Virginia Regulatory Town Hall

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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	Continuing education requirements
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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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 clarified and amended certain provisions of section 70, the continuing education (CE) requirements as stated in Chapter 20. The board has specified that courses for which the primary purpose is the sale of instruments or products are not acceptable for continuing education credit. Regulations specify that providers must provide a certificate of attendance based on verification of the attendee presence throughout the course or a post-test and that the record of attendance must be maintained for three years. Finally, the proposed regulations specify that a licensee who falsifies CE compliance may be subject to disciplinary action.

Changes to the regulation from publication of the proposed include: 1) reinsertion of two accrediting bodies into the listing of approved providers in subsection G with amendments in subsections C, E and G to describe the entities that may provide, sponsor or accredit CE; 2) deletion of Category 2 continuing medical education as approved CE for optometric licensure renewal; and 3) revision of the term “independent” to “designated” monitor for assurance of attendance.

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 continuing education.

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. …

There is a statutory mandate for the Board of Optometry to require continuing education for renewal of licensure provided in:

§ 54.1-3219. Continuing education.

As a prerequisite to renewal of a license or reinstatement of a license, each optometrist shall be required to take annual courses relating to optometry as approved by the Board. The courses may include, but need not be limited to, the utilization and application of new techniques, scientific and clinical advances and new achievements of research. The Board shall prescribe criteria for approval of courses of study and credit hour requirements. However, the required number of credit hours shall not exceed sixteen in any one calendar year. The Board may approve alternative courses upon timely application of any licensee. Fulfillment of education requirements shall be certified to the Board upon a form provided by the Board and shall be submitted by each licensed optometrist at the time he applies to the Board for the renewal of his license. The Board may waive individual requirements in cases of certified illness or undue hardship.

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.

Issues relating to the validity and value of continuing education for the optometrist have been apparent to the board through audits of continuing education, disciplinary cases and personal observation by members. For example, the current regulation allows courses that are primarily a sales pitch for a manufacturer product, so long as the course offers a miniscule segment relating to patient care. The board has determined that such courses should not be counted toward a practitioner's renewal requirement. Likewise, prescribing and treating with therapeutic pharmaceutical agents privileges has been expanded with many more classes of drugs available to optometrists, so the subject of required continuing education in treatment with pharmaceutical agents has been clarified. By adding value and substance to the continuing education requirements, the board intends to address the need to ensure continuing competency for the health and safety of consumers of optometric services.

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.

In section 70 of 18VAC105-20-10 et seq., the only changes proposed that could be substantive are:

1. To affirmatively state in regulation that falsifying the attestation or failure to comply with CE requirements may subject a licensee to disciplinary action by the board, consistent with § 54.1-3215 of the Code of Virginia. Currently, falsifying an application is grounds for disciplinary action, so this change is a clarification that makes it clear falsifying or failure to comply with requirements for a renewal application may provide grounds.

2. To specify that an approved CE sponsor must provide a certificate of attendance that shows the date, location, lecturer, content hours of the course and contact information of the provider/sponsor. The certificate of attendance must be based on verification by the sponsor of the attendee's presence throughout the course – either provided by a post-test or by a designated monitor. The proposal also adds a requirement for an approved CE provider/sponsor to maintain documentation about the course and attendance for at least three years following its completion. Specifying the provision and content of a certificate of attendance and the length of time that records must be maintained by a CE sponsor/provider is consistent with current expectations and practices and should not represent any change or increased burden.

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
2) the primary advantages and disadvantages to the agency or the Commonwealth; and
3) other pertinent matters of interest to the regulated community, government officials, and the public.
If there are no disadvantages to the public or the Commonwealth, please indicate.

1) The advantage to the public may be that optometrists will take continuing education more closely related to patient care and to the treatment of the eye with prescription drugs. Further specification of requirements for approved sponsors will necessitate closer monitoring of participation. Optometrists will benefit from assuring that sponsors are able to verify CE attendance during a board audit.

2) There are no disadvantages to the agency or the Commonwealth. Clarification of the board's intent and policies relating to continuing education should alleviate some misunderstanding by licensee relating to approval of sponsors and filing for extensions.

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
70	Two entities that accredit continuing education were deleted from the list of CE providers in subsection G and placed in a separate subsection H.	The new subsection H was deleted, and the two entities were put back in the list in subsection G. Likewise subsections C and E were amended to delete reference to subsection H and to include the term "accrediting body" to describe the entities listed in subsection G.	The comment on proposed regulations indicated some confusion about the applicability of requirements in subsections A and I for approved continuing education courses offered by providers accredited by the two accrediting bodies listed in subsection H, so the board determined that it was clearer to put them back in subsection G.
70	In subsection H (and in the current subsection G), continuing education designated as Category 2 CME accredited by ACCME is acceptable.	In reinserting the ACCME into subsection G, the board deleted Category 2, so only Category 1 CME would be acceptable for optometry.	The board agreed with the comment and eliminated Category 2 CME in the reinsertion of ACCME in subsection G. Since Category 2 CME is not verifiable by ACCME, it would be difficult

			for a licensee who is being audited to document hours of Category 2 (which may include consultation with a medical practitioner, etc).
70	In subsection I, there is a requirement for an independent monitor to verify attendance	The requirement was amended to require a "designated" monitor, who could be a part of the organization offering the continuing education course.	The board agreed that the term "designated" monitor was more reasonable, since the intent was to require approved continuing education providers to ensure attendance. The use of an independent monitor might increase the cost of continuing education for providers and licensees.

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 subsection H, clarify the term "accredited" as it pertains to COPE continuing education and specify that courses approved by COPE and ACCME must comply with requirements of subsection A.

- Specify that subsection I should apply to COPE and ACCME as well as sponsors listed in subsection G.

Board response:
Since the comment indicated some confusion about the applicability of requirements in subsections A and I for approved continuing education courses offered by providers accredited by the two accrediting bodies listed in subsection H, that section was deleted and the two bodies reinserted in subsection G. The original intent of listing COPE and ACCME in a separate subsection was to distinguish between the entities that accredit continuing education and the organizations listed in subsection G that sponsor or approve continuing education courses. With the reinsertion of current language in subsection G, subsections C and E were also amended to add "accrediting body" to the description of the entities recognized in subsection G.

- In subsection H, amend to disallow Category 2 continuing medical education.

Board response:
The board agreed with the comment and eliminated Category 2 CME in the reinsertion of ACCME in subsection G. Since Category 2 CME is not verifiable by ACCME, it would be difficult for a licensee who is being audited to document hours of Category 2 (which may include consultation with a medical practitioner, etc).

- In subsection I, include requirements for credentials of the person preparing and grading the post-test.

Board response:
The board did not choose to amend regulations to establish such credentials; there is no requirement for such a person to be registered or credentialed by the board so enforcement would be difficult and selective.

- In subsection I, clarify the meaning of an "independent monitor" or replace with the term "designated monitor."

Board response:
The board agreed that the term "designated" monitor was more reasonable, since the intent was to require approved continuing education providers to ensure attendance. The use of an independent monitor might increase the cost of continuing education for providers and licensees.

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
70	Sets out the requirements for continuing education, including the number of hours, approved sponsors and provision for extensions or exceptions.	Subsection A: • Amends #2 to change the description of two hours of CE for those certified in the use of therapeutic pharmaceutical agents. *Currently, the requirement states hours related to "prescribing and administration of such drugs" but the description of hours related to "treatment of the human eye and its adnexa with pharmaceutical agents" is more inclusive and descriptive of the types of courses that are related to patient care.* • Specifies that courses for which the primary purpose is to promote the sale of specific instruments or products and

		courses offering instruction on augmenting income are excluded and will not receive credit by the board. *Currently, the regulation provides that courses that are "solely" designed to promote the sale of specific instruments or products and courses offering instruction on augmenting income are excluded. The problem is that "solely" is too subjective and allows for acceptance of a course that is 99% sales pitch and 1% relating to patient care. The board intends to make it clearer that the principal purpose of an acceptable course cannot be to sell goods or augment income.* Subsection B: • Adds a requirement that any request for an extension or waiver shall be received prior to the renewal date of December 31 of each year. *The board has had instances in which licensees realize that they are missing CE hours at the time of renewal and request an extension after the renewal date has passed. The regulations require that the hours be completed by the renewal deadline or that an extension has been granted.* Subsections C and E: • Adds reference to the accrediting bodies reinserted in the listing in subsection G. Subsection G. • Reinserts the Council on Optometric Practitioner Education (C.O.P.E.) and the Accreditation Council for Continuing Medical Education (ACCME) of the American Medical Association and deletes subsection H. • Deletes Category 2 continuing medical education from the ACCME. *Since there is no provision for non-verifiable, undocumented continuing education, it is not appropriate to accept Category 2 CME, which may be consultation with another provider, etc .* Subsection I (subsection H in the final submission): • Adds requirements for sponsors in order to maintain approval for continuing education, including: 1. Provision of a certificate of attendance that shows the date, location, presenter or lecturer, content hours of the course and contact information of the provider/sponsor for verification. The certificate of attendance shall be based on verification by the sponsor of the attendee's presence

		throughout the course, either provided by a post-test or by an designated monitor. 2. Maintenance of documentation about the course and attendance for at least three years following its completion. *By observation and experience with audits of continuing education, the board is concerned that some sponsors do not provide a certificate of completion that gives sufficient information about the course nor do they provide verification of attendance. Requirements stated in subsection I will ensure that the certificate of attendance and all necessary information can be verified. In conducting an audit of a licensee continuing education, it is often necessary to contact a sponsor or provider to request additional information about a course or about the licensee's attendance. Therefore, the board has added a requirement for an approved CE provider/sponsor to maintain documentation about the course and attendance for at least three years following its completion.* Subsection J. • Adds as grounds for possible disciplinary action falsifying the attestation of compliance with continuing education on a renewal form or failure to comply with continuing education requirements. *While non-compliance with board regulations may constitute grounds for disciplinary action, the board felt it was necessary to specifically state that false attestation or failure to comply with continuing education requirements could subject the licensee to an action.*

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 review of continuing education requirements in section 70 of the regulations was initiated to consider utilization of OE Tracker, a system recently established the Association of Regulatory Boards of Optometry (ARBO) for the purpose of tracking and maintaining information about CE compliance with requirements for state licensure. The tracking system posts hours of approved

CE and allows optometrists to view the status of their continuing education. A committee of the board was appointed to consider OE Tracker and other issues relating to continuing education.

The committee reviewing the continuing education regulations did not recommend an amendment to require all licensees to participate. As the market evolves for OE Tracker's service, it may become possible to use OE Tracker, as optometrists have voluntarily agreed to record their continuing education credits through the system. Currently, many national continuing education vendors already require a tracker number to record participation, so a large portion of optometric continuing education is already being recorded by OE Tracker. Five states have mandated their licensees to participate. For them, ARBO provides tailored reports to the board office on all licensees or only those that do not have sufficient hours.

In addition to philosophical objections over the state compelling licensees to participate in OE Tracker, the Committee has concerns over its funding. Historically, ARBO has funded its activities through member board fees, national examination fees, and fees to vendors for reviewing continuing education. However, OE Tracker was initially funded by "sponsorships" from commercial companies. This funding relationship may represent some conflict for the regulatory use of OE Tracker. Further, there is a plan for discontinuation of corporate sponsorship, and further costs for an individual or a state board to participate in OE Tracker have not been definitely determined.

Therefore, the board did not elect to include a third-party verification requirement in this proposal of regulations. It will continue conversation with OE Tracker and with other states that have used the system to verify CE.

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.