To: Board Members

From: Jessica Sieferman
Executive Officer

Date: August 26, 2016

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Subject: Agenda Item 16 – Discussion and Possible Action Regarding Minimum Certification Requirements For All Optometrists to Practice in California

Background:
During the February 2016 Board meeting, the Board discussed minimum certification requirements for all optometrists. Specifically, the Board discussed whether an optometrist should be required to obtain a therapeutic pharmaceutical agent (TPA) certification in order to continue practicing in California.

It was reported that, as of January 18, 2016, the Board had 557 licensed optometrists who only have a diagnostic pharmaceutical agent (DPA) certification and 85 licensed optometrists with no certification. These optometrists were issued licenses after meeting the minimum licensing requirements at that time, and they continue to practice within their very limited scope of practice.

Some members opined that practicing without a TPA certification is below the standard of care because they cannot diagnose or treat patients for conditions outlined in BPC § 3041 (b) in order to determine the overall health of the eye. Licensees without a TPA certification are limited to the following scope:

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 that 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 purpose of the examination of the human eye or eyes for any disease or pathological condition.

In order to determine overall eye health, those licensees would need to refer the patients to a properly certified optometrist or ophthalmologist for a more in depth examination.

After discussion and allowing time for public comment, the Board directed staff and legal counsel to research what can be completed through creating and/or amending existing regulation. The Board voted

Pursuant to CCR § 1561, only DPA certified optometrists may use topical pharmaceutical agents.
(5-Aye; 3-Abstain) to approve moving forward with legislation requiring all optometrists to obtain a TPA certification.

**Standard of Care vs. Scope of Practice**
The "standard of care," established by an expert witness, is the level of care owed to a patient. The Board takes action against those licensees who deviate from the standard of care, specifically, in cases of unprofessional conduct, gross negligence or repeated negligent acts.

The "scope of practice" defines the acts a licensed optometrist is permitted to do. A licensee who competently practices within the scope of practice is not subject to discipline, because he/she is not violating the law.

As of August 8, 2016, the Board has 486 DPA licensed optometrists and 69 optometrists with no certification.

**Requirements**
The impacted California licensees graduated from an accredited school or college of optometry prior to 1992. Some obtained licensure in other states and may have obtained a TPA certification in that state. Therefore, the below statutes and regulations apply; the full text of each section is attached for your reference (Attachment 1):

**DPA Requirements:**
Business and Professions Code (BPC) § 3041.2
CCR § 1561
CCR § 1562
CCR § 1563

**TPA Requirements:**
BPC § 3041.3 (b), (d)(1,3)
CCR § 1568 (a), (d), (f), (i)

**Staff Comments:**
As requested, staff worked with legal counsel to determine if requiring all licensees to obtain a TPA certification as a condition of maintaining an active license in CA could be completed through regulation. It has been determined that legislation is needed to make this change.

**Requested Action:**
Please consider the additional information provided above. If the Board maintains its position to pursue legislation, please direct the Legislation and Regulation Committee to work draft language for the Board to consider at the November meeting.

**Attachments:**
1. Applicable Statutes and Regulations
DPA Requirements:
Business and Professions Code (BPC) § 3041.2 (Article 3 added by Stats. 1937, Ch. 423.)

a) The State Board of Optometry shall, by regulation, establish educational and examination requirements for licensure to ensure the competence of optometrists to practice pursuant to subdivision (a) of Section 3041. Satisfactory completion of the educational and examination requirements shall be a condition for the issuance of an original optometrist license under this chapter, on and after January 1, 1980. Only those optometrists who have successfully completed educational and examination requirements as determined by the State Board of Optometry shall be permitted the use of pharmaceutical agents specified by subdivision (a) of Section 3041.

b) Nothing in this section shall authorize an optometrist issued an original optometrist license under this chapter before January 1, 1996, to use or prescribe therapeutic pharmaceutical agents specified in subdivision (d) of Section 3041 without otherwise meeting the requirements of Section 3041.3.

(California Code of Regulations (CCR) § 1561)

(a) The purpose of this article is to implement Business and Professions Code Section 3041.2, as added to said code by chapter 418 of the 1976 statutes. Only those optometrists meeting the requirements of this article may use topical pharmaceutical agents in the examination of human eyes.

(b) In order to use topical pharmaceutical agents in the examination of human eyes, an optometrist must:
   (1) complete a course in pharmacology approved by the Board or have equivalent experience satisfactory to the Board; and
   (2) provide evidence of taking and passing either:
       (A) both the Applied Basic Science and Clinical Skills sections of the NBEO examination as it was constituted beginning in January 2010; or
       (B) a pharmacology examination equivalent to subdivision (b)(1) above and administered by an accredited school or college of optometry.

(c) The Board will issue a Diagnostic Pharmaceutical Agents certification to optometrists fulfilling the requirements of subsection (b) authorizing them to use topical pharmaceutical agents.

Note: Authority cited: Sections 3025, 3041.2 and 3053, Business and Professions Code. Reference: Sections 3041 and 3041.2, Business and Professions Code.

HISTORY
1. Amendment filed 5-20-83; effective upon filing pursuant to Government Code Section 11346.2(d) (Register 83, No. 21).
2. Amendment of subsection (b) filed 5-8-89; operative 6-7-89 (Register 89, No. 27).
3. Amendment of section and Note filed 2-8-2011; operative 3-10-2011 (Register 2011, No. 6).
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CCR § 1562. Pharmacology Courses.

(a) In order to be approved by the Board, a course in pharmacology must include instruction in general pharmacology, ocular pharmacology, and in ocular pharmacology applied to relevant clinical procedures. The course must be at least 55 hours in length and be subdivided as follows:
   General Pharmacology: 15 hours
   Ocular Pharmacology: 20 hours
   Clinical Laboratory (ocular pharmacology applied to relevant clinical procedures): 20 hours

(b) Approval by the Board shall be required of all pharmacology course instructors.

CCR § 1563. Pharmacology Examination.

(a) The pharmacology course examination shall cover coursework in general pharmacology, ocular pharmacology, and ocular pharmacology with relevant clinical procedures and shall be given in conjunction with the annual optometrist licensure examination or when otherwise designated by the Board.

(b) The examination fee shall not exceed thirty-five dollars ($35).

(c) The procedure specified in Section 1533 will be used for requests to inspect examination papers or to appeal examination scores.

Note: Authority cited: Section 3153, Business and Professions Code. Reference: Sections 3041.1 and 3041.2, Business and Professions Code; Sections 1560, 1561 and 1562, California Administrative Code.
TPA Requirements:

BPC § 3041.3 (Article 3 added by Stats. 1937, Ch. 423.)

(a) In order to be certified to use therapeutic pharmaceutical agents and authorized to diagnose and treat the conditions listed in subdivisions (b) and (e) of Section 3041, an optometrist shall apply for a certificate from the board and meet all requirements imposed by the board.

(b) The board shall grant a therapeutic pharmaceutical agents (TPA) certification to any applicant who graduated from a California accredited school of optometry prior to January 1, 1996, is licensed as an optometrist in California, and meets all of the following requirements:

(1) Completes a preceptorship of no less than 65 hours, during a period of not less than two months nor more than one year, with either a TPA-certified optometrist in good standing or a physician and surgeon board-certified in ophthalmology in good standing. The training received during the preceptorship shall be on the diagnosis, treatment, and management of ocular and systemic disease. The preceptor shall certify completion of the preceptorship using a form approved by the board. The individual serving as the preceptor shall schedule no more than three optometrist applicants for each of the required 65 hours of the preceptorship program. This paragraph shall not be construed to limit the total number of optometrist applicants for whom an individual may serve as a preceptor, and is intended only to ensure the quality of the preceptorship by requiring that the preceptor schedule the training so that each applicant optometrist completes each of the 65 hours of the preceptorship while scheduled with no more than two other optometrist applicants.

(2) Successfully completes a minimum of 100 hours of directed and accredited education in ocular and systemic diseases within two years prior to meeting the requirements of paragraph (1).

(3) Passes the National Board of Examiners in Optometry’s “Treatment and Management of Ocular Disease” examination or, in the event this examination is no longer offered, its equivalent, as determined by the State Board of Optometry.

(c) The board shall grant a therapeutic pharmaceutical agents certification to any applicant who graduated from a California accredited school of optometry on or after January 1, 1996, who is licensed as an optometrist in California, and who passes all sections of the National Board of Examiners in Optometry’s national board examination or its equivalent, as determined by the State Board of Optometry.

(d) The board shall grant a therapeutic pharmaceutical agents certification to any applicant who is an optometrist who obtained his or her license outside of California if he or she meets all of the requirements for an optometrist licensed in California to be granted a therapeutic pharmaceutical agents certification.

(1) In order to obtain a therapeutic pharmaceutical agents certification, any optometrist who obtained his or her license outside of California and graduated from an accredited school of optometry prior to January 1, 1996, shall be required to fulfill the requirements set forth in subdivision (b). In order for the applicant to be eligible for therapeutic pharmaceutical agents certification, the education he or she received at the accredited out-of-state school of optometry shall be equivalent to the education provided by any accredited school of optometry in California for persons who graduate before January 1, 1996. For those out-of-state applicants who request that any of the requirements contained in subdivision (b) be waived based on fulfillment of the requirement in another state, if the board determines that the completed requirement was equivalent to that required in California, the requirement shall be waived.

(2) In order to obtain a therapeutic pharmaceutical agents certification, any optometrist who obtained his or her license outside of California and who graduated from an accredited school of optometry on or after January 1, 1996, shall be required to fulfill the requirements set forth in subdivision (c). In order for the applicant to be eligible for therapeutic pharmaceutical agents certification, the education he or she received by the accredited out-of-state school of optometry shall be equivalent to the education provided by any accredited school of optometry for persons who graduate on or after January 1, 1996. For those out-of-state applicants who request that any of the requirements contained in subdivision (c) be waived based on fulfillment of the requirement in another state, if the board determines that the completed requirement was equivalent to that required in California, the requirement shall be waived.

(3) The State Board of Optometry shall decide all issues relating to the equivalency of an optometrist’s education or training under this subdivision.

(Amended by Stats. 2015, Ch. 443, Sec. 1. Effective January 1, 2016.)
CCR § 1568. Therapeutic Pharmaceutical Agents Usage - Purpose and Requirements. 
Only those optometrists meeting the requirements of this Article may apply for TPA Certification to use Therapeutic Pharmaceutical Agents. The Application for TPA Certification (Form TPA-1 Rev. 4/96), which is hereby incorporated by reference, may be obtained from the Board's Headquarters office. Requirements for TPA certification are as follows:

(a) If the applicant is licensed to practice optometry in California and graduated from an accredited school of optometry prior to January 1, 1992:
   (1) Completion of an 80-hour TPA didactic course provided either by the University of California at Berkeley School of Optometry or the Southern California College of Optometry or recognized ophthalmological residency review committee or at an accredited school or college located outside of California as provided in Section 1570 in this Article.
   (2) Pass the examination given at the conclusion of the TPA course.
   (3) Pass the TMOD component of the NBEO administered after July 1, 1992.
   (4) Complete 20 hours of self directed study in the treatment and management of ocular, systemic disease.
   (5) Complete a 65-hour preceptorship service as defined in Section 1567 in this Article.

(b) If the applicant is a licensed optometrist in California and graduated from an accredited school of optometry after January 1, 1992 but before January 1, 1996:
   (1) Complete 20 hours of self directed study in the treatment and management of ocular, systemic disease.
   (2) Complete a 65-hour preceptorship service as defined in Section 1567 in this Article.

(c) If the applicant is a graduate from an accredited school of optometry after January 1, 1996:
   (1) Obtain a California optometrist license.
   (2) Be certified by an accredited school of optometry that the applicant is competent in the diagnosis, treatment, and management of ocular, systemic disease.
   (3) Be certified by an accredited school of optometry that the applicant has completed 10 hours of experience with an ophthalmologist.

(d) If the applicant is licensed outside California and graduated from an accredited school of optometry before January 1, 1992:
   (1) Obtain a California optometrist license.
   (2) Completion of an 80-hour TPA didactic course provided either by University of California at Berkeley School of Optometry or Southern California College of Optometry or recognized ophthalmological residency review committee or at an out-of-state school as provided in Section 1570 in this Article.
   (3) Pass the examination given at the conclusion of the TPA course.
   (4) Pass the TMOD component of the NBEO administered after July 1, 1992.
   (5) Complete 20 hours of self directed study in the treatment and management of ocular, systemic disease.
   (6) Complete a 65-hour preceptorship service as defined in Section 1567 in this Article.

(e) If the applicant is licensed outside California and graduated from an accredited school of optometry after January 1, 1992 but prior to January 1, 1996:
   (1) Obtain a California optometrist license.
   (2) Complete 20 hours of self directed study in the treatment and management of ocular, systemic disease.
   (3) Complete a 65-hour preceptorship service as defined in Section 1567 in this Article.

(f) If the applicant is licensed in a state outside of California, graduated from an accredited school of optometry prior to January 1, 1992 and has practiced in that state, or on a reservation or a facility supported and maintained by the United States government with a TPA license:
   (1) Obtain a California optometrist license.
   (2) Pass the TMOD component of the NBEO administered after July 1, 1992.
   (3) Complete a 65-hour preceptorship service as defined in Section 1567 in this Article.

(g) If the applicant is licensed in a state outside of California, graduated from an accredited school of optometry after January 1, 1992 but before January 1, 1996 and has practiced in that state or on a reservation or a facility supported and maintained by the United States government with a TPA license:
(1) Complete 20 hours of self-directed study in the treatment and management of ocular, systemic disease.

(2) Complete a 65-hour preceptorship service as defined in Section 1567 in this Article.

(h) All TPA certified optometrists pursuant to this Article must complete 50 hours of continuing education in order to renew licensure. Thirty-five of the required hours shall be in the diagnosis, treatment and management of ocular, and systemic disease consistent with Business and Professions Code section 3059, subdivision (f).

(i) If the applicant is licensed in a state outside of California and requests that the 65-hour preceptorship service requirement contained in subdivisions (e), (f) and (g) be waived based on their optometric practice experience using TPA in another state, the Board, as authorized under Business and Professions Code Section 3041.3(d)(1), shall deem the experience as equivalent to the 65-hour preceptorship service required in California provided the following conditions are met:

(1) Applicant is licensed in good standing in their state of licensure.

(2) Applicant has graduated from an accredited school of optometry before January 1, 1996.

(3) Applicant has met the requirements to treat with therapeutic pharmaceutical agents in their state of licensure.

(4) Applicant has been practicing optometry in their state of licensure using therapeutic pharmaceutical agents for 5 continuous years immediately preceding the submission of their application.

Note: Authority cited: Sections 3025 and 3041.2, Business and Professions Code. Reference: Sections 3041.3 and 3059, Business and Professions Code.

HISTORY
1. New section filed 7-7-97; operative 8-6-97 (Register 97, No. 28).
3. New subsection (i) and amendment of Note filed 7-3-2008; operative 7-3-2008 pursuant to Government Code section 11343.4 (Register 2008, No. 27).

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16 CCR § 1568, 16 CA ADC § 1568