Form: TH- 06

Virginia Regulatory Town Hall

Periodic Review and Notice of Intended Regulatory Action Agency Background Document

Agency Name:	Board of Optometry
VAC Chapter Number:	18 VAC 105-30-10 et seq.
Regulation Title:	Regulations on Certification for Therapeutic Pharmaceutical Agents
Action Title:	Periodic review
Date:	

This information is required pursuant to the Administrative Process Act § 9-6.14:25, Executive Order Twenty-Five (98), and Executive Order Fifty-Eight (99) which outline procedures for periodic review of regulations of agencies within the executive branch. Each existing regulation is to be reviewed at least once every three years and measured against the specific public health, safety, and welfare goals assigned by agencies during the promulgation process.

This form should be used where the agency is planning to amend or repeal an existing regulation and is required to be submitted to the Registrar of Regulations as a Notice of Intended Regulatory Action (NOIRA) pursuant to the Administrative Process Act § 9-6.14:7.1 (B).

Summary

Please provide a brief summary of the regulation. There is no need to state each provision; instead give a general description of the regulation and alert the reader to its subject matter and intent.

Regulations establish the qualifications for optometrists to become certified to utilize therapeutic pharmaceutical agents in their practice, including postgraduate education and passage of a national examination. Regulations also set treatment guidelines and specify those therapeutic agents that certified optometrists are authorized to administer and prescribe. Fees for administrative and disciplinary activities and a schedule of renewal of certification are set.

Basis

Please identify the state and/or federal source of legal authority for the regulation. The discussion of this authority should include a description of its scope and the extent to which the authority is mandatory or discretionary. Where applicable, explain where the regulation exceeds the minimum requirements of the state and/or federal mandate.

The statutory authority for this regulation is found in § 54.1-2400 and Chapter 32 of Title 54.1 of the Code of Virginia.

Section 54.1-2400 establishes the general powers and duties of health regulatory boards including the responsibility to establish qualifications for licensure, to set fees and schedules for renewal, to establish requirements for an inactive license and to promulgate regulations, in accordance with the Administrative Process Act, which are reasonable and necessary to effectively 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:

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.*

Chapter 32 of Title 54.1 sets forth statutory provisions for the licensure and practice of optometrists, as listed below:

Article 1.
General Provisions.

§ 54.1-3200. Definitions.

As used in this chapter, unless the context requires a different meaning:
"Board" means the Board of Optometry.
"Optometrist" means any person practicing the profession of optometry as defined in this chapter and the regulations of the Board.
"Practice of optometry" means the examination of the human eye to ascertain the presence of defects or abnormal conditions which may be corrected or relieved by the use of lenses, prisms or ocular exercises, visual training or orthoptics; the employment of any subjective or objective mechanism to determine the accommodative or refractive states of the human eye or range or power of vision of the human eye; the use of testing appliances for the purpose of the measurement of the powers of vision; the examination, diagnosis, and optometric treatment in accordance with this chapter, of conditions and visual or

muscular anomalies of the human eye; the use of diagnostic pharmaceutical agents set forth in § 54.1-3221; and the prescribing or adapting of lenses, prisms or ocular exercises, visual training or orthoptics for the correction, relief, remediation or prevention of such conditions. An optometrist may treat certain diseases or abnormal conditions of the human eye and its adnexa with certain therapeutic pharmaceutical agents only as permitted under this chapter.

"TPA-certified optometrist" means an optometrist who is licensed under this chapter and who has successfully completed the requirements for TPA certification established by the Board pursuant to Article 5 (§ 54.1-3222 et seq.) of this chapter. Such certification shall enable an optometrist to treat certain diseases, including abnormal conditions, of the human eye and its adnexa, as determined by the Board, with certain therapeutic pharmaceutical agents specified by the Board. Such certification shall not, however, permit treatment through surgery, including, but not limited to, laser surgery or other invasive modalities, except for treatment of emergency cases of anaphylactic shock with intramuscular epinephrine.

The foregoing shall not restrict the authority of any optometrist licensed or certified under this chapter for the removal of superficial foreign bodies from the human eye and its adnexa or from delegating to personnel in his personal employ and supervised by him, such activities or functions as are nondiscretionary and do not require the exercise of professional judgment for their performance and which are usually or customarily delegated to such persons by optometrists, if such activities or functions are authorized by and performed for such optometrists and responsibility for such activities or functions is assumed by such optometrists.

Article 5.
Certification for Administration of Therapeutic Pharmaceutical Agents.

§ 54.1-3222. TPA certification; certification for treatment of certain diseases or abnormal conditions with certain therapeutic pharmaceutical agents.

A. The Board shall certify an optometrist to prescribe for and treat certain diseases or abnormal conditions of the human eye and its adnexa with certain therapeutic pharmaceutical agents, if the optometrist files a written application, accompanied by the fee required by the Board and satisfactory proof that the applicant:

1. Is licensed by the Board as an optometrist and certified to administer diagnostic pharmaceutical agents pursuant to Article 4 (§ 54.1-3220 et seq.) of this chapter;

2. Has satisfactorily completed such didactic and clinical training programs for the treatment of diseases and abnormal conditions of the eye and its adnexa as are determined, after consultation with a school or college of optometry and a school of medicine, to be reasonable and necessary by the Board to ensure an appropriate standard of medical care for patients; and

3. Passes such examinations as are determined to be reasonable and necessary by the Board to ensure an appropriate standard of medical care for patients.

B. TPA certification shall enable an optometrist to treat certain diseases and abnormal conditions of the human eye and its adnexa as determined by the Board with certain therapeutic pharmaceutical agents specified by the Board, within the following conditions:

1. Treatment with oral therapeutic pharmaceutical agents shall be limited to the analgesics included on Schedules III and VI, as defined in §§ 54.1-3450 and 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.), which are appropriate to alleviate ocular pain.

2. Prescriptions for oral analgesics to relieve ocular pain shall be limited to dosages for no more than seventy-two hours.

3. Therapeutic pharmaceutical agents shall include topically applied Schedule VI drugs as defined in § 54.1-3455 of the Drug Control Act.

4. Treatment of glaucoma shall require prior consultation with the patient's physician or other appropriate physician, and shall exclude treatment of congenital and infantile glaucoma. Treatment of angle closure glaucoma shall be limited to initiation of immediate emergency care.
5. Treatment through surgery or other invasive modalities shall not be permitted, except for treatment of emergency cases of anaphylactic shock with intramuscular epinephrine, such as that included in a bee sting kit.
6. Entities permitted or licensed by the Board of Pharmacy to distribute or dispense drugs, including, but not limited to, wholesale distributors and pharmacists, shall be authorized to supply TPA-certified optometrists with those therapeutic pharmaceutical agents specified by the Board on the TPA-Formulary.

§ 54.1-3223. Regulations relating to instruction and training, examination, and therapeutic pharmaceutical agents; Board to determine TPA-Formulary; appointment of TPA-Formulary Committee.
A. The Board shall promulgate such regulations governing the treatment of certain diseases and abnormal conditions of the human eye and its adnexa with certain therapeutic pharmaceutical agents by TPA-certified optometrists as are reasonable and necessary to ensure an appropriate standard of medical care for patients, including, but not limited to, determinations of the diseases and abnormal conditions of the human eye and its adnexa which may be treated by TPA-certified optometrists, treatment guidelines, and the drugs specified on the TPA-Formulary. In establishing standards of instruction and training, the Board shall consult with a school or college of optometry and a school or college of medicine and shall set a minimum number of hours of clinical training to be supervised by an ophthalmologist. The didactic and clinical training programs may include, but need not be limited to, programs offered or designed either by schools of medicine or schools or colleges of optometry or both or some combination thereof. The Board may prepare, administer, and grade appropriate examinations for the certification of optometrists to administer therapeutic pharmaceutical agents or may contract with a school of medicine, school or college of optometry, or other institution or entity to develop, administer, and grade the examinations.
In order to maintain a current and appropriate list of therapeutic pharmaceuticals on the TPA-Formulary, current and appropriate treatment guidelines, and current and appropriate determinations of diseases and abnormal conditions of the eye and its adnexa which may be treated by TPA-certified optometrists, the Board may, from time to time, amend such regulations. Such regulations shall be exempt from the requirements of the Administrative Process Act (§ 9-6.14:1 et seq.), except to any extent that they may be specifically made subject to §§ 9-6.14:14.1, 9-6.14:21, and 9-6.14:22; the Board's regulations shall, however, comply with § 9-6.18 of the Virginia Register Act (§ 9-6.15 et seq.). The Board shall, however, conduct a public hearing prior to making amendments to the TPA-Formulary, the treatment guidelines or the determinations of diseases and abnormal conditions of the eye and its adnexa which may be treated by TPA-certified optometrists. Thirty days prior to conducting such hearing, the Board shall give written notice by mail of the date, time, and place of the hearing to all currently TPA-certified optometrists and any other persons requesting to be notified of the hearings and publish notice of its intention to amend the list in the Virginia Register of Regulations. During the public hearing, interested parties shall be given reasonable opportunity to be heard and present information prior to final adoption of any TPA-Formulary amendments. Proposed and final amendments of the list shall also be published, pursuant to § 9-6.14:22, in the Virginia Register of Regulations. Final amendments to the TPA-Formulary shall become effective upon filing with the Registrar of Regulations. The TPA-Formulary shall be the inclusive list of the therapeutic pharmaceutical agents that a TPA-certified optometrist may prescribe.
B. To assist in the specification of the TPA-Formulary, there shall be a seven-member TPA-Formulary Committee, as follows: three Virginia TPA-certified optometrists to be appointed by the Board of Optometry, one pharmacist appointed by the Board of Pharmacy from among its licensees, two ophthalmologists appointed by the Board of Medicine from among its licensees, and the chairman who

shall be appointed by the Board of Optometry from among its members. The ophthalmologists appointed by the Board of Medicine shall have demonstrated, through professional experience, knowledge of the optometric profession. In the event the Board of Pharmacy or the Board of Medicine fails to make appointments to the TPA-Formulary Committee within thirty days following July 1, 1996, or within thirty days following any subsequent vacancy, the Board of Optometry shall appoint such members. The TPA-Formulary Committee shall recommend to the Board those therapeutic pharmaceutical agents to be included on the TPA-Formulary for the treatment of certain diseases and abnormal conditions of the eye and its adnexa by TPA-certified optometrists.

§ 54.1-3224. Denial, etc., of TPA certification; disciplinary actions; summary suspension under certain circumstances.

A. The Board of Optometry may deny, refuse to renew, revoke, or suspend any TPA-certificate issued to a TPA-certified optometrist, or applied for by a licensed optometrist in accordance with the provisions of this article, or may discipline or reprimand any certificate holder for violations of this chapter or the Board's regulations.

B. The Board may take action summarily to suspend a TPA-certified optometrist's certification under this section by means of a telephone conference call if, in the opinion of a majority of the Board, (i) a good faith effort to convene a regular meeting of the Board has failed and (ii) there is an imminent danger to the public health or safety which warrants this action.

Public Comment

Please summarize all public comment received as the result of the Notice of Periodic Review published in the Virginia Register and provide the agency response. Where applicable, describe critical issues or particular areas of concern in the regulation. Also please indicate if an informal advisory group was or will be formed for purposes of assisting in the periodic review or development of a proposal.

An announcement of the board's review of its regulations governing the certification of optometrists for use of therapeutic pharmaceutical agents was posted on the Virginia Regulatory Townhall, sent to the Registrar of Regulations, and sent to persons on the Public Participation Guidelines mailing list for the board. Public comment was received from November 1, 2000 until January 1, 2001. During that period, no comment was received from members of the public.

Effectiveness

Please provide a description of the specific and measurable goals of the regulation. Detail the effectiveness of the regulation in achieving such goals and the specific reasons the agency has determined that the regulation is essential to protect the health, safety or welfare of citizens. In addition, please indicate whether the regulation is clearly written and easily understandable by the individuals and entities affected.

1) Achieve high ratings on the Customer Service Satisfaction Survey for application process and renewal of licensure.

The Board reviewed the responses of recent licensees on the Customer Service Satisfaction Surveys and determined that the application process and renewal of certification was effective in

that instructions for making application are clear and easy to understand and complete. Of those that responded, 90.7% agreed or strongly agreed that the instructions were easy to understand. Asked if the application was processed promptly, 89.7% agreed or strongly agreed. Asked if the forms were easy to complete, 94.8% agreed or strongly agreed. Therefore, no changes in regulations are being considered in the application process. There are, however, certain recommendations regarding the reinstatement of an expired certification to make that process less burdensome.

Alternatives

Please describe the specific alternatives for achieving the purpose of the existing regulation that have been considered as a part of the periodic review process. This description should include an explanation of why such alternatives were rejected and this regulation reflects the least burdensome alternative available for achieving the purpose of the regulation.

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 may be reduced, but the fee for processing a returned check needs to be increased to cover the cost to the agency for the transaction. An administrative fee for a duplicate license or a duplicate wall certificate should be established. The Board will examine all of its fees in relation to the Principles for Fee Development.

In addition, the Board will consider under an APA exemption a time-limited reduction in renewal fees for all licensees. Projections for revenue and expenditures for this fiscal year indicate that the Board will likely have a surplus in excess of 10%. Following an analysis of the Board's fiscal status at the end of FY'00-'01, the Board will consider the appropriate amount of the reduction to bring the budget in balance without risking deficit spending in the next biennia.

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 will consider various alternatives for assuring such competency, but it is likely that it will designate 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 will set out requirements for re-certification to include such things as evidence of continuing education, practice in another jurisdiction, and verification that the licensee is not the subject of a disciplinary or malpractice action.

Recommendation

Please state whether the agency is recommending the regulation be amended or terminated and the reasons such a recommendation is being made.

The Board of Optometry is recommending that 18 VAC 105-30-10 et seq. be amended to specify some of the required hours of continuing education be directed to the use of therapeutic pharmaceutical agents, to require licensees who have allowed TPA certification to lapse to submit a reinstatement application with evidence of continued competency, and to revise the fees for consistency with the principles established by the Department. It will also consider any other issues raised during the public comment period on the Notice of Intended Regulatory Action.

Substance

Please detail any changes that would be implemented.

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.

Family Impact Statement

Please provide a preliminary 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.