

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

Form #2

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**FILED**

2003 JUL 22 P 1:04

OFFICE WEST VIRGINIA  
SECRETARY OF STATE

**NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE**

AGENCY: Board of Acupuncture TITLE NUMBER: 32

RULE TYPE: Legislative CITE AUTHORITY: 30-36-7 and 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: 32CRS2

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

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON August 29, 2003 AT 12:00 pm ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

Board of Acupuncture  
P O Box 252  
Huntington, West Virginia,  
25707-0252

Attn: Darrell E. Samples

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.

*Darrell E. Samples, MD, OMD*  
\_\_\_\_\_  
Authorized Signature

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

West Virginia Board of Acupuncture

Title 32

Summary of Proposed Legislative Rule, 32CRS2  
Rules for Dispensing Materia Medica, Formulary and Legend Drugs

The rule is proposed for the protection of the citizens and public at large with regard to the dispensing of materia medica, formulary and legend drugs by licensed acupuncturists. These items, more commonly known as herbs, homeopathics, glandulars, minerals and vitamins, are used by licensed acupuncture physicians in their practice. 32CRS2 establishes the Board of Acupuncture control over the use of these items by the licensees.

The rule establishes a broad set of guidelines which will allow an "accepted and standard of Oriental practice" in West Virginia regarding the use of material medica. This rule is in compliance with the US Drug Enforcement Agency guidelines for midlevel practitioners.

□  
APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Rules for Dispensing of Materia Medica, Formulary and Legend Drugs

Type of Rule:  Legislative     Interpretive     Procedural

Agency: Board of Acupuncture

Address: P O Box 252  
Huntington, West Virginia, 25707-0252

1. Effect of Proposed rule:

	ANNUAL FISCAL YEAR				
	INCREASE	DECREASE	CURRENT	NEXT	THEREAFTER
<b>ESTIMATED TOTAL COST</b>					
<b>PERSONAL SERVICES</b>					
<b>CURRENT EXPENSE</b>					
<b>REPAIRS &amp; ALTERATIONS</b>					
<b>EQUIPMENT</b>					
<b>OTHER</b>					

2. Explanation of Above Estimates:

There will be no effect on the cost of service to or by the agency.

3. Objectives of These Rules:

This rule establishes an increased level of safety for the public receiving materia medica from licensed acupuncturists.

Rule Title: Rules for Dispensing of Materia Medica, Formulary and Legend Drugs

4. Explanation of Overall Economic Impact of Proposed Rule:

A. Economic Impact on State Government:

There will be no specific impact upon the agency.

B. Economic Impact on Political Subdivisions; Specific Industries; Specific Groups of Citizens: There will be no foreseeable impact upon any other agency, group, industry or the citizens of West Virginia.

C. Economic Impact on Citizens/Public at Large.

There is no foreseeable economic impact upon the public by this proposed rule.

Date: July 22, 2003

Signature of Agency Head or Authorized Representative:

Darrell F. Sampus, MD, PhD

**QUESTIONNAIRE**

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

DATE: July 22, 2003

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency Name, Address & Phone No.) Board of Acupuncture, P.O. Box 252, Huntington, West Virginia, 25707-0252

LEGISLATIVE RULE TITLE: Rules for Dispensing of Materia Medica, Formulary and Legend Drugs

1. Authorizing statute(s) citation 30-36-7 and 30-36-14 (f)

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:  
July 22, 2003

b. What other notice, including advertising, did you give of the hearing?  
Mailed copies out to all of the license holders.

c. Date of Public Hearing(s) *or* Public Comment Period ended:  
August 29, 2003

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.  
Attached \_\_\_\_\_ No comments received \_\_\_\_\_

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

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

Darrell E. Samples, ND, OMD  
Secretary, Board of Acupuncture  
P O Box 252  
Huntington, West Virginia 25707-0252  
304 529-9355 (office)  
304 529-3710 (fax)  
d.drsamplesnd@verizon.net (e-mail)

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

same

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

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

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b. Date of hearing or comment period:

July 22, 2003 to August 29, 2003

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

\_\_\_\_\_

d. Attach findings and determinations and reasons:

Attached \_\_\_\_\_

32 CRS 2

FILED

**Title 32  
Legislative Rule  
Board of Acupuncture**

2003 JUL 22 P 1:04

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 and 30-36-14 (f).

1.3. Filing Date. --

1.4. Effective Date. --

**32-5-2. Application and enforcement.**

This legislative rules applies to all licensed acupuncture physicians, all student acupuncturists and all apprenticed 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 presence, by his 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, glandular and extracts of glands, formulas and compounds, 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 shall be 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 deem sufficient to a patient's course of treatment.

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

5.1. The dispensing acupuncture 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 acupuncture physicians intent.
  - 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 must 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 must have immediate access to the package insert, or its equivalent, for every legend drug dispensed to patients.
- 5.4 A dispensing acupuncture physician must 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 must 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 materia medica 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 must include the following language: "Every patient has the right to receive a written prescription as an alternative to having materia medica 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' bill and the patient shall be informed of the separate charge for said 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 must be packaged in its own separate container and labeled with its own specific directions.

- 7.2 Labels must be printed or typed legibly in English.
- 7.3 Materia medica, homeopathic and legend drugs that are not classified as controlled substances must be packaged in a container labeled with the following information:
- a. Dispensing acupuncture physicians name, address, and telephone number,
  - b. Patient's name,
  - c. Date dispensed,
  - d. Name of drug,
  - e. Full directions for use, and
  - f. Appropriate ancillary label(s), such as "Keep Refrigerated" or "This drug may cause drowsiness."
- 7.4 Materia medica, homeopathic and legend drugs that are classified as controlled substances must be labeled with the above (Section 7.4, 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."
- 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 must maintain records that are available for inspection by the Board or its designee.
- 8.2 Patient records must facilitate an audit trail for each patient to whom materia medica, homeopathic, legend drug or glandular are dispensed. They may be maintained either in a patient's chart or in an equivalent but separate.
- 8.3 For each legend drug dispensed patient records shall include:
- a. Patients name,
  - b. Drug name and strength,
  - c. Quantity dispensed, and

- d. Directions for use.

**32-5-9 Other legal authority.**

- 9.1 Dispensing acupuncture physicians must 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 Prescribing or dispensing 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 substance (s);
  - 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 substance (s) is occurring, or may result from such a practice; or
  - d. In such amounts that the licensee knows or has reason to know, under the attendant circumstances, that the amounts so prescribed or dispensed are excessive under accepted and prevailing Oriental medical standards of practice.

**32-5-11 Severability.**

- 11.1 If any provision of this rule or the application thereof to any person or circumstance is held invalid, the invalidity shall not affect the provisions or application of this rule which can be given effect without the invalid provisions or application and to this end the provisions of this rule are declared to be severable.