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## Proposed 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>	12/21/17

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Brief summary

*Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. 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.*

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RAP = Regulatory Advisory Panel

## Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.*

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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 Board of Medicine 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 new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.*

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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.*

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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 proposed regulatory action, 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, please indicate.*

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- 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 identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.*

There are no applicable federal requirements.

**Localities particularly affected**

*Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.*

There are no localities particularly affected.

**Public participation**

*Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.*

In addition to any other comments, the Board of Medicine is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments for the public comment file may do so by mail, email or fax to Elaine Yeatts at [elaine.yeatts@dhp.virginia.gov](mailto:elaine.yeatts@dhp.virginia.gov) or at 9960 Mayland Drive, Henrico, VA 23233 or by fax at (804) 527-4434.. Comments may also be submitted through the

Public Forum feature of the Virginia Regulatory Town Hall web site at: <http://www.townhall.virginia.gov>. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of this stage and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (<http://www.townhall.virginia.gov>) and on the Commonwealth Calendar website (<https://www.virginia.gov/connect/commonwealth-calendar>). Both oral and written comments may be submitted at that time.

**Economic impact**

*Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.*

<p><b>Projected cost to the state to implement and enforce the proposed regulation, including:</b>  <b>a) fund source / fund detail; and</b>  <b>b) a delineation of one-time versus on-going expenditures</b></p>	<p>As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners or entities for necessary functions of regulation. All notifications will be done electronically. There are no on-going expenditures.</p>
<p><b>Projected cost of the new regulations or changes to existing regulations on localities.</b></p>	<p>None</p>
<p><b>Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.</b></p>	<p>Doctors of medicine or osteopathic medicine, and physician assistants who want to be trained to perform laser hair removal and/or supervise unlicensed person in the performance.</p>
<p><b>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected.</b> Small business means a business entity, including its affiliates, that:  a) is independently owned and operated and;  b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>There is no estimate of the number who would choose to perform or supervise laser hair removal. There are 38,021 doctors of medicine, 3,362 doctors of osteopathic medicine, and 3,612 physician assistants licensed in Virginia. There is no estimate of the number of small businesses.</p>
<p><b>All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including:</b>  <b>a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and</b>  <b>b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new</b></p>	<p>The regulations do not specify the length or format for completion of training, so there are numerous ways in which the content requirements may be met, ranging from in-house training at no cost to seminars costing several hundred dollars.</p>

<b>regulations.</b>	
<b>Beneficial impact the regulation is designed to produce.</b>	Provides some assurance that a potentially harmful procedure can be performed without risk of injury to a patient and some accountability for the performance of laser hair removal.

## Alternatives

*Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.*

In the 2016 Session of the General Assembly, HB957 was introduced which would have required individuals who practice laser hair removal to be licensed by the Board of Medicine. The bill defined "laser hair removal" and established the Advisory Board on Laser Hair Removal to advise the Board of Medicine on this discipline. The Department of Health Professions did not support licensure for these practitioners, and the bill was carried over to 2017.

At the request of the patron of HB957 (the same patron of HB2119 in 2017), the Department of Professional and Occupational Regulation and the Department of Health Professions reviewed the issue of laser hair removal. Among its findings was information that the Food and Drug Administration Center for Drug Evaluation and Research warning consumers about serious and life-threatening side effects from laser hair removal treatments including blistering, discoloration, swelling, redness, and scarring. It recommended that both the procedure itself and the topical anesthetics often used should be performed only under the direction of a medical professional. Improper use of skin numbing products to lessen pain before or after laser hair removal has resulted in death.

According to a recent study published in the journal *JAMA Dermatology*, which reviewed nearly 200 cosmetic laser surgery lawsuits, data suggest an “increased inherent risk of injury” exists with non-physician operators. Laser hair removal was the most common procedure resulting in injury and litigation, followed by skin rejuvenation treatments. The authors found that 86% of laser hair removal litigation between 2008 and 2012 involved non-physician operators; in 2011, only one out 10 lawsuits filed was against a physician operator (90.9% of cases involved non-physicians).

In May 2016, the American Academy of Dermatology revised its official position statement on the practice of dermatology to include the use of all lasers and light sources capable of altering or causing biologic change or damage to skin and subcutaneous tissue. As such, procedures using lasers should be performed only by health professionals under physician supervision.

The American Society for Dermatologic Surgery Association (ASDSA) also strongly opposes the use of laser technology by anyone other than properly trained medical professionals.

On November 20, 2017, the Board convened a Regulatory Advisory Panel (RAP), consisting of Jane Piness, MD, Chair, James Robinson, MD, Sara Villalona, PA, and Pat Selig, PhD, FNP-BC. Several members have extensively experience in the performance and/or supervision of laser hair removal and were able to recommend regulations that set the level of training, direction and supervision necessary to protect the public without being overly restrictive and burdensome.

**Regulatory flexibility analysis**

*Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.*

Section 54.1-2973.1 of the Code of Virginia specifies 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.*

There are no alternative regulatory methods consistent with the mandate of the Code and public health and safety.

**Public comment**

*Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.*

The Notice of Intended Regulatory Action was published on October 2, 2017 with comment requested until November 1, 2017.

<b>Commenter</b>	<b>Comment</b>	<b>Agency response</b>
American Med Spa Association (AmSpa)	AmSpa is the primary trade group for medical spas, laser centers, etc. They asked to incorporate the impact statement of the International Aesthetic & Laser Association. The IALA recommended on-site or direct supervision for non-licensed health care providers, but off-site	The RAP and the Board considered the comment and decided to specify the content of additional training and general (off-site) supervision for all practitioners – licensed or unlicensed. The licensed doctor maintains responsibility for ensuring proper training.

	<p>supervision for delegation to other licensed health care practitioners (such as RNs). IALA acknowledged the need for healthcare practitioners to have some additional training.</p>	
American Society for Dermatologic Surgery Association	<p>The ASDSA commented that the use of medical lasers is the practice of medicine and should not be performed by non-medical personnel unless under on-site direct supervision. Also, laser hair removal requires the use of a medical-grade topical anesthetic which has resulted in at least 2 patient deaths.</p>	<p>See response above.  The Board has included in regulation that any prescription for a topical anesthetic must be written by a prescriber who has established a practitioner-patient relationship as defined in 54.1-3303 of the Code of Virginia.</p>
American Society of Plastic Surgeons	<p>Recommended that supervision should mean that doctor is immediately available and no further than 50 miles away so the patient can be seen within 24 hours. Recommended that physicians be deemed properly trained but others should have specific training in the content areas specified.</p>	<p>The Board did not specify the distance or time frame for supervision, but did specify that any patient who has experienced a complication must be seen by a physician before any further procedure can be performed. Proposed regulations deem any physician who has been performing laser hair removal as properly trained but did not exclude other physicians from the training requirements. Physician members of the RAP reported that they had additional training in laser hair removal before they incorporated it into their practice and concurred that it should be required. For example, a dermatologist or plastic surgeon may already be competent in skin physiology and histology but need additional training in laser and intense light physics and safety.</p>
Virginia Society of Plastic Surgeons	<p>Recommended supervision be defined as immediately available but not physically present. Concurred with the content areas for training as recommended by the American Society</p>	<p>The Board concurred.</p>

**Family impact**

*Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.*

There is no impact on the family.



**Detail of changes**

*Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.*

Proposed new section number, if applicable	Proposed change, intent, rationale, and likely impact of proposed requirements
18VAQ85-20-91	<p>Section 91 is added to establish the requirements for practice and supervision of laser hair removal.</p> <p>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:</p> <ol style="list-style-type: none"> <li>1. Skin physiology and histology;</li> <li>2. Skin type and appropriate patient selection;</li> <li>3. Laser safety;</li> <li>4. Operation of laser device or devices to be used;</li> <li>5. Recognition of potential complications and response to any actual complication resulting from a laser hair removal treatment; and</li> <li>6. A minimum number of 10 proctored patient cases with demonstrated competency in treating various skin types.</li> </ol> <p><i>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.</i></p> <p>Subsection B provides “grandfathering” for physicians who have been practicing laser hair removal prior to the effective date of the regulation. <i>There is an expectation that they have been practicing safely and have had the appropriate training.</i></p> <p>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. <i>The language is consistent with § 54.1-2973.1 of the Code.</i></p> <p>Subsection D requires ongoing training for doctors who perform laser hair removal or supervision its performance. <i>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.</i></p> <p>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</p>

	<p>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. <i>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 <u>in a physician’s office</u>. 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.</i></p> <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>