





California State Board of Optometry

### **Board Meeting**

Monday, October 4, 2010

Southern California College of Optometry 2575 Yorba Linda Blvd., TVCI Room Fullerton, CA 92831

and

The Department of Consumer Affairs 1625 North Market Blvd. Sacramento Room S306, 3<sup>rd</sup> Floor Sacramento, CA 95834







DEPARTMENT OF CONSUMER AFFAIRS

Arnold Schwarzenegger,
Governor
State of California

Bill Leonard, Secretary State and Consumer Services Agency

Brian Stiger, Senior Chief
Deputy Director
Department of Consumer Affairs



Lee Goldstein, OD, MPA President

Alejandro Arredondo, OD Vice President

> Monica Johnson Board Secretary

Kenneth Lawenda, OD Member

Fred Naranjo, MBA Member

Edward J. Rendon, MA Member

> Katrina Semmes Member

Susy Yu, OD, MBA, FAAO Member

**Board Staff** 

Mona Maggio.
Executive Officer

Administration
Andrea Leiva
Elizabeth Bradley
Krista Eklund

<u>Licensing</u> Jeff Robinson Nancy Day Elvia Melendrez

Enforcement
Margie McGavin
Lydia Bracco
Dillon Christensen
Cheree Kimball
Brianna Miller
Jessica Sieferman

#### **California State Board of Optometry**

2420 Del Paso Road, Suite 255, Sacramento, CA 95834 Telephone: (916) 575-7170 Fax: (916) 575-7292

-Website:-www.optometry.ca.gov E-Mail: optometry@dca.ca.gov

#### **MEETING NOTICE**

Monday, October 4, 2010 9:00 a.m. Southern California College of Optometry TVCI Room 2575 Yorba Linda Blvd. Fullerton, CA 92831

And

The Department of Consumer Affairs 1625 North Market Blvd. Sacramento Room S306, 3<sup>rd</sup> Floor Sacramento, CA 95834

- Welcome and Introductions
- II. Discussion and Adoption of Modified Text of Title 16 of the California Code of Regulations, Section 1571, Requirements for Glaucoma Certification
- III. Public Comment for Items Not On the Agenda
- IV. Adjournment

#### NOTICE

Public comments will be taken on agenda items at the time the specific item is raised. The Board may take action on any item listed on the agenda, unless listed as informational only. Agenda items may be taken out of order to accommodate speakers and to maintain a quorum.

The meeting is accessible to the physically disabled. A person who needs a disability-related accommodation or modification in order to participate in the meeting may make a request by contacting Krista Eklund at (916) 575-7170 or sending a written request to that person at the California State Board of Optometry 2420 Del Paso Road, Suite 255, Sacramento, CA 95834. Providing your request at least five (5) business days before the meeting will help ensure availability of the requested accommodation.

The Board of Optometry's mission is to serve the public and optometrists by promoting and enforcing laws and regulations which protect the health and safety of California's consumers, and to ensure high quality care.



## Memo

2420 Del Paso Road, Suite 255 Sacramento, CA 95834 (916) 575-7170, (916) 575-7292 Fax www.optometry.ca.gov

To:

**Board Members** 

Date:

October 4, 2010

From:

Dr. Lee Goldstein, OD, MPA

Telephone:

(916) 575-7170

**Board President** 

Subject: Agenda Item 1 – Welcomes and Introductions

#### Call to Order and Establishment of a Quorum

Lee Goldstein, O.D., M.P.A., Board President

Susy Yu, O.D., M.B.A., F.A.A.O.

Monica Johnson, Secretary

Edward J. Rendon, M.P.A.

Alejandro Arredondo, O.D., Vice-President

Kenneth Lawenda, O.D.

Fred Naranjo, M.B.A.

Katrina Semmes





2420 Del Paso Road, Suite 255 Sacramento, CA 95834 (916) 575-7170, (916) 575-7292 Fax www.optometry.ca.gov

To:

**Board Members** 

Date:

October 4, 2010

From:

Mona Maggio, Executive Officer

Telephone:

(916) 575-7170

Michael Santiago, Legal Counsel Andrea Leiva, Policy Analyst

Subject: Agenda Item 2 – Discussion and Adoption of Modified Text of Title 16, of the

California Code of Regulations (CCR), Section 1571, Requirements for

Glaucoma Certification

#### Action Requested:

Board staff and legal counsel have made the changes needed to the proposed language and addendum to the Final Statement of Reasons in order to comply with the Office of Administrative Law's (OAL) standards. Staff would like to request that the Board review, make any edits necessary and approve the proposed revisions in order to distribute the modified text and addendum to the Final Statement of Reasons. These items will available for a 15-day comment period in order to allow public input.

#### Background:

This proposal establishes the requirements for glaucoma certification for licensees that graduated prior to May 1, 2008. Senate Bill (SB) 1406 (Chapter 352, Statutes of 2008, Correa) became effective on January 1, 2009 and expanded the scope of practice of optometrists to include, among other things, the treatment of glaucoma. Business and Professions Code (BPC) section 3041.10 establishes procedures to be followed by the Board in order to make sure that the public is adequately protected during the transition to full certification for all licensed optometrists interested in treating and managing glaucoma patients.

Below is a timeline of the Board's progress so far:

August 24, 2009 - Board approves the language and initiates a rulemaking.

November 6, 2009 – The Notice is published and the 45-day comment period begins.

December 21, 2009 – 45-day comment period ends.

December 22, 2010 - Regulatory hearing is held, no comments received.

March 16, 2010 – Board makes final approval of the modified language after acknowledging all comments received.

March 24 - April 8, 2010 - 15-day comment period on modified text.

May 11, 2010 - Board makes final approval of the language after acknowledging all comments received and direct staff to complete the rulemaking file.

May 17 - August 23, 2010 - Package is approved by the Department of Consumer Affairs. Consumer Services Agency, and the Department of Finance.

August 25, 2010 - Staff submits the package for final review to the OAL.

September 24, 2010 - The Board votes to withdraw the regulation from the Office of Administrative Law after reviewing the Office's concerns with the regulation.

September 27, 2010 - The Board withdraws the regulation.

#### Issues/Discussion:

Upon completion of OAL's review of this regulatory proposal, OAL found that they cannot approve-the-file-for-the-following-reasons:

### 1. Clarity. OAL must review proposed regulations for Clarity. Government Code Sections 11349.1(a)(3), 11349(c), and 1 CCR Section 16.

Because proposed subsection (a)(4) appeared to conflict with subsections (a)(4)(A) and (B), it was unclear which provision prevailed or whether (a)(4)(A) and (B) act as an exception to or qualification of (a)(4), or whether the details of the yet-to-be-developed 16-hour case management course and grand rounds program were necessary to clarify the provisions.

Subsection (a)(4) requires that a minimum of 25 patients be "treated" for 12 consecutive months. The regulation does not contain a definition of the term "treated." However, B&P Code 3041(b)(2) defines "treat" as using therapeutic pharmaceutical agents (TPAs) as listed in 3041(c) and using the procedures listed in 3041(e). One of the categories of TPAs listed in sub 3041(c)(7) is specific to glaucoma treatment. From OAL's reading of the GDTAC – Optometrist Members report, page 17, it appears that the use of medications is a primary means of treating the disease. If to treat patients means to use TPAs with them, and if this must continue for 12 consecutive months, it is unclear whether the election of Options (A) and (B) results in treatment of 25 patients for that period of time consistent with (a)(4).

If the term "treated" in 1571(a)(4) has a different and more flexible meaning that does not require the practice of any of the interventions referenced in B&P Code 3041(b)(2), then the requirement in 1571(a)(4) may be satisfied by the election of Options (A) and (B). However, without including a different definition of "treated" in these regulations, and without knowing the specifics of the case management course and grand rounds program at this point in time, it is unclear whether the requirement of 1571(a)(4) is met, assuming that (a)(4) requires the kind of active and direct patient treatment described in B&P Code 3041(b)(2).

#### 2. Clarity.

It was unclear whether 1571(a)(4) required that at least 25 patients be treated for a minimum of 12 months <u>each</u>, or whether (a)(4) only required that a pool of 25 patients be treated for some period of time, perhaps on only one occasion, during a period of 12 consecutive months. Section 1571(a)(4)(C) is quite clear that the patients treated under the preceptorship program must be prospectively treated for a minimum of 12 months each. It is unclear whether a similar "12 consecutive months each" requirement was intended by 1571(a)(4).

#### 3. Clarity.

Section 1571(f) uses the phrase "at least one consecutive year." Other places in the regulation use the term "a minimum of 12 consecutive months" [1571(a)(4) and (a)(4)(C)]. If the latter is what is intended by section 1571(f), the subsection becomes unclear by introducing a new term. The phrase "one consecutive" is confusing, because "consecutive" applies to a series of items, i.e., more than one.

#### 4. Minor Text Issues

CCR Hierarchy needs to be edited to match OAL's preference.

#### 5. Absence of Summary and Response to Comment

The comment reference by OAL is a comment by the Academy of Eye Physicians and Surgeons (CAEPS) in their December 21, 2009 letter, on page 4. The Board needs to address the following underlined statement from the comment:

"Since the options may be chosen in any combination, simply choosing Option (A) and Option (B) together would allow the candidate for glaucoma certification to receive not just 25, but a full 30 patient credits. The candidate would thus complete the Case Management Requirements in just 32 hours, the equivalent of less than a single week of work, and without ever having to treat a single real patient.

This comment will be addressed at the October 22, 2010 meeting, along with any other comments received during the upcoming 15-day comment period.

#### 6. Updates to Factual/Basis Necessity of the Initial Statement of Reasons

Additions have been made to this document in order to further justify the necessity of each section of the regulation.

#### Next Steps:

- 1) The Modified Text will be posted for a 15-day comment period upon approval by the Board.
- 2) Comments received will be reviewed and addressed at the Board's October 22, 2010 Board meeting.
- 3) The rulemaking file will be resubmitted to the Department of Consumer Affairs, and then to OAL for final review by November 5, 2010.

#### Attachments:

- 1) CCR 1571 Modified Text
- 2) Addendum to Final Statement of Reasons To be provided at the meeting.

#### BOARD-OF-OPTOMETRY-MODIFED TEXT

Changes to the originally proposed language are shown by double underline for new text and underline with strikeout for deleted text.

Adopt section 1571 of Division 15 of Title 16 of the California Code of Regulations to read as follows:

- § 1571. Requirements for Glaucoma Certification.
- (a) Only optometrists meeting the requirements of this Article may apply for certification for the treatment of glaucoma as described in subdivision (j) of Section 3041, in patients over 18 years of age. The optometrist shall:
- (1) Hold an active license as an optometrist in California in good standing with the State Board of Optometry (Board);
- (2) Be certified to use Therapeutic Pharmaceutical Agents (TPA) pursuant to Section 3041.3;
- (3) Complete a didactic course of no less than 24 hours in the diagnosis, pharmacological and other treatment and management of glaucoma. The following topics may be covered in the course:
  - (A) Anatomy and physiology of glaucoma
  - (B) Classification of glaucoma
  - (C) Pharmacology in glaucoma therapy
  - (D) Diagnosis of glaucoma including risk factors analysis
  - (E) Medical and surgical treatment
  - (F) Participant performance assessment; and
- (4) Complete a Case Management Requirement where a minimum of 25 patients are <u>each</u> prospectively treated for a minimum of 12 consecutive months. For purposes of this section, "treat" means properly evaluating the patient, performing all necessary tests, diagnosing the patient, recognizing the type of glaucoma within a licensee's scope of practice, creating a treatment plan with proposed medications and target pressures, ongoing monitoring and reevaluation of the patient's condition, and making timely referrals to an ophthalmologist when appropriate. The following options may be chosen in any combination to fulfill this requirement:
- (A) Case Management Course: Completion of a 16-hour case management course developed cooperatively by the accredited California schools and colleges of optometry and approved by the Board, with at least 15 cases of moderate to advanced complexity. The course may be conducted live, over the Internet, or by use of telemedicine. One hour of the program will be used for a final competency examination. The program will count Although the Case Management Course does not involve treatment of patients, completion of the 16-hour Case Management Course is equivalent to prospectively treating 15 patients for 12 consecutive months. Therefore, completion of the 16-hour Case Management Course will count as a 15-patient credit towards the Case Management Requirement. The full course must be completed to receive the 15-patient credit. The course must include the following topics/conditions:
  - (1) 1. Presentation of conditions/cases that licensees may treat:
    - (a) a. All primary open-angle glaucoma:
    - (b) b. Exfoliation and pigmentary glaucoma.

- (2) <u>2.</u> <u>Presentation-of-conditions/cases-that-licensees-may-not-treat, but-must-recognize-and-refer to the appropriate physician and/or surgeon such as:</u>
  - (a) a. Pseudoglaucoma with vascular, malignant, or compressive etiologies;
  - (b) b. Secondary glaucoma;
  - (e) c. Traumatic glaucoma;
  - (d) d. Infective or inflammatory glaucoma;
  - (e) e. Appropriate evaluation and analysis for medical or surgical consultation;
  - (f) <u>f</u>. In an emergency, if possible, stabilization of acute attack of angle closure and immediate referral of the patient.
- (B) Grand Rounds Program: Completion of a 16-hour grand rounds program developed cooperatively by the accredited California schools and colleges of optometry and approved by the Board, wherein participants will evaluate and create a management plan for live patients. The program will count Completion of the 16-hour Grand Rounds Program is equivalent to prospectively treating 15 patients for 12 consecutive months. Therefore, the 16-hour grand rounds program will count as a 15-patient credit towards the Case Management Requirement. The full program must be completed to receive the 15-patient credit. Patients must be evaluated in person. The program must include the following:
- (1) 1. Presentation of various patient types such as: glaucoma suspects; narrow angle, primary open angle glaucoma (early, moderate, late); and secondary open angle glaucoma such as pigment dispersion and pseudoexfoliation. Patient data, including but not limited to, visual acuities, intra-ocular pressures, visual fields, imaging, and pachymetry, will be available on-site and presented upon request;
- (2) 2. Examination of patients, evaluation of data and test results, and commitment to a tentative diagnosis, treatment, and management plan;
  - (3) 3. Participation in group discussion of the cases with instructor feedback;
- (4) <u>4</u>. Attendance of follow-up meetings (within the 16-hour program requirement) where the same or different patients will be reviewed via serial data, including but not limited to visual fields and imaging photos.
- (C) Preceptorship Program: Completion of a preceptorship program where each patient must be initially evaluated by the optometrist licensee and co-managed with a preceptor. Each patient must be prospectively treated for a minimum of 12 consecutive months. A preceptor for purposes of this section is defined as:
  - (1) 1. A California licensed, Board certified ophthalmologist in good standing; or (2) 2. A California licensed optometrist in good standing, who has been glaucoma certified for two or more years.

Preceptors shall confirm the diagnosis and treatment plan, and then approve the therapeutic goals and management plan for each patient. Consultation with the preceptor must occur at appropriate clinical intervals or when the therapeutic goals are not achieved. Clinical data will be exchanged at appropriate intervals determined by the preceptor and the licensee.

Telemedicine and electronic exchange of information may be used as agreed upon by the preceptor and the licensee. Each patient that is seen by the optometrist in the program will count as a 1-patient credit towards the Case Management Requirement.

- (b) Licensees that are glaucoma certified pursuant to this Section shall be required to complete 10 hours of glaucoma specific optometric continuing education every license renewal period. These 10 hours shall be part of the required 35 hours on the diagnosis, treatment and management of ocular disease.
- (c) Licensees who completed their education from an accredited school or college of optometry on or after May 1, 2008, are exempt from the didactic course and case management

requirements-of-this-Section, provided-they-submit-proof-of-graduation-from-that-institution-to-the-Board.

- (d) Licensees who graduated from an accredited school or college of optometry prior to May 1, 2000, and who have not completed a didactic course of no less than 24 hours will be required to take the 24-hour course indicated in subsection (a). Licensees who graduated from an accredited school or college of optometry after May 1, 2000, are exempt from the didactic course requirement of this Section.
- (e) Licensees who graduated from an accredited school or college of optometry prior to May 1, 2008, and who have taken a didactic course of no less than 24 hours, but not completed the case management requirement under SB 929 [Stats. 2000, ch. 676, § 3], will be required to complete the 25-patient eCase m-Management r-Requirement indicated in subsection (a).
- (f) Licensees who started the process for certification to treat glaucoma under SB 929 [Stats. 2000, ch. 676, § 3] but will not complete the requirements by December 31, 2009, may apply all patients who have been co-managed prospectively for at least one 12 consecutive year-months towards the 25-patient case m-Management r-Requirement.

NOTE: Authority cited: Section 3025, 3041, 3041.10, 3059 Business and Professions Code. Reference: Section 3041 and 3041.3, Business and Professions Code.

DATED:	·
<del></del>	Mona Maggio, Executive Officer
	Board of Optometry



# Memo

2420 Del Paso Road, Suite 255 Sacramento, CA 95834 (916) 575-7170, (916) 575-7292 Fax www.optometry.ca.gov

To:

**Board Members** 

Date:

October 4, 2010

From:

Dr. Lee Goldstein, OD, MPA Board President

Telephone:

(916) 575-7170

Subject: Agenda Item 3 – Public Comment for Items Not on the Agenda



# Memo

2420 Del Paso Road, Suite 255 Sacramento, CA 95834 (916) 575-7170, (916) 575-7292 Fax www.optometry.ca.gov

To:

**Board Members** 

Date:

October 4, 2010

From:

Dr. Lee Goldstein, OD, MPA

**Board President** 

Telephone:

(916) 575-7170

Subject: Agenda Item 4 – Adjournment