

June 23, 2004

Federal Trade Commission  
Office of the Secretary  
Room H-159 (Annex L)  
600 Pennsylvania Avenue, NW  
Washington, DC 20580

RE: Contact Lens Study, Project No. V040010

To Whom It May Concern:

The Nebraska Board of Optometry submits the following comments regarding Contact Lens Study, Project No. V040010:

**2d. What role do state regulatory or self-regulatory bodies play in controlling prescriber advertisements, especially with respect to a prescriber's willingness to prescribe contact lenses that are available from alternative prescribers and sellers?**

Nebraska has unprofessional conduct regulations for optometry that address advertising. A copy of these regulations is enclosed for your information (172 NAC 120 Regulations Governing the Practice of Optometry – Section 011 Unprofessional Conduct). These regulations currently do not address advertisements regarding a prescriber's willingness to prescribe contact lenses.

**16. What role do state laws or regulations play in determining what a prescriber must include on a prescription, including whether a prescription must contain a brand name?**

Nebraska law specifically states what a contact lens prescription must include to be considered valid, but it does not require that brand name be noted. Neb. Rev. Stat. §69-303 states, "(1) A mail-order ophthalmic provider may dispense contact lenses in Nebraska or to a Nebraska resident if the contact lens prescription is valid. Such prescription is valid if it (a) contains the patient's name, date ordered, expiration date, instructions for use, optometrist or physician identifying information, date of patient's last examination, fabrication, and related information and (b) has not expired."

**19c. What role do state regulatory or self-regulatory bodies play in controlling prescriber advertisements with respect to their ability to prescribe custom labeled lenses or their willingness to prescribe contact lenses available from a variety of sellers?**

Nebraska has unprofessional conduct regulations for optometry that address advertising. A copy of these regulations is enclosed for your information (172 NAC 120 Regulations

Governing the Practice of Optometry – Section 011 Unprofessional Conduct). These regulations currently do not address advertisements regarding a prescriber's ability to prescribe custom labeled lenses or their willingness to prescribe contact lenses available from a variety of sellers.

- 26. Has the issuance and enforcement of the Eyeglass Rule caused or prompted states to change their laws or policies regarding prescription eyeglasses? If so, what changes were made and what effect did they have?**

Guidelines for Release of Spectacle or Contact Lens Prescriptions were developed by the Nebraska Board of Optometry August 29, 1990, in response to the Eyeglass Rule. These guidelines were originally intended to serve as a guide for practicing optometrists, but they have also been provided to the public in response to questions regarding the release of spectacle or contact lens prescriptions. A copy of the guidelines is enclosed for your information. Please note that these guidelines will need to be revised to address the Fairness to Contract Lens Consumers Act.

- 29. Do state licensing requirements affect out-of-state sellers' abilities to compete with in-state sellers or prescribers for the sale of prescription contact lenses?**

We require out-of-state sellers to register with the Board of Pharmacy. Once registered, they may compete with in-state sellers. In-state sellers are regulated through their professional licenses as optometrists, physicians, or pharmacies.

- 30. What role do state licensing requirements applicable to sellers of contact lenses play in protecting consumers?**

Contact lenses are legend devices that may only be sold based on a prescription. The sale of contact lenses is limited to the following entities that are regulated by the State in the interest of public protection: optometrists, physicians, pharmacies, or mail-order ophthalmic providers.

Sincerely,

(Signature on file with the Department)

Wayne E. Quincy, O.D.  
Chairman  
Nebraska Board of Optometry

WEQ/BW

Enclosures

Excerpt from 172 NAC 120 Regulations Governing the Practice of Optometry

011 UNPROFESSIONAL CONDUCT

In addition to the unlawful or unprofessional acts listed in Neb. Rev. Stat. 71-147 through 71-148, the following conduct shall be considered unprofessional acts as defined by the Board [71-147(10)]:

011.01 Conduct by an optometrist that is likely to deceive, defraud, or harm the public;

011.02 Making a false or misleading statement regarding his/her skill as an optometrist or the efficacy or value of the medicine, device, treatment, or remedy prescribed by him/her or used at his/her direction in the practice of optometry;

011.03 Gross negligence in the practice of optometry;

011.04 Practice or other behavior that demonstrates a willful rendering of substandard care, either individually or as a part of a third-party reimbursement agreement or other agreement;

011.05 The use of any false, fraudulent, deceptive or misleading statement in any document pertaining to the practice of optometry;

011.06 Commission of any act of sexual abuse, misconduct, or exploitation related to the person's practice of optometry;

011.07 Prescribing, selling, administering, or distributing, any drug legally classified as a prescription drug, other than with proper certification to prescribe topical ocular pharmaceutical agents which treat eye infection, inflammation and superficial abrasions;

011.08 Knowingly giving to a habitue or addict any drug legally classified as a controlled substance or recognized as an addictive or dangerous drug;

011.09 Prescribing, selling, administering, distributing, or giving a drug legally classified as a controlled substance or recognized as an addictive or dangerous drug to a family member or himself/herself;

011.10 Conviction of any state or federal law or regulation relating to a drug legally classified as a controlled substance;

011.11 Failure to report to the Department the relocation of any or all of his/her office(s) or place(s) of practice, in or out of the jurisdiction, within ninety (90) days of such relocation;

011.12 Failure to furnish the Board, its investigators or representatives, information legally requested by the Board;

011.13 Willful or repeated violation of any provision(s) of Neb. Rev. Stat. 71-1,133 through 71-1,136.09 or any Rules and Regulations promulgated thereto;

011.14 To advertise in a manner that deceives, misleads, or defrauds the public. The following advertising practices shall be considered to be deceptive:

011.14A To advertise or promote any optometric service as free or below the advertiser's or promoter's own cost without revealing in such advertising or promotion the minimum expenditure the consumer must incur in order to receive said service. If the consumer need not incur any expense to obtain said service, then the advertising or promotion shall state that there is no minimum purchase required;

011.14B To fail to advertise the names of all licensed optometrists who are providing optometric service that are addressed by the advertisement;

011.14C To fail to place in any advertisement either the word Optometrist or the abbreviation O.D. behind one's name when it appears in an advertisement. The lettering of the word Optometrist or the abbreviation O.D. shall be in lettering of the same height as those letters used in the optometrist's name;

011.14D To place in any advertisement a name which is different than the name that appears on the optometrist's license;

011.14E To fail to inform the patient of any time schedule within which a fee is to be effective, if such fee applies to a particular service for a given time;

011.14F To fail to charge the same fee for a service as that which is advertised;

011.14G To advertise that in exchange for a particular fee, a manifestly incurable disease can be permanently cured;

011.14H To fail to specify the name of the professional body from which certification or accreditation was received when referring to certificates from professional accrediting bodies;

011.14I To advertise or promote any optometric service without plainly revealing in such advertising or promotion the name(s) of all optometric licensees practicing at said outlet(s) as described in Neb. Rev. Stat. 71-107;

011.14J To advertise or promote any optometric service with statements that cannot be verified, substantiated or measured; and

011.14K To advertise or promote any optometric service in violation of 87-301 through 87-306, the Uniform Deceptive Trade Practices Act.

011.15 The designation of any person licensed under Neb. Rev. Stat. 71-1,133 other than by the terms Optometrist or O.D.;

011.16 Practicing optometry without the licensee's license and any applicable certificate to include certification for diagnostic or therapeutic certificate conspicuously displayed in each place of practice, and to place and keep placed, in a conspicuous place at each entrance thereto, in intelligible lettering not less than one inch in height, containing the name of such person and, in addition thereto shall be placed upon such signs, in lettering of equal height, the designation Optometrist or O.D. The same wording shall be used in all signs, announcements, stationery, and advertisements of such licensee's services [71-107];

011.17 Failure to report to the Department the name of every person without a license or certificate that he/she has reason to believe is engaging in the practice of any profession for which a license or certificate is required under the Uniform Licensing Law [71-168];

011.18 Receiving or giving fees for professional services to any person in exchange for referring patients; and

011.19 Failure of a licensed optometrist who administers or prescribes pharmaceutical agents for examination or for treatment to provide the same standard of care to patients as that provided by a physician licensed in this state to practice medicine and surgery utilizing the same pharmaceutical agents for examination or treatment.

011.20 Noncompliance with the regulations in section 011 of these regulations shall be considered unprofessional conduct as described in Neb. Rev. Stat. 71-147(10) and any licensee or person as defined herein in violation hereof shall be subject to revocation of license or to other penalties as described in Neb. Rev. Stat. 71-147 to 71-162.

## GUIDELINES FOR RELEASE OF SPECTACLE OR CONTACT LENS PRESCRIPTIONS

The Board of Examiners in Optometry (Board) has issued the following guide for the release of spectacle or contact lens prescriptions. These guidelines are distributed upon request and are intended to serve as a guide for practicing optometrists. The guidelines do not have the effect of law and the individual practicing optometrist remains accountable for all judgments and technical tasks performed.

### Prescriptions for Spectacles

The Ophthalmic Practice Rules from the Code of Federal Regulations, part 456 requires an optometrist or ophthalmologist to provide to the patient one copy of the patient's prescription immediately after the eye examination is completed. An optometrist or ophthalmologist may refuse to give the patient a copy of the prescription until the patient has paid for the eye examination, but only if that optometrist or ophthalmologist would have required immediate payment from that patient had the examination revealed that no ophthalmic goods were required.

The Board recommends that each spectacle prescription contain a reasonable (up to 24 months) expiration date. The patient should be advised of that date, and it should be noted in the patient's record.

The Board believes that providing a copy of an expired prescription to a patient or other unlicensed individual or providing spectacles made from an expired prescription is inadvisable for the following reasons:

- 1) It is not in the patient's best interest to purchase or wear spectacles that do not provide her/him with optimum vision. It is potentially hazardous, harmful, ineffectual, and uneconomical.
- 2) There is the potential for harm to the public. The wearing of spectacles that do not provide optimum vision could result in accident, injury to others, or property damage.
- 3) The optometrist may incur malpractice liability by providing a prescription known to be expired to a patient subsequently involved in a mishap.

### Prescription for Contact Lenses

Contact lenses are medical devices regulated by the U.S. Food and Drug Administration because of the potential for harm that they pose to the wearer. In Nebraska, contact lenses may be prescribed and fitted only by optometrists or physicians. (Neb. Rev. Stat. 71-1,133 and Neb. Rev. Stat. 71-1,134)

## Prescription Guidelines

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As of May 1, 2001, the Department shall require and provide for an annual registration for all mail-order ophthalmic providers located outside of this state, including those providing services via the Internet, that dispense contact lenses to Nebraska residents.

- 1) A mail-order ophthalmic provider may dispense contact lenses in Nebraska or to a Nebraska resident if the contact lens prescription is valid. A prescription is valid if it contains:
  - a) the patient's name, date ordered, expiration date, instructions for use, optometrist or physician identifying information, date of patient's last examination, fabrication, and related information and
  - b) has not expired.
- 2) A contact lens prescription shall be valid for the duration of the prescription as indicated by the optometrist or physician or for a period of twelve months from the date of issuance, whichever period expires first. Upon expiration, an optometrist or physician may extend the prescription without further examination.
- 3) An optometrist or physician shall offer the prescription to a patient following the fitting process and payment of all fees for services rendered.

The Board of Optometry has determined that the fitting process includes evaluating the lens on the eye after significant periods of wear on more than one occasion. Such evaluation may lead to lens replacement, adjustment or modification and subsequent reevaluation after additional periods of wear. Once determined, the final contact lens prescription should contain a reasonable (up to 12 month) expiration date which should be noted in the patient's record. The number of refills should be calculated and included in the prescription to ensure that there are adequate refills for the time the prescription is valid. The patient should be advised of the expiration date. The prescription should be renewed upon reexamination, when appropriate.

The Board believes that providing a copy of an expired contact lens prescription to a patient or other unlicensed individual or providing contact lenses made from an expired prescription is inadvisable due to the potential for harm to the wearer.

Issued: August 29, 1990  
Revised: October 2, 1992  
February 22, 1993  
May 17, 2000  
May 15, 2002  
June 23, 2004

Copies of these guidelines may be obtained by contacting:

The Nebraska Board of Optometry  
P.O. Box 94986  
Lincoln, NE 68509-4986