BOARD OF OPTOMETRY

SECOND ADDENDUM TO THE FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Requirements for Glaucoma Certification

Sections Affected: 1571

Updated Information:

The Initial Statement of Reasons is included in this rulemaking file. The information contained in the Factual Basis/Necessity was updated in the First Addendum to the Final Statement of Reasons contained in this tab.

The Board issued a second 15-day notice of Modified Text to amend the proposed language in California Code of Regulations (CCR) section 1571 for clarity purposes. Without the changes made in the modified text, the regulation would not be able to pass the Office of Administrative Law's (OAL) approval process. The proposed regulation was amended in the following manner:

- For clarity purposes – 1571 (a)(4): Clarified that 25 individual patients are to each be prospectively treated to be consistent with section 1571 (a)(4)(C). That was the Board's initial intent.

- For clarity purposes – 1571 (a)(4): Added a more flexible meaning to the word "treat." Since the current definition of treat in optometry's scope of practice is defined in Business and Professions Code (BPC) section 3041 (b)(2) as using therapeutic pharmaceutical agents (TPAs), a more flexible definition was needed to demonstrate what a candidate for glaucoma certification would be doing to become certified.

- For clarity purposes – 1571 (f): Changed the phrase "at least one consecutive year" to "at least 12 consecutive months" since the word consecutive applies to a series of items, i.e., more than one.

- Minor text issues – CCR hierarchy was edited to match OAL's preference.

The Board also responded to a comment submitted during this regulation's 45-day comment period which was left unanswered in the previous submission of the file.

Objections or Recommendations Received During the 45-day Comment Period/Responses (November 6, 2009 – December 21, 2009):

The following is a recommended response to a portion of a comment that was not addressed during this regulation's 45-day comment period.

The California Academy of Eye Physicians and Surgeons (CAEPS) in their comment dated December 21, 2009 opposed the text of the regulation for the following reason:

Comment: Simply choosing Option (A) and Option (B) together would allow the candidate for glaucoma certification to complete the Case Management Requirement in just 32 hours, the equivalent of less than a single week of work.

Response: This comment is rejected because it is an incorrect assumption. It is true that the total of Option (A) Case Management Course and Option (B) Grand Rounds Program equal to a total of 32 hours, but those 32 hours would not be completed in a week's time. Option (A) and Option (B) in the regulation are only a description of the minimum requirements for the development of these two courses and are not the final curriculum. Once this regulation is approved by the Secretary of State, the schools and colleges of optometry in California will present their proposed curriculums to the Board of Optometry (Board) for final approval. It is the Board's position that as educators, who are considered to be some of the best in the nation, the California schools and colleges of optometry should have the opportunity and flexibility to create a curriculum that they know will be rigorous and time well spent for glaucoma certification candidates taking the course. The Board would not approve courses that compromise the patient safety of California consumers. The Board will assure that the schools and colleges of optometry will develop courses that will produce students that are highly trained and skilled providers of medical eye care.

To be more specific, while it is possible that Option (A) Case Management Course may be completed in a weekend, Option (B) Grand Rounds Program would take longer, based on the fact that in the Grand Rounds Program, glaucoma certification candidates must participate in group discussions of cases with instructor feedback, attend follow-up meetings to properly evaluate the same or different patients, and perform all necessary tests to diagnose and create a treatment plan for the live patients all of which would take longer than a week to complete.

Also, CAEPS is not taking into account that the optometrists taking these courses already have prior training and experience that far exceeds the additional training Option (A) Case Management Course and Option (B) Grand Rounds Program will provide. Already licensed, practicing optometrists have the educational and clinical experiences, have already passed the national examination which requires that they be knowledgeable in glaucoma in order to pass it, and have spent years in practice in order to independently and effectively treat glaucoma. Additionally, pursuant to Business and Profession Code (BPC) section 3059, Therapeutic Pharmaceutical Agents (TPA) certified optometrists complete 50 hours of continuing education every two years as part of the license renewal requirement. Thirty-five of the 50 hours must be in ocular disease i.e., glaucoma.

Support, Objections or Recommendations Received During the 15-day Comment Period/Responses (October 5, 2010 – October 19, 2010):

The comments received during the 15-day comment period, which are contained in Tab 14 of the rulemaking file, are summarized below with the responses from the Board.

The California Optometric Association, Southern California College of Optometry, Western University of Health Sciences, College of Optometry, and the University of California Berkeley, School of Optometry support the proposed regulation as modified for the following reasons:

Comment (1): The proposed regulations are appropriate in establishing rigorous standards, while also allowing greater access to care to California patients.

Comment (2): The aging of California's population, and increasing diversity, will put a great strain on all available health care resources. Supplementing the existing numbers of providers who can treat glaucoma will result in better and more efficient delivery of care.

Comment (3): Optometrists in 48 other states across the nation have been safely managing and treating glaucoma patients for decades. Some of these states do not require that their licensees be certified to treat glaucoma. California optometrists should be allowed the same privilege as it will allow California patients the right to choose their eye doctor of choice.

Comment (4): The schools and colleges of optometry across the nation and in California are fully accredited and pass stringent criteria to ensure that all graduates receive the education and training to provide safe and effective care to their patients, including those with glaucoma.

Comment (5): The certification established by this regulation is the most rigorous in the country and optometrists in California who are certified under this process will be the best educated and best trained in the world.

Comment (6): Currently, there are nearly three times more licensed optometrists than ophthalmologists, practicing in over 100 cities and towns in 54 of California's 58 counties. More than 2,600 optometrists accept and treat Medi-Cal Patients, as opposed to about 1,200 ophthalmologists. Thus, because of their dispersion throughout the state, optometrists are more readily available to working families and potential patients.

Comment (7): The regulations have been well thought out and have been vetted publicly in a way that has given all stakeholders ample opportunity to participate.

Response: The Board acknowledges all of these comments of support.

The California Academy of Eye Physicians and Surgeons (CAEPS) oppose the proposed regulation as modified for the following reasons:

Comment (1): The Board's latest modified text continues to threaten patient safety because the proposed regulation's definition of treatment would not require actual medical management of glaucoma patients.

Response: The Board rejects this comment. The definition of "treat" in the proposed regulation does require actual medical management of glaucoma patients.

According to BPC section 3041, before a TPA-certified optometrist can treat glaucoma with TPAs (which includes prescribing anti-glaucoma medication), the TPA-certified optometrist must first receive certification from the Board to treat glaucoma.

BPC section 3041(c) states that a TPA-certified optometrist may use topical and oral anti-glaucoma agents to treat primary open angle glaucoma, and exfoliation and pigmentary glaucoma only if the TPA-certified optometrist is certified by the Board to treat glaucoma. One of the ways to obtain glaucoma certification is to complete a didactic course of no less than 24 hours and complete the case management requirements for glaucoma certification established by the Board through this proposed regulation. Thus, until a TPA-certified optometrist receives glaucoma certification, the TPA-certified optometrist cannot use anti-glaucoma agents to treat glaucoma.

For the purposes of this proposed regulation, treat had to be defined in a manner to comport with the aforementioned restriction in BPC section 3041. The definition of treat encompasses all the necessary steps that an optometrist must take in order to medically manage a glaucoma patient. Despite the fact that candidates for glaucoma certification are not allowed to use anti-glaucoma agents, they are working closely with those who are experienced with prescribing or

applying anti-glaucoma agents and are participating in the proper evaluation of the patient, the performing of all necessary tests, the diagnosis of the patient, recognizing the types of glaucoma within their scope of practice, creating a treatment plan with proposed medications and target pressures, ongoing monitoring and reevaluation of the patient's condition, including if the medication is lowering or controlling the patient's glaucoma, and making timely referrals to an ophthalmologist when appropriate. The candidate is in effect "treating" the patient without violating the requirement set forth in BPC section 3041 that only glaucoma certified optometrists may use anti-glaucoma medications to treat glaucoma. Thus, the definition of "treat" in the proposed regulation is consistent with the definition of "treat" in BPC section 3041 and does not compromise patient safety.

Comment (2): By using the Board's definition of "treat" for the purposes of this regulation, someone without any experience whatsoever using the class of drugs necessary for glaucoma management would be allowed to obtain certification to treat a serious, blinding disease.

Response: The Board rejects this comment because it is an incorrect statement. Although the candidate for glaucoma certification may not treat a patient by prescribing or applying anti-glaucoma medications to the patient, the candidate can and will work with those who are experienced with prescribing or applying anti-glaucoma medications to patients. Because the candidate would be closely monitoring the patient and working with the person who was glaucoma certified, the candidate is engaging in more than just a mere diagnosis of the patient. The candidate is in effect "treating" the patient without violating the requirement set forth in BPC section 3041 that only glaucoma certified optometrists may use anti-glaucoma medications to treat glaucoma.

By going through the proposed certification process in this regulation, glaucoma certification candidates will be able to recognize glaucoma at all stages of the disease, as well as all TPA treatment options available to a glaucoma certified optometrist.

Further, the drugs necessary for glaucoma management, which are TPAs, consist of topical and oral anti-glaucoma medications, such as eye drops and pills. As of May 2008, according to the Board's public licensure database, 94% of California licensed optometrists have attained TPA certification. Thus, it is incorrect to assume that California optometrists who seek glaucoma certification have "no experience whatsoever" with the required class of drugs necessary for glaucoma management. It is important to keep in mind that optometrists who are glaucoma certified do not administer any medication to the patient during the treatment of glaucoma, only in the case of an emergency, if possible, to stabilize an acute attack of angle closure which must then be immediately referred to the appropriate surgeon or physician. The patient must obtain their medication through a prescription written by the glaucoma certified optometrist. Then, the patient would have to administer the drug to themselves using the dosage and intake frequency authorized by the prescribing optometrist or ophthalmologist.

Comment (3): The proposed regulation's definition of "treat" is inconsistent with the statutory definition in BPC section 3041(b)(2) because at a minimum, it does not involve actual use of pharmaceutical agents and it fails the Office of Administrative Law's (OAL) clarity and authority standards.

Response: This comment is rejected. The Board rejects this comment because the definition of "treat" in the proposed regulation is consistent with BPC section 3041.

According to BPC section 3041, before a TPA-certified optometrist can treat glaucoma with TPAs (which includes prescribing anti-glaucoma medication), the TPA-certified optometrist must first receive certification from the Board to treat glaucoma.

BPC section 3041(c) states that a TPA-certified optometrist may use topical and oral anti-glaucoma agents to treat primary open angle glaucoma, and exfoliation and pigmentary glaucoma only if the TPA-certified optometrist is certified by the Board to treat glaucoma. One of the ways to obtain glaucoma certification is to complete a didactic course of no less than 24 hours and complete the case management requirements for glaucoma certification established by the Board through this proposed regulation. Thus, until a TPA-certified optometrist receives glaucoma certification, the TPA-certified optometrist cannot use anti-glaucoma agents to treat glaucoma.

For the purposes of this regulation, "treat" had to be defined in a manner to comport with the aforementioned restriction in BPC section 3041. The definition of treat encompasses all the necessary steps that an optometrist must take in order to medically manage a glaucoma patient. Despite the fact that candidates for glaucoma certification are not allowed to use anti-glaucoma agents, they are working closely with those who are experienced with prescribing or applying anti-glaucoma agents and are participating in the proper evaluation of the patient, the performing of all necessary tests, the diagnosis of the patient, recognizing the type of glaucoma within their scope of practice, creating a treatment plan with proposed medications and target pressures, ongoing monitoring and reevaluation of the patient's condition, and making timely referrals to an ophthalmologist when appropriate. The candidate is in effect "treating" the patient without violating the requirement set forth in BPC section 3041 that only glaucoma certified optometrists may use anti-glaucoma medications to treat glaucoma. Thus, the definition of "treat" in the proposed regulation is consistent with the definition of "treat" in BPC section 3041.

Comment (4): Senate Bill (SB) 1406 did not authorize the Board to create a new definition of "treat" via regulation.

Response: The Board rejects this comment because the Board has statutory authority to define "treat" for the purposes of the proposed regulation (See BPC section 3025). SB 1406 did not have to expressly grant the Board authority to redefine the term "treat" since the definition of "treat" in the proposed regulation is consistent with existing law. Thus, it is inappropriate to apply the same definition of "treat" to candidates who are seeking glaucoma certification as is applied to optometrists who are already certified and can practice at the full range of their scope of practice.

BPC section 3041.10 (promulgated by SB 1406) mandated the process that needed to be followed to create the guidelines for glaucoma certification. That portion of the process has been completed and BPC section 3041.10 was repealed on January 1, 2010, thus it no longer applies to this proposed regulation.

Comment (5): The proposed regulation's definition of "treat" is inconsistent with the definition provided in the Office of Professional Examination Services' (OPES) report, thus it violates OAL's authority standard. The Board draws from OPES' report for the proposed definition of "treat" in the regulation, but is altering OPES' findings by failing to include the report's full definition of treatment (i.e. the portions referring to the actual use of pharmaceuticals).

Given that the Board formally adopted the OPES report in its July, 2009 meeting, the contents of the report in its entirety is official Board policy. Therefore, the Board is not free to pick and choose the portions of a "complete" definition provided in OPES' report and to propose another, contrary definition.

Response: The Board rejects this comment because it is an incorrect statement. OPES' report did not define "treat," it merely described how optometrists who had been co-managing patients under SB 929 (the prior version of BPC section 3041) were treating glaucoma patients. Although BPC section 3041.10 mandated that the Board adopt the findings of OPES and implement them into regulation, that section was repealed on January 1, 2010; thus it no longer applies to this proposed regulation. For the same reason, this report is not official Board policy. At this time, the report is being used as a reference for further development of this regulation.

The Board was not attempting to alter OPES' findings. The report was used as a reference to create a definition that encompassed all procedures necessary for the treatment of glaucoma up to the point of prescribing the medication to the patient, while comporting with current law that only glaucoma certified licensees may use anti-glaucoma agents to treat glaucoma. As indicated in the chart on page 6 of CAEPS' comment, sections of OPES' description of treatment were omitted because they are not applicable to candidates for glaucoma certification.

Comment (6): The proposed regulation's creation of an "equivalency" mechanism whereby an optometrist may satisfy the "treatment" obligation by not treating actual patients is inconsistent with SB 1406 and violates OAL's consistency and authority standards. A classroom oriented experience clearly cannot replace the experience one gains from participating in the treatment of live patients in the Grand Rounds Program.

Response: The Board rejects this comment. The language in the proposed regulation stating that completion of the Case Management Course or the Ground Rounds Program is equivalent to prospectively treating 15 individual patients for 12 consecutive months does not violate the consistency and authority standards of the Government Code. For clarity purposes, it was necessary to add explanatory language in the proposed regulation indicating that the Case Management Course and the Grand Rounds Program are to be counted as if the candidate for glaucoma certification had treated 15 individual patients for 12 consecutive months. Although it is not explicitly stated in the OPES report, the intent was to incorporate two extremely effective teaching methods in the glaucoma certification process that would count as "15-patient credits." By allowing these courses to count as 15-patient credits, it logically follows that these courses are equivalent to prospectively treating 15 individual patients for 12 consecutive months as the proposed regulation states.

Furthermore, the Case Management Course is the only option that does not require that live patients be present, and this is clearly stated in the proposed regulation modifications. The Grand Rounds Program requires that live patients be evaluated for the purposes of the creation of a management plan and for follow-up meetings. Likewise, the Preceptorship Program requires that patients be co-managed with a preceptor, and this will most likely take place at the candidate's practice location. In all of these settings, the proposed regulation's definition of "treat" will be utilized, which means candidates will be fully involved in all aspects of managing an actual patient. Also, candidates for glaucoma certification would be under the supervision of those experienced with using anti-glaucoma agents, which would allow for the proper medication to be prescribed. Patient safety is never compromised as candidates are not allowed to use anti-glaucoma medications until glaucoma certified.

Comment (7): SB 1406 and OPES' report do not give the Board authority to declare that the Case Management Course and Grand Rounds Program are equivalent to prospectively treating 15 individual patients for 12 consecutive months.

Response: This comment is rejected. See response to Comment (6).

Comment (8): The proposed regulation's definitions of "Diagnosis" and "Monitoring" as "Treatment" creates inconsistencies with other portions of the optometric practice act, including the statutory definition of "treatment," and violates OAL's authority standard.

Response: This comment is rejected. The proposed regulation's definition of "treat", which includes diagnosing the patient and monitoring the patient's condition, does not create any inconsistency with the optometric practice act since it does not authorize the licensee to exceed his or her scope of practice. Although it is clear in BPC section 3041(h) that optometrists are not authorized to use therapeutic lasers and since the proposed regulation does not attempt to override or conflict with BPC section 3041(h), a candidate for glaucoma certification would not be able to utilize therapeutic lasers to "monitor" a glaucoma patient while completing the glaucoma certification requirements. Furthermore, BPC section 3041(h) authorizes optometrists to use diagnostic lasers whether or not they are glaucoma certified. Although treatment options are constantly changing as new technologies are introduced into the practice of optometry, this does not necessarily mean that the standard of care has changed to require the implementation of such new technology in the treatment of glaucoma patients. The standard of care remains focused on patient care and not on the technologies used to provide such care.

Comment (9): It is not clear in the proposed regulation's Case Management Requirement as to how many contacts with each patient will occur during the 12 month period of treatment.

Response: This comment is rejected because it would be impossible to determine how many contacts are necessary with each patient. Each patient's condition determines the appropriate glaucoma case management needed and the frequency of such contact that the candidate for glaucoma certification needs to have with the patient for effective treatment of glaucoma. The purpose of the Case Management Requirement is to be an effective means of evaluating patients from diagnosis to treatment and follow-up with a variety of conditions and circumstances. Glaucoma certification candidates would have the opportunity to evaluate a variety of cases and see the outcomes of each case.

Comment (10): Newly proposed regulation 1571 fails OAL's clarity standard because the regulation uses terms which do not have meanings generally familiar to those directly affected by the regulation, and those terms are defined neither in the regulation nor in the governing statute. The view of "general familiarity" is supported by the Glaucoma Diagnosis and Treatment Advisory Committee (GDTAC) optometry report.

Response: The Board rejects this comment. The Board believes the term it has used is specific enough that those who are affected by it will clearly understand what it encompasses. In the proposed regulation the terms diagnosis and referral have meanings generally familiar to those "directly affected" by the regulation - candidates for glaucoma certification. Such candidates have become familiar with these terms through their optometric education as well as through experience in the practice of optometry.

Comment (11): The proposed regulation's "Case Management Requirement" is internally inconsistent and therefore fails the clarity standard because the terms "individual" and "patient's condition" conflict with permitting "different" patients for follow-up in the Grand Rounds Program. For example, how can an applicant for certification monitor and reevaluate a patient's condition over a 12 month period if the same or different patients may be reviewed?

Response: The Board rejects this comment because there is no inconsistency or lack of clarity. Whether the same patient or different patients are seen or treated in the Grand Rounds Program, the regulation states that completion of the course will result in the candidate for glaucoma certification receiving 15-patient credits. Furthermore, cross-sectional observations

and studies are common in all fields of research as compared to longitudinal studies simply because it is often impossible to follow the same subject or patient over a long period of time to monitor for 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 patients may be seen at various levels of glaucoma progression.

Comment (12): The statement "prospectively treated for a minimum of 12 consecutive months" in section (a) (4) conflicts with the explicit acknowledgement that the Case Management Course "does not involve treatment of patients."

Response: The Board rejects this comment because there is no conflict. The types of patients actually seen during a case management course would span the spectrum of moderate to advanced cases of glaucoma. Whether only the minimum number of cases (15) or more are presented and discussed in the Case Management Course, the regulation states that completion of the course will result in the candidate for glaucoma certification receiving 15-patient credits.

The case management course requires that at least 15 cases of moderate to advanced complexity be presented. The definition of treat encompasses all the necessary steps that an optometrist must take in order to medically manage a glaucoma patient. Despite the fact that candidates for glaucoma certification are not allowed to use anti-glaucoma agents, they are working closely with individuals who are experienced with prescribing or applying anti-glaucoma agents and are participating in the proper evaluation of the patient, the performing of all necessary tests, the diagnosis of the patient, recognizing the types of glaucoma within their scope of practice, creating a treatment plan with proposed medications and target pressures, ongoing monitoring and reevaluation of the patient's condition, and making timely referrals to an ophthalmologist when appropriate. Also see response to CAEPS' comments (15) and (16).

Comment (13): The fundamental basis for the proposed regulation violates OAL's "authority" standard since, contrary to statute, it rests upon two sets of curricula issued by two groups of persons instead of a single curriculum issued by a single committee.

Response: The Board rejects this comment because it does not address the modified text. The OPES report accurately summarized the optometry and ophthalmology reports provided by the GDTAC members. Also, the Board took all of the OPES report's recommendations, as it was the final report and the report that needed to be followed as mandated by SB 1406, not the individual ophthalmology or the optometry GDTAC reports.

Comment (14): The Addendum to the Final Statement of Reasons contains factually-inaccurate language that suggests "support" of the Grand Rounds Program by the ophthalmologist members of the GDTAC.

Response: The Board rejects this comment. The language that is being referred to that suggests support for the proposed regulation's Grand Rounds Program from the ophthalmological members of GDTAC was language contained in the OPES report (pg. 37), not just from the optometry member's report. The OPES report was adopted by the Board in July, 2009 and made available to the public for review. The Board has relied on and referred to the report's findings during this entire regulatory process and has not received any other concerns from any person, group or organization regarding the veracity of the material contained in the report. Thus, the Board does not consider it necessary to remove it from the Addendum to the Final Statement of Reasons.

Comment (15): How can a candidate for glaucoma certification make a timely referral to an ophthalmologist when appropriate if the candidate does not see the same patients over the 12 month period in the Grand Rounds Program?

Response: The Board rejects this comment. In the treatment of any patient, an optometrist is obligated to refer the patient to an ophthalmologist or physician as required. The glaucoma education provided by the proposed regulation will result in a robust and thorough, examination, decision making, evaluation, treatment and possible referral requirement that will provide a complete longitudinal learning experience that will meet or exceed the care and treatment of any single patient.

A timely referral can be made to an ophthalmologist or physician as required even though the same patients are not seen over a 12 month period since the candidate will need to make the decision when to refer the patient, regardless of the time frame a patient may be seen by the candidate.

Comment (16): How has a candidate for glaucoma certification developed the decision-making capacity to meet the definition of treat proposed by the Board if the patient is not required to be the subject of evaluation at subsequent meetings?

Response: This commented is rejected. The Board has no authority to require a patient to return for any subsequent evaluation by the candidate for glaucoma certification. See also response to CAEPS' comment (15).

Comment (17): The existence of two reports makes the findings and recommendations upon which the proposed regulations were based null and void.

Response: This comment is rejected because it does not address the modified text. Also, neither report is binding on the Board since BPC section 3041.10 was repealed January 1, 2010.

Comment (18): The Board is attempting to promulgate a regulatory structure based upon two sets of recommendations issued by two groups.

Response: This comment is rejected because it does not address the modified text.

California Medical Association (CMA) opposes the proposed regulation as modified for the following reasons:

Comment (1): The Board's modifications to the proposed regulation fail to meet the statutory requirements of BPC section 3041.10(a) because the modifications threaten patient safety.

Response: The Board rejects this comment. Refer to response to CAEPS' comments (1) and (4) above.

Comment (2): The Board's modifications to the proposed regulation violate the consistency and authority standards in the California Administrative Procedure Act by defining treat in a way that conflicts with the definition of treat in the BPC section 3041.

Response: The Board rejects this comment. The definition of "treat" in the proposed regulation is not in conflict nor inconsistent with the definition of "treat" in BPC section 3041 because only a

TPA-certified optometrist who is also glaucoma certified by the Board may use topical or oral anti-glaucoma agents to treat glaucoma. Different definitions of "treat" are appropriate and necessary in order to distinguish between applicants who cannot yet actually use anti-glaucoma medications, and optometrists who are glaucoma certified. Also see response to CAEPS' comment (4).

Comment (3): The proposed regulation would allow an optometrist to become glaucoma certified without ever physically treating a glaucoma patient.

Response: The Board rejects this comment because it is not commenting on the modified text. Also, the Board has already addressed these concerns, which were presented during the 45-day comment period (November 6, 2009 – December 21, 2009) and the first 15-day modified text (October 5, 2010 – October 19, 2010). Although these concerns are now targeted at the second 15-day comment period, they are not new. Please refer to the original final statement of reasons included in the rulemaking file. Also see responses to CAEPS' comments (1)-(3).

Comment (4): A classroom oriented experience clearly cannot replace the experience one gains from participating in the treatment of live patients.

Response: The Board rejects this comment. The glaucoma certification process is designed for experienced practitioners who are actively engaged in optometric practice. They are already experts at assessing ocular tissue, ocular health status, and determining normal versus abnormal clinical findings. The training programs in the proposed regulation will develop practitioner skills to enhance clinical decision making. The two most important areas for decision-making enhancement are: 1) when to initiate the first treatment plan; and 2) when to modify the current treatment plan due to further progression. Also see response to CAEPS' comment (6), (15), and (16).

Comment (5): The Board's modifications to the proposed regulation violate the consistency and authority standards in the California Administrative Procedure Act because the Board was not granted the authority to state that the Case Management Course or the Grand Rounds Program is "equivalent" to prospectively treating 15 individual patients for 12 consecutive months.

Response: The Board rejects this comment. See response to CAEPS' comment (6), (15), and (16).

California Council of the Blind opposes the proposed regulation as modified for the following reasons:

Comment (1): The modifications to the proposed regulation are extremely dangerous and would result in reduced quality of care that will cause more glaucoma patients to lose their sight.

Response: The Board rejects this comment. The legislative and regulatory process that has been followed to date pursuant to the mandate of SB 1406 safeguards California's consumers and has allowed for full review by all impacted persons to disprove any assumptions of a reduction in quality of care.

Also, refer to response to CAEPS' comments (1) and (4), (6), (15) and (16) above.

Comment (2): The proposed regulation's modifications define the word "treatment" in a way that would not be understood by a patient to be actual "treatment." Optometrists need adequate

training to treat glaucoma, and this training must include actual treatment of patients with glaucoma.

Response: The Board rejects this comment. The Board is defining the word "treat," not "treatment." For the purposes of this regulation, treat had to be defined in a manner to comport with the aforementioned restriction in BPC section 3041. The definition of treat encompasses all the necessary steps that an optometrist must take in order to medically manage a glaucoma patient. Despite the fact that candidates for glaucoma certification are not allowed to use anti-glaucoma agents, they are working closely with those who are experienced with prescribing or applying anti-glaucoma agents and are participating in the proper evaluation of the patient, the performing of all necessary tests, the diagnosis of the patient, recognizing the type of glaucoma within their scope of practice, creating a treatment plan with proposed medications and target pressures, ongoing monitoring and reevaluation of the patient's condition, and making timely referrals to an ophthalmologist when appropriate. The candidate is in effect "treating" the patient without violating the requirement set forth in BPC section 3041 that only glaucoma certified optometrists may use anti-glaucoma medications to treat glaucoma. Thus, the definition of "treat" in the proposed regulation is consistent with the definition of "treat" in BPC section 3041 and does not compromise patient safety.

Comment (3): The proposed regulation should be modified to require candidates for glaucoma certification to treat glaucoma patients under the supervision of a practitioner who is certified to treat glaucoma.

Response: The Board rejects this comment. Adding to the regulation a requirement that a candidate must be supervised by a practitioner who is certified to treat glaucoma would exclude other practitioners, such as ophthalmologists (who by licensure are not required to have glaucoma certification to treat glaucoma), from the possible participation in the training of glaucoma certification candidates to become glaucoma certified.

Support, Objections or Recommendations Received After the 15-day Comment Period/Responses (October 5, 2010 – October 19, 2010):

Four-hundred and thirty-five optometrists, ophthalmologists and optometry students sent letters of support on various dates after the 15-day comment period (See Tab 16). All support the regulation as modified for the same reasons as the California Optometric Association, Southern California College of Optometry, Western University of Health Sciences, College of Optometry, and the University of California Berkeley, School of Optometry starting at the bottom of page two of this document.

One-hundred and forty-one ophthalmologists sent opposition letters which were received on various dates after the 15-day comment period (See Tab 16). All oppose the regulation as modified.

Response: The Board is not responding to these comments because they were received after the 15-day comment period.

The California Academy of Eye Physicians and Surgeons (CAEPS) submitted a comment requesting that the Board use a transcript prepared by their organization which covers only the comments provided at the October 22, 2010 Board Meeting by their representative Joe Lang (See Tab 16).

Response: The Board is not responding to this comment because it was received after the 15-day comment period. The Board has provided a recording of the October 22, 2010 Board Meeting in Tab 15 of this rulemaking file. The transcript provided by CAEPS with Joe Lang's comments was neither transcribed by the Board nor approved by the Board.