

STATE BOARD OF OPTOMETRY

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Meeting Minutes

Tuesday May 11, 2010

Department of Consumer Affairs

1625 N. Market Blvd.

2nd Floor, El Dorado Room

Sacramento, CA 95834

(916) 575-7170

AND

Via telephone at the following locations:

- 9033 Wilshire Blvd., Suite 402 Beverly Hills, CA 90211
- 155 Cadillac Drive, Sacramento, CA 95825
- Southern California College of Optometry
TVCI Conference Room
2575 Yorba Linda Boulevard, Fullerton, CA 92831-1699

Sacramento

Members Present

Lee Goldstein, OD, MPA, Board President

Fred Naranjo, Public Member

Katrina Semmes, Public Member

Members Absent

Susy Yu, OD

Staff Present

Mona Maggio, Executive Officer

Michael Santiago, Staff Counsel

Andrea Leiva, Policy Analyst

Guest List

On File

Fullerton and Beverly Hills

Members Present in Fullerton

Alex Arredondo, OD, Board Vice President

Monica Johnson, Board Secretary

Ed Rendon, Public Member

Members Present in Beverly Hills

Ken Lawenda, OD

Staff Present in Fullerton

Margie McGavin, Enforcement Manager

Guest List

On File

FULL BOARD OPEN SESSION

1. Call to Order – Establishment of a Quorum

Board President, Lee Goldstein, OD called the meeting to order at 10:05 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.

Public Member Edward Rendon arrived at 10:12 a.m.

2. Discussion and Possible Approval of the Responses Pertaining to the Comments Received During the 15-Day Comment Period for the Modified Text, Regarding the

Proposed Rulemaking, California Code of Regulations (CCR), Title 16, Section 1571, Requirements for Glaucoma Certification.

Dr. Goldstein asked staff counsel, Michael Santiago if he had any comments at this time, which he did not. Policy Analyst, Andrea Leiva requested that the Board review and fully consider all of the comments received during the 15-day comment period for the modified text of California Code of Regulations (CCR) section 1571, Requirements for Glaucoma Certification. She also requested that the responses show adequate consideration of each comment and thoroughly explain why a comment is being accepted or rejected.

No changes were made to the modified text.

Ms. Leiva then summarized a comment by the California Medical Association (CME) who opposed changes to the modified text for the following reasons:

- The modifications to the regulation are minimal and fail to take critical patient safety concerns into account.
 - 1) The three-option certification process in Section 1571(a)(4) is complicated and allows optometrists to become certified to independently treat glaucoma without having ever treated a single patient.
 - 2) Patient safety is being sacrificed in order to increase patient access
While the CME appreciates the addition of glaucoma-specific continuing education requirements, the regulation fails to consider and incorporate additional training requirements for future optometry graduates.

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

- The Board has already addressed these concerns, which were presented during the 45-day comment period. Although these concerns are now targeted at the 15-day modified text, they are not new.
- The Board considered CMA's comments regarding the addition of continuing education (CE) for glaucoma certified optometrists and amended the proposed language to require that 10 of the 35 hours of CE in ocular disease be specific to glaucoma. The Board believes the schools and colleges of optometry provide sufficient education and training to ensure that all graduates successfully pass the national exam required of all optometry students in the U.S.A., and that all graduates have the minimum qualifications to treat patients.

Dr. Goldstein opened the floor to questions or comments regarding this response.

Veronica Ramirez with CMA restated its opposition for the regulation as written.

Ms. Leiva then summarized comments made by the California Academy of Eye Physicians and Surgeons (CAEPS), which are in opposition of the modifications to the modified text for the following eight reasons:

- 1) The Board's proposed changes fail to address concerns over patient treatment and care and have in no way addressed the patient safety concerns outlined in their prior comments (during the 45-day comment period) and are therefore totally inadequate.**

The Board's proposed response is to reject this comment because all their concerns were addressed in the Board's responses to the comments they submitted during the 45-day comment period.

Dr. Goldstein opened the floor to questions or comments regarding this response.

Monica Johnson, asked if it is true that the regulations could not go to the Office of Administrative Law (OAL) for final review while the comment period is still open. Staff counsel, Michael Santiago confirmed that this is correct.

Dr. Craig Kliger, representing the Academy of Eye Physicians and Surgeons (CAEPS) restated CAEP's opposition for the regulation as written.

2) The proposed amended regulations fail to meet the legal requirements necessary to forward them to the Office of Administrative Law (OAL) for final review.

The Board's proposed response is to reject this comment because it is vague and does not specifically address or discuss what "legal requirements" the commentors are referring to. It is the jurisdiction and responsibility of OAL to determine whether or not the regulations meet its requirements.

Dr. Goldstein opened the floor to questions or comments regarding this response and there were none.

3) Even on its face, the proposed language fails the "clarity" standards since the minimally amended Section (a)(4) continues to state the same thing. The language is patently deceptive because the proposed regulations then goes on to describe three options, two of which can satisfy the entire requirement but involve no patients undergoing prospective treatment for any defined period.

The Board's proposed response is to reject this comment because the Board already addressed the concern in the Board's responses to the comments they submitted during the 45-day comment period.

Dr. Goldstein opened the floor to questions or comments regarding this response.

Dr. Kliger restated his belief that this language fails the "clarity" standards.

Ms. Johnson asked staff if optometry students manage patients and receive hands on experience while in school. Ms. Leiva confirmed this is correct.

CAEPS also introduced additional information to support their opposition of the regulations and refuted the Board's responses to the comments they submitted during the 45-day comment period as follows:

4) The Board refused to halt the regulatory process upon the urging of Brian Stiger, Director of the Department of Consumer Affairs, to allow for the appointment of a new consultant who was not an advocate of the California Optometric Association (COA), glaucoma and the scope of practice of optometry.

The Board's proposed response is to reject this comment because the Board already addressed this issue in the Board's responses to the comments they submitted during the 45-day comment period.

Dr. Goldstein opened the floor to questions or comments regarding this response.

Ms. Johnson asked for the page number of the April 7, 2010 drafted letter where this point is made. Ms. Leiva responded that there is nothing there that tells the Board to halt the

regulatory process. Mr. Santiago clarified that the comment is using the text of the letter whereby the Director asks the Board to consider postponing the process.

Ms. Johnson requested a summary of the process of hiring a consultant.

Dr. Goldstein responded that the process of hiring a consultant was not a responsibility of the Board of Optometry. The allegation is that he had been involved in setting up the process and arranging for who would be chosen. This is false. Dr. Goldstein reported that he attended one meeting with the Office of Professional Examination Services (OPES) in the fall of 2008. It was an informational meeting only and was attended by the Board's attorney, former attorney, and Executive Officer. His role in the meeting was only to discuss what glaucoma is, and possible places OPES may search for consultants. Dr. Goldstein noted that the consultant chosen was not one that he chose to discuss.

Public Member, Mr. Fred Naranjo expressed his disgust that anyone would accuse Dr. Goldstein of wrongdoing, and noted that Dr. Goldstein's integrity is exemplary.

5) The Board was inappropriately involved in the development of the optometry-friendly job description for the selection of the Special Consultant. The compromise language in SB 1406 expressly limited the role of the Board in establishing the new clinical training requirements for glaucoma certification.

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

The commentor cites no provision of law for any possible inappropriate actions taken by the Board. The Board followed its legislative mandate. Furthermore, the Board already addressed this concern in the Board's responses to the comments they submitted during the 45-day comment period. To clarify further, in light of the additional information provided by CAEPS, the Board's involvement in the development of the consultant's statement of work did not occur in the manner grossly exaggerated by CAEPS. It is true that OPES requested that the Board provide a draft Statement of Work to assist them. OPES themselves state that they do not possess the core competencies of curriculum review and in addition are not experts in the field of optometry. The Board's involvement served only to educate and provide context to OPES about the practice of optometry and the treatment of glaucoma. In the draft Statement of Work provided by the Board, only the minimum requirements of what would be considered an appropriate consultant were included. The Board only provided a starting point for OPES and the rest was up to them as they were mandated by SB 1406.

The Board did not assist in the final development of the Special Consultant Position Duty Statement. The Board did not assist in the selection of the candidates that responded to the Job Description on the State Personnel Board's Vacant Position Database. The Board was not advised of the names/qualifications of the individuals who applied to serve as the consultant to OPES, nor were board representatives present during the interview process, nor were they consulted in the final selection of the consultant.

Dr. Goldstein opened the floor to questions or comments regarding this response.

Dr. Andrew Calman, President of CAEPS, commented that comments have been about process and not to impugn the integrity of anyone on the Board.

6) The Board ignored its statutory obligation to respond to our "glaucoma treatment loophole" comments and other procedural requirement comments in violation of Government Code Section 11346.9.

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

This comment is an untrue and unsubstantiated statement. The loophole they are referring to is that an optometrist could become certified to treat glaucoma without actually treating a single patient. This comment was addressed in a document provided for this meeting which states "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. Furthermore 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. The comments CAEPS submitted during the 45-day comment period regarding the procedural requirements provided by SB 1406 are not comments that should be directed to the Board. As CAEPS themselves stated in their comment as follows:

"The key element of the compromise language in SB 1406 expressly limited the role of the Board establishing the new clinical training requirements. The advisory committee, not the Board of Optometry was to establish the new glaucoma standards, and this resulted from an explicit amendment that took the power to establish those standards away from the Board making the legislative intent clear".

Additionally, the legislation mandate of SB 1406 states that the Board is to "adopt the findings" and implement the certification requirements provided by the Office of Professional Examination Services (OPES). Thus, although CAEPS asserts that the Board has frequently (and often "conveniently") relied on the fact that the language of SB 1406 has tied their hands, essentially forcing the Board to move ahead despite the clear patient safety concerns expressed by CAEPS and other, it is the truth.

The Board strongly believes that optometrists have the training needed in order to become glaucoma certified following the requirements set by the proposed regulation.

Dr. Goldstein opened the floor to questions or comments regarding this response and there was none.

7) There was no investigation made regarding the incident at the Palo Alto Veteran's Affairs Hospital and was considered irrelevant to the rulemaking process.

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

The Board again believes this matter is irrelevant to the proposed regulations and it is an incorrect statement. The Board does not take claims such as these lightly and has already taken all the legal actions that are available without a complaint being filed by a consumer or patient. Business and Professions (B&P) Code section 3010.1 states that protection of the public shall be the highest priority for the Board in exercising its licensing, regulatory, and disciplinary functions. However, when the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. The Board strictly upholds this mandate.

In addition, the Board does not comment on complaints or open investigations. Accusations, Statement of Issues or other legal disciplinary actions are made public once the action has been filed. Only closed cases that result in discipline against a licensee are reported to the

public. There is no question that the Board would aggressively pursue this issue if a complaint were received in the future. The Palo Alto incident occurred on federal property and is beyond the Board's jurisdiction.

Dr. Goldstein opened the floor to questions or comments regarding this response and there was none.

8) The proposed changes CAEPS made to the regulations imposing the requested "consultation requirement" were within the purview of the Board to make even before SB 1406 was enacted. B&P Section 3025 clearly authorizes the Board to promulgate appropriate regulations.

The Board's proposed response is to reject this comment because it is false. The Board would not have been able to set any regulations regarding procedures for glaucoma certification until the scope of practice was expanded. SB 929 set the original guidelines and did not require regulations to clarify or effectuate the statute. SB 1406 expanded the scope of practice and established the process for these guidelines until their completion before overriding SB 1406 with other statutory authorities. Furthermore, the Board is aware of its mandate to protect the public. The Board strongly believes the proposed regulations are sufficient and the optometrists possess the necessary education and training to treat glaucoma safely.

Dr. Goldstein opened the floor to questions or comments regarding this response.

Joe Lang (lobbyist) retained by CAEPS to represent their interests, restated their belief that the process undertaken is flawed. He explained that due to insufficient time at the end of the legislative session, a process was recommended to the legislature intending to drive a consensus between the two professions (optometry and ophthalmology), which he asserts did not occur. Because a consensus was not achieved, two separate reports were submitted to the Office of Professional Examination Services (OPES). He further asserts that since SB 1406 was sunsetted, the Board has the authority to delay the regulatory process.

Ms. Johnson asked Mr. Lang what actions has he undertaken (on behalf of his client CAEPS) to correct the flaws he has identified (set up by SB 1406) in the legislative arena since SB 1406 was sunsetted.

Mr. Lang responded that since January 1, 2010 there have been many private discussions between representatives of the two professions, CME, and legislative staff which have resulted in their receipt of a framework for possible resolution. He added that they have not had time to fully evaluate that document.

Mr. Naranjo inquired if Mr. Lang had reached out to Board members or staff.

Mr. Lang responded he does not often become involved in the regulatory process and expressed his regret at not having been more involved at the advisory level.

Ms. Johnson requested clarification from staff counsel: Has SB 1406 been sunsetted and does the Board have authority to delay the regulatory process?

Mr. Santiago clarified that the entire bill was not sunsetted, rather a statute within the Business and Professions (B&P) Section 3041.10, which outlined the process the Board would follow in formulating regulations for treating glaucoma. He explained that although this statute was sunsetted, the Board is still charged with compliance in implementing the findings of the report that OPES provided for the Board. Ultimately, it will be up to the Office of Administrative Law (OAL) to make the final determination.

Dr. Calman restated Mr. Lang’s concern.

Terry McHale, with Aaron Reed and Associates, representing the California Optometric Association (COA), commented that he was involved in this legislation when the first draft was made almost four years ago. He noted that this process has been extraordinarily long, detailed, and fair. The Board and the COA have done everything possible to meet the concerns of the CAEPS and the CME. Mr. McHale stated that he worked with Mr. Lang in drafting this legislation. He recalls with absolute clarity how they evaluated the students. The result of that evaluation was the legislative agreement, which states:

“Those 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”.

He noted that this kind of agreement could not have occurred if there was any doubt regarding the quality of the education and experience of these students. Furthermore, the students must attend accredited schools and pass a State and a National examination. He concluded by noting that extreme care was taken in drafting SB 1406 in ensure that the bill protects and provides care for the consumer.

Ms. Ramirez restated the CMA’s opposition to the proposed regulation.

Dr. Lawenda moved to approve the responses to the comments received during the 15-day comment period for California Code of Regulations section 1571.

Mr. Naranjo seconded. The Board voted unanimous (7-0) to pass the motion.

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

Dr. Kliger expressed that his letter was intended to address a specific issue and not to malign a specific person.

3. Discussion and Possible Action To Adopt California Code of Regulations (CCR) Section 1520, Infection Control Guidelines

Since no comments were received during the January 19, 2010 hearing of the California Code of Regulations (CCR) section 1520, Board staff requests that the Board members adopt the proposed language and move to continue on with the rulemaking file.

Ms. Leiva provided a background summary of the proposed regulation. The Board initiated a rulemaking for CCR 1520 at the October 22-23, 2009 Board meeting. The proposed language expands and renames CCR section 1520, Hand Washing Facilities, and requires all Board licensees to follow minimum infection control guidelines in their practice in order to reduce the risk of transmission of infectious diseases or agents. This was prompted by the expansion of the scope of practice authorized by SB 1406, which now allows optometrists to perform venipuncture.

Dr. Goldstein opened the floor to questions or comments and there were none.

Ms. Katrina Semmes moved to adopt the proposed language and continue with the rulemaking file. Dr. Alejandro Arredondo seconded. The Board voted unanimous (7-0) to pass the motion.

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

4. Discussion and Possible Action to Initiate a Rulemaking to Add and Amend Sections of Division 15, of Title 16, of the CCR Related to the Board of Optometry’s Enforcement Authority

Executive Officer, Mona Maggio began the discussion with a summary of SB 1111 which created the Consumer Health Protection Enforcement Act. This legislation was sponsored by the Department of Consumer Affairs (DCA) and was intended to address deficiencies in the enforcement processes of healing arts boards within DCA. This bill failed passage in the Senate Business, Professions and Economic Development Committee on April 22, 2010.

In light of the recent information, the DCA completed an initial review of SB 1111 and determined that many of the provisions in the bill could be implemented through regulation. The DCA has requested that each board place an item on their next agenda for the board to consider authorizing initiation of a rulemaking to implement these provisions.

The DCA’s Legal Affairs Division has been working on specific language for particular boards that will be available to serve as a template for each board to use as deemed appropriate. In addition, the legislative office is preparing a stock initial statement of reasons that each board can work from.

Staff is asking the Board to give approval to initiate drafting the language into regulation for the provisions in SB 1111 (that fall under the Board’s jurisdiction) for the Board’s review and consideration. Staff is also requesting approval to initiate drafting language, to be included as appropriate, in the Board’s disciplinary guidelines and regulations which will include provisions from SB 1441 (Chapter 548, Ridley-Thomas) pertaining to healing arts practitioners and substance abuse. The goal is to bring a draft of the language to the July 28, 2010 Board meeting.

Dr. Goldstein opened the floor to questions or comments and there were none.

Monica Johnson moved to direct staff to initiate the rulemaking process. Fred Naranjo seconded. The Board voted unanimous (7-0) to pass the motion.

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

Ms. Semmes	X		
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5. Public Comment for Items Not on the Agenda

Gil De Luna, representative for DCA Director, Brian Stiger thanked the Board for going forward with the regulations for SB 1111 and SB 1441.

Mr. De Luna requested that the Board members remember to file their Form 700, Statement of Economic Interests. He also suggested that the Board consider holding meetings via webcasting.

6. Adjournment

Monica Johnson moved to adjourn the meeting. Fred Naranjo seconded. The Board voted unanimous (7-0) to pass the motion.

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

The meeting was adjourned at 11:35 a.m.