



Final Regulation Agency Background Document

Agency name	Board of Optometry, Department of Health Professions
Virginia Administrative Code (VAC) citation	18 VAC 105-20
Regulation title	Regulations Governing the Practice of Optometry
Action title	Standards of conduct
Date this document prepared	11/6/09

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (no more than 2 short 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

The board has amended and updated its standards of conduct and standards of practice to provide authority to address unprofessional actions or substandard patient care by optometrists.

Amendments will specify policy on patient records, continuity of care, prescribing for self or family, boundary violations, and compliance with law and regulations. The standard for content of a record during an eye examination is updated and clarified, and the specific requirements of federal rule for contact lens and eyeglass prescriptions are incorporated into state regulations.

In response to comment from the Virginia Optometric Association, the board deleted the cite reference to compliance with specific federal rules for a contact lens prescription and for a spectacle prescription and included the key requirements of those rules in this chapter.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

On October 29, 2009, the Board of Optometry adopted final amendments to 18VAC105-20-10 et seq., Regulations Governing the Practice of Optometry, in order to revise regulations for standards of practice and unprofessional conduct.

Legal 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 numbers, if applicable, and (2) promulgating entity, i.e., 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, 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. ...*

The Code of Virginia has established grounds for disciplinary actions by the Board of Optometry against its licensees. Regulations on standards of conduct would expand and clarify the statutory provisions.

§ 54.1-3215. Reprimand, revocation and suspension.

The Board may revoke or suspend a license or reprimand the licensee for any of the following causes:

1. *Fraud or deceit in his practice;*
2. *Conviction of any felony under the laws of the Commonwealth, another state, the District of Columbia or any United States possession or territory or of any misdemeanor under such laws involving moral turpitude;*
3. *Conducting his practice in such a manner as to endanger the health and welfare of his patients or the public;*
4. *Use of alcohol or drugs to the extent such use renders him unsafe to practice optometry or mental or physical illness rendering him unsafe to practice optometry;*
5. *Knowingly and willfully employing an unlicensed person to do anything for which a license to practice optometry is required;*
6. *Practicing optometry while suffering from any infectious or contagious disease;*
7. *Neglecting or refusing to display his license and the renewal receipt for the current year;*

8. *Obtaining of any fee by fraud or misrepresentation or the practice of deception or fraud upon any patient;*
9. *Advertising which directly or indirectly deceives, misleads or defrauds the public, claims professional superiority, or offers free optometrical services or examinations;*
10. *Employing, procuring, or inducing a person not licensed to practice optometry to so practice;*
11. *Aiding or abetting in the practice of optometry any person not duly licensed to practice in this Commonwealth;*
12. *Advertising, practicing or attempting to practice optometry under a name other than one's own name as set forth on the license;*
13. *Lending, leasing, renting or in any other manner placing his license at the disposal or in the service of any person not licensed to practice optometry in this Commonwealth;*
14. *Splitting or dividing a fee with any person or persons other than with a licensed optometrist who is a legal partner or comember of a professional limited liability company formed to engage in the practice of optometry;*
15. *Practicing optometry where any officer, employee, or agent of a commercial or mercantile establishment, as defined in subsection C of § 54.1-3205, who is not licensed in Virginia to practice optometry or medicine directly or indirectly controls, dictates, or influences the professional judgment, including but not limited to the level or type of care or services rendered, of the licensed optometrist;*
16. *Violating other standards of conduct as adopted by the Board;*
17. *Violating, assisting, inducing or cooperating with others in violating any provisions of law relating to the practice of optometry, including the provisions of this chapter, or of any regulation of the Board.*

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it 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.

In this regulatory action, the board has clarified and amended certain provisions of the section on unprofessional conduct to address issues and licensee conduct that has been problematic. The board added language relating to retention and destruction of patient records, disclosure of disciplinary actions in other states or malpractice judgments or settlements, prescribing and treating self or family members, practicing with an expired license or registration, sexual misconduct and other areas of practitioner conduct. Provisions are set out in regulation to ensure that the board has the necessary authority to protect the public health and safety from unprofessional conduct or substandard care. Likewise, explicit standards for issuance of a contact lens or spectacle prescription will protect consumers in accordance with federal regulations intended to ensure freedom of choice in the purchase of ophthalmic goods.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

The board reviewed unprofessional conduct regulations of other boards within the Virginia Department of Health Professions and the optometry regulations of other states. The following changes were made in the standards of conduct:

- 1) Adding language relating to treating self and family;
- 2) Adding language on record retention and a requirement to post or inform patients of patient record retention and destruction policies;
- 3) Adding a prohibition against failure to disclose disciplinary action in another state and malpractice cases;
- 4) Renaming of the section on Unprofessional Conduct to Standards of Conduct;
- 5) Including violation of Drug Control Act in the standards of conduct;
- 6) Requiring provisions for access to the practice for 24-hour patient care coverage;
- 7) Referencing §54.1-2405 (transfer of patient records, closure or sale of practice).
- 8) Including language regarding the practice on an expired or unregistered professional designation.
- 9) Including provisions for boundary violation or sexual misconduct as grounds for disciplinary action.
- 10) Including compliance with general provisions of law and law relating to controlled substances and patient confidentiality.
- 11) Revising and updating requirements for content of a patient record for consistency with current practice and federal rules.

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.*
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- 1) The advantage to the public may be that optometrists will become more aware of their professional responsibilities and compliance with state and federal law, relating to provision of prescriptions, maintenance of records, protection of patient confidentiality and continuity of care. Amended regulations will require that patients are informed about how long an optometrist will keep records, so a request for a patient record can be made and responded to in a timely manner. There are no disadvantages to the public.
- 2) There are no disadvantages to the agency or the Commonwealth. Clarification of the board's intent and policies relating to professional conduct and standards of practice will enhance public protection.

3) There is no other pertinent matter of interest related to this action.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar’s office, please put an asterisk next to any substantive changes.

Section number	Requirement at proposed stage	What has changed	Rationale for change
45	Subsections C and D were amended to reference federal rules for prescribing contact lens and eyeglasses.	Subsections C and D of section 45 were amended to delete the cite references to the Code of Federal Regulations for the Contact Lens Consumers Act and the Eyeglass Rule and incorporate the gist of those rules in the standards of practice of Virginia optometrists.	In response to concern that the board would be enforcing a federal rule, the references were deleted. However, in order to be consistent, the key requirements of the federal rules have been added in subsections C and D for the protection of the practitioner and his/her patients. If an optometrist follows state regulations, he/she should not risk violating FTC rules.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Proposed regulations were published in the Virginia Register of Regulations on June 8, 2009. Public comment was requested for a 60-day period ending August 7, 2009; there were no written or electronic comments received. A Public Hearing before the Board of Optometry was held on July 22, 2009 at which one person offered comment on proposed regulations.

Bruce Keeney for the Virginia Optometric Association provided the following comments:

In section 40:

- Include language from the Code of Virginia in regulation rather than using Code cites.

Board response:

The board did not elect to include the statutory language in regulation, but did agree to add hyperlinks to the cited Code sections – all of which are available on the board’s website.

- Incorporate provisions for electronic signature in subsection B, #4.

Board response:

The board could not find any requirement in regulation that would prevent electronic signatures on a patient record.

- In #7, clarify the meaning of a “reasonable time” to allow patients to obtain services of another practitioner.

Board response:

Since there is such variance in practice settings, geography and practitioner availability, the board did not amend its rule on allowing patients a “reasonable time” to find another doctor. What constitutes reasonable time in one situation may be unreasonable in another. The language is consistent with requirements for medical doctors.

- #13 infers that all optometrists must practice with a professional designation; clarify the meaning of that provision.

Board response:

The board did not agree that the standard that an optometrist shall not practice with an expired or unregistered professional designation (PD) means that all optometrists must have a PD, so the language was not amended.

In section 45:

- Include provision in subsection B stating that any prescription for ophthalmic goods that has expired is considered invalid.

Board response:

The board did not amend subsection B because an expired prescription should never be filled by a dispenser of ophthalmic goods, but the board does not regulate opticians or mail order companies that dispense.

- Clarify in subsection B that the accepted standard of care is an expiration date of one year from date of the examination or less if medically appropriate.

Board response:

The board did not amend subsection B because the accepted standard for the expiration of a prescription may depend on the medical condition of the patient.

- Reinstate existing language in subsections C and D on provision of eyeglass and contact lens prescriptions and delete references to FTC Contact Lens and Eyeglass Rules.

Board response:

The board did delete references to federal rules for contact lens and eyeglasses, so the board is not responsible for enforcing FTC rules. In order to be consistent, the gist of the federal rules has been added in subsections C and D for the protection of the practitioner and his/her patients. If an optometrist follows state regulations, he/she should not risk violating FTC rules.

- In subsection E, reduce record-keeping requirement from 5 years to 2 or 3 years.

Board response:

Since the five-year requirement for record-keeping is less than the medical requirement for maintaining records, the board did not amend its regulation. In addition, Medicare and some other third-party payers require records to be maintained even longer.

- Add language in subsection F to specify that the optometrist to whom records have been transferred is responsible for maintaining the patient record. Requirement to inform patients about record retention and destruction policy is unnecessary and should be deleted.

Board response:

The requirement to inform patients about the record retention and destruction policy was retained as protection for the practitioner and his/her patients. Patients should know that a practitioner is not going to maintain a record indefinitely, so they can plan to secure a copy of a record that is scheduled for destruction if they think they may need that record in the future. The proposed regulation already sets out an exception for record-keeping for those records that have been transferred to another practitioner.

All changes made in this regulatory action

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail new provisions and/or all changes to existing sections.

Current section number	Current requirement	Proposed change and rationale
40	Sets out the standards for practice, a violation of which is deemed unprofessional conduct	Section 40 is amended in the following ways: <ul style="list-style-type: none"> • The title of the section is changed from “Unprofessional conduct” to “Standards of conduct” to affirmatively state the standards by which an optometrist is expected to practice. • Since the Code only specifies sanctions of revocation, suspension or reprimand, the regulation is clarified to be inclusive of the range of disciplinary actions, including denial of a license or renewal for violation of law or regulation. • Maintenance of records currently set out in #2 is included in a new subsection on records in section 45. • The proposal adds a requirement that a person disclose any

		<p>disciplinary action taken by another board. This standard addresses a problem the board has had with optometrists practicing in Virginia who have been sanctioned in another state.</p> <ul style="list-style-type: none"> • An amendment in #4 adds a reference to the standards of practice set forth in section 45, which specify what must be documented in the patient record. • #5 is amended to include reference to a Virginia law recently enacted, which sets out the requirements for patient notification in the closure, sale or relocation of a practice. • #6 is added to address problems that have arisen when an optometrist practice is located in conjunction with a mall, big box store or other entity. The optometrist needs to ensure access to his records and practice location in case of a patient emergency after hours. • #7 - Continuity of care is an expectation in medical practices; this language was adopted from ethical standards in the regulations for doctors and is relevant to optometrists who may now be prescribing and providing follow-up care for conditions such as glaucoma or cataract surgery. • #8 was also adopted from the medicine regulations relative to compliance with Code requirements on patient confidentiality and access to patient records. • #9 - Since most optometrists now have prescriptive authority, a standard for treating or prescribing for self or family members was adopted. It requires adherence to legal requirements for a practitioner/patient relationship and recordkeeping and is similar to standards for other prescribers. This provision would replace Guidance Document 105-27 on prescribing for self and family. • #10 – Section 40 had not been amended since optometrists were authorized to prescribe scheduled drugs; therefore it is important to set a standard for compliance with the law and regulation related to controlled substance to allow the board to take disciplinary action for diversion, indiscriminate prescribing or other such violations. • #11 - The board has had no standard that could be cited for a professional boundary violation in which the practitioner has used his professional position to take advantage of a patient. The language adopted is similar to the standard for doctors of medicine, osteopathic medicine, podiatry and chiropractic. • #12 - Refusal to provide records or cooperation with an investigator of the Department is a violation of law or regulation for most professions, so it is added to this section. • #13 - The board has had difficulty in sanctioning an optometrist for practicing with an expired or unregistered professional designation, so this provision is added to address the problem. A professional designation must be registered if an optometrist practices under a name other
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		<p>than his own.</p> <ul style="list-style-type: none"> • #14 - In recent years, violations of the general provisions governing professions or health professions found in Chapters 1 and 24 were added to the unprofessional conduct sections of law for several professions, including all of the practitioners of the healing arts, so it is added in this section governing the conduct of optometrists.
45	Sets out the standards of practice for an optometrist in conducting a patient examination or in the provision of prescriptions.	<ul style="list-style-type: none"> • Subsection A of section 45 was updated and clarified for greater consistency with current practice. Rather than the specific aspects of an eye examination found in some other state regulations, the board chose to outline the general components of a routine or medical examination with additional requirements for prescribing and fitting contact lens. • Requirements for a contact lens prescription found in subsection C have been expanded by adoption of federal rules; the content of which is now incorporated. • Requirements for spectacle lens found in subsection D have been expanded by a federal rule, which is now incorporated. • Subsection E was added to include the current requirement for maintenance of records for five years and to add two exceptions to that requirement. The language was adopted from the medicine regulations. • Subsection F was also adopted from the medicine regulations and specified some notice to patients on how long records are maintained or destroyed and to require destruction in a manner that protects patient confidentiality.

Regulatory flexibility analysis

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.

The board has been aware that there was practitioner misconduct or substandard patient care not currently addressed in law or regulation. In some cases, current provisions are general enough to incorporate that conduct and establish grounds for disciplinary actions. However, there is a need to further specify certain provisions in order to give licensees a more precise regulatory standard by which to practice and to authorize the board to act more decisively.

To assist board members in consideration of issues relating to unprofessional conduct, board staff compiled an extensive document consisting of regulations of other health profession boards

(Medicine, Audiology & Speech-Language Pathology, Counseling, Physical Therapy, Psychology & Nursing) and of optometric regulations from most other states. From that document, the board has identified a number of provisions that are necessary for public protection in Virginia. In the development of regulatory language, the board has identified conduct that should be addressed in regulation and has utilized applicable language from other sources.

Family impact

Please assess the impact of the proposed 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 and family stability.