

**WEST VIRGINIA
SECRETARY OF STATE
Betty Ireland
ADMINISTRATIVE LAW DIVISION**

Form #1

Do Not Mark In This Box

2008 MAY 20 AM 9:05

SECRETARY OF STATE

NOTICE OF A PUBLIC HEARING ON A PROPOSED RULE

AGENCY: West Virginia Board of Medicine TITLE NUMBER: 11

RULE TYPE: Legislative CITE AUTHORITY: WV Code §30-3-7(a)(1)

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: Definition of Surgery

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 10

TITLE OF RULE BEING PROPOSED: _____

DATE OF PUBLIC HEARING: _____ TIME: _____

LOCATION OF PUBLIC HEARING: _____

COMMENTS LIMITED TO: ORAL WRITTEN BOTH

DATE WRITTEN COMMENT PERIOD ENDS: June 27, 2008 TIME: 4:30 P.M.

WRITTEN COMMENTS MAY BE MAILED TO:

The Department requests that persons wishing to make comments at the hearing make an effort to submit written comments in order to facilitate the review of these comments.

Robert C. Knittle, Executive Director
WV BOM

101 Dee Drive Suite 103

Charleston, WV 25311

The issues to be heard shall be limited to the proposed rule.

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL



Authorized Signature



R. Curtis Arnold, DPM
South Charleston

Michael L. Ferrebee, MD
Morgantown

Angelo N. Georges, MD
Wheeling

Doris M. Griffin, MBA
Martinsburg

M. Khalid Hasan, MD
Beckley

Beth Hays, MA
Bluefield

Carlos C. Jimenez, MD
Glen Dale

Vettivelu Maheswaran, MD
Charles Town

Bill May, DPM
Huntington

Joe E. Miller, LtCol USMC (Ret), MA
Hurricane

Badshah J. Wazir, MD
South Charleston

Kenneth Dean Wright, PA-C
Huntington

State of West Virginia

West Virginia Board of Medicine

101 Dee Drive, Suite 103

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Telephone 304.558.2921

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STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE PROPOSED RULE AND SUMMARY OF CONTENT OF PROPOSED RULE

Due to technological developments in surgery over the past decades, particularly the increasing use of lasers and pulsed light devices, it is necessary and in the interests of public safety and welfare to now define specifically what is meant by the practice of surgery in the Medical Practice Act and provide for proper standards and training for all those utilizing this equipment.

The proposed rule defines ablative and non-ablative treatments, appropriate professional standards, appropriate education and training, credentials, supervision, personal supervision, supervising physician, and surgery itself. It provides for supervision of non-physician advanced health care providers for ablative treatments and for non-ablative treatments. The proposed rule addresses the utilization of non-physician health care practitioners as assistants during the performance of surgery utilizing lasers, pulsed light, radiofrequency devices, chemicals or ionizing radiation.

The contents of required written protocols are set forth. Equipment safety and registration with the Board of Medicine are addressed. The supervising physician maintains full responsibility to patients and the Board of Medicine for the manner and results of all treatment rendered. Hospitals are specifically exempted from the provisions of the rule, and if there is a conflict between this rule and specific other rules, this rule controls.

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Point Pleasant

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COUNSEL
Deborah Lewis Rodecker
Charleston

DISCIPLINARY COUNSEL
John K. McHugh
Charleston

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Definition of Surgery

Type of Rule: Legislative Interpretive Procedural

Agency: West Virginia Board of Medicine

Address: 101 Dee Drive Suite 103
Charleston WV 25311

Phone Number: 304-558-2921 Email: deborahrodecker@wvdhhr.org

Fiscal Note Summary

Summarize in a clear and concise manner what impact this measure will have on costs and revenues of state government.

No impact on costs and revenues of state government.

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.

FISCAL YEAR			
Effect of Proposal	Current Increase/Decrease (use "-")	Next Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0.00	0.00	0.00
Personal Services			
Current Expenses			
Repairs & Alterations			
Assets			
Other			
2. Estimated Total Revenues	0.00	0.00	0.00

Rule Title: _____

Rule Title: Definition of Surgery

3. **Explanation of above estimates (including long-range effect):**
Please include any increase or decrease in fees in your estimated total revenues.

N/A

MEMORANDUM

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

Date: May 20, 2008

Signature of Agency Head or Authorized Representative

Patricia Knittel

TITLE 11

LEGISLATIVE RULE

WEST VIRGINIA BOARD OF MEDICINE

SERIES 10

DEFINITION OF SURGERY

2000 MAY 20 AM 9: 06

DEPARTMENT OF STATE

11-10-1. General.

1.1. Scope.- W. Va. Code § 30-3-4(3) defines the practice of medicine and surgery as the diagnosis or treatment of, or operation or prescription for, any human disease, pain, injury, deformity or other physical or mental condition. W. Va. Code § 30-3-7(a)(1) permits the Board of Medicine to adopt such regulations as are necessary to carry out the purposes of the article, which W. Va. Code § 30-3-2 states in pertinent part is to provide for the licensure and professional discipline of physicians and podiatrists and to provide a professional environment that encourages the delivery of quality medical services within the state. Due to technological developments in surgery over the years, it is necessary for the health and welfare of the citizens of the state and in the public interest to clarify and define by rule what constitutes surgery.

1.2. Authority.- W. Va. Code § 30-3-7(a)(1).

1.3. Filing date.-

1.4. Effective date.-

11-10-2. Definitions.

2.1. For purposes of this rule, the following definitions apply:

a. "ablative treatment" means treatment that is expected to excise, burn, destroy or vaporize the skin below the dermo-epidermal junction, and includes any procedure that may damage the eye (cornea to retina).

b. "appropriate professional standards" means comprehensive surgical training and experience, including the management of complications, and the acquisition of certification in the appropriate surgical specialties by a member board of the American Board of Medical Specialties (ABMS) and credentials in the use of lasers, pulsed light, radiofrequency devices, or other similar techniques.

c. "appropriately educated and trained" means training that pertains to the physics and safety of light based medical devices and to performing any act or procedure that may alter, transpose or damage live human skin, including fundamentals of laser operation; bio-effects of laser radiation on the eye and skin; significance of specular and diffuse reflections; non-beam hazards of lasers; non-ionizing radiation hazards; laser and laser systems classifications; and control measures. A training program for each device must be attended, and maintenance of competency to perform non-ablative procedures through documented training and

experience regarding the appropriate standard of care in the field of non ablative procedures and the use of specific device(s).

d. "credentials" means a minimum of sixteen hours of basic training devoted to the principles of lasers, pulsed light devices and thermal, radiofrequency and other non-ablative devices, their instrumentation, physiological effects and safety requirements, including clinical applications of various wavelengths and hands-on practical sessions with devices and their appropriate surgical or therapeutic delivery systems.

e. "dermis" means that layer of skin which provides nutrient delivery and waste disposal via diffusion through the dermo-epidermal junction.

f. "dermo-epidermal junction" means the undulating basement membrane that adheres the epidermis to the dermis.

g. "epidermis" means the layer of skin which is sustained and supported by the dermis.

h. "non-ablative treatment" means a treatment that is not expected or intended to excise, burn, or vaporize the epidermal surface of the skin, including treatments related to laser hair removal.

i. "personal supervision" means the physician must be in attendance in the room throughout the performance of the procedure by a non-physician health care provider.

j. "supervising physician" means a physician who holds a full and unrestricted medical license in West Virginia and meets appropriate professional standards.

k. "supervision" means the opportunity and ability of the physician to exercise continuous control and direction over the services of non-physician health care practitioners and requires the physician to be physically present on the premises, within the office suite, and immediately available at all times the non-physician health care provider may be on duty.

l. "surgery" means structural alteration of the human body by the incision or destruction of tissues and is part of the practice of medicine. Surgery includes ablative and non-ablative treatments. Surgery means the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue, which includes lasers, ionizing radiation, pulsed light, radiofrequency devices, scalpels, probes and needles. The tissue may be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reduction for major dislocations and fractures, or otherwise altered by any mechanical, thermal, light based, electromagnetic, or chemical means. Except for administration by nursing or physician assistant personnel of some injections, such as subcutaneous, intramuscular, and intravenous, when ordered by a physician, surgery means injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system.

11-10-3. Supervision of non-physician advanced health care providers for ablative treatments.

- 3.1. A supervising physician may delegate the performance of ablative treatments to advanced nurse practitioners and physician assistants, who are appropriately educated and trained, and licensed by the State of West

Virginia, provided the treatments are performed under the supervision of the supervising physician and provided further the ablative treatments performed fall within the statutory and/or regulatory scope of the practitioner's profession, and in the case of physician assistants, have been requested in a current job description and approved by the Board of Medicine.

- 3.2. The physician is responsible for assuring that the advanced nurse practitioner and/or the physician assistant are appropriately educated and trained, licensed by the State of West Virginia, are practicing within the scope of their licensure, only with the use of written protocols, and in the case of physician assistants, in accordance with a job description approved by the Board of Medicine.
 - 3.3. The supervising physician is responsible for the initial review of the patient and for authorizing the treatment plan, and the same is to be recorded in the patient's medical record prior to any initial ablative treatment
- 11-10-4. Supervision of non-physician health care providers for non-ablative treatments.
- 4.1. A supervising physician may delegate the performance of non-ablative treatments or procedures to advanced nurse practitioners, registered professional nurses, physician assistants, and aestheticians, appropriately educated and trained, licensed by the State of West Virginia, provided the treatments are performed under supervision by the physician.
 - 4.2. The physician is responsible for assuring that such persons are appropriately educated and trained, licensed in the State of West Virginia, are practicing within the scope of their licensure, and only with the use of written protocols.
 - 4.3. The supervising physician is responsible for the initial review of the patient and for authorizing the treatment plan, and the same is to be recorded in the patient's medical record prior to any initial non-ablative treatment.
- 11-10-5. Utilization of non-physician health care practitioners as assistants during the performance of surgery utilizing lasers, pulsed light, radiofrequency devices, chemicals, or ionizing radiation.
- 5.1. When a physician utilizes a non-physician health care practitioner during the performance of an ablative or non-ablative treatment involving lasers, pulsed light, radiofrequency devices, ultrasound, chemicals, or ionizing radiation, the assistant must be properly licensed to practice his or her profession and have been appropriately educated and trained for assisting the physician in such procedures and complete assigned duties under the personal supervision of the physician performing the procedure.
- 11-10-6. Written protocols.
- 6.1. Written protocols for the purpose of this section means physician's order, standing delegation order, standing medical order, or other written order that is maintained on site. A written protocol must provide, at a minimum, the following:

- a. A statement identifying the physician authorized to utilize the specific device and responsible for the delegation of the performance of the specified procedure;
 - b. A statement of the activities, decision criteria, and plan the non-physician health care provider shall follow when performing delegated procedures;
 - c. Selection criteria to screen patients for the appropriateness of non-ablative treatments;
 - d. Identification of devices and settings to be used for patients who meet selection criteria;
 - e. Methods by which the specified device is to be operated;
 - f. A description of appropriate care and follow-up for common complications, serious injury, or emergencies as a result of the non-ablative treatment; and
 - g. Documentation of decisions made and a plan for communication or feedback to the authorizing physician concerning specific decisions made.
- Documentation shall be recorded within a reasonable time after each procedure in the patient's medical record.

11-10-7. Equipment Safety and Registration.

- 7.1. Equipment used for the purposes stated in this rule must be inspected, calibrated and certified as safe to use according to the manufacturer's specifications and any use or operation of equipment named herein shall be in compliance with applicable federal law.
- 7.2. A physician who, for surgical purposes, uses or offers to use a laser, pulsed light device, ionizing radiation or radiofrequency device in any facility other than a hospital, as defined in West Virginia Code § 16-29B-3(e), shall register with the Board of Medicine, on a form provided by the Board.
- 7.3. After initial registration, it shall be the obligation of the physician to notify the Board in writing promptly of any change or addition of facility location where such devices are used.
- 7.4. Designated representatives of the Board are authorized to make on-site visits to such facilities to review compliance with this rule.

11-10-8. Responsibility of Supervising Physician.

- 8.1. The supervising physician maintains full responsibility to patients and the Board of Medicine for the manner and results of all treatment rendered.

11-10-9. Applicability of Rules.

- 9.1. These rules do not apply to persons who are duly licensed health care providers under other pertinent provisions of the West Virginia Code and who are acting within the scope of their license, and they do not apply to hospitals, as defined in West Virginia Code § 16-29B-3(e).
- 9.2. In the event of any conflict between this rule and the Board of Medicine rule applying to physician assistants or the Board of Registered Professional nurses rule applying to advanced nurse practitioners, or the Board of Barbers and Cosmetologists rule applying to Aestheticians, this rule shall control.