

STATE BOARD OF OPTOMETRY

2420 Del Paso Road, Suite 255, Sacramento, CA 95834 P [916] 575-7170 F [916] 575-7292 web: www.optometry.ca.gov



MEETING MINUTES

Tuesday, March 16, 2010
Department of Consumer Affairs
1625 N. Market Blvd.
2nd Floor, El Dorado Room
Sacramento, CA 95834
(916) 575-7182
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 Blvd., Fullerton, CA 92831-1699

Sacramento

Members Present

Lee Goldstein, OD, MPA, Board President Fred Naranjo, MBA, Public Member Katrina Semmes, Public Member

Staff Present

Mona Maggio, Executive Officer Andrea Leiva, Policy Analyst Michael Santiago, Staff Counsel

Guest List On File

Fullerton and Beverly Hills

Members Present - Fullerton

Alex Arredondo, OD, Board Vice President Monica Johnson, Board Secretary Ed Rendon, MA, Public Member Susy Yu, OD, MBA, FAAO

Staff Present - Fullerton

Margie McGavin, Enforcement Manager

Member Present – Beverly Hills

Ken Lawenda, OD

Guest List

On File

FULL BOARD OPEN SESSION

- I. Call to Order Establishment of a Quorum
 - Board President, Dr. Lee Goldstein, OD called the meeting to order at 9:06 a.m. Dr. Goldstein called roll and a quorum was established. Dr. Goldstein welcomed everyone in attendance. Board members, staff, and members of the audience in Sacramento, Fullerton, and Beverly Hills were invited to introduce themselves.
- II. 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.

 Dr. Goldstein requested that the Board members review and fully consider all the comments received in writing and verbally at the regulatory hearing. He also requested that the Board members discuss, make edits, if necessary, and approve the proposed responses to the comments drafted by Board staff. The responses must show adequate consideration of the comments, such as thoroughly explaining why a comment is being accepted or rejected.

Andrea Leiva, Policy Analyst began the discussion with a summary of comments 1-17, 19-24, 28, 37 and 39. All these comments state that the regulation should be accepted as proposed. There were no edits to the proposed responses to these comments from the Board members and the comments' support of CCR 1571 was accepted.

Ms. Leiva then summarized comment 18 by Dr. Tony Carnevali, O.D. This comment addressed the issues pertaining to his position as a special consultant to the Office of Professional Examination Services (OPES). Dr. Carnevali discusses:

- His 34 years of expertise in glaucoma diagnosis, treatment and management.
- Justifies that he was indeed an appropriate candidate to assist in the development of regulations for glaucoma certification.
- Details as to why there is no conflict of interest because of his employment at SCCO and his membership in various optometric associations.

The proposed response is to accept this comment because although this comment is not directly related to the proposed language, its support of the proposed regulation and the process in which it was developed should be acknowledged.

Dr. Craig Kliger, Executive Vice President of the Academy of Eye Physicians and Surgeons (CAEPS), and Veronica Ramirez from the California Medical Association (CMA) restated their opposition to CCR 1571.

Terry McHale and Cliff Berg, both on behalf of the California Optometric Association (COA) restated COA's support for the regulations and congratulated the Board for their hard work throughout this process. They also expressed COA's support of Dr. Carnevali and reminded all present that it was agreed to by the COA and CAEPS that a third party could be used for the development of the regulations.

The Board members made no edits to comment 18's proposed response and it was accepted as written.

Ms. Leiva then summarized written comments 25-26 regarding subsection 1571(b) by Jerry L. Jolley and Richard Van Buskirk. They state that although they support the proposed regulation, 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.

The proposed response is to reject this comment for the following reasons:

- 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.

The Board members made no edits to comments 25-26's proposed response and it was accepted as written.

Ms. Leiva then summarized comment 27 from COA who opposed the proposed language submitted in the CAEPS' comment.

The proposed response is to reject this comment for the following reasons:

- 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.

Monica Johnson, Board Secretary, made a grammatical edit to the wording of the summary of the comment. Board staff noted the edit and the proposed response was accepted.

Ms. Leiva then summarized comments 29-33 and comment 35 which are all in opposition of the regulation and believe it should be amended or redeveloped for the following reasons.

1) 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.

The proposed response is to reject this comment for the following nine reasons:

- The Board rejects this recommendation because the treatment and management of glaucoma can be learned in the schools and colleges of optometry.
- 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.
- 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.
- 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
- 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.
- 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.
- In addition, optometrists are required to be certified to use Therapeutic Pharmaceutical Agents (TPA) in order to treat glaucoma.
- 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.

Dr. Kliger again re-stated CAEP's opposition for the regulation as written.

The Board members made no edits to the proposed response to the first concern of comments 29-33 and 35 and it was accepted as written.

2) 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.

The proposed response is to reject this comment for the following reasons:

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 Case Management course will be designed to enhance optometrist's understanding of glaucoma, its subtleties and nuances, and its treatment.
- 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."
- It is important to note that SB 1406 expanded the scope of practice of optometry.
- 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.
- The proposed regulation furthers the intent of SB 1406, which is to increase access to care.

The Board members made no edits to the proposed response to the second concern of comments 29-33 and 35 and it was accepted as written.

3) 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.

The proposed response is to reject this comment for the following reasons:

- 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 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.

Ms. Johnson asked whether the Board was able to reject OPES' findings. Board staff responded that this was not an option.

The Board members made no edits to the proposed response to the third concern of comments 29-33 and 35 and it was accepted as written.

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

The Board's proposed response is to accept in part for the following reasons:

- 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, among other CE specifications but was eliminated because licensed optometrists found it difficult to meet the hourly requirements and the Board and the legislature agreed it was over-regulation of the profession.
- 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.

The Board members made no edits to the proposed response to the fourth concern of comments 29-33 and 35 and it was accepted as written.

5) 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.

The proposed response is to reject this comment for the following reasons:

- 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).

Dr. Kliger requested that the Board specifically provide what steps that were taken regarding the Palo Alto matter. He also pointed out that the Board should not rely on comment 40 as a sufficient response.

Board staff noted these recommendations and made edits to its response to better reflect the Board's position.

Ms. Johnson expressed her concern that she does not understand why Dr. Kilger continues to request that Board staff comment on the Palo Alto issue when the Board is not allowed to comment on pending investigations at Board meetings. Dr. Kliger was informed of this at the last

Board meeting and various other meetings and should be well aware of that. Ms. Johnson feels that Dr. Kilger's question is no longer germane to the issue being discussed today.

Michael Santiago, legal counsel for the Board addressed Dr. Kilger's comment and Ms. Johnson's concerns by clarifying that the comment was considered irrelevant for the purposes of this rulemaking and that the Board has given as much information as it can about the Palo Alto issue. The Board has considered CAEP's concern and already given their position as to why the comment is being rejected. The 45-day comment period has already ended so no further comments or requests need to be considered at this time.

Dr. Goldstein clarified that the intent of referring to comment 40 was not to justify the Board's proposed response or actions regarding this matter. Board staff and legal counsel have done everything they can in regards to the Palo Alto issue and will amend their response to reflect that more clearly.

Mr. Terry McHale stated that the Board's response is appropriate, as they have no jurisdiction over a federal situation. Mr. Cliff Berg echoed this sentiment. Dr. Kliger continued to push that the Palo Alto issue is relevant to the regulation and provided further justifications which can be found in the written comment provided by CAEPS during the 45-day comment period.

The Board members made no further edits to the proposed response to the fifth concern of comments 29-33 and 35 and it was accepted as amended.

6) 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).

The proposed response is to reject this comment for the following reasons:

- 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 Board members made no edits to the proposed response to the sixth concern of comments 29-33 and 35 and it was accepted as written.

7) 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.

The proposed response is to reject this comment for the following reasons:

- The Board rejects this recommendation because the public <u>is</u> being protected and optometrists and ophthalmologists should not be compared because they are different professions.
- 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.
- 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.
- 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
- 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.

Ms. Johnson provided one editorial edit to the proposed response and it was made by Board staff. The Board members made no further edits to the proposed response to the seventh concern of comments 29-33 and 35 and it was accepted as amended.

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

The proposed response is to reject this comment for the following reasons:

- 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, the Accreditation Council on Optometric Education (ACOE) accredits all the schools and colleges of optometry.

Dr. Calman, President of CAEPS, commented that the ophthalmology members of the GDTAC did not receive the data they needed in order to make an objective appraisal of optometric education. Dr. Kliger supported this comment.

Mr. McHale added that when the legislation (SB 1406) was being developed, the schools and colleges of optometry and the COA provided hundreds of pages to the ophthalmologists regarding optometric education. Why are they are asking for more information now?

The Board members made no edits to the proposed response to the eighth concern of comments 29-33 and 35 and it was accepted as written.

9) 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.

The proposed response is to reject this comment for the following reasons:

- 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, the legislature's intent was to increase access to quality eye care for underserved and rural populations.

- Also, according to the recommendation of the OPES report 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.
- Only 177 optometrists completed the glaucoma certification requirements from 2001 to the end of 2008 under SB 929 due to these barriers.

Ms. Johnson requested a clarification regarding the population of optometrist during the time SB 929 was being used for glaucoma certification.

Dr. Goldstein responded that when SB 929 was implemented, only 177 were able to complete the process out of 5500 licensed optometrists. Currently there are about 450 glaucoma certified optometrists out of 7000 licensed optometrists.

Kevin Schunke from the Medical Board of California ("Medical Board") questioned the statement in the proposed response that ophthalmologists changed the diagnosis from primary open angle glaucoma to a secondary form not permitted to be treated by optometrists. He wanted to know if that was the Board's position.

Ms. Leiva responded to Mr. Schunke that the statement came from the OPES report and is not the Board's position.

Mr. McHale stated that during the SB 1406 negotiations, nobody implied that ophthalmologists were not behaving appropriately and intentionally changing diagnoses.

Dr. Goldstein recommended that statement regarding the changing of diagnoses by ophthalmologist be removed from the proposed responses until further information made was available, if any, to prove that statement. The Board does not want to be the cause of any investigations spurred by a comment that may be incorrect. Board staff removed the sentence.

The Board members made no further edits to the proposed response to the ninth concern of comments 29-33 and 35 and it was accepted as amended.

Ms. Leiva then moved on to comment 34 made by the Medical Board. Their comment states that the regulation is 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 recommended adding additional continuing education requirements.

The Board's proposed response is to accept this comment. 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 modified text.

Discussion among the Board members and the public ensued for clarification purposes. The Board members made no edits to the proposed response to the Medical Board's comment and it was accepted as written.

Ms. Leiva then moved on to comment 36 and comment 38 from CAEPS. She stated that CAEPS agrees with comments 29-35 and have provided proposed language of their own within their comments. 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. CAEPS object the regulation for the following twelve reasons:

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

The Board's proposed response is to reject for the following reason:

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."

CAEPS then attempted to add an additional document to the rulemaking file as a comment in order to clarify their initial comment. The Board rejected the document since the 45-day comment period has already ended. Also, CAEPS would only be providing their document to the individuals and Board members present in Sacramento, not to the individuals and Board members in Southern California.

Mr. Santiago clarified that even if they provide their additional information to the Board and members and the public in Sacramento, it would not be included in the rulemaking file.

Despite the Board's rejection of the document CAEPS attempted to explain their document to the participants in Southern California unsuccessfully. It was decided by the Board that if Dr. Kilger had any further objections to the regulation, he could go ahead and make them verbally and not use the supplementary document as a basis, since everything in the document is included in their initial comment submitted during the 45-day comment period.

Dr. Kliger again expressed his opposition by stating that the regulation does not include any hands-on clinical experience and explained the comments CAEPS submitted during the 45-day comment period in detail.

Discussion ensured regarding the regulatory process and Dr. Goldstein and Board staff provided clarity for the public and Board members present.

Ms. Johnson noted that in BPC section 3041.10, it states that the Board should have had the regulations completed and in effect by January 1, 2010. She wondered why the Board is late and just now having a meeting to consider the comments. Is the Board still following 3041.10?

Mr. Santiago responded that even though it is taking longer to enact the regulations than expected, Board staff is following the process mandated by the legislature and 3041.10 until it is completed.

The Board members made no edits to the proposed response to the first concern in CAEPS' comments and it was accepted as written.

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

The Board's proposed response is to reject for the following reason:

• 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.

The Board members made no edits to the proposed response to the second concern in CAEPS' comments and it was accepted as written.

3) 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.

The Board's proposed response is to reject for the following reason:

 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 Board members made no edits to the proposed response to the third concern in CAEPS' comments and it was accepted as written.

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

The Board's proposed response is to reject for the following reasons:

- The number of cases proposed in the regulation 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.
- 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.
- 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.
- Only July 31, 2009 all the California schools and colleges of optometry met 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 Board members made no edits to the proposed response to the fourth concern in CAEPS' comments and it was accepted as written.

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

The Board's proposed response is to reject for the following reasons:

- 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.
- The Board rejects this comment because optometrists and ophthalmologists co-manage patients during their entire practice, whether it be for glaucoma or other conditions.

The Board members made no edits to the proposed response to the fifth concern in CAEPS' comments and it was accepted as written.

6) 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.

The Board's proposed response is to accept in part for the following reasons:

- The Board accepts the editorial changes for clarity purposes.
- The Board does not accept adding language requiring that the course add a monitoring program because it 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 this recommendation would be an expense to the schools and colleges and licensees.
- 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.

After some discussion, the Board felt that the proposed response should be changed to say that anyone could choose the preceptorship option. The option is not meant for any particular licensees as indicated in the response, but is meant for everyone. Board staff made the change in order to clarify that point.

The Board members made no additional edits to the proposed response to the sixth concern in CAEPS' comments and it was accepted with amendments.

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

The Board's proposed response is to reject for the following reasons:

 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.

The Board members made no edits to the proposed response to the seventh concern in CAEPS' comments and it was accepted as written.

8) 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.

The Board's proposed response is to reject for the following reasons:

- 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 <u>first</u> 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).
- Current Board staff and Board funding could not absorb the time, workload, and expense of establishing and maintaining a new license status.

The Board members made no edits to the proposed response to the eighth concern in CAEPS' comments and it was accepted as written.

(9) 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.

The Board's proposed response is to reject for the following reasons:

- 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.
- 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.

Ms. Ramirez of CMA again restated her opposition to the proposed regulation using information from the comments she submitted during the 45-day comment period.

Dr. Calman, President of CAEPS again restated their opposition and continued to note that the Board's proposed regulations would allow an optometrist to become glaucoma certified without ever actually treating a single patient. He supports CAEPS' suggested alternative, which they provided in their comments during the 45-day comment period. He feels that the proposed regulation is 90% of the way there, but needs to have a patient management component in order for CAEPS to support it.

Dr. Lawenda asked CAEPS to share with the Board ophthalmologists' educational requirements, since the Board has shared optometry's educational requirements.

Dr. Goldstein did not feel the question was germane to the matter at hand. This meeting is not for the discussion of whether one profession has more training than the other, whether the profession is optometry, ophthalmology, dentistry, podiatry etc. A discussion such as this could go on for 20 years. The Board was given a process to follow in order to establish glaucoma certification requirements and that is what they are doing here today.

The Board members made no edits to the proposed response to the ninth concern in CAEPS' comments and it was accepted as written.

10) 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).

The Board's proposed response is to reject for the following reasons:

- The intent of the legislature in passing the SB 1406, supported by letters from Senators Correa and Aanestad 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.
- Also 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 nine states (California included) that require co-management have eliminated that requirement for optometrists graduating after a particular date.

 Nevada and California are the only two states left that require a co-management component for glaucoma certification.

Dr. Kliger again restated CAEPS' opposition to the regulation and reiterated statements from their comments submitted during the 45-day comment period. He reasoned that all CAEPS wants optometrists to do is co-manage five patients prior to becoming glaucoma certified.

Terry McHale addressed the Board and indicated that CAEPS never provided an alternative like they are now when the legislation was being negotiated. He also further expressed his support for the Board and the regulation.

The Board members made no edits to the proposed response to the tenth concern in CAEPS' comments and it was accepted as written.

11) 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.

The Board's proposed response is to reject for the following reasons:

- 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 requirements 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.

The Board members made no edits to the proposed response to the eleventh concern in CAEPS' comments and it was accepted as written.

12) 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.

The Board's proposed response is to reject for the following reasons:

- 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.

The Board members made no edits to the proposed response to the twelfth concern in CAEPS' comments and it was accepted as written.

Ms. Leiva then moved on to comment 40 by Robert Tyler, a local attorney, who 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.

The Board's proposed response is to accept the comment. Although this comment is outside the scope of the proposed language, the Board acknowledges that it addresses the VAPAHCS issue appropriately.

Dr. Goldstein recommended that the sentence, "addresses the VAHAHCS issue appropriately," be amended to say that the issued was addressed (remove appropriately). This change matches the changes made earlier regarding using Mr. Tyler's response as the Board's response. The amendments were made by staff. It was also clarified that Mr. Tyler was representing himself and Ms. Johnson recommended that be added to the response. Board staff complied with this request.

The Board members made no further edits to the proposed response to comment 40 and it was accepted with amendments.

Dr. Calman, shared with the Board that he has co-managed patients with optometrists under SB 929, he employs four optometrists in his practice and has worked with optometry students. He emphasized that optometrist and ophthalmologist only differ in how much training is appropriate in order for an optometrist to treat glaucoma. He said that we are not that far apart.

Dr. Calman stated that ophthalmology students have thousands of encounters with glaucoma patients, but he is not suggesting that this should be required of optometrists. He doesn't believe that an optometrist should be able to treat glaucoma without actually seeing a single glaucoma patient during their training. He asked the Board to please make sure they enact regulations that protect the public. Dr. Calman then expressed his distress that the Board did not accept any of CAEPS' suggestions, and that he understands that some of those rejections are due to legal reasons. He hopes that this will not be the end of the dialogue between the Board, CAEPS and others regarding glaucoma certification.

Mr. McHale addressed the Board stating that he did not understand CAEPS' continued disagreement with the regulations and the Board. It's true that optometrists are not that far apart and that's only because the work the Board has put in is so well done. Mr. Berg echoed Mr. McHale's support.

Dr. Marsden, President of the Southern California College of Optometry thanked the Board for all their work and stated that she looked forward to Dr. Calman's invitation to continue the discussion regarding glaucoma certification.

Dr. Kenneth Lawenda moved to approve the proposed responses as amended to the comments received during the 45-day comment period for California Code of Regulations section 1571. Fred Naranjo seconded. The Board voted unanimous (8-0) to pass the motion.

Member	Aye	No	Abstention
Dr. Goldstein	Х		
Dr. Yu	Х		
Dr. Arredondo	Х		
Dr. Lawenda	Х		
Mr. Naranjo	Х		

Ms. Johnson	Х	
Mr. Rendon	Х	
Ms. Semmes	Х	

III. Review and Possible Approval of the Modified Text for the Proposed Rulemaking, CCR, Title 16, Section 1571, Requirements for Glaucoma Certification.

Staff requested 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 to allow the public an opportunity to address the modified text.

Staff also requested 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 comment directed to the modified text.

Dr. Kliger provided an editorial change to the proposed language. Board staff made the change.

Dr. Kenneth Lawenda moved to approve the modified text for California Code of Regulations section 1571. Fred Naranjo seconded. The Board voted unanimous (8-0) to pass the motion.

Member	Aye	No	Abstention
Dr. Goldstein	Х		
Dr. Yu	Х		
Dr. Arredondo	Х		
Dr. Lawenda	Х		
Mr. Naranjo	Х		
Ms. Johnson	Х		
Mr. Rendon	Х		
Ms. Semmes	Х		

IV. Public Comment for Items Not on the Agenda

There were no comments for items not on the agenda.

V. Adjournment

Katrina Semmes moved to adjourn the meeting. Dr. Kenneth Lawenda seconded. The Board voted unanimous (8-0) to pass the motion.

Member	Aye	No	Abstention
Dr. Goldstein	X		
Dr. Yu	Х		
Dr. Arredondo	Х		
Dr. Lawenda	Х		
Mr. Naranjo	Х		
Ms. Johnson	Х		
Mr. Rendon	Х		
Ms. Semmes	Х		

The meeting was adjourned at 11:42 a.m.