the application.

3.10. Amendments to and withdrawal of applications.

3.10.1. An applicant may amend or withdraw an application without permission of the Board at any time before the date on which the applicant receives an order to show cause, or before the date on which a notice of hearing on the application is published pursuant to W. Va. Code §60A-3-305, whichever is sooner. An applicant may amend or withdraw an application with permission of the Board at any time where good cause is shown by the applicant or where the amendment or withdrawal is in the public interest.

3.10.2 After an application has been accepted by the Board for filing, the Board shall consider a request by the applicant that it be returned or failure of the applicant to respond to official correspondence regarding the application, when sent by registered or certified mail, as withdrawal of the application.

3.11. Administrative review generally.

3.11.1. The Board may inspect, or cause to be inspected, the establishment of an applicant or registrant, pursuant to W. Va. Code §60A-5-501. The West Virginia Board of Pharmacy shall review the application for registration and other information gathered by the Board regarding an applicant in order to determine whether the applicable standards of W. Va. Code §60A-3-303 have been met by the applicant.

3.12. Applications for research in Schedule I substances.

3.12.1. In the case of an application for registration to conduct research with controlled substances in Schedule I, the Board 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 the 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 W. Va. Code §60A-3-303.

3.12.2. 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.

3.13. 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, and the expiration date of the registration. The registrant shall prominently display the controlled substance permit at the registered location.

3.14. Registration or any authority conferred may not be assigned or otherwise transferred except upon conditions specifically designated by the Board 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 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 Board 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~~ A wholesale drug distributor shall design and operate a system to disclose to the ~~registrant~~ wholesale drug distributor suspicious orders of controlled substances. ~~The registrant~~ A wholesale drug distributor shall inform the Office of the Board of suspicious orders of controlled substances when discovered by the ~~registrant.~~ wholesale drug distributor by providing a copy of the information which the wholesale drug distributor provides to the U.S. Drug Enforcement Administration (DEA) regarding such suspicious orders. The notification shall include the contact information for the wholesale drug distributor's department or staff responsible for coordinating with state regulatory or enforcement entities, unless such information has previously been provided in writing, including electronic or internet based means, to the Office of the Board. If a wholesale distributor detects no suspicious orders in a calendar month, then the wholesale drug distributor shall inform the Office of the Board in writing within fifteen days of the end of such month stating it is reporting no suspicious orders for that month. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

4.4.1. A wholesale drug distributor that ceases distribution of Schedule II through V controlled substances to a customer located in West Virginia due to concerns that the customer may be involved in dispensing controlled substances for other than a legitimate medical purpose shall notify the Office of the Board within 5 days of the cessation. The notification shall include the contact information for the wholesale drug distributor's department or staff responsible for coordinating with state regulatory or enforcement entities, unless such information has previously been provided in writing to the Office of the Board.

4.4.2. A wholesale drug distributor that decides not to commence distribution of Schedule II through V controlled substances to a customer in West Virginia due to a concern that the customer may be involved in dispensing controlled substances for other than a legitimate medical purpose shall notify the Office of the Board within 5 days of that decision. The notification shall include the contact information for the wholesale drug distributor's department or staff responsible for coordinating with state regulatory or enforcement entities, unless such information has previously been provided in writing to the Office of the Board.

4.5. The registrant shall notify the Office of the Board of any theft or significant loss of any controlled substances upon discovery of the theft or loss as provided in subsection 8.3.

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 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 had his or her registration revoked.

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

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

5.1.1. "Act" means the Uniform Controlled Substances Act (W. Va. Code §60A-1-101 et. seq.).

5.1.2. "Analogue" means a substance that, in relation to a controlled substance, has a substantially similar chemical structure.

5.1.3. "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. "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.

5.1.4. "Immediate derivative" means a substance which is the principal compound or any analogue of the parent compound manufactured from a known controlled substance primarily for use and which has equal or similar pharmacologic activity as the parent compound which is necessary to prevent, curtail or limit manufacture.

5.1.5. "Immediate precursor" means a substance which is the principal compound commonly used or produced primarily for use and which is an immediate chemical intermediary used or likely

to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail or limit manufacture.

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

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

5.1.8. "Label" means a display of written, printed, or graphic matter upon the immediate container of any drug or device.

5.1.9. "Labeling" means the process of preparing and affixing a label to a drug container exclusive, however, of a labeling by a manufacturer, packer or distributor of a nonprescription drug or commercially packaged prescription drug or device.

5.1.10. "Manufacture" means the producing, preparation, propagation, compounding, conversion or processing of a controlled substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance, or the labeling or relabeling of its container, except that this term does not include the preparation, compounding, packaging or labeling of a controlled substance:

5.1.10.~~(a)~~. By a practitioner as an incident to his or her administering or dispensing of a controlled substance in the course of his or her professional practice; or

5.1.10. ~~(b)~~. By a practitioner, or by his or her authorized agent under his or her supervision, for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale.

5.1.11. "Manufacturer" means any person who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging or labeling of a prescription drug, whether within or outside this state.

5.1.12. "Perpetual inventory" means an ongoing system for recording quantities of drugs received, dispensed or otherwise distributed by a pharmacy.

5.1.13. "Pharmacist" or "registered pharmacist" means an individual currently licensed by the jurisdiction in which he or she practices to engage in the practice of pharmacist care.

5.1.14. "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.

5.1.15. "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.

5.1.16. "Registrant" means a person who has obtained a controlled substance permit from the Board.

5.1.17. Any term not defined in this rule has the definition set forth in W. Va. Code §60A-1-101 and 60A-8-5.

5.2. Symbol required; exceptions.

5.2.1. Each commercial container of a controlled substance shall have printed on the label the symbol designating the schedule in which the controlled substance is listed. Each commercial container, if it otherwise has no label, shall bear a label complying with the requirement of this section.

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

5.2.3. 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.

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

5.2.5. 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.

5.2.6. 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.

5.2.7. 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.

5.3. Location and size of symbol on label.

5.3.1 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 shall be at least two (2) times as large as the largest type otherwise printed on the label.

5.3.2. In lieu of locating the symbol in the corner of the label, as prescribed in subsection 5.3.1 of this rule, the symbol may be overprinted on the label, in which case the symbol shall be printed at least one half ~~(2)~~ the height of the label and in a contrasting color providing clear visibility against the background color of the label.

5.3.3 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.

5.4. Location and size of symbol on labeling.

5.4.1. The symbol shall be prominently located on all labeling other than labels covered by subsection 5.3 of this rule. In all cases the symbol shall be clear and large enough to afford prompt identification of the controlled substance upon inspection of the labeling.

5.5. Effective dates of labeling requirements.

5.5.1. 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 subsection 5.2 of this rule.

5.5.2. The Board may, in the case of any controlled substance, require compliance with the requirements of subsection 5.2 of this rule, within a period of time shorter than required by this section if it finds that public health or safety necessitate an earlier effective date.

5.6. Sealing of controlled substances.

On each bottle, multiple dose vial, or other commercial container of any controlled substance, there shall be securely affixed to the stopper, cap, lid, covering or wrapper or other container, a seal to disclose upon inspection any tampering or opening of the container.

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

6.1. All records required to be kept shall be readily retrievable.

6.2. Maintenance of records and inventories.

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

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

6.2.2.~~(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

6.2.2.~~(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 a form that the information required is readily retrievable from the ordinary business records of the registrant.

6.2.3. Each registered individual practitioner and institutional practitioner required to keep records shall maintain inventories and records of controlled substances in the manner prescribed in subdivision 6.2.2 of this rule.

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

6.2.4.~~(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 the substances shall be maintained in a separate prescription file. Each pharmacy shall maintain a perpetual inventory of all Schedule II drugs received, dispensed, or otherwise distributed, with reconciliation at least monthly. Electronic monitoring at the pharmacy or by another entity that provides alerts for discrepancies between drugs received, drugs dispensed, or otherwise distributed is acceptable provided such alerts are reviewed at least monthly; and

6.2.4.~~(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 a form that the information required is readily retrievable from ordinary business records of the pharmacy, and prescriptions for the substances shall be maintained either in a separate prescription file for controlled substances listed in Schedules III, IV and V only, or in a form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions shall be considered 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 are considered 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 registrant shall make a separate inventory for each registered location. In the event controlled substances are in the possession or under the control of the registrant at a location for which he or she 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 registrant shall make a separate inventory for each independent activity for which he or she is registered, except as provided in subsection 6.10 of this rule.

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. A registrant shall maintain an inventory in a written, typewritten or printed form. An inventory taken by use of an electronic or oral recording device shall 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 subsections 6.4 through 6.7 of this rule, 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 Board or the DEA adding a substance to any schedule of controlled substances, when the 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 the substance shall be included in each inventory made by the registrant pursuant to subsection 6.5 of this rule.

6.7. Inventories of manufacturers.

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

6.7.1.~~(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:

6.7.1.a.~~(1)~~. The name of the substance; and

6.7.1.a.~~(2)~~. The total quantity of the substance to the nearest metric unit weight consistent with unit size.

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

6.7.1.b.~~(1)~~. The name of the substance;

6.7.1.b.~~(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

6.7.1.b.~~(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 of the substance.

6.7.1.~~(c)~~. For each controlled substance in finished form:

6.7.1.c.~~(1)~~. The name of the substance;

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

6.7.1.c.~~(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

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

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

6.7.1.d.~~(1)~~. The name of the substance;

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

6.7.1.d.~~(3)~~. The reason for the substance being maintained by the registrant and whether the 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 the inventory the same information required of manufacturers pursuant to subdivision 6.7.1.~~(c)~~ and subdivision 6.7.1.~~(d)~~ of this rule.

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 this rule, shall include in the inventory the same information required of manufacturers pursuant to subdivision 6.7.1.~~(c)~~ and subdivision 6.7.1.~~(d)~~ of this rule. 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:

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

6.9.1.~~(b)~~. If the substance is listed in Schedule III, IV or V, the dispenser 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 the dispenser shall 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 the inventory the same information required of manufacturers pursuant to subdivision 6.7.1.~~(c)~~ and subdivision 6.7.1.~~(d)~~ of this rule. Each registered importer and exporter who is also registered as a manufacturer or as a distributor shall include in the inventory as an importer or exporter only those stocks of controlled

substances that are actually separated from the 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 subdivision 6.7.1.~~(c)~~ and subdivision 6.7.1.~~(d)~~ of this rule, 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 Board 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. Every registrant required to keep records pursuant to subsection 6.3 of this rule, shall maintain on a current basis a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported or otherwise disposed of by the registrant.

6.12.2. A registrant shall maintain separate records 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 or she is not registered, the registrant shall include the substances 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. A registrant shall maintain separate records for each independent activity for which he or she is registered.

6.12.4. In recording dates of receipt, importation, distribution, exportation or other transfer, the registrant shall use the date on which the controlled substances are actually received, imported, distributed, exported or otherwise transferred 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 to account for all controlled substances used in the manufacturing process:

6.13.1.~~(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:

6.13.1.a.~~(1)~~. The name of the substance;

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

6.13.1.a.~~(3)~~. The quantity received from other persons, including the date and quantity of each delivery and the name, address and registration number of the other person from whom the substance was received;

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

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

6.13.1.a.5.A~~)~~. The date and batch or other identifying number of each manufacture;

6.13.1.a.5.B~~)~~. The quantity used in the manufacture;

6.13.1.a.5.C~~)~~. The finished form (e.g., ten (10) milligram tablets or ten (10) milligram concentration per fluid ounce or milliliter);

6.13.1.a.5.D~~)~~. The number of units of finished form manufactured;

6.13.1.a.5.E~~)~~. The quantity used in quality control;

6.13.1.a.5.F~~)~~. The quantity lost during manufacturing and the causes therefore, if known;

6.13.1.a.5.G~~)~~. The total quantity of the substance contained in the finished form;

6.13.1.a.5.H~~)~~. The theoretical and actual yields; and

6.13.1.a.5.I~~)~~. Any other necessary information;

6.13.1.a.~~(6)~~. The quantity used to manufacture other controlled and noncontrolled substances, including the name of each substance manufactured and the information required in subdivision 6.13.1(a)(5) of this rule;

6.13.1.a.~~(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;

6.13.1.a.~~(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; and

6.13.1.a.~~(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.

6.13.1.~~(b)~~. For each controlled substance in finished form:

6.13.1.b.~~(1)~~. The name of the substance;

6.13.1.b.~~(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);

6.13.1.b.~~(3)~~. The number of containers of each commercial finished form manufactured from bulk form by the registrant, including the information required pursuant to subdivision 6.13.1(a)(5) of this rule;

6.13.1.b.~~(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 delivery and the name, address and registration number of the person from whom the units were received;

6.13.1.b.~~(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;

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

6.13.1.b.6.A. The date and batch or other identifying number of each manufacture;

6.13.1.b.6.B~~)~~. The operation performed (e.g., repackaging or relabeling);

6.13.1.b.6.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

6.13.1.b.6.D~~)~~. Any other information necessary to account for all controlled

substances used in the manufacturing process;

6.13.1.b.~~(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;

6.13.1.b.~~(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

6.13.1.b.~~(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:

6.14.1.~~(a)~~. The name of the substance;

6.14.1.~~(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);

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

6.14.1.~~(d)~~. The number of commercial containers of each 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;

6.14.1.~~(e)~~. The number of commercial containers of each 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;

6.14.1.~~(f)~~. The number of commercial containers of each 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

6.14.1.~~(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 this rule, shall maintain records with the following information for each controlled substance:

6.15.1.~~(a)~~. The name of the substance;

6.15.1.~~(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);

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

6.15.1.~~(d)~~. The number of units or volume of each 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

6.15.1.~~(e)~~. The number of units or volume of each finished form and/or commercial container 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:

6.16.1.~~(a)~~. The name of the substance;

6.16.1.~~(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;

6.16.1.~~(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;

6.16.1.~~(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 is to be recorded pursuant to subdivision 6.13.1(a)(4) or subdivision 6.13.1(b)(5) of this rule, 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, for each controlled substance:

6.17.1.~~(a)~~. The name of the substance;

6.17.1.~~(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 that form (e.g., C.P., U.S.P., N.F., ten (10) milligram tablet or ten (10) milligram concentration per milliliter);

6.17.1.~~(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; and

6.17.1.~~(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 for controlled substances are set forth generally in W. Va. Code §60A-3-308 and West Virginia Code of State Rules § 15-1-21.

7.2. Reserved.

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, and is strictly limited to the schedule(s), class(es) or specific substance(s) which he or she is permitted by that jurisdiction to prescribe.

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. To be effective, an individual practitioner shall issue a prescription for a controlled substance for a legitimate medical purpose in the usual course of his or her 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 the Uniform Controlled Substances Act and the person knowingly filling such a purported prescription, as well as the person issuing it, are subject to the penalties provided for violations of the provisions of law relating to controlled substances.

7.4.2. An individual practitioner shall not issue a prescription in order for the individual practitioner to obtain controlled substances for the purpose of general dispensing to patients; i.e. office use. A pharmacy may provide controlled substances to a practitioner for office use, but must do so by providing appropriate documentation through the use of an invoice or other federally required documentation or forms.

7.4.3. A practitioner shall not issue a prescription for the dispensing of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his or her 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 the name, address and registration number of the practitioner. If the prescription is transmitted by e-prescribing, the signature may be an electronic signature. All paper prescriptions, including, but not limited to traditional paper prescription blanks, computer generated prescriptions that are printed out or faxed, and prescriptions received by the pharmacy as a fax prescription regardless of the method of transmission by the prescriber, must contain the prescriber's manual signature; an electronic

signature, an electronic reproduction of the signature, signature stamp, or other form of signature is not a valid signature for a paper prescription. A practitioner may sign a prescription in the same manner as he or she 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, typed, or computer-generated and printed with ink, 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 legislative rules. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed in this rule, Provided that: a pharmacist may make changes to a prescription order written for a controlled substance in accordance with the following:

7.5.1.~~(a)~~. the pharmacist may add or change the patient's address upon verification;

7.5.1.~~(b)~~. the pharmacist may add or change the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner.

7.5.1.~~(c)~~. such consultations and corresponding changes should be noted by the pharmacist on the prescription; and

7.5.1.~~(d)~~. the pharmacist is never permitted to make changes to the patient's name, controlled substance prescribed (except for generic substitution permitted by state law) or the prescriber's signature.

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. This rule does not apply to prescriptions written for patients of an institutional facility as defined by West Virginia Code of State Rules § 15-1-2.1.21, 15 CSR 1. No more than one controlled substance may 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 than 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. If the pharmacist in his or her professional judgment determines the immediate necessity for the patient to receive his or her medication, then the prescriptions may be dispensed and the pharmacist shall document in a log the prescription numbers and drugs dispensed. This log shall 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 Board.

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 shall be clearly distinguished upon the prescription. If a pharmacist receives a prescription that does not comply with this subsection, then the pharmacist shall refuse to fill the prescription. If the pharmacist in his or her professional judgment determines the immediate necessity for the patient to receive his or her medication, then the prescriptions may be dispensed and the pharmacist shall document in a log the date, patient name, practitioner name, prescription numbers, and drugs dispensed. This log shall 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 to 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 Board.

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 or her 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 considered to be within the meaning of the term "in the course of his or her 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. A physician who is not specifically registered to conduct a narcotic treatment program may administer, but not prescribe, narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. No more than one day’s medication may be administered to the person or for the person’s use at one time. The 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.

7.9.1.~~(~~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 paper prescription manually signed by the prescribing individual practitioner, or by electronic prescribing, except as allowed by subdivision 7.9.2 of this rule. A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment or other electronic transmission other than electronic prescribing, provided that the original paper, manually signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as provided by West Virginia Code of State Rules § 15-1-21, 15 CSR 1. A prescription for a Schedule II controlled substance is valid for ninety (90) days from the date issued. A pharmacist may fill the prescription after ninety (90) days if the prescriber confirms to the pharmacist that he or she still wants the prescription filled and the pharmacist documents upon the prescription that the confirmation was obtained.

7.9.1.~~(~~b~~)~~. An individual practitioner may administer or dispense a controlled substance listed in Schedule II in the course of his or her professional practice without a prescription, subject to subsection 7.8.1 of this rule.

7.9.1.~~(~~c~~)~~. An institutional practitioner may administer or dispense directly, but not prescribe, a controlled substance listed in Schedule II only pursuant to a paper prescription manually signed by the prescribing individual practitioner, an electronic prescription, or 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 practitioner may communicate a prescription for a Schedule II controlled substance orally or by way of electronic transmission other than electronic prescribing, provided that if the prescribing practitioner is not known to the pharmacist, the pharmacist shall make a reasonable effort to determine that the oral authorization came from a registered practitioner, which may include a call-back to the practitioner using the practitioner's phone number as listed in the telephone directory and other good faith efforts to insure his or her identity; and:

7.9.2.~~(~~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 shall be pursuant to a prescription issued in the normal course of practice as permitted in subsection 7.9.1 of this rule.

7.9.2.~~(~~b~~)~~. the orally communicated prescription is immediately reduced to writing by the pharmacist, or, if necessary, the prescription communicated by way of electronic transmission other

than electronic prescribing is immediately reduced to a hard copy;

7.9.2.~~(c)~~. within seven (7) days after authorizing an emergency oral prescription, the practitioner delivers a valid paper or electronic prescription for the emergency quantity prescribed 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 paper prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail, it shall be postmarked within the seven (7) day period; if sent by electronic prescription, it must be transmitted by the prescriber 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 Board if the prescribing practitioner fails to deliver a written prescription.

7.10. Refilling Schedule II prescriptions; issuance of multiple prescriptions.

7.10.1. The refilling of a prescription for a controlled substance listed in Schedule II is prohibited. However, a prescriber may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance provided each separate prescription provides instructions (other than the first prescription if the prescriber intends for that prescription to be filled immediately) indicating the earliest date on which each prescription may be dispensed. The signatures on such prescriptions must be dated as of the date they were actually signed, and may provide the instructions for when they may be filled by indicating "do not full until", "may not be filled before", or other similar language, followed by the earliest date on which it may be dispensed.

7.11. Partial filling of Schedule II prescriptions.

7.11.1. A pharmacist may dispense a partial filling of a prescription for a controlled substance listed in Schedule II, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he or she 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 notify the prescribing individual practitioner. No further quantity of controlled substances 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 the 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 the Uniform Controlled Substances Act and this rule.

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

7.14.1. Requirement of prescription.

7.14.1.~~(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 paper prescription manually signed by a prescribing individual practitioner, a facsimile of a paper prescription or order for medication, an electronic prescription, or an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist containing all information required by this rule, except for the signature of the prescribing individual practitioner.

7.14.1.~~(b)~~. An individual practitioner may administer or dispense a controlled substance listed in Schedule III, IV, or V in the course of his or her professional practice without a prescription, subject to the provisions of section 7.8 of this rule.

7.14.1.~~(c)~~. An institutional practitioner may administer or dispense directly, but not prescribe, a controlled substance listed in Schedules III, IV, or V pursuant to a paper prescription signed by a prescribing individual practitioner, an electronic prescription, or 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 this rule, 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 this rule.

7.15. Refilling of Schedule III or IV prescriptions.

7.15.1. A pharmacist shall not fill or refill a prescription for a controlled substance listed in Schedule III or IV more than six (6) months after the date on which the prescription was issued and any prescription authorized to be refilled may not 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 or she shall be considered 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 this rule, 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. No refill may be provided more than three days prior to the date the prior dispensing would be exhausted unless special circumstances justifying the early refill exist. If an early refill is made, the pharmacist is encouraged to consult with the prescriber, and must document on the prescription record the special circumstances justifying the early dispensing.

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:

7.16.1.~~(a)~~. Each partial filling is recorded in the same manner as a refilling;

7.16.1.~~(b)~~. The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed; and

7.16.1.~~(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 the 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 6.15 of this rule.

7.19. Dispensing without prescription.

7.19.1. A pharmacist may dispense 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, without a prescription to a purchaser at retail, unless:

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

7.19.1.~~(b)~~. Not more than 240 cc. (8 ounces) of any controlled substance containing

opium, nor more than 120 cc. (4 ounces) of any other controlled substance nor more than 48 dosage units of any controlled substance containing opium, nor more than 24 dosage units of any other controlled substance may be dispensed at retail to the same purchaser in any given forty eight (48) hour period;

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

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

7.19.1.~~(e)~~. A bound record book for distributions of controlled substances under this section, other than by prescription, is maintained by the pharmacist. The 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 6.2 of this rule; and

7.19.1.~~(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 shall submit with the notification 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 is considered 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.

8.2.2. Registrants may become registered with the DEA as an authorized collector to receive the transfer from ultimate users any unwanted and unused pharmaceutical controlled substances in their lawful possession for safe, secure, and responsible disposal. Any authorized collector must comply fully with the DEA requirements for such an authorized collection program.

8.3. Reporting theft of drugs.

8.3.1. In the event of any controlled substances being lost or stolen, the registrant shall immediately submit a report of the drug theft or loss (DEA Form 106) to the Board of Pharmacy.

8.4. Ordering of Controlled Substances.

8.4.1. A registrant shall complete an order form (DEA Form 222) 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.