California State Board of Optometry

Board Meeting

Friday, September 24, 2010

Western University of Health Sciences, College of Optometry
Health Education Center, Classroom A 1205
309 E. Second Street
Pomona, CA 91766
MEETING NOTICE

California State Board of Optometry
Friday, September 24, 2010
9:00 a.m.
Western University of Health Sciences, College of Optometry
Health Education Center, Classroom A 1205
309 E. Second Street
Pomona, CA 91766
(909) 706-3506
And
Via telephone at the following locations:
• 9033 Wilshire Blvd., Suite 402, Beverly Hills, CA 90211
• 325 Copa De Oro Drive, Brea, CA 92823
• 329 Bryant Street, Suite C, San Francisco, CA 90211

9:00 a.m.
FULL BOARD MEETING
I. Call to Order – Establish Quorum

II. Discussion and Adoption of Amendments to Title 16, of the California Code of Regulations (CCR), Section 1520, Infection Control.

III. Discussion and Adoption of Amendments to Title 16, of the CCR Section 1571, Glaucoma Certification.

IV. Public Comment for Items Not On the Agenda

V. Adjournment

NOTICE
Public comments will be taken on agenda items at the time the specific item is raised. The Board may take action on any item listed on the agenda, unless listed as informational only. Agenda items may be taken out of order to accommodate speakers and to maintain a quorum.

The meeting is accessible to the physically disabled. A person who needs a disability-related accommodation or modification in order to participate in the meeting may make a request by contacting Krista Eklund at (916) 575-7170 or sending a written request to that person at the California State Board of Optometry 2420 Del Paso Road, Suite 255, Sacramento, CA 95834. Providing your request at least five (5) business days before the meeting will help ensure availability of the requested accommodation.

The Board of Optometry’s mission is to serve the public and optometrists by promoting and enforcing laws and regulations which protect the health and safety of California’s consumers, and to ensure high quality care.
To: Board Members

From: Dr. Lee Goldstein, OD, MPA
      Board President

Telephone: (916) 575-7170

Date: September 24, 2010

Subject: Agenda Item 1 – Call to Order- Establishment of a Quorum

Legislative and Regulation Committee Members
Lee Goldstein, O.D., M.P.A., Board President

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

Monica Johnson, Secretary

Edward J. Rendon, M.P.A.

Board Members (Teleconference)
Alejandro Arredondo, O.D., Vice-President

Kenneth Lawenda, O.D.

Fred Naranjo, M.B.A.

Katrina Semmes
To:        Board Members                  Date:       September 24, 2010

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

Subject:  Agenda Item 2 – Discussion and Adoption of Amendments to Title 16, of the
          California Code of Regulations (CCR), Section 1520, Infection Control
          Guidelines

Action Requested:
Staff requests that the Board review, make any edits necessary, and approve the proposed revisions to
the language in order to distribute the modified text and begin the 15-day comment period. The public
will have the chance to address the modified text during the 15-day comment period.

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

As soon as the 15-day comment period ends, staff will resubmit the file to the DCA’s Division of
Legislative and Policy Review, and Legal Office before resubmitting to OAL.

The Board has until December 4, 2010 to complete this rulemaking file.

Background:
This proposal amends the regulation in order to establish infection prevention practices for proper hand
hygiene, appropriate use of personal protective equipment, handling of sharp instruments, and
appropriate cleaning of patient care equipment, instruments, devices and environmental care. This
proposed regulation will require licensees to adhere to the most current guidelines and standards
published by federal, state and local, and other regulatory and accrediting agencies.

The Board is not creating new standards, just explicitly publishing established standards to the CCR in
order to inform and clarify what is already expected of licensees.

October 22, 2009 – Board approves the language and initiates a rulemaking.
December 4, 2009 – The Notice is published and the 45-day comment period begins.
January 18, 2010 – 45-day comment period ends.
January 19, 2010 – Regulatory hearing is held, no comments received.
May 11, 2010 – Board makes final approval of the language and acknowledgement that no comments
were received and votes to complete the rulemaking.
May 24, 2010 – Staff submits the completed rulemaking package to the Department of Consumer Affairs
(DCA) for review. It is approved.
July 2, 2010 – Agency approves the package.
August 3, 2010 – Board staff submits the final package to the Office of Administrative Law (OAL).
Issues/Discussion:
The rulemaking package for CCR 1520 was withdrawn from the OAL on September 3, 2010 after it was brought to staff's attention that there were a few discrepancies found during the final review. The issues have been addressed as follows:

1) Amended the proposed language to reflect OAL's recommended CCR hierarchy for regulations subsections.
2) Amended the proposed language for consistency when referring to optometrists and staff.
3) Amended the proposed language's grammar for consistency and clarity throughout.
4) Amended the proposed language to replace the occurrences of the word "should" with "shall", "must", or "may" in order to reduce ambiguity.

Attachments:
1) CCR 1520 Modified Text
Amend section 1520 in Division 15 of Title 16 of the California Code of Regulations to read as follows:


(a) Optometrists and staff, which also includes assistants in the office of an optometrist, and staff must comply with all the applicable Standard Precautions.

(b) Standard Precautions combine the major features of Universal Precautions and Body Substance Isolation and are based on the principle that all blood, body fluids, secretions, excretions (except sweat), non-intact skin, and mucus membranes may contain transmissible infectious agents. All contact with these substances is treated as if known to be infectious for Human Immunodeficiency Virus (HIV), Hepatitis, and other transmissible infectious agents. Standard Precautions are also intended to protect patients by ensuring that optometric staff do not carry infectious agents to patients on their hands or via equipment used when providing optometric services. Standard Precautions must be used in the care of all patients, regardless of suspected or confirmed infection status, and in all settings wherein optometric services are provided. Standard Precautions include:

1) Proper Hand Hygiene

(A) (a) Each office shall be provided with have a hand washing facility which shall be that is entirely within the confines of the premises or space occupied by such office and not elsewhere, and which shall be for the exclusive use of the optometrist or optometrists practicing in such office and his/her or their assistants and patients and shall not be used by other persons.

(B) (b) For the purpose of this section, a hand washing facility is a facility affording, at minimum, the following:

1. (4) A wash basin or sink with hot and cold running water which complies with Title 24, California Administrative Code, Part 5 (commencing with Section P100).

2. (2) Liquid or powdered hand washing detergent in a dispensing device.

3. (3) Single service sanitary towels in a dispensing device or a sanitary hot-air blower hand drying apparatus.

(C) (e) Hand washing facilities shall be maintained in a condition of cleanliness and good repair.

(D) (d) The optometrists and staff shall maintain at all times a high standard of cleanliness and personal hygiene in order to ensure proper patient care.

(E) The optometrists and staff shall avoid unnecessary touching of face, nose, and surfaces in close proximity to the patient to prevent both contamination of clean hands from environmental
surfaces and transmission of pathogens from contaminated hands to surfaces, when providing optometric services.

(F) When hands are visibly soiled, hands shall be washed with soap and water for a 20-second scrub and 10-second rinse or an antimicrobial hand wash. If hands are not visibly soiled, an acceptable alternative of hand decontamination is with an alcohol-based hand rub (except in cases of spores, as described below).

(G) Hands shall be washed or decontaminated as follows:

1. (i) Before having direct contact with any patient, immediately after a procedure (such as eye examinations or other procedures involving contact with tears), and in between patients.

2. (ii) After removing gloves, ensure that hands will not carry potential infectious material that might have penetrated through unrecognized cuts tears or lacerations in the gloves, or that could contaminate the hands during glove removal.

3. (iii) Artificial fingernails or extenders shall not be worn if duties include direct contact with patients at high risk for infection and associated adverse outcomes.

(H) After each patient session ends, hands must be washed with soap and water or an antimicrobial hand wash if contact with spores (including but not limited to C. difficile or Bacillus anthracis) is likely to have occurred. The physical action of washing and rinsing hands in such circumstances is required because alcohols, chlorhexidine, iodophors, and other antiseptic agents have poor activity against spores.

(I) If the an optometrist or staff member has have exudative lesions or weeping dermatitis of the hand, direct patient care and the handling of patient care equipment by the person with the condition must stop until the condition resolves.

(2) Use of Personal Protective Equipment

(A) Gloves: The optometrists and staff All health care workers must routinely use appropriate barrier precautions gloves to prevent skin and mucous membrane exposure when anticipating direct contact with blood or body fluids, mucous membranes, nonintact skin, and other potentially infectious material or surfaces soiled with such fluids.

(B) The optometrists and staff shall discard gloves after contact with each patient to prevent transmission of infectious material.

(C) The optometrists and staff shall if necessary change gloves if patient interaction involves touching portable computer keyboards or other mobile equipment that is transported from room to room.

(D) The optometrists and staff shall not reuse Gloves must not be reused.

(E) The optometrists and staff must wear Gowns, masks and protective eye wear must be worn in situations where blood, respiratory secretions, or contaminated fluids may be sprayed or splashed into the eyes of the an optometrist or their staff member.

(F) The optometrists and staff must wear Gowns, masks and protective eye wear must be worn if the patient is known or suspected to have a pathogen which can be transmitted by airborne means, or if the an optometrist or staff member is infected with a pulmonary or other
disease that is transmitted by airborne means, then that optometrist or staff member must wear a gown, mask, and protective eyewear to protect the patient.

(G) Face shields and protective eyewear must be washed and disinfected between each patient or when visibly soiled.

(3) Handling of Sharp Instruments

(A) Precautions must be taken in order to prevent injuries caused by needles, scalpels, and other sharp instruments or devices when:

1. Perform procedures, including but not limited to venipuncture;
2. Cleaning used instruments;
3. Disposing of used needles; and
4. Handling sharp instruments after procedures.

(B) To prevent needle stick injuries, optometrists, assistants in the office of an optometrist, and staff shall be instructed in the proper handling of needles, including but not limited to when needles must not be recapped, or purposely bent or broken by hand, removed from disposable syringes, or otherwise manipulated by hand.

(C) Optometrists, assistants in the office of an optometrist, and staff must be instructed to place disposable syringes and needles, scalpels, blades, and other sharp items in puncture-resistant containers following their use. Puncture-resistant containers shall be provided and should be located as close as practical to the area where needles and syringes are in use.

(D) Pursuant to Cal/OSHA’s Bloodborne Pathogens Standard, Title 8, Cal. Code Regs., Section 5193, employers governed by this rule must establish, maintain, review, and update at least annually and whenever necessary their Exposure Control Plan to reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens, and establish and maintain a Sharps Injury Log. This rule applies to all employers with employees who have occupational exposure to blood or other potentially infectious materials.

(E) Optometrists, assistants, and staff shall adhere to all federal and state requirements for handling of sharp instruments (including but not limited to the Medical Waste Management Act, California Health and Safety Code sections 117600-118360).

(4) Instrument Disinfection Requirements

(A) Germicides and/or disinfectants must be used in order to eliminate most of all pathogenic microorganisms from inanimate objects, such as medical devices or equipment. If there are questions on how to disinfect a particular medical device, the office may contact the manufacturer of the product.

(B) Contact lenses and carrying cases used in trial and follow-up fittings shall be handled in the following manner:

1. Discarding the trial contact lenses is recommended. This procedure however is inapplicable to rigid gas permeable and non-disposable hydrogel trial contact lenses.

2. Disinfecting between each fitting by one of the following regimens:
   a. U.S. Food and Drug Administration (FDA) approved chemical disinfection system appropriate for the contact lens type.
   b. Heat disinfection.
(C) When using eye drops, optometrist and assistants shall not permit the bottle tip to come into direct contact with the patient’s tears or conjunctiva. If the tip touches the patient, the bottle shall be discarded.

(D) The optometrists, assistants, and staff shall follow employer-established policies and procedures for routine and targeted cleaning of environmental surfaces as indicated by the service-delivery setting, the level of patient contact, and degree of soiling.

(E) The optometrists, assistants, and staff shall clean and disinfect surfaces that are likely to be contaminated with pathogens, especially those in close proximity to the patient and frequently touched surfaces in the patient care environment.

(c) The optometrists and staff practitioners shall comply with all minimum standards for infection control practices issued by and comply with local, state, or federal governmental agencies recommendations, issued in response to an emergency health and safety situations.

Note: Authority cited: Sections 3010.1, 3025, 3025.5, and 3110, Business and Professions Code. Reference: Sections 2544, 2564.5, 3025.5, 3025.6, and 3110, Business and Professions Code.

DATED: ____________________________

Mona Maggio, Executive Officer
Board of Optometry
To: Board Members  

From: Andrea Leiva  
Policy Analyst  

Subject: Agenda Item 3 – Discussion and Adoption of Amendments to Title 16, of the California Code of Regulations (CCR), Section 1571, Requirements for Glaucoma Certification

**Action Requested:**
To be determined at the meeting.

**Background:**
This proposal establishes the requirements for glaucoma certification for licensees that graduated prior to May 1, 2008. Senate Bill (SB) 1406 (Chapter 352, Statutes of 2008, Correa) became effective on January 1, 2009 and expanded the scope of practice of optometrists to include, among other things, the treatment of glaucoma. Business and Professions Code (BPC) section 3041.10 establishes procedures to be followed by the Board in order to make sure that the public is adequately protected during the transition to full certification for all licensed optometrists interested in treating and managing glaucoma patients.

The Board has followed and completed the process established by BPC section 3041.10 and is awaiting the Office of Administrative Law’s (OAL) final decision.

August 24, 2009 – Board approves the language and initiates a rulemaking.  
November 6, 2009 – The Notice is published and the 45-day comment period begins.  
December 21, 2009 – 45-day comment period ends.  
December 22, 2010 – Regulatory hearing is held, no comments received.  
March 16, 2010 – Board makes final approval of the modified language after acknowledging all comments received.  
March 24 – April 8, 2010 - 15-day comment period on modified text.  
May 11, 2010 – Board makes final approval of the language after acknowledging all comments received and direct staff to complete the rulemaking file.  
May 17 – August 23, 2010 – Package is approved by the Department of Consumer Affairs, Consumer Services Agency, and the Department of Finance.  
August 25, 2010 – Staff submits the package for final review to the OAL.

**Issues/Discussion:**
To be provided at the meeting.

**Potential Next Steps:**
Scenario One: OAL approves the file and the regulation becomes effective upon approval.
Scenario Two: OAL disapproves the file and the Board has 120 days to address their concerns. OAL will accept a resubmittal of the file without the Notice or Public Hearing requirements if the regulation has not been significantly changed. The director of the office may, upon showing of good cause, grant an extension to the 120-day time period. (See Attachment 1 for more detail.)

Scenario Three: The Board withdraws the file to address OAL’s concerns but has only until November 6, 2010 (One year from the Notice publication date) to resubmit the file.

Scenario Four: The Board issues a Notice of Decision not to Proceed with Rulemaking action prior to the rulemaking proposals one-year period expiration.

Scenario Five: The Board appeals OAL’s disapproval to the Governor’s office within tens days of receiving OAL’s opinion.

Scenario Six: If the Governor refuses to overturn OAL’s decision, the Board may then resort to judicial remedies, including petition for writ of mandate. If the court disagrees with OAL, it can order OAL to immediately file the regulation with Secretary of State.

Attachments:
1) CA Rulemaking Law Section 11349.4
11349.4. Returned regulations; readoption; limited review

(a) A regulation returned to an agency because of failure to meet the standards of Section 11349.1, because of an agency's failure to comply with this chapter may be rewritten and resubmitted within 120 days of the agency's receipt of the written opinion required by subdivision (b) of Section 11349.3 without complying with the notice and public hearing requirements of Sections 11346.4, 11346.5, and 11346.8 unless the substantive provisions of the regulation have been significantly changed. If the regulation has been significantly changed or was not submitted within 120 days of receipt of the written opinion, the agency shall comply with Article 5 (commencing with Section 11346) and readopt the regulation. The director of the office may, upon a showing of good cause, grant an extension to the 120-day time period specified in this subdivision.

(b) Upon resubmission of a disapproved regulation to the office pursuant to subdivision (a), the office shall only review the resubmitted regulation for those reasons expressly identified in the written opinion required by subdivision (b) of Section 11349.3, or for those issues arising as a result of a substantial change to a provision of the resubmitted regulation or as a result of intervening statutory changes or intervening court orders or decisions.

(c) When an agency resubmits a withdrawn or disapproved regulation to the office it shall identify the prior withdrawn or disapproved regulation by date of submission to the office, shall specify the portion of the prior rulemaking record that should be included in the resubmission, and shall submit to the office a copy of the prior rulemaking record if that record has been returned to the agency by the office.

(d) The office shall expedite the review of a regulation submitted without significant substantive change.
To: Board Members

From: Dr. Lee Goldstein, OD, MPA
Board President

Subject: Agenda Item 4 – Public Comment for Items Not on the Agenda

Date: September 24, 2010
Telephone: (916) 575-7170
To: Board Members  
Date: September 24, 2010

From: Dr. Lee Goldstein, OD, MPA  
Board President  
Telephone: (916) 575-7170

Subject: Agenda Item 5 – Adjournment