California State Board of Optometry

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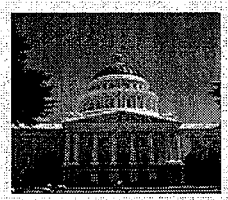

The mission of the California State Board of Optometry is to implement and promote just laws and regulations protecting the health and safety of consumers and to assure that Californians have access to appropriate high quality eye and vision care.

California State Board of Optometry
2420 Del Paso Road, Suite 255, Sacramento, CA 95834

Board Meeting
Tuesday, March 16, 2010
9:00 a.m.
Department of Consumer Affairs
1625 N. Market Boulevard
2nd Floor, El Dorado Room
Sacramento, CA
(916) 575-7170
And

Via telephone at the following locations:

- 9033 Wilshire Blvd., Suite 402, Beverly Hills, CA 90211
- Southern California College of Optometry
  TVCI Conference Room
  2575 Yorba Linda Boulevard
  Fullerton, CA 92831-1699

FULL BOARD OPEN SESSION

1. Call to Order - Establishment of a Quorum
2. Review and Possible Approval of the Responses Considering the Comments Submitted During the 45-Day Comment Period and Testimony Provided at December 22, 2009 Regulatory Hearing Pertaining to the Proposed Rulemaking, California Code of Regulations (CCR), Title 16, Section 1571, Requirements for Glaucoma Certification.
3. Review and Possible Approval of the Modified Text for the Proposed Rulemaking, CCR, Title 16, Section 1571, Requirements for Glaucoma Certification.
4. Public Comment for Items Not on the Agenda
5. Adjournment

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.

NOTICE: 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."

Call to Order – Establish a Quorum **Agenda Item 1**

Board Member Roll Call

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

Alejandro Arredondo, O.D., Board Vice President

Monica Johnson, Board Secretary

Ken Lawenda, O.D.

Fred Naranjo, Public Member

Edward J. Rendon, M.A., Public Member

Katrina Semmes, Public Member

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

California State Board of Optometry

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Memo

To: Board Members **Date:** March 16, 2010

From: Andrea Leiva, Policy Analyst **Telephone:** (916) 575-7182

Subject: **Agenda Item 2 – Review and Possible Approval of the Responses Considering the Comments Submitted During the 45-day Comment Period and Testimony Provided at the December 22, 2009 Regulatory Hearing Pertaining to the Proposed Rulemaking, California Code of Regulations (CCR), Title 16, Section 1571, Requirements for Glaucoma Certification**

Action Requested:

Staff requests that the Board review and fully consider all the comments received at the December 22, 2009 regulatory hearing for CCR section 1571, Requirements for Glaucoma Certification. A proper response will show adequate consideration of a comment and will thoroughly describe why the comment is being accepted or rejected (As required by Government Code section 11346.9, subdivision (a)(5). If a comment is being rejected, the Board must show why the regulation is still necessary despite the rejecter's concerns.

Suggested responses to the comments have been included in the ***Discussion*** portion of this document. Staff requests that the Board review, make any edits necessary and approve the suggested responses in order to move forward with the rulemaking file.

Background:

* *Dates and procedures mandated by SB 1406*

September 26, 2008 - Governor Arnold Schwarzenegger signs Senate Bill 1406 (Chapter 352, Statutes 2008) making significant changes to Business and Professions Code Section 3041 regarding the scope of practice for optometrists

* **November 20, 2008** - The Board appoints the Glaucoma Diagnosis Treatment and Advisory Committee (GDTAC).

January 1, 2009 - Senate Bill 1406 becomes effective.

February 5, 2009 – GDTAC Public Meeting.

February 26, 2006 – GDTAC Public Meeting.

March 5, 2009 – GDTAC Public Meeting.

March 27, 2009 – GDTAC Public Meeting. (CANCELLED)

* **April 1, 2009** – GDTAC submits its recommendations via two separate reports, one from the optometrists and one from the ophthalmologists, to the Office of Professional Examination Services (OPES) for review.

* **July 1, 2009** - The final report from OPES is submitted to the Board. (Add hyperlink to the report.)

* **July 16, 2009** – The Board approves the Report of the OPES pertaining to the recommended curriculum and case management requirements for optometrists licensed in California to diagnose and treat glaucoma.

July 31, 2009 – Representatives from the three California schools and colleges of optometry meet to discuss and develop a curriculum for glaucoma certification and potential regulations based on the recommendations in the report by OPES.

August 24, 2009 - The Board reviews, makes edits and approves the proposed language for California Code of Regulations 1571. Requirements for Glaucoma Certification. The Board also makes a motion directing Board staff to begin the rulemaking file.

September 21, 2009 – Board staff submits the proposed language, Notice for Publication, Initial Statement of Reason and Economic/Fiscal Impact State Form 399 to Department of Consumer Affairs, Division of Legislative & Policy Review and Legal Affairs to begin the internal review process.

September 22, 2009 to October 14, 2009 – Filing of Notices postponed while the Office of Administrative Law (OAL) considers whether or not to allow waiver of signature on Form 399 Economic and Fiscal Impact Statement.

October 14, 2009 - Waiver obtained to allow Notices for Publications to be filed without Agency signatures.

October 22, 2009 – Staff presents the glaucoma regulation proposed language for Board's approval due to a few non-substantial changes made to the language. The Board approves language and directs staff to continue on with the rulemaking package.

October 27, 2009 – Staff submits the rulemaking package for publication.

November 6, 2009 – The Notice and Initial Statement of Reasons is published for notification of the regulatory action in the California Regulatory Notice Register. This prompts the beginning of the 45-day comment period where the public has the opportunity provide their input on the proposed regulation.

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

December 22, 2009 – The Board holds a hearing to receive comments from the public regarding the proposed glaucoma regulations.

December 31, 2009 – (CANCELLED) The Board was to reconvene and respond to the comments received in the hearing but this meeting was cancelled. Board staff found that more time was needed in order to provide thoughtful and thorough responses to the comments received so that the best decision could be made in regards to this issue. The Board meeting to address the comments received is still pending a rescheduled date.

March 16, 2010 – Board reconvenes to consider and respond to comments received during the hearing.

Discussion:

Objections or Recommendations Received During the 45-day Comment Period/Responses:

The following associations and individuals were in support of the regulations as written:

Written Comment 1 - Curtis Knight, O.D., Inglewood, California

Written Comment 2 - John D. Robinson, O.D., Executive Director, North Carolina State Board of Examiners in Optometry

Written Comment 3 - Russell Hosaka, O.D., Torrance, California

Written Comment 4 - Greg McFarland, O.D., Desert Palm Springs

Written Comment 5 - Clifford Silverman, O.D., Lancaster, California

Written Comment 6 - Robert L. Shapiro, O.D., Los Angeles, California

Written Comment 7 - Ellis Miles, O.D., Northridge, California

Written Comment 8 - Greg Evans, O.D., Palm Desert, California

Written Comment 9 - C.K. Chan O.D., Monterey Park, California

Written Comment 10 - Frank G. Balestrery, O.D., M.S., University of California Berkeley School of Optometry

Written Comment 11 - Steven J. Fronk, O.D., Jackson, California

Written Comment 12 - Chris L. Bartelson, O.D., Fillmore, California

Written Comment 13 - Michael E. Jacobs, O.D., Pismo Beach, California

Written Comment 14 - Alan Lubanes, O.D., Georgetown, California

Written Comment 15 - Trajan J. Soares, O.D. F.A.A.O., Los Banos, California

Written Comment 16 - Robert Meisel, O.D. F.A.A.O., Southern California

Written Comment 17 - Wayne Johnson, O.D. F.A.A.O, Los Alamitos, California

Written Comment 19 - Tim Welton, O.D., Anaheim, California

Written Comment 20 - Nicky R. Holdeman, O.D., M.D., Houston, Texas

Written Comment 21 - Kevin L. Alexander, O.D., Ph.D., F.A.A.O., President, Southern California College of Optometry

Written & Verbal Comment 22 - Hilary Hawthrone, O.D., President, California Optometric Association

Written & Verbal Comment 23 - Elizabeth Hoppe, O.D., Founding Dean, Western University of Health Science, College of Optometry

Written & Verbal Comment 24 - David A. Cockrell, O.D., Oklahoma

Written Comment 28 - Eric E. Gaylord, O.D., Optometric Specialties, Inc.

Verbal Comment 37 – Robert DiMartino, O.D., M.S., F.A.A.O., University of California Berkeley School of Optometry

Verbal Comment 39 – David Sendrowski, O.D., F.A.A.O., Southern California College of Optometry

Verbal Comment 41 – Tim Hart, California Optometric Association

The listed associations and individuals believe the regulation should be accepted as proposed for the following reasons:

- The previous glaucoma certification guidelines that were established by Senate Bill 929 were difficult to implement because many optometrists could not find an interested, cooperating ophthalmologist to fulfill the co-management requirement.

- Optometrists who practice in rural and underserved areas were forced to refer glaucoma patients to an ophthalmologist who often was located hours away from their patient's home because there were no ophthalmologists nearby. Patients were forced to travel long distances, which increased their expenses, and often times discouraged them from seeking further care.

- The requirement to co-manage 50 patients with an ophthalmologist usually resulted in the optometrist having to see more than 50 patients due to the fact that a significant number of patients did not complete the two year co-management period. Reasons for this include: death, illness, re-location, change of insurance coverage or panel doctors and failure to return for treatment.

- The proposed regulations will give optometrists the ability to become glaucoma certified in an appropriate and timely basis and will benefit the patient by increasing access to care, treatment and appropriate glaucoma management.

- It is well known throughout the eye care industry that the optometric practice emphasizes patient education along with clinical expertise. These skills help optometrists meet their patient's needs and help patients to understand their vision conditions and diseases such as glaucoma. Patients are then much more apt to comply with treatment requirements and follow-up visits.

- Optometrists in forty-nine of the fifty states can treat glaucoma. California patients need to have the same access to care as those in other states and optometrists should be allowed to treat glaucoma when trained to do so.

- California has two of the finest schools of optometry in the nation.

- Only 177 optometrists were able to become glaucoma certified under the terms of Senate Bill 929 in six years. That indicates that Senate Bill 929 was not effective in meeting the needs of patients in California.

- Optometrists are well trained to diagnose and treat glaucoma, which is a core part of their optometric curriculum and clinical training at the California schools and colleges of

optometry.

- Optometrists are capable practitioners that can distinguish between what they can and can't treat and when to refer appropriately.

- Optometric and ophthalmologic training and licensure is thorough and rigorous. Both educational models achieve the same goal, which is to treat patients appropriately and effectively.

- Professional liability data for states that have bestowed optometrists with authority to diagnose and manage glaucoma has not revealed an increase in disciplinary action or litigation as a result.

- The prevalence of glaucoma in California is estimated to be 430,000 and multiple studies have shown that Latinos, African Americans and people with diabetes have higher risks of developing glaucoma. Many of those cases go untreated, so having optometrists earn glaucoma treatment privileges will greatly improve access to glaucoma treatment.

- Most medical treatment of glaucoma requires the use of eye drops and over the past decade, there have been many improvements in medical treatment. Most glaucoma patients can be managed by their optometrist with an appropriate referral to an ophthalmologist (if or when required), for surgical care to control their glaucoma or when that is the best treatment option for the patient.

- The proposed case management requirement goes far beyond what the majority of other states require but the regulations represent a step in the right direction.

Accept: The Board acknowledges these comments of support.

Written & Verbal Comment 18 - Tony Carnevali, O.D., addresses the issues presented by the California Academy of Eye Physicians and Surgeons, the California Medical Association and the American Glaucoma Society pertaining to his position as a special consultant to the Office of Professional Examination Services. Dr. Carnevali discusses his 34 years of expertise in glaucoma diagnosis, treatment and management, and justifies that he was indeed an appropriate candidate to assist in the development of regulations for glaucoma certification in California by pointing out that:

- The fact that he is an employee of the Southern California School of Optometry is not a conflict of interest because the passage of the proposed regulations would not provide him with further compensation in any form, directly or indirectly.

- The schools and colleges of optometry are typically charged by the legislature to conduct training and certification programs for California optometrists.

- His research was not solely based on California optometric training, but training from several other schools and colleges of optometry in the country.

- His tenure as a past California Optometric Association is also not a conflict of interest because he served in 1991-1992, which was 18 years ago. He also identifies other optometric organizations of which he is a member, but has recused himself when it comes to discussing glaucoma certification due to his position as special consultant.

- He fit the criteria and was hired by the Office of Professional Examination Services.

Accept: Although this comment is not directly related to the proposed language, the Board acknowledges its support of the proposed regulation and the process in which it was developed.

Written Comments 25-26 regarding subsection 1571(b) - Jerry L. Jolley and Richard Van Buskirk state that although they support the proposed regulation, the extensive training in glaucoma, which has been part of an optometrist's basic education for years, is not recognized. They recommend that subsection (b) be modified to permit optometrists that graduated on or after May 1, 1990 be exempt from the didactic course and case management requirements, instead of optometrists that graduated on May 1, 2008 or after.

Reject: Business and Professions Code (BPC) section 3041, the scope of practice of optometry as amended by Senate Bill 1406, states that, "[f]or licensees who graduated from an accredited school of optometry on or after May 1, 2008, submission of proof of graduation from that institution [is required for glaucoma certification]." In order to implement this recommendation, BPC section 3041 would need to be amended. The Board does not have the authority to amend a statute, only the California legislature has this authority.

Written Comment 27 - The California Optometric Association opposed the proposed language submitted in the California Academy of Eye Physicians and Surgeon's (CAEPS) comment.

Reject: The Board finds this comment to be irrelevant for the purposes of this rulemaking file because they are commenting on the comment provided by CAEPS. The proposed language provided by CAEPS will be addressed in the response to Comment 36 below.

The following associations and individuals were in opposition of the regulation as written and believe it should be amended or redeveloped:

Written Comment 29 - Martin L. Fishman, M.D., M.P.A., Los Gatos, California

Written Comment 30 - Anita S. Aaron, Executive Director, LightHouse for the Blind and Visually Impaired

Written Comment 31 - JoAnn Giaconi, M.D., Assistant Clinical Professor of Ophthalmology, David Geffen School of Medicine, UCLA

Written Comment 32 - James D. Brandt, M.D., Professor of Ophthalmology, Glaucoma Service, University of California, Davis.

Written Comment 33 - California Medical Association

Written Comment 35 - Jane Vogel and Kathy Goodspeed, Joint Action Committee of Organizations Of and For the Visually Impaired (JAC)

The listed associations and individuals believe the regulation should be rejected because of the following reasons:

- The diagnosis and treatment of glaucoma cannot be learned from textbooks or lectures and practical hands-on experience is necessary. The current regulation allows an optometrist to treat glaucoma patients without actually managing a single glaucoma patient. A minimal number of patients should be treated in a supervised manner prior to certification.

Reject: The Board rejects this recommendation because the treatment and management of glaucoma can be learned in the schools and colleges of optometry. Additionally, optometry students actually manage patients while in school getting hands-on experience, and almost all other states do not require optometrists to manage patients for glaucoma certification.

The proposed regulations take into account the education of optometrists who graduated on or after May 1, 2008, as well as the experience of optometrists who graduated prior to May 1, 2008 and are already licensed and practicing in California. The proposed Case Management Course in subsection (a)(4)(A) and the Grand Rounds Program in subsection (a)(4)(B) are sufficient as requirements for glaucoma certification in addition to the 24-hour didactic course in subsection (a)(3). The 24-hour didactic course was a requirement established by Senate Bill (SB) 929 and was not modified in SB 1406.

Furthermore, optometrists have had the obligation and were held to the same standard as ophthalmology to detect glaucoma since the 1970's. **(See pages 30-31 of Optometry GDTAC report & AOA bulletin from counsel regarding DPA)** As a result, the California schools and colleges of optometry have incorporated into their curriculum the training necessary to allow optometrists to recognize, diagnose, and refer patients with glaucoma to the appropriate physician or surgeon. Optometry students spend the first two years of their education studying the visual system and its ocular diseases extensively in lectures/seminars, laboratories, and clinics. For the last two years of their education, students spend the majority of their time in the school's clinic as interns examining, diagnosing, treating, and referring patients with ocular disease (this includes glaucoma) under the supervision of experienced, optometric professionals and ophthalmologists. With this evidence, it is inaccurate to assert that an optometrist would have no "hands-on" experience, when their four years of optometry school are spent solely focusing on all aspects of the eye. **(See page 26 and accompanying Tables 1&2 of Optometry GDTAC report).**

Students must also pass all portions of the National Board of Examiners in Optometry (NBEO) Examination, which is required nationwide and represents a national standard of entry-level competence to practice Optometry. The NBEO was established in 1951 as a private, nonprofit 501(c)3 organization that develops, administers, and scores examinations, and reports the results, that state regulatory boards utilize in licensing optometrists to practice eye care. Licensure is a regulatory function designed to protect the public in the competent provision of health care. In serving the profession and public for 56 years, the NBEO has compiled a distinguished record of accomplishments that include being the first national board among the doctoral level health professions to eliminate grading-on-a-curve, and one of the few national boards in any profession with a repertoire of examinations that includes conventional multiple-choice tests, a computer-based test, a clinical skills test with live patients, and an advanced competence examination.

The exam is comprised of Part 1, Applied Basic Science, Part II, Patient Assessment and Management/Treatment and Management of Ocular Disease (TMOD), and Part 3, Clinical Skills – a "hands-on" portion of the exam. All 50 states, the District of Columbia, and Puerto Rico require Parts I and II, and 47 states plus the District of Columbia and Puerto Rico require Part III. Also, 43 states plus the District of Columbia require the TMOD examination as one step toward therapeutic privileges. **(See pages 20-25 of Optometry GDTAC report).**

Forty-seven states in the country allow their optometrists to treat glaucoma without further requirements after completing optometry school and passing the NBEO exams **(See pages 30-31 of Optometry GDTAC report).** Optometrists in all these other states have been treating glaucoma successfully for years and optometrists in California need to be able to practice at a level equivalent to their colleagues in the United States.

In addition, optometrists are required to be certified to use Therapeutic Pharmaceutical Agents (TPA) in order to treat glaucoma. They are strongly encouraged to have this certification before

applying to the Board of Optometry for licensure. Licensees were first authorized to become TPA certified effective in 1997, following the enactment of SB 668 in 1996. As of May 2008 according to the Board of Optometry's public licensure database, 94% of California licensed optometrists had attained this status.

In order to become TPA certified, optometrists receive extensive training in ocular disease with "hands-on" experience as a key component. Those graduating prior to January 1, 1992 had to complete an 80-hour TPA didactic course and exam provided by the schools and colleges of optometry, pass the TMOD component of the NBEO exam, and complete 20 hours of self-directed study in the treatment and management of ocular, systemic disease (including glaucoma). They also had to complete a 65-hour preceptorship in a maximum of one year with a Board Certified California ophthalmologist that may have included patients with glaucoma. Those that graduated January 1, 1992 but before January 1, 1996 had to complete 20 hours of self directed study in the treatment and management of ocular, systemic disease and complete the 65-hour preceptorship. Those that graduated after January 1, 1996 had to obtain their California optometry license, be certified by an accredited school of optometry that they were competent in the diagnosis, treatment and management of ocular, systemic disease and had completed 10 hours of experience with ophthalmologist. Today, all these requirements have been incorporated into the curriculum of the schools and colleges of optometry, the same way that glaucoma certification requirements are now incorporated in the curricula. This is why students graduating on May 1, 2008 or after can be glaucoma certified upon graduation.

Approximately 430,000 Californians are estimated to have glaucoma. It is extremely likely that the 7,000 actively licensed optometrists in California have encountered many of these patients in their practice and during their optometric training. Glaucoma diagnosis, testing, referral, and treatment (when certified) are a routine part of optometric practice in California.

- The understanding of glaucoma management cannot be achieved in a one-year crash course because, most likely, no changes in vision will occur within the one particular year that the optometrist is training.

Reject: The proposed regulation takes this claim into account. For those optometrists that graduated prior to May 1, 2000, in addition to the didactic course, the proposed Case Management and Grand Rounds options allow an optometrist to see a number of patients with different levels and complexity of glaucoma. The optometrists will be trained in a manner that ensures that they have the appropriate diagnostic and treatment skills required to competently practice. The Case Management course will be designed to enhance optometrist's understanding of glaucoma, it's subtleties and nuances, and its treatment. The course will be designed to ensure that optometrists recognize glaucoma at all stages of the disease, and are proficient in identifying the treatment and referral options. Not only will they be educated on the different modalities of glaucoma, but also on the types of glaucoma an optometrist cannot treat and must refer and the treatments available that ophthalmologists can provide once the patient is referred. It is also important to recognize that optometrists who graduated prior to May 1, 2000 have spent a minimum of 10 years in practice, during which time they will have already diagnosed, referred, and co-managed a number of patients with glaucoma.

For those optometrists who graduated after May 1, 2000 but prior to May 1, 2008, and are already licensed and practicing in California, the didactic course would not be required because it was part of their education. They would have to choose up to two of the three options outlined in subsection (a)(4)(A), (a)(4)(B), and (a)(4)(C) in order to meet the 25-patient requirement. In addition, these experienced optometrists will have already been practicing for several years diagnosing and referring glaucoma patients and many will also have been treating glaucoma under the guidelines of SB 929.

For those that graduated on May 1, 2008 and after, since the education from the schools and colleges of optometry always expands to include scope expansions in order to provide the most up to date education to optometry students, the didactic course and all clinical training for glaucoma certification are already incorporated into their curriculum.

Based on this evidence, no matter what category an optometrist seeking to become glaucoma certified is in, their prior training and experience far exceed what is being considered a "one-year crash course." The commenter is not taking into account the education and clinical experiences of optometrists, the national examination they must pass which requires that candidates be knowledgeable in glaucoma in order to pass it, or the years spent in practice for those that are not new graduates.

It is important to note that SB 1406 expanded the scope of practice of optometry to include the non-surgical treatment of open-angle glaucoma, exfoliation and pigmentary glaucoma and, in an emergency, the stabilization of an acute attack of angle closure if possible, which, when stabilized, must be immediately referred to an ophthalmologist. The three types of glaucoma identified above are treated with topical and oral medications or drops and pills, which are TPAs. TPA certified optometrists in California are familiar with these kinds of medications and the effects they could have on a patient. From the beginning of their training, optometrists are taught when to refer to an ophthalmologist if a medication does not achieve the desired results, or causes intolerable side effects. Thus, it is inaccurate to presume that an optometrist would not know when something was going wrong with a glaucoma patient, whether they have been treating the patient for five years or one year.

The Case Management and Grand Round options will, in a directed and planned educational setting, allow optometrist to see many different stages of glaucoma, examine patients, and have a comprehensive learning experience. These training options are contemporary and would be more effective than random cases seen in a co-management program.

The proposed regulation furthers the intent of SB 1406, which is to increase access to care. Optometrists are capable practitioners that are very well prepared to treat glaucoma, a disease they have been diagnosing and co-managing for years. The additional training required in the proposed regulation may only be supplementary, but it will assure the public that optometrists are well trained to diagnose and treat glaucoma.

- The regulations do not impose any additional requirements on students who graduated on or after May 1, 2008 and they should. It is recommended that they at least demonstrate the equivalent experience requirements of Senate Bill 929.

Reject: Business and Professions Code (BPC) section 3041, as amended by SB 1406, does not require that there be any additional training for individuals who graduated on May 1, 2008 or after. SB 1406 mandated the Glaucoma Diagnosis and Treatment Advisory Committee (GDTAC) to do the following:

> In developing its findings, the committee shall presume that licensees who apply for glaucoma certification and who graduated from an accredited school of optometry on or after May 1, 2008 possess sufficient didactic and case management training in the treatment and management of patients diagnosed with glaucoma to be certified. After reviewing training programs for representative graduates, the committee in its discretion may (emphasis added) recommend additional glaucoma training to the Office of Professional Examination Services (OPES) pursuant to subdivision (f) to be completed before a license renewal application from any licensee described in this subdivision is approved.

The language of the statute is permissive, so the GDTAC and OPES did not have to include additional training. OPES had to then examine the GDTAC's reports (two were submitted, one from the optometrists and one from the ophthalmologists) and recommend curriculum requirements to the Board. The Board was then mandated to only adopt the findings of the office and implement certification. Since no additional training was recommended for those graduating on May 1, 2008 or after, the Board did not include additional training in the regulation.

- The proposed regulation does not require additional continuing education for glaucoma certified optometrists.

Accept in part: The OPES report gives the Board the discretion to consider specifying a given number of additional hours of continuing education (CE) to glaucoma certified optometrists to be completed every two year renewal period. This CE would be a part of the 35 hours in ocular disease requirement within the 50 hours of CE, and no more.

Historically, from 2001 to 2006, there was a specific requirement of 12 hours in glaucoma CE. Since then, pursuant to AB 2464 (Chapter 426, Statutes 2004), specified CE hours for subcategories of ocular disease were eliminated. The Board and the legislature agreed that the specified hours of CE for the subcategories of the diagnosis, treatment and management of ocular disease was onerous and overly regulatory of the profession. Licensed optometrists found it difficult to meet the hourly requirements because national providers did not designate their courses by the sub-categories and many courses addressed more than one sub-category. This elimination allowed optometrists to stay up to date with a full range of CE on ocular disease without constricting them to very specific hourly requirements.

Despite the past action by the legislature to eliminate sub-categories, the Board is willing to accept this comment in part and designate that the glaucoma sub-category now require 10 hours specifically. To clarify, of the 35 hours of ocular disease, 10 hours must be in glaucoma education for glaucoma certified optometrists. Language was added to the proposed regulation to reflect this change.

- The Board should investigate and consider the incident at the Palo Alto Veteran's Hospital before developing regulations at all. The Department of Consumer Affairs (DCA) mandated an investigation requested by CMA, CAEPS and the American Glaucoma Society and granted by Brian Stiger, Director of the DCA.

Reject: The Board finds this comment to be irrelevant for the purposes of this rulemaking file. The Director's response did not impose a mandate on the Board. The Board has already taken the necessary steps to deal with this issue, which do not affect the regulation in any way (See Comment 40).

- The Board should not be basing this regulation on a report from an optometrist who is not glaucoma certified, treats glaucoma without a proper license from the State Board, and who is directly in a position to benefit personally and benefit his institution from allowing the broadest possible licensing for optometrists regarding glaucoma. An appropriate and unbiased consultant should be chosen to re-evaluate the report from the Glaucoma Diagnosis and Treatment Advisory Committee (GDTAC).

Reject: Pursuant to BPC section 3041.10, the Board had no authority to choose what recommendations were to be followed. BPC section 3041.10 reads:

"The board shall adopt the findings of the office and shall implement certification requirements pursuant to this section on or before January 1, 2010."

The Office of Professional Examination Services hired the consultant, and this decision was based on their understanding of BPC section 3041.10. Comment 18 by Dr. Tony Carnevali addresses this issue in depth, explaining why these accusations are false.

- The regulations violate Business and Professions Code section 3041.10 because the public is not being adequately protected. The current requirement is minimal compared to the extensive glaucoma training met by ophthalmologists.

Reject: The Board rejects this recommendation because the public is being protected and optometrists and ophthalmologists should not be compared because they are different professions. According to Nicky R. Holdeman, O.D., M.D., (Comment 20), it is true that there are similarities between optometrists and ophthalmologists, but at times, these comparisons become misguided. Both must receive four years of postgraduate training in an accredited school or college and pass a multi-part, uniform, national board examination to become eligible for state licensure. Both optometrists and ophthalmologists are skilled in refracting and correcting vision abnormalities. Both disciplines are capable of diagnosing a wide range of ophthalmic disorders and systemic conditions that might manifest in the eye or be detected by various ancillary tests or imaging modalities. Optometry is a single system specialty that emphasizes *noninvasive* detection and therapeutic management of diseases and conditions of the eye and ocular adnexa. Ophthalmology is a *surgical* sub-specialty that focuses on correction or treatment of ophthalmic disorders that cannot be effectively managed by less invasive means.

The curricular comparisons of four years' postgraduate work at three California colleges of medicine, dentistry, and optometry, which are on public record **(See pages 27-29 of Optometry GDTAC report)** illustrate a point. Optometrists, like dentists, focus on a single bodily system, so their specialized training begins the first year. In contrast, medical students spend their first four years in classroom and clinical training studying the entire human body. They have rotations in selected disciplines, in what will become medical and surgical specialties after graduation via internships and residencies. Like other physicians, ophthalmologists receive their specialty training in residencies and fellowships that focus heavily on disease and surgery, which is entirely appropriate. The fact that optometrists do no receive the same training in regards to a skill set they are not legally authorized to perform, does not seem to be a substantial concern; again, much akin to dentistry.

Optometrists diagnose and treat eye disorders always within their scope of practice and refer to other medical and surgical sub-specialists, such as ophthalmology when more invasive treatment such as surgery or injection, is indicated or when a second opinion is appropriate. Optometrists identify and assess ocular surgical candidates, and co-manage theses patients postoperatively with the assistance and oversight of the surgeon.

The claim that the proposed regulation is violating BPC section 3041.10 because the public is not being adequately protected is incorrect. By definition, optometrists do not engage in the same level of risk as eye surgeons, but they are legally held to the same standard of care as their medical counterparts. As of 2004, California optometrists are held to the same standard as physicians and surgeons pursuant to BPC section 3041.1 that states:

"With respect to the practices set forth in subdivision (b), (d), and (e) of BPC section 3041, optometrists diagnosing or treating eye disease shall be held to the same standard of care to which physicians and surgeons and osteopathic physicians and surgeons are held."

Thus, if an optometrist commits unprofessional conduct by not following the standard of care established above, the Board may take action pursuant to section 3110 (a)(w), Unprofessional conduct. Also, the Board's main mandate is to protect the public. The Board is well aware of that mandate and finds that the proposed regulations are sufficient and provide the appropriate foundation for optometrists to treat and diagnose glaucoma.

- The Board should do an objective appraisal of the current clinical education in glaucoma provided by optometric training.

Reject: The Board finds this comment to be irrelevant for the purposes of this rulemaking file. The Board was mandated to follow the process in BPC section 3041.10, which required it to accept and implement the recommendations from OPES, not evaluate them. Performing an objective appraisal of the current clinical education in glaucoma provided by optometric training was completed by the GDTAC and OPES. Their results are reflected in the reports provided within this rulemaking file.

Furthermore, all the schools and colleges of optometry are accredited by the Accreditation Council on Optometric Education (ACOE). ACOE serves the public by establishing, maintaining, and applying standards to ensure the academic quality and continuous improvement of optometric education that reflect the evolving practice of optometry. ACOE is the only accrediting body for professional optometric degree (O.D.) programs, optometric residency programs, and optometric technician programs in the United States and Canada. Both the U.S. Department of Education and the Council on Higher Education Accreditation recognize the ACOE as a reliable authority concerning the quality of education of the programs the Council accredits. ACOE accreditation means the programs that have attained accredited status:

- Meet the Council's standards of educational effectiveness; and
- Show a demonstrated commitment to quality assessment and improvement.
  (See ACOE Accreditation Process attachment)

- The regulation is not consistent with the legislative intent of SB 1406 and is not sufficient to ensure the type of eye care that patients deserve.

Reject: The proposed regulations are sufficient because the Board is doing everything it is entrusted to do to ensure that patients get the type of eye care they need and deserve. According to the Bill Analysis of SB 1406 by the Assembly Committee on Business and Professions **(See Attached Bill Analysis)**, the legislature's intent was to increase access to quality eye care for underserved and rural populations. Optometrists are usually the first and only health providers that most people will see when it comes to their vision. Given that there are 7,000 actively licensed optometrists in California and there are less than 3,000 ophthalmologists, it is only logical to make use of their numbers and geographic distribution to reach the people that need primary care services the most. Thus, the regulation is consistent with the legislative intent.

Also, according to the recommendation of the OPES report, SB 1406 rejected the previous process required for glaucoma certification under SB 929 (Chapter 676, Statutes of 2000, Polanco) because it was too complex and cumbersome for both optometrists and ophthalmologists. There were too many barriers that prevented a timely completion of certification, such as:

- A lack of ophthalmologists willing to co-manage with optometrists;
- Insufficient number of ophthalmologists in a patient's geographic area;
- Patients being required to pay for multiple visits because their insurance only covers one visit;

- Change in doctor access caused by change in insurance coverage;
- Ophthalmologists changing diagnosis from primary open angle glaucoma (POAG) to a secondary form not permitted to be treated by optometrist;
- Ophthalmologists refusing to sign forms after co-managing patients;
- Patients moving or changing doctors prior to the conclusion of the 2 year requirement;
- Patient health, mobility and compliance issues.

Thus, only 177 optometrists completed the glaucoma certification requirements from 2001 to the end of 2008 under SB 929. The intent of SB 1406 was to develop a process that would lead to a more appropriate and timely route for certification by resolving some of these problems, while at the same time ensuring the competency of the doctor and not compromising public safety.

Written Comment 34 - The Medical Board states that the regulations are missing: a) the statement that "the requirement for uniform curriculum and procedures established cooperatively by California schools and universities of optometry," and b) "the uniform curriculum and procedures be granted approval by the Board of Optometry." These elements were included in the recommendations made by the Office of Professional Examinations Services and the Board should add them or else they would not comply with the "consistency" standard of the Administrative Procedures Act. The two recommendations should be added in sections 1571 (a)(4)(A) and (B), which reference the curriculum and procedures, and case management and grand rounds program. The Medical Board also recommends adding additional continuing education requirements.

Accept: The Board accepts all the suggested changes to sections 1571 (a)(4)(A) and (B) of the regulation in order to conform to the "consistency standard and have added additional continuing education requirements to the language. All changes have been incorporated in the 15-day notice of modified text.

Written Comment 36 and Verbal Comment 38 - The California Academy of Eye Physicians and Surgeons (CAEPS) agrees with comments 29-35 and have provided proposed language of their own. They request that the Board withdraw the regulations and redevelop them in a manner consistent with patient safety and the legislative intent of SB 1406 or consider the proposed amendments in their language.

Title: CAEPS recommends adding "and Treatment" to the title Requirements for Glaucoma Certification.

Reject: The purpose of the regulations is to set forth the requirements for California licensed optometrist to become certified to diagnose and treat glaucoma. Adding "and Treatment" is not necessary as the treatment for glaucoma, including referral requirements, is defined in Business and Professions Code Section 3041, Acts Constituting Practice of Optometry. Also, BPC section 3041.10 states, "[t]he Board shall adopt the findings of the office and shall implement certification requirements pursuant to this section..." Thus, the Board is in compliance with BPC section 3041.10 when it titles this proposes regulation as "Requirements for Glaucoma Certification."

Subsection 1571(4): CAEPS recommends removing the language stating that a minimum of 25 patients be prospectively treated in a consecutive 12-month period.

Reject: The recommendations by OPES state that 25 patients must be treated for 1 year prospectively and the Board is to adopt these recommendations. By removing this key

sentence, 1571(4)(A) and 1571(4)(B) would have no time requirement for when the treatment should be completed.

Subsection 1571(4)(A): CAEPS recommends that the 16-hour Case Management Course be approved by the Board and developed in collaboration with a board certified academic ophthalmologist with fellowship training in glaucoma. The Board may require collaboration of institutions to ensure a uniform experience.

Reject: This recommendation is redundant because the schools and colleges of optometry in California are already using these kinds of resources in order to develop their courses and curriculums, which must all be Board approved. The assumption that the same resources and procedures would not be used in order to develop the 16-hour Case Management Course is erroneous. The schools and colleges of optometry have a long history of developing quality education and training curriculum for their respective programs that prepares optometry students as primary healthcare professionals to practice full-scope optometry. The schools have adjunct ophthalmologists on staff and faculty regularly consults with ophthalmologists/eye specialists to collaborate on the treatment and care of patients. To further elaborate, the school and colleges of optometry are well qualified to develop this course for the following reasons:

➢ The Southern California College of Optometry (SCCO), Fullerton, CA

- Established in 1904.
- The Carling Huntington Childs Family Eye Care Center is the main clinical teaching facility of the College serving more than 25,000 patients annually.
- SCCO owns and operates a major teaching and community eye and vision care facility in Los Angeles – the Optometric Center of Los Angeles.
- SCCO offers 16 different postdoctoral residency programs, with 30 residency positions.
- All programs are fully accredited and structured in accordance with the guidelines of the ACOE Curriculum
- World-renown didactic and clinical optometric program.
- Curriculum prepares students as a primary healthcare professional to practice full-scope optometry.
- Strong basic science component that stresses clinical medicine and therapeutic pharmacology, as well as clinical patient care and practice administration and management.
- Faculty of leading optometric practitioners, educators and researchers.
- SCCO's curriculum prepares students and graduates to take any and all licensing exams in the United States and Canada.
- SCCO students consistently earn high pass rates on all national licensing exams.

➢ The University of California, Berkeley (UCB) School of Optometry, Berkeley, CA

- Established in 1923.
- The U. C. Berkeley School of Optometry is the #1 ranked optometric teaching institution in the United States.
- All programs are fully accredited and structured in accordance with the guidelines of the ACOE Curriculum

- Berkeley Optometry makes a major contribution to the field of health care by training skilled practitioners through a curriculum that is continuously updated to reflect the latest in research and clinical training.

- Berkeley Optometry is dedicated to keeping pace with the expanding field of optometry and the profession's move toward a more extensive health science model of primary care.

- Students have progressively more clinical training and responsibility as they advance through the four-year degree program. Third-year students spend about half their time in clinic, while fourth-year students spend virtually all their time in clinic.

- There are more than 80,000 patient visits each year for which the faculty and students at the Berkeley School of Optometry provide a full range of services from primary eye care to the diagnosis and management of vision problems caused by diseases such as glaucoma, cataracts, and diabetes. All students also participate in external clinical rotations. At the end of the four-year OD Program, each student will have, on average, examined 2,400 patients.
- Berkeley School of Optometry offers three clinics that provide a variety of patient services. The Tang Center is conveniently located in the University Health Services building. Tang offers the full range of primary eye-care services including contact lens fittings and specializes in sports vision. Minor Hall is the University's main clinic and is located adjacent to the School of Optometry. Minor Hall offers several specialty clinics in addition to comprehensive eye exams. The Refractive Surgery Center provides the best refractive laser correction one can obtain.
- Berkeley School of Optometry is now widely recognized as the international leader in eye and vision research. Its enduring reputation for excellence and innovation in the visual sciences is reflected not only in the school's distinguished history of important advances, but also in the range of pioneering research projects pursued by its current faculty.
- Benefiting from such research efforts, the School's graduates often go on to become world leaders in training, research, and professional eye care, and each year the School's clinics provide state-of-the-art care to about 65,000 members of the campus and local communities.

➢ The Western University of Health Sciences, College of Optometry, Pomona, CA

- Established in 2008.
- Western University of Health Sciences has a distinguished history, and has set out to be known as a distinctive institution, as expressed by its Institutional Mission Statement.

- The over-arching themes of the curriculum include:
  1. Early entry into patient care
  2. Integration of basic and clinical sciences
  3. Interprofessional education in collaboration with other health disciplines
  4. Preparation for entry-level optometry care along with a special emphasis on neuro-science and neuro-optometry

- Students enrolled in the College of Optometry take courses presented by the medical school faculty, side by side with students from the medical school, and the colleges of dental and podiatric medicine thereby ensuring an in-depth understanding of basic science foundational material

- Students in the first year of the program are already participating in clerkship rotations, including time spent in ophthalmology practices and in primary care optometric settings where they are observing the treatment of glaucoma. These types of clerkship rotations do not occur until the third year of the medical school curriculum

- The planned curriculum includes dedicated didactic, laboratory and clinical time to provide education and experience in the diagnosis and management of the scope of glaucoma conditions

- The University has recently built a state-of-the-art 80,000 square foot interprofessional patient care center where students in the College of Optometry will deliver eye care services in a collaborative way with other health care professionals.

Furthermore, both SCCO and UCB School of Optometry are fully accredited institutions through ACOE. Western University of Health Sciences, College of Optometry was granted the pre-accreditation classification of "Preliminary Approval" by the ACOE on February 15, 2008 and will be granted full accreditation when the program is fully operational (i.e. nearing the end of its fourth year of implementation.)

SCCO and Western University of Health Sciences hold an additional accreditation by the Accrediting Commission for Senior Colleges and Universities of the Western Association of Schools and Colleges (WASC). When a University that is already accredited by WASC makes what is called a "substantive" change to its program, it is required to obtain prior approval. The "substantive change" process is designed to ensure the consistency of quality across all institutional operations.

- All optometrists are required to participate in ongoing continuing education courses to stay current on the latest standards of care.

- Optometrists must pass a rigorous national examination administered by the National Board of Examiners in Optometry (NBEO). The three-part exam includes basic science, clinical science and patient care.

- Curricula and continuing education are updated on an ongoing basis to reflect technological advances, including surgery techniques, prescriptive medications and other medical treatments related to eye diseases and disorders.

- In addition to being the experts on eye and vision diseases and disorders, doctors of optometry have the education and training to diagnose the ocular manifestations of diseases that affect the entire body, such as diabetes and hypertension. They also are qualified to evaluate their patients for surgery when appropriate and often manage their patients' care pre- and post-operatively.

Subsection 1571(4)(A): CAEPS recommends that the case management course increase the cases from 15 to 50 cases of moderate to advanced complexity.

Reject: The Case Management Course proposed in the regulation includes presentation of selected clinical cases with emphasis on the exchange of information and the application of reasoning skills, specifically for unusual and challenging cases. The cases would be sufficient in number, quality, complexity, and length to provide the participant with a credible and worthwhile experience. Requiring more cases in this course would compromise the quality of the content being taught and force educators to spend less time on each case. The case management course as proposed in the regulation states the course would include at least 15 cases of moderate to advanced complexity. This gives the schools and colleges flexibility in the number and types of cases that could be presented in each course and allows for *quality* instead of quantity. The course would be developed to consist of 15 hours in case presentations of the conditions and types of glaucoma an optometrist can treat as well as the recognition of conditions that licensees cannot treat and must refer. Fifteen cases over a 15 hour course allows for approximately one hour (60 minutes) per case for discussion and review;

whereas 50 cases over a 15 hour period would equate to approximately 15 minutes allotted to each case. One hour of the course is for an examination following the cases in the course.

Furthermore, one of the recommendations in the report by OPES was to have the schools and colleges of optometry develop and recommend to the Board for approval the specific format and content of the case management course. Thus, the representatives from all the California schools and colleges of optometry met on July 31, 2009 in order collaborate on determining what components would need to be included in the case management program. The recommendations adopted by the Board from OPES were of course used as the foundation of the case management program and all program suggestions were discussed and agreed upon by the representatives. The schools and colleges were brought together in order to ensure that a uniform program was being envisioned by all the educators which also met what was recommended by OPES **(See "Guidelines for Glaucoma Certification," the final product of the July 31, 2009 meeting).**

Subsection 1571(4)(C): CAEPS recommends that the name of the Preceptorship Program be changed to Co-management Program.

Reject: A preceptorship can be defined as a period of practical experience and training for a student, especially of medicine or nursing, that is supervised by an expert or specialist in a particular field.

Co-management can be defined as the shared delegated care of a patient's medical condition among providers with either similar or disparate clinical expertise and/or professional credentials. Although practiced widely within many specialties of medicine, co-management is most commonly practiced after surgery.

With these definitions in mind, the Board rejects this comment because optometrists and ophthalmologists co-manage patients during their entire practice, whether it be for glaucoma or other conditions. A preceptorship is a training period, which is what this regulation is establishing for glaucoma certification and is not permanent. The word preceptorship better encompasses this requirement.

Subsection 1571(4)(C): CAEPS recommends editorial changes to the language for clarity purposes regarding the treatment of glaucoma patients for one year each as well as adding language requiring that the course add a monitoring program entails.

Accept in part: The Board accepts the editorial changes for clarity purposes. The Board does not accept adding language requiring that the course add a monitoring program. The monitoring program CAEPS is suggesting would need to be established by an accredited school or college of optometry utilizing qualifying preceptors. This recommendation was not part of the final report by OPES and the Board is mandated by BPC section 3041.10 to adopt their findings as submitted to the Board.

Also, requiring the schools and colleges of optometry to set up a monitoring program would be an expense to them, thus adding to the fee licensees would need to pay in order to obtain this type of monitoring. The preceptorship program option is meant to allow licensees who are not able to go to one of the schools and colleges of optometry the opportunity to become glaucoma certified on their own with a preceptor like in the SB 929 requirements.

In addition, this suggestion for the language is permissive because the word "may" is used. The Board finds this suggestion unnecessary and chooses to exclude it.

Subsection 1571(4)(C): CAEPS also recommends adding in the language that the patient be informed of the training arrangement in the preceptorship program.

Reject: The care being provided, and the ultimate clinical decision-making, is still the responsibility of the supervising preceptor. The inclusion of a training experience does not alter this relationship and informed consent is not required, as there is no change in the standard of care or quality of care being delivered.

Subsection 1571(4)(C): CAEPS also recommends adding a requirement to have licensees submit a Statement of Intent to the Board in order to participate in the program which would then authorize the licensee to prescribe anti-glaucoma medication (without a fee). The Board would then have to develop a suffix to the license number of the participant that will identify him/her as having such authority. This authority is automatically revoked if the participant ceases participation in the process or for any other reason at the discretion of the Board.

Reject: The Board rejects this recommendation because according to BPC section 3041, before a TPA-certified optometrist can diagnose or treat glaucoma with TPAs (which includes prescribing anti-glaucoma medication), the TPA-certified optometrist must first receive certification to treat glaucoma. Thus, in order for the Board to implement this recommendation, the legislature would first have to amend BPC section 3041 to provide those TPA certified optometrists in glaucoma training programs with the ability to prescribe anti-glaucoma medication (without a fee).

Additionally, current Board staff and Board funding could not absorb the time, workload, and expense of establishing and maintaining a new license status. Establishing such a license status category would require a large amount of time from Board staff and other staff from other departments at DCA (i.e. printing out a temporary license, evaluation of Statements of Intent, tracking licensees going through the certification process, verification of licensure from outside health entities and consumers etc.) Also, preliminary discussions with DCA revealed that the Department's current licensing databases are unable to accommodate the addition of a suffix to a participant's license number in the immediate future. The Department's main focus at this time is to research and transfer to a new licensing database due to a Governor backed initiative to improve all of the DCA's Board's and Bureau's enforcement processes. In addition to legislation, the Board would also need to request a Budget Change Proposal to request additional funds for staff, equipment, and space for the additional staff to manage the temporary license program.

Subsection 1571(4)(B): CAEPS recommends modifying the Grand Rounds Program. Their Grand Rounds course would allow up to 20 optometrists to form a group and each individual in the group would follow a minimum of five patients in his or her own practice. The patients would be "pooled" for educational purposes. The groups would meet initially and two other evenly spaced times, spanning the 12 months period, and at each meeting a participant would present two of their patients, followed by discussions led by faculty. One of the faculty members would be an academic glaucoma specialist ophthalmologist. Patients would be followed using the procedures CAEPS' recommended in their co-management program described above.

Reject: The Board rejects this proposal because CAEPS' recommended Grand Rounds program is very similar to their recommended Preceptorship program. In the current proposed regulation, the purpose of having three different options is to maximize the learning experience, not provide repetitive courses. Each proposed training choice has ample education and "hands-on" training to ensure optometrists are more than prepared to treat glaucoma.

To add perspective, grand rounds can be defined as a ritual of medical education, consisting of

presenting the medical problems and treatment of a particular patient to an audience consisting of doctors, residents, and medical students. There is a prevalent acceptance of this program, which is an important and effective teaching tool in the health professions, including optometry. Grand rounds have evolved considerably over the years, and have many advantages including the opportunity for in-depth presentation of clinical data that has been gathered over a series of visits, a collaborative approach to clinical decision-making, and inclusion of advanced imaging techniques. Grand rounds formats encourage more interactive learning of interesting, challenging and complex clinical cases, as well as greater participation by attendees in a structured educational format. Also, grand rounds programs provide an opportunity to showcase some of the nation's most distinguished clinicians and educators.

The Grand Rounds Program in the proposed regulation is based on the traditional model by using live patients for a "hands-on" approach to the clinical experience. This is immensely valuable from a clinical perspective and provides students with an excellent educational experience. The regulation specifies that the types of patients selected for presentation should include those with various types of glaucoma, at various stages of progression and complexity. Participants must actually examine the patient, do the necessary evaluation and testing, commit to a diagnosis, and finally make all decisions necessary for successful management of the patient. This approach will allow participants the opportunity to match their own diagnostic and clinical management skills with those of the experts, faculty and others in attendance. The program will be designed to assess the patient, plot the clinical course of the disease, and reveal the most contemporary thinking and principles that underlie the treatment and management decisions in glaucoma.

CAEPS continues to stress a co-management component in all their recommendations, but there are no advantages to co-management when compared to the proposed glaucoma certification regulations. As stated in the report by OPES:

> Cross sectional observations and studies are common in the fields of research as compared to longitudinal studies simply because it is often impossible to follow the same subject or patient over a longer period of time to monitor changes. Cross-sectional observations allow for a snapshot view at any particular point in time for any single patient thus permitting a composite assessment and comparisons over an entire population of patients. New patients if caught early generally will show very little damage to the optic nerve and visual field loss might be minimal; but established glaucoma patient may be seen at various levels of glaucoma progression. Therefore a shorter period of consultation will accomplish the same goal.

The grand rounds program in the proposed regulation is sufficient training and does not need the additional "co-management" component suggested by CAEPS, which would further complicate the process and delay optometrists from treating glaucoma in a timely manner. As stated by Senator Correa in his March 31, 2009 letter to Sonja Merold, Chief of OPES:

> We wanted to guarantee that SB 1406 would make it possible for more optometrists to be treating vulnerable populations in the state of California. At a time when health care is expensive to the point of being prohibitive, this bill will allow people at risk for visions loss to receive much needed attention.

Subsection 1571(b): CAEPS recommends adding language to impose a 10 patient credit requirement on licensees that graduated after May 1, 2008 to be completed under either their suggested co-management or grand rounds programs. This would allow for retrospective review of existing patients to satisfy the requirement and exempt graduates (functionally graduating May 1, 2011 or after to allow for the development of a documentation system) who

can document 75 one-patient, one-supervisor, one-trainee encounters with patients on (or begun on) active medication treatment for authorized glaucoma (thus establishing a "meet it or not" standard based on actual individualized education experience).

Reject: The intent of the legislature in passing the SB 1406, supported by letters from Senators Correa and Aanestad **(See OPES report pages 74-76)** is very clear - graduates after May 1, 2008 are "presumed" to have met all prerequisites for glaucoma certification and therefore need no additional training. The Board has the authority to monitor and impose additional requirements as it deems appropriate.

After reviewing the didactic and clinical programs at various schools and colleges in California, it is evident the current curriculum provides a comprehensive foundation of knowledge and skills for the entry-level practice of optometry and glaucoma diagnosis, treatment, and management. Based upon reports from the schools and colleges of optometry, students graduate with adequate proficiencies and clinical experiences in patient care, patient numbers, and patient encounters. Moreover, internal mechanisms consisting of course grades, chart reviews, and clinical evaluations by faculty for ensuring proficiency and competency by students are well established and effective.

Also, the curriculum review process at each institution is more than adequate to ensure the continuing evolution of the curriculum to make certain that it is always current and addresses the changing nature of the profession (i.e. entry level definition, standards of care, etc).

The laws in most states, even those that had co-management requirements, are taking into consideration the comprehensive nature of the training that new optometry graduates receive and therefore have been willing to abolish co-management requirements. Seven of the nie states (California included) that require co-management have eliminated that requirement for optometrists graduating after a particular date. In 2009, Maine repealed its co-management requirement for those graduating after 1996, and waivers were given to those that graduated prior to 1996 based on education, training, practical experience, or due to their licensure in another jurisdiction. Nevada and California are the only two states left that require a co-management component for glaucoma certification.

Subsection 1571(e): CAEPS recommends adding language allowing optometrists who began the glaucoma certification process under the SB 929 legislation to continue to follow that process until the 12 month case management requirement is met.

Reject: Making this change to the regulation would require a legislative amendment to BPC section 3041, which states:

"For licensees who have substantially completed the certification requirements pursuant to this section in effect between January 1, 2001, and December 31, 2008, submission of proof of completion of those requirement on or before December 31, 2009. Treatment of 50 glaucoma patients with a collaborating ophthalmologist for a period of two years for each patient that will conclude on or before December 31, 2009."

The process mandated by SB 929 requiring licensees to co-manage 50 patients in two years expired on January 1, 2010. The Board does not have the authority to amend a statute, only the California legislature has this authority.

Subsection 1571(f): This completely new section recommended by CAEPS requires that an optometrist always consult with an ophthalmologist if the glaucoma patient they are treating has one or more of certain listed conditions. **(See Exhibit A of Comment 36)**

Reject: This recommendation is outside of the scope of this regulation as stated in the Initial Statement of Reasons. The treatments for glaucoma, including referral requirements are defined in Business and Professions Code Section 3041, Acts Constituting Practice of Optometry. It would be over-regulation of the practice of optometry to add a list of conditions, which will most likely change as the medical field learns more about glaucoma and how to treat it. After glaucoma certification is in place the Board may consider additional regulations regarding possible referral requirements while treating glaucoma.

Verbal Comment 40 - Robert Tyler, a local attorney, addressed the action taken against optometrists working at the Veterans Affairs Palo Alto Health Care System (VAPAHCS) who allegedly treated a 62-year old male veteran who suffered significant visual loss in one eye as a result of poorly controlled glaucoma. Mr. Tyler clarified that the use of this incident to justify that the glaucoma regulations be re-written is not valid due to various problems with complaint, the lack of documentation, and more importantly, a lack of provable breaches in patient safety.

Accept: Although this comment is outside the scope of the proposed language, the Board acknowledges that it addresses the VAPAHCS issue appropriately.

Attachments:

1. Written Comments 1-36 received with Table of Contents
2. Transcript – December 22, 2009 Regulatory Hearing (includes Verbal Comments 37-41)
3. Glaucoma Diagnosis & Treatment Advisory Committee Optometry Report
4. AOA Bulletin from Counsel regarding DPAs
5. ACOE Accreditation Process
6. Assembly Committee on Business and Professions Codes Senate Bill 1406 Analysis
7. Guidelines for Glaucoma Certification – Final Product of the July 31, 2009 Meeting by the schools and colleges of optometry to assist in the development of CCR 1571
8. Final Report - Office of Professional Examination Services

California State Board of Optometry

Memo

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To: Board Members **Date:** March 16, 2010

From: Andrea Leiva, Policy Analyst **Telephone:** (916) 575-7182

Subject: **Agenda Item 3 – Review and Possible Approval of the Modified Text for the Proposed Rulemaking, CCR, Title 16, Section 1571, Requirements for Glaucoma Certification**

Action Requested:
Staff requests that the Board review, make any edits necessary and approve the proposed revisions to the language in order to distribute the modified text and allow for a 15-day comment period in order to allow the public to address the modified text.

Staff would also like to request that the Board members make a motion to delegate to the Executive Officer the authority to adopt the modified text at the expiration of the 15-day comment period, provided the Board does not receive any adverse comments directed to the modified text.

Proposed Revisions:

1. **Sections (a)(4), (a)(4)(C)**– Editorial changes made by the Board for clarity purposes.
2. **Sections (a)(4)(A) and (a)(4)(B) –** Accepted recommendations from the Medical Board for clarity purposes.
3. **Section (b) –** Accepted recommendations from various comments that additional continuing education (CE) credits be added for glaucoma certified optometrists.
4. **NOTE: Authority Cited section –** added Business and Professions Code section 3059. This is the statute that gives the Board authority to add CE.

Modified 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 prospectively treated for a minimum of 12 consecutive months ~~12-month period~~. 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 ~~an~~ the accredited California schools ~~or~~ 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 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) Presentation of conditions/cases that licensees may treat:
(a) All primary open-angle glaucoma;
(b) Exfoliation and pigmentary glaucoma.
(2) Presentation of conditions/cases that licensees may not treat, but must recognize and refer to the appropriate physician and/or surgeon such as:
(a) Pseudoglaucoma with vascular, malignant, or compressive etiologies;
(b) Secondary glaucoma;
(c) Traumatic glaucoma;
(d) Infective or inflammatory glaucoma;
(e) Appropriate evaluation and analysis for medical or surgical consultation;
(f) 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 ~~an~~ the accredited California schools ~~or~~ 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 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) 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) Examination of patients, evaluation of data and test results, and commitment to a tentative diagnosis, treatment, and management plan~~.~~ ;

(3) Participation in group discussion of the cases with instructor feedback~~.~~ ;

(4) Attendance of follow-up meetings (within the 16-hour program requirement) where the same or different patients will be used via serial data, including but not limited to ~~from~~ visual fields~~, and~~ imaging photos~~, and etc~~.

(C) **Preceptorship Program:** Completion of a preceptorship program where each patient must be initially evaluated by the optometrist and co-managed with a preceptor. Each patient must be prospectively treated for ~~in~~ a minimum of 12 consecutive months ~~12-month period~~. A preceptor for purposes of this section is defined as:

(1) A California licensed, Board certified ophthalmologist in good standing; or

(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~~b~~) 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~~c~~) 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~~d~~) 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 case management requirement indicated in subsection (a).

(f~~e~~) 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 consecutive year towards the 25-patient case management requirement.

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

Tentative Next Steps:

March 23, 2010 – Post Modified Text on Board Web site and mail out to all interested parties and individuals who provided comments at the December 22, 2009 hearing. Beginning of 15-day comment period. Comments can only pertain to the modified text.

April 7, 2010 – End of 15-day comment period.

If no negative comments or comments requiring substantive revisions received:

April 8- 23, 2010 – Preparation of final rulemaking package.

April 26, 2010 – Submit to Department of Consumer Affairs (DCA) for final review. DCA Legal (2 weeks) → Executive-Director (30 days) → State and Consumer Services Agency (4 weeks) → Department of Finance (2 months) → DCA Legislation/Regulation and Policy Review Unit (1 week) → Back to Board Staff and delivered to the Office of Administrative Law for review (45 days) → If approved, regulation becomes effective in 30 days, but staff will request the regulation becomes effective upon filing with the Secretary of State to avoid this wait period.

December 1, 2010 – Regulation becomes effective.

If OAL disapproves, the Board has 120 days to re-submit the rulemaking package.

If negative comments and comments requiring substantive revisions received:

The comments would need to be considered (rejected/accepted) and discussed once more via teleconference or public meeting, and the Board would need to direct Board staff to move forward with the rulemaking packet or make further changes to the language.

The Board has until November 6, 2011 to complete this rulemaking. If the process is not completed within one year from the date on which the notice of the proposed change was published, the Board must start the regulatory process over again if the Board wishes to implement these regulations.

Public Comment for Items Not on the Agenda **Agenda Item 4**

Adjournment **Agenda Item 5**