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Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC85-20 18VAC85-50
Regulation title(s)	Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry, and Chiropractic Regulations Governing the Practice of Physician Assistants
Action title	Direction and supervision of laser hair removal
Date this document prepared	7/14/17

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*.

Subject matter and intent

Please describe briefly the subject matter, intent, and goals of the planned regulatory action.

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. The intent of this action is to 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.

Legal basis

Please identify the (1) the agency (includes any type of promulgating entity) and(2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable. Your citation should 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’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 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 describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, please explain any potential issues that may need to be addressed as the regulation is developed.

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. While the Code has been amended as of July 1, 2017, the level and extent of “direction and supervision” has not been defined. 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.

Substance

Please briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

Regulations will specify the responsibility of the licensed doctor or physician assistant for ensuring that someone is “properly trained” and for the required level of direction and supervision.

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 of 10 lawsuits was filed 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.

The Board will have to determine the level of direction of supervision necessary to protect the public without be overly restrictive and burdensome.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments. Please include one of the following choices: 1) a panel will be appointed and the agency's contact if you're interested in serving on the panel is _____; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Townhall website , www.townhall.virginia.gov, or by mail, email or fax to Elaine Yeatts, Agency Regulatory Coordinator, 9960 Mayland Drive, Richmond, VA 23233 or elaine.yeatts@dhp.virginia.gov or by fax to (804) 527-4434. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action 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.

The Board may convene a Regulatory Advisory Panel to develop proposed regulations based on comments it receives from the NOIRA.