Form: TH- 02

Virginia Regulatory Town Hall

Proposed Regulation
Agency Background Document

Agency Name:	Board of Optometry / Department of Health Professions
VAC Chapter Number:	18 VAC 105-30-10 et seq.
Regulation Title:	Regulations Governing Certification for Therapeutic Pharmaceutical Agents
Action Title:	Regulatory review
Date:	02 / 21 / 02

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

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The Board of Optometry is recommending that 18 VAC 105-30-10 et seq. be amended to reduce the burden of reinstating an expired certification, to reduce the late renewal fee and add some miscellaneous fees consistent with other boards, and to specify that two of the continuing education hours required for renewal of licensure must be directly related to prescribing and administration of prescription drugs.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided. Please state that 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.

Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations, levy fees, administer a licensure and renewal program, and discipline regulated professionals.

§ 54.1-2400. General powers and duties of health regulatory boards.–The general powers and duties of health regulatory boards shall be:

1. *To establish the qualifications for registration, certification or licensure in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.*

2. *To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.*

3. *To register, certify or license qualified applicants as practitioners of the particular profession or professions regulated by such board.*

4. *To establish schedules for renewals of registration, certification and licensure.*

5. *To levy and collect fees for application processing, examination, registration, certification or licensure and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions and the health regulatory boards.*

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 and Chapter 25 of this title.*

7. *To revoke, suspend, restrict, or refuse to issue or renew a registration, certificate or license which such board has authority to issue for causes enumerated in applicable law and regulations.*

8. *To appoint designees from their membership or immediate staff to coordinate with the Intervention Program Committee and to implement, as is necessary, the provisions of*

Chapter 25.1 (§ 54.1-2515 et seq.) of this title. Each health regulatory board shall appoint one such designee.

9. *To take appropriate disciplinary action for violations of applicable law and regulations.*

10. *To appoint a special conference committee, composed of not less than two members of a health regulatory board, to act in accordance with § 9-6.14:11 upon receipt of information that a practitioner of the appropriate board may be subject to disciplinary action. The special conference committee may (i) exonerate the practitioner; (ii) reinstate the practitioner; (iii) place the practitioner on probation with such terms as it may deem appropriate; (iv) reprimand the practitioner; (v) modify a previous order; and (vi) impose a monetary penalty pursuant to § 54.1-2401. The order of the special conference committee shall become final thirty days after service of the order unless a written request to the board for a hearing is received within such time. If service of the decision to a party is accomplished by mail, three days shall be added to the thirty-day period. Upon receiving a timely written request for a hearing, the board or a panel of the board shall then proceed with a hearing as provided in § 9-6.14:12, and the action of the committee shall be vacated. This subdivision shall not be construed to affect the authority or procedures of the Boards of Medicine and Nursing pursuant to §§ 54.1-2919 and 54.1-3010.*

11. *To convene, at their discretion, a panel consisting of at least five board members or, if a quorum of the board is less than five members, consisting of a quorum of the members to conduct formal proceedings pursuant to § 9-6.14:12, decide the case, and issue a final agency case decision. Any decision rendered by majority vote of such panel shall have the same effect as if made by the full board and shall be subject to court review in accordance with the Administrative Process Act. No member who participates in an informal proceeding conducted in accordance with § 9-6.14:11 shall serve on a panel conducting formal proceedings pursuant to § 9-6.14:12 to consider the same matter.*

12. *To issue inactive licenses and certificates and promulgate regulations to carry out such purpose. Such regulations shall include, but not be limited to, the qualifications, renewal fees, and conditions for reactivation of such licenses or certificates.*

The statutory authority for licensure and regulation of optometrists, including the mandate for continuing education, is found in Chapter 32 of Title 54.1 of the Code of Virginia: http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+TOC54010000032000000000000

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the amended regulation is to reduce the burden of reinstatement for a few optometrists who allow their TPA certification to expire. Fees are reduced or added for consistency with the Principles for Fee Development. By requiring at least two hours of

continuing education directed toward drug therapies, the Board is seeking to protect the public health and safety by ensuring that optometrists who use therapeutic pharmaceutical agents have remained abreast of drug interactions and efficacy and are familiar with newer drugs as they are introduced.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement providing detail of the regulatory action's changes.

Substantive changes to the existing sections of the regulations include: 1) an additional two hours of continuing education in prescribing and administration of drugs; 2) the reduction or addition of certain fees consistent with the Principles of Fee Development; and 3) a provision for reinstatement of an expired certificate as opposed to requiring the optometrist to take the TPA examination and apply as a new applicant.

Issues

Please provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 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 include a sentence to that effect.

The primary advantages to the public of implementing the amended regulations are as follows: a) A change in requirements for reinstatement of an expired TPA certificate may result in a few additional licensed optometrists being available to provide those services in the Commonwealth; and b) An additional requirement for two hours of continuing education in prescription drugs for optometrists who use therapeutic pharmaceutical agents will offer some assurance that the practitioner is current in his knowledge of appropriate drug therapies.

There are no disadvantages to the public as all amendments are intended to provide better access to qualified optometrists who have remained current in their knowledge and skills.

There are no advantages or disadvantages to the agency or the Commonwealth in the adoption of these regulations. While the addition of miscellaneous fees and the increase in the returned check charge may result in a very modest increase in income, the reduction in the late fee will likely offset that amount.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

Projected cost to the state to implement and enforce:

(i) Fund source: 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 practitioners for necessary functions of regulation.

(ii) Budget activity by program or subprogram: There is no change required in the budget of the Commonwealth as a result of this program.

(iii) One-time versus ongoing expenditures: The agency will incur some one-time costs (less than $1,000) for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending copies of final regulations to regulated entities. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled.

Projected cost on localities:

There are no projected costs to localities.

Description of entities that are likely to be affected by regulation:

The entities that are likely to be affected by these regulations would be licensed optometrists with certification in the use of therapeutic pharmaceutical agents (TPA).

Estimate of number of entities to be affected:

Currently, there are approximately 940 licensed doctors of optometry who are authorized to use therapeutic pharmaceutical agents.

Projected costs to the affected entities:

The cost for compliance will relate to the additional two hours of continuing education proposed by the Board. Costs for those hours will vary depending on the practitioner and the method chosen for obtaining continuing education. A review of courses being offered for the months of February and March by the Council on Optometric Practitioner Education (COPE) and by other Board approved providers (universities, national association affiliates) indicate that there is a wide variety available with some offering at no cost to members of an organization or affiliated group.

Internet courses (including a variety for therapeutic pharmaceutical agents) generally run about $20 to $25 per hour. For courses offered at meetings, the cost is approximately $8 to $15 per hour. Registration for the entire meeting is generally required to receive credit for any of the offerings. Examples include one meeting which offered 40 hours of CE for $335 registration and another offered 20 continuing education hours for a registration of $250. Acquiring a total of 16 hours of continuing education should not be too burdensome, as hours are available from so many sources.

For more details on COPE and other Board approved CE, the following on the Association of Regulatory Boards in Optometry's website provides a wealth of information: www.arbo.org/opt/opthome.htm.

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.

18 VAC 105-30-90. Renewal of certification.

- The Board will consider an amendment to specify that a certain number of the continuing education hours required for renewal of an optometrist's license be directed to topics related to therapeutic pharmaceutical agents for those optometrists holding TPA certification.

18 VAC 105-30-100. Expiration of certification.

- Reinstatement of a lapsed certification currently requires the applicant to submit a new application. Amendments are recommended to change the rule to require a reinstatement application and to specify that the applicant must provide certain evidence of continued competency to practice.

18 VAC 105-30-120. Fees.

- During the promulgation of amendments to fees for other boards within the Department of Health Professions, principles were established to provide more consistency across boards for similar fees (such as late renewal) and a rationale for setting of fees relative to the basic renewal fee for each profession. Certain fees, such as the penalty for late renewal may be reduced; others, such as the returned check fee may be increased. In addition, the administrative cost for issuing a duplicate license or a duplicate wall certificate may be reflected in fees charged to licensees.

Alternatives

Please describe the specific 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.

Alternatives for addressing the following issues:

Fee adjustments:

During the promulgation of amendments to fees for other boards within the Department of Health Professions, principles were established to provide more consistency across boards for similar fees (such as late renewal) and a rationale for setting of fees relative to the basic renewal fee for each profession. For example, the penalty fee for late renewal has been reduced, but the fee for processing a returned check is increased to cover the cost to the agency for the transaction. Administrative fees for a duplicate license or a duplicate wall certificate are established. Since the amended regulation would permit reinstatement of an expired certification, a fee for reinstatement is established to include a reinstatement application, the annual renewal and the late fee.

Continuing education:

In its review of regulations from other states, it is apparent that most states (at least 35) require additional hours of continuing education for optometrists with TPA privileges. Some incorporate those hours into the basic CE requirement for all optometrists and designate a certain number related to TPA. Others require CE hours related to TPA in addition to the requirement for renewal of optometric licensure. The number of hours required for TPA-authorization ranges from 5 or 6 every two years in several states to 150 hours over a three-year period in New Hampshire. The Code of Virginia (§ 54.1-3219) authorizes the Board to require up to 16 hours of optometric continuing education each year; some of those hours should be directed to current knowledge on therapeutic pharmaceutical agents if an optometrist is authorized to treat patients with such drugs.

Other professions that have recently been authorized to prescribe scheduled drugs (nurse practitioners and physician assistants) have also been mandated in the legislation to provide evidence of continuing competency related to patient safety and the use of new pharmaceuticals. The Board believes that it is essential for optometrists to demonstrate continued competency in their ability to administer and prescribe appropriately. The Board considered various alternatives for assuring such competency, but it determined that the least burdensome method was to designate that a certain number of the prescribed hours of continuing education be specific to pharmacology, treatment with therapeutic agents or similar subjects.

Reinstatement of a lapsed certification currently requires the applicant to submit a new application for certification. Since the licensee has previously been TPA-certified, it is inappropriate and unnecessary for a new application with transcripts verifying post-graduate education and examination results from the National Board be submitted. That information was submitted with the original application and should be on file with the Board. To reinstate an

optometrist's TPA certification, the Board needs some assurance that the licensee continues to be competent to practice, treat and prescribe. In amending the regulations, the Board has set requirements for re-certification to include evidence of continuing competency to practice, which may include continuing education or active practice with TPA certification in another state.

Public Comment

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

An announcement of the board's intent to amend its regulations 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 received until December 5, 2001. During the 30-day comment period, no comments were received from members of the public.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

Members of the Board met in open session to work on draft regulations, and the public has been invited to comment during the course of those meetings. No comments have been received regarding the need for clarity in the proposed amendments. The Assistant Attorney General who provides counsel to the Board has been involved during the development and adoption of proposed regulations to ensure clarity and compliance with law and regulation.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

Public participation guidelines require the Board to review regulations each biennium or as required by Executive Order. Regulations governing the certification of optometrists to use therapeutic pharmaceutical agents will be reviewed again during the 2004-05 fiscal year.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential impact on the institution of the family and family stability including the extent to which 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.

In its preliminary analysis of the proposed regulatory action, the agency has determined that there is no potential impact on the institution of the family and family stability and no effect on family income.