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 Competition[1] submit these comments to the North Carolina Board of Opticians ("Board") regarding proposed changes to the Board's rules governing the dispensing of prescription eyewear.[2] The Board's proposed rules would affect the ability of consumers to obtain prescription eyewear from vendors other than their prescribing eye doctor. Accordingly, we urge the Board to consider the potential impact of the proposed rules on competition and 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 for 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, F
staff urges the Board to consider carefully th

The FTC’s 2005 Report provides a useful summ

lenses, raise consumer costs, and harm public

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

Moreover, to the extent that the Proposed Rule appears to grant opticians the authority to refuse to release ancillary measurements that would not delete 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 for 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]

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[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 10.0210(1). Given that a contact lens prescription is required to contain 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 "prescription" 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).

> 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]
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> **[For contact lenses]** E-businesses shall, as part of the 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 waiver 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 eyecare practitioner 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

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[64] Id. at 40.0202(e)(1)(emphasis added)

[65] Id. at 40.0202(e)(2). The Proposed Rule 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 under 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

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 nonprescribing 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 prescriber 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] 02

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 records pertaining to all transactions conducted by out-of-state Internet businesses that do 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 requirements[74] 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)

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 only of 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 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 sales. 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, and 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

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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 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).

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 an appropriate 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 consumers[92] 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]

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[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 2004 FTC 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 individuals' 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 FCLC, the Contact Lens Rule, and the Eyeglass Rule.

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[95] In competition terms, licensure requirements or scope of practice restrictions may sometimes offer an efficient response to certain types of market failure that 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.

Respectfully submitted,

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