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## Final Regulation Agency Background Document

<b>Agency name</b>	Board of Medicine, Department of Health Professions
<b>Virginia Administrative Code (VAC) citation(s)</b>	18VAC85-20 18VAC85-50
<b>Regulation title(s)</b>	Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry, and Chiropractic Regulations Governing the Practice of Physician Assistants
<b>Action title</b>	Direction and supervision of laser hair removal
<b>Date this document prepared</b>	2/14/19

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations*.

### Brief Summary

*Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.*

Consistent with provisions of HB2119 of the 2017 General Assembly, laser hair removal must be performed by a “properly trained person” who is a licensee or by a “properly trained person under the direction and supervision” of a doctor, physician assistant, or nurse practitioner. Proposed regulations establish the knowledge and training that a practitioner supervising or performing laser hair removal must have, allows for delegation to a properly trained person provided the supervising practitioner is readily available when laser hair removal is being performed, and limits any prescribing of controlled substances to practitioners authorized to prescribe in accordance with statutory requirements for establishment of a practitioner-patient relationship.

## Acronyms and Definitions

*Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the “Definition” section of the regulations.*

RAP = Regulatory Advisory Panel

## Statement of Final Agency Action

*Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.*

On February 14, 2019, the Board of Medicine adopted amendments to 18VAC85-20-10 et seq., Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry, and Chiropractic and 18VAC85-50-10 et seq., Regulations Governing the Practice of Physician Assistants.

## Mandate and Impetus

*Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding the mandate for this regulatory change, and any other impetus that specifically prompted its initiation. If there are no changes to previously-reported information, include a specific statement to that effect.*

Section 54.1-2973.1 of the Code of Virginia specifically mandates that *“The practice of laser hair removal shall be performed by a properly trained person licensed to practice medicine or osteopathic medicine or a physician assistant as authorized pursuant to § 54.1-2952 or a nurse practitioner as authorized pursuant to § 54.1-2957 or by a properly trained person under the direction and supervision of a licensed doctor of medicine or osteopathic medicine or a physician assistant as authorized pursuant to § 54.1-2952 or a nurse practitioner as authorized pursuant to § 54.1-2957 who may delegate such practice in accordance with subdivision A 6 of § 54.1-2901.*

To implement provisions of the Act, the Board is mandated to adopted regulations for licensure to set the standard for a “properly trained person” and for “direction and supervision.”

## Legal Basis

*Please identify (1) the agency or other promulgating entity, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity’s overall regulatory authority.*

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Boards of Medicine and Nursing the authority to promulgate regulations to administer the regulatory system:

**§ 54.1-2400 -General powers and duties of health regulatory boards**

*The general powers and duties of health regulatory boards shall be:*

...

*6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ [54.1-100](#) et seq.) and Chapter 25 (§ [54.1-2500](#) et seq.) of this title. ...*

The specific authority to promulgate this regulation is found in Chapter 390 of the 2017 Acts of the Assembly, which added:

*§ [54.1-2973.1](#). Practice of laser hair removal.*

*The practice of laser hair removal shall be performed by a properly trained person licensed to practice medicine or osteopathic medicine or a physician assistant as authorized pursuant to § [54.1-2952](#) or a nurse practitioner as authorized pursuant to § [54.1-2957](#) or by a properly trained person under the direction and supervision of a licensed doctor of medicine or osteopathic medicine or a physician assistant as authorized pursuant to § [54.1-2952](#) or a nurse practitioner as authorized pursuant to § [54.1-2957](#) who may delegate such practice in accordance with subdivision A 6 of § [54.1-2901](#).*

**Purpose**

*Please explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.*

A review of the practice of laser hair removal in 2016 concluded that the lack of comprehensive regulation over the use of laser technology for hair removal poses a risk of harm to the public’s health, safety and welfare. The purpose of this action is to develop regulations for some mechanism for determining whether someone has been “properly trained” and for the required direction and supervision.

The proposed regulations provide a regulatory framework for “direction and supervision” so the laser hair technician, the supervising practitioner and the public will understand the scope of responsibility for such direction and supervision. The intent is to establish minimum competencies for practitioners or persons to whom they delegate the practice of laser hair removal and to specify the responsibilities of licensed practitioners for oversight and supervision in order to protect the health and safety of citizens of the Commonwealth who may become their patients.

**Substance**

*Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.*

Proposed regulations establish the knowledge and training that a practitioner supervising or performing laser hair removal must have, allows for delegation to a properly trained person provided the supervising practitioner is readily available when laser hair removal is being performed, and limits any prescribing of controlled substances to practitioners authorized to prescribe in accordance with statutory requirements for establishment of a practitioner-patient relationship.

**Issues**

*Please identify the issues associated with the regulatory change, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.*

- 1) The primary advantage to the public is assurance of basic training and technique to avoid serious injury to members of the public. There are no disadvantages; regulations will offer greater protection to clients/patients seeking laser hair removal.
- 2) There are no advantages or disadvantages to the agency.
- 3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. The Board is authorized under § 54.1-2400 to *"To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title."* Any restraint on competition as a result of promulgating this regulation is a foreseeable result of the statute requiring laser hair removal to be performed by a properly trained person under direction and supervision according to regulations promulgated by the Board in order to protect the safety and health of clients/patients in the Commonwealth.

**Requirements More Restrictive than Federal**

*Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any requirement of the regulatory change which is more restrictive than applicable federal requirements. If there are no changes to previously-reported information, include a specific statement to that effect.*

There are no applicable federal requirements.

**Agencies, Localities, and Other Entities Particularly Affected**

*Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any other state agencies, localities, or other entities that are particularly affected by the regulatory change. If there are no changes to previously-reported information, include a specific statement to that effect.*

Other State Agencies Particularly Affected - None

Localities Particularly Affected - None

Other Entities Particularly Affected - None

### Public Comment

*Please summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Ensure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency or board. If no comment was received, enter a specific statement to that effect.*

Proposed regulations were published October 29, 2018 with comment requested until December 28, 2018; a public hearing was conducted on December 7, 2018. No comment was received or posted on Townhall.

### Detail of Changes Made Since the Previous Stage

*Please list all changes made to the text since the previous stage was published in the Virginia Register of Regulations and the rationale for the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. \* Please put an asterisk next to any substantive changes.*

There were no changes made since the previous stage.

### Detail of All Changes Proposed in this Regulatory Action

*Please list all changes proposed in this action and the rationale for the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. \* Please put an asterisk next to any substantive changes.*

Proposed new section number, if applicable	Proposed change, intent, rationale, and likely impact of proposed requirements
18VAQ85-20-91	Section 91 is added to establish the requirements for practice and supervision of laser hair removal. Subsection A sets out the training that a doctor of medicine or osteopathic medicine must have to perform or supervise the performance of laser hair removal including:

1. Skin physiology and histology;
2. Skin type and appropriate patient selection;
3. Laser safety;
4. Operation of laser device or devices to be used;
5. Recognition of potential complications and response to any actual complication resulting from a laser hair removal treatment; and
6. A minimum number of 10 proctored patient cases with demonstrated competency in treating various skin types.

*The Code specifies that laser hair removal must be performed by a “properly trained” practitioner or person under his or her supervision. To determine the proper training, the Board relied on the expertise and experience of RAP members who have practiced laser hair removal and the comments received on the NOIRA, specifically those of the American Society of Plastic Surgeons and the Virginia Society of Plastic Surgeons.*

Subsection B provides “grandfathering” for physicians who have been practicing laser hair removal prior to the effective date of the regulation. *There is an expectation that they have been practicing safely and have had the appropriate training.*

Subsection C places the regulatory responsibility on a doctor who supervises an unlicensed person in the performance of laser hair removal to ensure that such person has been “properly trained” in accordance with competencies and provisions of subsection A. *The language is consistent with § 54.1-2973.1 of the Code.*

Subsection D requires ongoing training for doctors who perform laser hair removal or supervision its performance. *Such ongoing training is essential to ensure continuing competency because the technology of the devices and techniques are evolving. Such training would be acceptable for continuing competency requirements for doctors, either as Type 1 or Type 2 hours, depending on the source of the training.*

Subsection E requires delegation to properly trained individual to be under the “direction and supervision” of a doctor, who is himself properly trained in accordance with subsection A. Direction and supervision means that the supervising doctor is readily available when laser hair removal is being performed, but does not require the doctor to be physically present. If there are complications from the procedure, the doctor is required to see and evaluate the patient prior to continuance of treatment.

*The RAP discussed at length the comments on the NOIRA from the organizations – some of which favored “on-site or direct supervision of non-licensed providers” of laser hair removal. There were also recommendations for more specificity in the supervision by setting distance and time restraints on supervision. The commenters did not feel it necessary to require on-site supervision if the laser hair removal was being performed by properly trained individuals in a physician’s office. The Board accepts the recommendation of the RAP for indirect supervision in all settings, acknowledging that there are already a number of “spas” and related businesses that already offer laser hair removal without physician oversight.*

	<p>Subsection E requires that any prescribing of medication must be in accordance with § 54.1-3303 of the Code for the establishment of a practitioner-patient relationship. <i>Subsection E was added to remind physicians that a practitioner-patient relationship is required prior to prescribing.</i></p>
<p>18VAC85-50-191</p>	<p>Section 191 in Chapter 50 is identical for physician assistants as section 91 for physicians in Chapter 20</p>