

**WEST VIRGINIA
SECRETARY OF STATE
BETTY IRELAND
ADMINISTRATIVE LAW DIVISION**

Form #4

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OFFICE WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: West Virginia Board of Medicine TITLE NUMBER: 11

CITE AUTHORITY: West Virginia 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: _____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: _____

TITLE OF RULE BEING PROPOSED: Definition of Surgery to Include the Use of Lasers, Ionizing Radiation,
Pulsed Light and Radiofrequency Devices

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

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Definition of Surgery to Include the Use of Lasers, Ionizing
Light and Radiofrequency Devices

OFFICE WEST VIRGINIA
SECRETARY OF STATE**11-10-1. General**

- 1.1. **Scope.-** Due to technological developments in surgery over the last twenty-five years, it is necessary for the health and welfare of the citizens of the state and in the public interest to clarify that the use of lasers, ionizing radiation, pulsed light and radio-frequency devices constitute surgery.
- 1.2. **Authority.-** 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.
- 1.3. **Filing date.-**
- 1.4. **Effective date.-**

11-10-2. Definitions.

- 2.1. For purposes of this rule, the following words and terms mean the following:
 - a. "Ablative treatment" means surgery that is expected to excise, burn, destroy or vaporize the skin below the stratum corneum.
 - 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 and radiofrequency devices, ionizing radiation, or other similar techniques.
 - c. "Appropriately educated and trained" means completion of training for a device and the maintenance of competency to perform procedures that may alter, transpose or damage live human skin, through documented training and experience regarding the appropriate standard of care; the fundamentals of laser operation; the physics and safety of light based medical devices; bio-effects of laser radiation on the skin; significance of specular and diffuse reflections; non-beam hazards of lasers; non-ionizing radiation hazards; laser and laser systems classifications; and control measures.

- 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. "Deep ablative treatment" means treatment below the dermo-epidermal junction.
- f. "Dermis" means that layer of skin which provides nutrient delivery and waste disposal via diffusion through the dermo-epidermal junction.
- g. "Dermo-epidermal junction" means the undulating basement membrane that adheres the epidermis to the dermis.
- h. "Epidermis" means the layer of skin which is sustained and supported by the dermis.
- i. "Direct Supervision" means the opportunity and ability of the supervising physician to exercise continuous control and direction over the services of a practitioner and requires the supervising physician to be physically present within the office suite and immediately available at all times to the practitioner throughout the performance of a procedure.
- j. "Non-ablative treatment" means a surgery by any laser or intense pulsed light treatment or other energy source, chemical or modality that is not expected or intended to excise, burn, or vaporize the epidermal surface of the skin, including treatments related to laser hair removal.
- k. "Personal supervision" means the supervising physician must be physically present in the room throughout the performance of the procedure by a practitioner.
- l. "Stratum corneum" means the outermost layer of the epidermis.
- m. "Supervising physician" means a physician licensed under article, three chapter thirty and meets the appropriate professional standards.
- n. "Written protocols" means the supervising physician's order, standing delegation order, standing medical order, or other written order that is maintained on site.

11-10-3. Practice of Medicine and Surgery.

The practice of medicine and surgery for the purposes of this rule, as defined in section four, article three, chapter thirty includes the following:

1. Deep ablative, ablative and non-ablative treatments.
2. The use of lasers, ionizing radiation, pulsed light and radiofrequency devices.
3. The alteration of the tissue by any mechanical, thermal, light based, electromagnetic, or chemical means.

11-10-4. Practitioner qualifications.

4.1 A practitioner shall meet and practice under the following conditions:

- a. Be licensed as an aesthetician by the Board of Barbers and Cosmetologists, a person licensed by the Board of Examiners for Registered Professional Nurses or a person licensed by the Board of Examiners for Licensed Practical Nurses;
- b. Be appropriately educated and trained;
- c. Perform within his or her scope of practice;
- d. Work within established written protocols.

11-10-5. Supervision of practitioners for deep ablative surgery.

- 5.1 A supervising physician may delegate the performance of deep ablative surgery to a practitioner.
- 5.2 The practitioner shall perform deep ablative surgery under the personal supervision of the supervising physician.
- 5.3 The supervising physician shall confirm that practitioner meets the requirements in section 4.
- 5.4 The supervising physician is responsible for the patient's examination and treatment plan which shall be recorded in the patient's medical record prior to any treatment.

11-10-6. Supervision of a practitioner for ablative surgery and non-ablative surgery.

- 6.1 A supervising physician may delegate the performance of ablative and non-ablative surgery to a practitioner.
- 6.2 The practitioner shall perform ablative and non-ablative surgery under the direct supervision of the supervising physician.

- 6.3 The supervising physician shall confirm that practitioner meets the requirements in section 4.
- 6.4 The supervising physician is responsible for the examination 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 treatment.
- 11-10-7. Utilization of a practitioner as an assistant during a procedure utilizing lasers, pulsed light and radiofrequency devices, chemicals, or ionizing radiation.
- 7.1 A physician may utilize a practitioner during the performance of a deep ablative, ablative or non-ablative surgery involving lasers, pulsed light devices, radiofrequency devices, chemicals, or ionizing radiation.
- 7.2 The supervising physician shall confirm that practitioner meets the requirements in section 4 to assist the physician in such surgery.
- 11-10-8. Written protocols.
- 8.1 A written protocol must provide, at a minimum:
- a. A statement identifying the physician authorized to utilize the specific device and responsible for the delegation of the performance of the specified surgery;
 - b. A statement of the activities, decision criteria, and the practitioner 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;
 - g. Documentation of decisions made and a plan for communication or feedback to the authorizing physician concerning specific decisions made shall be recorded in the patient's chart pre-operatively; and,

h. Documentation of a post-operative note shall be recorded within 24 hours after each treatment in the patient's medical record.

11-10-9. Equipment Safety and Registration.

- 9.1 Equipment used for the purposes stated in this rule shall be inspected, calibrated and certified as safe to use according to the manufacturer's specifications and in compliance with applicable federal law.

11-10-10. Responsibility of Supervising Physician.

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

11-10-11. Applicability of Rule.

- 11.1 This rule does not apply to:

- a. Hospitals, as defined in West Virginia Code 16-29B-3(e);
- b. Clinics, organized in whole or in part for the delivery of health services to needy and indigent patients without charge;
- c. Advanced practice nurses, advanced nurse practitioners, or certified nurse midwives, acting pursuant to a collaborative agreement with a licensed physician; and,
- d. Licensed physician assistants acting pursuant to job descriptions approved by the Board of Medicine, supervised by a supervising physician(s).