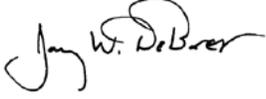




November 23, 2016

MEMORANDUM

TO: Members
House Committee on Health, Welfare and Institutions

FROM: Jay W. DeBoer, J.D., Director 
Department of Professional & Occupational Regulation

David E. Brown, D.C., Director 
Department of Health Professions

CC: The Honorable Mark L. Keam

RE: Report on House Bill 957 (2016) | Laser hair removal technicians; licensure

As requested, attached please find the results of our departments' joint effort to evaluate Virginia's existing regulatory framework governing the use of laser technology for hair removal. In order to protect the public's health, safety, and welfare, we recommend the Code of Virginia be amended to provide that the use of laser technology for hair removal be performed only under the supervision of certain licensed health practitioners.

PURPOSE

Evaluate Virginia’s existing regulatory framework governing the use of laser technology for purposes of minimally invasive cosmetic procedures (e.g., laser hair removal) on human beings. Suggest potential appropriate regulatory scheme(s) for practitioners and/or facilities offering such services.

PROBLEM STATEMENT

Physicians, dentists, and other health professionals practicing in Virginia are licensed by the Department of Health Professions (DHP). Scope of practice for cosmetologists and estheticians, who are licensed by the Department of Professional and Occupational Regulation (DPOR), prohibits the use of laser technology and limits hair removal specifically to tweezing, chemical, or mechanical means.¹

Lasers are radiologic equipment regulated as medical, prescription devices by the U.S. Food and Drug Administration (FDA). X-rays are similarly regulated by the FDA, but currently also registered and inspected at the state level by the Virginia Department of Health’s Office of Radiological Health.² The Board of Medicine at DHP licenses Radiological Technologists who operate x-ray machines.

The existing regulatory scheme for laser hair removal and other minimally invasive cosmetic procedures is complex and, as a result, may place the health, safety, and welfare of Virginians at risk.

BACKGROUND

Lasers have been used for dermatological-related applications such as removal of birthmarks, dark skin spots, acne scars, and other blemishes for decades. Increasingly, however, lasers are being used for a number of elective, personal care, cosmetic treatments including hair removal, wrinkle treatment, tattoo removal, and tooth whitening.³

FEDERAL REGULATION

The FDA Center for Devices and Radiological Health (CDRH) regulates medical and non-medical radiation-emitting electronic products, such as lasers and x-ray systems, in order to prevent unnecessary exposure to radiation. (Laser is an acronym for Light Amplification by the Stimulated Emission of Radiation.) When such products are also classified as medical devices—as in the case of lasers—manufacturers must also comply with 21 CFR Subchapter J-Radiological Health.

FOR EXAMPLE: Lasers with pre-market clearance for stable, long-term, or permanent hair reduction are assigned a Class II designation—*Laser surgical instrument for use in general and plastic surgery and dermatology*.

¹ § 54.1-700 of the *Code of Virginia*

² <http://www.vdh.virginia.gov/radiological-health/>

³ <http://www.fda.gov/radiation-emittingproducts/resourcesforyourradiationemittingproducts/ucm252757.htm>

The FDA classifies lasers into four major hazard classes (I to IV); the higher the class, the more powerful the laser, with the greater potential to pose serious injury if used improperly.⁴

IV	4	<p>Immediate skin hazard and eye hazard from exposure to either the direct or reflected beam; may also present a fire hazard.</p>	<ul style="list-style-type: none"> • laser light show projectors • industrial lasers • research lasers • medical device lasers for eye surgery or skin treatments
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Lasers as Prescription Medical Devices

Lasers, as [radiation emitting products](#) with medical application and claims, are medical devices as defined by federal law (similar to ultrasound products and x-ray machines). Any product labeled, promoted, or used in a way that meets the following definition of the federal Food Drug & Cosmetic Act is regulated by the FDA as a **medical device**:

“an instrument, apparatus, implement, machine, . . . or other similar or related article, including a component part, or accessory . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, . . . or intended to affect the structure or any function of the body . . . and which does not achieve its primary intended purposes through chemical action within or on the body . . . and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.”⁵

Lasers are further regulated as “**prescription devices**,” requiring the equipment to be “in the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device.” Labels for such prescription devices must contain the statement:

“Caution: Federal law restricts this device to sale by or on the order of a _____, the blank to be filled in with the word ‘physician,’ ‘dentist,’ ‘veterinarian,’ or with the descriptive designation of any practitioner licensed by the law of the State in which (s)he practices to use or order the use of the device.”

State law cannot change the federal determination of whether a device is a prescription device. According to the FDA (emphasis added):

“States regulate **who** can use lasers for various therapeutic procedures. Medical lasers are **prescription devices** available for sale only to licensed practitioners. You should check with your state medical licensing board to determine who qualifies as a licensed practitioner in your state.”⁶

⁴ <http://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/homebusinessandentertainment/laserproductsandinstruments/default.htm>

⁵ <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm>

⁶ <http://www.fda.gov/radiation-emittingproducts/resourcesforyourradiationemittingproducts/ucm252757.htm>

STATE SURVEY

Appendix A summarizes the regulatory landscape governing the use of laser technology in other states. Requirements vary, with half of all jurisdictions mandating some level of physician supervision for all laser hair removal; while one-third restrict the use of laser technology to health practitioners.

Just six states issue licenses to allow non-health practitioners (e.g., cosmetologists, estheticians) to practice with lasers independently. Virginia and New York do not regulate the use of laser hair removal by non-health professionals.

VIRGINIA REGULATION

Regulation of hair removal services in Virginia depends partially on how the removal is performed:

- DPOR licenses **barbers** who *shave* hair, **cosmetologists** and **wax technicians** who remove hair by *waxing* or *tweezing*, and **estheticians** who are restricted by law to **non-laser** hair removal by *tweezing*, *chemical* or *mechanical* means.
- Physicians and nurses licensed by DHP are exempt from DPOR's licensing requirements.

The **statutory definition of esthetics** explicitly excludes laser technology and laser devices and stipulates that esthetics *does not constitute the practice of medicine*. Master-level estheticians are permitted to perform para-medical treatments such as chemical peels and lymphatic drainage. Nothing in the esthetics curricula or any other DPOR-regulated subject matter area covers topics related to the use of medical devices such as laser technology.

The Board of Medicine in 2008⁷ found that the use of intense pulsed light (IPL) devices “solely for the removal of hair does not appear to be the practice of medicine.” Lasers and light-based devices fall under the statutory definition of surgery, however, when used for “revision, destruction, incision or other structural alteration of human tissue.” Physicians must observe standard delegation protocol and scope of practice responsibilities if they perform or delegate any aspect of laser hair removal.

RISK TO PUBLIC HEALTH, SAFETY & WELFARE

The FDA Center for Drug Evaluation and Research warns consumers about serious and life-threatening side effects from laser hair removal treatments including blistering, discoloration, swelling, redness, and scarring. Both the procedure itself and the topical anesthetics often used should be performed only under the direction of a medical professional.⁸

⁷ Guidance for light-based hair removal in physician practices, Virginia Board of Medicine Guidance Document, <http://townhall.virginia.gov/L/ViewGDoc.cfm?gdid=3645>

⁸ <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048995.htm>

Improper use of skin numbing products to lessen pain before or after laser hair removal has resulted in serious and life-threatening side effects. In Virginia, only persons authorized by the Drug Control Act (§ 54.1-3408) may possess and administer a Schedule VI topical anesthesia. Laser hair technicians have no such authorization.

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.⁹ Laser hair removal was the most common procedure resulting in injury and litigation, followed by skin rejuvenation treatments (primarily IPL). 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.¹⁰ 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.¹¹

RECOMMENDATION

The lack of comprehensive regulation over the use of laser technology for hair removal specifically, as well as conflicting oversight regarding minimally invasive cosmetic procedures generally, poses a risk of harm to the public’s health, safety and welfare. Therefore, DHP and DPOR recommend that:

The Code of Virginia be amended to provide that the use of laser technology for hair removal be performed under the supervision of a person licensed by the Board of Medicine or the Board of Nursing who holds prescriptive authority and who is responsible for the training of laser hair technicians under his supervision and for the safety of equipment used for such purpose.

⁹ <http://jamanetwork.com/journals/jamadermatology/fullarticle/1754984>

¹⁰ <https://www.aad.org/Forms/Policies/Uploads/PS/PS-Practice%20of%20Dermatology-Protecting%20Preserving%20Patient%20Safety%20Quality%20Care.pdf>

¹¹ <http://asdsa.asds.net/uploadedFiles/ASDSA/Policymakers/ASDSA-Laser%20Procedures.pdf>

STATE	Laser Hair Removal (LHR) considered practice of medicine	Conditions, if any, under which licensed cosmetologists, estheticians, other NON-medical professionals are allowed to perform LHR or use laser/IPL	Regulatory Authority
Alabama	Yes	Direct physician supervision	Alabama Board of Medical Examiners
Alaska	Yes	None	Alaska State Medical Board
Arizona	Yes	Licensed cosmetologists and estheticians with additional laser training may perform LHR under indirect physician supervision; all other cosmetic procedures using laser/intense pulsed light (IPL) require direct supervision	Arizona Radiation Regulatory Agency
Arkansas	Yes	None	Arkansas State Medical Board
California	Yes	None (misdemeanor for cosmetologist to use a laser)	Medical Board of California
Colorado	Yes	Direct physician supervision	Colorado Medical Board
Connecticut	Yes	None	Connecticut Medical Examining Board

STATE	Laser Hair Removal (LHR) considered practice of medicine	Conditions, if any, under which licensed cosmetologists, estheticians, other NON-medical professionals are allowed to perform LHR or use laser/IPL	Regulatory Authority
Delaware	Yes	None	Delaware Board of Medical Licensure and Discipline
Florida	Yes	None (electrologists are licensed by BOM and may perform LHR only under direct physician supervision)	Florida Board of Medicine (Electrolysis Advisory Council)
Georgia	No	Licensed cosmetologists and estheticians with additional laser training may obtain BOM-issued Cosmetic Laser Practitioner license to perform LHR + IPL under supervision	Georgia Composite Medical Board
Hawaii	Yes	None	Hawaii Department of Commerce & Consumer Affairs/Professional & Vocational Licensing
Idaho	Yes	None	Idaho Board of Medicine
Illinois	Yes	None	Illinois Department of Financial and Professional Regulation
Indiana	Yes	None	Medical Licensing Board of Indiana

STATE	Laser Hair Removal (LHR) considered practice of medicine	Conditions, if any, under which licensed cosmetologists, estheticians, other NON-medical professionals are allowed to perform LHR or use laser/IPL	Regulatory Authority
Iowa	Yes	Licensed estheticians and electrologists with additional training are eligible for Laser Services endorsement to perform LHR independently; cosmetologists prohibited from obtaining laser endorsement unless grandfathered (licensed before 7/1/15)	Iowa Board of Cosmetology Arts and Sciences
Kansas	Yes	Direct physician supervision	Kansas Board of Healing Arts
Kentucky	Yes	Direct physician supervision	Kentucky Board of Medical Licensure
Louisiana	Yes	Direct physician supervision	Louisiana State Board of Medical Examiners
Maine	Yes	Direct physician supervision	Maine Board of Licensure in Medicine
Maryland	Yes	None	Maryland Board of Physicians
Massachusetts	No	Laser Electrolysis license required to perform LHR independently. Licensed cosmetologists and estheticians with additional training may use IPL (not lasers) for hair removal.	Massachusetts Board of Registration of Cosmetology and Barbering

STATE	Laser Hair Removal (LHR) considered practice of medicine	Conditions, if any, under which licensed cosmetologists, estheticians, other NON-medical professionals are allowed to perform LHR or use laser/IPL	Regulatory Authority
Michigan	Yes	Direct physician supervision	Department of Licensing and Regulatory Affairs/Michigan Board of Medicine
Minnesota	Yes	Direct physician supervision	Minnesota Board of Medical Practice
Mississippi	Yes	Direct physician supervision	Mississippi State Board of Medical Licensure
Missouri	Yes	Direct physician supervision	Missouri Board of Registration for the Healing Arts
Montana	Yes	None	Montana Board of Medical Examiners
Nebraska	Yes	None	Nebraska Dept. of Health and Human Services/Division of Public Health
Nevada	Yes	Direct physician supervision	Nevada Board of Medical Examiners

STATE	Laser Hair Removal (LHR) considered practice of medicine	Conditions, if any, under which licensed cosmetologists, estheticians, other NON-medical professionals are allowed to perform LHR or use laser/IPL	Regulatory Authority
New Hampshire	Yes	Direct physician supervision	New Hampshire Board of Medicine
New Jersey	Yes	None	New Jersey State Board of Medical Examiners
New Mexico	Yes	Direct physician supervision (laser tech also must be covered by physician's malpractice insurance)	New Mexico Medical Board
New York	Yes	unregulated by Divison of Licensing Services; not part of curriculum	New York Department of State
North Carolina	Yes	Direct physician supervision	North Carolina Medical Board
North Dakota	Yes	None	North Dakota Board of Medicine
Ohio	Yes	None	State of Ohio Medical Board

STATE	Laser Hair Removal (LHR) considered practice of medicine	Conditions, if any, under which licensed cosmetologists, estheticians, other NON-medical professionals are allowed to perform LHR or use laser/IPL	Regulatory Authority
Oklahoma	Yes	Direct physician supervision	Oklahoma Medical Board
Oregon	No	Certified Advanced Esthetician license required to perform LHR independently; newly created regulatory program (bill enacted 7/20/15; effective date 7/1/16)	Oregon Board of Certified Advanced Estheticians
Pennsylvania	Yes	Direct physician supervision	Pennsylvania Board of Medicine
Rhode Island	Yes	Direct physician supervision	Rhode Island Department of Health
South Carolina	Yes	Direct physician supervision	South Carolina State Board of Medical Examiners
South Dakota	Yes	None	South Dakota Board of Medical and Osteopathic Examiners
Tennessee	Yes	Electrologist license required to perform LHR independently; Limited Electrologist license requires sponsoring dermatologist	Tennessee Department of Health/Electrolysis Registry

STATE	Laser Hair Removal (LHR) considered practice of medicine	Conditions, if any, under which licensed cosmetologists, estheticians, other NON-medical professionals are allowed to perform LHR or use laser/IPL	Regulatory Authority
Texas	Yes	LHR Apprentice, Technician, or Professional license required to perform LHR independently; all other laser/IPL requires direct physician supervision	Texas Dept. of State Health Services/Radiation Control Program
Utah	Yes	Direct physician supervision	Utah Physician Licensing Board
Vermont	Yes	Electrologists with special license endorsement are allowed to perform LHR independently	Vermont Office of Professional Regulation
Virginia	No	<i>Statutory scope of practice for cosmetology and esthetics expressly prohibits use of laser technology</i>	<i>DHP/DPOR</i>
Washington	Yes	Direct physician supervision	Washington Medical Commission
West Virginia	Yes	Direct physician supervision	West Virginia Board of Medicine
Wisconsin	Yes	Licensed cosmetologists and estheticians with additional training may perform LHR under physician supervision	Wisconsin Department of Safety and Professional Services

STATE	Laser Hair Removal (LHR) considered practice of medicine	Conditions, if any, under which licensed cosmetologists, estheticians, other NON- medical professionals are allowed to perform LHR or use laser/IPL	Regulatory Authority
Wyoming	Yes	Direct physician supervision	Wyoming Board of Medicine
Washington DC	Yes	None	Washington DC Board of Medicine