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Proposed 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
Document preparation date	10/1/07

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the Virginia Register Form, Style, and Procedure Manual.

Brief summary

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

In its proposed regulatory action, the Board intends to clarify and amend certain provisions of section 70, the continuing education requirements as stated in Chapter 20. The Board has addressed issues relating to the validity and value of continuing education for the practitioner. by requiring that four of the 16 hours be obtained in face-to-face courses, that half of the hours be offered by sponsors approved by two educational accrediting bodies, that additional documentation and verification be provided and maintained by approved sponsors and that the hours relating to therapeutic pharmaceutical agents be increased from two to four for optometrists with prescribing privileges.

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 number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, 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 by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal and the problems the proposal is intended to solve.

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 required continuing education in treatment with pharmaceutical agents has been expanded from two to four hours annually. A requirement for half of the continuing education hours to be acquired in face-to-face or interactive courses is also seen an necessary to ensure that optometrists have the experience of gaining in knowledge, skills and professionalism by interacting with other licensees in a learning environment. 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 briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)

In section 70 of 18VAC105-20-10 et seq., the following substantive changes are proposed:

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.

2. To require that four of the 16 hours must be obtained from courses that are face-to-face or real-time interactive.

3. To limit the number of hours that may be obtained by providers that are not approved by the two accrediting bodies – the Council on Optometric Practitioner Education (COPE) and the Accreditation Council for Continuing Medical Education of the American Medical Association to half of the 16 hours.

4. To specify that an approved CE sponsor must provide a certificate of attendance that shows the date, location, lecturer, and content hours of the course; 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 an independent monitor. To add a requirement for an approved CE provider/sponsor to maintain documentation about the course and attendance for at least three years following its completion.

5. To increase the required hours from 2 to 4 hours in the treatment of the human eye and its adnexa with pharmaceutical agents; those hours would continue to be included in the required16 hours of continuing education.

Issues

Please identify the issues associated with the proposed regulatory action, including:

1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;

2) the primary advantages and disadvantages to the agency or the Commonwealth; and

3) other pertinent matters of interest to the regulated community, government officials, and the public.

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

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. The possible disadvantage to the public would be the requirement for an optometrist to obtain CE in a live format which may necessitate his/her absence from practice for half a day and make him/her unavailable for patient appointments.

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.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	a) 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; b) 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 notice of final regulations. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. There are no on-going costs to the agency.
Projected cost of the regulation on localities	There are none.
Description of the individuals, businesses or other entities likely to be affected by the regulation Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales	The individuals that may be affected by the regulation are optometrists. There are 1194 optometrists who are TPA-certified. It is estimated that the majority would be classified as small businesses. There are 250 optometrists who do not have TPA-certification and would not be subject to the increase in CE hours for treating with pharmaceutical agents.
of less than \$6 million. All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.	While the total hours for CE are not being increased, there may be a very modest increase in costs relating to the requirements for 4 hours in face-to-face courses and half of the required hours in COPE or ACCME approved courses.

COPE reports that COPE approval for individual
courses is \$45 for the first hour and \$35 for each
hour thereafter. Therefore, a 2-hour COPE-
approved course with 30 optometrists would cost
an additional \$3 per licensee.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

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 OETracker's service, it may become possible to use OETracker, 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 OETracker. 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 OETracker, 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, OETracker has also been funded by "sponsorships" from commercial companies. This funding relationship may represent some conflict for the regulatory use of OETracker. Further, there is a plan for discontinuation of corporate sponsorship, and further costs for an individual or a state board to participate in OETracker 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 OETracker and with other states that have used the system to verify CE.

Public comment

Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.

The Notice of Intended Regulatory Action was published on June 11, 2007 with comment accepted until July 11, 2007. The following comment was received and considered by the Board prior to the adoption of proposed regulations:

Virginia Optometric Association – The VOA: 1) supports requiring 4 of the 16 hours of CE in face-to-face or interactive courses as having a positive impact on patient care with a more meaningful educational experience in a setting that allows for learning to occur beyond the information presented by a presenter. There is widespread availability of such courses, so it would not be financially burdensome or inconvenient to licensees; 2) opposes a requirement that half of the hours be COPE or AMA-CME accredited as burdensome without any value added; and 3) supports maintaining a listing of approved sponsors in regulation with further specification of the responsibilities of a sponsor for maintenance of records and monitoring attendance.

Northern Virginia Optometric Society – Opposes a requirement to specify a number of CE hours that must be obtained face-to-face as limiting the pool of CE available to the Virginia optometrist. Also opposes increasing the number of hours required annually for renewal.

Dr. Robin Rinearson – Opposes any mandate for face-to-face courses; on-line courses are generally more demanding.

Board response:

The Board considered the opposing points of view within the profession and its professional organizations. Initially, its intent was to require half of the 16 hours to be face-to-face, but scaled the requirement back to four hours out of concern for some objection from licensees. As stated by the VOA, face-to-face courses are widely available throughout the state, so while obtaining hours through interaction in a live course may be somewhat less convenient for some, it should not be burdensome. The Board believes its licensees benefit from interaction with other practitioners and from hearing questions posed to lecturers and the discussions that follow. Two-thirds of the hours may continue to be taken on-line or by whatever means chosen by the licensee.

The Board also considered the comment by the VOA in opposition to a requirement that courses be COPE or AMA-CME approved. While the Board has confidence that VOA-sponsored courses are of professional quality, well-monitored, and primarily related to patient care, it has no mechanism for ensuring that other sponsors offer the same quality. The two professional entities that accredit CE (COPE for optometry and ACCME of the AMA for medicine) do review course content, lecturer qualifications and other aspects of continuing education to ensure quality. Therefore, the Board believes it is necessary for assurance of continuing competency to require at least half of the hours optometrists take to have accreditation from one of those two bodies. The Board did not increase the total number of continuing education hours; it remains 16 per annum. It also did not eliminate the listing of approved sponsors, so the VOA remains an approved sponsor in regulation.

Family impact

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

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

Detail of changes

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

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

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: Adds a requirement that four of the 16 hours shall be obtained from courses that are face-to-face or real-time interactive. Such a limitation is typical of CE requirements in other states. Face-to-face courses or interactive programs have the benefit of an exchange of ideas and experiences with other practitioners that reading a journal article does not offer. Since many optometrists practice in solo or small practices, the Board believes there may be a benefit to interaction at professional meetings and a positive impact on health and safety of patient in their care.
		 Requires that for optometrists who are certified in the use of therapeutic pharmaceutical agents, at least four (rather than the current number of two) hours be directly related to the treatment of the human eye and its adnexa with pharmaceutical agents. Given the expansion of therapeutic pharmaceutical agents in the practice of optometry, the Board has increased the required hours from 2 to 4 hours in the treatment of the human eye and its adnexa with pharmaceutical agents; those hours would

	continue to be included in the required16 hours of continuing
	education but there would be a greater emphasis on that aspect of the optometrist's practice.
	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 listed in subsection H, which are now separate from the sponsors listed in subsection G.
	Subsection G.
	• Deletes the Council on Optometric Practitioner Education (C.O.P.E.) and the Accreditation Council for Continuing Medical Education of the American Medical Association and places those entities in a new subsection H.
	Subsection G is a listing of sponsors that the Board automatically approves to provide CE courses. COPE and ACCCME are not sponsors of continuing education; they are accrediting bodies that accredit the sponsors/providers of CE.

Therefore, they are listed separately to clarify the rules.
Subsection H:
• Adds a requirement that at least eight of the 16 hours of continuing education required for renewal shall be accredited by COPE or ACCME.
Those entities provide an assurance of quality for the content offerings and maintain records of attendance for verification in an audit.
Subsection I:
• 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 independent 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.
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