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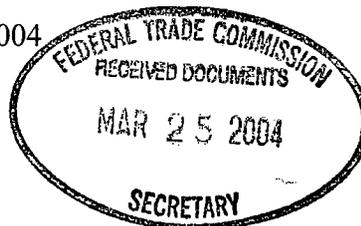
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March 24, 2004



\*PROFESSIONAL CORPORATIONS

**SENT VIA FEDERAL EXPRESS**

FEDERAL TRADE COMMISSION  
Office of the Secretary  
Room 159-H (Annex A)  
600 Pennsylvania Avenue N.W.  
Washington, DC 20580

**RE: Comment of the California Optometric Association Regarding "Contact Lens Rule, Project No. R411002"**

Dear Sir or Madam:

The California Optometric Association (hereafter "COA") is pleased to provide its comments regarding the proposed regulations implementing the Contact Lens Rule (15 U.S.C. §§ 7601-7610).

The COA is a statewide professional association of optometrists practicing in the state of California and, in that regard, represents over 3,200 optometrists and optometry students.

The COA believes that it is in a unique position to provide comments on the proposed regulations since the state of California previously enacted a contact lens prescription release law in September 2002, and the provisions of that law (AB 2020) are similar in many respects to the federal statute. A copy of AB 2020 is appended hereto.

Preliminarily, it should be noted that the California legislation resulted from, among other things, the joint negotiation efforts of the COA and representatives of 1-800 CONTACTS, a large mail order contact lens seller. Accommodations were made on both sides regarding a variety of issues. The law went into effect on January 1, 2003 and, to date, the law has been implemented with no serious problems. More specifically, complaints on both sides have been minimal and the COA is not aware of any enforcement action by any California regulatory body

regarding violations of the law. However, there have been anecdotal complaints of problems with the verification process and the COA believes that improvement could be made to this area of the legislation.

From its perspective based on the California legislation, COA offers the following comments:

**I.**

**GENERAL QUESTIONS**

This part and the COA's response is directed to the general questions posed by the Commission:

“Please provide comment on any or all of the provisions in the proposed contact lens rule and the proposed clerical amendments to the ophthalmic practices rules. For each provision commented on please describe (a) the impact of the provision(s) (including benefits and costs), if any, and (b) what alternatives, if any, the Commission should consider, as well as the costs and benefits of those alternatives.”

Section 315.2 - Business Hours - The calculation of business hours should be clarified to mean business hours in the prescriber's domicile, and all calculations should be based on the time that the request is received by the prescriber in the prescriber's time zone. COA believes that this clarification should result in a reduction of potential confusion concerning the time in which a prescriber has available within which to correspond and/or communicate with a contact lens seller.

Rule 315.2 contains the definition of a business hour which is clear and understandable. It should however be revised to accommodate situations that can occasionally occur when a doctor is not physically present at his or her practice location. For example, if the doctor is on vacation, ill, attending continuing education or otherwise out of the office.

Expired or inaccurate prescriptions should not be filled by default as a result of a doctor's temporary absence from his or her office. Accordingly, COA recommends that language accommodating exceptions to the rule's time parameters be developed.

The California's contact lens release statute's time parameters are in conflict with the time parameters in the proposed rule. COA believes that if accommodations can be made for a doctor's absence from his or her office, the proposed rule is preferable to the California statute as it is more clearly stated and will be more readily understood by doctors and sellers. Among other things, the California law treats Saturday as a business day and that appears to conflict with

a large number of professional practices. COA also believes that in addition to federal holidays, state holidays should also be excluded from "business days".

Section 315.3 of the proposed rule precludes the prescriber from requiring that a patient purchase contact lenses from the prescriber - as a condition of providing the patient with a copy of the patient's prescription.

This requirement poses a hardship on optometrists and ophthalmologists who must use contact lenses on the patient during the fitting process. In the case of disposable contact lenses, it should not be a problem since doctors routinely receive "diagnostic" lenses from the manufacturers without cost. It would, however, be a problem for more complicated contact lenses that may be custom fitted to the patient or any non-disposable contact lenses (i.e., rigid gas permeable lenses). In those cases the doctor must purchase the lenses and should be able to recoup the costs incurred from the patient. Accordingly, COA recommends that Section 315.3(b)(1) be amended to read:

"(b) Limitations. A prescriber may not:

1. Require the purchase of contact lenses from the prescriber or from another person as a condition of providing a copy of a prescription under paragraph (a)(1) or (a)(2) of this section or as a condition of verification of a prescription under paragraph (a)(2) of this section. This section shall not preclude a prescriber from charging the patient for the cost of any contact lenses utilized in the fitting process."

Section 315.5 - COA recommends that Section 315.5 be amended to include a seller's email address in the information that a seller must provide to a prescriber. The email address should exist for verification purposes and should not be a website address.

The rules require "direct communication for verification of a contact lens prescription by a prescriber." Adding seller's email address to the information furnished to the prescriber will serve to facilitate "direct communication" by providing a third method of communication in addition to telephone and facsimile numbers.

This addition would be consistent with Section 315.1 of the rule which defines "direct communication" as including electronic mail.

Section 315.5(2) of the rule precludes a seller from altering a contact lens prescription. The California Contact Lens Release Law allows a seller to change the color of a contact lens<sup>1</sup> without penalty, and experience in California has shown that allowing a change in color of the lens has not resulted in any problems.

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<sup>1</sup> B&P Code section 2546.6(c).

Section 315.5(b) provides that a contact lens seller furnish the prescriber with certain information. The date and time of the request is included in the information to be furnished to the prescriber and COA believes that it should be. The current California law does not require that information and that has created problems for doctor's trying to determine when the request was made.

Section 315.5(d) - This section of the rule provides that if a prescriber informs a seller that a contact lens prescription is "inaccurate, expired, or otherwise invalid" the seller shall not fill the prescription.

COA recommends that this section be revised to provide that upon notification that a prescription is inaccurate, expired or otherwise invalid the seller shall not fill, ship or otherwise supply the prescription.

Section 315.6(3)(b) - COA believes that the rule would be enhanced by a provision that would allow a prescriber to retain professional discretion regarding the release of a contact lens prescription when the patient wears one of the following types of contact lenses:

1. Rigid gas permeables.
2. Bitoric gas permeables.
3. Bifocal gas permeables.
4. Keratoconus lenses.
5. Custom designed lenses that are manufactured for an individual patient and are not mass produced.

While Section 315.6(3)(b) of the proposed rule may be construed as providing the prescriber with discretion to limit a prescription to a time shorter than one year, we find nothing in the proposed rule that would enable a provider to conclude, based on the prescriber's judgment, that a prescription for these highly technical contact lenses should not be made available to the patient. COA believes that the great weight of competent medical authority would support clarification of the rule on that point.

The cost of amending the rule should be insignificant since the lenses in question are not in common usage and the lenses themselves are unlikely to be inventoried by contact lens sellers.

## II.

### ADDITIONAL COMMENTS

These comments track specific questions in Section IX of the Notice of Proposed Rulemaking - Questions on the Proposed Contact Lens Rule and the Proposed Clerical Amendments to the Ophthalmic Practice Rules.

FEDERAL TRADE COMMISSION

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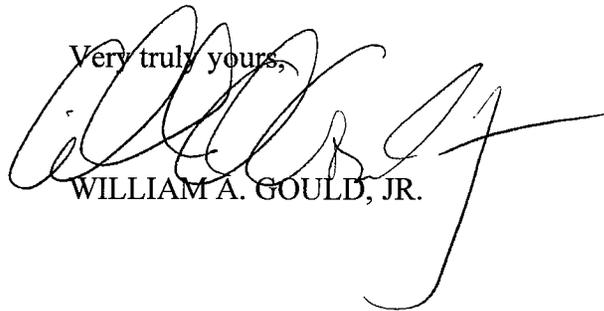
6. The definition of contact lenses should include non-corrective or cosmetic contact lenses since they are a medical device that is placed on the eye. California law limits the prescribing of non-corrective contact lenses to physicians and optometrists<sup>2</sup>.

7. The definition of direct communication should require an acknowledgment of receipt of a successful transmission.

The COA would be happy to respond to any questions that the Commission may have regarding its submission.

Respectfully submitted,

Very truly yours,



WILLIAM A. GOULD, JR.

WAG:cas

Enclosure

cc: Jennifer Kent, Director (w/encl.)  
Government and External Affairs  
CALIFORNIA OPTOMETRIC ASSOCIATION

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<sup>2</sup> California Business and Professions Code section 2540.

## Assembly Bill No. 2020

### CHAPTER 814

An act to amend Sections 2543, 2545, 2546.5, and 2546.6 of, and to add Sections 2541.2, 2546.10, and 2564.6 to, the Business and Professions Code, relating to optometry.

[Approved by Governor September 23, 2002. Filed with Secretary of State September 23, 2002.]

#### LEGISLATIVE COUNSEL'S DIGEST

AB 2020, Correa. Optometry.

(1) Existing law provides for the regulation of prescription lenses and prohibits any person other than a physician and surgeon or optometrist from prescribing ophthalmic or contact lenses or plano contact lenses. Existing law also prohibits any person other than licensed physicians and surgeons, licensed optometrists, or registered dispensing opticians from dispensing, selling, or furnishing prescription lenses.

This bill would prohibit the expiration date of a contact lens prescription from being less than one to 2 years from the date of issuance, with certain exceptions. The bill would also require a prescriber or registered dispensing optician to provide the patient with a copy of his or her prescription, subject to certain exceptions. The bill would prohibit the prescriber or optician from conditioning the release of the prescription on the patient paying a fee or purchasing contact lenses. The bill would make the prescriber's willful violation of these requirements unprofessional conduct. The bill would provide that it is a deceptive marketing practice to represent by advertisement or sales presentation that contact lenses may be obtained without confirmation of a prescription. The bill would provide that a violation of the laws regulating prescription lenses is punishable by a fine, not to exceed \$2,500 that would be available upon appropriation to the Medical Board of California. The bill would also require money derived from fines on optometrists to be deposited in the Optometry Fund and to be available upon appropriation to the State Board of Optometry.

(2) Existing law requires a person located outside California to be registered with the Medical Board of California in order to ship, mail, or deliver contact lenses at retail to a patient at a California address.

This bill would require a nonresident contact lens seller to provide a toll-free telephone number, facsimile line, or e-mail address where contact lens prescribers may confirm their prescriptions. The bill would also provide that violation of the provisions regulating nonresident

contact lens sellers is punishable by a fine not to exceed \$2,500 that would be available upon appropriation to the Medical Board of California.

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

SECTION 1. Section 2541.2 is added to the Business and Professions Code, to read:

2541.2. (a) (1) The expiration date of a contact lens prescription shall not be less than one to two years from the date of issuance, unless the patient's history or current circumstances establish a reasonable probability of changes in the patient's vision of sufficient magnitude to necessitate reexamination earlier than one year, or the presence or probability of visual abnormalities related to ocular or systemic disease indicate the need for reexamination of the patient earlier than one year. If the expiration date of a prescription is less than one year, the health-related reasons for the limitation shall be documented in the patient's medical record. In no circumstances shall the prescription expiration date be less than the period of time recommended by the prescriber for reexamination of the patient.

(2) For the purposes of this subdivision, the date of issuance is the date the patient receives a copy of the prescription.

(3) Establishing an expiration date that is not consistent with this section shall be regarded as unprofessional conduct by the board that issued the prescriber's license to practice.

(b) Upon completion of the eye examination or, if applicable, the contact lens fitting process for a patient as described in subdivision (f), a prescriber or a registered dispensing optician shall provide the patient with a copy of the patient's contact lens prescription signed by the prescriber, unless the prescription meets the standards set forth in subdivision (c).

(c) A prescriber shall retain professional discretion regarding the release of the contact lens prescription for patients who wear the following types of contact lenses:

- (1) Rigid gas permeables.
- (2) Bitoric gas permeables.
- (3) Bifocal gas permeables.
- (4) Keratoconus lenses.

(5) Custom designed lenses that are manufactured for an individual patient and are not mass produced.

(d) If a patient places an order with a contact lens seller other than a physician and surgeon, an optometrist, or a registered dispensing optician, the prescriber or his or her authorized agent shall, upon request

of the contact lens seller and in the absence of the actual prescription, attempt to promptly confirm the information contained in the prescription through direct communication with the contact lens seller.

(e) The contact lens prescription shall include sufficient information for the complete and accurate filling of a prescription, including, but not limited to, the power, the material or manufacturer or both, the base curve or appropriate designation, the diameter when appropriate, and an appropriate expiration date. When a provider prescribes a private label contact lens for a patient, the prescription shall include the name of the manufacturer, the trade name of the private label brand, and, if applicable, the trade name of the equivalent national brand.

(f) The contact lens fitting process begins after the initial comprehensive eye examination, and includes an examination to determine the lens specifications, an initial evaluation of the fit of the lens on the patient's eye, except in the case of a renewal prescription of an established patient, and followup examinations that are medically necessary, and ends when the prescriber or registered dispensing optician determines that an appropriate fit has been achieved, or in the case of a prescription renewal for an established patient, the prescriber determines that there is no change in the prescription.

(g) The payment of professional fees for the eye exam, fitting, and evaluation may be required prior to the release of the prescription, but only if the prescriber would have required immediate payment from the patient had the examination revealed that no ophthalmic goods were required. A prescriber or registered dispensing optician shall not charge the patient any fee as a condition to releasing the prescription to the patient. A prescriber may charge an additional fee for verifying ophthalmic goods dispensed by another seller if the additional fee is imposed at the time the verification is performed.

(h) A prescriber shall not condition the availability of an eye examination, a contact lens fitting, or the release of a contact lens prescription on a requirement that the patient agree to purchase contact lenses from that prescriber. A registered dispensing optician shall not condition the availability of a contact lens fitting on a requirement that the patient agrees to purchase contact lenses from that registered dispensing optician.

(i) A prescriber or a registered dispensing optician shall not place on the contact lens prescription, deliver to the patient, or require a patient to sign a form or notice waiving or disclaiming the liability or responsibility of the prescriber or registered dispensing optician for the accuracy of the ophthalmic goods and services dispensed by another seller. This prohibition against waivers and disclaimers shall not impose liability on a prescriber or registered dispensing optician for the

ophthalmic goods and services dispensed by another seller pursuant to the prescriber's prescription.

(j) The willful failure or refusal of a prescriber to comply with the provisions of this section shall constitute grounds for professional discipline, including, but not limited to, the imposition of a fine or the suspension or revocation of the prescriber's license. The Medical Board of California and the State Board of Optometry shall adopt regulations, to implement this subdivision, including, but not limited to, standards for processing complaints each receives regarding this subdivision.

(k) For the purposes of this section, "prescriber" means a physician and surgeon or an optometrist.

(l) Nothing in this section shall be construed to expand the scope of practice of a registered dispensing optician as defined in Sections 2542, 2543, and Chapter 5.5 (commencing with Section 2550).

SEC. 2. Section 2543 of the Business and Professions Code is amended to read:

2543. (a) Except as provided in the Nonresident Contact Lens Seller Registration Act (Chapter 5.45 (commencing with Section 2546)), the right to dispense, sell or furnish prescription lenses at retail or to the person named in a prescription is limited exclusively to licensed physicians and surgeons, licensed optometrists, and registered dispensing opticians as provided in this division. This section shall not be construed to affect licensing requirements pursuant to Section 111615 of the Health and Safety Code.

(b) It shall be considered a deceptive marketing practice for any licensed physician and surgeon, licensed optometrist, or registered dispensing optician to publish or cause to be published any advertisement or sales presentation relating to contact lenses representing that contact lenses may be obtained without confirmation of a valid prescription.

SEC. 3. Section 2545 of the Business and Professions Code is amended to read:

2545. (a) Whenever any person has engaged, or is about to engage, in any acts or practices which constitute, or will constitute, an offense against this chapter, the superior court in and for the county wherein the acts or practices take place, or are about to take place, may issue an injunction, or other appropriate order, restraining the conduct on application of the State Board of Optometry, the Division of Licensing of the Medical Board of California, the Osteopathic Medical Board of California, the Attorney General, or the district attorney of the county.

The proceedings under this section shall be governed by Chapter 3 (commencing with Section 525) of Title 7 of Part 2 of the Code of Civil Procedure.

(b) (1) Any person who violates any of the provisions of this chapter shall be subject to a fine of not less than one thousand dollars (\$1,000) nor more than two thousand five hundred dollars (\$2,500) per violation. The fines collected pursuant to this section from licensed physicians and surgeons and registered dispensing opticians shall be available upon appropriation to the Medical Board of California for the purposes of administration and enforcement. The fines collected pursuant to this section from licensed optometrists shall be deposited into the Optometry Fund and shall be available upon appropriation to the State Board of Optometry for the purposes of administration and enforcement.

(2) The Medical Board of California and the State Board of Optometry shall adopt regulations implementing this section and shall consider the following factors, including, but not limited to, applicable enforcement penalties, prior conduct, gravity of the offense, and the manner in which complaints will be processed.

(3) The proceedings under this section shall be conducted in accordance with the provisions of Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

SEC. 4. Section 2546.5 of the Business and Professions Code is amended to read:

2546.5. In order to obtain and maintain registration, a nonresident contact lens seller shall:

(a) Be in good standing and either registered or otherwise authorized in the state in which the selling facility is located and from which the contact lenses are sold.

(b) Comply with all directions and requests for information made by the board as authorized under this chapter.

(c) Maintain records of contact lenses shipped, mailed, or delivered to patients in California for a period of at least three years.

(d) Provide a toll-free telephone service for responding to patient questions and complaints during the applicant's regular hours of operation, but in no event less than six days per week and 40 hours per week. The toll-free number shall be included in literature provided with each mailed contact lens prescription. All questions relating to eye care for the lens prescribed shall be referred back to the contact lens prescriber.

(e) Provide the following or a substantially equivalent written notification to the patient whenever contact lenses are supplied:

WARNING: IF YOU ARE HAVING ANY UNEXPLAINED EYE DISCOMFORT, WATERING, VISION CHANGE, OR REDNESS, REMOVE YOUR LENSES IMMEDIATELY AND CONSULT YOUR EYE CARE PRACTITIONER BEFORE WEARING YOUR LENSES

AGAIN.

(f) Disclose in any price advertisement any required membership fees, enrollment fees, and indicate that shipping costs may apply unless the advertisement specifically and clearly states otherwise.

(g) Provide a toll-free telephone number, facsimile line, and electronic mail address that are dedicated to prescribers and their authorized agents for the purposes of confirmation of contact lens prescriptions. These numbers, along with an electronic mail address, shall be included in any communication with the prescriber when requesting confirmation of a contact lens prescription.

(h) It shall be considered a deceptive marketing practice for any nonresident contact lens seller to publish or cause to be published any advertisement or sales presentation relating to contact lenses representing that contact lenses may be obtained without confirmation of a valid prescription.

SEC. 5. Section 2546.6 of the Business and Professions Code is amended to read:

2546.6. (a) Contact lenses may be sold only upon receipt of a written prescription or a copy of a written prescription and may be sold in quantities consistent with the prescription's established expiration date and the standard packaging of the manufacturer or vendor. If the written prescription or a copy of it is not available to the seller, the seller shall confirm the prescription by direct communication with the prescriber or his or her authorized agent prior to selling, shipping, mailing, or delivering any lens, and maintain a record of the communication. A prescription shall be deemed confirmed upon the occurrence of one of the following:

(1) The prescriber or the prescriber's agent confirms the prescription by communication with the seller.

(2) The prescriber fails to communicate with the seller by 2 p.m. of the next business day after the seller requests confirmation, or the prescriber fails to communicate with the seller by the next business day on or before the same time of day that the seller requested confirmation, whichever is sooner. For purposes of this paragraph, "business day" means each day except a Sunday or a federal holiday.

(b) If a prescriber communicates with a seller before the time period described in paragraph (2) of subdivision (a) elapses and informs the seller that the contact lens prescription is invalid, the seller shall not fill the prescription. The prescriber shall specify in the communication with the seller the basis for invalidating the prescription.

(c) A seller shall not alter any of the specifications of a contact lens prescription other than the color or substitute a different manufacturer,

brand, or other physical property of the lens. Notwithstanding the provisions of this subdivision, if the contact lens is manufactured by a company, but sold under multiple private labels by that same company to individual providers, the seller may fill the prescription with a contact lens manufactured by that company if the contact lens prescription and the related parameters are not substituted, changed, or altered for a different manufacturer or brand.

SEC. 6. Section 2546.10 is added to the Business and Professions Code, to read:

2546.10. (a) Any person who violates any of the provisions of this chapter shall be subject to a fine of not less than one thousand dollars (\$1,000) nor more than two thousand five hundred dollars (\$2,500) per violation. The fines collected pursuant to this section shall be available upon appropriation to the Medical Board of California for the purposes of administration and enforcement.

(b) The Medical Board of California shall adopt regulations implementing this section and shall consider the following factors, including, but not limited to, applicable enforcement penalties, prior conduct, gravity of the offense, and the manner in which complaints will be processed.

(c) The proceedings under this section shall be conducted in accordance with the provisions of Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

SEC. 7. Section 2564.6 is added to the Business and Professions Code, to read:

2564.6. A registered dispensing optician shall comply with the applicable provisions of Section 2541.2.