

**WEST VIRGINIA
SECRETARY OF STATE
JOE MANCHIN, III
ADMINISTRATIVE LAW DIVISION**

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Form #4

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE
OFFICE WEST VIRGINIA
SECRETARY OF STATE

AGENCY: Board of Acupuncture TITLE NUMBER: 32 Series 2

CITE AUTHORITY: 30-36-7, 30-36-14 (F)

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: Title 32, Series 2

TITLE OF RULE BEING PROPOSED: Rules for Dispensing of Materia
Medica, Formulary and Legend Drugs

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.



Authorized Signature

**Title 32
Legislative Rule
Board of Acupuncture**

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OFFICE WEST VIRGINIA
SECRETARY OF STATE

**Series 2
Rules for Dispensing of Materia Medica, Formulary
and Legend Drugs**

32-5-1. General.

1.1. Scope. --West Virginia Code § 30-36-7 authorizes the Board of Acupuncture to promulgate rules which are necessary to perform the duties and responsibilities of the Board. This rule establishes standards of practice for the dispensing of materia medica, formulary and legend drugs by licensed acupuncture physicians.

1.2. Authority. -- W. Va. Code §§ 30-36-7.

1.3. Filing Date. --

1.4. Effective Date. --

32-5-2. Application and enforcement.

This legislative rule applies to all licensed acupuncture physicians, all student acupuncturists and all apprentice acupuncturists. The enforcement of these rules is vested with the Board.

32-5-3. Definitions.

3.1. "Materia Medica" means all those substances generally used in a course of treatment by Oriental Medicinal practitioners and acupuncturists, including but not limited to: vitamins, minerals, glandulars or pharmaceutical analogue, herbs or pharmaceutical analogue, homeopathic drugs, natural formulas or compounds and the naturally occurring human metabolic compounds or pharmaceutical analogue.

3.2. "Formulary" means those substances found in the USP-NF (United States Pharmacopeia - National Formulary) as defined by US Code and the USFDA (Food and Drug Agency).

3.3. "Legend Drug" means a drug that may be dispensed under federal or state law only pursuant to the prescription of an authorized prescriber. This includes but is not

limited to: vitamins, minerals, glandulars, homeopathics, herbs and their extracts, formulas and compounds.

3.4. "Homeopathic Drug" means a drug, formula or compound found in the HPUS (Homeopathic Pharmacopeia of the United States) as defined by US Code and the USFDA (Food and Drug Agency).

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

- a. An acupuncture physician or, in his or her presence, by his or her authorized agent; or
- b. The patient or research subject at the direction of the acupuncture physician.

3.6. "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 to the next scheduled or anticipated office visit for a chronic disease.

3.7 "Dispense" means to deliver a homeopathic, natural formula, vitamin, herb, mineral, glandular, legend drug, to an ultimate user or research subject by or pursuant to the lawful order of a licensed acupuncturist, including the prescribing, packaging, labeling, administering or compounding necessary to prepare the drug for that delivery.

32-5-4. General rules for dispensing acupuncture physicians.

4.1. Each acupuncture physician who wishes to dispense herbs, vitamins, minerals, homeopathic drugs, glandulars and extracts of glands , formulas and compounds, and legend drugs to patients shall register with the Board as a dispensing acupuncturist, on a form provided by the Board. The annual fee for registration as a dispensing acupuncturist is fifteen dollars (\$15.00).

4.2. Acupuncturists who are registered with the Board as dispensing acupuncturists may dispense and compound for their own patients and may fill written prescriptions or orders by other licensed acupuncture physicians. They may make reasonable charges for their services, including selling at retail, and may dispense amounts of drugs as they determine sufficient to a patient's course of treatment.

32-5-5 Duties of the dispensing acupuncture physician.

5.1. The dispensing acupuncture physician shall personally perform the following duties:

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- a. Discuss with patients matters pertaining to the herbs, vitamins, minerals, homeopathic drugs, glandulars and extracts of glands, formulas and compounds, legend drugs; the reasons for usage, and contraindications or answer questions regarding the dispensing acupuncture physician's intent; and
 - b. Perform any other functions of any kind which require the knowledge, judgement, ability, or skill of a dispensing acupuncture physician.
- 5.2. A dispensing acupuncture physician shall have access to reference books relating to the dispensing of materia medica and homeopathic drugs, including the USP-NF or the USP-DI (United States Pharmacopeia Drug Information).
- 5.3. A dispensing acupuncture physician shall have immediate access to the package insert, or its equivalent, for every legend drug dispensed to patients.
- 5.4. A dispensing acupuncture physician shall maintain a dispensing area, where all stock quantities of materia medica maintained for dispensing to patients are stored under conditions which meet USP-NF criteria published in the USP DI, to prevent deterioration. Legend drugs shall be stored in a locked or otherwise secure area to prevent access when the dispensing acupuncturist is not present in the office.

32-5-6 Freedom of Choice.

- 6.1. Every patient has the right to receive a written prescription as an alternative to having herbs, vitamins, minerals, homeopathic drugs, glandular and extracts of glands, formulas and compounds, or legend drugs being dispensed by a dispensing acupuncture physician.
- 6.2. A sign no smaller than 8 ½" by 11" shall be posted in a conspicuous place in the office of every dispensing physician, which shall include the following language: "Every patient has the right to receive a written prescription as an alternative to having herbs, vitamins, minerals, homeopathic drugs, glandular and extracts of glands, formulas and compounds, or legend drugs dispensed by your acupuncture physician."
- 6.3. If an acupuncture physician charges for dispensing materia medica, the charge for materia medica shall be separately listed on the patients's bill and the patient shall be informed of the separate charge for the materia medica prior to having the prescription filled by the acupuncture physician.

32-5-7 Labeling.

- 7.1. Each materia medica dispensed by a dispensing acupuncture physician shall be

packaged in its own separate container and labeled with its own specific directions.

- 7.2 Labels shall be printed or typed legibly in English.
- 7.3 Materia medica, homeopathic and legend drugs that are not classified as controlled substances shall be packaged in a container labeled with the following information:
- a. The dispensing acupuncture physicians name, address, and telephone number;
 - b. The patient's name;
 - c. The date dispensed;
 - d. The name of the drug;
 - e. Full directions for use; and
 - f. Appropriate ancillary labels, such as "Keep Refrigerated" or "This drug may cause drowsiness."
- 7.4 Materia medica, homeopathic and legend drugs that are classified as controlled substances shall be labeled in accordance with subsection 7.3 of this section 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."
- 7.5 The directions "Take as directed" are permitted only as an exception to the general rule requiring full directions for use, and only when the patient has received a printed direction, other than an insert, from the dispensing acupuncture physician.
- 7.6 If a generic drug product is dispensed, the label shall be labeled with the generic name of the drug. The container may not be labeled with the brand name unless the product dispensed is actually the brand name product.

32-5-8 Dispensing records.

- 8.1 The dispensing acupuncture physician shall maintain records that are available for inspection by the Board or its designee.
- 8.2 Patient records shall facilitate an audit trail for each patient to whom materia medica, homeopathic or legend drugs or glandulars are dispensed. They may be maintained either in a patient's chart or in an equivalent but separate record.
- 8.3 For each legend drug dispensed patient records shall include:

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- a. The patient's name;
- b. The drug name and strength;
- c. The quantity dispensed; and
- d. Directions for use.

32-5-9 Other legal authority.

- 9.1 Dispensing acupuncture physicians shall comply with all federal and state laws applicable to dispensing acupuncture physicians.

32-5-10 Restrictions.

- 10.1 Acupuncture physicians shall not pre-sign blank prescription forms.
- 10.2 Acupuncture physicians shall not prescribe, order, dispense, administer, supply, sell or give any drug which is an amphetamine or sympathomimetic amine drug and a compound designated as a Schedule II controlled substance under W. Va. Code § 60A-1-101 to 60A-1-707, to or for any person.
- 10.3 Acupuncture physicians shall not prescribe or dispense any "Controlled Substance" as defined in W. Va. Code § 60A-1-101 to 60A-1-707:
 - a. With the intent or knowledge that a controlled substance will be used or is likely to be used other than medicinally or for an accepted Oriental medicinal therapeutic purpose;
 - b. With the intent to evade any law with respect to the sale, use or disposition of the controlled substances;
 - c. For the licensee's personal use, or for the use of his or her immediate family when the licensee knows or has reason to know that an abuse of controlled substances are occurring, or may result from the practice; or
 - d. In amounts that the licensee knows or has reason to know, under the attendant circumstances, that the amounts prescribed or dispensed are excessive under accepted and prevailing Oriental medical standards of practice.