WEST VIRGINIA SECRETARY OF STATE

NATALIE E. TENNANT

ADMINISTRATIVE LAW DIVISION

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OFFICE OF
WEST VIRGINIA SECRETARY OF STATE

FORM 3 -- NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

AGENCY **Medicine**
RULE TYPE **Legislative** AMENDMENT TO EXISTING RULE **Yes** TITLE-SERIES **11-05**
RULE NAME **Dispensing of Legend Drugs by Practitioners**

CITE AUTHORITY **§30-3-7(a)(1); §30-3E-2(3); and §60A-3-301**

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.

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

Yes
Robert C Knittle -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

Title-Series: 11-05

Rule Id: 10223

Document: 28858

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FORM 10 -- LEGISLATIVE QUESTIONNAIRE (Page 1)

AGENCY **Medicine**
RULE TYPE **Legislative** AMENDMENT TO EXISTING RULE **Yes** TITLE-SERIES **11-05**
RULE NAME **Dispensing of Legend Drugs by Practitioners**

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PRIMARY CONTACT
Robert C. Knittle, Executive Director
West Virginia Board of Medicine
101 Dee Drive, Suite 103
Charleston, STATE ZIP

SECONDARY CONTACT
Jamie C. Frame
West Virginia Board of Medicine
101 Dee Drive, Suite 103
Charleston, STATE SECONDARY ZIP SECONDARY

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FORM 10 -- LEGISLATIVE QUESTIONNAIRE (Page 1)

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AUTHORIZING STATUTE(S) CITATION
§30-3-7(a)(1); §30-3E-2(3); and §60A-3-301

DATE FILED IN STATE REGISTER WITH NOTICE OF HEARING OR PUBLIC COMMENT PERIOD
Tuesday, July 12, 2016

WHAT OTHER NOTICE, INCLUDING ADVERTISING, DID YOU GIVE OF THE HEARING?
The Board publicized notice of this proposed rule change by: including a notice of the proposed amendments and comment period on the Board's website with a link to the proposed rule; sending an email notification to licensees of the Board regarding notice of the proposed amendments and comment period; and notifying interested professional associations and governmental entities including: West Virginia State Medical Association; West Virginia Board of Pharmacy; West Virginia Academy of Family Physicians; and West Virginia University.

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED
Thursday, August 11, 2016

Robert C Knittle -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

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FORM 10 -- LEGISLATIVE QUESTIONNAIRE (Page 2)

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CITE AUTHORITY **§30-3-7(a)(1); §30-3E-2(3); and §60A-3-301**

ATTACH LIST OF PERSONS WHO APPEARED AT HEARING, COMMENTS RECEIVED, AMENDMENTS, REASONS FOR AMENDMENTS.

Attached

DATE YOU FILED IN STATE REGISTER THE AGENCY APPROVED PROPOSED LEGISLATIVE RULE FOLLOWING PUBLIC HEARING: (BE EXACT)

Wednesday, August 24, 2016

Robert C Knittle -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

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CITE AUTHORITY **§30-3-7(a)(1); §30-3E-2(3); and §60A-3-301**

IF THE STATUTE UNDER WHICH YOU PROMULGATED THE SUBMITTED RULES REQUIRES CERTAIN FINDINGS AND DETERMINATIONS TO BE MADE AS A CONDITION PRECEDENT TO THE PROMULGATION, 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.

Robert C Knittle -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

Title-Series: 11-05 Rule Id: 10223 Document: 28858

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FORM 10 -- LEGISLATIVE QUESTIONNAIRE (Page 4)

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CITE AUTHORITY **§30-3-7(a)(1); §30-3E-2(3); and §60A-3-301**

DATE OF HEARING OR COMMENT PERIOD

ON WHAT DATE DID YOU FILE IN THE STATE REGISTER THE FINDINGS AND DETERMINATIONS REQUIRED TOGETHER WITH THE REASONS THEREFOR?

ATTACH FINDINGS AND DETERMINATIONS AND REASONS
None

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

Yes
Robert C Knittle -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

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FORM 11 -- FISCAL NOTE FOR PROPOSED RULES (Page 1)

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CITE AUTHORITY **§30-3-7(a)(1); §30-3E-2(3); and §60A-3-301**

PRIMARY CONTACT
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CITE AUTHORITY **§30-3-7(a)(1); §30-3E-2(3); and §60A-3-301**

SUMMARIZE IN A CLEAR AND CONCISE MANNER WHAT IMPACT THIS MEASURE WILL HAVE ON COSTS AND REVENUES OF STATE GOVERNMENT.

the Board does not anticipate any fiscal impact.

Robert C Knittle -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

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FORM 11 -- FISCAL NOTE FOR PROPOSED RULES (Page 2)

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CITE AUTHORITY **§30-3-7(a)(1); §30-3E-2(3); and §60A-3-301**

FISCAL NOTE DETAIL -- SHOW OVER-ALL EFFECT IN ITEM 1 AND 2 AND, IN ITEM 3, GIVE AN EXPLANATION OF BREAKDOWN BY FISCAL YEAR, INCLUDING LONG-RANGE EFFECT.

Effect Of Proposal	Current Increase/Decrease (use ' - ')	Next Increase/Decrease (use ' - ')	Fiscal Year (Upon Full Implementation)
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
ESTIMATED TOTAL REVENUES	0	0	0

Robert C Knittle -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

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3. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT). PLEASE INCLUDE ANY INCREASE OR DECREASE IN FEES IN YOUR ESTIMATED TOTAL REVENUES.

N/A

Robert C Knittle -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

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FORM 11 -- FISCAL NOTE FOR PROPOSED RULES (Page 4)

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CITE AUTHORITY **§30-3-7(a)(1); §30-3E-2(3); and §60A-3-301**

PLEASE IDENTIFY ANY AREAS OF VAGUENESS, TECHNICAL DEFECTS, REASONS THE PROPOSED RULE WOULD NOT HAVE A FISCAL IMPACT, AND OR ANY SPECIAL ISSUES NOT CAPTURED ELSEWHERE ON THIS FORM.

N/A

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

Robert C Knittle -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

Title-Series: 11-05 Rule Id: 10223 Document: 28858

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FORM 12 -- BRIEF SUMMARY AND STATEMENT OF CIRCUMSTANCES (Page 1)

AGENCY **Medicine**
RULE TYPE **Legislative** AMENDMENT TO EXISTING RULE **Yes** TITLE-SERIES **11-05**
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CITE AUTHORITY **§30-3-7(a)(1): §30-3E-2(3): and §60A-3-301**

SUMMARIZE IN A CLEAR AND CONCISE MANNER CONTENTS OF CHANGES IN RULE AND STATEMENT OF CIRCUMSTANCES REQUIRING THE RULE.

Series 5 establishes the rules of the Board of Medicine related to the office based dispensing of prescription drugs by licensees of the Board. The rule has not been reviewed or amended since 1989. The Board undertook a review of the rule and identified a need for clarification and modernization of the registration requirements for licensees who seek to engage in the office-based dispensing and administering of prescription drugs, as well the standards for engaging in a dispensing practice. A summary of the content of changes appears below:
Section 1: The scope has been amended to add updated authority and section 1.5 has been added to provide for a sunset provision as required by Senate Bill 619.
Section 2: The definitions section has been amended to remove some obsolete terms, update the definitions of some terms, and to add some new terms to the definitions section including drug, drug dispensing practitioner, practitioner, registered controlled substance dispensing practitioner, prescription drug and returned or surrendered drug.
Section 3: This section has been completely rewritten. It establishes that a practitioner must register with the Board to dispense or administer controlled substances in an office-based setting. This section also sets

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

Yes
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FORM 12 -- BRIEF SUMMARY AND STATEMENT OF CIRCUMSTANCES (Page 2)

AGENCY **Medicine**
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RULE NAME **Dispensing of Legend Drugs by Practitioners**

CITE AUTHORITY **§30-3-7(a)(1); §30-3E-2(3); and §60A-3-301**

SUMMARIZE IN A CLEAR AND CONCISE MANNER CONTENTS OF CHANGES IN RULE AND STATEMENT OF CIRCUMSTANCES REQUIRING THE RULE.

forth required application information, the registration process, eligibility criteria, a biennial renewal cycle for registrants, and circumstances under which a registration may terminate. This section also clarifies that a practitioner must register each and every site where he or she seeks to engage in the office based dispensing of controlled substances.
Section 4: The language in section 4 of the current rule has been modernized and incorporated into the prosed section 5 General Practice Requirements Applicable to All Drug Dispensing Practitioners The language of the proposed amendment for section 4 clarifies that practitioners who dispense or administer drugs which are not controlled substances do not have to register with the Board.
Section 5: Section 5 sets forth the general practice requirements for all drug dispensing practitioners. It incorporates the prohibition of sale at retail from the current section 5, as well as other practice requirements related to patient freedom of choice, acceptable charges, patient counseling, disposal of expired drugs, and general recordkeeping requirements.
Section 6: The substance of the current section 6 has been incorporated into the proposed amendments to section 5.

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

Yes
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SUMMARIZE IN A CLEAR AND CONCISE MANNER CONTENTS OF CHANGES IN RULE AND STATEMENT OF CIRCUMSTANCES REQUIRING THE RULE.

The proposed amendments create a new section 6, which sets forth security, packaging and labeling standards for a dispensing practice.
Section 7: The packaging requirements which appear in the current section 7 are antiquated and unnecessarily complicated. The revised packaging requirements are incorporated in the proposed amendments at section 6. Section 7 in the proposed amended rule sets forth additional requirements for practitioners who dispense or administer controlled substances in an office-based setting. It establishes a prohibition on the administering and dispensing of controlled substances by an unregistered practitioner, requires practitioners who dispense controlled substances to make all required reports to the West Virginia Controlled Substance Monitoring Program, prohibits practitioners from writing prescriptions for pharmacy filling (as opposed to federally required documents or forms) for office use of controlled substances.
Section 8: The current section 8 related to labeling has been revised and incorporated into the proposed amended rule at section 6. The proposed amended rule includes a new section 8 which provides guidance on when a practitioner may accept unused or unwanted prescription drugs from a

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Yes
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FORM 12 -- BRIEF SUMMARY AND STATEMENT OF CIRCUMSTANCES (Page 4)

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SUMMARIZE IN A CLEAR AND CONCISE MANNER CONTENTS OF CHANGES IN RULE AND STATEMENT OF CIRCUMSTANCES REQUIRING THE RULE.

patient for disposal. Consistent with federal law, the rule prohibits a practitioner from accepting any unused or unwanted controlled substances. It provides guidelines, including documentation requirements for other prescription drugs. This section also clarifies that a practitioner may not dispense, administer or reuse any returned medication. After the comment period, subsection 8.9 was revised to permit reuse of returned non-controlled prescription drugs only as part of an authorized prescription drug donation program established by this state.
Section 9: This section identifies required dispensing records which must be maintained by a dispensing practitioner. Amendments have been made to clarify how long dispensing records must be maintained and to clarify that such records must be readily retrievable. This section has also been amended to incorporate standards for Board inspections and audits of locations where practitioners dispense controlled substances.
A detailed summary of post-comment period modifications to the Boards initially proposed amendments is provided as a separate document along with all comments received.

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

Yes
Robert C Knittle -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

11CSR5

TITLE 11
LEGISLATIVE RULES
BOARD OF MEDICINE

SERIES 5
BOARD OF MEDICINE RULES FOR DISPENSING OF ~~LEGEND~~ PRESCRIPTION DRUGS BY ~~PHYSICIANS AND PODIATRISTS~~ PRACTITIONERS

§11-5-1. General.

1.1. Scope. -- West Virginia Code §30-3-7(a)(1) and §30-3E-2(3) authorize~~s~~ the Board of Medicine to promulgate rules which are necessary to perform the duties and responsibilities of the Board, and West Virginia Code §60A-3-301 ~~requires the Board of Medicine to collect a registration fee from licensees who dispense controlled substances.~~ authorizes the Board of Medicine to promulgate rules and charge fees relating to the registration and control of the dispensing of controlled substances within this state by Board of Medicine licensees. West Virginia Code §29A-3-19(b) requires the incorporation of a sunset provision in existing rules which are modified after April 1, 2016.

1.2. Authority. -- W. Va. Code §30-3-7(a)(1); §30-3E-2(3); and §60A-3-301.

1.3. Filing Date. -- ~~May 3, 1989.~~

1.4. Effective Date. -- ~~July 1, 1989.~~

1.5. Sunset Date. – This legislative rule shall terminate five years from the effective date unless renewed and/or reauthorized prior to that date.

§11-5-2. Definitions.

2.1. "The Board" means the West Virginia Board of Medicine.

~~2.2. "Dispensing physician" means a physician or podiatrist registered with the Board to dispense legend drugs within the scope of his or her practice.~~

~~2.3~~. 2.2. "Administer" means the direct application of any ~~legend~~ prescription drug whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject by:

~~(a)~~ 2.2.a. A physician or ~~podiatrist~~ podiatric physician, ~~(or, in his presence, by~~ or his or her authorized agent~~)~~; ~~or~~

~~(b)~~ 2.2.b. A physician assistant practicing within the scope of a duly authorized practice agreement; or

~~(b)~~ 2.2.c. The patient or research subject at the direction and in the presence of the ~~physician or podiatrist~~ practitioner.

~~2.4.~~ 2.3. "Controlled substance" means a drug that is classified by federal or state law in Schedules I, II, III, IV or V.

~~2.5.~~ 2.4."Course of treatment" means the period of time necessary to effect a cure for an acute disease, or the period of time from one office visit until the next scheduled or anticipated office visit for a chronic disease.

~~2.6.~~ 2.5. "Dispense" ~~means to deliver a legend drug to an ultimate user or research subject by or pursuant to the lawful order of a physician or podiatrist, including the prescribing, packaging, labeling, administering or compounding necessary to prepare the drug for that delivery.~~ means the preparation and delivery of a prescription drug, in an appropriately labeled and suitable container, by a practitioner to a patient under the practitioner's care.

2.6 "Drug" means: (1) Substances recognized as drugs in the official "United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary", or any supplement to any of them; (2) substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals; (3) substances (other than food) intended to affect the structure or any function of the body of man or animals; and (4) substances intended for use as a component of any article specified in subdivision (1), (2) or (3) of this subdivision. It does not include devices or their components, parts or accessories.

2.7. "Drug dispensing practitioner" means a practitioner who dispenses or administers prescription drugs to a patient under his or her care within West Virginia in the course of his or her professional practice and consistent with his or her scope of practice and/or authorization. This term includes, but is not limited to, practitioners who are registered with the Board pursuant to section 3 of this rule.

~~2.7.~~ 2.8. "Generic drug product" means a drug marketed without a trade name as a substitute for an innovator or previously patented pioneer drug.

2.9. "Label" means a display of written, printed, or graphic matter affixed upon the immediate container of a dispensed drug.

~~2.8.~~ 2.10. ~~"Legend drug" means a drug that may be prescribed, administered or~~ dispensed ~~under federal or state law only pursuant to the prescription of an authorized prescriber. Legend drugs are commonly referred to as prescription drugs.~~

~~2.9.~~ 2.10. "Package insert" means the official labeling information sheet that accompanies a ~~legend~~ prescription drug when it is distributed by the manufacturer.

2.11. "Practitioner" means: (1) a physician or podiatric physician licensed by the Board; or (2) a physician assistant licensed by the Board whose authorization to practice includes the delegation

of authority from the supervising physician to prescribe, administer or dispense one or more prescription drugs.

2.12. "Prescription drug" means a drug that may be prescribed, administered or dispensed under federal or state law only pursuant to the prescription of an authorized prescriber. Prescription drugs are also referred to as legend drugs.

~~2.10~~. 2.13. "Professional samples" means complimentary drugs packaged and distributed in accordance with federal and state statutes and regulations and provided to a ~~physician or podiatric physician~~ practitioner free of charge by manufacturers or distributors and distributed free of charge by the ~~physician or podiatric physician~~ practitioner to his or her patients.

2.14. "Registered controlled substance dispensing practitioner" means a practitioner who is registered with the Board to dispense controlled substances to a patient under the practitioner's care within West Virginia in the course of his or her professional practice and consistent with his or her scope of practice and/or authorization.

2.15. "Returned or surrendered drug" means a prescription drug which has been dispensed to an end user by any entity, and which is subsequently returned or surrendered to a practitioner for any reason.

~~2.11~~. 2.16. "Sale at retail" means dispensing ~~legend~~ prescription drugs to persons other than current active patients of a ~~physician~~ dispensing practitioner during the course of treatment of such patients.

~~2.12~~. 2.17. "Free clinic" means a clinic where medical and other health-related services are rendered at no charge to the patient.

~~2.13. "USP DI" means "United States Pharmacopeia Drug Information."~~

~~§11-5-3. Registration as a Drug Dispensing Physician Required; Application and Registration Renewal.~~

~~3.1. Each physician or podiatrist who wishes to dispense legend drugs to patients shall register with the Board as a dispensing physician, on the form provided by the Board. The annual fee for registration as a dispensing physician shall be fifteen dollars ($15.00).~~

~~3.2. Physicians or podiatrists who are registered with the Board as dispensing physicians may dispense drugs to their own patients but not fill prescriptions written by other physicians or podiatrists, nor sell at retail such legend drugs. They may make reasonable charges for their services, including any legend drugs they may dispense, and may dispense amounts of drugs as they deem sufficient to a patient's course of treatment.~~

~~3.3. Physicians or podiatrists who are not registered with the Board as dispensing physicians may not dispense legend drugs. However, the following activities by a physician or podiatrist shall be exempt from the requirements of section 3 through 8 applicable to dispensing physicians:~~

~~(a) Legend drugs administered to the patient, which are not controlled substances when an appropriate record is made in the patient's chart.~~

~~(b) Professional samples distributed free of charge by a physician or podiatrist or certified~~

~~physician assistant under his or her supervision to the patient when an appropriate record is made in the; patient's chart; or~~

~~(c) Legend drugs which are not controlled substances provided by free clinics or under West Virginia state authorized programs, including the medicaid, family planning, maternal and child health, and early and periodic screening and diagnosis and treatment programs: **Provided, however,** That all labeling provisions of section 8 shall be applicable except the requirements of section 8.3(a).~~

§11-5-3. Registration to Administer or Dispense Controlled Substances Required; Application and Registration Renewal.

3.1. Every practitioner who dispenses any controlled substance to a patient under his or her care within West Virginia, including free or professional samples of controlled substances, shall first register with the Board as a registered controlled substance dispensing practitioner. A separate registration is required for each and every practice location where the practitioner dispenses controlled substances.

3.2. Every practitioner who administers any controlled substance to a patient under his or her care in an office based setting within West Virginia shall first register with the Board as a registered controlled substance dispensing practitioner. A separate registration is required for each and every practice location where the practitioner administers controlled substances. This registration requirement does not apply to practitioners who administer controlled substances exclusively to patients who are receiving inpatient health care services at a hospital or other inpatient health care facility, a hospital-based emergency department, or an ambulatory surgical center.

3.3. An application for registration as a registered controlled substance dispensing practitioner at one or more locations shall be completed on a Board-approved application. The Board's controlled substance dispensing application shall include, and applicants must provide, the following information:

3.3.a. The applicant’s full name and West Virginia Board of Medicine license number;

3.3.b. The applicant’s current individual DEA controlled substance registration number;

3.3.c. Verification by the applicant that he or she is currently registered to access the West Virginia Controlled Substance Monitoring Program (“WVCSMP”), if required to be so registered by law, and that he or she understands his or her obligation to report the dispensing of controlled substances to the WVCSMP; and

3.3.d. The practice name, physical address and telephone number of each and every practice location where the applicant seeks to be registered to dispense and/or administer controlled substances.

3.4. Any application submitted by a physician assistant licensed by the Board for registration as a controlled substance dispensing practitioner shall be authorized by the applicant's supervising physician who is a controlled substance registered dispenser, and shall be accompanied by a copy of the physician assistant's current, authorized practice agreement which includes a delegation of dispensing authority consistent with the submitted application.

3.5. The Board shall not grant a registration, and an applicant is ineligible to register as a controlled substance dispensing practitioner, if the applicant:

3.5.a. Does not possess a current, valid and unexpired individual DEA controlled substance registration number;

3.5.b. Has been convicted of a felony offense relating to controlled substances in any jurisdiction; or

3.5.c. Is currently subject to any administrative or court order which places restrictions or limitations of any kind upon the practitioner's prescriptive authority in any jurisdiction.

3.6. An initial controlled substance dispensing registration shall expire on the same date as the practitioner's medical, podiatric or physician assistant license, unless renewed prior to that date. Thereafter, registration shall be valid for a period of two years.

3.7. If the initial registration period is less than one year, an application for registration as a controlled substance dispensing practitioner must be accompanied by payment of a nonrefundable annual registration fee in the amount of fifteen dollars per dispensing location. If the initial registration period is greater than one year, an application for registration as a controlled substance dispensing practitioner must be accompanied by payment of a nonrefundable biennial registration fee in the amount of thirty dollars per dispensing location.

3.8. After the initial registration period, all controlled substance dispensing registrations shall be valid for a period of two years, and the annual registration fee shall be collected biennially at a rate of thirty dollars per dispensing location.

3.9. Controlled substance dispensing registrations issued by the Board to a practitioner are granted for specific practice locations, and are not transferable from one location to another.

3.10. Controlled substance dispensing registrations issued by the Board automatically terminate if a registered controlled substance dispensing practitioner is no longer authorized to prescribe controlled substances in West Virginia.

3.11. The Board shall waive the registration fee and renewal registration fees for all controlled

substance dispensing registrations which are obtained to administer and/or dispense controlled substances free of charge to patients at a free clinic or summer camp.

3.12. Registered controlled substance dispensing practitioners may engage in office-based dispensing and/or administering of controlled substances to a patient under his or her care at registered controlled substance dispensing locations.

~~**§11-5-4. Duties of Dispensing Physicians.**~~

~~4.1. A dispensing physician may not delegate the dispensing function to another physician or podiatrist, nor to other office personnel. However, a dispensing physician may delegate nonjudgmental functions to supportive personnel, subject to the requirement that the dispensing physician must personally perform the following duties:~~

~~(a) Discuss with patients matters pertaining to the drug, its reasons for usage, and contraindications or answer questions regarding the dispensing physician's intent.~~

~~(b) Perform any other functions of any kind which require the knowledge, judgment, ability or skill of a dispensing physician.~~

~~4.2. A dispensing physician who is the supervising physician for a "Type A" Physician Assistant may delegate the dispensing function to that "Type A" Physician Assistant. A "Type A" Physician Assistant must follow all rules applicable to the dispensing physician. A "Type A' Physician Assistant may dispense only those legend drugs that he or she is authorized to prescribe. A "Type A" Physician Assistant may dispense legend drugs to those patients for whom the "Type A" Physician Assistant has prescribed the legend drugs at the direction of the supervising physician, but may not dispense legend drugs to patients for whom the supervising physician has prescribed legend drugs.~~

~~4.3. A dispensing physician must have access to reference books relating to the dispensing of medication, including the most recent edition of USP DI.~~

~~4.4. A dispensing physician must have immediate access to the package insert, or its equivalent, for every legend drug dispensed to patients.~~

~~4.5. A dispensing physician must maintain equipment necessary for the dispensing of legend drugs, including a typewriter or computer and~~

~~(a) For solid oral dosage forms, two (2) pill counting trays and two (2) spatulas;~~

~~(b) For liquid oral dosage forms (including antibiotic powders for reconstitution), distilled water, two (2) glass stirring rods, two (2) glass or plastic funnels, filter paper and one 1/2cc to 500cc graduate.~~

~~4.6. A dispensing physician must maintain a dispensing area, where all stock quantities of legend~~

~~drugs maintained for dispensing to patients must be stored under conditions that meet USP criteria as published in USP DI, to prevent deterioration. Legend drugs must be stored in a locked or otherwise secure area to prevent access when the dispensing physician is not present in the office.~~

§11-5-4. Registration Not Required for Practitioners Administering and Dispensing ~~Legend~~ Prescription Drugs Which Are Not Classified as Controlled Substances.

4.1. A practitioner may administer or dispense prescription drugs which are not classified as controlled substances to patients under his or her care without registering with the Board. However, he or she may be required to report office-based dispensing activity on his or her biennial license renewal application.

4.2. Every drug dispensing practitioner, regardless of registration status, shall comport his or her dispensing practice with the requirements set forth in this rule, and with all applicable state and federal rules and regulations.

~~**§11-5-5. Sale at Retail Prohibited.**~~

~~5.1. The sale at retail of legend drugs by dispensing physicians is prohibited.~~

§11-5-5. General Practice Requirements Applicable to All Drug Dispensing Practitioners.

5.1. Drug dispensing practitioners may not fill prescriptions written by other practitioners.

5.2. Drug dispensing practitioners may only administer or dispense prescription drugs to a patient under the practitioner's care in the course of his or her professional practice.

5.3. The sale at retail of prescription drugs by dispensing practitioners is prohibited.

5.4. A legible notice, no smaller than 8 1/2" by 11", shall be posted in a conspicuous place in every office of where a drug dispensing practitioner engages in dispensing. The notice must include the following language: "Every patient has the right to receive a written prescription as an alternative to having prescription medications dispensed to you by your physician, podiatric physician or physician assistant."

5.5. A drug dispensing practitioner may administer those drugs to a patient under his or her care, which are, in the practitioner's medical judgment, therapeutically beneficial or necessary for the patient's treatment and in keeping with approved use of the medication.

5.6 A drug dispensing practitioner shall comply with all appropriate record keeping requirements applicable to the drugs administered. A practitioner must assure compliance with said record keeping requirements by persons acting under his or her direction and supervision.

5.7. A practitioner may charge a fee for the administration of drugs to a patient that is separate from fees charged for other medical services. The separate fee shall allow the practitioner to

recover the cost of administration, including the cost of the drug itself.

5.8. Prior to dispensing a prescription drug to a patient, a drug dispensing practitioner shall offer to provide a written prescription to the patient, which the patient may elect to have filled by the practitioner or by any licensed pharmacy of the patient's choice.

5.9. The dispensing of prescription drugs shall be the personal act of the drug dispensing practitioner to a patient under his or her care. A drug dispensing practitioner may not delegate any aspect of dispensing prescription drugs which requires the utilization of the knowledge, judgment, ability or skill of a drug dispensing practitioner.

5.10. Drug dispensing practitioners may make reasonable charges for their services, including reasonable charges for any prescription drugs they dispense. If a drug dispensing practitioner charges for dispensing prescription drugs, a charge for prescription drugs shall be separately listed on the patient's bill, and the patient shall be informed of the separate charge for said prescription drug prior to the medication being dispensed by the practitioner.

5.11. When a patient receives a generic drug product from a dispensing practitioner, the patient shall be informed that a generic drug product is being dispensed.

5.12. Except as otherwise limited by state or federal law, drug dispensing practitioners may dispense amounts of drugs as they deem sufficient to a patient's course of treatment. Provided, that a drug dispensing practitioner may not dispense a quantity or classification of prescription drugs which exceeds the quantity or classification that the practitioner is authorized by law to prescribe.

5.13. Prior to dispensing a prescription drug, a dispensing practitioner shall discuss with the patient matters pertaining to the drug, why the dispensing practitioner has prescribed the drug, contraindications to the drug's use, and he or she shall provide the patient with an opportunity to ask questions regarding the drug, any side effects and/or the directions for usage.

5.14. A drug dispensing practitioner must clearly document in the patient medical record each and every occasion upon which a prescription drug is administered or dispensed to a patient. Such documentation must include:

5.14.a. The date the prescription drug was administered or dispensed;

5.14.b. The name of the prescription drug which was dispensed or administered;

5.14.c. The quantity and/or dose of prescription drug dispensed or administered; and

5.14.d. The basis or reason the prescription drug was prescribed, dispensed or administered.

5.15. Dispensing practitioners are prohibited from:

5.15.a. Dispensing or administering any unit or quantity of a prescription drug which has

exceeded its expiration or beyond use date on the date; and

5.15.b. Dispensing any unit or quantity of a prescription drug which will exceed its expiration or beyond use date prior to the end user's reasonable use of the dispensed quantity.

5.16. A dispensing practitioner shall ensure that expired prescription drugs are promptly removed from his or her prescription drug office use and dispensing inventory.

5.17. Practitioner disposal of expired or unwanted controlled substances in the practitioner's office use or dispensing inventory shall comport with the requirements of 21 C.F.R. §1317.05(a), and any other applicable state or federal requirements for the documentation and disposal of controlled substances.

~~**§11-5-6. Freedom of Choice.**~~

~~6.1. Every patient has the right to receive a written prescription as an alternative to having legend drugs dispensed by a dispensing physician.~~

~~6.2. A sign no smaller than 8 1/2" by 11" shall be posted in a conspicuous place in the office of every dispensing physician, which must include the following language: "Every patient has the right to receive a written prescription as an alternative to having legend drugs dispensed by your physician."~~

~~6.3. If a physician charges for dispensing legend drugs, a charge for legend drugs shall be separately listed on the patient's bill and the patient shall be informed of the separate charge for said legend drug prior to having the prescription filled by the physician.~~

~~6.4. When a patient receives a generic drug product from a dispensing physician, the patient shall be told that a generic drug product is being dispensed.~~

§11-5-6. Security, Packaging and Labeling.

6.1. A dispensing practitioner must have immediate access to reference materials relating to the dispensing of medication, and must also have immediate access to the package insert, or its equivalent, for every prescription drug dispensed to patients.

6.2. A dispensing practitioner shall maintain at all times the minimum professional and technical equipment and sanitary appliances and environmental conditions that are necessary to prepare and dispense prescriptions properly.

6.3. A dispensing practitioner must maintain a dispensing area, where all stock quantities of prescription drugs maintained for dispensing to patients must be stored under conditions that prevent deterioration.

6.4. Prescription drugs must be stored in a locked or otherwise secure area to prevent access when the drug dispensing practitioner is not present in the office. All registered controlled substance

dispensing practitioners shall provide effective, enhanced controls and procedures to guard against theft and diversion of controlled substances. Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operations. At a minimum, such security controls shall include the storage of all controlled substances in an environmentally controlled, separately locked safe or cabinet with the access code or key limited to registered controlled substance dispensing practitioners.

6.5. A drug dispensing practitioner shall notify the Board, in writing, of any theft or significant loss of any controlled substances upon discovery of the theft.

6.6. Each prescription drug dispensed by a dispensing practitioner must be packaged in its own separate container and labeled with its own specific directions.

6.7. Dispensing practitioners shall package prescription drugs in appropriate containers, and shall generally utilize child-proof and tamper-resistant packaging. In determining the appropriate packaging container, the drug dispensing practitioner should evaluate whether the dispensed drug is susceptible to damage or deterioration if exposed to light, moisture or other environmental conditions. Paper or plastic bags, boxes or envelopes do not meet packaging requirements for prescription drugs and should not be used.

6.8. Labels for dispensed medications must be legible.

6.9. Prescription drugs that are not classified as controlled substances must be packaged in a container labeled with the following information:

6.9.a. The name, address and telephone number of the dispensing practitioner;

6.9.b. The name of the patient for whom the prescription drug was dispensed;

6.9.c. The date the prescription drug was dispensed;

6.9.d. The name of the actual drug dispensed (if a generic drug product is dispensed, the container shall be labeled with the generic name of the drug and the name of the manufacturer or distributor of the generic drug product. The container may not be labeled with a brand name unless the product dispensed is actually the brand name product);

6.9.e. The strength of the drug dispensed;

6.9.f. The quantity of the drug dispensed;

6.9.g. Full directions for use of the dispensed drug and any special storage requirements;

6.9.h. Any cautions which may be required by federal or state law; and

6.9.i. The expiration or beyond use date of the drug dispensed.

6.10. The directions "Take as directed," or any formulation thereof which does not provide full

and specific directions to the patient may cause patient confusion and do not constitute compliance with the labeling requirements of this rule.

6.11. Practitioner dispensed prescriptions for controlled substances must be packaged in a container labeled with all of the information required in subsection 6.9. Labels for dispensed controlled substances must also include:

6.11.1. An identification of the controlled substance classification of the dispensed drug (C-II, C-III, C-IV, etc.); and

6.11.2. The following statement: *"Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."*

~~**§11-5-7. Packaging.**~~

~~7.1. Dispensing physicians shall package legend drugs in appropriate containers. The Board recognizes the United States Pharmacopeia standards as expressed in USP DI as the standard reference for determining legend drug packaging requirements.~~

~~(a) If a legend drug is susceptible to light, it must be packaged in a light resistant container, as specified in USP DI.~~

~~(b) If a legend drug is susceptible to moisture, it must be packaged either in a well closed container or in a tight container, as specified in USP DI.~~

~~(c) Paper or plastic bags, boxes or envelopes do not meet packaging requirements for legend drugs and should not be used.~~

~~7.2. All legend drugs must be dispensed in containers that comply with the child-resistant packaging standards mandated by the Federal Poison Prevention Packaging Act of 1970 (PPPA).~~

~~(a) The Board recognizes that under the PPPA child-resistant packaging is to be the rule and not the exception.~~

~~(b) The Board further recognizes that under the PPPA there are specific exceptions to the requirement of child-resistant packaging.~~

~~(1) If the patient receiving the legend drug requests, or if the prescriber determines that it is appropriate, a legend drug may be dispensed in a noncomplying container that is not child-resistant.~~

~~(2) The following legend drugs are exempt from the requirement of the PPPA:~~

~~(A) Cyclically administered oral contraceptives in manufacturer's memory-aid dispenser packages.~~

~~(B) Sublingual dosage forms of nitroglycerin.~~

~~(C) Sublingual and chewable forms of isosorbide dinitrate in dosage unit containing10mg or less.~~

~~(D) Aqueous solutions and tablets containing sodium fluoride with no more than 265mg / package.~~

~~(E) Betamethasone in tablet form in packages containing not more than 12.6mg of the drug.~~

~~(F) Mebendazole in tablet form in packages containing not more than 600mg of the drug.~~

~~(G) Methylprednisolone in tablet form in packages containing not more than 84mg of the drug.~~

~~(H) Colestipol in powder form in packages containing not more than 5g of the drug.~~

~~(I) Erythromycin ethylsuccinate in tablet form, each tablet containing no more than 250mg of the drug and dispensed in packages of no more than 80 tablets.~~

~~(J) Erythromycin ethylsuccinate granules for oral suspension in packages containing not more than 8g of the drug.~~

~~(K) Anhydrous cholestyramine (chloride salt of a basic anion exchange resin) in powder form.~~

~~(L) Individually packaged effervescent potassium supplement tablets containing not more than 50mgEq of potassium per tablet.~~

~~(M) Pancrelipase preparations in tablet, capsule or powdered form.~~

§11-5-7. Additional Requirements for the Dispensing of Controlled Substances.

7.1. A licensee of this Board who is not a registered controlled substance dispensing practitioner, or who is ineligible to register, shall not administer or dispense any controlled substances at any outpatient or office-based practice location in West Virginia.

7.2. When dispensing a prescription drug that is classified as a controlled substance, a registered controlled substance dispensing practitioner shall make all required reports to the West Virginia Controlled Substance Monitoring Program ("CSMP"). Reports to the CSMP may also be required for certain prescription drugs which are not classified as controlled substances, and as set forth in the West Virginia Board of Pharmacy's legislative rule, series 8, related to the Controlled Substance Monitoring Program. W. Va. Code R. § 15 CSR 8.

7.3. A practitioner shall not issue a prescription for the purpose of obtaining controlled substance drugs for dispensing to patients or for "office use." A practitioner may obtain controlled substances from a pharmacy 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. When dispensing a controlled substance a registered controlled substance dispensing practitioner shall comport his or her dispensing practice with all applicable state and federal laws.

~~**§11-5-8. Labeling.**~~

~~8.1. Each legend drug dispensed by a dispensing physician must be packaged in its own separate container and labeled with its own specific directions.~~

~~8.2. Labels must be machine made or printed legibly.~~

~~8.3. Legend drugs that are not classified as controlled substances must be packaged in a container labeled with the following information:~~

~~(a) Dispensing physician's name, address and telephone number. (b)~~

~~Patient's name~~

~~(c) Date dispensed~~

~~(d) Name of drug~~

~~(e) Full directions for use~~

~~(f) Appropriate ancillary label(s), such as "Keep Refrigerated" or "This drug may cause drowsiness."~~

~~8.4. Legend drugs that are classified as controlled substances must be labeled with the above information (8.3, a-f) in addition to the following statement: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."~~

~~8.5. The directions "Take as directed" are permitted only as an exception to the general rule requiring full directions for use, because they are not specific and can lead to patient confusion and error.~~

~~8.6. If a generic drug product is dispensed, the container shall be labeled with the generic name of the drug and the name of the manufacturer or distributor of the generic drug product. The container may not be labeled with a brand name unless the product dispensed is actually the brand name product.~~

§11-5-8. Returned or Surrendered Drugs; Authorization and Procedures for Destruction; Prohibition on Reuse

8.1. In accord with current federal Drug Enforcement Agency (DEA) regulations, licensees of the Board are prohibited from accepting unused and/or unwanted controlled substances from or on behalf of patients.

8.2. A licensee may refer individuals in lawful possession of unwanted and unused controlled substances and who are seeking disposal assistance to:

8.2.a. Entities which are registered with the Drug Enforcement Agency (DEA) as authorized collectors to receive the transfer from ultimate users of any unwanted and unused pharmaceutical controlled substances in their lawful possession for safe, secure, and responsible disposal pursuant to 21 C.F.R. §1317.40;

8.2.b. Local law enforcement operating federally authorized take-back events, mail-back programs, or collection receptacles; and/or

8.2.c. The DEA website for information regarding proper methods of self-disposal by the lawful possessor.

8.3. With the exception of controlled substances, a licensee of the Board may accept unused prescription drugs from or on behalf of patients for the purpose of proper disposal.

8.4. The disposal of returned or surrendered prescription drugs shall occur promptly, and no later than thirty days after receipt.

8.5. Until disposed of, returned or surrendered prescription drugs shall be stored in a locked or otherwise secure area to prevent access by unauthorized individuals.

8.6. Returned or surrendered prescription drugs may not be stored with a practitioner's office use or dispensing inventory.

8.7. A licensee who accepts returned or surrendered prescription drugs shall maintain a log which lists:

8.7.a. The name of the patient to whom the retuned or surrendered drug was dispensed;

8.7.b. The strength of the returned or surrendered drug;

8.7.c. The quantity returned or surrendered;

8.7.d. The date and manner of disposal; and

8.7.e. The printed name and signature of the individual who actually disposed of the drug.

8.8. Logs required by subsection 8.7 must be maintained for a period of two years after disposal of the returned or surrendered prescription drug.

8.9. A practitioner may not dispense, administer or reuse any returned or surrendered drug unless such dispensing, administering or reuse occurs pursuant to a prescription drug donation program established by this state.

§11-5-9. Dispensing Records; Inspection and Audit of Dispensing Locations.

9.1. A ~~dispensing physician~~ drug dispensing practitioner must maintain records that are available for inspection by the Board and any other state or federal entity authorized to conduct such an inspection. All dispensing records:

9.1.a. Shall be maintained for a period of at least five years; and

9.1.b. Must be readily retrievable.

9.2. Patient records must facilitate an audit trail for each patient to whom ~~legend~~ prescription drugs are dispensed. They may be maintained either in a patient's chart or in an equivalent but separate patient medication record.

9.3. Daily records must facilitate an audit trail for each day on which scheduled controlled substances are dispensed. They may be maintained in a daily log or in a file of prescriptions.

~~(a)~~ 9.3.a. Daily records of dispensed Schedule II controlled substances must be maintained in a separate daily log or file of prescriptions, apart from all other records.

~~(b)~~ 9.3.b. Daily records of dispensed Schedule III, IV and V controlled substances may be maintained either in another separate daily log or in a file of prescriptions.

9.4. For each ~~legend~~ prescription drug dispensed, both patient records and daily records shall include:

~~(a)~~ 9.4.a. Patient's name;

~~(b)~~ 9.4.b. Drug name and strength;

~~(c)~~ 9.4.c. Quantity dispensed;

~~(d)~~ 9.4.d. Date dispensed; and

9.4.e. Directions for use.

9.5. An authorized representative or investigator for the Board may, without prior notice, enter at any reasonable hour a registered drug dispensing location and/or a location where the Board believes the unregistered dispensing of controlled substances is occurring by a licensee of the Board to conduct an audit:

9.5.a. To verify general compliance with this rule; or

9.5.b. To investigate an allegation or complaint with respect to a practitioner's dispensing practice.

9.6. A person may not deny or interfere with an entry under this section.

9.7. The Board's representative may require a practitioner or facility where dispensing occurs by a licensee of this Board to provide access to:

9.7.a. Any records relating to the practitioner's dispensing practice;

9.7.b. Any records a practitioner is required to maintain pursuant to this rule; and

9.7.c. All inventories of prescription drugs, including controlled substances, maintained at the location subject to audit.

9.8. It is a violation of this rule for a licensee of this Board to refuse to undergo or cooperate with a dispensing review or audit by the Board.

9.9. The Board's representative shall refer possible compliance issues to the appropriate Committee of the Board and/or to any other agency that has jurisdiction over a facility, place of practice or practitioner.

§11-5-10. Other Legal Authority.

10.1. Drug ~~D~~dispensing practitioners ~~physicians~~ must comply with all federal and state laws applicable to drug dispensing ~~physicians~~ practitioners.

§11-5-11. Disciplinary Action.

11.1. Any ~~V~~violation of these rules ~~concerning dispensing physicians~~ shall constitute unprofessional conduct and shall subject~~s~~ the violator to disciplinary action by the Board under the provisions of West Virginia Code §30-3-14.