



UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of Policy Planning
Bureau of Economics
Bureau of Competition

January 13, 2011

Sue M. Kornegay
NC State Board of Opticians
PO Box 25336
Raleigh, NC 27611

Dear Ms. Kornegay:

The staffs of the Federal Trade Commission's Office of Policy Planning, Bureau of Economics, and Bureau of Competition¹ appreciate this opportunity to comment on the proposed additional regulations ("Proposed Rules") issued by the North Carolina State Board of Opticians ("the Board").² As discussed below, the Proposed Rules would affect not only opticians, but also ophthalmologists, optometrists, and vendors of prescription eyewear and could increase prices to North Carolina consumers without any countervailing benefits to consumers.

Among other things, the Proposed Rules would:

- a) redefine the meaning of "prescription" for eyeglasses, contact lenses, or other ophthalmic appliances, so that "[m]easurements taken by opticians are not considered part of the patient's prescription, and are not required to be released as part of a prescription;"
- b) impose certain requirements solely on "[e]lectronic optical businesses, including internet sites," but not "bricks-and-mortar" vendors; and
- c) impose certain new requirements on out-of-state vendors, including Internet sellers.

Existing federal and state regulations already provide extensive protections for the health and safety of contact lens wearers and others who obtain ophthalmic goods and services. The Board has provided no explanation why these additional rules are necessary. Rather, the Proposed Rules discussed in this letter appear likely to impose higher costs on vendors of prescription eyewear, which may raise prices to North Carolina consumers for those goods.

¹ This letter expresses the views of the Federal Trade Commission's Office of Policy Planning, Bureau of Economics, and Bureau of Competition. The letter does not necessarily represent the views of the Federal Trade Commission ("Commission") or of any individual Commissioner. The Commission has, however, voted to authorize us to submit these comments.

² See 25 N.C. Reg. 1205 (Nov. 15, 2010) (Proposed 21 N.C. ADMIN. CODE 40) [hereinafter Proposed Rule].

In the absence of countervailing health and safety rationales for the Proposed Rules, FTC staff urges the Board to consider carefully the impact of the Proposed Rules and to avoid adopting provisions that hamper affordable access to optical goods more strictly than patient protection requires. In particular, we urge the Board to consider potential conflicts between its Proposed Rules and the Fairness to Contact Lens Consumers Act (the Act or FCLCA),³ the Contact Lens Rule,⁴ and the Eyeglass Rule.⁵ The FTC enforces the FCLCA,⁶ and the FTC issued and administers the Contact Lens Rule and the Eyeglass Rule, which may preempt state and local laws restricting patients' ability to obtain their contact lens and eyeglass prescriptions so they can comparison shop for the deal that best suits their preferences.

Interest and Experience of the Federal Trade Commission

The FTC is charged under the FTC Act with preventing unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.⁷ Competition is at the core of America's economy,⁸ and vigorous competition among sellers in an open marketplace gives consumers the benefits of lower prices, higher quality products and services, more choices, and greater innovation. Because of the importance of health care competition to the economy and consumer welfare, anticompetitive conduct in health care markets has long been a key target of FTC law enforcement,⁹ research,¹⁰ and advocacy.¹¹

In particular, the FTC has more than three decades of regulatory and research experience regarding the optical goods industry. As noted above, the Commission enforces the Eyeglass Rule, initially promulgated in 1978.¹² Prior to the Eyeglass Rule, many prescribers ("ECPs")¹³

³ 15 U.S.C. §§ 7601-7610.

⁴ 16 C.F.R. § 315.

⁵ 16 C.F.R. § 456.

⁶ 15 U.S.C. § 7608.

⁷ Federal Trade Commission Act, 15 U.S.C. § 45.

⁸ *See, e.g., National Society of Professional Engineers v. United States*, 435 U.S. 679, 695 (1978) ("The heart of our national economy long has been faith in the value of competition.").

⁹ *See generally, e.g.,* FED. TR. COMM'N [FTC], FTC ANTITRUST ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS (Mar. 2008), available at <http://www.ftc.gov/bc/0608hcupdate.pdf>; *see also* Competition in the Health Care Marketplace: Formal Commission Actions, available at <http://www.ftc.gov/bc/healthcare/antitrust/commissionactions.htm>.

¹⁰ *See, e.g.,* FED. TR. COMM'N & U.S. DEP'T OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION, Chapter 7 (2004), available at <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf>.

¹¹ FTC and staff advocacy may comprise letters or comments addressing specific policy issues, Commission or staff testimony before legislative or regulatory bodies, amicus briefs, or reports. *See, e.g.,* Letter from FTC Staff to Hon. Timothy Burns, Louisiana Legislature, (May 1, 2009) (regarding proposed restrictions on mobile dentistry); available at http://www.ftc.gov/os/2009/05/V090009_louisianadentistry.pdf; FED. TR. COMM'N AND U.S. DEP'T OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION, *supra* note 11.

¹² Advertising of Ophthalmic Goods and Services, Statement of Basis and Purpose and Final Trade Regulation Rule, 43 Fed. Reg. 23,992 (June 2, 1978) [hereinafter "Eyeglass rule"]. The Eyeglass Rule was revised in 1992, with the revisions codified at 16 C.F.R. § 456. FED. TR. COMM'N, 16 C.F.R. § 456, Ophthalmic Practice Rules, 57 Fed. Reg. 18822 (May 1, 1992).

either refused to release prescriptions to their patients or charged an additional fee to do so.¹⁴ Prices for glasses varied widely (as much as 300 percent). Without their prescriptions, however (or without paying a fee to obtain their prescriptions), consumers could not comparison shop to identify and purchase from discount sellers that met their needs.¹⁵ To address this problem, the Eyeglass Rule requires optometrists and ophthalmologists to provide their patients, immediately after completion of an eye examination, a free copy of their eyeglass prescription.¹⁶

To achieve similar freedom of choice for contact lens consumers, Congress in 2003 passed the FCLCA,¹⁷ which assigned three duties to the FTC: 1) prescribe rules to carry out the Act; 2) enforce the Act and rules implementing it; and 3) prepare a study on the strength of competition in the sale of prescription contact lenses. In 2004, the Commission issued the Contact Lens Rule,¹⁸ which implements the Act. Similar to the Eyeglass Rule, the Contact Lens Rule requires that “[w]hen a prescriber completes a contact lens fitting, the prescriber . . . shall provide to the patient a copy of the contact lens prescription.”¹⁹ Pursuant to its congressional mandate, the FTC also issued a study of competition in the contact lens industry in 2005.²⁰

In addition to these efforts, the Commission has used administrative litigation under the FTC Act to challenge anticompetitive restrictions on competition in ophthalmic goods and services,²¹ and FTC staff has provided comments to state agencies and legislatures regarding, for example, the effects of restrictions on the sale of replacement contact lenses.²²

¹³ Optical goods prescribers are sometimes – and herein – referred to as prescribing eye care practitioners, or “ECPs.”

¹⁴ Eyeglass Rule, 43 Fed. Reg. at 23,998. The Commission found, for example, that in nearly every survey of practicing optometrists considered in the rulemaking record, more than 50 % of optometrists imposed a restriction on the availability of eyeglass prescriptions to patients. *See id.*

¹⁵ FED. TR. COMM’N, THE STRENGTH OF COMPETITION IN THE SALE OF RX CONTACT LENSES: AN FTC STUDY, 45-46 (2005), available at <http://www.ftc.gov/reports/contactlens/050214contactlensrpt.pdf> [hereinafter 2005 CONTACT LENS REPORT].

¹⁶ 16 C.F.R. § 456.2 (separation of examination and dispensing). The FTC also has studied the effects of state-imposed restrictions in the optical goods industry. FED. TR. COMM’N, THE EFFECTS OF RESTRICTIONS ON ADVERTISING AND COMMERCIAL PRACTICE: THE CASE OF OPTOMETRY, FTC BUREAU OF ECONOMICS STAFF PAPER REPORT (1980).

¹⁷ Fairness to Contact Lens Consumers Act, Pub. L. No. 164, 117 Stat. 2024 (codified at 15 U.S.C. §§ 7601-7610 (2003)).

¹⁸ Contact Lens Rule, 69 Fed. Reg. 40482 (July 2, 2004) (Contact Lens Rule) (codified at 16 C.F.R. pts. 315 and 456).

¹⁹ 16 C.F.R. § 315.3(a)(1).

²⁰ 2005 CONTACT LENS REPORT, *supra* note 15. *See also* FED. TR. COMM’N, POSSIBLE BARRIERS TO E-COMMERCE: CONTACT LENSES: A REPORT FROM THE STAFF OF THE FEDERAL TRADE COMMISSION (Mar. 29, 2004) [hereinafter 2004 CONTACT LENS REPORT], at <http://www.ftc.gov/os/2004/03/040329clreportfinal.pdf>.

²¹ *See, e.g., In re Collegio de Optometras*, Dkt. No. C-4199 (Sept. 11, 2007) (decision and order regarding alleged price fixing by not-for-profit optometrists association); *Massachusetts Board of Registration in Optometry*, 110 F.T.C. 549 (1988) (challenging Board regulation that unreasonably restricted truthful advertising by optometrists; final order required Board to allow truthful advertising and to repeal regulation).

²² *See, e.g.,* Letter from Maureen K. Ohlhausen *et al.* to Arkansas State Representative Doug Matayo (Oct. 4, 2004), at <http://www.ftc.gov/os/2004/10/041008matayocomment.pdf>; FTC Staff Comment Before the Connecticut Board

I. Background: A Brief Overview of the Ophthalmic Goods Industry and Its Regulation.

More than a third of all Americans suffer from myopia (nearsightedness) or hyperopia (farsightedness),²³ which commonly are treated with eyeglasses or contact lenses.²⁴ Corrective lenses also may be prescribed for astigmatism and presbyopia (poor focusing with reading material and other near vision tasks).²⁵ Contact lens wearers alone number approximately 36 million.²⁶

The use and sale of contact lenses involve significant health issues.²⁷ According to the Federal Food and Drug Administration (“FDA”), improper use of contact lenses is associated with “the risk of infections such as pink eye (conjunctivitis), corneal abrasions, and eye irritation.”²⁸ Consumers may endanger the health of their eyes if they obtain and wear replacement contact lenses without a valid prescription or fail to remove and replace contact lenses according to their doctors’ recommendations.²⁹ At the same time, “[m]any of these complications can be avoided through everyday care of the eye and contact-lenses.”³⁰

Federal law currently requires that contact lenses be sold only to patients with valid prescriptions, which they receive after eye examinations. The Fairness to Contact Lens Consumers Act and the FTC’s Contact Lens Rule prohibit sales of contact lenses unless the seller has a copy of the patient’s prescription or has verified that prescription with the prescriber.³¹ The FDA has strict labeling requirements for contact lenses, and it has the authority to take action against the sales of such lenses (medical devices) without a valid prescription.³²

of Examiners for Opticians (Mar. 27, 2002) (“Connecticut Board Comment”), at <http://www.ftc.gov/be.v020007.htm>.

²³ National Institutes of Health, National Eye Institute, Statistics and Data: Summary of Eye Disease Prevalence Data (web page last modified August 2010), available at http://www.nei.nih.gov/eyedata/pbd_tables.asp. According to the NEI, 25.4% suffer myopia and 9.9% suffer hyperopia.

²⁴ See, e.g., National Institutes of Health, National Eye Institute, Facts About Hyperopia, available at <http://www.nei.nih.gov/health/errors/hyperopia.asp>; National Institutes of Health, National Eye Institute, Facts About Myopia, available at <http://www.nei.nih.gov/health/errors/myopia.asp>.

²⁵ See, e.g., Federal Food and Drug Administration (FDA), Contact Lenses, available at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/ContactLenses/default.htm> (page last updated: 10/21/2010; last checked 12/21/10).

²⁶ 2005 CONTACT LENS REPORT, *supra* note 15, at 6.

²⁷ See, e.g., 2004 CONTACT LENS REPORT, *supra* note 20, at 8-9.

²⁸ FDA, For Consumers: Focusing on Contact Lens Safety, available at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048893.htm> (updated Nov. 18, 2008; last checked 12/21/10).

²⁹ See *id.*

³⁰ *Id.*

³¹ See 16 C.F.R. § 315.5 (seller may sell contact lenses only in accordance with prescription that is (a) presented directly by patient or prescriber or (b) verified by direct communication). See, e.g., *United States v. Chapin N. Wright II*, Civil Action No. 08 Civ 11793, FTC File No. 082 3020 (D. Mass. 2008) (consent decree & order for civil

The FTC's 2005 Report provides a useful summary of competition in the contact lens industry. Two of the main points pertinent to the Proposed Rules are the following:

- ***Sales of Replacement Lenses.*** “The evolution in contact lens technology now allows the sale of replacement contact lenses to be unbundled from the fitting exam.”³³

In the 1960s and 1970s, each new pair of (rigid) contact lenses – including replacement lenses -- had to be fit to the wearer. With today's soft disposable lenses, re-fittings of replacement lenses are generally unnecessary. Technical improvements in manufacturing such lenses since the 1980s have enabled consumers to acquire replacement lenses that are identical to the others they have obtained under a given prescription, regardless of whether the patient receives this lens from the prescribing ECP or another seller.³⁴

- ***Differences between online and offline sellers.*** “The FTC surveyed availability and prices for a six-month supply of ten popular contact lenses at 20 online and 14 offline outlets. The data indicate that most lenses are widely available through the various retail channels. Overall, independent ECPs and optical chains offer the highest prices, and wholesale clubs offer the lowest prices. Not accounting for intrachannel differences, contact lenses sold online were on average \$15 less expensive than those sold offline.”³⁵

As directed by Congress, the FTC's 2005 Report also reviews other issues that affect competition in the contact lens industry, including the effects of the Eyeglass Rule. The Report concluded that “the FTC's Eyeglass Rule appears to have made it easier for consumers to comparison shop, leading to lower prices and more choices for consumers.”³⁶ The Report also observes that, “State laws and regulations have the potential to limit competition in contact

penalties, permanent injunction, and other relief), available at <http://www.ftc.gov/os/caselist/0823020/081211seerightvisionconsent.pdf> (alleged sales of contact lenses without receipt or verification of prescription and without maintaining required records); *United States v. Contact Lens Heaven*, Civil Action No. 08-CV-61713, FTC File No. 082-3006 (S.D. Fla. 2008) (consent decree & order for civil penalties, permanent injunction, and other relief), available at <http://www.ftc.gov/os/caselist/0823006/081211contactlensheavenconsent.pdf> (same); *United States v. Pretty Eyes, LLC*, Civil Action No.: 07-cv-02462-REB, FTC File No. 072-3132 (D. Co. 2007) (consent decree & order for civil penalties, permanent injunction, and other relief), available at <http://www.ftc.gov/os/caselist/0723132/071210consent.pdf> (same).

³² See 21 U.S.C. §§ 331(a), 333, 352(f), and 353(b)(1).

³³ 2005 CONTACT LENS REPORT, *supra* note 15, at 5.

³⁴ *Id.*

³⁵ *Id.* at 3 (data were collected during the week of November 29, 2004). There is no indication that this general finding has changed in the intervening years.

³⁶ *Id.* at 3.

lenses, raise consumer costs, and harm public health. Licensing requirements may insulate in-state sellers from out-of-state competition or insulate ECPs from competing non-ECP sellers.”³⁷

II. Discussion

A. Portions of the Proposed Rule Appear to Conflict with Federal Statutes and Regulations.

The FCLCA and the Contact Lens Rule further two goals: ensuring consumer safety (by requiring adherence to properly written prescriptions) and promoting consumer choice (by enabling consumers to obtain their prescriptions, so they have a choice of where to purchase contact lenses, including replacement lenses). Similarly, the Eyeglass Rule defines the following as unfair acts or practices under Section 5 of the FTC Act: failing to provide to the patient one copy of the patient’s [eyeglass] prescription immediately after the completion of an eye exam or charging the patient a fee (in addition to the examination fee) to release the prescription to the patient.³⁸

Certain provisions regarding the proposed definition of prescription and the proposed requirement for Internet businesses to obtain waivers in the Proposed Rules appear to conflict with the federal requirements of making prescriptions available to eyeglass and contact lens consumers in a timely manner and without conditions. In particular, these provisions in the Proposed Rule may be expressly or impliedly preempted by the FCLCA and the Contact Lens Rule.

(1) Definition of “Prescription”

The Proposed Rules would redefine the term “prescription” to allow opticians to refuse to release to patients – or require patients to pay for the release of – the fitting measurements that are, under federal law and regulations, part of an optical goods prescription that must be released to the consumer. Those provisions could limit the ability of consumers to fill prescriptions via a provider other than a local optician. This result, if applied to contact lens prescriptions in particular, is diametrically opposed to Congress’s purpose in enacting the FCLCA³⁹ and the FTC’s purpose in enacting the Contact Lens Rule.⁴⁰

Specifically, the Proposed Rule excludes measurements from the definition of a prescription for “eyeglasses, contact lenses, or other ophthalmic appliances.”⁴¹ According to the

³⁷ *Id.* at 4.

³⁸ 16 C.F.R. § 456.2(a), (c).

³⁹ Congress enacted the FCLCA to protect competition in contact lens markets by increasing consumers’ ability to fill their contact lens prescriptions with sellers other than their prescribing eye care practitioner (“ECP”). *See* H.R. Rep. No. 108-318, at 4-5 (2003) (purpose and summary; background and need for legislation); *see also* 2005 CONTACT LENS REPORT, *supra* note 15, at 1.

⁴⁰ *See, e.g.*, Contact Lens Rule, 69 Fed. Reg. 40482, 40482 (July 2, 2004) (codified at 16 CFR pts. 315 and 456) (summary; statement of basis and purpose).

⁴¹ Proposed Rules at 40.0210 (Prescription and Interpretation).

Proposed Rule, ophthalmologists and optometrists still write prescriptions specifying eyeglasses or contact lenses, as appropriate, and “retain[] discretion *in determining the number and type of measurements* which will be placed upon the prescription.”⁴² However,

*[t]he optician shall take the measurements necessary to fill the prescription and shall determine the makeup of the lenses, supplementing but not contradicting the prescription. Measurements taken by opticians are not considered part of the patient's prescription, and are not required to be released as part of a prescription. The optical place of business, and the licensed optician in charge of the business, retains discretion as to the release of the ancillary measurements and any administrative processes associated with their release.*⁴³

On its face, the Proposed Rule conflicts with the definition of “contact lens prescription” in the FCLCA. That statute defines “contact lens prescription” to “mean[] a prescription, issued in accordance with State and Federal law, that contains *sufficient information for the complete and accurate filling of a prescription.*”⁴⁴ Information on contact lens fitting is required for the “complete and accurate filling” of a prescription. Even the Proposed Rule acknowledges this by stating that “the optician shall take the measurements *necessary to fill the prescription.*”⁴⁵

The Proposed Rule thus suggests restrictions on the release of prescription information that are inconsistent with federal law and regulations. The FCLCA requires that “[w]hen a prescriber completes a contact lens fitting, the prescriber (1) whether or not requested by the patient, shall provide to the patient a copy of the contact lens prescription; and (2) shall, as directed by any person designated to act on behalf of the patient, provide or verify the contact lens prescription by electronic or other means.”⁴⁶ Typically, a prescriber will determine whatever fitting measurements are necessary to complete a contact lens prescription.⁴⁷ In that case, federal law requires the prescriber to give the prescription to the patient, whether or not the patient requests it. It does not appear that the Board of Opticians in North Carolina has the authority to prohibit a prescriber from following this federal law.

⁴² *Id.* (emphasis added).

⁴³ *Id.* (emphasis added).

⁴⁴ 15 U.S.C. § 7610(3) (emphasis added). The same analysis reveals an apparent conflict with the Eyeglass Rule, which defines “prescription” to mean “the written specifications for lenses for eyeglasses which are derived from an eye examination, including all of the information specified by state law, if any, *necessary to obtain lenses for eyeglasses* (emphasis added).” 16 C.F.R. § 456.1(g).

⁴⁵ *Id.*

⁴⁶ 15 U.S.C. § 7601(a). The Contact Lens Rule contains the same requirement. 16 C.F.R. § 315.3(a)(1).

⁴⁷ “Prescriptions for eyeglasses and prescriptions for contact lenses differ in several respects. In addition to the information about the degree of vision correction that is present in both types of prescriptions, contact lens prescriptions include information regarding the fit of the lens on the surface of the eye, which is determined by the base curve (shape) and diameter of the lens. Also, unlike the case for eyeglass prescriptions, eye care practitioners generally denote the brand name of the contact lens in the prescription.” 2004 CONTACT LENS REPORT, *supra* note 20, at 10-11 (citing Comments of James F. Saviola, O.D., Captain, U.S. Public Health Service, Chief, Vitreoretinal and Extraocular Implants Branch, Division of Ophthalmic and ENT Devices, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration).

Moreover, to the extent that the Proposed Rule appears to grant opticians the authority to refuse to release ancillary measures that would complete contact lens prescriptions to consumers, or to require payment for prescriptions,⁴⁸ this provision also appears contrary to the prescription portability provisions of the FCLCA and Contact Lens Rule.⁴⁹ The FCLCA and the Contact Lens Rule prohibit a prescriber from “(1) requir[ing] purchase of contact lenses from the prescriber or from another person as a condition of providing a copy of a prescription. . . .” or “(2) requir[ing] payment in addition to, or as part of, the fee for an eye examination, fitting, and evaluation as a condition of providing a copy of the prescription.”⁵⁰ FTC staff recognizes that non-prescribing opticians, such as those in North Carolina, are not covered by the FCLCA or the Contact Lens Rule, because they do not fall within the statutory and regulatory definition of “prescriber.”⁵¹ To allow opticians to prevent the release of prescriptions as mandated by federal law, however, could thwart the accomplishment of Congress’s objectives in enacting that law.

The Supremacy Clause of the United States Constitution, Article VI, clause 2, preempts any state law that conflicts with the exercise of federal power.⁵² Conflict preemption occurs either “where it is impossible for a private party to comply with both state and federal law” or where state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”⁵³ Federal law preempts state law when a Congressional intent to preempt state law is expressed in the statutory language itself (express preemption) or when it is implied in the structure and purpose of federal law (implied preemption).⁵⁴ Federal regulations “have no less pre-emptive effect than federal statutes,”⁵⁵ and federal agencies implementing their Congressional mandates may expressly preempt state laws to achieve that purpose.⁵⁶

⁴⁸ The Proposed Rules state that an optician “retains discretion as to the release of the ancillary measurements and any administrative processes associated with their release.” Proposed Rules at 40.0210(1). Given that a contact lens prescription is required to contain a brand, eye curvature parameters, and power, the extent to which a consumer would require any “ancillary measurements” from an optician to fill a contact lens prescription from an alternative seller is unclear.

⁴⁹ See, e.g., Contact Lens Rule at § 315.11 (expressly preempting state and local laws that “restrict prescription release”) and House Report, *supra* note 39, at 5 (regarding administrative impediments to prescription portability, such as active verification requirements). In addition, it does not appear that the Board is authorized to make rules concerning the definition of “prescriptions” for eyeglasses or contact lenses. See N.C. Gen. Stat. § 90-249 (listing “areas of the business of opticianry in North Carolina” as to which the Board has the power to make rules, but not including “prescriptions” in the list).

⁵⁰ 15 U.S.C. § 7601(b)(1) and (b)(2).

⁵¹ The statute defines “prescriber” to “mean[], with respect to contact lens prescriptions, an ophthalmologist, optometrist, or other person permitted under State law to issue prescriptions for contact lenses in compliance with any applicable requirements established by the Food and Drug Administration.” 15 U.S.C. § 7610(2). N. C. GEN. STAT. § 90-235, which defines a “dispensing optician,” does not authorize an optician to issue prescriptions for eyeglasses or contact lenses.

⁵² *Fid. Fed. Sav. & Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 153 (1982).

⁵³ *Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363, 372-73 (2000). Other forms of preemption are express preemption and field preemption, e.g., *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 698-99 (1984).

⁵⁴ *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992).

⁵⁵ *Fid. Fed. Sav. & Loan Ass’n*, 458 U.S. at 153.

⁵⁶ *City of New York v. F.C.C.*, 486 U.S. 57, 63-64 (1988).

In implementing the FCLCA, the FTC adopted an express preemption provision:

- (a) State and local laws and regulations that establish a prescription expiration date of less than one year *or that restrict prescription release* or require active verification are preempted.⁵⁷

Thus, it appears that Section 40.0210 of the Proposed Rules would be expressly preempted by the Contact Lens Rule because it would “restrict prescription release.” Implied preemption concerns are also raised in that Section 40.0210 of the Proposed Rule would stand “as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress”⁵⁸ in seeking to “provid[e] consumers with a greater ability to fill their contact lens prescriptions from sellers other than their prescribing eye care practitioner (‘ECP’).”⁵⁹

There are similar conflicts between the Proposed Rules and the Eyeglass Rule, which also aims to protect consumer access to prescriptions and the portability of those prescriptions. For example, the Eyeglass Rule defines a “prescription” as “the written specifications for lenses for eyeglasses which are derived from an eye examination, including all of the information specified by state law, if any, necessary to obtain lenses for eyeglasses.”⁶⁰ In addition, the Eyeglass Rule requires the release of a prescription to the patient “immediately after the eye examination is completed”⁶¹ and prohibits the types of waivers addressed in the FCLCA and the Contact Lens Rule.⁶²

(1) Requirement for Only E-Businesses to Obtain Waivers from Customers

The Proposed Rules also contain certain provisions that apply only to “electronic optical businesses, including internet sites, whether located in- or out-of-state, as a condition of registration [with the Board of Opticians].”⁶³ Two of those provisions require e-businesses to comply with the following for either eyeglass or contact lens prescriptions:

[For eyeglasses] E-businesses shall, as part of the order process, inform the customer regarding the importance of fitting/final adjustment after receipt of prescription eyewear, and inform the customer as to the importance of their follow-up with an eyecare practitioner for the final adjustment. The order process shall require customer acknowledgement of the information, *and a statement that*

⁵⁷ 16 C.F.R. § 315.11(a) (*emphasis added*).

⁵⁸ See *supra* note 53.

⁵⁹ 2005 CONTACT LENS REPORT, *supra* note 15, at 1; see also House Report, *supra* note 39, at 5 (regarding consumers’ ability to shop for best price and importance of ability to obtain prescription and have it filled at choice of vendor).

⁶⁰ 16 C.F.R. § 456.1.

⁶¹ *Id.* at § 456.2.

⁶² *Id.*

⁶³ Proposed Rules at 40.0202(e).

*if the customer does not follow-up with an eyecare practitioner, no practitioner shall be held responsible for any damages or injury resulting from the customer's failure to follow-up.*⁶⁴

[For contact lenses] E-businesses shall, as part of a contact lens order process, comply with G.S. 90-236.1 by informing a customer of the requirement of follow-up with the prescribing physician after receipt of the lenses. The order process shall require customer acknowledgement of the information, *and a statement that if the customer does not follow-up with the prescribing physician, neither the prescribing physician nor the dispensing optician shall be held responsible for any damages or injury resulting from the customer's failure to follow-up* (emphasis added).⁶⁵

Both of these provisions in the Proposed Rule may conflict with federal law and regulations. The FCLCA and the Contact Lens Rule contain language prohibiting a prescriber from “deliver[ing] to the patient a form or notice waiving or disclaiming the liability or responsibility of the prescriber for the accuracy of the eye examination.”⁶⁶ To the extent that the waiver required by the Proposed Rule would be issued by an ophthalmologist, optometrist, or other prescriber and would disclaim damages or injury caused by the inaccuracy of an eye examination, there is a direct conflict between the language of the Proposed Rule and the FCLCA and the Contact Lens Rule.⁶⁷

Moreover, these provisions in the Proposed Rule appear to conflict with the FCLCA's apparent purpose to prevent prescribers from using a requirement for follow up after a prescription is filled, and a threat of liability waiver if the consumer does not follow up, to discourage consumers from filling prescriptions through diverse competing vendors.⁶⁸ For example, these provisions could require an e-business to send consumers a potentially false and misleading notice that, if they do not follow-up as suggested, “no practitioner” (for eyeglasses) and “neither the prescribing physician nor the dispensing optician” (for contact lenses) “shall be

⁶⁴ *Id.* at 40.0202(e)(1) (emphasis added).

⁶⁵ *Id.* at 40.0202(e)(2). The Proposed Rules state that this provision enables e-businesses to comply with N.C. GEN. STAT. § 90-236.1. That statute basically requires any person that dispenses contact lenses on the prescription of a legal prescriber to “at the time of delivery of the lenses, inform the recipient both orally and in writing that he return to the prescriber for the insertion of the lens, instruction on lens insertion and care, and to ascertain the accuracy and suitability of the prescribed lens. *The statement shall also state that if the recipient does not return to the prescriber after delivery of the lens for the purposes stated above, the prescriber shall not be responsible for any damages or injury resulting from the prescribed lens, except that this sentence does not apply if the dispenser and the prescriber are the same person.*” *Id.* (emphasis added).

⁶⁶ 15 U.S.C. § 7606; 16 C.F.R. § 315.8. For the same reasons, portions of N.C. GEN. STAT. § 90-236.1 may conflict with federal laws and regulations.

⁶⁷ Similarly, the Eyeglass Rule states it is an unfair act or practice under Section 5 of the FTC Act for an ophthalmologist or optometrist to “deliver to the patient a form or notice waiving or disclaiming the liability or responsibility of the ophthalmologist or optometrist for the accuracy of the eye examination or the accuracy of the ophthalmic goods and services dispensed by another seller.” 16 C.F.R. § 456.2(d). Again, the Proposed Rules' requirements for a waiver or notice to be sent to customers could directly conflict with the Eyeglass Rule.

⁶⁸ See House Report, *supra* note 39 (regarding impediments to comparison shopping for contact lenses).

held responsible for any damages or injury resulting from the customer’s failure to follow-up.”⁶⁹ This would not be true if the damages or injury resulted from the inaccuracy of an eye examination.

FTC staff recognizes that non-prescribing opticians, such as those in North Carolina, are not directly covered by the waiver provision of the FCLCA, which does not expressly prohibit opticians, in particular, from sending such notices to consumers.⁷⁰ However, Congress *did* expressly prohibit such waivers with regard to prescribers, and thus allowing opticians at e-businesses to provide notice of such waivers on behalf of the prescribers would conflict with clear Congressional intent. Thus, the provisions in the Proposed Rule regarding notifying consumers of potential waivers of liability may be impliedly preempted by the FCLCA and the Contact Lens Rule.

B. Portions of the Proposed Rules Appear Likely to Impose Unnecessary Costs on Internet and Other Out-of-State Sellers and, Ultimately, on North Carolina Consumers.

As discussed below, the Proposed Rule also contains provisions that appear likely to raise costs in particular for Internet and other out-of-state vendors of prescription eyewear. As such, they are likely to diminish price competition for optical goods in North Carolina, potentially raising prices and increasing inconvenience for North Carolina consumers who seek to fill or refill prescriptions for contact lenses or eyeglasses. Those consequences do not appear to be justified by countervailing consumer protection benefits.

(1) Requirements that Apply Only to E-Businesses

As noted above, the requirement for customer notices concerning prescriber follow-up and waivers of liability apply *only* to “[e]lectronic optical businesses, including internet sites, whether located in- or out-of-state”⁷¹ The reason this requirement is restricted solely to e-businesses is unclear. The provision will likely have a chilling effect on consumers’ use of e-businesses, limiting the ability of e-businesses to compete with “brick-and-mortar” establishments and leading consumers to pay higher prices for replacement contact lenses and similar products.

There is no apparent consumer health or safety rationale for the Proposed Rules’ waiver requirements. Indeed, at least for replacement contact lenses, as explained in Section I above, there is typically no need for the customer to follow-up with the prescribing physician after receipt of the lenses from an e-business.⁷² Thus, the Proposed Rule’s mandate that an e-business

⁶⁹ Proposed Rules at 40.0202(e)(1), (e)(2).

⁷⁰ See note 51, *supra*.

⁷¹ Proposed Rules at 40.0202(e).

⁷² This does not, of course, diminish the potential utility of periodic or – if needed – emergency eye care from an ophthalmologist or optometrist. Rather, follow-up with regard to the filling of the completed prescription is not required by law and is not medically required for the consumer to safely use replacement lenses, as prescribed by

inform the customer “of the *requirement* of follow-up” appears inaccurate and likely to impose unnecessary costs on consumers who are obtaining only replacement contact lenses.

Moreover, the scope of the proposed requirement – including the recordkeeping implications – is unclear and appears overbroad. The Proposed Rules would require e-businesses, “as a condition of registration, [to] permit the Board complete access to site transmission/transaction files.”⁷³ Presumably, the Board does not intend to inspect *all* records pertaining to *all* transactions conducted by out-of-state Internet businesses that do *any* business with North Carolina residents, but the literal language would require extremely broad access to all such records. Given the proposed regulatory language, out-of-state e-businesses may be justifiably concerned about the potential scope of this provision, as it may exceed federal record-keeping requirements⁷⁴ and may implicate sensitive personal and business information protected under a variety of federal and state laws.⁷⁵ Additionally, because compliance with this provision would be “a condition of registration with the Board,” Internet sellers could be subject to “a restraining order and injunction” for failure to comply.⁷⁶

(2) Requirements that Apply to Out-of-State Vendors, including Internet Vendors.

Certain provisions in the Proposed Rules could be interpreted to require all out-of-state vendors to employ, as an “optician in charge,” an optician licensed in the state of North Carolina. The Proposed Rules also would require the employment of licensed opticians by vendors that do not currently employ opticians, because they sell only replacement lenses and therefore do not provide the fitting services offered by opticians.

The Board’s current rules state:

Every optical place of business shall be registered with the Board within 10 days following its opening for business and thereafter annually and in the event of relocation, change of ownership or change of licensed optician in charge. The registration fee shall be paid for each registration.⁷⁷

their eye doctors. *See, e.g.*, 2004 CONTACT LENS REPORT, *supra* note 20, at 8-9 (citing the FDA and testimony from the American Optometric Ass’n.).

⁷³ Proposed Rules at 40.0202 (e).

⁷⁴ *See, e.g.*, 15 U.S.C. § 7603(b) (Record Requirement); 16 C.F.R. 315.1(f)-(g) (record keeping requirements).

⁷⁵ Numerous federal and state laws protect the privacy of consumer financial and health information. Because the staff is unsure of the intended scope of the Proposed Rules’ access provisions, we have not attempted to analyze concerns that might be raised under, e.g., the FTC Act, the Health Insurance Portability and Accountability Act (HIPAA), Public Law 104-191, or the Gramm-Leach-Bliley Act (Pub. L. 106-102, 113 Stat.1338, codified in relevant part at 15 U.S.C. §§ 6801-6809 and §§ 6821-6827, as amended).

⁷⁶ Under the Proposed Rules, “[i]f an optical place of business violates the registrations requirements, or is unregistered, the Board may seek a restraining order and injunction, as provided by G.S. 90-254.” *Id.* at 40.0202(g). Section 90-254 permits the Board “to apply to the superior court for a restraining order and injunction to restrain the violation” of a Board rule or regulation promulgated under Article 17, “Dispensing Opticians.”

⁷⁷ Proposed Rules at 40.0202(c). The Proposed Rules would change “the registration fee” to “a registration fee,” and move this provision to 21 N.C. ADMIN. CODE 40.0202(a). N.C. GEN. STAT. § 90-246 authorizes the Board to

In addition, the Board’s current rules provide that “[e]very optical place of business shall have a *licensed optician in charge*, who shall serve as the licensee in charge of *only one optical place of business* (emphasis added).”⁷⁸ The current rules state an “optical place of business” means the principal office as well as each branch office of such business.”⁷⁹

It appears that optical places of business may have assumed these rules applied only to brick-and-mortar establishments located in North Carolina, because the Board now seeks to define “optical place of business” to include “[a]ny out-of-state place of business that prepares, manufactures, dispenses, or sells eyeglasses or contact lenses to a citizen of North Carolina.”⁸⁰

This proposed change raises a number of concerns. As an initial matter, it is unclear how the Board proposes to require that out-of-state Internet and other vendors register annually and re-register “in the event of relocation, change of ownership or change of licensed optician in charge.”⁸¹ This requirement could impose unnecessary costs on Internet vendors that do not employ opticians because they do not provide fitting services. Indeed, it is unclear why such vendors should be required to register with the Board of Opticians in any case, much less to employ a licensed optician. Unnecessary costs for out-of-state vendors that do not need to employ any opticians would likely be passed along to North Carolina and other consumers as higher prices.

Moreover, it is unclear what the Board intends by requiring “a licensed optician in charge . . .” of out-of-state vendors, including Internet sellers. It appears that the Board might interpret the Proposed Rule to require all vendors of prescription eyewear to North Carolina residents to “have a [*North Carolina-*] registered licensed optician in charge”⁸² This would likely raise costs to out-of-state vendors of prescriptive eyewear to North Carolina residents. Out-of-state vendors may be located throughout the United States, may not have easy access to a North Carolina registered licensed optician, and presumably operate subject to the optician-related laws and regulations of the state in which they operate. Any requirement to hire an optician registered and licensed by North Carolina would add to that business’s expenses the fees and other costs associated with licensure, continuing education, and registration of an optician in North

charge \$50.00 for “each registration of an optical place of business.” That statute specifies that the Board is authorized to charge and collect the fees listed in the legislation to support the Board’s work in administering and enforcing its rules and performing other duties.

⁷⁸ Proposed Rules at 40.0202(c). The Proposed Rules would add the requirement that the licensed optician also be “registered.” The Proposed Rules lack any explanation of a “registration” process for opticians, however, so it is unclear what requirements the Board wishes to impose in addition to the licensing requirements contained in the Board’s existing and Proposed Rules.

⁷⁹ Proposed Rules at 40.0202(b)

⁸⁰ Proposed Rules at 40.0202(b)(3). The Proposed Rules also would define “optical place of business” to include “(2) [a]ny business registered with the N.C. Secretary of State, or any business paying fees or taxes to the N.C. Department of Revenue for the preparation, manufacture, dispensing, or sale of eyeglasses or contact lenses in North Carolina” *Id.* at 40.0202(b)(2). As a practical matter, these definitions appear largely overlapping.

⁸¹ Proposed Rules at 40.0202(a).

⁸² *Id.* at 40.0202(c).

Carolina,⁸³ in addition to the costs imposed by licensure, continuing education, and registration requirements for opticians in the state in which the vendor operates.⁸⁴

The concerns raised by these specific proposals are similar to the concerns raised by other licensing restrictions. As a general matter, restricting the entry of competing professionals limits the supply or services, which can increase the income of incumbents (at consumer expense) or decrease the pressure on incumbents to improve non-price aspects of their services, such as quality or convenience.⁸⁵ Such restrictions – among others – have had substantial price effects in the eye-care industry more generally.⁸⁶ Studies of other health care professions have indicated substantial licensing costs as well.⁸⁷ In any case, there appears to be no reason to require out-of-state vendors to hire North Carolina-licensed opticians, because the practice of opticianry does not vary widely from state to state.⁸⁸

⁸³ See Proposed Rules at 40.0104, 40.0206, 40.0302, 40.0303, 40.0320, and 40.0323 (discussing fees). In addition to the required fees, costs would be imposed by, for example, the costs of the application process itself – see, e.g., *id.* at 40.0301-40.0303, 40.0319 (requiring out-of-state applicants to obtain and submit affidavits from prior employers for the four preceding years, two licensed eye doctors, and others) – and both direct costs and opportunity costs associated with internship requirements – *id.* at 40.0319 – and continuing education – *id.* at 40.0206.

⁸⁴ It is worth noting that out-of-state vendors may struggle to meet this requirement. One can imagine that an out-of-state vendor might ask an optician licensed by another state to become registered and licensed in North Carolina as well. N.C. GEN. STAT. § 90.241(a) states the Board “shall grant a license without examination to any applicant” who, among other things, “[h]olds a license in good standing as a dispensing optician in another state.” The Board’s rules governing applicants from other states, however, require that applications submitted under N.C. GEN. STAT. § 90.241(a) must be received in the Board’s office “not more than 90 days following the termination of the applicant’s out-of-state opticianry work for which the applicant claims credit (emphasis added).” Proposed Rules at 40.0319(e) and 40.0319(d). To the extent the Board assumes that an optician licensed by another state must surrender his or her out-of-state optician’s license simply to apply for a North Carolina license, this provision could make it impracticable – if not impossible – for out-of-state vendors to comply with the Board’s rules. Thus interpreted, the provision would strongly discourage out-of-state opticians from applying for North Carolina licensure.

⁸⁵ See generally CAROLYN COX & SUSAN FOSTER, FED. TR. COMM’N, BUREAU OF ECONOMICS, THE COSTS AND BENEFITS OF OCCUPATIONAL REGULATION (1990), available at <http://www.ftc.gov/be/consumerbehavior/docs/reports/CoxFoster90.pdf>; see also George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGT. SCI. 3, 13-14 (1971); Morris M. Kleiner, *Occupational Licensing*, 14 J. ECON. PERSPECTIVES 189, 192 (2000) (“The most generally held view on the economics of occupational licensing is that it restricts the supply of labor to the occupation and thereby drives up the price of labor as well as of services rendered.”); cf. MILTON FRIEDMAN & SIMON KUZNETS, INCOME FROM INDEPENDENT PROFESSIONAL PRACTICE, National Bureau of Economic Research (1954) (early study of income effects of restrictions on professional entry in five professions, including medicine).

⁸⁶ Although the staff have no precise accounting of the total potential costs of these proposed provisions in the Proposed Rules, we note that studies of the eye care market report price increases from 5 percent to 33 percent that are attributable to a variety of regulations, although not necessarily optician regulations. COX & FOSTER, *supra* note 85, at 31. *But cf.* Philip Parker, “Sweet Lemons:” *Illusory Quality, Self-Deceivers, Advertising, and Price*, 32 J. Mktg. Research 291 (suggesting that the results of some early studies of the costs of advertising regulations in the eye care market may be sensitive to alternative model specifications).

⁸⁷ Studies of licensing costs in dentistry, perhaps the most analyzed of the professions, find price increases of from 4 percent to 15 percent. Cox & Foster at 31; Morris M. Kleiner & Robert T. Kudrle, *Does Regulation Affect Economic Outcomes? The Case of Dentistry*, 43 J.L. & ECON. 547 (2000).

⁸⁸ The North Carolina legislature has implicitly recognized this by requiring the Board to grant a license *without examination* to a dispensing licensed optician in good standing in another state who meets other requirements. N.C. GEN. STAT. § 90-241(3). And, as noted above, to the extent that out-of-state Internet vendors do not provide fitting services at all, there appears to be no consumer need that the vendors employ an optician licensed by any state.

In addition, it is unclear how the Board plans to apply to out-of-state businesses, including Internet sellers, the requirement that an optician must be “in charge” of the optical place of business or that the optician “shall serve as licensee in charge of *only one optical place of business* (emphasis added).”⁸⁹ These requirements may be enforceable if applied to brick-and-mortar establishments located in North Carolina. How they would be applied to out-of-state businesses is uncertain, and such uncertainty itself may increase costs to out-of-state vendors.

Finally, under the Proposed Rule a provider may be subject to a charge of “gross negligence” for “[d]ispensing contact lenses on or before the [prescription] expiration date in an amount more than the sufficient quantity of replacement contact lenses needed through the prescription's expiration date.”⁹⁰ As noted by the Commission in adopting the Contact Lens Rule, the quantity of lenses ordered “may be a legitimate basis for a prescriber to treat a request for verification of a prescription as ‘inaccurate.’”⁹¹ Unless verification attempts indicate such an inaccuracy, however, it is unclear how a vendor could determine that some particular quantity of lenses is excessive. Again, the uncertainty created by this provision may itself increase costs to out-of-state vendors.

(3) The Potential Harm to North Carolina Consumers.

The provisions of the Proposed Rule would likely increase costs for out-of-state and Internet vendors. Increased costs could, in turn, lead to an increase in the prices consumers face for prescription eyewear. Out-of-state vendors faced with higher costs may exit the North Carolina market or decline to enter it, leading to higher prices by, for example, limiting the availability of lower cost suppliers to consumers⁹² and reducing the convenience with which consumers can fulfill their optical goods requirements. As noted above, FTC research indicates that the most popular types of contact lenses tend to be least expensive at wholesale clubs and pure online sellers, more expensive at optical chains, and most expensive when purchased from independent ECPs.⁹³ Fewer out-of-state vendors participating in North Carolina markets may lead to even higher prices charged by those businesses that remain – both brick-and-mortar and Internet businesses – due to reduced price competition. Those consumers who lack ready access to lenses sold by wholesale clubs may face the greatest price increases. Reduced competition from out-of-state vendors may also decrease the pressure on incumbents to improve non-price aspects of their services, such as quality or convenience.⁹⁴

⁸⁹ Proposed Rules at 40.0202(c).

⁹⁰ *Id.* at 40.0213.

⁹¹ See Contact Lens Rule, *supra* note 18, at 69 Fed. Reg. 40488.

⁹² See *id.*

⁹³ See *supra* note 35, and accompanying text. A description of the study is found in Chapter 3 of the 2005 CONTACT LENS REPORT, *supra* note 15, at 36-44.

⁹⁴ See generally COX & FOSTER, *supra* note 85; Stigler, *The Theory of Economic Regulation*, *supra* note 85; Kleiner, *Occupational Licensing*, *supra* note 85.

The costs of additional licensing and registration restrictions for out-of-state and Internet vendors do not appear to be justified by countervailing consumer protection benefits. Although patient safety or consumer protection concerns can justify licensure requirements and scope of practice restrictions,⁹⁵ existing federal and state regulatory requirements already address the primary health and safety concerns at issue and, if enforced, ensure that appropriate safeguards will be maintained to protect consumers' health and safety when purchasing replacement contact lenses online.⁹⁶

Indeed, any safety or health issue with respect to sales of replacement lenses appears highly unlikely. Typically, online sellers of replacement lenses simply provide customers with contact lenses that come from the manufacturer in sealed boxes labeled with the relevant specifications.⁹⁷ Concerns about quality of care related to follow-up examinations can be addressed by enforcing contact lens prescription requirements, rather than by inhibiting sales by online providers.⁹⁸ North Carolina state law does not allow opticians to examine eyes or treat eye problems, so forcing consumers to purchase replacement lenses from a licensed optician does not advance the health goal of more frequent eye exams.

Requiring customers to return to an eye care professional – virtually or in-person – to purchase replacement lenses does not reduce the individual's incentive or ability to wear lenses for too long. Indeed, excessive licensing regulations may actually harm consumer health. As noted above, consumers risk eye infections and other health problems if they fail to remove and replace contact lenses according to their doctors' recommendations.⁹⁹ Increasing the cost and inconvenience of obtaining disposable or other replacement lenses may induce more consumers to over-wear their replacement lenses. Imposing such licensing costs on stand-alone sellers of replacement lenses thus has the potential to increase health risks for consumers by raising the price or inconvenience of purchasing replacement lenses.

III. Conclusion

FTC staff suggests that the Board seriously consider whether there are benefits to consumers from the Proposed Rule's additional, more restrictive regulations that would outweigh the additional consumer costs identified herein. So far, no health or safety rationale, or documentation of consumer harms, has been advanced to justify the extra requirements and costs of the Proposed Rule. In addition, FTC staff urges the Board to consider carefully the apparent conflicts between certain provisions in the Proposed Rule and the FCLCA, the Contact Lens Rule, and the Eyeglass Rule.

⁹⁵ In competition terms, licensure requirements or scope of practice restrictions may sometimes offer an efficient response to certain types of market failure that can occur in professional services markets. *See* COX & FOSTER, *supra* note 85, at 5-6.

⁹⁶ *See supra* notes 31 - 32, and accompanying text; *see also* 2004 CONTACT LENS REPORT, *supra* note 20, at Section IVc.

⁹⁷ 2004 CONTACT LENS REPORT, *supra* note 20, at 4-6.

⁹⁸ *See id.* at 4-6, 22-23.

⁹⁹ *See supra* text accompanying notes 27 - 30.

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