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## Final Regulation Agency Background Document

<b>Agency name</b>	Board of Optometry, Department of Health Professions
<b>Virginia Administrative Code (VAC) Chapter citation(s)</b>	18VAC105-20
<b>VAC Chapter title(s)</b>	Regulations of the Virginia Board of Optometry
<b>Action title</b>	Regulations for laser surgery certifications
<b>Date this document prepared</b>	November 8, 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 [Ch. 16](#) and [Ch. 17](#) 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.

### Statement of Final Agency Action

*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.*

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On November 8, 2024, the Board of Optometry voted to adopt final regulatory amendments to 18VAC105-20, Regulations Governing the Board of Optometry.

### Mandate and Impetus

*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.*

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The mandate for this action comes from [Ch. 16](#) and [Ch. 17](#) 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.*

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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 [Ch. 16](#) and [Ch. 17](#) 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.*

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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 proctoring and criteria for requiring such proctoring; and (vi) implementation of a quality assurance review 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.*

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The final 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 [Ch. 16](#) and [Ch. 17](#) 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.*

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- 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

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**

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**

Summarize 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.

Board note: of 529 comments received on Town Hall, 511 were received during the last 36 hours that the comment period was open. Those all fell into eight categories as listed in the last rows of the table below.

Commenter	Comment	Agency response
John McCallister, MD and Michael Keverline, MD on behalf of Virginia Society Eye Physicians and Surgeons via public hearing	Expressed concerns that proposed regulations do not require live proctored cases prior to certification. Stated surgery performed on model eyes are not sufficient to replicate surgery on a human eye, where a patient’s eye may move microscopically or actions such as breathing can cause changes that will impact surgery. Requested amendments to require 10 proctored surgeries of peripheral iridotomy, 10 proctored surgeries of selective laser trabeculoplasty, and 8 proctored surgeries of YAG capsulotomy.	The Board appreciates the comment. The requirements for laser surgery were created with input from a regulatory advisory panel that studied requirements in other locations and contained extensive discussion regarding model eyes and live patient surgery. The Board believes the requirements contained in the final regulation adequately protect the public and comport with the requirements of the enacting legislation.
Bo Keeney, Virginia	Supports the current draft regulations. The current proposed	The Board has made no changes from the proposed stage.

Optometric Association via public hearing and Town Hall	draft presents the consensus from the Regulatory Advisory Panel, which included an ophthalmologist. Supports 2 proctored cases for each procedure as included in the proposed regulations.	
Scott Mann, OD via public hearing	Supports the proposed regulations as written. Patients will benefit from the availability of laser surgery provided by optometrists, particularly in rural areas or in underserved populations. Will eliminate duplicate visits, patient cost, and patient wait times. Will reduce the travel burden in rural areas.	The Board has made no changes from the proposed stage.
Jeff Michaels, OD via public hearing and Town Hall	Supports the proposed regulations as written. Other states with similar scopes of practice for optometrists that include laser surgery have not reported detriments to patients. Instead, benefits to patients have been noted due to greater access to care.	The Board has made no changes from the proposed stage.
13 individual commenters via Town Hall	Support the regulations as adopted at the proposed stage which mirror the recommendations of the regulatory advisory panel. The regulatory advisory panel included input from ophthalmologists.	The Board has made no changes from the proposed stage.
Dr. Scott Mann via Town Hall	Legislation will prevent patients from duplicate visits that create duplicate co-pays and out of pocket expenses; will reduce waiting times from 3 months to 3 days; and will decrease travel burdens for rural patients.	The Board recognizes the comment.
Dr. Joseph Droter	12 states permit laser surgery in-office by optometrists. 146,000 procedures have been performed by optometrists across the country since the 1990s.	The Board recognizes the comment.
266 comments via Town Hall	Support the regulations as published at the proposed stage.	The Board has made no changes from the proposed stage.
45 comments via Town Hall	Generally disagreed with the training requirements contained in the proposed regulations. Provided no alternative or specific suggestions.	The Board appreciates the comment. The requirements for laser surgery were created with input from a regulatory advisory panel that studied requirements in other locations and contained extensive discussion regarding model eyes and live patient surgery. The Board believes the requirements contained in the final regulation adequately protect the public and comport with the requirements of the enacting legislation.

41 comments via Town Hall	Generally requested different training requirements that include live patient proctoring and didactic training.	The Board appreciates the comment. The requirements for laser surgery were created with input from a regulatory advisory panel that studied requirements in other locations and contained extensive discussion regarding model eyes and live patient surgery. The Board believes the requirements contained in the final regulation adequately protect the public and comport with the requirements of the enacting legislation.
5 comments via Town Hall	Requested residency be required prior to certification.	The Board appreciates the comment. The requirements for laser surgery were created with input from a regulatory advisory panel that studied requirements in other locations and contained extensive discussion regarding model eyes and live patient surgery. The Board believes the requirements contained in the final regulation adequately protect the public and comport with the requirements of the enacting legislation.
76 comments via Town Hall	Opposing laser surgery performed by optometrists.	This scope of practice change was created by legislation in the 2022 session. See Chapters <a href="#">16</a> and <a href="#">17</a> of the 2022 Acts of Assembly. The Board was directed to promulgate regulations consistent with the legislation. These comments should have been directed to the General Assembly as it considered legislation. The Board has no ability to alter statutory language and cannot change the scope of practice as approved by the legislature and Governor's office.
88 comments via Town Hall	Support laser surgery performed by optometrists.	This scope of practice change was created by legislation in the 2022 session. See Chapters <a href="#">16</a> and <a href="#">17</a> of the 2022 Acts of Assembly. The Board was directed to promulgate regulations consistent with the legislation.
6 comments via Town Hall	Contained no discernible position.	The Board has no response to these comments.
2 comments received via Town Hall	Received after the cut off period.	The Board has no response to these comments.

**Detail of Changes Made Since the Previous Stage**

*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. 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. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. \* Put an asterisk next to any substantive changes.*

No changes were made at the final stage.

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

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

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of updated 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.	<p>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.</p> <p>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.</p> <p>The Board felt that a date eight or nine years from the eventual effective date of these amendments would provide sufficient notification to applicants.</p>
20-20		Sets forth required fees for the Board.	<p>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.</p> <p>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</p>

			<p>requirements for laser surgery certification, including verification of training and proctored sessions.</p> <p>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.</p> <p>A temporary fee from 2018 is deleted. The need for the temporary fee has expired and the language is no longer needed in regulation.</p>
20-60		Provides for renewal of licensure and reinstatement	<p>The reference to renewal fees in the section caption is removed. The inclusion is confusing since renewal fees are set forth in 20-20.</p> <p>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.</p> <p>Amendments to subsection C provide clearer statements regarding the impact of the subsection.</p>
	20-80		<p>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.</p> <p>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.</p> <p>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</p>



		<p>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.</p> <p>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.</p>
	20-90	<p>Enactment clause 2 of <a href="#">Ch. 16</a> and <a href="#">Ch. 17</a> 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.</p> <p>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.</p> <p>Subsection B addresses the requirements for proctors. B 1 states that for proctored sessions on live</p>

			<p>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 certified to perform laser surgery. If an applicant wishes to complete proctoring on live patients, it must be done with a doctor of medicine or osteopathy as a proctor. The Board added a requirement for the proctor to be an ophthalmologist to ensure patient safety and to ensure that the applicant receives adequate proctoring for laser eye surgeries.</p> <p>B 2 states that proctored sessions performed on model eyes may be proctored by an individual holding a license in the Commonwealth or another jurisdiction who is authorized to perform laser surgery on the eye and does so as a regular course of practice. Because proctored sessions on model eyes do not involve live patients, these sessions will not be subject to the same restrictions as those addressed in B 1. Any optometrist able to perform laser surgery, whether in the Commonwealth or another jurisdiction, or a physician, may act as a proctor for these sessions provided the proctor performs laser eye surgery as part of a regular course of practice.</p> <p>B 3 requires the proctor to be present in the room in which the proctored session occurs. The Board did not feel public safety would be adequately protected using virtual or semi-virtual proctored sessions.</p> <p>B 4 requires submission of evidence of the proctored sessions to the Board. The Board will provide a form for such</p>
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			<p>submissions. The form will include evaluation of the clinical competency of the individual being proctored, the number and type of cases proctored, and the proctor's name, license type, license number, and state of licensure.</p>
	20-100		<p>Enactment clause 4 of <a href="#">Ch. 16</a> and <a href="#">Ch. 17</a> of the 2022 Acts of Assembly required the Board to promulgate regulations requiring optometrists to provide certain information annually to the Board. The provision has a sunset clause of July 1, 2025.</p> <p>The Board adopted new section 100 to address this enactment clause. The provisions in subsection A mirror the enactment clause language, requiring specified information on a quarterly basis. The Board did not add or change any of the required reporting.</p> <p>Subsection B provides an expiration date for Section 100 of July 1, 2025.</p>
	20-110		<p>Enactment clause 2 of <a href="#">Ch. 16</a> and <a href="#">Ch. 17</a> of the 2022 Acts of Assembly requires the Board to implement “a quality assurance review process” for laser surgery procedures provided by licensees in regulation. The Board adopted new section 110 to address this provision of the enactment clause.</p> <p>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.</p> <p>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.</p> <p>Subsection B states that the Board may conduct random audits of</p>

			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.
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