

WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #4

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DEC 16 10 05 AM '98

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: BOARD OF ACUPUNCTURE TITLE NUMBER: 32

CITE AUTHORITY W.Va. CODE § 30-36-7

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 NEW RULE BEING PROPOSED: 32 CRS 6

TITLE OF RULE BEING PROPOSED: STANDARDS OF PRACTICE
OF ACUPUNCTURE BY LICENSED ACUPUNCTURISTS

THE ABOVE PROPOSED LEGISLATIVE RULE, 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

\$3.00

FILED

32 CRS 6

DEC 16 10 05 AM '98

**Title 32
Legislative Rule
Board of Acupuncture**

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

**Series 6
Standards of Practice
Of Acupuncture By Licensed Acupuncturists**

32-6-1. General.

- 1.1. Scope. --This rule establishes the minimum standards of practice for acupuncture in this state.
- 1.2. Authority. -- W. Va. Code § 30-36-7.
- 1.3. Filing Date. --
- 1.4. Effective Date. --

32-6-2. Application.

This legislative rule applies to all licensed acupuncturists, all student acupuncturists and all apprenticed acupuncturists.

32-6-3. Definitions.

- 3.1. Clean Needle Technique. -- The standard protocol test as administered by the CCAOM.
- 3.2. CCAOM. -- The Council of Colleges of Acupuncture and Oriental Medicine.
- 3.3. FDA. -- The federal Food and Drug Administration.
- 3.4. OSHA. -- The federal Occupational Safety and Health Administration.

32-6-4. Condition of Office.

4.1. Each acupuncture office, clinic, treatment center or institution shall be maintained in a clean and sanitary condition at all times, and shall have a readily accessible bathroom facilities for both male and female patients.

4.2. The Board or its representative may make announced or unannounced office inspections during regular business hours to insure that sanitary conditions are being maintained. The Board or its representative may inspect treatment as well as non treatment areas. Patient files and records shall be made available to any authorized inspection by the Board or its official representative.

32-6-5. Disposable needles; sterilization equipment.

5.1. Disposable needles.-- All acupuncture offices, clinics, treatment centers and institutions shall use only pre-sterilized disposable needles. A practitioner shall use pre-sterilized disposable needles according to "clean needle technique" and standards of practice established by the CCAOM.

5.2. Sterilization Equipment. --All acupuncture offices, clinics, treatment centers and institutions shall have functioning sterilization equipment for sanitizing non-needle equipment which is used in the normal and regular treatment of patients, or they shall contract with a local hospital or medical service for the transportation and sterilization of the non-needle equipment. Sterilization equipment shall be inspected at least once every two years by qualified inspectors.

32-6-6. Treatment Procedures.

A licensed acupuncturist shall practice the standard protocols of the FDA and the CCAOM during treatments by adhering to the following procedures:

6.1. Hand washing. -- The acupuncturist shall vigorously scrub his or her hands with soap and warm water immediately before examining patients or handling acupuncture needles and other instruments, and between patients.

6.2. Sterilization of Instruments. --All non-needle instruments shall be sterilized before use in a manner which will destroy all microorganisms. All needle trays which contain sterile needles shall also be sterile. Each time non-needle instruments are sterilized, the acupuncturist shall use a tape or strip indicator which shows that sterilization is complete.

6.3. Acupuncture needles. -- A practitioner shall use only pre-packaged, pre-sterilized disposable needles for acupuncture treatments. Needles may not be reused on the same patient, even during the same treatment.

6.4. Acupuncture points. -- The practitioner shall clean area of the patient's body where needles are to be inserted with an appropriate antiseptic before insertion of the needle.

6.5. Subcutaneous needle breakage. --In the event an acupuncture needle inserted in a patient breaks subcutaneously, the treating acupuncturist shall immediately consult a medical physician. An acupuncturist shall not sever or penetrate the tissues in order to excise the needle.

6.6. Medical treatment for complications. -- A acupuncturist shall refer any complications, including but not limited to, hematoma, peritonitis or pneumothorax arising out of an acupuncture treatment shall refer immediately to a western medical doctor, osteopath or podiatrist, if appropriate, when immediate medical treatment is required.

6.7. Pointpuncture (aquapuncture). --A practitioner shall perform point-puncture injections using sterile disposable needles and sterile solutions.

6.8. Needle Disposal. --A practitioner shall dispose of all acupuncture needles, pointpuncture needles and instruments to be discarded into rigid biohazard containers. A practitioner shall discard needles in one of the two following ways:

6.8.1. They shall be sterilized and discarded in a sealed container; or

6.8.2 They shall be placed in a sealed unbreakable container marked "Hazardous Waste" and disposed of in a manner consistent with OSHA biohazardous waste regulations.

32-6-7. Informed Consent.

The practitioner shall notify patients in writing and verbally, as any treatment requires, regarding any potential complications arising from the treatment plan.

32-6-8. Treatments Outside the Office.

8.1. A practitioner who provides acupuncture treatment outside the office shall carry the required sterile needles and other instruments in a sterile airtight container.

8.2. A practitioner shall adhere to all standards of practice applicable to treatment when providing the treatment out of his or her office.

32-6-9. Content and Retention Acupuncture Medical Records.

9.1. Acupuncturists shall maintain written medical records justifying the course of treatment of each patient. These records shall include for each patient at least the following:

- 9.1.1. The patient's medical history;
- 9.1.2. Acupuncture and Oriental Medical diagnostic impressions;
- 9.1.3. Points used and any treatment procedures administered at each visit;
- 9.1.4. The practitioner's recommendations; and
- 9.1.5. Patient progress notes.

9.2. The practitioner shall maintain all medical records for a period of five (5) years from the date of the last entry to the record.

32-6-10. Financial Responsibility.

10.1. Financial Responsibility. --As a prerequisite for licensure or license renewal every acupuncturist shall maintain medical malpractice insurance or professional liability insurance and shall provide the Board with proof of that financial responsibility. Each licensee shall have one of the following:

10.1.1. A licensed acupuncturist shall obtain and maintain professional liability coverage in an amount not less than \$10,000 per claim, with a minimum annual aggregate of not less than \$30,000 from an authorized insurer.

10.1.2. Obtaining and maintaining an unexpired, irrevocable letter of credit in the amount not less than \$10,000 per claim, with a minimum aggregate availability of credit of not less than \$30,000. The letter of credit shall be payable to the acupuncturist as beneficiary upon presentment of a final judgement indicating liability and awarding damages to be paid by the acupuncturist or upon presentment of a settlement agreement signed by all parties to such agreement

when the final judgement or settlement is a result of a claim arising out of the rendering of, or the failure to render, acupuncture services. The letter of credit shall be nonassignable and nontransferable. The letter of credit shall be issued by any bank or savings association organized under the W. Va. Code .

10.1.3. Obtaining and maintaining a surety bond in an amount not less than \$10,000 per claim, with a minimum annual aggregate of not less than \$30,000 written by a company licensed to do business in West Virginia.

10.2. Exemptions. -- Upon application to the Board, the following licensees are exempt from the requirements of this section:

10.2.1. Any acupuncturist who practices exclusively as an officer, employee or agent of the federal government or of the state of West Virginia or its agencies or subdivisions. For the purposes of this rule, an agent of the State of West Virginia, its agencies or its subdivisions is a person who is eligible for coverage under any plan offered by the State of West Virginia;

10.2.2. Any licensee whose license has become inactive and who is not practicing in this state. Any licensee applying for reactivation of a license shall show either that the licensee maintained tail insurance coverage which provided liability coverage for incidents that occurred on or after January 1, 1998, or the initial date of licensure in West Virginia, whichever is later, and incidents that occurred before the date on which the license became inactive; or such licensee shall submit an affidavit stating that the licensee has no unsatisfied medical malpractice judgements or settlements at the time of application for reactivation;

10.2.3. Any licensee who practices only in conjunction with his or her teaching duties at an accredited school. That licensee may engage in the practice of acupuncture to the extent that the practice is incidental to and a necessary part of duties in connection with the teaching position in the school;

10.2.4. Any licensee holding an active license under W. Va. Code § 30-36-1 et seq. who is not practicing in West Virginia. If that person initiates or resumes practice in this state, he or she shall notify the Board of the activity and fulfill his or her obligation to obtain coverage; and

10.2.5. Any licensee who can demonstrate to the Board that he or she has no malpractice exposure in the State of West Virginia.



FILED
Nov 16 12 17 PM '98
OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

WEST VIRGINIA LEGISLATURE
Legislative Rule-Making Review Committee

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November 12, 1998

Senator Mike Ross, Co-Chairman
Delegate Mark Hunt, Co-Chairman
Debra A. Graham, Counsel

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NOTICE OF ACTION TAKEN BY LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

TO: Ken Hechler, Secretary of State, State Register

TO: Dr. Darrell E. Samples
Board of Acupuncture
P.O. Box 252
Huntington, WV 25707

FROM: Legislative Rule-Making Review Committee

Proposed Rule: **Standards of Practice of Acupuncture by Licensed Acupuncturists,
32CSR6**

The Legislative Rule-Making Review Committee recommends that the West Virginia Legislature:

1. Authorize the agency to promulgate the Legislative Rule
(a) as originally filed
(b) as modified by the agency
2. Authorize the agency to promulgate part of the Legislative rule;
a statement of reasons for such recommendation is attached.
3. Authorize the agency to promulgate the Legislative rule with
certain amendments; amendments and a statement of reasons
for such recommendation is attached.
4. Authorize the agency to promulgate the Legislative rule as
modified with certain amendments; amendments and a
statement of reasons for such recommendation is attached.

ANALYSIS OF PROPOSED LEGISLATIVE RULES

Agency: Board of Acupuncture

Subject: Standards of Practice of Acupuncture by Licensed Acupuncturists, 32CSR6

PERTINENT DATES

Filed for public comment: April 17, 1998
Public comment period ended: May 20, 1998
Filed following public comment period: August 3, 1998
Filed LRMRC: August 3, 1998
Filed as emergency:

Fiscal Impact: None

OFFICE OF THE CLERK
SECRETARY OF STATE
SEP 16 10 31 AM '98
FILED

ABSTRACT

The proposed rule is new. The following is a section by section synopsis of the proposed rule.

Section 1 is the standard general section, setting forth the scope, authority, filing date and effective date of the proposed rule.

Section 2 states that the proposed rule applies to all licensed, student and apprenticed acupuncturists.

Section 3 defines terms.

Section 4 requires acupuncture clinics etc. to be clean and sanitary and provides for inspections by the Board.

Section 5 requires the use of pre-sterilized disposable needles. It also requires clinic to have sterilization equipment for non-needle equipment or to contract the sterilization out. The equipment is required to be inspected every two years.

Section 6 relates to treatment procedures and contains provisions regarding hand washing, instrument sterilization, subcutaneous needle breakage, etc.

Section 7 requires that the patient be given written and oral notification regarding any potential complications arising from the treatment plan.

Section 8 contains standards where the treatment occurs outside of the clinic.

Section 9 requires the practitioner to maintain written records on each patient and to maintain them for 5 years from the last date of entry. It specifies the information which must be contained in the records.

Section 10 contains provisions for the maintenance of patient records of a practitioner who dies, terminates his practice or relocates.

Section 11 requires licensees to maintain medical malpractice insurance or professional liability insurance. It sets forth certain licensees who may be exempt from the financial responsibility requirements.

AUTHORITY

Statutory authority: W.Va. Code, §30-36-7, which provides, in part, as follows:

(a) The board may propose for promulgation legislative rules to carry out the provisions of this article in accordance with the provisions of article three, chapter twenty-nine-a of this code...

ANALYSIS

I. HAS THE AGENCY EXCEEDED THE SCOPE OF ITS STATUTORY AUTHORITY IN APPROVING THE PROPOSED LEGISLATIVE RULE?

No.

II. IS THE PROPOSED LEGISLATIVE RULE IN CONFORMITY WITH THE INTENT OF THE STATUTE WHICH THE RULE IS INTENDED TO IMPLEMENT, EXTEND, APPLY, INTERPRET OR MAKE SPECIFIC?

Yes.

III. DOES THE PROPOSED LEGISLATIVE RULE CONFLICT WITH OTHER CODE PROVISIONS OR WITH ANY OTHER RULE ADOPTED BY THE SAME OR A DIFFERENT AGENCY?

No.

IV. IS THE PROPOSED LEGISLATIVE RULE NECESSARY TO FULLY ACCOMPLISH THE OBJECTIVES OF THE STATUTE UNDER WHICH THE PROPOSED RULE WAS PROMULGATED?

Yes.

V. IS THE PROPOSED LEGISLATIVE RULE REASONABLE, ESPECIALLY AS IT AFFECTS THE CONVENIENCE OF THE GENERAL PUBLIC OR OF PERSONS AFFECTED BY IT?

The provisions of Section 10, while reasonable from the point of patients are probably not reasonable from the point of those required to publish the notices and maintain records. Many of the provisions are unenforceable in that the Board has no authority over the persons it is attempting to regulate.

VI. CAN THE PROPOSED LEGISLATIVE RULE BE MADE LESS COMPLEX OR MORE READILY UNDERSTANDABLE BY THE GENERAL PUBLIC?

No.

VII. WAS THE PROPOSED LEGISLATIVE RULE PROMULGATED IN COMPLIANCE WITH THE REQUIREMENTS OF CHAPTER 29A, ARTICLE 3 AND WITH ANY REQUIREMENTS IMPOSED BY ANY OTHER PROVISION OF THE CODE?

Yes.

VIII. OTHER.

Counsel has technical modifications to suggest.