WEST VIRGINIA SECRETARY OF STATE
KRIS WARNER
ADMINISTRATIVE LAW DIVISION

eFILED
8/25/2026 2:02:31 PM
Office of West Virginia
Secretary Of State

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY:	Medicine		
RULE TYPE:	Legislative	TITLE-SERIES:	11-05
RULE NAME:	Dispensing of Prescription Drugs by Practitioners		
CITE AUTHORITY:	W. Va. Code §§30-3-7(a)(1), 30-3E-2(3) and 60A-3-301.		

The above proposed Legislative rules, following review by the Legislative Rule Making Review Committee, is hereby modified as a result of review and comment by the Legislative Rule Making Review Committee. The attached modifications are filed with the Secretary of State.

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

Mark A Spangler -- 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 11
LEGISLATIVE RULES
BOARD OF MEDICINE

SERIES 5
DISPENSING OF PRESCRIPTION DRUGS BY 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 related to the regulation and control of controlled substances by a practitioner.

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

1.3. Filing Date. -- ~~May 9, 2022.~~

1.4. Effective Date. -- ~~June 1, 2022.~~

1.5. Sunset Provision. -- This rule shall terminate and have no further force or effect upon August 1, ~~2027~~ ~~2037~~ 2032.

§11-5-2. Definitions.

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

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

~~2.2.a.~~ 2.2.1. A physician or podiatric physician, or his or her authorized agent;

~~2.2.b.~~ 2.2.2. A physician assistant practicing in collaboration with physicians; or

~~2.2.c.~~ 2.2.3. The patient or research subject at the direction and in the presence of the practitioner.

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

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.

2.5. “Dispense" 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.

2.8. "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.

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

2.11. "Practitioner" means a physician, podiatric physician, or physician assistant licensed by the Board.

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

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

2.14. “Registered controlled substance dispensing practitioner” means a practitioner who is registered with the Board to dispense or administer 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.

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

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

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

3.1. A practitioner who dispenses a 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 practice location where the practitioner dispenses controlled substances.

3.2. A practitioner who administers a 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 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.~~ 3.3.1. The applicant's full name and West Virginia Board of Medicine license number;

~~3.3.b.~~ 3.3.2. The applicant's current individual Drug Enforcement Agency (DEA) controlled substance registration number;

~~3.3.c.~~ 3.3.3. 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.~~ 3.3.4. The practice name, physical address and telephone number of each practice location where the applicant seeks to be registered to dispense and/or administer controlled substances.

3.4. A physician assistant must have an active practice notification on file with the Board for the proposed controlled substance dispensing location identified on the physician assistant's registration application.

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

~~3.5.a.~~ 3.5.1. Does not possess a current, valid and unexpired individual DEA controlled substance registration number;

~~3.5.b.~~ 3.5.2. Has been convicted of a felony offense relating to controlled substances in any jurisdiction; or

~~3.5.c.~~ 3.5.3. Is currently subject to any administrative or court order in any jurisdiction 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 a controlled substance dispensing registration which is obtained to dispense and/or administer controlled substances free of charge to patients at a free clinic or summer camp.

3.12. A registered controlled substance dispensing practitioner 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. Registration not Required for Practitioners Dispensing and Administering Prescription Drugs Which are not Classified as Controlled Substances.

4.1. A practitioner may dispense or administer 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. A 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. General Practice Requirements Applicable to All Drug Dispensing Practitioners.

5.1. A drug dispensing practitioner may not fill prescriptions written by other practitioners.

5.2. A drug dispensing practitioner may only dispense or administer 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: "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 the record keeping requirements by persons acting under his or her direction and supervision.

5.7. 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.

5.8. 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.

5.9. 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.

5.10. 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.

5.11. Except as otherwise limited by state or federal law, a drug dispensing practitioner may dispense amounts of drugs as the provider determines is sufficient to a patient's course of treatment. 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.

5.12. 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.

5.13. A drug dispensing practitioner must clearly document in the patient's medical record when a prescription drug is dispensed or administered to a patient. The documentation must include:

~~5.13.a.~~ 5.13.1. The date the prescription drug was dispensed or administered;

~~5.13.b.~~ 5.13.2. The name of the prescription drug which was dispensed or administered;

~~5.13.c.~~ 5.13.3. The quantity and/or dose of prescription drug dispensed or administered; and

~~5.13.d.~~ 5.13.4. The basis or reason the prescription drug was prescribed, dispensed or administered.

5.14. Dispensing practitioners are prohibited from:

~~5.14.a.~~ 5.14.1. Dispensing or administering any unit or quantity of a prescription drug which has exceeded its expiration or beyond use date; and

~~5.14.b.~~ 5.14.2. 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.

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

5.16. 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. 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. A registered controlled substance dispensing practitioner 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, these 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 registered controlled substance 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. A prescription drug dispensed by a dispensing practitioner must be packaged in its own separate container and labeled with its own specific directions.

6.7. A practitioner shall package prescription drugs in appropriate containers, and shall generally utilize child-proof and tamper-resistant packaging. In determining the appropriate packaging container, the 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.~~ 6.9.1. The name, address and telephone number of the dispensing practitioner;

~~6.9.b.~~ 6.9.2. The name of the patient for whom the prescription drug was dispensed;

~~6.9.c.~~ 6.9.3. The date the prescription drug was dispensed;

~~6.9.d.~~ 6.9.4. 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~~. 6.9.5. The strength of the drug dispensed;

~~6.9.f~~. 6.9.6. The quantity of the drug dispensed;

~~6.9.g.~~ 6.9.7. Full directions for use of the dispensed drug and any special storage requirements;

~~6.9.h.~~ 6.9.8. Any cautions which may be required by federal or state law; and

~~6.9.i~~. 6.9.9. The expiration or beyond use date of the drug dispensed.

6.10. The directions "Take as directed," or any formulation thereof which do~~es~~ 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. 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 dispense or administer 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 §15 CSR 8.

7.3. A practitioner shall not issue a prescription to obtain a controlled substance drug 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. Returned or Surrendered Drugs; Authorization and Procedures for Destruction; Prohibition on Reuse

8.1. In accord with current federal 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~~. 8.2.1. Entities which are registered with the 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.~~ 8.2.2. Local law enforcement operating federally authorized take-back events, mail-back programs, or collection receptacles; and/or

~~8.2.c~~. 8.2.3. 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.~~ 8.7.1. The name of the patient to whom the retuned or surrendered drug was dispensed;

~~8.7.b.~~ 8.7.2. The strength of the returned or surrendered drug;

~~8.7.c.~~ 8.7.3. The quantity returned or surrendered;

~~8.7.d.~~ 8.7.4. The date and manner of disposal; and

~~8.7.e.~~ 8.7.5. 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 and in accord with the requirements of a prescription drug donation program established by this state.

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

9.1. A 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.~~ 9.1.1. Shall be maintained for a period of at least five years; and

~~9.1.b.~~ 9.1.2. Must be readily retrievable.

9.2. Patient records must facilitate an audit trail for each patient to whom 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.

~~9.3.a.~~ 9.3.1. 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.

~~9.3.b.~~ 9.3.2. 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 prescription drug dispensed, both patient records and daily records shall include:

~~9.4.a.~~ 9.4.1. The name of the patient to whom the drug was dispensed;

~~9.4.b.~~ 9.4.2. The name of the drug and the strength dispensed;

~~9.4.c.~~ 9.4.3. The quantity of the drug dispensed;

~~9.4.d.~~ 9.4.4. The date that the drug was dispensed; and

~~9.4.e.~~ 9.4.5. The 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.~~ 9.5.1. To verify general compliance with this rule; or

~~9.5.b.~~ 9.5.2. 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.~~ 9.7.1. Any records relating to the practitioner's dispensing practice;

~~9.7.b.~~ 9.7.2. Any records a practitioner is required to maintain pursuant to this rule; and

~~9.7.c.~~ 9.7.3. 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. Disciplinary Action.

10.1. Any violation of these rules shall constitute unprofessional conduct and shall subject the violator to disciplinary action by the Board under the provisions of West Virginia Code §§30-3-14 and 30-3E-17.