



Virginia
Regulatory
Town Hall

Proposed Regulation Agency Background Document

Agency Name:	Board of Optometry / Department of Health Professions
VAC Chapter Number:	18 VAC 105-20-10 et seq. 18 VAC 105-30-10 et seq.
Regulation Title:	Regulations Governing the Practice of Optometry
Action Title:	Amendments to Chapter 20 to incorporate TPA certification Repeal of Chapter 30 – current TPA regulations
Date:	January 27, 2005

This information is required pursuant to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99), and the *Virginia Register Form, Style and Procedure Manual*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

The second enactment clause of Chapter 744 of the 2004 Acts of the Assembly, which states “*That the Board of Optometry shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment,*” required the Board to adopt emergency regulations to incorporate the requirements for initial licensure with therapeutic pharmaceutical agents (TPA) certification, fees for applications and renewals, and the continuing education requirement for TPA-certified optometrists into Chapter 20, Regulations Governing the Practice of Optometry. This action is necessary to replace the emergency regulations that have been in effect since December 8, 2004.

The Board is also repealing Chapter 30, Regulations on Certification of Optometrists to Use Therapeutic Pharmaceutical Agents.

Basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400 (6) 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. ...

Chapter 744 of the 2004 General Assembly mandates the promulgation of regulations for optometrists newly licensed in Virginia to be TPA certified:

<http://leg1.state.va.us/cgi-bin/legp504.exe?041+ful+CHAP0744>

The Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the regulatory action is to implement provisions of Chapter 744 of the 2004 General Assembly, which requires that all persons newly licensed to practice optometry after June 30, 2004 must meet the qualifications for a TPA-certified optometrist. Therefore, the general regulations for the practice of optometry are being amended to incorporate the qualifications for TPA certification that are currently found in a separate chapter of the VAC. Since TPA qualification is now a prerequisite for licensure, the Board has amended examination requirements to allow entry into Virginia for optometrists who may have been TPA-qualified by an examination other than the NBOE examination including TMOD. The goal of the regulation is to maintain the standard for TPA certification but reduce the cost and allow for some flexibility in applying the requirements for evidence of minimal competency.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)

Amendments are proposed to incorporate the requirement for certification in therapeutic pharmaceutical agents into the qualifications for initial licensure in optometry, as mandated by Chapter 744 of the 2004 General Assembly. Modifications to the current rules for TPA will allow the Board the flexibility to 1) accept examinations other than the TPA portion of the national examination, which is the current standard for licensure; and 2) order some type of remediation for someone who has failed the TPA three times rather than require a postgraduate educational program for such a candidate. Fees for general licensure and TPA certification are combined and the total amount reduced for optometrists who hold both credentials.

Since a separate set of regulations has been in effect for certification of TPA and that is now a requirement for initial licensure, Chapter 30 is repealed.

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 the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

Advantages or disadvantages to the public:

There are no advantages or disadvantages to the public. Requirements for TPA certification have not been changed by this action; they are being moved from a separate set of regulations into the general regulations for optometry in Chapter 20.

Advantages or disadvantages to the agency:

There are no specific advantages or disadvantages to the agency or the Commonwealth. More specificity in the rules for optometry may alleviate questions and misunderstandings from applicants.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

Projected cost to the state to implement and enforce the proposed regulation, including	a) As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-
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(a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation; b) The agency will incur some one-time costs (less than \$2,000) for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. There will be no on-going expenditures related to amending this chapter.
Projected cost of the regulation on localities	None
Description of the individuals, businesses or other entities likely to be affected by the regulation	The entities that are likely to be affected by these regulations would be applicants for licensure as optometrists. Optometrists without TPA certification will be able to continue practicing, so the regulation does not affect them. Optometrists with TPA certification will have a reduction in their annual renewal fee.
Agency's best estimate of the number of such entities that will be affected	There are 1032 optometrists with TPA certification – each will save \$25 at annual renewal Applicants for licensure in optometry with TPA certification will save \$145; there are an estimated 50 persons who apply for licensure each year.
Projected cost of the regulation for affected individuals, businesses, or other entities	There are no additional costs; most optometrists will have a cost reduction in fees.

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.

There are no alternatives to the adoption of regulations, as it is mandated by the enactment clause of Chapter 744 of the 2004 Acts of the Assembly that amended regulations be in effect within 280 days of enactment, which was April 12, 2004. Through the emergency promulgation process, the Board has amended regulations stating educational and examination requirements for TPA certification and fees for applications and renewal; this action replaces the emergency regulation.

Since § 54.1-3211 requires that after June 30, 2004, every person initially licensed to practice optometry must meet the qualifications of a TPA-certified optometrist, the Board considered amendments that would allow a person to meet the criteria for certification whether applying for licensure by examination or by endorsement. For those applying for initial licensure by examination, meeting the qualifications should not be an issue. Currently, approved optometric educational programs incorporate didactic and clinical training in TPA's, and the national examination incorporates a section (TMOD) to test minimal competency in the administration and prescribing of controlled substances.

For persons applying for licensure by endorsement, who may have been TPA-certified by a state examination, the current requirement for passage of TMOD may be problematic. The only option for such an applicant would be to retake the TMOD portion of the examination, since all newly licensed optometrists have to be TPA qualified. In its amended regulations, the Board has provided for those optometrists seeking licensure by endorsement, if the state examination was comparable to the TMOD portion of national board examination. That determination would likely be made by a special conference committee that would review information provided by the candidate and the jurisdiction in which the optometrist took the examination.

The Board has modified the current requirement for additional postgraduate training that meets the requirement for initial certification. Optometric schools will no longer be offering separate & distinct TPA training, so it may be too burdensome to maintain the current rule. At the request of the Board, the optometry schools have fashioned remedial courses for applicants or optometrists who are the subject of a disciplinary action. Therefore, the Board has modified the current language to require an applicant who failed the required examination three times to complete additional postgraduate training as determined by the board (through a hearing before the Credentials Committee).

The amended regulations will also result in a cost savings to those applying for licensure and optometrists who are currently licensed with TPA certification. For applicants, there will be a net reduction of \$145; for current licensees with TPA, annual renewal will be reduced by \$25. The Board is operating well within the revenue being produced, so it does not believe the reduction in fees will be problematic or necessitate a future fee increase.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

An announcement of the Board's intention to amend its regulations to replace emergency regulations currently in effect was posted on the Virginia Regulatory Townhall, sent to the Registrar of Regulations, and sent to persons on the PPG mailing list for the Board. Public comment was accepted from November 29, 2004 until December 29, 2004. During the 30-day comment period, there was no public comment on the Notice of Intended Regulatory Action.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

There is no impact on the institution of the family and family stability.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.

Amendments to Chapter 20 and repeal of Chapter 30: The “**current section numbers and requirements**” reference those found in Chapter 30.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
105-30-10	105-20-05	Sets out the definitions for “board,” “TPA,” and “TPA certification”	There is no change in the definitions, other than relocation to a new section in Chapter 20.
105-30-30	105-20-10 105-20-15	Sets out the requirements for an applicant to be licensed as an optometrist	These sections are amended in accordance with an amendment to § 54.1-3221, which specifies that everyone initially licensed as an optometrist after June 30, 2004 must meet the qualifications for a TPA-certified optometrist.
105-30-35 105-30-40	105-20-16	Sets out the education and examination requirements for TPA certification & specifies postgraduate training for someone who fails the TMOD examination 3 times	<p>1) Requirements for completion of a graduate level training program approved by the board with a minimum of 20 hours of clinical supervision by an ophthalmologist are identical to current rules in Chapter 30 and consistent with provisions of § 54.1-3223.</p> <p>2) Requires passage of the TMOD portion of the national examination or of another examination acceptable to the Board; or if TPA-certified in another state based on a state examination, requires the applicant to document that the exams were comparable. (TMOD is the standard by which the vast majority of optometrists are qualified to be TPA-certified. Presently, TMOD is one portion of the NBOE exam taken by all graduates of optometric schools and accepted in all states. There may be an occasionally applicant who has been TPA-certified in another state based on passage of that state exam, so the Board wanted to be able to license that person if the exams were comparable. In addition, there is an examination in development that would replace the current examination and would have a different name, so the Board has provided that it may accept other examinations in order to be able to recognize any replacement for TMOD.)</p> <p>3) Current regulations require an applicant who fails the examination 3 times to repeat the portion of</p>

105-30-120	105-20-20	Sets the fees for applications, renewal, late renewal and other miscellaneous processes	<p>postgraduate educational program relating to TPA's. Optometric schools will no longer be offering separate & distinct TPA training, so it may be too burdensome to maintain the current rule. At the request of the Board, the optometry schools have fashioned remedial courses for applicants or optometrists who are the subject of a disciplinary action. Therefore, the Board has modified the current language to require an applicant who failed TMOD three times to complete additional postgraduate training as determined by the board (through a hearing before the Credentials Committee)</p> <p>Fees for TPA certification are incorporated into the fees for licensure and will result in a net reduction for practitioners.</p> <p>Application fee – Currently \$245 for optometric license and \$200 for TPA certification – <i>New fee is \$300 for both.</i></p> <p>A fee for endorsement of certification to use DPA's is being eliminated because current regulations require every optometrist, whether newly licensed by examination or endorsement, to be DPA-qualified. It is now part of the application process and not a separate endorsement.</p> <p>Annual licensure renewal without TPA certification – <i>unchanged at \$150</i></p> <p>Annual licensure renewal with TPA certification – Currently \$150 for license plus \$75 for TPA certification – <i>New fee is \$200 for both.</i></p> <p><i>Late renewal fees are approximately 1/3 of the annual renewal fee, consistent with the Principles for Fee Development.</i></p>
105-30-90	105-20-70	Requires annual renewal of TPA certification and at least 2 of the CE hours be directly related to prescribing and administering TPA	Specifies that 2 hours of the current 16-hour requirement for optometrists with TPA certification be directly related to prescribing and administering TPA's.

Repeal of Chapter 30: The “**current section numbers and requirements**” reference those found in Chapter 30, which is being repealed in this action.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
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105-30-10		See above chart	Relocation to a new section in Chapter 20 (section 05).
105-30-20		Refers the Public Participation Guidelines in Chapter 10	Repealed; no similar amendment to Chapter 20 is necessary.
105-30-30		See above chart	Provisions in section 30 of Chapter 30 are included in amended sections 10 and 20 of Chapter 20.
105-30-35 105-30-40		See above chart	Provisions of sections 35 and 40 of Chapter 30 are now included in amended section 16 of Chapter 20.
105-30-60 105-30-70		Sets out the treatment guidelines and formulary of TPA's that may be used	Provisions of sections 60 and 70 are being amended and promulgated in Chapter 20 under an exemption from the APA but in accordance with specific requirements for recommendation from a TPA Formulary Committee, notification, public hearing, and publication of proposed and final regulations. These sections will become sections 46 and 47 within Chapter 20.
105-30-90		See above chart	A requirement for 2 hours of continuing education related to prescribing and administration is incorporated into section 70 of Chapter 20. Renewal will be simultaneous with renewal of a license to practice optometry.
105-30-100		Sets out provisions for expiration of TPA certification and requirements for reinstatement	Requirements for renewal and reinstatement are provided in section 60 of Chapter 20 and are now being amended.
105-30-120		See above chart	Fees for TPA certification are incorporated into section 20 of Chapter 20.