BOARD OF OPTOMETRY Minutes of Public Hearing on the Adoption of California Code of Regulations 1571 Requirements for Glaucoma Certification

DEPARTMENT OF CONSUMER AFFAIRS 1625 N. Market Blvd... 1st Floor Hearing Room Tuesday, December 22, 2009 9:00 a.m. - 12:00 p.m.

Staff Present:

Mona Maggio, Executive Officer Michael Santiago, Legal Counsel

Margie McGavin, Enforcement Manager

Andrea Leiva, Policy Analyst

Michelle Linton-Shed, Enforcement Analyst Elvia Melendrez, Licensing Technician

Attendees:

Dr. Lee Goldstein, President, California State Board of Optometry

Bill Gould, Wilke Fleury Hoffelt Robert Tyler, Wilke Fleury Hofflet

Erica Eisenlauer, DCA Legislation and Regulation

Dr. Hilary Hawthrone, OD, California Optometric Association

Duane deCroupet, California Optometric Association

Tim Hart, California Optometry Association

Julia Blanton, Porter Novelli on behalf of California Optometric

Association

C. Berg, Berg and Associates

Terrence McHale, Legislative Advocate, Aaron Read & Associates

Veronica Ramirez, California Medical Association

Dr. Jim Ruben, California Academy of Eye Physicians and Surgeons Dr. Craig Kliger, California Academy of Eye Physicians and Surgeons Dr. David P. Sendrowski. Southern California College of Optometry

Dr. David A. Cockrell, American Optometric Association

Dr. Tony Carnevali, Representing Himself

Dr. Robert DiMartino, UC Berkelev

Dr. James Brandt, UC Davis

Dr. Elizabeth Hoppe, Western University of Health Sciences

Executive Officer: Good Morning, my name is Mona Maggio, I am the Executive Officer of the California State Board of Optometry. With me today are Michael Santiago, Legal Counsel for the Board, Andrea Leiva, Policy Analyst for the Board, Elvia Melendrez, Licensing Technician for the Board, Margie McGavin, Enforcement Manager for the Board and handling our sign in table is Michelle Linton-Shed, Enforcement Analyst for the Board.

It is 9:00 a.m. on Tuesday, December 22, and we are gathered here today at the Hearing Room of the Department of Consumer Affairs, located at 1625 North Market Blvd, Sacramento, CA 95834 to receive public comments on a proposed rulemaking action by the California State Board of Optometry. The Board has proposed language in order to establish requirements for optometrists to become glaucoma certified. The Board regulation we are concerned with today is: California Code of Regulations section 1571, "Requirements for Glaucoma Certification."

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Under the rulemaking provisions of the California Administrative Procedures Act also know as the APA, this is the time and the place set for the presentation of statements, arguments and contentions, orally or in writing, for or against changes in the Board of Optometry's regulations, notice which has previously been both published and sent by mail to interested parties.

This is a quasi-legislative hearing in which the Board carries out a rulemaking function delegated to it by the Legislature. Witnesses presenting testimony at this hearing will not be sworn-in, nor will we engage in cross-examination of witnesses. We will take under submission all written and oral statements submitted or made during this hearing. We will respond to these comments in writing in the final statement of reasons.

This entire APA rulemaking hearing will be recorded. The transcript of the hearing and all exhibits and evidence presented during the hearing will be made part of the rulemaking record.

The record of this hearing is being kept open until close of business today, December 22, 2009, in order to receive additional relevant evidence in writing from interested parties. If you have brought written comments with you to submit during the hearing today, please give them to our staff member, Andrea Leiva [indicating].

As you entered the room, you were offered the attendance sheet to sign your name, and a space to indicate if you wanted to stand up and make oral comments on the proposed regulations or a space to indicate if you just wanted to attend the hearing.

Does anyone in the audience need to fill out the attendance sheet at this time? If you do, please step to the back of the room and fill out the attendance sheet. If you filled out the attendance sheet and you provided your email address, we will notify you before the final adoption of any changes to this proposal or about any new material relied upon in proposing these regulations. Such a notice will be sent to everyone who submits written comments during the written comment period, including those written comments that are received today, and to everyone who testifies today and to everyone who asks for such a notification. While no one may be excluded from participation in these proceedings for failure to identify themselves, the names and addresses on the attendance sheet will be used to provide the notice.

If you have not yet signed on the attendance sheet, and wish to do so, please step to the back of the room and complete the attendance sheet.

We will listen to oral comments in the order you signed the attendance sheet. After we hear from everyone who signed in, we will hear from any latecomers or anyone else who wishes to be heard.

When you are called to speak, we ask that you do certain things so that the audience may hear you and so that your comments are entered into the record. First we ask you to come to the microphone, please step up to the table here. To turn the microphone on press the button on the bottom base of the microphone and a small green light will appear. Second, please begin by stating your name, please spell you last name for the record and identify the organization you represent, if any, if you are representing yourself, please state that you are represent yourself.

If you agree with comments that have already been stated, please do not restate those comments, you may just say that you agree with, state the individuals name and/or organization that the comments have already been made and please make any comments that are new.

These regulations were duly noticed more than 45 days prior to today's hearing. Copies of the notice, together with the regulations and the statement of reasons, were mailed to all interested parties who had requested rulemaking notices.

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Now, if you have not done so, please turn off your cell phones or turn them to vibrate so that they will not interrupt any of our speakers. Please do not have any side conversations during our hearing today. If you feel you need have a conversation with another person in the audience please step outside of the room. We will be timing our hearing today. Each speaker will be given a maximum of five minutes to make comments. Our timer is Elvia Melendrez. Ms. Melendrez will show you the green card at three minutes, you have spoken for three minutes, she will show you the yellow card at four minutes indicating you have spoken for four minutes, we will tell you "thank you" if you continue to speak. She will show you the red card at five minutes at five minutes, please stop speaking. Now, may I please have the attendance sheet and we will begin taking oral comments.

Executive Officer: David Cockrell, AOA.

Dr. David Cockrell (Comment 24): Good Morning, thank you very much for this opportunity to present testimony at this hearing. I am David Cockrell. I represent the American Optometric Association of Louisville, and the Oklahoma State Board of Examiners in Optometry. I am a currently practicing Optometrist in Oklahoma. I have serverd on the Oklahoma State Board of Examiners in Optometry since 1996. I have served in all position on the Board including, Board member, Vice President and President of the Board.

Technology and education have continued to broaden the field of healthcare providers who are capable of safely and responsibly practicing all areas of healthcare. Optometric treatment of Glaucoma is an excellent example of the increased access to care for our patients that has occurred as a result of these changes.

As a practicing optometric physician in Oklahoma, I have treated Glaucoma for over 25 years. I along with all other Oklahoma licensed optometrists are responsible for diagnosing and treatment of the disease. I am certain that we have some OD's that do not treat Glaucoma, however the great majority do treat glaucoma and so very effectively, to the benefit of the citizens of Oklahoma. The Oklahoma State Board of Examiners in Optometry currently licenses 780 optometrists. Between 550 and 580 are in active clinical practice in Oklahoma, the remainder include academicians at the Oklahoma College of Optometry and optometrists that live and practice in other states and also hold an Oklahoma license. The majority of out-of-state licensees practice in federal setting, including the Public Health Service, Indian Health Service, the Veteran's Administration and all branches of the Armed Services. The reason for the number of federal practitioners holding Oklahoma licenses is the broad scope of practice law allowed by Oklahoma is suited to the scope of practice required of those practitioners.

Board and regulating bodies are frequently asked to support legislation or promulgate rules regarding legislation, with little or no long term study of the effect of outcomes for patients, of the newly enacted legislation or regulations. The Boards consider many variables in these decisions; among those variables are educational background, efficacy of proposed treatment, as well as the capabilities of the applicants, and as in this case, the specific education of an optometrist on the management of glaucoma and the eventual outcome of the legislation for the citizens of California. Regarding the treatment of glaucoma, optometry can point to a 30 year, successful track record across the United States.

The timeline of glaucoma treatment by optometry began in the late 1970's. In Oklahoma glaucoma has been treated by optometrists since 1982. While the current regulations for glaucoma treatment being studied here are quite specific, the types of glaucoma treated by optometrists as well as treatment modalities in Oklahoma are much more expensive and therefore the results should be valid as a metric for successful treatment of glaucoma by optometrists. The practice act in Oklahoma allows Optometric treatment of glaucoma including all forms of topical pharmaceuticals, with no restrictions on treatment regiment or length of treatment. In the early 1990's we began to utilize all current oral pharmaceutical treatment for

glaucoma available when appropriate and in the best interest of the patient. In addition to pharmaceutical treatment, optometrists also utilize laser surgical treatment as well including Argon Laser Trabeculoplasty (ALT), Peripheral Iridotomy (PI); those procedures have been performed for almost 20 years by optometry in Oklahoma. Within the past few years Selective Laser Trabeculoplasty has been developed for surgical treatment of glaucoma and is now part of optometric treatment as well. As you can see our treatment of glaucoma has expanded as new pharmaceutical treatments have been developed and as new technological advances are brought into play.

During the twenty-five plus years that optometry has treated glaucoma in Oklahoma, we have demonstrated an excellent record of safety for the public. During this period of glaucoma treatment including both pharmaceutical and laser surgical treatment, the Oklahoma State Board of Examiners in Optometry has had no formal or informal complaints from the public, any Oklahoma state agency, or any state or national medical society during that time, concerning pharmaceutical treatment or laser surgery for glaucoma.

One rough measure of the efficacy of a procedure or successful treatment by a practitioner is, the rate or cost of Professional Liability Insurance. In Oklahoma we are still at the lowest rate for PLI for optometry in the United States. Since 1990 the National Practitioner Data Bank has identified 21 cases of medical malpractice by optometry in Oklahoma, none of those have been reported to the Oklahoma Board of Examiners as a result of failed treatment plans for glaucoma.

To move from Oklahoma to a national view of glaucoma treatment; glaucoma is now treated by optometrists in 49 states, one territory in Guam and the District of Columbia. I have had a unique perspective to view pharmaceutical treatment by optometry, as the change in the scope of practice of optometry has occurred. Of the 49 state that treat glaucoma only eight have required co-management. To this date, there still is not a verifiable, documented study that proves any of the allegations of lack of training, qualification, limited education or experience, let along that has show inferior outcomes for patients.

In summation, optometrists are well qualified to treat glaucoma with a proven track record of success.

Thank you very much for this opportunity to present testimony.

Executive Officer: Thank you very much Dr. Cockrell. Have you submitted your written document?

Dr. David Cockrell: Yes.

Executive Officer: Ok, thank you.

Dr. David Cockrell: And I forgot to spell out my last name earlier, C-O-C-K-R-E-L-L.

Executive Officer: Thank you. Craig Kliger.

Dr. Craig Kliger (Comment 36): Good morning, thank you. I am Craig Kliger, K-L-I-G-E-R, the Executive Vice President of the California Academy of Eye Physicians and Surgeons and I'm speaking on behalf of the society. We have submitted written comments that you received and I will not rehash all of them, however I would like to make the following comments:

The glaucoma regulations of the Board create a glaucoma treatment loophole not authorized by SB 1406 that virtually eliminates any actual hands-on safety. What is at issue here is not the

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privilege of being able to treat glaucoma, which was actually established by SB 929 in the year 2000. What is at issue here is the standard by which people are certified.

We also believe that the regulations are based on a process that fails to include a legitimate legislatively mandated examination of optometric student training to balance presumptions of sufficient experience to be certified without an advance review from the legislature. And therefore, the regulations unreasonably include additional training is not required for graduates after May 1, 2008.

Furthermore, subsequent reports of optometric mismanagement of glaucoma patients at the Palo Alto Veterans Affairs Hospital call into question both the lack of referral requirements for optometrists treating glaucoma and the adequacy of training received by these students.

I would like to comment that at a committee meeting of the Board just last week discussing continuing education standards for cardiopulmonary resuscitation, the Board President Dr. Goldstein, who is very involved with the Red Cross and so this issue appeared important to him expressed dismay that the Board was giving continuing education credits for CPR courses where people were just watching a video and hand no hands-on experience. We are thereafter confused why he and the Board wouldn't want similar experience for practicing optometrists to treat a potentially blinding disease like glaucoma. We agree that hands-on experience is vital and the current regulation allows a specific pathway where that does not happen. Again, I will point out as I did at a prior Board meeting that this was an option for the Board if it limited the certification requirements to only the preceptorship option, which is in the regulation or by not offering the grand rounds course which we believe offers no meaningful training in treatment.

Again, the regulation language, I'm sorry, pardon me, the language of the old report, from the OPES report from the Office of Professional Examination Services that generated these regulations specifically was specifically permissive in the concept that it says "you may offer three options", but it didn't say "had to" so you were allowed to decide which of those options, and the Board, when I made those comments chose not to take action.

Again this is an extremely important issue in patient safety. We are not opposing the treatment of glaucoma by the optometric population we just do not believe these regulations lead to certification that benefits that physician and we ask the Board to withdraw these regulations, develop them in manner that is more consistent with SB 1406 which we do not I believe happened. There are many procedural errors throughout the whole process. Those are outlined in our written comments and we hope that the Board will behave responsibly and work with us to develop standards that will protect the public. Thank you.

Executive Officer: Tony Carnevali

Dr. Tony Carnevali (Comment 18): Good morning, and thank you for the opportunity of allowing me to speak of my own behalf. I'm Tony Carnevali, C-A-R-N-E-V-A-L-I. I am not representing a particular organization, I am representing myself. Since the last time I appeared before the Board on July 16, 2009 to present my report, I have been the focus of controversy. As the author of that report on glaucoma certification that was commissioned by the Office of Professional Examination Services. At that meeting, Dr. Craig Kliger said that these attacks were not personal. I beg to differ. Criticism which makes or attacks my credibility, my competence, above all my personal ethics are personal. It is apparent that these attacks are designed to divert the focus from the message to the messenger. The report and recommendations that I submitted were well researched and documented. To my knowledge, the Petitioners have never addressed any of my specific findings and recommendations presented in the report. However, the Petition that was filed by CAEPS, CMA and AGS specifically, claim:

I am not glaucoma certified under SB 929; I am an employee of the Southern California College of Optometry which would stand to benefit financially from the conduct of glaucoma courses; I am President of the Board of Directors of the Public Vision League.-the litigative arm of COA; and I am a past president and was a long-time member of the COA's Board of Trustees. These facts, they claim, render me unfit and anything produced by me as Special Consultant is therefore tainted and should be discarded as invalid and unreliable.

Allow me to set the record straight. The facts are these. First, the Petitioners claim that I am not glaucoma certified and therefore not an expert in glaucoma. They even have claimed in correspondence that I may be practicing illegally or treating glaucoma illegally. What is interesting is that while the ophthalmologists make that claim this point in the petition, they also suggest that an "educator" with no such expertise would have been a better choice as Special Consultant.

Since my expertise regarding glaucoma and perhaps even the legality of my actions have been questioned. I must respond. It is correct that I am not currently certified to treat glaucoma under the law in effect between January 2001 and this year. The reality, however, that 34 years of clinical practice in private practice as well as in relation to my association with the College of Optometry in teaching clinicians and treating and managing glaucoma patients throughout the years. I have had a tremendous amount of expertise in glaucoma treatment and management. The petitioners have pointed out in a letter to Sonja Merold, Chief of OPES that I treat glaucoma and that they consider that illegal. That's because they have misinterpreted the law 929 in claiming that the law does not permit me to treat glaucoma. The reality however is, that 929 prescribed set protocols in which we can treat glaucoma during a two year period of time of which co-management takes place. And I have done so and that what we do at the Optometric Center of Los Angeles. And a further point, my assignment did not require any particular knowledge of glaucoma treatment or management. It required the ability to be able to analyze data and information from other states, laws that are in place in other states and curriculum that is available at other schools of optometry as well as the accreditation process and the National Board of Examiner's examinations. Based upon those assignments I have the skills and the expertise to be able to do that kind of analysis.

As a faculty member at SCCO I have absolutely no benefit from any engagement with SCCO....[Five minute time period ended]

Executive Officer: Thank you.

Dr. Tony Carnevali: Thank you for your time. You have my written statement on this?

Executive Officer: Yes, thank you. Dr. DiMartino.

Dr. DiMartino (Comment 37): Good Morning.

Executive Officer: Good Morning.

Dr. DiMartino: My name is Robert DiMartino, last name spelled D-I-M-A-R-T-I-N-O. I am an optometrist and professor of optometry at University California Berkley School of Optometry. Thank you for the opportunity to address this hearing.

One of the roles I had in the implementation of 1406 was as the chair of the Glaucoma Diagnosis and Treatment Advisory Committee. In our meetings we attempted to reach an agreement with our ophthalmologic counterparts on the training necessary for optometrists to become certified under 1406. Unfortunately, the majority of our time was centered on the 50 patient requirement that was present under SB 929. It was as if 1406 had never been passed.

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We tried numerous attempts at resolving that issue of 50 patients and unfortunately were unable to reach an agreement. One of the criticisms that the ophthalmologist brought was that we were not forthcoming with our student training at the university. In fact we had provided both the Southern California College of Optometry curriculum California Berkeley School of Optometry curriculum to the ophthalmologists prior to the passage of SB 1406 and this information was also available to the legislature. So unfortunately, at the conclusion of our three meetings, we were unable to reach an agreement. As a result the ophthalmologist and the optometrists each wrote separate reports. In our report we feel that we laid out the appropriate strategy for the certification of optometrists, we encouraged and are thankful that the Board has followed it.

One of the other roles that I had are that I'd like to speak this morning as a representative of the school as a faculty member of where I teach students in our clinic in terms of our clinic. The students there are bright and we are actively involved in treating glaucoma throughout our curriculum. Students are trained in pharmacology, anatomy and physiology, visual fields and the critical management and diagnosis and treatment of glaucoma throughout their clinical program. This provides them with an excellent opportunity. But in addition to the training they receive at the university, the general clinic and our ophthalmology clinic, they attend numerous rotations throughout California and elsewhere in the country where they get extensive exposure to glaucoma. This wide exposure will allow them to treat effectively diagnose and treat especially in California, in fact our graduates from other states already have their license to treat glaucoma for a number of years.

Finally, I'd like to address the hearing as a representative of the Dean of the school of optometry where special effort has been made to establish the appropriate training and that our students who graduate are ready to treat glaucoma in California. We thank the Board for their time and the effort in this regard. Thank you very much for allowing me to address this hearing.

Executive Officer: Hilary Hawthorne.

Dr. Hilary Hawthorne (Comment 22): Good morning, my name is Dr. Hilary Hawthorne, H- A-W-T-H-O-R-N-E, I am a licensed optometrist in the state of California. As one of the proudest moments that I signed was the little certificate every two years. I practice and I deliver care. I'm here before you today at this hearing to emote some reasons as to why I support the proposed regulations. As a practitioner who's delivering care in South Los Angeles there's nothing more that we need than more care for glaucoma in my community. It is something that I think has been put into regulations and needs to move forward. They are something that I support and they speak to exactly what the needs are for every patient that I treat.

Coming from another state and being ready to be certified for glaucoma seems to have been for 16 year struggle. I was licensed in 1992. I became licensed in Oregon and decided to come back home to Los Angeles, California. But glaucoma treated by an optometrist can be done in every other state, by colleagues of mine that graduated with me, and I feel at this point in time California needs to move and match the requirements and training and qualifications of all other states and have the heart and the minds of those that are ready treat. I am one of those that desire to treat glaucoma. I did prepare a statement and I submitted it and I want to highlight some of the things in the statement, and just want to start out by saying am I certified as a TPA certified OD. That is something that I was happy to see us succeeding, this is another place where I'm willing to advocate for my patients and encourage and support the Board and the DCA staff.

In my community, it's Black and Hispanic patients. The highest rate of glaucoma care is needed in these communities. They have other issues that pose high risk for disease, and in this community there's a lot of care that's being delivered outside the community. There's a problem, there's disconnect, there's a gap. Probably one of the things I'd like to see put to rest is some of this unnecessary referral. There's been a flaw in the way the previous bill was

written as SB 929. SB 1406 is much better and gets rid of some of the co-management flaws that were in it. An example would be that a disease such as glaucoma is a painless, symptomless disease. Making patients understand about this disease is what doctors do, we are educators.

I chose to become a practitioner with hands-on care and training in the community because that's what's needed in order to keep clients alive. Having more practitioners available, having optometrists there that can provide these services are probably the best thing we can do in every community. I'm not just talking about Los Angeles, but every county in this state. Now I am asking the state Board to adopt the recommendations. Those proposed recommendations are going to be part of what I cherish, the optometric practice. That's what runs the practice, that's what runs the type of care that I deliver to the community, to the public and everyone I serve on a day-to-day basis. Those regulations I support. I'm going to say it over and over again in my testimony. Again, I've been waiting 16 years from a personal standpoint for someone who's advocating for how glaucoma needs to be treated in this state is too long. I support these regulations and I hope to be able to deliver the care soon. Thank you.

Executive Officer: James Brandt.

James Brandt (Comment 32): My name is James Brandt, B-R-A-N-D-T. I am a Professor of Ophthalmology at the University of California, Davis and for the past 20 years have served as the Director of the glaucoma service at UC Davis. In that role I wear many hats – Most of the time I am clinician, taking care of patients with glaucoma. I am a researcher, running laboratory and clinical studies in my field, and most relevant to the topic at hand, an educator, teaching medical students, residents and fellows about glaucoma. I have the added perspective of someone who sees the end product of American ophthalmic and specifically glaucoma education.

Before I address clinical education however, allow me to some observation about glaucoma, based on two decades of focusing my entire career on this disease. First, this is a complicated disease. In many ways, I feel that I understand glaucoma less well now than I did when I finished my training or at least it's not as simple as I thought it was then. I say this to emphasize that this is not a disease that can be treated according to a simple algorithm, flow chart or preferred practice. Indeed, all such guidelines contain the disclaimer that they quote "do not substitute for clinical judgement."

So where does clinical judgement come from? The hallmark of modern medical education is the combination of graded responsibility with breadth, depth and length of patient care. Let me explain how this plays out in the UC Davis Medical Center. When our brand new first year residents arrive, we focus first on the skills needed to properly diagnose glaucoma. We do this on real patients with real disease presenting in a myriad of ways, hundreds of them, with direct one-to-one supervision. These are patients who come in with early disease and end-stage disease along with other disease like diabetes and heart disease. These are individuals with all the social and personal issues that affect treatment decisions. This is what I mean by breadth. During a rotation during glaucoma service a resident will see thirty to forty glaucoma patients a day, combined with graded experience in the operating room and laser suite. By their second year a resident will have personally seen, examined and cared for as many as two thousand, yes thousand, patients. This is what I mean by both breadth and depth. A new resident takes care of patients with training wheels and does little without the direct supervision. By the end of the second year the training wheels come off and the resident does more with less direct supervision. In their final year the whole package comes together, with the residents acting with increasing independence but still with the safety net of an experienced clinician at hand to offer suggestions, consultation or gentle correction. By the time they complete a residency and sit for board certification, an ophthalmology resident will have cared for thousands of patients with

glaucoma and have provided glaucoma care for a few hundreds patients over the course of three years. Breadth, depth and length.

This is where clinical judgement comes from. There is a saying that good judgement comes from experience, but that experience comes from bad judgement. Nowhere is this more important that in medicine. The whole goal, in fact the whole design of medical education is to allow trainees to gradually gain experience while being supervised so that the patients don't pay the price of a trainee's bad judgement. Now let's contrast this with what the Board of Optometry is proposing.

First, it is proposed that current and future graduates of schools of optometry have already received training sufficient to treat glaucoma without additional training requirements. Optometry students see mostly healthy patients. In their eye disease clinics the glaucoma patients are mostly those who are glaucoma suspects or with ocular hypertension. They may see only a handful of patients with moderate to advanced disease and are rarely given graded responsibility for their long-term care. They are supervised, in most cases, by other optometrists.

Second, it is proposed that practicing optometrists gain certification by one of three mechanisms, none of which require the optometrist to have a therapeutic relationship with more than a token number of patients. There is no breadth, depth or length and certainly no graded responsibility. Remarkably, under the proposed regulations it would be possible for an optometrist to gain certification to independently treat glaucoma without ever having treated a single patient. Common sense surely tells us that this doesn't make sense and is not in the public interest.

In closing I would like to remind you of Sir William Osler, who helped revolutionize medical education in the early part of the last century, in large part by helping shut down diploma mills that granted medical degrees without clinical experience. Quote, "He who studies medicine without books sails an uncharted sea, but he who studies medicine without patients does not go to sea at all." In the 21st century, despite dazzling Powerpoint lectures, YouTube lectures, online collaboration, virtual reality and educational media yet to be invented, his words still ring true. Thank you.

Executive Officer: Elizabeth Hoppe.

Elizabeth Hoppe (Comment 23): Good Morning. My name is Elizabeth Hoppe, my last name is spelled H-O-P-P-E. I am here as the Dean of Western University of Health Sciences, College of Optometry. I would like the Board to know that I have over 21 years of experience in optometric education and as a clinical preceptor in Department of Veterans Affairs where I enjoyed residency training alongside ophthalmologists ophthalmology residents trained by the Yale University School of Medicine.

This is my third college of optometry and I'm also an active member of the Association of Schools and Colleges of Optometry and have a very good perspective on contemporary optometric education by virtue of experience, and hands-on day-to-day activity. I'd like to thank Dr. Brandt for an excellent description of the education process that also applies to the educational process of optometry. However, his description is not accurate and it is not based on current data describing the optometric educational process. First I would like the Board to recall that our current students and graduates from the schools and colleges of optometry have passed the National Board of Examiner's in Optometry examination. The NBEO sets a standard that ensures the same level of competency regardless of the state of where an optometric practice is located and regardless of the state of where a student's education occurs.

In my written testimony I provided additional information about the National Board but at this point, I'd like to point out that the NBEO has worked very diligently to keep the examination content in line with the contemporary practice of optometry. Specifically related to Oklahoma, the NBEO must use this information that constitutes critical judgement, they must base this judgement on sound experience, and they are required to demonstrate competency on the diagnosis and management of primary and secondary glaucoma. I would also like the Board to know that the quantity, quality and diversity of hands-on clinical education are rigorously evaluated by every school and college of optometry in the country using a variety of methods. Evaluation, monitoring and assessment of clinical education is required of our national accreditation council on optometric education and every school as part of this process should must document this process to maintain their accreditation standard. Ensuring entry-level competency, including diagnosis, treatment and management of glaucoma is mandated as a responsibility of the school or college prior to awarding a degree of doctor of optometry.

I'd also like the Board to know that as the Dean of one of the three schools and colleges of optometry in California I am actively engaged in hiring faculty members who are responsible for the education of the next generation of practicing optometrists. Many of these doctors have practiced for many years and successfully care for patients with glaucoma in other states and federal facilities. The minute they join my faculty and come to work in the state of California they are no longer able to apply that expert clinical judgement years of experience and handson expertise in diagnosis and management of glaucoma and I urge the Board to adopt the regulations as recommended.

Executive Officer: Tim Hart.

Tim Hart: Madame Chairwoman, can I defer until the end of the hearing, please.

Executive Officer: Yes. James Ruben.

James Ruben (Comment 38): Greetings, good morning and happy Holidays to everybody. My name is James Ruben, R-U-B-E-N. I am the President of the Academy of Eye Physicians and Surgeons. A current professor of ophthalmology at UC Davis and a clinical professor of ophthalmology at UC Davis and a practicing pediatric ophthalmologist for at a very large integrated managed care system where I've worked for over 20 years prior to my eight years of training. I work very closely with many fine optometrists. We work as a team. I'm a strong believer in that teamwork with those optometrists. I have also work with four-year optometry residents who rotate through our offices at UC Berkeley and I do see what their competencies are and their training levels, and many of them are excellent individuals.

As I said, I feel very strongly that we should work together as MD's and OD's to benefit patient care and it's because of this that I stand before you today. First and foremost I think that with this process what should come first is patients and patient safety, and I believe that's our paramount goal for everyone in this room. I have no financial interest in any of this, when making decisions in this regard, and I will admonish them to please err on the side of caution. Glaucoma is a very dangerous disease. It is a slowly progressive disease, it is irreversible as the progression occurs and it is very essential that policies put into place now be good policies because we don't want to find out in 10 years that people went blind from policies that were thought through. So again, if we are going to err, I caution that we err on the side of caution.

With that said, I don't think any of us at the California Academy of Eye Physicians and Surgeons, certainly myself, object to anybody treating glaucoma if they have the proper training. We think that's the critical piece. And we do believe it's possible for optometrists to gain that training if they go through a rigorous process similar to what we go through in medicine. So, it's no about us or them it's really about the training. What we believe is that this, this current iteration of the process has been somewhat tainted. We don't believe that this was the

legislative intent to have a single person who, while I don't want to expunge them as an individual but more that there are conflicts of interest involved. We believe those conflict of interests came across, and this pubic deserves a clean process in which all can participate in and agree on.

We also believe that there should be patient safeguards including referral requirements for patients that are not performing well in the care of a less trained individual. And we believe that management over time does require one-on-one following the patient as Dr. Brandt suggested. I think the analogy is that you have to have stick time before you can fly a commercial airplane, and we believe that similar analogy applies here. So as I said before, we are not debating right now whether an optometrist should treat glaucoma or not, because all the discussions are centered around that sometimes, it's about what kind of training is required. And we hope that the Board, organizations of optometry and everyone else involved will work together to reach an agreement with mutual benefit to the patient so that patients can have the safety and the quality care regardless of where they receive their care. Thank you and Merry Christmas.

Executive Officer: Veronica Ramirez.

Veronica Ramirez (Comment 33): Good Morning. My name is Veronica Ramirez, R-A-M-I-R-E-Z, representing the California Medical Association. And I would like to agree with Dr. Kliger about the need for hands-on training in the current proposed regulation. While CMA values the Board's efforts to promulgate regulations...

Executive Officer: Ms. Ramirez, could you speak up a little.

Ms. Ramirez: Oh, sure. While CMA values the Board's efforts to promulgate regulations to implement the legislative intent of SB 1406, we believe there are many issues both with the way the regulations were developed as wells as the content of the proposed legislation. We feel that the (unintelligible) to negotiation many which (unintelligible) the outcome of what is now included in our language. I would like to reiterate our statement in the petition referred to by Dr. Carnevali that (unintelligible) is called into question the substance of the regulation.

The CMA feels that the committee failed to discuss any vocational training requirements to newer optometry residents. As illustrated by the recent issued findings that the Veterans Affairs health care system clinical glaucoma training is essential to maintain safety. It's difficult to imagine that the public will be adequately protected by the proposed regulations that do not require any training involving supervised treatment of patients. Under the proposed regulations an optometrist could actually become certified to independently treat glaucoma without ever having a glaucoma patient.

Again, we appreciate the efforts of the Board to promulgate regulations to implement the legislative intent of Senate Bill 1406 treatment, however (unintelligible) for certification is not the solution. We urge the Board to either amend the proposed legislation or have them redevelop through the SB 1406 process in a manner consistent with its legislative intent. Thank you.

Executive Officer: David Sendrowski.

David Sendrowski (Comment 39): Good morning. My name is David Sendrowski, S-E-N-D-R-O-W-S-K-I. I am a Professor of Optometry at the Southern California College of Optometry where I'm also the Chief of the ocular disease service there. I'm here in representation of Dr. Kevin Alexander, President of the Southern California College of Optometry.

We are here to favor the regulations proposed by the State Board. Dr. Alexander's letter, which was sent to the Board and I will just be hitting the highlights of it. But in his capacity as a past president of the American Optometric Association, past president of the Ohio Optometric

Association and he served on an oversight board in which the glaucoma certification in Ohio was evaluated in terms of the practice of optometry and their usage of pharmaceutical agents to treat glaucoma. In his letter, he states three points that are very important that I would like bring forward to the Board.

One, the educational aspects that are put forward by the regulation far exceed those of other states. We believe that this regulation will definitely put forth the safety of the constituents of the state of California. Two, that the case management portion is also, basically, very thoroughly thought through with educational benefits for the optometrists. I have been basically teaching some of the optometrists in their certification process, I am Board certified to practice glaucoma. And in that capacity I can tell you that the optometrists in that doctorate program are well educated and have been diagnosing glaucoma since 1976 when this state allowed optometry to use diagnostic pharmaceutical agents. So it has not been a matter of optometrists being able to diagnose the disease, that's been done for many decades. What we are asking now is just the ability to treat what we've been seeing over that time period.

Another point that Dr. Alexander brings up in his letter is to consider that basically the care that California constituents is well taken care of by this regulation and that we support them and the Southern California College of Optometry supports them as well. Thank you very much for your time.

Executive Officer: Tim Hart.

Mr. Hart: Madame Chairwoman, can I ask your indulgence to hear some additional testimony from Mr. Tyler? I don't think he signed up for testimony. Thank you.

Mr. Robert Tyler: You'll see my name in there, it has a question mark regarding testimony.

Executive Officer: Okay.

Robert Tyler (Comment 40): My name is Robert Tyler, I'm a local attorney. I have familiarity with the VA, certain actions that were taken against optometrists in the VA system. I will make my comment very brief about what has been brought up a couple of times here. The original complaints against the optometrists within the VA system were based upon purported lapses in clinical judgement. Patient safety was being referred to in those. There were various problems with those complaints, the lack of documentation and, more importantly, a lack of provable breaches of patient safety.

What those ultimately evolved down to, they were withdrawn and then brought back as a second series of allegations against the same optometrist, which were basically based solely upon charges of breaches of their at will clinical privilege, specifically clinical privilege grants that have been provided them within the VA system requiring that they co-manage glaucoma patients with an ophthalmologist. Those were the ultimate charges that came to be decided within the VA system. But in the vast majority of those cases the patient was only a glaucoma suspect or had idiopathic ocular hypertension without any indicia of glaucoma changes. The vast majority of these were in that precise fashion.

In the instances of glaucoma, where glaucoma was diagnosed there was in most cases an immediate referral to an ophthalmologist and sometimes what was also shown was that the VA system had erroneously contended that that did not occur, when in fact it had. In very few cases where there was active co-management that was done with persons who were actually licensed to do so and in many of the cases there was contemporaneous co-management from ophthalmologists outside the VA system which was apparently ignored by the VA system in making the charges.

In very few cases there were co-management within the VA system with an optometrist who was licensed to treat glaucoma in the state from which he had his optometry license, which is quite permissible in the federal system. In all cases they were able to show no harm to the patients. This ultimately resulted in a decision by the VA that basically reduced the proposed charges down to a basis where they become non-appealable. Had they been appealable they would have been appealed because there is not factual basis for them and the VA basically retired from the field, so to say.

There was one instance where they claimed that there had been a patient who had been harmed. The patient, who for legal reasons I cannot mention their name for HIPAA reasons, had showed no glaucoma changes whatsoever. The patient was totally non-compliant and had been referred on many occasions for additional visual field examinations. He was referred but did not show for examinations multiple times which ultimately, at the point when his interocular pressures actually rose, he was then immediately reported to ophthalmology within the VA system and he did not show for that examination either. That was the patient that hit the papers in the San Jose Mercury. I will finish with just the following comment. I deal with a fair amount of malpractice litigation and have never seen, as it occurred with that patient, a situation where a patient is encouraged follow a claim. I have also never seen, as it occurred with that patient, where immediately upon filing the claim it was immediately paid and it was rather odd, to say the least. And with that I think that puts the VA charges in context. Thank you.

Michael Santiago: Mr. Tyler, before you leave, are you representing yourself or...?

Robert Tyler: I am representing myself.

Michael Santiago: Thank you.

Executive Officer: Tim Hart.

Tim Hart (Comment 41): Thank you Madame Chairwoman, my name is Tim Hart, H-A-R-T Director of the Government and External Relations Division of the California Optometric Association. A question Madame Chairwoman, we saw a draft of the proposed amendments to the regulations this morning, has that document been submitted for the record?

Mona Maggio: No.

Tim Hart: And of course you did say that the record will remain open until the close of business today?

Mona Maggio: Yes. Yes.

Craig Kliger: Madame Chairwoman, can you explain what that document is before you proceed since you're discussing a document non of us have seen?

Mona Maggio: It's the document that you sent to me.

Craig Kliger: The document I sent you?

Mona Maggio: Yes.

Craig Kliger: That is in the record, because I submitted it.

Time Hart: It is in the record, thanks. Just a couple of observations, the witnesses that have testified in support of those regulations have already covered most of the points. As Dr. Cockrell pointed out, glaucoma is being treated and managed in 48 states and the District of

Columbia. Essentially what organized medicine has proposed in California, if I indulge my own self is California is the last outpost of co-management. Look at the facts and the evidence. There are only seven states that require co-management of any sort.

Secondly, I just wanted to respond, I attended the same meeting Dr. Kliger did where Dr. Goldstein talked about cardiopulmonary resuscitation at the State Board. For the record, the meeting was on December 17th?

Mona Maggio: Yes.

Tim Hart: I heard Dr. Goldstein making a point, that many medical doctors have not been required to be certified for CPR for some time and that requirement was eliminated for optometric doctors a couple of years ago. I think the point the Dr. Goldstein, at least I heard him make was that if health professionals of any kind were going to become CPR certified, they should take reputable and sanctioned CPR courses and he would hope that Dr. Goldstein would apply the same standards for glaucoma surgeons.

We have submitted our science advisory committee report for this hearing record. We believe it makes the best integrated case and support of the regulations as written. We address conduct at the advisory committee meetings. Dr. DiMartino has already made the point that information was provided to the Academy of Ophthalmology representative on March 21st, 2008, when SB 1406 was under discussion. The representatives of the three schools have made the point about that information. It's not a secret. It's not hidden from anyone.

The other point we would like to make is that we believe our side addressees both the etiology and epidemiology of that disease. It's approaching epidemic proportions in California. We've conservatively estimated 435,000 Californians have gotten glaucoma and don't know it. What are we going to do about it? Are we going to prevent our optometrists who are trained to a very high standard to manage that disease in the state or not?

I think that's the central focus. Look at the facts and evidence of glaucoma treatment in all jurisdictions. We believe this supports your decision. Thank you very much.

Craig Kliger: Madame Chairwoman, may I raise a procedural issue, if you don't mind. You can tell me...

Michael Santiago: Do you have a question?

Craig Kliger: I would like to share a concern that the Board has shared our comment with the California Optometric Association, but have not shared their comments with us. I believe there is a double standard here and I apologize it's not reasonable for you to favor providing information to the California Optometric Association without reciprocating. He is arguing that he can file comments on our proposal before the end of the day, and we could just as easily file comments on what they said as a rebuttal but you have not given us that opportunity. That's not reasonable for you to...

Michael Santiago: We can discuss that outside of the regulatory hearing but the purpose here, right now is to make comments, so if you want to bring that up, you will have to bring that up later.

Craig Kliger: Indeed, but I'll add he has made the claim in the regulatory hearing that he has the ability to file comments what we said and that's...

Attachment 2

Michael Santiago: Anybody can file comments on whatever they want, so that's where we are at and we are going to proceed with the hearing to take any further comments, so, like I said we can discuss that later because that's not proper right now as a basis for this hearing.

Executive Officer: Is there anyone else who wishes to speak concerning the Board's proposed regulation at this time? Our hearing will remain open until 12:00 noon today. If you wish to stay around until the end of the hearing, you are welcome to do so, otherwise staff will stay here to accept any additional comments until 12 noon.

If you have attended this hearing today, we appreciate everyone's assistance whether you spoke or just came in attendance. If you would like to be on the Board's rulemaking mailing list, you may give your name, mailing address and email address to Andrea and you will receive information regarding this rulemaking package and future rulemaking packages. Otherwise, at this portion our hearing is closed until we have additional attendees who wish to comment. Thank you.

[Whereupon a recess was taken starting at 10:06 a.m.]

Executive Officer: Again, if you would like to be on the Board's rulemaking mailing list, or our general mailing list and you are not currently receiving information from the Board, please give you name, mailing address and email address to our staff member Andrea Leiva. At this time it is 12:00 p.m. and the hearing is adjourned.

[Whereupon the hearing was adjourned at 12:00 p.m.]

April 1, 2009

Sonja Merold Chief Office of Professional Examination Services 2420 Del Paso Road, Suite 265 Sacramento, CA. 95834

Dear Ms. Merold:

Pursuant to our charge from the Legislature, as set forth in Senate Bill 1406 (Stats. 2008, Chap. 352, §2, attached is the report from the optometric members of the State Board of Optometry's Glaucoma Diagnosis and Treatment Advisory Committee.

While we were unable to reach final agreement on glaucoma certification requirement recommendations, we would like to acknowledge and thank Drs. Fishman, Morton, and Giaconi, our colleagues in vision care, for their interest and participation. We'd also like to thank the Board's Executive Officer, Mona Maggio, legal counsel Michael Santiago, and the rest of the Board's staff for their support, guidance, and patience.

We stand ready to answer any questions arising from our recommendations and to assist your Office in any way we can to both protect the public and help meet the serious public health challenge posed by glaucoma in California, by giving at-risk patients the access to diagnosis, therapies, and management they deserve.

Sincerely,

Robert B. DiMartino, O.D., M.S., F.A.A.O

University of California - Berkeley School of Optometry

piro, O.D., F. A.A.O.

406 Minor Hall

Berkeley, CA 91720-2020

(510) 643-9517 bobd@berkeley.edu

Peter R. Col, O.D., F.A.A

P. O. Box 730

Pine Grove, CA 95665

(209) 296-5565

prcol@volcano.net

Robert L. Shapiro, O.D., F.A.A.O

555 S. Broadway

Los Angeles, CA 90013-2301

(213) 627-5911

Rshap2020@aol.com

GLAUCOMA CERTIFICATION FOR OPTOMETRISTS LICENSED BEFORE MAY 1, 2008: REPORT AND RECOMMENDATIONS

of the Optometrist Members of the Glaucoma Diagnosis and Treatment Advisory Committee:

Robert B. DiMartino, O.D., M.S., F.A.A.O Peter R. Col, O.D., F.A.A.O Robert L. Shapiro, O.D., F.A.A.O

STATE BOARD OF OPTOMETRY

to the

OFFICE OF PROFESSIONAL EXAMINATION SERVICES

California Department of Consumer Affairs

Pursuant to California Business & Professions Code §3041.10 as enacted by SENATE BILL 1406 (Stats. 2008, Chap. 352)

April 1, 2009

INTRODUCTION

The Glaucoma Diagnosis and Treatment Advisory Committee (GDATAC) was created under the State Board of Optometry by Senate Bill 1406, sponsored by the California Optometric Association (COA) and introduced in the California State Legislature on February 21, 2008. (See Appendix A.)

As introduced, SB 1406 proposed to make substantial changes to the laws governing the scope of optometric practice in California. The bill was opposed by the California Medical Association (CMA), representing physicians and surgeons, and the California Academy of Eye Physicians and Surgeons (CAEPS), representing physicians and surgeons practicing in the surgical subspecialty of ophthalmology. These parties met to discuss and negotiate the ultimate provisions of SB 1406 over some 57 hours in total, culminating in agreement on August 18, 2008. SB 1406 was amended in the Assembly to reflect that agreement on August 20, 2008. CMA and CAEPS formally removed their opposition on August 21. The bill passed the Assembly that day, 74-0, and the Senate concurred in the Assembly amendments on August 29, 38-0. At CAEPS' request and with the consent of the other parties, Senator Lou Correa, the bill's principal author, entered into the Senate Journal a letter clarifying the intent of three specific provisions in the negotiated bill. The letter acknowledged in pertinent part that, as SB 1406 clearly states, GDATAC was authorized in its discretion, "after reviewing training programs for representative graduates," to "recommend additional training to the Office of Examination Resources...to be completed before a license renewal application...is approved." Senate Bill 1406 was signed by Governor Schwarzenegger on September 26, 2008, and enacted into law effective January 1, 2009.

Finding and declaring that "it is necessary to ensure that the public is adequately protected during the transition to full certification for all licensed optometrists who desire to treat and manage glaucoma patients," the Legislature provided for the appointment of six members – three optometrists and three physicians and surgeons – to GDATAC expert in the diagnosis, treatment, and management of glaucoma patients, as follows:

- "(1) Two members shall be optometrists who were certified by the board to treat glaucoma pursuant to the provisions of subdivision (f) of Section 3041, as that provision read on January 1, 2001, and who are actively managing glaucoma patients in full-time practice.
- (2) One member shall be a glaucoma-certified optometrist currently active in educating optometric students in glaucoma.
- (3) One member shall be a physician and surgeon board-certified in ophthalmology with a specialty or subspecialty in glaucoma who is currently active in educating optometric students in glaucoma.
- (4) Two members shall be physicians and surgeons board-certified in ophthalmology who treat glaucoma patients."

The parties submitted their respective three nominees to the State Board. At its meeting on November 20, 2008, the Board appointed them to GDATAC.

The statute's charge to GDATAC is clear in its priorities, as stated in new Section 3041.10 of the California Business and Professions Code:

- "(d) The committee *shall establish requirements for glaucoma certification*, as authorized by Section 3041, *by recommending both of the following*:
- (1) An appropriate curriculum for case management of patients diagnosed with glaucoma for applicants for certification described in paragraph (4) of subdivision (f) of Section 3041, and
- (2) An appropriate combined curriculum of didactic instruction in the diagnostic, pharmacological, and other treatment and management of glaucoma, and case management of patients diagnosed with glaucoma, for certification described in paragraph (5) of subdivision (f) of Section 3041.

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

The two classes of glaucoma applicants referred to above are described in amendments to Section 3041(f), the subdivision in pre-existing law governing glaucoma certification:

- (4) For licensees who completed a didactic course of not less than 24 hours in the diagnosis, pharmacological, and other treatment and management of glaucoma, submission of proof of satisfactory completion of the case management requirements for certification established by the board pursuant to Section 3041.10.
- (5) For licensees who graduated from an accredited school of optometry on or before May 1, 2008 and not described in paragraph (2), (3), or (4), submission of proof of satisfactory completion of the requirements for certification established by the board pursuant to Section 3014.10.¹

The first class of applicants consists of licensed optometrists who completed a State Board-approved didactic course "of not less than 24 hours in the diagnosis, pharmacological and other treatment and management of glaucoma...developed by an accredited California school of optometry." (Note: any applicant who graduated from an accredited California school of optometry on or after May 1, 2000 was exempted from this requirement.) Applicants in the second class are licensed optometrists who:

- Graduated from an accredited school of optometry prior to May 1, 2008;
- Were not certified to diagnose, treat, and manage glaucoma patients under the provisions in effect between January 1, 2001 and January 1, 2009;
- Will not have exercised the option to become certified under those provisions on or before December 31, 2009; and
- Had not taken the prescribed 24-hour didactic course by January 1, 2009.²

GDATAC met for approximately 18 hours over three days – February 5, February 26, and March 13. The members agreed that, for pre-May 1, 2000 optometric graduates falling into the second class of prospective applicants, requiring an updated 24-hour didactic course approved by the State Board would

meet the didactic curriculum requirement specified in Section 3041.10(d)(2). The members were unable to agree on curriculum requirements for "case management of patients diagnosed with glaucoma."

Finally, the Office of Professional Examination Services (known as the Office of Examination Resources when SB 1406 was enacted) is required to "examine the committee's recommended curriculum requirements to determine whether they will do the following:

- (A) Adequately protect glaucoma patients.
- (B) Ensure that defined applicant optometrists will be certified to treat glaucoma on an appropriate and timely basis.
- (C) Be consistent with the department's and board's examination validation for licensure and occupational analyses policies adopted pursuant to subdivision (b) of Section 139."

This report and its recommendations address and attempt to balance those three requirements. All of the information provided in this report was made available to legislators and their staffs while SB 1406 was under consideration.

STATE BOARD OF OPTOMETRY

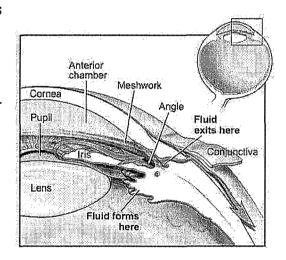
Glaucoma Diagnosis and Treatment Advisory Committee - Optometrist Members

GLAUCOMA DEFINED

In General

From 2001 to 2009, licensed optometrists who met the requirements specified in California Business and Professions Code Sections 3041 generally and 3041.3 and who completed the certification requirements prescribed by Section 3041(f) were certified to diagnose, treat, and manage glaucoma patients independently. By law, treatment was restricted to diagnosed cases of primary open-angle glaucoma in patients over 18 years of age. Patients could be treated by candidates during the two-year patient-management phase of the certification process, under the direct supervision of an ophthalmologist and subject to specific therapeutic restrictions and consultation and referral requirements.

Senate Bill 1406 specifically authorizes certified optometrists to treat primary open-angle glaucoma, exfoliation glaucoma, and pigmentary glaucoma independently, and requires every optometrist to "stabilize, if possible, and immediately refer any patient who has an acute attack of angle closure to an ophthalmologist." The bill repealed the two-year, 50 "newly-diagnosed cases" ophthalmological co-management requirement for independent certification – except for those candidates who elect to complete those requirements by the end of 2009 – and with it all the attendant restrictions on management and treatment. As is discussed in detail in "Glaucoma Certification under SB 929 – A Failed Experiment," ff., the sponsors demonstrated that the former law's case management requirements did not work, largely



because ophthalmologists were either not "geographically appropriate" or willing to co-manage patients with candidate optometrists. Joint supervision also meant that glaucoma patients would have to endure the expense and inconvenience of being seen by two practitioners for the same condition. By agreement among and at the suggestion of the parties – COA, CMA, and CAEPS – the Legislature created a collaborative administrative process to establish appropriate glaucoma certification requirements, beginning with the "appropriate curriculum" recommendations of Glaucoma Diagnosis and Treatment Advisory Committee (GDATAC) and ending with the State Board promulgating regulations adopting the "final findings" of the Office of Professional Examination Services, after its review of GDATAC's reports.

Following are general definitions of the disease state and descriptions of relevant types of glaucomas – primary open-angle, exfoliation syndrome, pigmentary, and angle closure. Other glaucoma classifications may be found in *Appendix B*.

General Definition

In the normal eye, the clear fluid leaves the anterior chamber at the open angle where the cornea and iris meet. When the fluid reaches the angle, it flows through a spongy meshwork, like a drain, and leaves the eye. (*See illustration at right*.) Sometimes, when the fluid reaches the angle, it passes too slowly through the meshwork drain, *Source:* NIH SeniorHealth

(www.nihseniorhealth.gov)

causing the pressure inside the eye to build. If the pressure damages the optic nerve, **open-angle glaucoma** – a progressive disease that painlessly damages the eye's optic nerve and causes vision loss and blindness – may result.

It is the eye's optic nerve that is responsible for carrying the retinal image to the brain so any disruption in this transmission can result in irreversible blind spots or field loss that, over time ,can lead to total blindness. For this reason glaucoma is often referred to as the "silent thief of sight." A view of the optic nerve during a dilated eye exam combined with visual field testing, intraocular pressure testing (IOP), and other tests can often reveal damage at an early stage, thus providing opportunity for treatment.³

Primary Open Angle Glaucoma

Between one and two percent of Americans have Primary Open Angle Glaucoma (POAG), making it the most common form of glaucoma in our country. It is the prevalent form of open-angle glaucoma, one of the two main types of glaucoma – the less prevalent being angle-closure glaucoma. (See below.) POAG occurs mainly in the over-50 age group. (See "Glaucoma – Epidemiology," ff.)

There are no symptoms associated with POAG. The internal pressure in the eye — intraocular pressure, or IOP — slowly rises. If the cornea did swell, which is usually a signal that something is wrong, then it would be symptomatic. But this is not the case; thus, this disease can go undetected without appropriate examination. It is painless, and the patient often does not realize that he or she is slowly losing vision until the later stages of the disease. By the time the vision is impaired, the damage is irreversible.

A cause of increased pressure in the eye is that the fluid does not drain effectively out of the eye through the trabecular meshwork similar to a clogged drain of a sink. In POAG, there is no visible abnormality of the trabecular meshwork. (The trabecular meshwork—the tissue in the eye through which fluid drains—is situated in the angle formed where the cornea and the iris meet.) It is believed that something is wrong in the ability of the cells in the trabecular meshwork to carry out their normal function, or that there may be fewer cells present, as a natural result of the aging process. Some believe it is due to a structural defect of the eye's drainage system. Others believe it is caused by an enzymatic abnomality. These theories, as well as others, are currently being studied and tested at numerous research centers across the country.

Glaucoma pathology leads to death of retinal ganglion cells and axons which occurs as a result of increased intraocular pressure (IOP). The average IOP in a normal population is 14-16 millimeters of mercury (mmHg). In a normal population pressures up to 20 mmHg may be within normal range. A pressure of 22 is considered to be suspicious and possibly abnormal. Not all patients with elevated IOP, however, develop glaucoma-related eye damage. What causes one person to develop damage while another does not is a topic of active research. This increased pressure can ultimately destroy the optic nerve cells. Once a sufficient number of nerve cells are destroyed, 'blind spots' begin to form in the field of vision. These blind spots usually develop first in the peripheral field of vision, the outer sides of the field of vision. In the later stages, the central vision, which we experience as 'seeing,' is affected. Irreversible visual loss occurs because, once the nerve cells are dead, nothing can regenerate them.

POAG is a chronic disease. It may be hereditary. There is no cure for it at present, but the disease can be slowed or arrested by treatment. Since there are no symptoms, many patients find it difficult to understand why lifelong treatment with expensive drugs is necessary, especially when these drugs are

often bothersome to take and have a variety of side effects. Using medications regularly, as prescribed, is crucial to preventing vision-threatening damage.

Pigmentary Glaucoma

Pigmentary glaucoma is a type of inherited open-angle glaucoma which develops more frequently in men than in women. It most often begins in the twenties and thirties, which makes it particularly dangerous to a lifetime of normal vision. Nearsighted patients are more typically afflicted.

The anatomy of the eyes of these patients appears to play a key role in the development of this type of glaucoma. Myopic (nearsighted) eyes have a posterior concavity to the peripheral iris which creates an unusually deep angle. This causes the pigment layer of the eye to rub on the zonules, the supporting structure of the crystalline lens. This rubbing action causes the iris pigment to shed into the aqueous humor and onto neighboring structures, such as the trabecular meshwork. While the exact mechanism is not understood, the pigment may restrict the outflow of aqueous fluid or damage the endothelial cells which are essential to normal drainage.

Miotic therapy is the treatment of choice in these cases, but these drugs in drop form can cause disabling visual blurring and headaches in younger patients. Fortunately, a slow-release form that decreases side effects is available. Laser iridotomy is presently being investigated in the treatment of this disorder.

Exfoliation Syndrome

This common cause of glaucoma is found everywhere in the world, but is most common among people of European descent. In about 10% of the population over age 50, a whitish material, which upon examination looks somewhat like tiny flakes of dandruff, builds up on the lens of the eye. This exfoliation material is rubbed off the lens by movement of the iris and at the same time, pigment is rubbed off the iris. Both pigment and exfoliation material interfere with the normal functioning of the trabecular meshwork, leading to elevated IOP, sometimes to very high levels.

Exfoliation syndrome can lead to both open-angle glaucoma and angle-closure glaucoma, often producing both kinds of glaucoma in the same individual. Not all persons with exfoliation syndrome develop glaucoma. However, if a patient has exfoliation syndrome, his or her chances of developing glaucoma are about six times higher than those who do not have this syndrome. It often appears in one eye long before the other, for unknown reasons. If glaucoma presents in one eye only, exfoliation syndrome is the most likely cause. It can be detected before the glaucoma develops, so that patients can be more carefully observed to minimize chances of vision loss.

Angle Closure Glaucoma

Angle-closure glaucoma affects nearly a half million people in the United States. There is a tendency for this disease to be inherited, and often several members of a family will be afflicted. It is most common among people of Asian descent and people who are far-sighted. People with smaller eyes have a tendency toward angle-closure glaucoma, in which the anterior chamber is crowded or shallow. As mentioned earlier, the trabecular meshwork is situated in the angle formed where the cornea and the iris meet. In most people, this angle is about 45 degrees. The narrower the angle, the closer the iris is to the

trabecular meshwork. As we age, the lens routinely grows larger. The ability of aqueous humor to pass between the iris and lens on its way to the anterior chamber decreases, causing fluid pressure to build up behind the iris, further narrowing the angle. If the pressure becomes sufficiently high, the iris is forced against the trabecular meshwork, blocking drainage, similar to putting a stopper in a sink. When this space becomes completely blocked, an angle-closure glaucoma attack (acute glaucoma) results.⁴

GLAUCOMA – EPIDEMIOLOGY

Prevalence

Age-related eye diseases affect more than 35 million Americans age 40 and older. The most common eye diseases in that age group are macular degeneration, glaucoma, diabetic retinopathy, and cataracts. A longitudinal study that followed Medicare patients found that after nine years, almost 50% of survivors had developed glaucoma, cataracts, or macular degeneration. 6

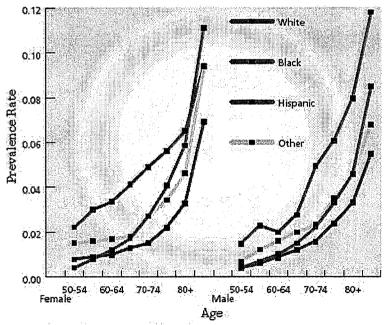
Glaucoma is the second-leading cause of blindness in the United States.⁷ Approximately 120,000 people have gone blind because of glaucoma -- 9-12% of all cases of blindness in the U.S.⁸ Three quarters of Americans who are legally blind from glaucoma are over 65.⁹

Glaucoma affects one in 200 people aged 50 and younger. The rate increases to 1 in 10 for individuals over the age of 80. In 2002, an estimated 2.2 million Americans aged 40 and older had open-angle glaucoma – 1.9% of the population 40 and older and 7.7% of those 80 and over, or about 711,000 Americans. That number is expected to grow by 50% to 3.36 million by 2020. Half of those with glaucoma are not aware that they have the disease. In

Populations

Figure 1.

Estimated Specific Prevalence Rates for Open-Angle Glaucoma



Friedman et al. 2002, Vision Problems in the U.S.

Open-angle glaucoma occurs about five times more often in African-Americans, and blindness from glaucoma is about six times more common. In addition to this higher frequency, glaucoma often occurs earlier in life in African-Americans—on average, about 10 years earlier than in other ethnic populations. ¹² It has been estimated that making prescription eye drops available could delay or prevent glaucoma-caused loss of vision in at least half of that population's cases. ¹³

Recent studies indicate that the risk for Hispanic populations is greater than those of predominantly European ancestry, and that the risk increases among Hispanics over age 60.¹⁴ Glaucoma is one of the leading causes of blindness among age-related eye diseases in Latinos, accounting for 28.6% of cases of blindness.¹⁵ Of the study participants in the Los Angeles Latino Eye Study (LALES) who had openangle glaucoma, 75% were previously undiagnosed.¹⁶ (See Figure 1.)

Figure 2.

CALIFORNIA POPULATION 2005, BY RACE/ETHNICITY

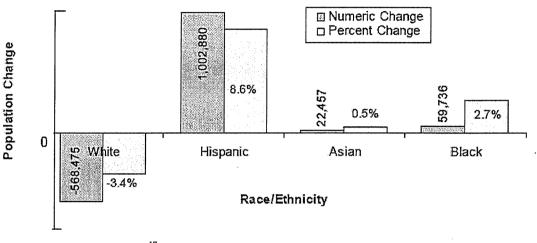
Race/Ethnicity	Number	Percent
White	15,915,737	44.4%
Hispanic	12,664,639	35.3%
Asian	4,121,895	11.5%
Black	2,252,215	6.3%
American Indian	106,095	0.3%
Hawaiian/Pacific Islander	163,466	0.5%
Two or More	625,753	1.7%
Total*	35,849,801	100.0%

Source: CA Dep't. Finance.

Figure 2 portrays California's total population as of March 2005, broken down by race and ethnicity, as estimated by the State Department of Finance in August 2006. Of the total, 26,563,992 (74.0%) are under the age of 50 and 9,285,809 (25.9%) are older than that. Persons of all races and ethnicities over age 65 are 10.8% (N=3,882,988) of the total population. Extrapolating from the results of the Friedman, et al. 2002 study, above:

- Glaucoma affected an estimated 132,820 Californians of all races and ages under the age of 50 in 2005
- Assuming a prevalence factor of 2.0% for all races and ethnic groups, 108,056 Californians between 50 and 65 had open-angle glaucoma.
- Assuming a prevalence factor of 5.0% for all races and ethnic groups, 194,149 Californians aged 65 and over had open-angle glaucoma.
- More than 30,000 cases of blindness in California will be caused by glaucoma.
- African-American Californians over the age of 50 accounted for at least 32,234 potential diagnoses of open-angle glaucoma in 2005.
- Assuming a slightly higher risk factor that Whites, 72,417 Latinos were diagnosable, and at least 20,000 of that number will result in blindness.

• Conservatively, more than 435,000 Californians with glaucoma are unaware they have it.



Source: CA Dep't. Finance¹⁷:

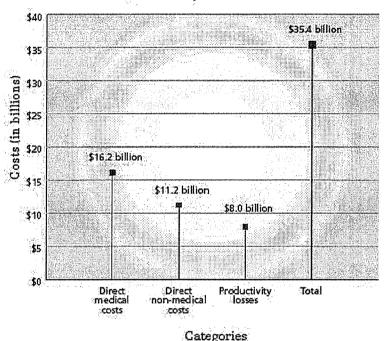
Figure 3 summarizes population changes in California from 2004 to 2005 among the major ethnic groups surveyed by the California Department of Finance. It's noteworthy that growth was significant in ethnic populations at significantly higher risk for glaucoma and blindness, particularly Latinos. In 2007, the Department projected that the state's population will reach 39,135,676 by 2010 – 9.1% in five years. The Latino segment is expected to grow by 14.6% to 14,512,817 over that period, to constitute 37.1% of the total population. African-Americans are projected to grow by 3.1% to make up 5.8% of California's total population, at 2,287,190. 18

Economic Burden and Utilization Costs

The annual burden to the U.S. economy in 2001 of age-related macular degeneration (AMD), cataract, diabetic retinopathy, glaucoma, refractive errors, visual impairment, and blindness in adults age 40 and older was estimated at \$35.4 billion-- \$16.2 billion in direct medical costs, \$11.2 billion in other direct costs, and \$8 billion in lost productivity. (See Figure 4.) The annual direct medical costs (including outpatient, inpatient, and prescription drug services) for Americans age 40 and older with glaucoma was \$2.86 billion. 19

Figure 4.

Annual Total Burden to the U.S. Economy of AMD, Cataract, Diabetic Retinopathy, Glaucoma, Refractive Errors, Visual Impairment and Blindness



Rein at al. 2006, The Economic Burden of Major Adult Visual Disorders in the United States

A study of glaucoma patients found that compared with control subjects, they were over three times more likely to have fallen in the previous year, over six times more likely to have been involved in one or more motor vehicle collisions in the previous five years, and more likely to have been at fault in the collision.²⁰

In 2004:

- The average cost per glaucoma patient age 40 to 64 using inpatient services was \$2,270; the average cost per patient 65 years and older for the same services was \$4,929.
- The average cost per glaucoma patient age 40 to 64 using outpatient services was \$276; for patients 54 years and older, the average cost was \$254.
- The average cost in 2004 per glaucoma patient age 40 to 64 using medications and vitamins was \$806.²¹

The average direct cost of glaucoma treatment ranges from \$623 per year for patients with early-stage glaucoma, to \$2,511 per year for end-stage patients. Because the resource use and direct cost of glaucoma treatment and management increases as the disease severity worsens, a glaucoma treatment that delays the disease progression could significantly reduce its economic burden. Medication costs make up the largest proportion of the total direct costs for all stages of the disease.²²

Utilization

In 2001, approximately 2.9 million glaucoma patients visited physicians or hospitals for treatment of their disease and approximately 5.6 million prescriptions were filled for glaucoma patients.²³ Glaucoma now accounts for more than 7 million physician visits each year.²⁴.

Early Diagnosis and Treatment Benefits

A patient diagnosed in early-stage glaucoma can be managed more cost effectively using medical therapy. Treatment costs for a patient with early-stage glaucoma are about \$2,000 less than those of a patient diagnosed with a later stage of the disease. The NEI-sponsored Ocular Hypertensive Treatment Study (OHTS) found that lowering intraocular pressure (IOP) by at least 20% produced a 50% protective benefit for individuals who had an elevated IOP but no optic, disc or visual field deterioration. description of the disease of the disease of the NEI-sponsored Ocular Hypertensive Treatment Study (OHTS) found that lowering intraocular pressure (IOP) by at least 20% produced a 50% protective benefit for individuals who had an elevated IOP but no optic, disc or visual field deterioration.

Treatment Options

Intraocular pressure (IOP) can be lowered by administration of medications, or by laser, drainage, or cyclodestructive surgery, either alone or in combination. In many instances, topical medications constitute effective initial therapy. Prostaglandin analogs and beta adrenergic antagonists are the most frequently used eye drops for lowering IOP in patients with glaucoma. Agents less frequently used include alpha adrenergic agonists, topical and oral carbonic anhydrase inhibitors, and parasympathomimetics. As with all surgical interventions, surgery to arrest or reverse vision loss due to glaucoma has inherent risks. For example, in one study sponsored by the National Eye Institute, trabeculectomy, a surgical procedure to relieve pressure in the eyes of glaucoma patients where other treatments have not been effective, was found to increase the risk of cataract formation by 78%.²⁷

THE OPTOMETRIC STANDARD OF PRACTICE: PRIMARY OPEN-ANGLE GLAUCOMA

Introduction

The effective management of glaucoma represents a paradigm shift from the treatment of most ophthalmic disorders. Most non-glaucomatous conditions that optometrists manage are treated with a short course of medication. Similarly, angle closure is the only type of glaucoma that is "cured" with short-term treatment, such as surgery. Absent this exception, glaucoma therapy is long-term, because chronic glaucoma has no "cure."

It's impossible to address the broad disease state of glaucoma in all its variations in this context. Following is an outline of the methodology and goals a licensed optometrist would employ to diagnose, treate, and manage a case of the most prevalent type of glaucoma, primary open-angle glaucoma (POAG).

Diagnosis

The first step in properly diagnosing POAG in a patient with elevated intraocular pressure (IOP) is to determine the status of the anterior chamber angle. Once it has been established that the angle is open, the focus of the examination is redirected to identifying the etiology of the elevated IOP:

- Is there pigment in the angle or exfoliative material on the anterior capsule of the lens?
- Does the patient have a history of topical or oral steroid treatment?
- Has there been a history of recurrent Herpes Simplex in the affected eye?
- Has there been a history of ocular trauma?
- Does the patient have a history of sleep apnea or peripheral vasculopathy?

All of these could be an etiology for a secondary glaucoma. Only after determining that the anterior chamber is open and the cause for the abnormal IOP is not due to an extrinsic event or condition, should the clinician conclude that the patient has POAG.

Management

POAG may be managed with appropriate treatment and realistic goals. The ideal outcome for the treatment of POAG is to maintain useful sight for the lifetime of the patient. To achieve this outcome, the astute practitioner sets a target intraocular pressure that, if maintained, will likely preserve the patient's sight. Wide clinical variability exists in setting target pressure goals, given the many factors that must be considered:

- Will the progression of this degenerative disease occur gradually, or will the patient's disease advance quickly?
- Will the patient acquire systemic conditions that contribute to the rate of progression?
- Studies have shown that lowering intraocular pressure increases the likelihood of preserving vision. ²⁸ Therefore, should the initial therapy be an aggressive attempt to reduce the intraocular

pressure as low as possible, or simply an attempt to achieve a pressure within normal range of the general population?

- How does the patient's age factor into the determination of an appropriate target pressure?
- Finally, and perhaps most important, how much glaucomatous damage has the patient sustained?

All of these issues play a role in establishing an appropriate target IOP. Establishing a target IOP is based on the clinician's judgment rather than any "hard and fast" set of rules. For this reason, there is rarely a "wrong" target pressure. The target IOP is an educated estimate of what IOP should be to prevent or slow additional glaucomatous damage. The validity of this target or goal is determined over time by evaluating any changes in the appearance of the optic nerve, the nerve fiber layer, and visual field in the months and years following the initial diagnosis. If additional damage occurs while the patient has been at or below the target IOP, the clinician should set a new, lower target pressure. As such, the target IOP should always be subject to thoughtful modification.

Measuring IOP

In an effort to preserve ocular structure and function, the initial goal of glaucoma therapy is to reduce the IOP. Without a clearly documented target pressure, the clinician has no goal or measurable standard to judge the effectiveness of the glaucoma therapy.

IOP measurement has been the foundation in the diagnosis of glaucoma. At one time, the diagnosis of glaucoma was based almost entirely on IOP. If the IOP was statistically elevated (2 standard deviations above the mean of the general population), the patient was given the diagnosis of glaucoma and started on life-long therapy. However, clinicians have become more sophisticated in their physical examination skills and their ability to assess psychophysical aspects of vision (i.e. visual field assessment) has improved. Less significance is now placed solely on the patient's IOP. The declining relative value of using tonometry alone to diagnose glaucoma has been further justified by the observation that some patients with statistically elevated IOP (who were untreated) did not exhibit the classic physical changes associated with glaucoma. Conversely, there have been patients that had signs of glaucoma in the absence of an elevated IOP. It was during this period of "enlightenment" in glaucoma treatment history, that clinicians became less inclined to treat patients based solely on an elevated IOP. As a result, therapy was often delayed until there were other indications of associated damage.

In 2002, the Ocular Hypertensive Treatment Study (OHTS) released findings that had a major influence on contemporary glaucoma therapy. This study found that treatment of ocular hypertension (IOP > 24 mm Hg) resulted in a 50% reduction in the risk of developing glaucoma. This finding partially reestablished the importance of tonometry in the diagnosis of glaucoma. The OHTS also revealed some other important information about the IOP.²⁹ Central corneal thickness (CCT) was shown to be a risk factor in the diagnosis of glaucoma. From the OHTS, we know that the CCT must be measured by pachymetry for the true value of the tonometric readings to be revealed. This is because most tonometers are calibrated for an average corneal thickness. Pachymetry must be measured for the "true" IOP to be known.³⁰

An IOP measurement in a patient with a thin cornea will be an underestimation of true pressure. This is evident in patients that have CCT reduction after LASIK surgery. Conversely, a slightly elevated IOP is less significant if it is measured in an eye with a thick cornea. However, even with a CCT modified eye

pressure, the IOP is still of limited diagnostic importance as an isolated finding. While a diurnal tonometric series improves our ability to model the patient's IOP, the practitioner's sense of the true eye pressure is limited to a handful of measurements per year.

Contemporary glaucoma diagnosis takes into account all of a patient's risk factors for this disease:

- > Is there a family history of glaucoma?
- ➤ How old is the patient?
- ➤ How high is the IOP?
- ➤ What is the CCT/IOP?
- > Is the standard perimetric visual field normal?
- > What is the appearance of the optic nerve?
- ➤ What do the new technologies tell us about the patient's anatomy?

Each of these factors influences the patient's risk for glaucoma. Epidemiologists and clinicians have collaborated to create a quantitative risk assessment calculator that predicts the likelihood that a patient has or will likely develop glaucoma. While tools like this are useful, the best analysis of a patient's predisposition is made by a knowledgeable and thoughtful practitioner seated next to the patient in the examination room.

The Optic Nerve Head

In contrast to the easily measured and quantifiable IOP, careful examination of the optic nerve head (ONH) has a much higher sensitivity and specificity than a single tonometric value. In fact, the evaluation of the ONH has been shown to be highly predictive of glaucoma.³¹

The classic approach has been to estimate the cup to disc (C/D) ratio. The integrity of this estimation is predicated on accurately determining the borders of the ONH and the cup contour. While the standard continues to be a horizontal and vertical cup-to-disc ratio, these two values may not tell the entire ONH story.

Consider the following two examples.

- A large (1.75 mm) healthy ONH with a 0.70 C/D ratio has a neural rim area of 1.23 mm2. In comparison, a small (1.25 mm) ONH with a 0.4 C/D would have a neural rim area of 1.03 mm2. The smaller nerve has almost 25% fewer ganglion cells, which is very suggestive of pathology.
- The ONH of the right eye has a focal notch at 8 o'clock. Vertical and horizontal C/D ratio may lead the clinician to miss the notch, because the examination focused on the 12-6 and 3-9 meridians.

It is therefore important to assess neural rim thickness rather than relying on C/D ratio alone. Attention should be given to localizing the thinnest rim width. A recently popularized clinical approach has proven to be useful in analyzing the ONH for glaucoma.

The "ISNT Rule"

In spite of the variation in ONH appearance, glaucoma specialists have been able to conclude that the normal optic nerve head should have a particular configuration. From this observation, experts were able to create a simple and systematic approach that facilitates OHN evaluation. This approach, called the "ISNT rule," suggests that a normal, healthy ONH will have an —

- > Inferior neural rim that is thicker than the
- > Superior neural rim, which is thicker than the
- Nasal neural rim, which is in turn thicker than the
- > Temporal neural rim.

An ONH that does not follow the ISNT rule is indicative of risk – perhaps even high risk – of POAG.³² This examination is easy to perform at the slit-lamp with a high-plus non-contact condensing lens. While the ISNT rule is a significant aid in the ONH analysis, most experts continue to rely on stereo ONH photographs as the "gold standard" in glaucoma diagnosis.

Visual Fields

The value of a threshold visual field (VF) study in the diagnosis of early glaucoma has been debated in the literature. Some authorities have suggested that, because of redundancy of the ganglion cells of the retina, up to 50% of the nerve fiber layer would need to be lost from glaucoma before a clinically significant VF defect could be detected. While that may have been true of early threshold VF, the instruments used in contemporary practice are much more sensitive in detecting visual loss from glaucoma. Total and pattern deviation plots give the clinician the ability to differentiate between a reduction in sensitivity and a true scotoma. Further refinements include algorithms that allow a threshold VF study to be conducted in less than seven minutes. Finally, current innovations include robust statistical tools that are capable of delineating glaucoma progression.

Some new VF instruments utilize a non-traditional stimulus such as sinusoidal wave gratings. Unlike traditional VFs, the stimulus used by these new instruments stimulates only a subset of retinal ganglion cells. The supposition is that this special type of ganglion cells, which comprises only a fraction of the total nerve fiber layer (NFL), is either preferentially damaged in glaucoma or has less redundancy in the NFL. If this is true, glaucoma may be detected earlier by this form of psychophysical testing than with traditional white on white (WOW) VFs.

While this new type of VF may have the advantage of early detection, the standard of care for reevaluation of a patient with glaucoma remains the traditional WOW threshold VF. Regardless of the instrument used to evaluate a patient, proper documentation is critical. Good clinical technique requires that a logical analysis of visual field study be conducted. The first part of the analysis should summarize what kind of study was conducted, its reliability, and the parameters used in the study. The second part is to describe the type and severity of any findings disclosed in the study. In terms of patient care, there are two additional steps. The next step is to use the information from the study to reach a diagnosis or modify a diagnosis (e.g.: "glaucoma suspect" if there is no defect, or "conversion to POAG" if the patient has a previously undisclosed scotoma). The final step is to describe how the VF study will contribute to the overall plan for this patient. This could be as simple as, "repeat visual field in six months" or as significant as "start medical therapy."

Gonioscopy

Although a POAG diagnosis is predicated on an open anterior chamber angle, the responsible clinician should perform gonioscopy and grade the anterior chamber angle on an annual basis.

Emerging Technology

The importance of changes in diagnostic technology is increasing. The past decade has seen a period of rapid advances that have brought about a renaissance in glaucoma diagnosis and management. Scanning lasers and polarimeters are able to measure the peripapillary nerve fiber layer in detail. New instruments are capable of digitizing the ONH. All of these instruments hold the promise of earlier glaucoma detection than through the use of physical examination and psychophysical testing alone. Instruments such as optical coherence tomography (OCT) have become an integral part of glaucoma care. Just as with visual fields studies, though, the output from these technologies must be analyzed with the same four-step ISNT process.

Appropriate Therapy

Although some studies have shown benefit to surgery as initial therapy,^{33 34} medical treatment remains the clinical standard of care in the United States. Choosing the best drug or combination of drugs that achieve a target IOP remains as much art as science.

Maintaining Aqueous Humor

Aqueous humor has two main functions within the eye:

- Helping to supply nutrients to the crystalline lens, iris, and posterior corneal surface; and
- Removing toxins from within the eye.

It is undesirable to control the IOP by reducing aqueous formation, because the aqueous humor modulates an essential process for normal intraocular health. Yet, with the exception of pilocarpine, this is how glaucoma had been treated until relatively recently. In the last decade clinicians have benefitted from a new class of medications that are very effective in reducing IOP by increasing aqueous outflow. This family of drugs consists of synthetic prostaglandins or prostamides. They stimulate receptors in the uveal-scleral anatomy, which enhances the outflow of aqueous via this pathway. There are two aqueous outflow pathways. The trabecular or conventional pathway accounts for about 80% of outflow and the remaining 20% occurs via the uveal-scleral, or non-conventional, pathway. Most experts agree that POAG is a function of a failing trabecular outflow pathway. By enhancing the effectiveness of the uvealscleral pathway, these anti-glaucoma agents can cause a significant reduction in the IOP of most patients. The medicines in this group include 0.005% Latanoprost (Xalatan®), 0.004% Travaprost (Travatan Z®), and 0.03% Bimatoprost (Lumigan®), all of which are approved for once per day dosing at bedtime. In addition to their convenience, each of these medicines has been shown to blunt diurnal pressure spikes. This is important because some experts suspect that spikes in the IOP may be the etiology of disease progression in patients with otherwise well "controlled" IOP. Caution is also advised when a patient has cystoid macular edema. These medications have become widely prescribed because they have so few contraindications or side effects, and because they are very effective in reducing the

IOP. Most experts agree that a 25-30% reduction in IOP should occur in the first 30 days of using these medications.

Patient Noncompliance

With any prescriptive therapy for chronic disease there is the risk of non-compliance. Patients must be made to understand the consequences of incomplete therapy and in the absence of immediate symptoms, realize that they play a major role in the short and long term success of their therapy. Because patients can also mask their treatment behavior, it is important to have an ongoing discussion about compliance. The patient needs to know that not taking the medicine might lead his or her doctor to consider changing medications or adding a second drug, both of which might be unnecessary if the current treatment was followed.

Careful Re-evaluation

Glaucoma patients should be carefully evaluated at every encounter:

- ➤ Has the visual field changed?
- > Did the neural rim become thinner?
- > Is there a change in the optical coherence tomography?
- > Is the patient using the prescribed medicine appropriately?
- ➤ Is there tachyphylaxis to the medicine?
- ➤ Is the target IOP low enough?
- > Should another medicine be added or are the results satisfactory enough to check the IOP again in three months?
- > Is the monitoring schedule adequate?

Other Caveats

Important clinical considerations that should be borne in mind when managing patients diagnosed with POAG are:

- Never use two medications from the same class of drugs at the same time. While all glaucoma medications are intended to lower the IOP, they do so by different actions. Using two medications that block the beta-receptors of the ciliary body or two prostaglandin analogs will likely be no more effective than the single agent and increases the likelihood of side effects.
- Don't underestimate the value of a monocular treatment trial. This well-proven clinical technique is used when evaluating the effectiveness of a medication. In its traditional form, a medication is started in the eye with the most advanced glaucoma. After an appropriate treatment period with the new medicine, the patient is re-evaluated and IOP in the eye with the new medication is compared to the fellow eye. This approach can help control for non-medication related fluctuations in IOP, such as the diurnal variation. Monocular treatment trials can also be performed in reverse to determine the contribution of a medicine that the patient has previously been using. Simply document the treated IOP, discontinue the medicine in question in one eye, and then re-evaluate the IOP. A significant increase in the IOP of the eye where the drug in question was discontinued is an indication that this treatment was still effective. Little or no change in the treated IOP suggests that the drug being evaluated was not contributing much to

the overall treatment profile. By demonstrating little effect, one can discontinue a therapy that would be a waste of both time and money. It would be inappropriate patient care to add a medication without knowing that the current treatment is effective in lowering the IOP. Although the monocular trial is critical in determining the effect of a glaucoma medication, it has one caveat. Some glaucoma medications are absorbed systemically and can reach the contralateral eye. While this is not as significant as directly applying the medication to the eye, this cross-over can mask some of the therapeutic effect.

Never start two medications at the same time. This is particularly true with the combination medications that are made up of two drugs. Always evaluate each drug independently. Only when it's certain that the IOP is responsive to each of the individual drugs should consideration be given to the convenience and improvement in compliance of a combination medication.³⁵

TESTING OF GLAUCOMA EDUCATION FOR NATIONAL LICENSURE – THE NATIONAL BOARD OF EXAMINERS IN OPTOMETRY

The ophthalmological members of the Advisory Committee made it their overarching priority in our deliberations to examine in detail the training, including patient encounters, and clinical externships or residencies that California optometric students receive. (That issue is discussed briefly elsewhere in this report.) Inasmuch as the Legislature decided that students graduating on and after May 1, 2008 are sufficiently trained to diagnose, treat, and manage glaucoma patients independently upon passage of their prescribed examinations – as has long been the case for medicine and dentistry – it seems to us more instructive to look at what all optometry graduates are tested on before they can be licensed. (Presumably, California will continue to receive applications from graduates who have studied in other states.)

To be eligible to practice optometry in California or any of the other 50 states or the District of Columbia, a candidate must have graduated from an accredited school of optometry and must have passed an examination administered by the National Board of Examiners in Optometry (NBEO – www.optometry.org).

NBEO was established in 1951 as a private, nonprofit 501(c)(3) organization that develops, administers, and scores examinations, and reports the results, that state regulatory boards utilize in licensing optometrists to practice eye care. Licensure is a regulatory function designed to protect the public in the competent provision of health care. NBEO was the first national board among the doctoral level health professions to eliminate grading on a curve, and one of the few national boards in any profession with a repertoire of examinations that includes conventional multiple-choice tests, a computer-based test, a clinical skills test with live patients, and an advanced competence examination.

All 50 states, the District of Columbia, and Puerto Rico require Parts I and II, and 47 states – including California – plus the District of Columbia and Puerto Rico require Part III. Also, 43 states plus the District of Columbia require the Treatment and Management of Ocular Disease (TMOD) examination as one step toward therapeutic privileges.

NBEO has had several forms, but the last 29 years have been the most significant for the modern practice of optometry because it was in 1980 that the Board shifted to an objective-style examination, which was criterion-referenced and content-outline driven. Since that time, the NBEO has striven to keep the content outline consistent with the contemporary practice of optometry. This has involved subtle annual changes in examination content and periodic major shifts in content. Those major shifts occurred –

- In 1984, with the addition of Treatment and Management of Ocular Disease (TMOD);
- In 1986 with the expansion of Parts I and II;
- In 1991 with the addition of Clinical Skills Examination (CSE) and Visual Recognition and Interpretation of Clinical Signs (VRICS);
- In 1992, when TMOD was imbedded in Part II;
- In 1993 with the addition of Patient Management of Problems (PMP) to CSE and VRICS to form Part III; and

• In 2000 with the merger of PMP and VRICS into one examination, which formed Patient Assessment and Management (PAM) which – along with CSE – now constitutes Part III.

Testing Ocular Disease Management

To give a sharper historical perspective, consider one examination: TMOD. Though all the examinations that now constitute the NBEO exam in its entirety have content that is directly related to the diagnosis and management of glaucoma, TMOD has direct relevance. At the inception of testing in the mid-1980s, the NBEO had been testing the treatment of glaucoma in Part II ocular pharmacology; the addition of TMOD gave added emphasis to testing glaucoma. Over the ensuing years the content outline has evolved to further evaluate candidates' ability to not only diagnose, but also to treat and manage glaucoma cases.

Patient Case Management

As standards of practice in optometry continued to evolve, another watershed change was the introduction of examining patient management practices with PMP in 1993 and its development since. This examination evaluates the candidates' clinical decision making skills using five cases and a case history. Candidates needed to obtain relevant clinical findings, render a diagnosis, and develop a treatment and follow-up plan based upon the patient's prognosis. This was done with latent image processing and initially involved a booklet that was lengthy and difficult to manage for the candidate. In the late 1990s, NBEO began investigating ways to test more cases, to decrease the paperwork involved in PMPs and to merge the VRICS examination into one examination. In 2000, PAM was inaugurated. This examination combines clinical scenarios, images, and multiple-choice items on one examination that presents 40 cases with three or four questions per case. Again – as is the case with PMPs, PAM is designed to assess the candidate's clinical decision-making skills. The ability to assess the candidates diagnostic and management skills has been greatly expanded both in depth and breadth with PAM.

More to the point in glaucoma, now the licensure candidate must demonstrate in real time the use of Intraocular Pressure (IOP); gonioscopy; scanning laser ophthalmoscopy; and fundus photographic and visual field analysis to successfully diagnosis and manage cases of primary and secondary glaucoma to become licensed.

NBEO's examination is scheduled to next be updated in 2010. In summary, the current three-part NBEO examination, which has been administered since 2006, tests glaucoma and related skills in the following areas:

PART I – BASIC SCIENCE

* * * * *

B. Ocular/Visual Biology-90 Items (21%) "Ocular/Visual Biology" tests the fundamental knowledge and scientific principles that support the application of these principles in the prevention, diagnosis, treatment and management of ocular diseases and traumatic conditions that can present to the optometrist by patients seeking primary eye care. It is composed of four major subdivisions:

Anatomy of the Eye, Ocular Adnexa, and Visual Pathway; Ocular and Visual Pathway Development; Ocular Physiology/Neurophysiology; Ocular Pharmacology.

* * * * *

4. Ocular Pharmacology (13-21 Items)*

* * * * *

- C. Antiglaucoma drugs
 - 1. Parasympathetic agonists
 - 2. Sympathetic agonists
 - 3. Sympathetic antagonists
 - 4. Carbonic anhydrase inhibitors
 - 5. Prostaglandins and analogues
 - 6. Serotonin antagonists

PART II - CLINICAL SCIENCE

* * * * *

B. Ocular Disease/Trauma - 180 Items (41%) "Ocular disease/trauma" applies the knowledge of Basic Science to the prevention, diagnosis, treatment and management of ocular pathologic conditions that can present to the optometrist by patients seeking primary eye care. It is composed of 7 major subdivisions, each having a common 4-part format (epidemiology, history and symptoms; observation, inspection, recognition of signs, and techniques and skills required; pathophysiology and diagnosis; treatment and management options, and prognosis). Treatment options include the use of both topical and systemic medications for ocular disease. A list of the generic/brand name equivalents, containing most but not all of the commonly prescribed medications, is provided on this web site and will also be reproduced in front of the test booklet.

* * * * *

3. Glaucoma (20-30 Items)

- A. Epidemiology, history and symptom inventory
- B. Observation, inspection, recognition of signs, and techniques and skills
- C. Pathophysiology and diagnosis
- D. Treatment and management options, and prognosis

PART III - PATIENT CARE

Part III, unlike the Basic Science and Clinical Science examinations, which assess cognitive skill (i.e., knowledge), assesses a candidate's ability to examine actual patients, evaluate actual clinical data, and render patient care decisions. This multifaceted examination consists of two administratively distinct sections and formats: a five-station Clinical Skills performance (i.e. practical) test, and a written test in Patient Assessment and Management (PAM).

In the Clinical Skills section, the candidate examines a patient at each of 5 stations in the performance of 19 clinical skills. Although this section measures primarily psychomotor skills, it contains an assessment of affective (i.e., clinical habits and attitudes) and communication skills, as well as some interpretation of clinical findings. This test section is administered in one 3.5 hour session; however, because of the limited number of candidates who may be examined per session, multiple sessions are scheduled.

The Patient Assessment and Management (PAM) section consists of 40 abridged patient scenarios, each of which is followed by three multiple-choice items. Each item, which contains as many as ten options, focuses on resolving assessment and management such as diagnosis, interpretation and correlation of clinical data, treatment, follow-up, prognosis, and patient education. The Clinical Skills section accounts for 60% of the Part III score, while the PAM section accounts for 40%.

Student candidates are permitted to take Part III (both sections) just before they graduate from a COE accredited institution. However, an individual candidate's official score report containing Part III scores will not be released until the National Board has received official notification that the candidate has graduated. Also, no official score reports containing Part III scores will be released to any candidate until the dates for Release of Score Reports. If the National Board has not received written notification of a candidate's graduation from his/her school or college by March 1st of the year following the test administration, the candidate's Part III scores will be nullified. Candidates are required to take both sections (i.e., Clinical Skills and PAM) in one administration (i.e., spring or fall). However, candidates who have previously passed Part III may take either individual section alone at their own discretion if they wish to improve a prior score.

A. Clinical Skills - Practical Exam with 5 Stations and 19 skills (60%)

Station 1:

- 1. Case History/Patient Communication
- 2. Near Cover Test Evaluation
- 3. Pupil Testing
- 4. Extraocular Motility Evaluation
- 5. Blood Pressure Measurement

Station 2:

- 6. Biomicroscopy
- 7. Goldmann Applanation Tonometry
- 8. Gonioscopy
- 9. Collagen Implant Insertion and Removal Station

Station 3:

- 10. Retinoscopy
- 11. Distance Subjective Refraction
- 12. Accommodation Testing
- 13. Heterophoria and Vergence Testing at Near

Station 4:

- 14. Patient Communication/Education and Prescription Writing in Ocular Disease Management
- 15. Ophthalmic Materials Evaluation

Station 5:

- 16. Binocular Indirect Ophthalmoscopy
- 17. Non-Contact Fundus Lens Evaluation
- 18. Soft Contact Lens Insertion, Evaluation, and Removal
- 19. Rigid Gas Permeable Contact Lens Insertion, Evaluation, and Removal

B. Patient Assessment and Management Exam (PAM) - 40 Patient Scenarios (40%)

- 1. Ocular Disease/Trauma Diagnosis, Data Interpretation, Clinical Correlation
- 2. Ocular Disease/Trauma Treatment, Pathophysiology/Etiology, Follow-Up, Prognosis
- 3. Refractive/Functional Conditions Diagnosis, Data Interpretation, Clinical Correlation
- 4. Refractive/Functional Conditions Treatment, Pathophysiology/Etiology, Follow-Up, Prognosis

TMOD® - TREATMENT AND MANAGEMENT OF OCULAR DISEASE

The Treatment and Management of Ocular Disease (TMOD) examination is endorsed by the Association of Regulatory Boards of Optometry (ARBO). This 150-item examination primarily assesses the candidate's knowledge regarding the appropriate use of medications to treat and manage eye diseases as defined by the broadest scope of current optometric practice statutes. The specific test items relate to ocular conditions for which expanded responsibilities allow optometric therapeutic management.

The TMOD examination focuses primarily on the administration of prescription drugs. However, some items include the use of over-the-counter medications, and other items involve non-pharmacologic interventions. In addition, some items may test the candidate's knowledge of whether additional diagnostic data are needed before initiating treatment. These additional considerations are part of optometrists' responsibilities where the scope of practice has been expanded.

The majority of questions on the TMOD examination are presented in a "case scenario" format. The candidate is given a patient's signs and/or symptoms along with any pertinent clinical data and patient history information, and is asked to make a treatment/management decision regarding the patient.

The candidate must form a diagnosis to determine the patient's proper treatment/management. An understanding of systemic conditions that have a clinical correlation to ocular signs and symptoms and an understanding of systemic conditions/medications that may contraindicate certain ocular therapies are integral to the therapeutic management of ocular disease. Therefore, up to 30% of the items on the TMOD examination may include systemic considerations to reflect these clinical interrelationships. However, items on the TMOD examination do not test directly the pathophysiology or treatment of specific systemic diseases.

The TMOD test is composed of two sets of categorical breakdowns. The first breakdown consists of 13 major anatomical subdivisions of the eye and adnexa. The second breakdown represents five areas of clinical application. Each test item is classified within an anatomical subdivision and a clinical application category. Each category contains numbers in parentheses that indicate the range of items (minimum and maximum) that will appear on the examination. These ranges are included to inform candidates of the relative emphasis placed on each anatomical subdivision and clinical application.

The percentage indicated is for the number represented by the mid-point of the range.

Student Candidates for Part II (Clinical Science)

The Part II (Clinical Science) examination includes a subtest equivalent to the Treatment and Management of Ocular Disease (TMOD) examination. The TMOD subtest contains 90 items embedded within the Ocular Disease/Trauma Section of Part II (Clinical Science). A candidate who passes the TMOD examination embedded within Clinical Science does not need to take the stand-alone TMOD examination unless specifically required by the state board(s) of the state(s) to which the candidate plans to apply for licensure. Candidates who pass Part II (Clinical Science) but do not receive a scaled score at or above 75 on the TMOD subtest will be eligible to take the TMOD stand-alone examination at a later date. Candidates who fail Part II (Clinical Science) must repeat the entire Part to achieve a passing status for the Part. Candidates who fail Part II (Clinical Science) but who attain a scaled score at or above 75 on the TMOD subtest will retain a passing score for the TMOD examination.

		TMOD Cor	ntent Outline			
Content Area	# of Items	% of Questions	Clinical Application	# of Items	% of Questions	
1. Orbit, Adnexa, Lacrimal System	27-39	22	A. Section of treatment/management, including systemic considerations	80-100	60	
2. Cornea/External Disease	46-60	35	B. Dose, form, schedule, and duration of treatment	5-15		
3. Glaucoma	22-32	18	C. Contraindications and side effects of medication, including	15-25	13	
4. Lens/Cataract	5-11	.5	systemic considerations			
5. Uveitis, Sclera/Episclera	12-22	11	D. Follow-up and prognosis, including reassessment of diagnosis after initiating treatment	15-25	13	
6. Retina/Vitreous	4-10	5	E. Treatment and management			
7. Neuro-Ophthalmic Disorders	3-7	3	of ocular emergencies and urgencies	5-15	7	

Source: National Board of Examiners in Optometry.

OPTOMETRIC EDUCATION IN CALIFORNIA

Tables 1 and 2 summarize the glaucoma education and training that students graduating from the University of California – Berkeley's School of Optometry and the Southern California College of Optometry, respectively, in May of 2008 received over four years of postgraduate education. This information was requested of each of the schools by and provided to the State Board staff. While these estimates may be useful for general discussion purposes, as we described in the preceding section we believe the *knowledge and skills* all optometry graduates were and are being tested on as a condition-precedent to becoming licensed in any state are a much better bellwether of what, on paper, recent graduates actually *took* as they enter practice in California.

In the second and third GDATAC meetings, CAEPS' representatives contended that they were "denied" appropriate information on optometric education to assist them in their deliberations. This was predicated on a February 16 email to the Committee's moderator, directing her to obtain for distribution to them the following "from each of the three (3) California optometry schools...[which] we expect to receive one week prior the next meeting:³⁷

- 1. Hours in the curriculum for glaucoma related didactic education, broken out by topic and year of presentation.
- 2. Case management experience in the curriculum for students with glaucoma, showing hours by year of training, numbers of patients, time with each patient and continuity of care for each patient over time."³⁸

The moderator forwarded the message to the deans at the two active schools. The fact that neither the moderator nor the physicians received a written response in the nine days before the next meeting convened was apparently the basis for this continuing assertion. A COA representative in attendance reminded them that on two occasions last year, while SB 1406 meetings were in progress, CAEPS representatives were provided the following:

- March 21, 2008, COA provided all available public information on curricula and training at both schools in hard copy, including prerequisites; course descriptions by title, summary, and year; and summaries of available residencies, clinical rotations, and externships. In addition, a Dean *emeritus* with 40 years' experience and a clinical faculty member/ practitioner with 20 years' experience in accreditation and examination attended to respond to questions about examination and training. One of the CAEPS Advisory Committee members was in attendance.
- On April 4, the Southern California College of Optometry hosted a tour of its academic and clinical facilities and made senior instructional and clinical faculty and staff available for discussion and questioning. Two of the CAEPS Advisory Committee members attended throughout.

From our perspective, we were frustrated by this request and persistent charge. All of us obtained our glaucoma certifications under the old law and one of us is "currently active in educating optometric students in glaucoma," as the statute requires. Since the statute also required one of their nominees to be "board-certified in ophthalmology with a specialty or subspecialty in glaucoma who is currently active in educating optometric students in glaucoma," we thought it reasonable to assume that the basic

GLAUCOMA EDUCATION AT U.C.-BERKELEY SCHOOL OF OPTOMETRY December 2008

Part 1. DIDACTIC INSTRUCTION

First Year of Instruction (32 Hours):

Course	Hours	Торіс
Vision Science 206A	2	Aqueous Production
	2	Aqueous Drainange and Glaucoma
Vision Science 206B	2	Optic Nerve Blood Supply
Vision Science 206C	3	PBL: Open Angle Glaucoma Case
Vision Science 206D	2	Visual Fields: Structure and Function
	2	Optic Nerve: Anatomy and Blood Supply
Optometry 200B	2	Goldmann Tonometry (Lecture)
•	9	Goldmann Tonometry (Laboratory)
	2	Optic Nerve Evaluation (Lecture)
	6	Optic Nerve Evaluation (Laboratory)

Second Year of Instruction (38 Hours):

Course	Hours	Торіс
Optometry 226A	6	Glaucoma Pharmacology
Optometry 236	2	Congenital Ocular Disorders: Glaucoma
Optometry 200C	2	Gonioscopy (Lecture)
	4	Gonioscopy (Laboratory)
	2	Visual Fields (Lecture)
	2	Tonometry (Laboratory)
Optometry 200D	2	Optic Nerve Drawing (Lecture)
. ,	4	Optic Nerve Evaluation (Laboratory)
	2	Visual Fields (Lecture)
	4	Visual Fields (Laboratory)
	2	Tonometry Techniques
	2	Pachymetry (Laboratory)
	4	Gonioscopy (Laboratory)

Third Year of Instruction (12 Hours):

Course	Hours	Торіс
Optometry 246	2	Ocular Emergency: Iris/Lens
Optometry 256	2	Perimetry
•	2	Perimetry
	6	Glaucoma
Optometry 435	1	Angle Evaluation
	4	Gonioscopy (Laboratory)
	1	Laboratory: 4-Mirror Gonioscopy
Optometry 430	2	Glaucoma Seminars

Table 1. (Continued)

GLAUCOMA EDUCATION AT U.C.-BERKELEY SCHOOL OF OPTOMETRY December 2008

ESTIMATED AVERAGE GLAUCOMA PATIENT EXPOSURES¹

Third/Fourth Year Clinic:

Course	Hours	Торіс	
Optometry 430/431	46	In-house Clinics	
	120	External Rotations	
TOTAL DATIENT EYPOSURES		166	

OVERALL ESTIMATED GLAUCOMA EDUCATION:

86* Hours' Didactic Instruction

166** Patient Exposures

^{*} Estimate, based on glaucoma-related course content.

11 Based on patient encounters, from clinic database and logs.

SOUTHERN CALIFORNIA COLLEGE OF OPTOMETRY GLAUCOMA EDUCATION

Glaucoma diagnosis, management, and treatment are covered extensively in the professional curriculum at SCCO. Lecture presentations are complemented with laboratory proficiency experience, grand rounds, and direct patient care.

Glaucoma instruction is integrated into the following courses:

SECOND PROFESSIONAL YEAR

- # 6160 Clinical Methods II Introduction to tonometry and its use in glaucoma diagnosis
- # 6162 Ocular Health Procedures Continued discussion of tonometry (from # 6160) and its use in diagnosis; various forms of tonometry; accuracy issues and new concepts in corneal biomechanical issues affecting tonometry (corneal hysteresis); update on new tonometric techniques – i.e., Pascal DCT, Reichert ORA, etc.
- # 6261 Ocular Health Procedures (Dr. Comer)
- # 6310 Ocular Pharmacology II (Dr. Jankowski)
- # 6361 Ocular Disease Diagnosis and Management I (Dr. Sendrowski)

THIRD PROFESSIONAL YEAR

- # 7161 Ocular Disease Diagnosis and Management II (Dr. Sendrowski)
- # 7162 Ocular Health Assessment Includes threshold perimetry; gonioscopy; serial tonometry and pachymetry for glaucoma diagnosis and management
- # 7360 Ocular Disease Case Management (Dr. Yacoub)
- # 7361 Ocular Health Procedures III (Dr. Jankowski)
- # 6361 Ocular Disease Diagnosis and Management Newer types of perimetry (FDT, Matrix, HEP) and imaging modalities (OCT, GDx, HRT) for glaucoma diagnosis and management. Also included are procedures for glaucoma (SLT, ALT) and surgical management of glaucoma (trabeculectomy, tubes/shunts, canaloplasty, etc.) (Dr. Sendrowski)

After Dr. Comer's experience in his Ocular Disease residency – where he attended all the same basic science courses, seminars, lectures, hospital rounds, and grand rounds that ophthalmology residents were exposed to in the Department of Ophthalmology – his impression was that SCCO's curriculum in glaucoma is far more extensive that the typical ophthalmology resident receives.

resources required to discuss glaucoma education were already in the room when meetings began, and we could focus our attention on designing collaborative didactic and case management curricula for glaucoma education. At the beginning of the first meeting, CAEPS' Executive Vice President gave a 40-minute presentation advocating retention of the 50 patient/two year, preceptored glaucoma certification program that the Legislature had just discarded – presumably with their assent. Their representatives spent most of the rest of the first meeting focused on the Committee's discretionary ability to recommend continuing education for recent graduates, rather than on the law's mandatory charge. In the second meeting, we were gratified that there seemed to be flexibility on their part as to providing both didactic and case management education in group or "grand rounds" style – much as medical residents are trained – and remote instruction, as well. Unfortunately, they returned to a demand for minimum "numbers" of patients over a mandatory period of time for case management, upon which they could not agree internally. Less than two days before the last meeting they distributed another plan to require both case management and continuing education for prospective graduates. prompting Department of Consumer Affairs counsel to advise them that they were exceeding their legislative mandate. We attempted to engage them on issues or subjects that case management curricula should include for 2000-2008 graduates and pre-2000 graduates but were unsuccessful.

In short, we believe that optometric education in this state is an open book. We stand ready to assist OPES with any specific questions or information they desire and we're confident that the schools of optometry will consult with anyone who approaches them on a reasonable and respectful basis.

LICENSING, REGULATION, AND POSTGRADUATE CURRICULUM OF HEALTH PRACTITIONERS WITH FOUR YEARS' POSTGRADUATE EDUCATION: MEDICAL DOCTORS, DOCTORS OF DENTISTRY, AND DOCTORS OF OPTOMETRY

Table 3 summarizes the manner in which California licenses and regulates three independent health care practice professions that require four or more years of postgraduate study for licensure – Medical Doctors (M.D. or "physician and surgeon;" Doctors of Dentistry (D.D.S. – for "Doctor of Dental Surgery" – or dentist); and Doctors of Optometry (O.D., or optometrist).

Licensure and Scope of Practice - Similarities

Following are similarities in the study prerequisites, required education, licensure requirements, and permitted scope of practice among the three professions:

- *Undergraduate prerequisites*. All three professions require at least three years' undergraduate study with required study in anatomy, biology, chemistry, physics, and mathematics.
- Education. Graduation from a nationally-accredited school, as defined, after four years of postgraduate study, is required for licensure.
- Examination. Candidates in all three professions must pass nationally-administered examinations and specified California exams before applying for licensure. All three examinations have mandatory written, clinical, and practice-based segments.
- *Ability to diagnose*. Licensees in each profession are permitted by law to diagnose all diseases associated with the anatomical systems of their professions.
- *Regulators*. All three professions are regulated by statutory boards in the Department of Consumer Affairs, consisting of a majority-minority combination of professional and public members appointed by the Governor. All are supported exclusively from fees and assessments levied against licensees.
- Continuing education. Licensees in each profession must complete a specified number of hours of continuing education as a precondition to license renewal.

Licensure and Scope of Practice- Differences

- Undergraduate prerequisites. California medical and dental students can begin postgraduate studies after three years of undergraduate studies; both California optometry schools require Bachelor of Science degrees prior to admission.
- *Education*. Medical students are required to complete a minimum of one-year of approved, postgraduate residency training before applying for licensure; dental and optometry students are not.
- Ability to treat. Once licensed, physicians and dentists are permitted by law to treat all diseases and conditions associated with the anatomical systems of their professions in each case, the entire physiognomy and the teeth, gums, jaw, and adjunctive structures. Optometrists are limited by statute as to which diseases or conditions of the eye, adnexa, and visual systems they may treat and must navigate a "ladder" of progressive certifications to practice fully within their permitted statutory structure of diseases, conditions, and therapies.

Table 3.

2015 1 2015 2016 2 2016 2016 2016		California: Education, Licensure & Prostgraduate Health Professionals	actice Privileges for
	OPHTHALMOLOGISTS (M.D.)	DOCTORS OF DENTAL SURGERY (D.D.S.)	OPTOMETRISTS (O.D.)
Prerequisites	MCAT & three years undergraduate Required: 1.5 yrs. Biological Sciences; 1 yr. Gen. & Organic Chemistry; 1 yr. Mathematics; 1 yr. English	DAT & three years undergraduate – Required: 2 yrs. Biological Sciences w/lab; 1 yr. Physics w/lab; 1 yr. ea. Gen. (w/lab) & Organic Chemistry; 1 yr. English, Communications or Speech	3+ yr. undergraduate (usu. Bachelor of Sciences) – Required: 1 yr. ea. Gen. Biology, Physics, Organic Chemistry; .5 yr. ea Gen. Chemistry, Biochemistry, Anatomy, Physiology, Microbiology; 1 yr. ea. Calculus & Reading/Composition; .5 yr. ea. Statistics & Psychology
Education	Four years' postgraduate study in general medicine.	Fours years' postgraduate study in general dentistry.	Four years' postgraduate study specializing in eye and visual systems.
	Must complete at least 3 years of resident training in order to apply for board certification in ophthalmic surgical subspecialty. (Not required for licensure.)	May complete postdoctoral residencies in oral surgery or other dental subspecialties.	May complete one-year, post-doctoral residency program or clinical rotation (25-50% of current graduates), incl. OD/Ph.D
Curriculum	[See Attached]	[See Attached]	[See Attached]
Licensure	Graduate from accredited medical school.	Graduate from accredited dental school.	Graduate from accredited optometry school.
Requirements	Must pass all three "steps" of the United States Medical Licensing Examination (USMLE) to apply for licensure.	Must pass Parts I & II of National Board Written Exams to apply for licensure.	Must pass all three parts of the National Board of Examiners of Optometry's examination to apply for licensure.
	Must complete—at a minimum—one year of approved post-graduate, resident training before applying for licensure.	Must pass state examination that includes written, practical, and clinical restoration elements.	Must pass the State Board of Optometry's California Laws and Regulations Examination.
Diagnose – All Systemic Disease	Yes	Yes	Yes
Treat – All Systemic Disease	Yes	Yes	No - Statutory restrictions on condition diagnosis, treatment, & medication use
Perform Surgery	Yes	Yes	No
Administer Injections	Yes	Yes	No (anaphylaxis only)
Regulated by	Medical Board of California	Dental Board of California	State Board of Optometry
Prescriptive Authority	Yes – No restrictions	Yes – No restrictions	Limited by statute & only if certified by State Board (98% of current licensees since 1996)
Required Continu-ing Education for License Renewal	100 hours every four years.	50 hours every two years. (Min. 2 hrs. ea. Infection Control & CA Dental Practice Act & Basic Life Support on first renewal.)	50 hours every two years. (Min. 35 hours in ocular disease treatment and management.)

Table 3. (Continued)

Curricula of Study for Four-Year Postgraduate Health Professional Schools in Medicine, Dentistry and Optometry

ШŅ	IVERSITY OF CALIFORNIA = DAVIS SCHOOL OF MEDICINE		UNIVERSITY OF THE PACIFIC SCHOOL OF DENTISTRY	UNIV	ERSITY OF CALIFORNIA — BERKELEY SCHOOL OF OPTOMETRY
1st Yr.:	MolecCell Biology; Cell-Tissue Biology; Human Physiology; Gross-Radio-Devel. Anatomy; Genetics; Microbiology; Immunology; Pathology; Pharmacology; Metabolism; Endocrinology; Reproduction; Nutrition.	1 st Yr.:	Biochemistry; Human Anatomy (I, II Classrm. & Seminar); Physiology; Basic Disease Processes; Human Growth & Devel.; Fund. Of Restorative Dentistry; Dental Anatomy Lab.; Orientation, Clin. Practice of Gen. Dentistry; Operative Dentistry Lab.; Fixed Prosthodontics & Lab.; Orthodontics; Block Assgts.;	1 st Yr.:	Clinical Exam. Of Visual System; Optical System & Physical Optics; Anatomy & Physiology of the Eye & Visual System; Oculomotor Functions & Neurology; Binocular Vision & Space Perception; Eyecare Business & Professional Mgmt. I.
2 nd Yr.:	Systemic Path; Pharmacology; Neurobiology; Clin. Neuroscience; Gastro-Intestinal; Oncology; Psychiatry; Elective/Remedial Courses.	2 nd Yr:	Gen. & Oral Pathology; Microbiology; Pharmacology; Pediatric Dentistry; Radiographic Interp.; Occlusion & Lab.; Oral/MF Surgery; Periodontics; Removable Prosthodontics, Clinical & Lab.; Integrated Clinical Sciences; Clinical Practice (500 hrs.)	2 Nd Yr.:	Clinical Exam. Of Visual System; Infant Vision; Optics of Ophthalmic Lenses; Ocular & Systemic Pharmacology; Systemic Disease & Ocular Manifestations; Eyecare Business & Professional Mgmt. II; Ophthalmic Optics & Environ. Vision; Diagnosis & Treatment of Sensory/Motor Anomalies; Exam. Of Contact Lens Patient.
3 rd Yr.:	Medicine; Surgery; Pediatrics; Obstetrics- Gynecology; Psychiatry; Primary Care.	3rd. Yr.:	Clinical Care of Complex Needs; Oral Pathology; Differential Diagnoses of Oral Diseases; Integrated Clinical Sciences Seminar; Radiographic Interp.; Group Practice Mtgs.; Jurisprudence; Practice Mgmt.; Prep., State Licensure; Clinical Practice (1,000 hrs.)	3 rd . Yr.:	Optometry Clinics; Advanced Mgmt. & Rehab. of Sensory/Motor Anomalies; Diagnosis & Treatment of Anterior Segment Ocular Disease; Low Vision; Optometry Clinic; Advanced Procedures in Ocular Disease Diagnosis; Diagnosis & Treatment of Posterior Segment Ocular Disease; Eyecare Business & Professional Mgmt. III; Optometry Clinics; Summer Research.
4th Yr.:	Electives (32wks.); Special Study Modules/Scholarly Projects (4 wks.)			4 th Yr.:	Advanced Optometry Clinic; Specialty Clinics; Grand Rounds & Seminar; Current Concepts in Ocular Disease; Summer Research.
Residenc	y/Clinical Rotations*:	Residen	cy/Clinical Rotations:	Residence	y Programs*:
	diagnosis); operative mgmt.; strabismus & corneal surgery Oculoplastic/Cosmetic Surgery; Pediatric Ophthalmology Chief Residency; Corneal & Vitreo-Retinal Surgery; Practice establishment al subspecialty rotations occur over 3 yrs. of	necessa from nat surgery;	es may take additional didactic and clinical training ry to attain certification in recognized subspecialties ional boards (e.g., endodontics; oral & maxillofacial orthodontics; pediatric dentistry; periodontics) and to be appropriate hospital privileges		Primary Care Ocular Disease Contact Lenses Low Vision Binocular Vision Pediatrics *On-campus & affiliate
reside					:

- Authority to prescribe. Once licensed, physicians and dentists may prescribe without restriction, subject only to the requirements of California prescription regulation laws and federal laws and regulations. Optometrists are limited to use of "Diagnostic Pharmaceutical Agents" (DPAs) generally, topical solutions used for diagnostic purposes and fourteen categories of "Therapeutic Pharmaceutical Agents" (TPAs), some with additional, categorical restrictions on use.
- *Invasive procedures*. Once licensed, physicians and dentists can "break the skin" that is, they are authorized to give injections, draw blood, and perform systemic surgery, without additional statutory restrictions. Optometrists are permitted to use only auto-injectors in cases of anaphylaxis (as can anyone, in an anaphylactic emergency) and, with the passage of Senate Bill 1406, are now permitted to draw blood for purposes of diabetic testing.
- Testing. Subject to conflict of interest requirements, physicians and dentists may order tests without restriction and perform and evaluate tests and images in their offices; for those purposes they are exempt from being trained and licensed as clinical laboratory directors. By statute, optometrists may order only specified categories of tests, may order only X-rays independently, and must become licensed to perform in-office tests.
- Continuing Education. Physicians must complete 100 hours of unspecified continuing education every four years to have their licenses renewed. Dentists must complete 50 hours every two years, six hours of which must be taken in specified topics. Optometrists must also take 50 hours of continuing education courses for biennial renewal; 35 hours of the total must be devoted to six specific categories of ocular disease including glaucoma.

Curricula

Page 2 of *Table 3* summarizes the curricular requirements and options for postgraduate study at three representative professional schools – the University of California – Davis School of Medicine; the University of the Pacific School of Dentistry; and the University of California – Berkeley School of Optometry. Some key differences:

- Systemic education. Because physicians and surgeons will be licensed to treat the entire body, almost all the education they receive in four years of medical school is "whole-body," rather than concentrated on one system, as are UOPSD and UCBSO students. (Note, for example, that at UCDSM there is no specific ophthalmological rotation in third year; education in "basic ophthalmological skills" are not focused on until the first year of residency.)
- Residencies. Three years of ophthalmology-intensive residencies and rotations are required by UCDSM to specialize in ophthalmology, whereas residencies or internships after the third and fourth years at UPOSD and UCBSO, respectively, are optional. (Because they will not be licensed to be "whole-body" practitioners, the latter begin their system-specific education much earlier in their four-year programs. A much greater proportion of their curricular time is spent in patient interaction and clinical case management in third and fourth years, compared to medical students. Increasingly, dental students are beginning their examinations required for licensure before graduation. Optometry students take all three parts of their national exam before graduating and more are opting to take postgraduate residencies. (Our two schools estimate that 25-33% of most recent graduates did so.)

Medicine and dentistry are "single-license" professions; physicians and dentists may upon licensure practice "as trained." What this means is that, strictly as a matter of state licensure law and regulation, a "physician and surgeon" or "dentist" can practice fully without being required to fulfill any additional post-licensure requirements. A physician can practice any aspect of medicine so long as he or she has completed the required one-year postgraduate residency and become properly licensed. Beyond restrictions on specialty advertising, there are no additional statutory certification requirements. Medical subspecialties – and ophthalmology is considered by medicine to be a "surgical subspecialty" – are regulated nationally and privately by nonprofit accreditation organizations who "board-certify" licensed physicians who meet their established requirements, which may include additional examination. These certifications are also used to determine and define medical staff privileges at hospitals and other types of inpatient and outpatient surgical care facilities. "Doctors of Dental Surgery" can practice generally without restriction, as well, unless they choose to perform cosmetic surgery. In that case, there are additional requirements they must meet imposed recently by statute in order to qualify for hospital staff privileges. (These requirements were also the result of a negotiated legislative compromise between organized medicine and organized dentistry.)

The Medical Board of California has promulgated no regulations affecting the scope of practice of a "physician and surgeon;" the only such rules they've established are for allied professionals with whom they practice and over which the Board has jurisdiction. Other than statutorily-required regulations on the use of anesthetic used in dental operatories, materials used in restorations, and in-office infection control, the same can be said of the Dental Board of California.

Optometrists, to the contrary, are not given the freedom to practice "as taught" upon licensure. In California, there is no general grant of authority that defines a broad scope of practice. Over time, because of persistent opposition from organized medicine and dentistry, the entire profession has been required to seek and achieve specific legislative permission in every state to dilate eyes for diagnosis; prescribe most topical and some oral medication to treat eye disease; manage glaucoma; perform therapeutic injections, in a few states; and – in only one state thus far – use lasers for therapeutic and limited surgical purposes, rather than just for diagnostic evaluation. Some states require additional certification beyond graduation to perform certain procedures or therapies. California has traditionally been one of the most prescriptive of practice states – DPAs were first authorized in 1976³⁹—and optometrists were first authorized to become certified to prescribe TPAs in 1997. Our state did not recognize optometry's potential for glaucoma management until eight years ago and is well behind the rest of the country in optometric management of glaucoma. (See, e.g., "Licensing and Certification of Optometrists to Manage and Treat Glaucoma Patients – California and Other States," ff.)

LICENSING AND CERTIFICATION OF OPTOMETRISTS TO MANAGE AND TREAT GLAUCOMA PATIENTS – CALIFORNIA AND OTHER STATES

Doctors of Optometry were first authorized to diagnose glaucoma cases in the United States in 1976, in the State of West Virginia – the same year that California optometrists were permitted to dilate patients' eyes to diagnose eye disease. Eleven more states followed suit by 1990. By 2000, 34 more provided that authority. As noted in the preceding section, the National Board of Examiners in Optometry began testing optometry school students for licensure in glaucoma in 1993 and has progressively expanded the scope of didactic and clinical examination in glaucoma since. California is only one of five states that has first allowed optometric treatment of glaucoma in this century. In the United States in 1976, in the State of West Virginia – the same year that California optometrists were permitted to dilate patients' eyes to diagnose eye disease. By 2000, 34 more provided that authority. As noted in the preceding section, the National Board of Examiners in Optometry began testing optometry school students for licensure in glaucoma in 1993 and has progressively expanded the scope of didactic and clinical examination in glaucoma since. California is only one of five states that has first allowed optometric treatment of glaucoma in this century.

Table 4 summarizes the state of the law in the 50 States and the District of Columbia governing optometric treatment of glaucoma patients, through December 31, 2007. Study of these various scope of practice laws reveals the following:

- Thirty-four states impose no special conditions on licensed optometric graduates before they are authorized to diagnose, treat, and manage glaucoma patients.
- In 29 of those 34 states optometrists are permitted to use both topical and oral medications to treat glaucoma and to use oral medications to stabilize emergency angle-closure cases prior to referral.
- Thirteen states require referral of certain types of glaucoma cases diagnosed or managed by optometrists to subspecialists, typically ophthalmologists.
- Three states require consultation between a diagnosing optometrist and ophthalmologists for specified diagnoses or disease states.

Table 5 summarizes the state of the laws in the eight states, including California, that do require licensed Doctors of Optometry to take additional postgraduate didactic instruction or manage a number of glaucoma patients with an ophthalmologist before being permitted to manage and treat them independently.⁴² Analysis of these states discloses that:

- Only two states besides California have established such requirements in the past eight years New Hampshire 2006 and Vermont in 2004. The other five were enacted in the 1990s New York and Maine in 1995; Kansas in 1996; Rhode Island in 1997; and Nevada in 1999.
- Four states required some level of additional classroom instruction; two New Hampshire and Vermont also mandate passing an examination following instruction, while Rhode Island offers an examination after a specified date as an alternative to 14 hours of classroom study. In all four States the didactic requirement can be waived under specified circumstances. 43
- While all states established some level of medical prediagnosis by, consultation or comanagement with, or referral to a physician of a fixed number of glaucoma cases over a specified period of time, every state but California and Nevada established exemptions from the case management requirement imposed:
 - o Under SB 929 in California, there were no exemptions allowed from the requirement that an optometrist co-manage 50 "newly diagnosed" glaucoma patients over two years with a

SUMMARY – TREATMENT OF GLAUCOMA BY OPTOMETRISTS

STATE:	All Topical Medications To Treat Glaucoma	All Oral Medications To Treat Glaucoma	Emergency Orals	Consultation Requirement	Comanage- ment Requirement ¹	Special Conditions as Required by State Law
Alabama	Y	Y	Υ			None
Alaska	Y	Y	Y			None
Arizona	Υ					None
Arkansas	Y	Y	Y			None
California	Y ⁴			certain Dx	limited1,2	refer certain types
Colorado	Υ	Y	Y			None
Connecticut	Υ		Υ			refer certain types
Delaware	Y	Υ	Υ			None
D.C.	Y		Υ	Υ		None
Florida	Y			Υ		refer certain types
Georgia	Υ	Y	Υ			refer certain types
Hawaii	Υ	Υ	Y		· · · · · · · · · · · · · · · · · · ·	None
Idaho	Υ	Y	Y			None
Illinois	Y	Υ	Υ			oral carbonic anhydrase inhibitors for no more than 72 hrs
Indiana	Y	Y	Υ			None
Iowa	Υ	Υ	Υ			None
Kansas	Y	Υ	Υ		limited ²	None
Kentucky	Y	Υ	Υ		····	None
Louisiana	Y	Υ	· Y			None
Maine	Υ				limited ²	None
<u>Maryland</u>	Y				Y	None
Massachusett s						
Michigan	Υ	Υ	Υ		•	None
Minnesota	Y	Y	Y			oral carbonic anhydrase inhibitors for no more than 7 days
Mississippi	Υ	Υ	Υ			None
Missouri	Υ	Y	Υ			None
<u> Montana</u>	Y	Y	Υ			None
Nebraska	Y	•				refer certain types
Nevada	Y		Υ	Y	limited ²	refer certain types
New Hampshire	Υ ⁵		Y	Y	limited ²	refer certain types
New Jersey	Υ	Y	Y			None
New Mexico	Y	Y	Y			no osmotics
New York	Y				limited ²	None
North Carolina	Y	Y	Y			None
North Dakota	Υ	Y	Y			None
Ohio	Υ	Y	Υ			None
Oklahoma	Y	Y	Y			None

SUMMARY – TREATMENT OF GLAUCOMA BY OPTOMETRISTS

Oregon	Υ	Y	Υ	certain Dx		None
Pennsylvania	Υ					refer certain types
Rhode Island	Υ			Y	limited ²	refer certain types
South Carolina	Y	Y	Y			None
South Dakota	Y	Y	Υ			None
Tennessee	Υ	Υ	Υ			None
Texas	Y		Υ	γ3		refer certain types
Utah	Υ	Y	Y			None
Vermont	Y	Y	Y	only when oral Rx'd	limited ²	refer certain types
Virginia	Y	Y	Y			refer certain types
Washington	Y	Υ	Υ			None
West Virginia	Y	Y	Υ			None
Wisconsin	Y	Υ	Y			refer certain types
Wyoming	Y		Y			None

Last Revised December 21, 2007

Footnotes:

- ¹ Co-management includes periodic face-to-face visits with an ophthalmologist.
- ² Optometrists in these states co-manage either a specific number of patients with glaucoma or patients with glaucoma for a specific period of time prior to obtaining authorization to independently treat glaucoma in the future.
- ³ The Texas optometry law requires consultation with an ophthalmologist to include confirmation of diagnosis and co-management, however the parameters, including any requirement for face-to-face visits, are at the discretion of the co-managing ophthalmologist.
- ⁴ May use any topical glaucoma drug but may not use more than two drugs concurrently.
- ⁵ May use those topical glaucoma drugs as determined by the Joint Pharmaceutical Formulary and Credentialing Committee. May treat with no more than two concurrent topical legend drugs. The Committee will determine which combination legend drugs shall be considered one medication for this purpose.

Source: State Gov't. Relations Center, Amer. Optometric Assn.

STATES WITH POST-LICENSURE REQUIREMENTS FOR OPTOMETRISTS PRIOR TO INDEPENDENT GLAUCOMA DIAGNOSIS & TREATMENT

The following table summarizes requirements established by eight of the 50 States and the District of Columbia that licensed Doctors of Optometry must fulfill before they are permitted to independently diagnose and treat glaucoma, as defined.

STATE	YEAR	SUMMARY	EDUCATION/COMANAGMENT REQUIREMENTS & EXCEPTIONS
CALIFORNIA	2008 (Stat.)	Authorized treatment of adult (18+ yrs.) of primary open angle (POAG), exfoliative, and pigmentary glaucoma, and emergency treatment of acute angle closure glaucoma. Provided for glaucoma certification upon graduation of post 5/1/2008 graduates. "Grandfathered" ODs certified between 2000-2009. Requires State Bd. Optometry (SBO) to adopt "appropriate" case management requirements for licensees w/ 24 hr. didactic course, and didactic and case management curricula for pre 5/1/2000 graduates. (All licensees who took 24-hr. didactic course offered 2001-2009 exempt from additional didactic training. All ODs glaucoma certified as defined may use topical and oral TPAs.)	Requirements: SBO Advisory Committee must — Presume >5/1/2008 grads fully certifiable. Recommend "appropriate" — Case mgmt. curricula for pre-2008 grads w/24 hr. didactic course. Didactic & case mgmt. curricula for pre-200 grads w/o 24 hr. course. Submit recommendations to Office of Prof. Exam Services (OPES) by 4/1/2009. SBO Advisory Committee may recommend additional training for pre-2008 graduates. OPES must issue final findings to SBO by 7/1/2009 SBO must adopt OPES findings & implement certification requirements by 12/31/2009. Process self-repeals 1/1/2010.
KANSAS	1996 (Stat.)	Added oral & topical glaucoma TPAs to treat "adult open angle glaucoma."	Requirements: • 24-hr. didactic course approved by State Bd. • Comanagment of 20 diagnosed cases for 24 mos. Exceptions: • Above waived for post-7/1/1998 graduates. Note: All KS ODs must be both TPA and glaucoma qualified after 5/31/2010.
MAINE	1995 (Stat.)	Added non-emergent glaucoma treatment w/ topical TPAs.	Requirements: • 50 referrals + OMD consult: • 20 retrospective from 7/1/1995 to license date. • 30 new/existing cases w' agreed-to treatment plan. Exceptions: • 20 retrospective patient requirement waived if graduated two years before license application. • Waived on approval for recent graduates w/1-yr. residency or equivalent.
NEVADA	1999 (Stat.)	Added glaucoma treatment w/topical and emergency oral TPAs. (Referral to OMD required for juvenile, malignant, neovascular, or acute angle closure glaucoma or glaucoma caused by diabetes.)	Requirements: Treatment of 15 cases diagnosed by OMD & Treated in consultation w/OMD for at least 12 consecutive months.

Table 5.

STATES WITH POST-LICENSURE REQUIREMENTS FOR OPTOMETRISTS PRIOR TO INDEPENDENT GLAUCOMA DIAGNOSIS & TREATMENT

NEW HAMPSHIRE	2006 (Stat.)	Requirements to treat glaucoma independently substantially rewritten. (Adult POAG may be treated independently, using two concurrent topicals "as determined by Joint Pharmaceutical Formulary and Credentialing Committee." Acute angle closure glaucoma cases may be diagnosed and stabilized using oral TPAs and immediately referred to OMD.)	 Requirements: 40 hrs. specified didactic education + SBO exam = TPA Rx during comanagement of patients. Provide "evidence of written referrals & consultation" w/OMD. 25 cases (incl.5 "established patients") for 18 mos. (each patient) comanaged w/OMD. (Six specified comanagment criteria.) Post-certification consultation required for 24 mos. Exceptions: Didactic, exam & "written referral & consultation" requirements may be waived for ODs: Licensed & treating glaucoma in another state for 12+ mos., or Completing 12-mo. accredited residency or equivalent.
NEW YORK	1995 (Stat.)	Established post-"initial diagnosis" consultation w/OMDs for glaucoma cases.	Requirements: Written consultation required for later of 36 mos. or 75 cases. Exceptions: Post-1/1/1999 grads w/DPA-TPA certification and proof of 75 glaucoma diagnoses in training under MD supervision exempt.
RHODE ISLAND	1997 (Reg.)	State Board approved regulations for "amplified practice" glaucoma & anterior uveitis treatment w/TPAs. (Treatment excludes "infantile & congenital" glaucoma and adult angle closure cases limited to "initiation of immediate emergency care." Use of beta blocker requires patient consent and MD prior consultation.)	Requirements: 14 hrs. classroom study on advanced glaucoma diagnosis & treatment, OR Pass IABP exam on ocular disease after 1/1/1999. Written consultation & treatment of 20 cases for one yr. or until patient stabilized. Exceptions: 10 of 20 required cases diagnosed during training can be counted.
VERMONT	2004 (Stat.)	Added all oral and topical drugs and authorized treatment of adult (16+ yrs.) of POAG, exfoliative, pigmentary, low tension, and uveitic glaucoma, and emergency treatment of angle closure glaucoma. (Topical use in glaucoma cases limited to three TPAs "at any one time"; use of orals requires consultation but not referral.)	Requirements: TPA certified, pre-2003 graduates not glaucoma-certified elsewhere must: Take 18-hr. approved course & pass exam, AND Collaborate w/ OMD for 5 new cases over six mos.

Source: CA Optometric Assn.

- "geographically appropriate" ophthalmologist, who in turn was required to approve a treatment plan in advance and examine each patient personally.
- o In Kansas, licensees who graduated after July 1, 1998 were exempted. In Maine, licensees who graduated within the two years before becoming licensed (following 1995) are exempt from its retrospective case management requirement and recent graduates who completed a one-year residency or its equivalent may have all requirements waived.
- o Nevada's requirement that an optometrist treat 15 cases diagnosed by an ophthalmologist for 12 consecutive months in consultation with that ophthalmologist is nonwaivable.
- Optometrists seeking certification in New Hampshire are exempt from that state's additional requirements if they were licensed and treating glaucoma in another state for at least one year or completed a one-year residency or its equivalent.
- o In New York, any optometrist graduating after January 1, 1999 who can provide proof of diagnosis of 75 glaucoma cases under medical supervision is exempt from its three year/75 patient (whichever is later) case management requirement.
- o Half of the 20 cases comanaged over a year or until stabilization as required by Rhode Island can be cases diagnosed during optometric training.
- Vermont exempts post-2003 graduates who are TPA-certified and those who have been certified to treat glaucoma elsewhere.

In summary, the more stringent of the post-licensure glaucoma certification requirements were established in the handful of states that imposed them within five or six years of the time when optometrists first began being examined for and treating glaucoma independently. Even then, allowances were made for recent graduates and experience acquired in active practice. None of the requirements imposed since have approached those enacted by SB 929, let alone those proposed by the Advisory Committee representatives nominated by the California Academy of Eye Physicians and Surgeons.

GLAUCOMA CERTIFICATION UNDER SB 929 - A FAILED EXPERIMENT

By enacting SB 1406, the Legislature acknowledged that its initial plan to certify more Doctors of Optometry to diagnose, treat, and manage glaucoma patients in California by enacting SB 929 in 2000 has been a failure. The seven-year moratorium on new legislation imposed by that bill on the profession, by agreement of the parties to give it sufficient time to work, produced little in the way of results. As of March 9, 2009, out of a pool of over 6,000 active-practice candidates over eight years, only 221 optometrists had earned that designation under its provisions. (By comparison, 162 May 2008 graduates have become certified upon licensure or renewal in nine months, under SB 1406.)

Not that TPA-certified California optometrists showed little interest in becoming glaucoma qualified. Both of California's optometry schools began offering versions of the 24-hour didactic courses approved by the State Board of Optometry, the first step toward certification, in 2000. By December 2001, approximately 2,000 TPA-certified optometrists who had graduated prior to May 2000 had completed those courses. Thus, an estimated 45% to 50% of licensees required to take the didactic course have already fulfilled that condition.

Before becoming eligible to apply to the Board for certification, a candidate was first required to be certified by the State Board to prescribe Therapeutic Pharmaceutical Agents (TPAs). Licensees were first authorized to become TPA-qualified effective in 1997, following enactment of SB 668 in 1996. ⁴⁵ TPA certification remains a prerequisite, which is appropriate since, as of May 2008, 94% of California-licensed optometrists had attained that status. ⁴⁶ The members of the Advisory Committee agreed that the additional prerequisite that candidates who graduated and initially licensed before 2000 take 24 hours of didactic instruction offered by accredited school of optometry is also appropriate, to assure that they are current in pharmacological management of glaucoma.

The real obstacles to the program's success were built into a rigorous and complex two-plus-year path requiring close "co-management" by both a candidate optometrist and a "preceptoring" ophthalmologist before the former could be authorized by the State Board to diagnose, treat, and manage primary openangle glaucoma in adult patients (18+ years) independent of ophthalmological supervision. Here is the catalogue of statutory prerequisites, as enacted by SB 929⁴⁷:

- Collaboration with ophthalmologist for 50 patients required; each patient must be newly-diagnosed by the optometrist and followed over two years by same ophthalmologist only.
- Optometrist must make initial diagnosis, not after referral of potential patient from following ophthalmologist.
- More than one optometrist may not take credit for the same patient.
- Patients counted in the first 50 required must not have had a previous diagnosis of glaucoma or ocular tension.
- Ophthalmologist must heed Medical Board of California's recommendations requiring only one optometrist per patient and only newly-diagnosed glaucoma patients in preceptored first 50.
- Collaborating ophthalmologist must be geographically accessible to patient and must examine each patient.
- Collaborating ophthalmologist must initially confirm diagnosis and approve treatment

- plan presented in writing by optometrist.
- After confirmation of diagnosis and approval of treatment plan by ophthalmologist, optometrist may begin treatment with any topical glaucoma medication.
- Any change in medication must be communicated to ophthalmologist in writing.
- Annual written report of treatment results to ophthalmologist required, which must be acknowledged in writing by ophthalmologist within 10 days of receipt.
- Treatment limited to two topical medications components of each medication are counted separately.
- Patient must be re-referred to ophthalmologist if requested by patient, if treatment goals are not met with two medications, or if secondary glaucoma develops.
- Ophthalmologist may choose to examine the patient at any time.
- Optometrist must provide to patient in writing: the nature of the working or suspected diagnosis; the need for consultation with collaborating ophthalmologists; treatment plan goals; expected follow-up care; and a description of referral requirements. Both optometrist and ophthalmologist must sign the document and both must keep it in each patient's chart.
- Upon completion of diagnosis and treatment of 50 newly-diagnosed and preceptored patients with POAG, optometrist must apply to Board of Optometry for certification. Collaborating ophthalmologists will be asked to verify patients diagnosed and treated. If ophthalmologist does not respond within 60 days, the Board may act on available information.
- After certification, optometrist may treat only POAG and must refer patients requiring more than two medications for all further treatment.
- All ophthalmologists serving in consultation, referral, or collaborative roles must be geographically accessible to patient.
- All consultations require a written report by the optometrist of the information provided to the ophthalmologist, the ophthalmologist's responses, and any other relevant information. The consulting ophthalmologist may request a copy of these records at any time.

Aside from the sheer logistics involved, several factors were brought to the Legislature's attention that were likely responsible for the failure of the SB 929. Based on surveys of their members conducted by the California Optometric Association, chief among these were:

- The requirement that each of the 50 glaucoma cases be "newly diagnosed' and unique to a single optometrist.
- The lack of a "geographically appropriate" ophthalmologist both available and willing to preceptor an optometrist and jointly follow 50 distinct patients over a two-year period and to remain available for post-certification referrals when required.
- The unwillingness of patients and payers to absorb the cost and inconvenience of duplicate office visits for purposes of diagnose confirmation, review of ongoing treatment plan, and final verification.

In truth, all but a small fraction of optometrists who were certified to manage glaucoma patients before January 1 of this year achieved that status in group courses conducted at the two schools of optometry in Berkeley and Fullerton, due to the fact that each has clinics with sufficient numbers of new patients and

attending ophthalmologists as clinical faculty. These ventures were expensive to conduct and by definition were largely unavailable to optometrists in most areas of the state.

Given this experience, the Legislature has elected to eliminate this list of statutory prescriptions in favor of a system of certification ultimately under the supervision and control of the State Board of Optometry. This is desirable and consistent both with the regulatory models in use for other California licensees with four years of postgraduate education and as used for optometry in most every other state.

MANAGEMENT OF GLAUCOMA PATIENTS BY OPTOMETRISTS THE POTENTIAL FOR PATIENT HARM

Since 2002, by law the highest priority of every Department of Consumer Affairs regulator is protection of the public. The State Board of Optometry's mandate is codified in California Business and Professions Code Section 3010.1:

3010.1. Protection of the public shall be the highest priority for the State Board of Optometry in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

The charge to the Office of Professional Examination Services in evaluating this report's recommendations and other information submitted is to balance the need to "adequately protect glaucoma patients" with "ensur[ing] that defined applicant optometrists will be certified to treat glaucoma on an appropriate and timely basis," consistent with established OPES examination validation policies.

To us, the best existing data that can be analyzed to assess the likelihood of harm to optometric patients is to use the data on malpractice and disciplinary complaints collected through the National Practitioner Data Bank and Healthcare Integrity and Protection Data Banks, administered by the Health Resources and Services Administration of the U.S. Department of Health and Human Services. *Table 6* uses that data to compare total adverse actions against physicians, dentists, and optometrists in California, Oklahoma, and in the United States, reported as required by law to those two entities between September 1, 1990 and March 17, 2008. (The table was created by the California Optometric Association. The State of Oklahoma was chosen for comparison purposes because it is the only state that has authorized optometrists to use invasive laser therapies, procedures that carry a higher inherent risk of harm than others optometrists are authorized to use.)

We believe the data speak for themselves. We are not suggesting that these findings can be easily extrapolated to draw conclusions. Because of the way in which the data are collected and reported at both the state and national levels, further study would be needed to answer specific questions. For example, reports of adverse actions against Medical Doctors are not reported by subspecialty, but rather by procedure or incident location; therefore, one would have to subclassify surgical incidents to try to determine whether eye surgery was involved, which may not be possible. Another complication in that area is that data on licensed California physicians and surgeons are not subspecialty-specific, either; one must rely on responses to the Medical Board's Annual Physician Survey or external data for that purpose. Other limitations on the data can be found on the data banks' web pages⁴⁸ or are otherwise noted in the Table's footnotes.

Presumably, though, "Licensure/Clinical Privileges" and "State Agency Adverse Actions" would capture actions taken against state licensees by their regulators. OPES may wish to sample more current data from states that do not have additional glaucoma certification requirements after graduation or licensure to determine if their reporting rates vary from states that do. We believe contacting state optometric boards would likely provide the most accurate guidance.

Table 6.

MALPRACTICE & DISCIPLINARY COMPLAINTS: MEDICAL DOCTORS, DOCTORS OF DENTAL SURGERY & DOCTORS OF OPTOMETRY **SELECTED JURISDICTIONS: CALIFORNIA, OKLAHOMA & UNITED STATES**

September 1, 1990 - March 17, 2008

TYPE OF COMPLAINT	MEDICA	L DOCTOR	S(M.D) ²	DENTISTS (D.D.S.)		D.S.)	OPTOMETRIŠTS (O.D.)		(O.D.)
	CA	ок	US	CA	OK	US	CA	ок	US
National Practitioner Data Bank Reports:								<u>il</u>	
Medical Malpractice Reports	24,561	1,672	232,727	8,250	396	40,261	36	21	580
Licensure/Clinical Privileges	8,143	808	62,394	625	126	13,016	6	0 :	16
Medicare-Medicaid Exclusion	974	70	6,184	328	26	2,246	26	5	197
								# 2	
Healthcare Integrity & Protection Data Bank Reports:									
Data bank Reports:									
State Agencies/Health Plans							,	i	
Adverse Actions	5,091	393	39,642	544	81	11,940	106	1	1,342
Judgments or Convictions	33	4	310	29	0	204	1	0 :	16
- · · · · · · · · · · · · · · · · · · ·									
Federal Agencies (Combined):3	4.000	70	0.074	200	00	0.070	00	<u>- 1</u>	400
Adverse Actions	1,000	72	6,674	329	26	2,278	26	5	198
Judgments or Convictions	12	0_	91	1	0	27	0	0:	0
Organizations: ⁴									
Adverse Actions	9	. 0	247	3	2	61	0	0	18
Judgments or Convictions	2	0	2	1	0	19	0	0	3
					1	1		;	,
TOTAL COMPLAINTS/ACTIONS	39,825	3,019	348,271	10,110	6167	70,052	201	32	2,370

² All subspecialties; excludes Interns/Residents; Osteopathic Physicians; Podiatrists. (Complaint data not compiled by subspecialty.) *Source*: Health Resources & Svcs. Admin., U.S. Dep't. Health & Human Svcs., *NPDB/HIPDB Public Reports* (Apr. 2008).

³ All Federal agencies' and facilities' report totals are combined.

⁴ Ambulatory surgery centers and group practices only; acute care/inpatient facilities excluded.

⁵ Totals are M.D.s only designated as providing patient care through 2006. Total specializing in Ophthalmology by category are: CA, 2,120 (Primary Specialty + PS & Board-Certified; OK, 142; US, 17,480. Source: Physician Survey Data File, Med. Bd. CA; Amer. Medical Assn., Physician Characteristics and Distribution in the US (2008 Ed.)

⁶ Sources: BHPR/HRSA/DHHS (2004)/Dental Bd. of CA (2008); OK Bd. Dentistry (2008); Bur. Labor Statistics, U.S. Dep't. Labor (2006).

⁷ Sources: CA State Bd. Optometry (Active in CA - 2008); OK Bd. Examiners in Optometry (Active in OK - 2008); Amer. Optometric Assn. (2008).

We are informed by the State Board that they have filed only two glaucoma-related accusations against licensees since January 1, 2003; neither of those practitioners was glaucoma-certified.

In evaluating the relative safety of authorizing optometric diagnosis, management, and treatment of glaucoma suspects and patients, we ask OPES to keep these points in mind:

- As is discussed in more detail elsewhere, glaucoma is a progressive disease of undetermined origin, for which there is no "cure."
- SB 1406 authorizes certified optometrists to treat and manage only those types of glaucoma for which medical therapy, rather than surgical intervention, is appropriate. Optometrists would still be required and bound by the standard of care to refer intervention cases to subspecialists.
- As a primary eye care specialist and non-surgeon, the greatest harm that a certified optometrist could inflict on a glaucoma suspect would be to fail to diagnose the disease as early as possible, to fail to prescribe the appropriate therapy, or to fail to refer to an appropriate surgical subspecialist in time to intervene successfully.
- Practiced at its most skillful level, optometric glaucoma management will postpone the onset of blindness and provide a higher level of comfort and quality of life for the diagnosed patient over that period of time.
- The best tools for treatment and management of glaucoma are diagnosis and introduction of appropriate therapy at the earliest possible stage of the disease.

We believe the greatest harm that could befall glaucoma suspects and patients would be to deny them access to otherwise qualified practitioners and management therapies by throwing in their way unnecessary obstacles to their certification – especially if based on unfounded claims of lack of training or anecdote, rather than sound data and analysis.

CONCLUSION

Doctors of Optometry may be California's most underutilized primary care resource – especially as applied to glaucoma. Until Senate Bill 1406 was enacted, California had the most restrictive scope of practice law in the United States in that regard. How restrictive it will remain depends on the additional post-licensure requirements that will be imposed on pre-2008 graduates to allow them to diagnose, treat, and manage patients independently.

Optometrists (ODs) are essentially "primary care specialists" – that is, they are extensively educated and trained through four years' postgraduate study, externships, and residencies to diagnose and treat all diseases and abnormalities of the visual and associated systems. Optometrists can do much more than measure and correct vision and prescribe and fit lenses. Using as many as 26 distinct measurements of the patient's ocular (eye) and neurological (nerve pathways) systems in comprehensive eye exams conducted in their offices, they are qualified to diagnose and either treat, manage, or consult for treatment patients who have:

- Vision problems that affect neurological development, learning, balance, and on-the job performance.
- Eye disease.
- Cataracts.
- Corneal disease.
- Retinal detachment.
- Glaucoma.
- Diabetes.
- Hypertension.
- Pre-cancerous and cancerous tumors.
- Vascular disease.
- Viral and other diseases revealed through the eye.
- Foreign bodies or lesions of the eye and related structures.

Seven out of 10 eye care patients see an Optometric Doctor first; for many of them the optometrist is the first – and, sometimes, only – health care provider they will see. Given that there are at present 6,919 actively-licensed California ODs in over 100 cities and towns in 54 of 58 California counties, ⁴⁹ it only makes sense to capitalize on their numbers and geographic distribution to get more and better primary care services to as many of our citizens who need them as possible. If permitted to practice as trained, optometrists could treat many more patients efficiently and more economically and get them into necessary treatment provided by other practitioners faster.

The Legislature responded to this argument by enacting Senate Bill 1406, removing a substantial number of statutory restrictions that have operated to keep optometrists from becoming a more valuable asset in our state's health care delivery system. As has been discussed in this report, the greatest number of impediments to better utilization existed in the law in two areas: glaucoma certification and independent management, using appropriation therapies. The Legislature made its intentions known by:

> Expanding the optometric scope of practice to cover over 95% of the types of glaucoma cases that can be managed independently through medical therapy without additional re-referrals;

- > Requiring optometrists to stabilize and immediately refer angle closure cases, using appropriate therapy;
- > Eliminating existing restrictions on glaucoma therapies; and
- > Scrapping a costly, duplicative glaucoma certification process that failed to achieve its purpose and leaving it to this Advisory Committee, the Office of Professional Examination Services, and the State Board of Optometry to design a process that works.

We trust OPES and the State Board to come to fair and responsible resolution in making and adopting final findings based on this report's recommendations.

RECOMMENDATIONS

We, the optometric members of the Advisory Committee, did not take our responsibilities as imposed by the Legislature lightly. We consulted broadly with our 2008 graduates, whose qualifications and training are the prospective benchmark for independent treatment of glaucoma in California; their academic and clinical faculty; our fellow optometrists at varying levels of experience in active practice; and our colleagues in ophthalmology who co-manage glaucoma patients with us. Their cooperation and insight have informed our thinking and our recommendations.

At the outset, we are grateful to the representatives from the California Academy of Eye Physicians and Surgeons for their participation with us on the Glaucoma Diagnosis and Treatment Advisory Committee over the past three months. We are also pleased that we could agree on the following points, at least in principle:

- Additional didactic training should not be required for licensed optometrists who graduated between May 1, 2000 and May 1, 2008, for two reasons:
 - o These graduates were exempt from the 24-hour, didactic course requirement under the original SB 929 glaucoma certification process, and
 - o In 2004, the Legislature amended existing continuing education requirements to add glaucoma as one of the six specific disease states that optometrists must take courses in over 35 hours every two years for license renewal.
- Given the Legislature's elimination of individual, in-person co-management requirements to gain case management experience toward certification, attention should be given to utilizing more efficient tools to provide both didactic and case management instruction, such as real-time group instruction, both in-person and remotely via telemedicine.
- The curriculum of a glaucoma case management course could be presented to certification candidates in a "grand rounds" setting, similar to the type of training provided to medical residents. As an example, the CAEPS representatives suggested a 16-hour course, offered over two days.
- The qualifications and experience of glaucoma-certified optometrists should be utilized for instruction and supervision of certification candidates, if required.
- 1. For an "appropriate...curriculum of didactic instruction in the diagnostic, pharmacological, and other treatment and management of glaucoma," for licensed Doctors of Optometry who, as specified by Business and Professions Code Section 3041.10(f)(5):
 - Graduated from an accredited school of optometry prior to May 1, 2008;
 - Were not certified to diagnose, treat, and manage glaucoma patients under the provisions in effect between January 1, 2001 and January 1, 2009;
 - Will not have exercised the option to become certified under those provisions on or before December 31, 2009; and
 - Were required to and did not take the 24-hour didactic course prescribed by SB 929, by January 1, 2009,

We recommend that OPES find that the State Board of Optometry should require by regulation, as a prerequisite to glaucoma certification, "satisfactory completion of a didactic

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course of not less than 24 hours in the diagnostic, pharmacological and other treatment and management of glaucoma, the course curriculum to be developed by an accredited California school of optometry." This requirement should be imposed on all licensed optometrists who graduated before May 1, 2000, as described above, who desire to apply to become glaucomacertified. The language quoted is identical to the initial prerequisite established by SB 929 in Business and Professions Code Section 3041(f)(1), prior to being amended by SB 1406.

- 2. For an "appropriate...curriculum of "case management of patients diagnosed with glaucoma," for licensed Doctors of Optometry who, as specified by Business and Professions Code Section 3041.10(f)(4):
 - Graduated from an accredited school of optometry prior to May 1, 2008;
 - Were not certified to diagnose, treat, and manage glaucoma patients under the provisions in effect between January 1, 2001 and January 1, 2009;
 - Will not have exercised the option to become certified under those provisions on or before December 31, 2009; and
 - Took the 24-hour didactic course prescribed by former Business and Professions Code Section 3041(f)(1) by January 1, 2009,

<u>We recommend that OPES find</u> that the State Board of Optometry should require by regulation, as a prerequisite to glaucoma certification, satisfactory completion of a Board-approved course in case management of patients diagnosed with glaucoma. To be eligible for Board approval, any such course shall provide for the following, at a minimum:

- 1. The course shall consist of not less than 16 hours of instruction in case management of patients diagnosed with glaucoma, including individual analysis and presentation by each candidate of at least 10 patient case scenarios most likely to be encountered by certified optometrists in likely practice settings.
- 2. Course instruction and case analysis and presentation shall be supervised by at least one glaucoma-certified optometrist in active practice or one board-certified in ophthalmologist with a specialty or subspecialty in glaucoma in active practice.
- 3. A written examination administered to each candidate at the conclusion of the course.
- 4. Initial course content shall address the following subjects in the context of case management:
 - a. Identification of glaucoma risk factors
 - b. Initial glaucoma diagnosis
 - c. Classifying the glaucoma diagnosis
 - d. Role and use of in-office instrumentation
 - e. Treatment options
 - f. Emerging concerns in glaucoma diagnosis
 - g. Trends in glaucoma diagnostics
 - h. Trends in glaucoma therapies

We also recommend that OPES find that the State Board, in its final glaucoma regulations, reserve sufficient authority to –

- Review individual certification applications, including the licensee's practice records, course work, and examination results;
- Require the submission of additional information on the applicant's practice based diagnosis and case management experience; and
- Impose additional case management requirements in those cases where it finds it necessary to do so, to fully protect the public.

We also recommend that OPES find that the State Board should review its certification regulations periodically to assure that course subject requirements reflect the contemporary standard of care in glaucoma diagnosis, treatment, and management.

- 3. For an "appropriate combined curriculum of didactic instruction in the diagnostic, pharmacological, and other treatment and management of glaucoma, and case management of patients diagnosed with glaucoma," for licensed Doctors of Optometry who, as specified by Business and Professions Code Section 3041.10(f)(5):
 - Graduated from an accredited school of optometry prior to May 1, 2008;
 - Were not certified to diagnose, treat, and manage glaucoma patients under the provisions in effect between January 1, 2001 and January 1, 2009;
 - Will not have exercised the option to become certified under those provisions on or before December 31, 2009; and
 - Were required to and did not take the 24-hour didactic course prescribed by SB 929, by January 1, 2009,

We recommend that OPES find that the courses recommended in paragraphs 1 and 2 above be combined to form this required curriculum, with the understanding that the didactic and case management courses are not required to be offered and taken on consecutive days.

4. SB 1406 also conferred on the Advisory Committee the discretion, "[a] fter reviewing training programs for representative graduates," to recommend additional glaucoma training to be completed before any licensee's renewal application is approved. As noted, the CAEPS representatives focused on this provision inordinately throughout our meetings; as noted, for the third meeting they proposed additional glaucoma training prior to license renewal for future graduates.

We recommend that OPES find that the State Board of Optometry, as part of the exercise of its responsibility to protect the public, periodically evaluate glaucoma continuing education courses submitted for their approval to determine whether they reflect the contemporary standard of care in glaucoma diagnosis, treatment, and management. If necessary, the State Board can either amend its regulations or seek legislation to amend Business and Professions Code Section 3059 to assure that every certified licensee's continuing education in glaucoma is sufficient to warrant license renewal.

APPENDICES

APPENDIX A:

Amendments to Existing Law Made by SENATE BILL 1406 (CORREA & AANESTAD)

As Chaptered by the Secretary of State September 26, 2008 - Statutes of 2008, Chapter 352

Section 3041 of the Business and Professions Code is amended, to read:

- 3041. (a) The practice of optometry includes the prevention and diagnosis of disorders and dysfunctions of the visual system, and the treatment and management of certain disorders and dysfunctions of the visual system, as well as the provision of rehabilitative optometric services, and is the doing of any or all of the following:
- (1) The examination of the human eye or eyes, or its or their appendages, and the analysis of the human vision system, either subjectively or objectively.
- (2) The determination of the powers or range of human vision and the accommodative and refractive states of the human eye or eyes, including the scope of its or their functions and general condition.
- (3) The prescribing or directing the use of, or using, any optical device in connection with ocular exercises, visual training, vision training, or orthoptics.
- (4) The prescribing of contact and spectacle lenses for, or the fitting or adaptation of contact and spectacle lenses to, the human eye, including lenses which may be classified as drugs or devices by any law of the United States or of this state.
- (5) The use of topical pharmaceutical agents for the sole purpose of the examination of the human eye or eyes for any disease or pathological condition. The topical pharmaceutical agents shall include mydriatics, cycloplegics, anesthetics, and agents for the reversal of mydriasis.
- (b) (1) An optometrist who is certified to use therapeutic pharmaceutical agents, pursuant to Section 3041.3, may also diagnose and exclusively treat the human eye or eyes, or any of its appendages, for all of the following conditions:
- (A) Through medical treatment, infections of the anterior segment and adnexa, excluding the lacrimal gland, the lacrimal drainage system and the sclera *in patients under 12 years of age* Nothing in this section shall authorize any optometrist to treat a person with AIDS for ocular infections.
 - (B) Ocular allergies of the anterior segment and adnexa.
- (C) Ocular inflammation, nonsurgical in cause except when comanaged with the treating surgeon, limited to inflammation resulting from traumatic iritis, peripheral corneal inflammatory keratitis, episcleritis, and unilateral nonrecurrent nongranulomatous idiopathic iritis in patients over 18 years of age. Unilateral nongranulomatous idiopathic iritis recurring within one year of the initial occurrence shall be referred to an ophthalmologist. An optometrist shall consult with an ophthalmologist if a patient has a recurrent case of episcleritis within one year of the initial occurrence. An optometrist shall consult with an ophthalmologist if a patient has a recurrent case of peripheral corneal inflammatory keratitis within one year of the initial occurrence.
 - (D) Traumatic or recurrent conjunctival or corneal abrasions and erosions.
 - (E) Corneal surface disease and dry eyes.
- (F) Ocular pain, not related to surgery except when comanaged with the treating surgeon, associated with conditions optometrists are authorized to treat.
- (G) Pursuant to subdivision (f), primary open-angle glaucoma in patients over 18 years of age, as described in subdivision (j).
- (2) For purposes of this section, "treat" means the use of therapeutic pharmaceutical agents, as described in subdivision (c), and the procedures described in subdivision (e).

- (c) In diagnosing and treating the conditions listed in subdivision (b), an optometrist certified to use therapeutic pharmaceutical agents pursuant to Section 3041.3, may use all of the following therapeutic pharmaceutical agents *exclusively*:
- (1) All-of the topical p Pharmaceutical agents listed in paragraph (5) of subdivision (a) as well as topical miotics for diagnostic purposes.
 - (2) Topical lubricants.
- (3) Topical a Antiallergy agents. In using topical steroid medication for the treatment of ocular allergies, an optometrist shall do the following consult with an ophthalmologist if the patient's condition worsens 21 days after diagnosis:
 - (A) Consult with an ophthalmologist if the patient's condition worsens 72 hours after diagnosis.
- (B) Consult with an ophthalmologist if the inflammation is still present three weeks after diagnosis.
- (C) Refer the patient to an ophthalmologist if the patient is still on the medication six weeks after diagnosis.
 - (D) Refer the patient to an ophthalmologist if the patient's condition recurs within three months.
 - (4) Topical and oral antiinflammatories. In using topical steroid medication for:
- (A) Unilateral nonrecurrent nongranulomatous idiopathic iritis or episcleritis, an optometrist shall consult with an ophthalmologist *or other appropriate physician and surgeon* if the patient's condition worsens 72 hours after the diagnosis, or if the patient's condition has not resolved three weeks after diagnosis. If the patient is still receiving medication for these conditions six weeks after diagnosis, the optometrist shall refer the patient to an ophthalmologist *or other appropriate physician and surgeon*.
- (B) Peripheral corneal inflammatory keratitis, excluding Moorens and Terriens diseases, an optometrist shall consult with an ophthalmologist *or other appropriate physician and surgeon* if the patient's condition worsens 48 72 hours after diagnosis. If the patient is still receiving the medication two weeks after diagnosis, the optometrist shall refer the patient to an ophthalmologist.
- (C) Traumatic iritis, an optometrist shall consult with an ophthalmologist if the patient's condition worsens 72 hours after diagnosis and shall refer the patient to an ophthalmologist if the patient's condition has not resolved one week after diagnosis.
 - (5) Topical antibiotic agents.
 - (6) Topical hyperosmotics.
- (7) Topical *and oral* antiglaucoma agents pursuant to the certification process defined in subdivision (f).
- (A) The optometrist shall not use more than two concurrent topical medications in treating the patient for primary open-angle glaucoma. A single combination medication that contains two pharmacological agents shall be considered as two medications.
- (B) The optometrist shall refer the patient to an ophthalmologist if requested by the patient, if treatment goals are not achieved with the use of two topical medications or if indications of narrowangle or secondary closure glaucoma develops.
- (CB) If the glaucoma patient also has diabetes, the optometrist shall consult in writing with the physician treating the patient's diabetes in developing the glaucoma treatment plan and shall notify the physician in writing of any changes in the patient's glaucoma medication. The physician shall provide written confirmation of those consultations and notifications.
 - (8) Nonprescription medications used for the rational treatment of an ocular disorder.
- (9) Oral antihistamines. In using oral antihistamines for the treatment of ocular allergies, the optometrist shall refer the patient to an ophthalmologist if the patient's condition has not resolved two weeks after diagnosis.
- (10) Prescription oral nonsteroidal antiinflammatory agents. The agents shall be limited to three days' use. If the patient's condition has not resolved three days after diagnosis, the optometrist shall refer the patient to an ophthalmologist.

- (11) The following o Oral antibiotics for medical treatment of ocular disease. -as set forth in subparagraph (A) of paragraph (1) of subdivision (b): tetracyclines, dicloxacillin, amoxicillin, amoxicillin with clavulanate, crythromycin, clarythromycin, cephalexin, cephalexin, cephalexin, cefaclor, trimethoprim with sulfamethoxazole, ciprofloxacin, and azithromycin. The use of azithromycin shall be limited to the treatment of cyclid infections and chlamydial disease manifesting in the cycs.
- (A) If the patient has been diagnosed with a central corneal ulcer and the condition has not improved 24 48 hours after diagnosis, the optometrist shall eonsult with refer the patient to an ophthalmologist. If the central corneal ulcer has not improved 48 hours after diagnosis, the optometrist shall refer the patient to an ophthalmologist. If the patient is still receiving antibiotics 10 days after diagnosis, the optometrist shall refer the patient to an ophthalmologist.
- (B) If the patient has been diagnosed with preseptal cellulitis or dacryocystitis and the condition has not improved 72 48 hours after diagnosis, the optometrist shall refer the patient to an ophthalmologist. If a patient with preseptal cellulitis or dacryocystitis is still receiving oral antibiotics 10 days after diagnosis, the optometrist shall refer the patient to an ophthalmologist.
- (C) If the patient has been diagnosed with blepharitis and the patient's condition does not improve after six weeks of treatment, the optometrist shall consult with an ophthalmologist.
- (D) For the medical treatment of all other medical conditions as set forth in subparagraph (A) of paragraph (1) of subdivision (b), if the patient's condition worsens 72 hours after diagnosis, the optometrist shall consult with an ophthalmologist. If the patient's condition has not resolved 10 days after diagnosis, the optometrist shall refer the patient to an ophthalmologist.
- (12) Topical *and oral* antiviral medication and oral acyclovir for the medical treatment of the following: herpes simplex viral keratitis, herpes simplex viral conjunctivitis, and periocular herpes simplex viral dermatitis; and varicella zoster viral keratitis, varicella zoster viral conjunctivitis, and periocular varicella zoster viral dermatitis.
- (A) If the patient has been diagnosed with herpes simplex keratitis or varicella zoster viral keratitis and the patient's condition has not improved seven days after diagnosis, the optometrist shall refer the patient to an ophthalmologist. If a patient's condition has not resolved three weeks after diagnosis, the optometrist shall refer the patient to an ophthalmologist.
- (B) If the patient has been diagnosed with herpes simplex viral conjunctivitis, herpes simplex viral dermatitis, varicella zoster viral conjunctivitis, or varicella zoster viral dermatitis, and if the patient's condition worsens seven days after diagnosis, the optometrist shall consult with an ophthalmologist. If the patient's condition has not resolved three weeks after diagnosis, the optometrist shall refer the patient to an ophthalmologist.
- (C) In all cases, the use of topical antiviral medication shall be limited to three weeks, and the use of oral acyclovir shall be limited to 10 days.
 - (13) Oral analgesics that are not controlled substances.
- (14) Codeine with compounds and hydrocodone with compounds as listed in the California Uniform Controlled Substances Act (Section 11000 of the Health and Safety Code et seq.) and the United States Uniform Controlled Substances Act (21 U.S.C. Sec. 801 et seq.). The se of these agents shall be limited to three days, with a referral to an ophthalmologist if the pain persists.
- (d) In any case where this chapter requires that an optometrist consult with an ophthalmologist, the optometrist shall maintain a written record in the patient's file of the information provided to the ophthalmologist, the ophthalmologist's response and any other relevant information. Upon the consulting ophthalmologist's request *and with the patient's consent*, the optometrist shall furnish a copy of the record to the ophthalmologist.
- (e) An optometrist who is certified to use therapeutic pharmaceutical agents pursuant to Section 3041.3 may also perform all of the following:
 - (1) Corneal scraping with cultures.
 - (2) Debridement of corneal epithelia.

- (3) Mechanical epilation.
- (4) Venipuncture for testing patients suspected of having diabetes.
- (5) Suture removal, with prior consultation with the treating physician and surgeon.
- (6) Treatment or removal of sebaceous cysts by expression.
- (7) Administration of oral fluorescein to patients suspected as having diabetic retinopathy.
- (8) Use of an auto-injector to counter anaphylaxis.
- (9) Ordering of smears, cultures, sensitivities, complete blood count, mycobacterial culture, acid fast stain, and urinalysis, and X-rays necessary for the diagnosis of conditions or diseases of the eye or adnexa. An optometrist may order other types of images subject to prior consultation with an ophthalmologist or appropriate physician and surgeon.
- (3 10) Punctal occlusion by plugs, excluding laser, cautery, diathermy, cryotherapy, or other means constituting surgery as defined in this chapter subdivision (h).
- (4 11) The prescription of therapeutic contact lenses, including lenses or devices that incorporate a medication or therapy the optometrist is certified to prescribe or provide.
- (5 12) Removal of foreign bodies from the cornea, eyelid, and conjunctiva with any appropriate instrument other than a scalpel or needle. Corneal foreign bodies shall be nonperforating, be no deeper than the anterior mid-stroma, and require no surgical repair upon removal. Within the central three millimeters of the cornea, the use of sharp instruments is prohibited.
- (6 13) For patients over 12 years of age, lacrimal irrigation and dilation, excluding probing of the nasal lacrimal tract. The State Board of Optometry shall certify an optometrist to perform this procedure after completing 10 of the procedures under the supervision of an ophthalmologist as confirmed by the ophthalmologist.
 - (7) No injections other than the use of an auto-injector to counter anaphylaxis.
- (f) The State Board of Optometry shall grant a certificate to an optometrist certified pursuant to Section 3041.3 for the treatment of primary open-angle glaucoma, as described in subdivision (j), in patients over 18 years of age only after the optometrist meets the following requirements:
- (1) Satisfactory completion of a didactic course of not less than 24 hours in the diagnosis, pharmacological and other treatment and management of glaucoma. The 24-hour glaucoma curriculum shall be developed by an accredited California school of optometry. Any applicant who graduated from an accredited California school of optometry on or after May 1, 2000, shall be exempt from the 24-hour didactic course requirement contained in this paragraph.
- (2) After completion of the requirement contained in paragraph (1), collaborative treatment of 50 glaucoma patients for a period of two years for each patient under the following terms:
- (A) After the optometrist makes a provisional diagnosis of glaucoma, the optometrist and the patient shall identify a collaborating ophthalmologist.
- (B) The optometrist shall develop a treatment plan that considers for each patient target intraocular pressures, optic nerve appearance and visual field testing for each eye, and an initial proposal for therapy.
- (C) The optometrist shall transmit relevant information from the examination and history taken of the patient along with the treatment plan to the collaborating ophthalmologist. The collaborating ophthalmologist shall confirm or refute the glaucoma diagnosis within 30 days. To accomplish this, the collaborating ophthalmologist shall perform a physical examination of the patient.
- (D) Once the collaborating ophthalmologist confirms the diagnosis and approves the treatment plan in writing, the optometrist may begin treatment.
- (E) The optometrist shall use no more than two concurrent topical medications in treating the patient for glaucoma. A single combination medication that contains two pharmacologic agents shall be considered as two medications. The optometrist shall notify the collaborating ophthalmologist in writing if there is any change in the medication used to treat the patient for glaucoma.

- (F) Annually after commencing treatment, the optometrist shall provide a written report to the collaborating ophthalmologist about the achievement of goals contained in the treatment plan. The collaborating ophthalmologist shall acknowledge receipt of the report in writing to the optometrist within 10 days.
- (G) The optometrist shall refer the patient to an ophthalmologist if requested by the patient, if treatment goals are not achieved with the use of two topical medications, or if indications of secondary glaucoma develop. At his or her discretion, the collaborating ophthalmologist may periodically examine the patient.
- (H) If the glaucoma patient also has diabetes, the optometrist shall consult in writing with the physician treating the patient's diabetes in preparation of the treatment plan and shall notify the physician in writing if there is any change in the patient's glaucoma medication. The physician shall provide written confirmation of the consultations and notifications.
- (I) The optometrist shall provide the following information to the patient in writing: nature of the working or suspected diagnosis, consultation evaluation by a collaborating ophthalmologist, treatment plan goals, expected followup care, and a description of the referral requirements. The document containing the information shall be signed and dated by both the optometrist and the ophthalmologist and maintained in their files.
- (3) When the requirements contained in paragraphs (1) and (2) have been satisfied, the optometrist shall submit proof of completion to the State Board of Optometry and apply for a certificate to treat primary open angle glaucoma. That proof shall include corroborating information from the collaborating ophthalmologist. If the ophthalmologist fails to respond within 60 days of a request for information from the State Board of Optometry, the board may act on the optometrist's application without that corroborating information.
- (4) After an optometrist has treated a total of 50 patients for a period of two years each and has received certification from the State Board of Optometry, the optometrist may treat the original 50 collaboratively treated patients independently, with the written consent of the patient. However, any glaucoma patients seen by the optometrist before the two-year period has expired for each of the 50 patients shall be treated under the collaboration protocols described in this section.
- (5) For purposes of this subdivision, "collaborating ophthalmologist" means a physician and surgeon who is licensed by the state and in the active practice of ophthalmology in this state.
- (1) For licensees who graduated from an accredited school of optometry on or after May 1, 2008, submission of proof of graduation from that institution.
- (2) For licensees who were certified to treat glaucoma under this section prior to January 1, 2009, submission of proof of completion of that certification program.
- (3) 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. "Substantially completed" means:
- (A) Satisfactory completion of a didactic course of not less than 24 hours in the diagnosis, pharmacological and other treatment and management of glaucoma, and
- (B) 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.
- (4) For licensees who completed a didactic course of not less than 24 hours in the diagnosis, pharmacological, and other treatment and management of glaucoma, submission of proof of satisfactory completion of the case management requirements for certification established by the board pursuant to Section 3041.10.
- (5) For licensees who graduated from an accredited school of optometry on or before May 1, 2008 and not described in paragraph (2), (3), or (4), submission of proof of satisfactory completion of the requirements for certification established by the board pursuant to Section 3014.10.

- (g) Notwithstanding any other provision of law, an optometrist shall not treat children under one year of age with therapeutic pharmaceutical agents.
- $\frac{}{}$ (h) Other than for prescription ophthalmic devices described in subdivision (b) of Section 2541, aAny dispensing of a therapeutic pharmaceutical agent by an optometrist shall be without charge.
- (i h) Notwithstanding any other provision of law, t The practice of optometry does not include performing surgery. "Surgery" means any procedure in which human tissue is cut, altered, or otherwise infiltrated by mechanical or laser means in a manner not specifically authorized by this chapter. "Surgery" does not include those procedures specified in subdivision (e). Nothing in the act amending this section shall limit an optometrist's authority, as it existed prior to the effective date of the act amending this section, to utilize diagnostic laser and ultrasound technology within his or her scope of practice.
- (j) All collaborations, consultations, and referrals made by an optometrist pursuant to this section shall be to an ophthalmologist located geographically appropriate to the patient.
- ($\pm i$) An optometrist licensed under this chapter is subject to the provisions of Section 2290.5 for purposes of practicing telemedicine.
 - (j) For purposes of this chapter, "glaucoma" means either of the following:
 - (1) All primary open-angle glaucoma.
 - (2) Exfoliation and pigmentary glaucoma.
- (k) In an emergency, an optometrist shall stabilize, if possible, and immediately refer any patient who has an acute attack of angle closure to an ophthalmologist.

Section 3041.10 is added to the Business and Professions Code, to read:

- 3041.10. (a) The Legislature hereby finds and declares that it is necessary to ensure that the public is adequately protected during the transition to full certification for all licensed optometrists who desire to treat and manage glaucoma patients.
- (b) The board shall appoint a Glaucoma Diagnosis and Treatment Advisory Committee as soon as practicable after January 1, 2009. The committee shall consist of six members currently licensed and in active practice in their professions in California, with the following qualifications:
- (1) Two members shall be optometrists who were certified by the board to treat glaucoma pursuant to the provisions of subdivision (f) of Section 3041, as that provision read on January 1, 2001, and who are actively managing glaucoma patients in full-time practice.
- (2) One member shall be a glaucoma-certified optometrist currently active in educating optometric students in glaucoma.
- (3) One member shall be a physician and surgeon board-certified in ophthalmology with a specialty or subspecialty in glaucoma who is currently active in educating optometric students in glaucoma.
- (4) Two members shall be physicians and surgeons board-certified in ophthalmology who treat glaucoma patients.
- (c) The board shall appoint the members of the committee from a list provided by the following organizations:
 - (1) For the optometrists' appointments, the California Optometric Association.
- (2) For the physician and surgeons' appointments, the California Medical Association- and the California Academy of Eye Physicians and Surgeons.
- (d) The committee shall establish requirements for glaucoma certification, as authorized by Section 3041, by recommending both of the following:
- (1) An appropriate curriculum for case management of patients diagnosed with glaucoma for applicants for certification described in paragraph (4) of subdivision (f) of Section 3041, and

(2) An appropriate combined curriculum of didactic instruction in the diagnostic, pharmacological, and other treatment and management of glaucoma, and case management of patients diagnosed with glaucoma, for certification described in paragraph (5) of subdivision (f) of Section 3041.

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

- (e) The committee shall meet at such times and places as determined by the board and shall not meet initially until all six members are appointed. Committee meetings shall be public and a quorum shall consist of four members in attendance at any properly noticed meeting.
- (f) (1) The committee shall submit its final recommendations to the Office of Examination Resources of the department on or before April 1, 2009. The office shall examine the committee's recommended curriculum requirements to determine whether they will do the following:
 - (A) Adequately protect glaucoma patients.
- (B) Ensure that defined applicant optometrists will be certified to treat glaucoma on an appropriate and timely basis.
- (C) Be consistent with the department's and board's examination validation for licensure and occupational analyses policies adopted pursuant to subdivision (b) of Section 139.
- (2) The office shall present its findings and any modifications necessary to meet the requirements of paragraph (1) to the board on or before July 1, 2009. The board shall adopt the findings of the office and shall implement certification requirements pursuant to this section on or before January 1, 2010.
- (g) This section shall remain in effect only until January 1, 2010, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2010, deletes or extends that date.

Section 3152 of the Business and Professions Code is amended to read:

- 3152. The amount of fees and penalties prescribed by this chapter shall be established by the board in amounts not greater than those specified in the following schedule:
- (a) The fee for applicants applying for a license shall not exceed two hundred seventy-five dollars (\$275).
 - (b) The fee for renewal of an optometric license shall not exceed five hundred dollars (\$500).
- (c) The annual fee for the renewal of a branch office license shall not exceed seventy-five dollars (\$75).
 - (d) The fee for a branch office license shall not exceed seventy-five dollars (\$75).
- (e) The penalty for failure to pay the annual fee for renewal of a branch office license shall not exceed twenty-five dollars (\$25).
- (f) The fee for issuance of a license or upon change of name authorized by law of a person holding a license under this chapter shall not exceed twenty-five dollars (\$25).
 - (g) The delinquency fee for renewal of an optometric license shall not exceed fifty dollars (\$50).
- (h) The application fee for a certificate to treat lacrimal irrigation and dilation shall not exceed fifty dollars (\$50).
- (i) The application fee for a certificate to treat primary open angle glaucoma shall not exceed fifty dollars (\$50).
- (j) The fee for approval of a continuing education course shall not exceed one hundred dollars (\$100).
 - (k) The fee for issuance of a statement of licensure shall not exceed forty dollars (\$40).

- (l) The fee for biennial renewal of a statement of licensure shall not exceed forty dollars (\$40).
- (m) The delinquency fee for renewal of a statement of licensure shall not exceed twenty dollars (\$20).
 - (n) The application fee for a fictitious name permit shall not exceed fifty dollars (\$50).
 - (o) The renewal fee for a fictitious name permit shall not exceed fifty dollars (\$50).
- (p) The delinquency fee for renewal of a fictitious name permit shall not exceed twenty-five dollars (\$25).

APPENDIX B: TYPES OF GLAUCOMA DEFINED

Low or Normal Tension Glaucoma

Normal-tension glaucoma, also known as low-tension glaucoma, is characterized by progressive optic nerve damage and visual field loss with a statistically normal intraocular pressure. This form of glaucoma, which is being increasingly recognized, may account for as many as one-third of the cases of open-angle glaucoma in the United States.

Normal-tension glaucoma is thought to be related, at least in part, to poor blood flow to the optic nerve, which leads to death of the cells which carry impulses from the retina to the brain. In addition, these eyes appear to be susceptible to pressure-related damage even in the high normal range, and therefore a pressure lower than normal is often necessary to prevent further visual loss.

Research in the field of optic nerve blood flow and its role in glaucoma is a source of much excitement at the present time and may lead to new methods of treating this disorder. Since the best therapy for normal-tension glaucoma is largely unknown, much attention is being given to a study known as the International Collaborative Low Tension Glaucoma Protocol.

Acute Glaucoma

Unlike POAG (Primary Open-Angle Glaucoma), where the IOP increases slowly, in acute angle-closure, it increases suddenly. This sudden rise in pressure can occur within a matter of hours and become very painful. If the pressure rises high enough, the pain may become so intense that it can cause nausea and vomiting. The eye becomes red, the cornea swells and clouds, and the patient may see haloes around lights and experience blurred vision.

An acute attack is an emergency condition. If treatment is delayed, eyesight can be permanently destroyed. Scarring of the trabecular meshwork may occur and result in chronic glaucoma, which is much more difficult to control. Cataracts may also develop. Damage to the optic nerve may occur quickly and cause permanently impaired vision.

Many of these sudden 'attacks' occur in darkened rooms, such as movie theaters. Darkened environments cause the pupil to dilate, or increase in size. When this happens, there is maximum contact between the eye's lens and the iris. This further narrows the angle and may trigger an attack. The pupil also dilates when one is excited or anxious. Consequently, many acute glaucoma attacks occur during periods of stress. A variety of drugs can also cause dilation of the pupil and lead to an attack of glaucoma. These include antidepressants, cold medications, antihistamines, and some medications used to treat nausea.

Acute glaucoma attacks are not always full-blown. A patient may have a series of minor attacks. A slight blurring of vision and halos (rainbow-colored rings around lights) may be experienced, but without pain or redness. These attacks may end when the patient enters a well-lit room or goes to sleep – two situations which naturally cause the pupil to constrict, thereby allowing the iris to pull away from the drain.

An acute attack may be stopped with a combination of drops which constrict the pupil and drugs that help reduce the eye's fluid production. As soon as the IOP has dropped to a safe level, the

ophthalmologist will perform a laser iridotomy. A laser iridotomy is an outpatient procedure in which a laser beam is used to make a small opening in the iris. This allows the fluid to flow more freely. Drops will be used to anesthetize the eye and there is no pain involved. The entire procedure usually takes less than thirty minutes. Laser surgery may be performed prophylactically on the other eye, as well. Since it is common for both eyes to suffer from narrowed angles, operating on the unaffected eye is done as a preventive measure.

Routine examinations using a technique called gonioscopy can predict one's chances of having an acute attack. A special lens which contains a mirror is placed lightly on the front of the eye and the width of the angle examined visually. Patients with narrow angles can be warned of early symptoms, so that they can seek immediate treatment. In some cases, laser treatment is recommended as a preventive measure.

Not all angle-closure glaucoma sufferers will experience an acute attack. Instead, some may develop what is called chronic angle-closure glaucoma. In this case, the iris gradually closes over the drain, causing no overt symptoms. When this occurs, scars slowly form between the iris and the drain, and the IOP will not rise until there is a significant amount of scar tissue formed -- enough to cover the drainage area. I f the patient is treated with medication, such as pilocarpine, an acute attack may be prevented, but the chronic form of the disease may still develop.

Trauma-Related Glaucoma

A blow to the eye, chemical burn, or penetrating injury may all lead to the development of glaucoma, either acute or chronic. This can be due to a mechanical disruption or physical change within the eye's drainage system. It is therefore crucial for anyone who has suffered eye trauma to have check-ups at regular intervals.

Juvenile Glaucoma

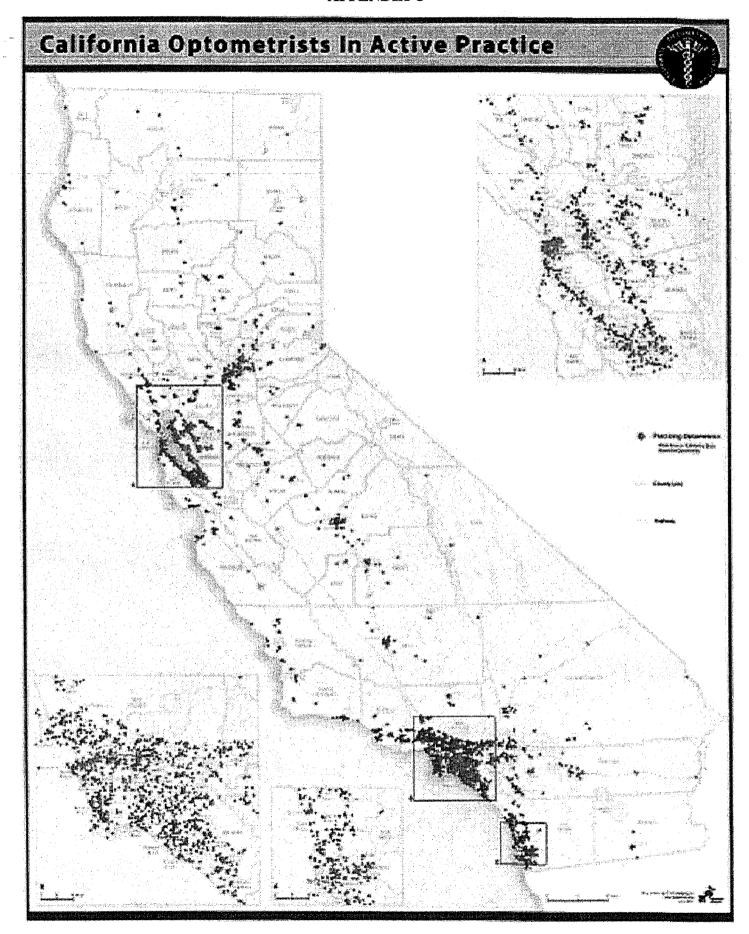
Childhood glaucoma is an unusual eye disease and significant cause of childhood blindness. It is caused by disease related abnormal increases in intraocular pressure. The many possible causes fall into one of two categories and may be primary or secondary to some other disease process. Primary congenital glaucoma results from abnormal development of the ocular drainage system. It occurs in about one out of 10,000 births in the United States and is the most common form of glaucoma in infants. Secondary glaucomas result from disorders of the body or eye and may or may not be genetic. Both types may be associated with other medical diseases.

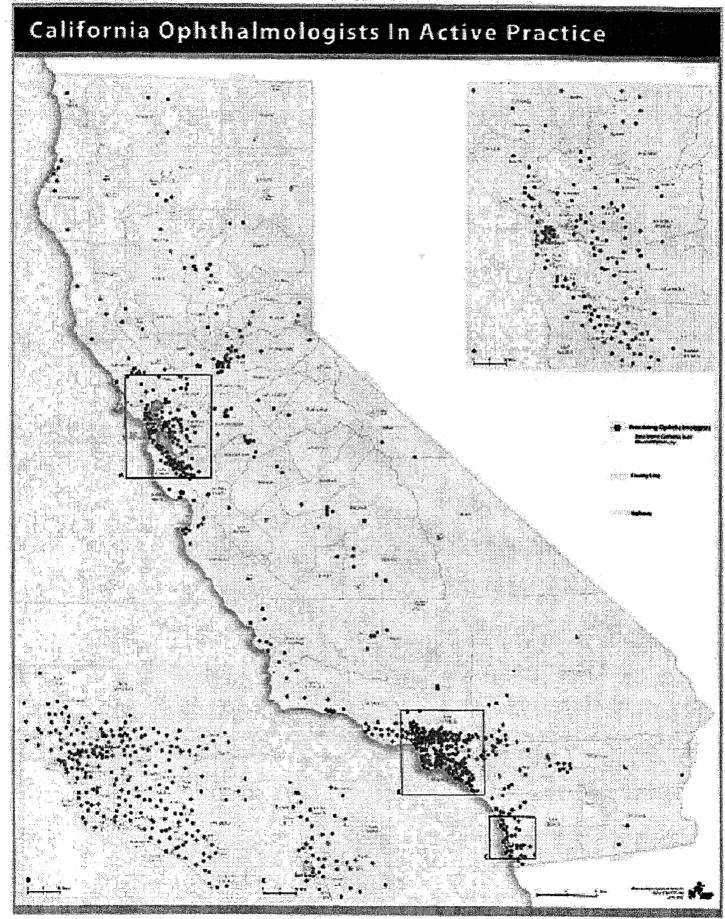
Ten percent of primary congenital glaucomas are present at birth, and 80 percent are diagnosed during the first year of life. The pediatrician or family first notice eye signs of glaucoma including clouding and/or enlargement of the cornea. The elevated intraocular pressure (IOP) can cause the eyeball itself to enlarge and injure the cornea. Important early symptoms of glaucoma in infants and children are poor vision, light sensitivity, tearing, and blinking.

Pediatric glaucoma is treated differently from adult glaucoma. Most patients require surgery and this is typically performed early. The aim of pediatric glaucoma surgery is to reduce IOP, either by increasing the outflow of fluid from the eye or decreasing the production of fluid within the eye. One operation for pediatric glaucoma is goniotomy. Its rate of success is associated with the age of the child at the time of diagnosis, the type and severity of the glaucoma, and the surgical technique. Other surgical options are trabeculectomy and glaucoma drainage tubes.

Approximately 80-90% of babies who receive prompt surgical treatment, long-term care, and monitoring of their visual development will do well, and may have normal or nearly normal vision for their lifetime. Sadly, primary congenital glaucoma results in blindness in 2 to 15 percent of childhood patients. When childhood glaucoma is not recognized and treated promptly more permanent visual loss will result.

APPENDIX C





ENDNOTES

¹ SB 1406, Stats. 2008, Chap. 352, §3.

² SB 929, Stats. 2000, Chap. 676, §3.

³ The Eye Diseases Prevalence Research Group. "Causes and prevalence of visual impairment among adults in the United States." Archives of Ophthalmology 2004; Vol. 122, No. 4, pp. 477-485.

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⁵ Eye Disease Prevalence Research Group. "Blindness". Archives of Ophthalmology 2004; Vol. 122, No. 4, pp. 437-676.

⁶ Lee, Paul P., Zachary W. Feldman, Jan Ostermann, Derek S. Brown, and Frank A. Sloan. "Longitudinal Prevalence of Major Eye Diseases". Archives of Ophthalmology. Vol. 121, No. 9, pp. 1303-10.

⁷ National Institutes of Health, National Eye Institute; and Prevent Blindness America. "Vision Problems in the U.S., 2002".

⁸ Glaucoma Research Foundation: "Glaucoma Facts and Stats." 2006.

⁹ Quigley, Harry A, and Henry D Jampel. "How Are Glaucoma Patients Identified?". Journal of Glaucoma. Vol. 12, No. 6, pp. 451-55.

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³⁶ Unlike medicine, optometric scope of practice varies from state to state; therefore, the latter's national examination must be calibrated to the highest level of practice to assure that licensure candidates are appropriately qualified and trained. This means that each school of optometry must educate its candidates accordingly to maintain accreditation. Among other factors, the ability to practice as trained and tested is an important consideration for graduates when they're making that decision.

³⁷ The School of Optometry at the Western University of Health Sciences in Pomona will not admit its first class until August 2009.

³⁸ Email message from Martin Fishman, MD, MPA, to Mona Maggio, Exec. Officer, State Bd. Of Optometry, Feb. 16, 2009. The request was forwarded to the school's Deans on February 17 with return of the information requested by February 19.

ENDNOTES

- ⁴² California's requirements are those imposed by Senate Bill 1406, effective January 1, 2009. All of the seven other States' statutes and regulations were in effect as of December 31, 2007.
- ⁴³ In California under SB 929, glaucoma certification applicants who graduated on or after May 1, 2000 were exempt from completing the otherwise required 24-hour didactic course. Stats. 2000, Ch. 352, §3; *see* CA Business & Professions Code §3041(f)(1) before amendments made by SB 1406 took effect on January 1, 2009.

³⁹ SB 863, Stats. 1976, Chap. 418, §2.

⁴⁰ California was among the first nine states to authorize use of DPAs by optometrists – the last time it was among the nation's leaders in allowing optometrists to practice more fully in line with their training. Amer. Optometric Assn. *Bulletin from Counsel*, Vol. XXXV, No. 2. July 13, 1976.

⁴¹ State Gov't. Relations Ctr., Amer. Optometric Assn. "Optometric Prescriptive Authority/Scope of Practice Chronology (By Dates of Original Enactment)." Dec. 31, 2007.

⁴⁴ Interestingly, Kansas is requiring all licensees to be both DPA and TPA-qualified by May 31, 2010.

⁴⁵ SB 668, Stats. 1996, Chap. 13, §§6, 9.

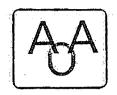
⁴⁶ According to the State Board of Optometry's public licensure database, as of May 22, 2008, 355 of 5,739 licensed optometrists were not TPA-certified. The percentage will continue to decline over time because optometrists who graduated after January 1, 1996 and became licensed have received and been tested upon sufficient TPA training before graduating from optometry school to meet California's TPA-certification requirements. *See* CA Business & Professions Code §3041.3.

⁴⁷ SB 929, supra, n. 2.

⁴⁸ For the National Practitioner Data Bank: http://www.npdb-hipdb.hrsa.gov/npdb.html; for the Healthcare Integrity and Protection Data Bank: http://www.npdb-hipdb.hrsa.gov/hipdb.html;

⁴⁹ See maps, "California Optometrists in Active Practice" and "California Ophthalmologists in Active Practice," Appendices C and D.

AMERICAN OPTOMETRIC ASSOCIATION



BULLETIN from COUNSEL

VOLUME XXXV, BULLETIN NO. 2

July 13, 1976

TO:

State Association Presidents, Legal-Legislative Chairmen, Attorneys, Executives, Legislative Counsel

FROM:

Thomas E. Eichhorst, J.D., Counsel; AOA, St. Louis

SUBJECT: California Legislation

DIST:

O, T, Division Executive Committee Chairmen, ED, WOD, GC, C, AA, Division Directors, E, NE, Administrative Heads of Schools and Colleges, State Board Presidents, Secretaries, Attorneys, Optometric Legislators

On Friday, July 9, 1976, California Governor Edmund G. Brown, Jr., signed into law Senate Bill No. 863, as amended. This law revises the acts that constitute the practice of optometry and permit the use of topical pharmaceutical agents in the examination of the eye for any disease or pathological condition.

A copy of this bill, as enacted, is attached.

The bill, in its final form, passed the Assembly on June 21 by a vote of 44 to 23, and the Senate on June 24 by a vote of 22 to 4.

California is the ninth state to enact legislation authorizing optometrists to utilize pharmaceutical agents. Six other states authorize optometrists to utilize diagnostic pharmaceutical agents; the dates of the enactment of these laws are Rhode Island (July 16, 1971), Pennsylvania (March 1, 1974), Tennessee (May 8, 1975), Oregon (May 20, 1975), Maine (June 24, 1975), Louisiana (July 6, 1975), and Delaware (July 10, 1975). On March 4, 1976, the West Virginia Legislature authorized the use of drugs for diagnostic or therapeutic purposes by optometrists who meet educational requirements set by the optometry board.

[In addition, there are nine other states that do not statutorily prohibit the use of DPAs by optometrists; several of these states have attorney general opinions (+ favorable) (- unfavorable) on this point: Alabama, Florida (AG+), Idaho, Indiana (AG+), Kansas, Minnesota, Nevada (State Board statement +), New Jersey (AG+), Virginia (AG-).]

AMENDED IN ASSEMBLY APRIL 29, 1976
AMENDED IN ASSEMBLY FEBRUARY 5, 1976
AMENDED IN ASSEMBLY FEBRUARY 28, 1976
AMENDED IN ASSEMBLY JANUARY 28, 1976
AMENDED IN ASSEMBLY AUGUST 19, 1975
AMENDED IN ASSEMBLY AUGUST 7, 1975
AMENDED IN SENATE MAY 20, 1975
AMENDED IN SENATE MAY 12, 1975

SENATE BILL

No. 863

Introduced by Senator Zenovich (Coauthor: Assemblyman Papan)

April 10, 1975

An act to add Sections 3041, 3041.1, 3041.2, 3109, and 3153 to, and to repeal Sections 3041 and 3041.1 of, the Business and Professions Code, relating to optometry.

LEGISLATIVE COUNSEL'S DICEST

SB 863, as amended, Zenovich. Optometry.

Existing law defines the practice of optometry as the doing of certain acts related to the eye. This definition does not permit the use of drugs.

This bill would revise the acts that constitute the practice of optometry. It would, among other things, include the prescribing, fitting, or adaptation of spectacle lenses in such definition and would permit the use of topical pharmaceutical agents in the examination of the eye for any disease or pathological condition.

The bill would require the Board of Optometry, with the advice and consent of the Division of Allied Health Profes-

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sions of the Board of Medical Quality Assurance, to specify those pharmaceutical agents that may be used. The bill would also require the board with the advice and consent of the division to adopt rules and regulations to insure professional competence in the use of such agents and would require optometrists to complete a course of study and pass an examination at a specified maximum fee, before using such agents.

The bill requires that after January 1, 1980, an optometrist must complete specified educational and examination requirements relating to the use of such agents as a condition of receiving a new for the issuance of an original certificate to practice optometry.

Existing law prescribes the various acts which constitutes grounds for revocation or suspension of a certificate of registration to practice optometry, including various acts of unprofessional conduct.

This bill would add that failure to refer a patient to a physician where examination of the eyes indicates a substantial likelihood of any pathology which requires the attention of the appropriate physician shall constitute unprofessional conduct.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 3041 of the Business and 2 Professions Code is repealed.
- 3 SEC. 2. Section 3041 is added to the Business and 4 Professions Code, to read:
- 5 3041. The practice of optometry is the doing of any or 6 all of the following:
- 7 (a) The examination of the human eye or eyes, or its 8 or their appendages, and the analysis of the human vision 9 system, either subjectively or objectively.
- 10 (b) The determination of the powers or range of 11 human vision and the accommodative and refractive 12 states of the human eye or eyes, including the scope of its
- 13 or their functions and general condition.
- 14 (c) The prescribing or directing the use of, or using,

any optical device in connection with ocular exercises.

visual training, vision training, or orthoptics.

(d) The prescribing of contact and spectacle lenses 4 for, or the fitting or adaptation of contact and spectacle 5 lenses to, the human eye, including lenses which may be 6 classified as drugs by any law of the United States or of . 7 this state.

8 (e) The use of topical pharmaceutical agents for the 9 sole purpose of the examination of the human eye or eyes 10 for any disease or pathological condition. The State Board 11 of Optometry, with the advice and consent of the 12 Division of Allied Health Professions of the Board of 13 Medical Quality Assurance, to be provided within six 14 months of the effective date of this section, shall 15 designate the specific topical pharmaceutical agents, 16 known generically as mydriatics, cycloplegics, and topical 17 anesthetics, to be used.

SEC. 3. Section 3041.1 is added to the Business and

19 Professions Code, to read:

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3041.1. (a) The State Board of Optometry with the 21 advice and consent of the Division of Allied Health 22 Professions of the Board of Medical Quality Assurance, to 23 be provided within six months of the effective date of this 24 section, shall adopt rules and regulations, including 25 additional education qualifications, necessary to insure 26 professional competence by those practitioners whose 27 activities fall within the definition of the practice of 28 optometry in subdivision (e) of Section 3041.

(b) Only those optometrists who have satisfactorily 30 completed such courses and successfully passed an examination prepared and given by the State Board of 32 Optometry, with the advice and consent of the Division 33 of Allied Health Professions of the Board of Medical 34 Quality Assurance, to be provided within six months of 35 the effective date of this section, shall be permitted the 36 use of such pharmaceutical agents as specified by subdivision (e) of Section 3041.

37 38 This section shall remain in effect until December 31,

39 1979, and on such date is repealed.

SEC. 4. Section 3041.2 is added to the Business and

1

1 Professions Code, to read:

3041.2. The State Board of Optometry shall by regulation, with the advice and consent of the Division of Allied Health Professions of the Board of Medical Quality 5 Assurance establish educational and examination 6 requirements for licensure to insure the competence of 7 optometrists to practice pursuant to subdivision (e) of 8 Section 3041. Satisfactory completion of the educational 9 and examination requirements shall be a condition of 10 receiving a new for the issuance of an original certificate 11 of registration under this chapter, on and after January 1, 12 1980. Only those optometrists who have successfully 13 completed educational and examination requirements as determined by the State Board of Optometry with the advice and consent of the Division of Allied Health 16 Professions of the Board of Medical Quality Assurance 17 shall be permitted the use of pharmaceutical agents specified by subdivision (e) of Section 3041. 19

SEC. 5. Section 3109 is added to the Business and

20 Professions Code, to read:

21 3109. It shall be unprofessional conduct for an optometrist to fail to refer a patient to an appropriate physician where an examination of the eyes indicates a 24 substantial likelihood of any pathology which requires the attention of the appropriate physician.

SEC. 6. Section 3153 is added to the Business and

Professions Code, to read:

3153. Notwithstanding Section 3152, the fee for the examination required by Section 3041.1 shall not exceed thirty-five dollars (\$35).

Source: http://www.aoa.org/x5157.xml



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ACOE Accreditation Process

Accreditation is a process of self-study and external review that ensures that an educational program meets or exceeds predetermined standards. The ACOE is recognized by the United States Department of Education as an authority on the quality of the educational programs it accredits. The ACOE uses the following steps in the accreditation process:

Development and publication of standards

The ACOE develops educational standards that are the requirements for programs to be accredited. Prior to adopting standards, the Council seeks input from the higher education community, the profession of optometry and the public at large to ensure that standards reflect requirements that are essential to operating an optometric program. The standards of accreditation for each of the three types of programs accredited by the ACOE are published in its Accreditation Manuals. Click on these links to find the manuals for the **professional optometric degree (OD) programs**, **optometric residency programs**, or **optometric technician programs**.

Self-study

The professional optometric degree, optometric residency or optometric technician program examines itself in light of how well it achieves its own mission, goals and objectives for the purpose of self-improvement and planning. The self-study also documents how the program meets the standards of the ACOE. The self-study is submitted to the ACOE with a letter of application for accreditation from the chief executive officer of the institution offering the program.

Invitation for comments about accredited programs

ACOE's accreditation process includes the consideration of third-party comments. The calendar of site visits (click here to see the upcoming site visits calendar) contains the accreditation status and the month and year of all site visits currently scheduled for the next year. For those programs that are seeking initial accreditation, the notation of "Initial" is listed. Third party comments must address substantive matters relating to the quality of the program and the ACOE standards and should be addressed to the administrative director of the Council at ACOE, 243 N. Lindbergh Blvd., St. Louis, MO 63141. Comments must be received 30 days prior to the program's scheduled site visit date. (In cases where the exact date is not yet determined, the month and year of the visit is listed, and the comments must be received by not later than the first day of the month preceding the site visit. All third party comments must be signed.) Comments will be forwarded to the evaluation team and to the appropriate program director for response during the evaluation visit process.

Evaluation visit

The ACOE sends a team of evaluators with expertise in optometric education and practice to visit the program to assess its compliance with the ACOE's standards. The team validates the self-study by interviewing students, faculty and administrators, reviewing records and files, and examining the facilities. ACOE strives to ensure that the team is impartial, objective and without conflict of interest.

Report of visit

Following the evaluation visit, the team writes a report of its findings that includes the team's findings relating the program's compliance with the ACOE standards. The report is forwarded to the program to review its factual accuracy before the finalized report is presented to the ACOE.

Determination of accreditation status

At regularly scheduled meetings, the ACOE reviews accreditation reports to determine if the programs meet the standards of accreditation and to award an appropriate accreditation category. The category of "accredited" means the program generally meets the standards of accreditation. "Accredited" indicates that the program has no major deficiencies that compromise the educational effectiveness of the total program. However, recommendations to address marginal compliance with certain standards and suggestions for program improvement may be included in the evaluation report. The category of "accredited with conditions" indicates major deficiencies or weaknesses in reference to the standards.

Publishing accreditation status

The Council publishes lists of accredited programs, which are updated regularly. **Click here** to view the current lists.

Monitoring accredited programs

The ACOE monitors accredited programs in between evaluation visits through annual reports, progress reports and, in some cases, interim visits to ensure that the programs address the recommendations to come into compliance with any unmet standards in a timely fashion.

Accreditation fees

The ACOE assesses programs seeking accreditation or pre-accreditation an application fee. Application fees for new programs should be submitted with the program's initial self-study and letter of application. The current application fees follow:

Professional Optometric Degree Programs

\$4,500

Optometric Residency Programs (VA and Non-VA)

\$500

Optometric Technician Programs

\$500

The following is the schedule of annual accreditation fees charged to each accredited program.

Type of program	ACOE Fees Beginning in 2006-07per program
Professional Optometric Degree Programs*	\$2,250
Optometric Residency Programs at VA facilities**	\$1,050
Optometry Residency Programs (Non-VA) *	\$750
Optometric Technician Programs*	\$750

^{*}Non-VA programs will also be billed for expenses related to site visits. **The annual fees for VA residency programs include a prorated average cost of evaluation visit expenses distributed over a 7-year period.

Invoices for annual fees are sent in October, and payment is due to the ACOE by January 1 of each year.

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BILL ANALYSIS

SB 1406 Page 1

Date of Hearing: June 24, 2008

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS Mike Eng. Chair

SB 1406 (Correa) - As Amended: June 19, 2008

SENATE VOTE : 33-1

SUBJECT : Optometry

<u>SUMMARY</u>: Deletes the requirement that an optometrist who has prescribed specified pharmaceutical agents consult with an ophthalmologist after specified time periods has elapsed, and expands the authority of optometrists to treat glaucoma and perform other specified procedures. Specifically, <u>this bill</u>:

- 1) Deletes the specification that optometrists use only topical pharmaceutical agents for treatment.
- 2) Specifies that optometrists certified to use therapeutic pharmaceutical agents may treat:
 - a) Patients under 12 years of age for certain infections;
 - b) Individuals with acquired immune deficiency syndrome (AIDS).
 - c) Ocular inflammations, including those caused by surgery, in patients over 12 years of age, and should there be a recurrence of conditions, as specified, an optometrist may consult with an appropriate health care provider besides an ophthalmologist;
 - d) Ocular pain, including that related to surgery, associated with conditions optometrists are authorized to treat; and,
 - e) Glaucoma in patients over 18 years of age, as specified, though not restricted to primary open angle glaucoma.
- 3) Deletes the restriction that optometrists may use only the pharmaceuticals listed in present law.
- 4) Deletes the restriction that topical miotics be used only for diagnostic purposes.

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- 5) Deletes the protocol for the use of topical steroid medications in treating ocular allergies.
- 6) Permits optometrists certified to use therapeutic pharmaceutical agents to use oral anti-inflammatories in addition to topical.
- 7) Revises the amount of time necessary before an optometrist consults or refers to an ophthalmologist or other appropriate health care provider, as specified.
- 8) Deletes the prohibition on optometrists using two concurrent topical medications in treating a patient for primary open-angle glaucoma.
- 9) Permits an optometrist to consult with, rather than exclusively refer to, an ophthalmologist if requested by a patient or if a condition develops, as specified.
- 10) Requires an optometrist to inform in writing, rather than consult with, the treating physician if a glaucoma patient also has diabetes.
- 11) Deletes limits related to the duration a patient may be on specified pharmaceuticals.
- 12) Specifies that optometrists certified to use therapeutic pharmaceutical agents may:
 - a) Perform procedures necessary for the diagnosis or treatment of a condition of the eye or visual system, including, but not limited to:
 - i) Biopsies not requiring sutures;
 - ii) Corneal scraping with cultures;
 - iii) Debridement;
 - iv) Epilation, including with cryo or electro cautery;
 - v) Nonintraoribital injections;
 - vi) Lacrimal probing, with or without dilation;

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- vii) Skin lesion removal;
- viii) Removal of skin tags;
- ix) Shaving of epidermal or dermal lesions;
- x) Stromal micropuncture;
- xi) Suture removal, with prior consultation; and,
- xii) Treatment or removal of lymphatic or sebaceous
 cysts.
- Order other tests or procedures necessary for the diagnosis of conditions or diseases of the eye or adnexa;
- c) Perform punctual occlusion by cautery; and,
- d) Prescribe lenses or devices that incorporate a medication or therapy the optometrist is certified to prescribe or provide.
- 13) Deletes the restriction on optometrists certified to use therapeutic pharmaceutical agents using sharp instruments within the central three millimeters of the cornea.
- 14) States that the State Board of Optometry (Board) shall certify any optometrist who graduated from an accredited school of optometry before May 1, 2000 to probe the nasal lacrimal tract of patients over 12 years old after submitting proof that the optometrist successfully completed 10 procedures under the supervision of an ophthalmologist. Exempts any optometrist graduating from an accredited school of optometry after May 1, 2000 from these requirements.
- 15) Deletes the limitation on injections to only the use of an auto-injector to counter anaphylaxis.
- 16) Requires the Board to certify any certified optometrist for the treatment of glaucoma in patients over 18 years old if:
 - a) The optometrist graduated from an accredited school of optometry on or after May 1, 2008 and submits proof of

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graduation;

b) The optometrist was certified to treat glaucoma prior to January 1, 2009;

- c) The optometrist graduated from an accredited school of optometry after May 1, 2000 and submits proof of completion of at least 12 hours in case management for glaucoma patients;
- d) The optometrist has completed a didactic course of no less than 24 hours in the diagnosis, pharmacological, and other treatment and management of glaucoma developed by an accredited school of optometry, and submits proof of completion of at least 12 hours in case management for glaucoma patients; and,
- e) The optometrist not described above, but who submits proof of satisfactory completion of a didactic course of no less than 24 hours in the diagnosis, pharmacological, and other treatment and management of glaucoma developed by an accredited school of optometry, and submits proof of completion of at least 12 hours in case management for glaucoma patients.
- 17) Specifies that nothing shall limit optometrists' authority to use therapeutic lasers within their scope of practice.
- 18) Defines "glaucoma" as either:
 - a) All primary open angle glaucoma; or,
 - b) All secondary open angle glaucoma, as specified.
- 19) Requires an optometrist to immediately refer any patient who has an acute attack of angle closure to an ophthalmologist.

EXISTING LAW:

1) Regulates the practice of optometry through the licensure and regulation of approximately 6,500 optometrists by the Board, within the Department of Consumer Affairs (DCA).

SB 1406

- 2) Defines the practice of optometry as including the prevention and diagnosis of disorders and dysfunctions of the visual system, and the treatment and management of certain disorders and dysfunctions of the visual system, as well as the provision of rehabilitative optometric services, and includes specified practices, including:
 - Examination of the eye or its appendages, and analysis of the vision system;

- Determination of the powers or range of vision and the accommodative and refractive states of the eye;
- c) Prescribing or directing the use of optical devices;
- d) Prescribing of contact and spectacle lenses for, or their fitting; and,
- e) The use of topical pharmaceutical agents for the sole purpose of the examination of the human eye or eyes for any disease or pathological condition.
- 3) Prescribes certain eye or eye appendage conditions for which an optometrist who is certified to use topical pharmaceutical agents may diagnose and treat, as specified.
- 4) Describes the specific topical pharmaceutical agents that an optometrist may see in diagnosing or treating eye or eye appendage conditions as indicated above.
- 5) Requires an optometrist to consult with an ophthalmologist in diagnosing or treating specified conditions, and establishes record-keeping responsibilities, and provides that the ophthalmologist shall have access to those records.
- 6) Permits topical pharmaceutical agent certified optometrists to carry out specific activities, including:
 - a) Performing specified diagnostic tests, excluding techniques that would constitute surgery; and,
 - b) Removing foreign bodies from the cornea, provided that the foreign bodies are nonperforating, no deeper than the anterior stroma, and the removal does not involve surgical techniques.

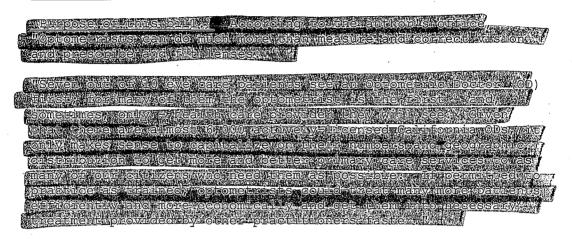
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- 7) Authorizes the Board to certify a topical pharmaceutical agent certified optometrist to perform lacrimal irrigation and dilation of patients over age 12, subject to specified limitations, only after the optometrist has completed at least 10 of these procedures under the direct supervision of an ophthalmologist.
- 8) Prohibits optometrists from performing injections, except auto-injectors to counter anaphylaxis.
- 9) Authorizes the Board to certify topical pharmaceutical agent certified optometrists to treat primary open angle glaucoma in

patients over 18 years old, provided the optometrist has successfully completed specified educational requirements and has provided treatment for at least two years to at least 50 patients in a collaborative relationship with an ophthalmologist.

FISCAL EFFECT : Unknown

COMMENTS :



<u>Background</u>. According the Board, optometrists are independent, primary heath care providers who conduct examinations to determine the overall health of the eyes. Optometrists screen for diseases such as glaucoma, cataracts, macular degeneration, hypertensive retinopathy, and diabetic retinopathy. They also prescribe corrective lenses when needed. Therapeutically certified optometrists prescribe medications to treat many eye

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diseases, such as red eye and conjunctivitis. The Board licenses and regulates these eye care professionals. There are nearly 6,000 actively-licensed optometrists in California, and supporters of this bill advocate expanding optometrists' ability to treat more patients for conditions within their current training. This bill's sponsors seek changes in three primary areas: Optometry Practice Act (OPA) structure, glaucoma treatment, and prescribing authority.

OPA Structure: The proponents of this bill advocate revising the OPA to be structurally comparable to the Medical Practice Act (MPA). MPA defines the parameters of physicians' and surgeons' practice, ensuring it is consistent with their education and training. The Medical Board of California (MBC) then further defines the scope through regulations. By contrast, the sponsors argue that the OPA is highly detailed, leaving the Board little discretion to interpret those

requirements. This limits the Board's authority to adapt the profession to emerging technologies and circumstances.

Glaucoma treatment: SB 929 (Polanco), Chapter 676, Statutes of 2000 expanded optometrists' scope practice by specifying additional diseases and conditions that optometrists may treat, including certain types of glaucoma, with specified medications. SB 929 authorized optometrists certified by the Board to treat open-angle glaucoma in patients over 18 years of age. To become certified, an optometrist must complete 24 hours of didactic instruction from an accredited optometry school and must treat 50 glaucoma patients in collaboration with an ophthalmologist (a medical doctor specializing in eye care, or OMD) for a period of two years for each patient. This process depends on the availability and active cooperation of a consulting OMD and the finance of a patient, who must pay two doctors for care.

According to sponsors, due to the extensive restrictions fewer than 110 optometrists out of nearly 6,000 licensees had been certified to treat glaucoma patients as of November 2007. Although that absolute figure is low, the bill may be considered a success; of those certified, the Enforcement Committee of the Board writes that "since the enactment of SB 929, there have not been any enforcement actions by the Board related to the enhanced scope of practice of optometrists in that bill. In addition, we are not aware of any complaints against optometrists regarding the added privileges given to optometrists in that legislation."

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Prescribing authority: This bill's sponsor argues that the current limitations on prescribing authority hamper optometrists' ability to treat patients effectively, even among those who are certified to treat glaucoma.

To be certified to use or prescribe any controlled substance in California, an optometrist must fulfill various statutory requirements to become certified as a "Therapeutic Pharmaceutical Agent (TPA)." These requirements are based on an individual's graduation date from optometry school (as curriculum changed). The sponsors argue that because graduates after January 1, 2000 are required to pass a three-part national licensing examination administered by the National Board of Examiners in Optometry (which covers the same material), the California certification requirements are largely obsolete.

According to the Senate floor analysis of SB 929, the California Academy of Ophthalmologists acknowledged that the bill, while expanding optometric scope of practice in significant ways, keeps California's law among the narrowest. For example, 45

other states allow optometrists to treat glaucoma to some extent, and every one of those 45 states allows a broader scope than was allowed by SB 929. 50 other states/territories already allow use of topical steroids; 39 allow use of oral steroids. In fact, the University of California at Berkeley's optometry school trains its graduates to perform far broader services than they can perform in California as to qualify them to practice in other states.

Support . The California Partnership writes in support that, "the eye care provided by doctors of optometry provides the same quality of care as ophthalmologists. No significant problems have been reported in any of the 50 states that permit the Doctors of Optometry to use therapeutic pharmaceutical agents nor have malpractice premiums increased because of optometrists' broader use of pharmaceuticals.

"This bill will provide greater access and affordability to vision services for millions of Medi-Cal recipients, many of whom are children and seniors. For these reasons, we ask that you support SB 1406 and help increase health services to all Californians."

Opposition . The California Society of Anesthesiologists state,

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"A clinical pathway for broadening the lawful practices of optometrists was enacted as SB 929 of 2000, but was pursued by only a small number of optometrists. Instead of demonstrating their capabilities for engaging in more expansive practices on a step-by-step basis, optometrists generally would have a broader scope through SB 1406.

The California Medical Association (CMA) has an "oppose unless amended" position on this bill. CMA seeks amendments that eliminate or restrict certain procedures, and establish a joint regulatory authority between MBC and the Board for purposes of determining educational standards and appropriate practice authority for optometrists.

REGISTERED SUPPORT / OPPOSITION :

Support

California Optometric Association (sponsor) ETC Foundation Operation Clear Vision The California Partnership Numerous individuals

Opposition -

California Academy of Family Physicians
California Academy of Ophthalmologists
California Medical Association
California Society of Anesthesiologists
The American College of Obstetricians and Gynecologists,
District IX, California
The California Academy of Eye Physicians & Surgeons (CAEPS)

Analysis Prepared by : Sarah Huchel / B. & P. / (916) 319-3301

July 31, 2009

Requirements for Glaucoma Certification – Curriculum and Case Management Course Development Meeting

Guidelines for California Glaucoma Certification Requirements

The topics covered in the 24-hour course will include the following:

Anatomy and physiology of glaucoma

Classification of glaucoma

Pharmacology in glaucoma therapy

Diagnosis of glaucoma including risk factors analysis

Medical and surgical management

Participant performance assessment

Case Management 16-hour Course

Include at least 15 cases of moderate to advanced complexity. Knowledge will be assessed by a final competency examination. These cases may include the following topics/conditions:

Pseudoglaucoma with vascular, malignant, and compressive etiologies

Secondary (including traumatic) glaucoma

Low-tension (normal pressure) glaucoma

Infective or inflammatory glaucoma

Appropriate evaluation and analysis for medical or surgical consultation

Grand Rounds 16-hour Program

Patients in a grand rounds program shall be evaluated by the participants either in person or via digital imaging. Participants should create a management plan for each patient.

Preceptor Program

Preceptors may be either (a) Board Certified ophthalmologists with a California license in good standing or (b) a California licensed optometrist who meets one or more of the following requirements:

- 1) be glaucoma certified for two (2) or more years
- 2) have completed a primary care or ocular disease residency
- 3) have completed optometric training in 2008 or later and have been licensed for two or more years

Preceptors must confirm the diagnosis and treatment plan of each patient in the preceptor program and approve the therapeutic goals and management plan for the patient. Re-evaluation by the preceptor must occur at appropriate clinical intervals or when therapeutic goals are not achieved. There should be an exchange of clinical data at appropriate re-evaluation intervals.