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Proposed Regulation Agency Background Document

Agency name	Board of Optometry, Department of Health Professions	
Virginia Administrative Code 18VAC105-20 (VAC) Chapter citation(s)		
VAC Chapter title(s)	Regulations of the Virginia Board of Optometry	
Action title	Action title Regulations for laser surgery certifications	
Date this document prepared July 15, 2023, revised April 22, 2024		

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

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.

These amendments to an existing chapter provide certification for optometrists to perform laser surgery pursuant to <u>Ch. 16</u> and <u>Ch. 17</u> of the 2022 Acts of Assembly. That legislation required the Board to promulgate regulations to establish criteria for certification of optometrists to provide certain laser surgery.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

SLT = selective laser trabeculoplasty

All other acronyms used in this document are included in current 18VAC105-20-5 or the amendments proposed in this action.

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in the ORM procedures, "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

The mandate for this action comes from <u>Ch. 16</u> and <u>Ch. 17</u> of the 2022 Acts of Assembly, which required the Board to promulgate regulations regarding certification of optometrists to perform certain laser surgery.

Legal Basis

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

Regulations of the Board of Optometry are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Virginia Code § 54.1-2400(6) specifically states that the general powers and duties of health regulatory boards shall be "[t]o promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system."

Enactment clauses 2 and 4 of <u>Ch. 16</u> and <u>Ch. 17</u> of the 2022 Acts of Assembly require the Board to promulgate regulations related to certification of optometrists to perform laser surgery.

Purpose

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 is intended to solve.

The agency was required by legislation to promulgate regulations. The legislation specifically stated that the Board "shall promulgate regulations establishing criteria for certification of an optometrist to perform certain procedures . . ." The legislation further stated that the regulations shall include provisions for (i) promotion of patient safety; (ii) identification and categorization of procedures for the purpose of issuing certificates; (iii) establishment of an application process for certification to perform such procedures; (iv) establishment of minimum education, training, and experience requirements for certification to perform such procedures; (v) development of protocols for process for such procedures performed by certificate holders. See Ch. 16 and Ch. 17 of the 2022 Acts of Assembly, enactment clause 2.

Substance

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.

The proposed changes include:

- Definitions specific to laser surgery, including "laser surgery certification," definitions related to laser surgery examination, "proctored session," and "proctoring.
- Requirements to obtain a laser surgery certification, including fees, education, and clinical training, whether in a school setting or via proctored sessions.
- Specific requirements for proctoring and proctors.
- Reporting requirements as required by <u>Ch. 16</u> and <u>Ch. 17</u> of the 2022 Acts of Assembly, enactment clause 4.
- Reporting requirements to maintain a quality assurance review process.
- Fees related to certification.
- Renewal requirements.

Issues

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 advantages to the public are more available practitioners to perform laser surgery of the eye. There are no disadvantages to the public.
- 2) There are no primary advantages or disadvantages to the agency or the Commonwealth.
- 3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. Any restraint on competition as a result of promulgating these regulations is a foreseeable, inherent, and ordinary result of the statutory obligation of the Board to protect the safety and health of citizens of the Commonwealth. The Board is authorized under § 54.1-2400 "[t]o 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." The promulgated regulations do not conflict with the purpose or intent of Chapters 1 or 25 of Title 54.1.

Requirements More Restrictive than Federal

Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and 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 specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Consistent with § 2.2-4007.04 of the Code of Virginia, identify any other state agencies, localities, or other entities particularly affected by the regulatory change. Other entities could include local partners such as tribal governments, school boards, community services boards, and similar regional organizations. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected – none

Localities Particularly Affected - none

Other Entities Particularly Affected – none

Economic Impact

Consistent with § 2.2-4007.04 of the Code of Virginia, identify all specific economic impacts (costs and/or benefits) anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is the proposed change versus the status quo.

Impact on State Agencies

 For your agency: projected costs, savings, fees, or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources. 	Projected agency and Board costs related to the certification of optometrists to perform laser surgery include: (1) investigative and disciplinary costs for any complaints related to optometrists performing laser surgery; and (2) administrative costs of issuing a new certification and new license type which requires significant additional verification of competency to practice. These will be ongoing costs for the Board which cannot be absorbed by existing resources of the Board. The Board (and the agency), as a special fund agency, must obtain all operating costs from licensure fees. Therefore, although the cost for obtaining a license with laser certification will be higher than obtaining a standard license to practice optometry, the cost is necessary to ensure the Board can continue to operate.
<i>For other state agencies</i> : projected costs, savings, fees, or revenues resulting from the regulatory change, including a delineation of one- time versus on-going expenditures.	There are no expected costs, savings, fees, or revenues to other state agencies from this regulatory change.
<i>For all agencies:</i> Benefits the regulatory change is designed to produce.	The changes are not designed to produce benefits to agencies.

Impact on Localities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a or 2) on which it was reported. Information provided on that form need not be repeated here.

Projected costs, savings, fees, or revenues	There are no expected costs, savings, fees or
resulting from the regulatory change.	revenues to localities from this regulatory change.
Benefits the regulatory change is designed to	There are no expected benefits to localities from
produce.	this regulatory change.

Impact on Other Entities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a, 3, or 4) on which it was reported. Information provided on that form need not be repeated here.

Description of the individuals, businesses, or	Individuals impacted are existing and future
other entities likely to be affected by the	licensed optometrists in the Commonwealth.
regulatory change. If no other entities will be	
affected, include a specific statement to that	
effect.	
Agency's best estimate of the number of such	As of March 31, 2023, there were 1,808 TPA-
entities that will be affected. Include an estimate	certified optometrists in the Commonwealth. The
of the number of small businesses affected. Small	only licensed optometrists who will be able to
business means a business entity, including its	obtain certification to perform laser surgery are
affiliates, that:	TPA-certified optometrists.
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.	
All projected costs for affected individuals,	Optometry students graduating in approximately
businesses, or other entities resulting from the	2015 or after have received the education
regulatory change. Be specific and include all	required in these amendments in standard
costs including, but not limited to:	instruction at schools of optometry. Those
a) projected reporting, recordkeeping, and other	optometrists will not incur any additional costs to
administrative costs required for compliance by	obtain the certification other than the fee for
small businesses;	certification (\$200) and higher renewal fee that is
b) specify any costs related to the development of	\$50 higher than renewal without laser
real estate for commercial or residential purposes	certification.
that are a consequence of the regulatory change;	
c) fees;	Licensed optometrists who graduated prior to
d) purchases of equipment or services; and	2015 may need to obtain appropriate training and
e) time required to comply with the requirements.	proctored testing. These programs run regularly
	and cost approximately \$1,200 according to the Oklahoma College of Optometry continuing
	education course offering. The \$1,200 covers
	education and two model eyes for proctored
	sessions per procedure.
Benefits the regulatory change is designed to	Optometrists can perform and bill for laser
produce.	surgery of the eye.

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the

regulatory change. 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 regulatory change.

There are no alternatives to regulation. Regulation is required by the enacting legislation and the Board must enact regulations to institute a new certification process.

Regulatory Flexibility Analysis

Consistent with § 2.2-4007.1 B of the Code of Virginia, 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) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards requirements contained in the regulatory change.

1) The Board cannot impose less stringent certification requirements on individuals that happen to work for small businesses without endangering the health and welfare of the citizens of the Commonwealth. The changes will allow practitioners to perform laser surgery of the eye, which clearly impacts the public health and safety. 2) The Board has no ability to change the compliance or reporting requirements for any individual under the enacting legislation. 3) See previous answer. 4) There are no performance standards, operational standards, or design standards in the proposed regulations to consider. 5) Businesses are not subject to these changes. Additionally, the Board cannot exempt individuals working at small businesses from certification requirements under the enacting legislation.

Periodic Review and Small Business Impact Review Report of Findings

If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the NOIRA stage, indicate whether the regulatory change meets the criteria set out in EO 19 and the ORM procedures, e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable. In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, discuss why the agency's decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.

Not applicable.

Public Comment

Town Hall Agency Background Document

<u>Summarize</u> all comments received during the public comment period following the publication of the previous stage, and provide the agency's response. Include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. If no comment was received, enter a specific statement to that effect.

Commenter	Comment	Agency response
Virginia Society of Eye Physicians and Surgeons comment received on Town Hall and by email.	Requests that the Board to create separate certifications for each of the three named procedures due to their differing indications, safety profiles, and complications.	The enacting legislation does not appear to support three separate certifications for individual procedures. Additionally, the 2022 legislation amended the scope of practice of optometry to include these three procedures. It would be inefficient and inconsistent with policies across the agency to create individual credentials for portions of the scope of practice. The Board must create the single certification to begin incorporating laser surgery into the licensure of optometry, but it does so out of necessity.
	Requests independent third-party testing.	Testing may be obtained from the NBEO. The Board is not able to require this testing of all practitioners, however, because the General Assembly directed the Board to promulgate regulations for proctoring and did not require an examination.
	Requests that the number of surgical cases for training be increased to require 10 YAG capsulotomy, 10 SLT, and 8 iridotomy cases.	The Board voted to require two proctored sessions for each procedure.
	Requests live proctoring with real- time monitoring with a training scope by an ophthalmologist certified by the American Board of Ophthalmology.	The Board does not intend to specify the instruments used for proctoring as requested by the commenter. That becomes too prescriptive and prohibitive in regulation and would be exceedingly difficult for the Board to enforce.
	Requests creation of a data repository that includes pre-op, intra-op, and post-op data collection and an annual renewal policy demonstrating safety and continued surgical practice.	The Board has no jurisdiction to require a data repository, and to do so would make the certification fee almost cost-prohibitive for licensees.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

The Board of Optometry is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, (iii) the potential impacts of the regulation, and (iv) the agency's regulatory flexibility analysis stated in that section of the background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at <u>https://www.townhall.virginia.gov</u>. Written comments must include the name and address of the commenter. Comments may also be submitted by mail, email or fax to Erin Barrett, Agency Regulatory Coordinator, 9960 Mayland Drive, Henrico, VA 23233 or <u>erin.barrett@dhp.virginia.gov</u> or by fax to (804) 915-0382. 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 the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (<u>http://www.townhall.virginia.gov</u>) and on the Commonwealth Calendar website (<u>https://www.virginia.gov/connect/commonwealth-calendar</u>). Both oral and written comments may be submitted at that time.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

If an <u>existing</u> VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between the existing VAC Chapter(s) and the proposed regulation. If the existing VAC Chapter(s) or sections are being repealed <u>and replaced</u>, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter- section number	New chapter- section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
20-5		Provides definitions for the chapter.	Definitions for "laser surgery certification," LSPE," "proctored session," and "proctoring" are added.
20-10		Provides requirements for licensure.	New subsection B is added to the regulation. This amendment states that all applicants after January 1, 2033 must meet requirements for laser surgery as outlined in 18VAC105-20-80.
			The intent of the Board is to ultimately issue one license that covers the full scope of practice of an optometrist in the Commonwealth. This is the same approach that was taken for TPA-certified optometrists. All initial applicants for a licensure in optometry must now meet the requirements for TPA-

			certification. This is also consistent with how other states that permit laser surgery by optometrists license optometrists, including Oklahoma, Indiana, and Alaska. Only ten states currently allow optometrists to perform laser surgery.
			The Board felt that a date eight or nine years from the eventual effective date of these amendments would provide sufficient notification to applicants.
20-20		Sets forth required fees for the Board.	Fees for initial application for licensure with TPA certification and laser surgery certification, applications for laser surgery certification only, and licensure renewal with TPA certification and laser surgery certification are added. The fee increase for licensure with laser surgery certification and the initial cost of laser surgery certification will address the additional administrative costs of verifying compliance with requirements for laser surgery certification, including verification of training and proctored sessions.
			All late renewals are combined and amended to be \$50, which is a decrease for late renewals with TPA certification and an increase for late renewal of inactive license. As this fee is a deterrent to late renewal, the Board feels there is no justification to impose different fees for different license types. Any licensee filing a late renewal will already submit a varied fee on renewal consistent with the administrative burden of renewal of the license type.
			A temporary fee from 2018 is deleted. The need for the temporary fee has expired and the language is no longer needed in regulation.
20-60		Provides for renewal of licensure and reinstatement	The reference to renewal fees in the section caption is removed. The inclusion is confusing since renewal fees are set forth in 20-20.
		Tensialement	In subsection A, language that was meant to coordinate the change of renewal date from December 31 to March 31 of each year is deleted. All licensees currently renew on March 31, so this language is no longer needed.
			Amendments to subsection C provide clearer statements regarding the impact of the subsection.
20-80	Requirements for laser surgery certification.		New section 80 provides the requirements to obtain a laser surgery certification. These requirements were the result of a regulatory advisory panel held by the Board in 2022.
			In subsections 1 and 2, applicants are required to submit a completed application and the fee prescribed in 20-20. These are standard requirements for licensure or certification from agency boards.

		In subsection 3, an applicant must provide an educational attestation from a dean or designee of a school of optometry or an instructor of a laser surgery certification course approved by the board. This attestation will verify that the applicant received training in the listed subjects. The listed subjects were gathered from schools of optometry and instructors of stand-alone laser surgery certification courses. The Board included the ability to provide the attestation from either a school or a course, recognizing that some optometrists will not have covered these subjects in standard training and will need to obtain training from courses outside of a school setting.
		Under subsection 4, applicants must provide evidence of either (1) passage of the Laser Section of the LSPE or (2) proctored sessions in compliance with 20-90. These two options allow an applicant to bypass proctored sessions if the applicant would prefer to take an exam, or to utilize proctored sessions if proctored sessions are more practical.
20-90	Requirements for proctoring.	Enactment clause 2 of <u>Ch. 16</u> and <u>Ch. 17</u> of the 2022 Acts of Assembly requires the Board to "[develop] protocols for proctoring and criteria for requiring such proctoring." The regulatory advisory panel and the Board developed requirements for proctoring contained in new section 90. The Board, however, allowed applicants for certification for laser surgery to avoid the need for proctored sessions by submitting the results of the Laser Section of the LSPE, as described above in section 80. Subsection A clarifies that evidence of proctored
		session for the three procedures, performed at least twice each, must be submitted in support of certification if evidence of a passing score on the Laser Section of the LSPE is not submitted. The Board felt that two proctored procedures for each type of laser surgery was the minimum required to ensure safety of the public was protected.
		Subsection B addresses the requirements for proctors. B 1 states that for proctored sessions on live patients, sessions must be proctored by doctors of medicine or osteopathy that specialize in ophthalmology. Virginia Code § 54.1-2400.01:1 only allows physicians, optometrists with a certification to perform laser surgery, or those "acting pursuant to the orders and under the appropriate supervision of a licensed doctor of medicine, osteopathy, podiatry, or dentistry" to perform surgery in the Commonwealth. Therefore, an <i>applicant</i> for certification for laser surgery cannot be proctored by another optometrist, even if that optometrist is

		w m oc re tc ap st B m h y st of e n a a la a la a la a la a la a la b m n c c c c c c tc c ap st c c c c c c c c c c c c c c c c c c	ertified to perform laser surgery. If an applicant vishes to complete proctoring on live patients, it nust be done with a doctor of medicine or steopathy as a proctor. The Board added a equirement for the proctor to be an ophthalmologist of ensure patient safety and to ensure that the pplicant receives adequate proctoring for laser eye urgeries. 2 states that proctored sessions performed on nodel eyes may be proctored by an individual olding a license in the Commonwealth or another urisdiction who is authorized to perform laser urgery on the eye and does so as a regular course f practice. Because proctored sessions on model yes do not involve live patients, these sessions will ot be subject to the same restrictions as those ddressed in B 1. Any optometrist able to perform aser surgery, whether in the Commonwealth or nother jurisdiction, or a physician, may act as a roctor for these sessions provided the proctor erforms laser eye surgery as part of a regular ourse of practice.
20-100	Reporting	fc ev bu pi lic	essions to the Board. The Board will provide a form or such submissions. The form will include valuation of the clinical competency of the individual eing proctored, the number and type of cases roctored, and the proctor's name, license type, cense number, and state of licensure. Enactment clause 4 of <u>Ch. 16</u> and <u>Ch. 17</u> of the
	requirements for individuals certified to provide laser surgery.	pi pi T T ei m sj di	022 Acts of Assembly required the Board to romulgate regulations requiring optometrists to rovide certain information annually to the Board. The provision has a sunset clause of July 1, 2025. The Board adopted new section 100 to address this nactment clause. The provisions in subsection A hirror the enactment clause language, requiring pecified information on a quarterly basis. The Board id not add or change any of the required reporting.
00.445		10	Subsection B provides an expiration date for Section 00 of July 1, 2025.
20-110	Quality assurance review process.	20 in la re	Enactment clause 2 of <u>Ch. 16</u> and <u>Ch. 17</u> of the 022 Acts of Assembly requires the Board to nplement "a quality assurance review process" for aser surgery procedures provided by licensees in egulation. The Board adopted new section 110 to ddress this provision of the enactment clause.

	Subsection A states that the requirements become effective July 1, 2025. The Board placed this effective date on the requirements in section 110 to coincide with the sunset provision in section 100 and enactment clause 4.
	A 1 and 2 require licensees with certifications to perform laser surgery to maintain documentation for three years of the number and type of laser surgeries performed and any adverse treatment outcomes. This information was included in the quarterly reporting listed in section 100 and enactment clause 4. The Board felt these two topics would provide sufficient information for quality assurance.
	Subsection B states that the Board may conduct random audits of licensees certified to perform laser surgery for the information specified in subsection A. The Board adopted this random audit requirement to comply with the directive of the General Assembly to implement a quality assurance review process.