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Proposed Regulation
Agency Background Document

Agency name	Board of Optometry, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC105-20-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Optometry
Action title	Periodic review
Date this document prepared	8/29/17

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

In addition to editorial changes, the Board proposes deletion of unnecessary or unenforceable rules, inclusion of a definition for active practice, more specificity about evidence of continued competency required for licensure by endorsement and reinstatement, clarification about the expiration date that may be included on an eyeglass prescription, and a waiver of graduation from an accredited school if an applicant was educated in a foreign country but has been actively practicing in another state.

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.

NBEO = National Board of Examiners in Optometry
TMOD = Treatment and Management of Ocular Disease
TPA = therapeutic pharmaceutical agents

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.

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 Optometry 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. ...

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.

By updating the current regulations, eliminating any that are unnecessarily burdensome, and adding requirements for evidence of continued competency, the Board's intent is greater clarity and understanding by applicants and licensees of the applicable rules. Amended regulations will make it less onerous for an applicant who is currently licensed and practicing in another state and wants to become licensed in Virginia. If he/she has been actively practicing and has a current license, the applicant would not be required to do additional CE. If not actively practicing, the Board believes some CE is necessary to ensure minimal competency for public health and safety in providing patient care.

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.

In addition to editorial changes, the Board proposes deletion of unnecessary or unenforceable rules, inclusion of a definition for active practice, more specificity about evidence of continued competency required for licensure by endorsement and reinstatement, clarification about the expiration date that may be included on an eyeglass prescription, and a waiver of graduation from an accredited school if an applicant was educated in a foreign country but has been actively practicing in another state.

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.

1) The primary advantage to the public is the potential for additional practitioners to become licensed in Virginia if they are licensed in another state and actively practicing without a history of disciplinary action. It is also less onerous to reinstate a lapsed license, which could increase the supply of optometrists available to provide eye care. There are no disadvantages.
2) There are no advantages or disadvantages to the Commonwealth.
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.*" There is no restraint on competition as the regulation will provide an opportunity for some optometrists to be licensed in Virginia who are currently not able to meet the requirements.

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 Optometry 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 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.

Projected cost to the state to implement and enforce the proposed regulation, including: **a) fund source / fund detail; and** **b) a delineation of one-time versus on-going**	a) 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

expenditures	practitioners for necessary functions of regulation; b) The agency will incur no additional costs for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. Since most mailings to the PPG list are handled electronically, there is very little cost involved. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. There are no on-going expenditures.
Projected cost of the new regulations or changes to existing regulations on localities.	None
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Licensed optometrists and persons seeking licensure in Virginia
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. 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.	There are 1,638 TPA-certified optometrists and 117 non-certified optometrists for a total of 1,755 licensed in Virginia. Almost all are employees of optometric practices which would be considered small businesses.
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: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **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 regulations.**	The Board does not believe there are any additional costs associated with these proposed amendments.
Beneficial impact the regulation is designed to produce.	The primary benefit is deletion or revision of outdated regulation and clarification for applicants and licensees.

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.

During the periodic review of regulation, the Board intended to amend sections that were burdensome or confusing. There were no less intrusive or costly alternatives that could accomplish that intent.

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.

There are no alternative regulatory methods consistent with 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.

Commenter	Comment	Agency response
Bruce Keeney, Legislative Counsel, Va. Optometric Association	Should not include regulations that are not in the Board of Medicine regulations for ophthalmology.	While the optometry and ophthalmology both treat conditions of the eye, they are different professions, under different boards. There are requirements for MDs that are not found in optometry regulations and vice versa.
	Should not make changes regarding commercial or corporate practice.	None were proposed.
	Continuing education should require 50% to be face-to-face.	Current law and regulation require at least 10 of the 20 hours to be real-time, interactive or in person; there is no requirement for "face-to-face" which is normally interpreted to mean the parties are in one physical location.
	Should retain requirement that an applicant for endorsement who has been practicing in a federal facility should have a commanding officer verify that he is in good standing.	The requirement was retained and moved from the section on endorsement to the requirements for licensure.
	Recommends the Board set the passing score on the national examination.	The Board does not have the expertise to set passing scores based on a number of factors; additionally, it is preferable for there to be consistency across state boards.

	Board should not duplicate federal rules for eyeglasses and contact lenses.	Standards for eyeglasses and contact lens are not duplicative of federal rules but are consistent with such rules for protection of the patient and the practitioner.
	Opposed to any provision to require inclusion of documentation for the necessity of an expiration date on a contact lens prescription.	The proposed rule, which is consistent with FTC rules, states that, if an expiration date is less than one year, the medical reason for a shorter expiration must be in the patient record.
	Opposes to limitations on prescriptions for hydrocodone-combination agents, especially any requirement on referral to an ophthalmologist.	The limitation on prescribing of opioids are found in the emergency regulations adopted by the Board in another action.
	Listing of category of drugs that may be prescribed by a TPA-certified optometrist should be updated for consistency with Code.	Proposed amendments do update the regulations.
	Supports a December 31 renewal date.	There is no change to the renewal date proposed at this time.
	Support 40 hours of live CE in order to reinstate a lapsed license.	The requirement for 40 hours of live CE would be inconsistent with the Code and burdensome for optometrists who may have been practicing in another state while their Virginia license was lapsed.
	Board does have jurisdiction over CE sponsors to specify what they put on a certificate. Should require that they identify if a course is acceptable for business hours.	The Board has listed approved providers/sponsors in regulation. If the Board wanted to remove a provider from the approval list for failure to meet regulatory requirement, it would necessitate an amendment to regulations. The Board has chosen to place the burden on its licensees to ensure certain information is documented on courses they take for continuing education credits.

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.

Current section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
05	Sets out definitions for words and terms used in the chapter	The term "active clinical practice" is defined as an average of 20 hours per week or 640 hours per year of providing patient care. *A definition is needed because the term is used in licensing and reinstatement requirements and is open to wide interpretation. The Board's intent is to allow practice hours less than full-time but in a quantity sufficient to demonstrate continuing competency to practice.* The word "adnexa" is currently defined in section 46; it is moved to the definitions section for consistency. A definition of TMOD is added because the acronym is used in regulation.
10	Currently titled "Licensure by examination" but it is amended to include all requirements for licensure	The requirements for licensure by examination and licensure by endorsement are virtually the same, so the Board has eliminated the distinction to avoid some of the confusion experienced by applicants who are not sure which type of application they need to complete. The changes in this section are: 1) Addition of "other accrediting body deemed by the board to be substantially equivalent" to allow recognition of another educational accrediting body if there is one in the future. 2) Moved requirement to sign a statement that the applicant has read laws and regulations and will comply to subsection A; this requirement is currently found in subsection C and in section 15. 3) Subsection B allows the Board to waive the requirement of graduation from an accredited school of optometry for an applicant who holds a current, unrestricted license in another U. S. jurisdiction and has been engaged in active clinical practice for 36 out of the 60 months immediately preceding application for licensure in Virginia. *The intent of this amendment is to allow a pathway to licensure for foreign-trained optometrists who have been engaged in active practice in another state. Currently, regulations require graduation from an accredited program. The Board believes the requirement of passage of the national examination and active practice*

		for at least 36 months is sufficient evidence of qualification to practice. 4) The required examination section is amended to include the TMOD examination, which is now taken as part of the NBEO examination. TMOD is required for TPA certification, and subsection A currently requires all applicants to meet the requirements for TPA certification. 5) An applicant who has been licensed in another state and has not been engaged in active practice within the 12 months immediately preceding application is required to complete 20 hours (equivalent of one year) of CE. The Board has deleted the requirement that an applicant must complete 32 hours of CE if he has not passed all parts of the examination within the five years prior to application. *The Board is trying to make it less onerous for an applicant who is currently licensed and practicing in another state and wants to become licensed in Virginia. If he/she has been actively practicing and has a current license, the applicant would not be required to do additional CE. If not actively practicing, the Board believes some CE is necessary to ensure minimal competency for providing patient care.* 6) The requirement for a federal service optometrist to have verification of good standing from a commanding officer is current language from section 15, which is being repealed.
15	Sets out the requirements for licensure by endorsement	The Board has repealed the section and incorporated all licensure requirements into section 10.
16	Sets out requirements for TPA certification	Currently, the regulation provides that an applicant who is certified in TPA by a state examination must provide evidence of comparability to the NBEO exam. The Board has found that comparability is difficult, if not impossible, to prove; so the proposed regulation will provide that an applicant must be TPA-certified by an examination satisfactory to the Board.
17	Establishes the fees charged to applicants and licensees	The fee for an application for TPA certification is eliminated because every application now has to include TPA certification; a separate fee is not necessary. The fee reduction for the renewal in 2015 can now be eliminated.
40	Sets out the standards of conduct for optometrists	The authority of the Board includes refusal to issue a license or renew a license for grounds established in law or regulation. That clarification and one edit are the only changes in this section.
45	Sets out the standards of practice for an optometrist	Subsection B is amended to clarify the provision about whether an expiration date on a prescription is required. Currently, the regulation states that the patient record should include an expiration date "if medically appropriate." Rules of the FDA state that if there is an expiration date, it should not be less than one year unless there is a medical reason for the

		shorter date. *An optometrist is not required to place an expiration date on a prescription for contact lenses or eyeglasses.* Subsection G is added to include provisions regarding a provider-patient relationship that were added to the Code of Virginia in the 2017 General Assembly.
46	Sets out the treatment guidelines for TPA-certified optometrists	The definition of "adnexa" in subsection A has been moved to section 05 Definitions.
47	Sets out the therapeutic pharmaceutical agents within the scope of practice for an optometrist	Subsection B is amended to be inclusive of Schedule II controlled substance consisting of hydrocodone in combination with acetaminophen (other Schedule II drugs are not allowed to be prescribed).
60	Establishes the requirements for renewal and reinstatement of a lapsed license	Subsection D is amended to clarify the requirement that an applicant for reinstatement "demonstrate continuing competence." Without a specific standard, it is very difficult for an applicant to comply or for staff to determine compliance. Therefore, the amended language requires a current, unrestricted license in another U. S. jurisdiction and active clinical practice within the 12 months immediately preceding application; or completion of CE as required in section 70 for a maximum of 40 hours (equivalent of two years of CE). Subsection E is deleted because it would be extremely burdensome for an applicant who has allowed his license to expire to take and pass all parts of the examination.
70	Sets out requirements for continuing education	Subsection D is amended to give licensees 30 days (rather than 14) after receiving notification of an audit (rather than after the renewal date). *Audits are not conducted within 14 days of the renewal date, so the current requirement is unreasonable.* Other boards have a regulation allowing a board to grant an exemption from all or part of the CE requirement for circumstances beyond the control of the licensee; the Board of Optometry is adding subsection G to include that provision. Subsection I is amended to place the burden on the licensee to ensure that the certificate of completion he/she receives from a CE provider includes the information necessary to receive credit from the Board for meeting regulatory requirements. The Board does not oversee the sponsors or providers, other than to list them as approved by regulation. An additional piece of information that the certificate should include is whether the course was in real-time and interactive, including in-person or electronic presentations, to meet the statutory requirement of 10 of the 20 hours.