

**Supporting Statement for Information Collection Provisions of
the Contact Lens Rule, 16 CFR Part 315**
(OMB Control # 3084-0127)

(1) & (2) Necessity for and Use of the Information Collected

The Fairness to Contact Lens Consumers Act (the “Act”), Pub. L. No. 108-164 (December 6, 2003), helps consumers by requiring the release and verification of contact lens prescriptions, among other things. The Act directed the Federal Trade Commission (“FTC” or “Commission”) to prescribe rules implementing the Act not later than 180 days after the Act took effect on February 4, 2004.¹ Accordingly, the Commission issued the final Contact Lens Rule (“Rule”), 16 C.F.R. Part 315, on July 2, 2004. As mandated by the Act, the Rule contains disclosure and recordkeeping requirements applying to prescribers and sellers of contact lenses. The extent to which these requirements are subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35 (“PRA”), is described below.

(a) Disclosures

The Rule requires that contact lens prescribers provide patients with a copy of their contact lens prescriptions upon completion of a contact lens fitting and provide prescriptions to, or verify prescriptions with, third parties authorized to act on behalf of patients. The primary purpose of the prescription release requirement is to enable consumers to purchase their contact lenses from the seller of their choice. Without their prescription, consumers may be forced to purchase lenses from their prescriber. By requiring prescribers to provide prescriptions to their patients, the Act enables consumers to compare prices and modes of delivery among competing sellers, and ultimately purchase their lenses from the seller of their choice.

(b) Recordkeeping

The Rule also implements recordkeeping requirements imposed by the Act. First, the Act sets a minimum expiration date of one year for contact lens prescriptions, with an exception based on the medical judgment of a prescriber with respect to a patient’s eye health. In cases in which a prescriber sets an expiration date shorter than one year, the Rule requires the prescriber to document in the patient’s record the medical reasons for the shorter period. The Rule further requires that such records be kept for three years.

Second, the Act provides that a contact lens seller may sell contact lenses only in accordance with a prescription that the seller either (a) has received from the patient or prescriber, or (b) has verified with the prescriber. The Act, and hence the Rule, requires contact lens sellers to maintain records of verification communications with prescribers. The records to be kept depend on the mode of communication – telephone, facsimile, or email. The Rule also requires sellers to keep the prescriptions they receive directly from the patient or

¹ 15 U.S.C. § 7607.

prescriber. The Rule requires that sellers keep these records for three years and make them available for inspection by the Commission, but does not otherwise require production of the records.

The required records will be used by the Commission to determine compliance with the Rule and may also provide a basis for the Commission to bring an enforcement action. Without the required records, it would be difficult to ensure that entities are complying with the Rule's requirements or to bring enforcement actions for Rule violations.

(3) Consideration of the Use of Information Technology to Reduce Burden

The Rule contemplates that covered entities may use information technologies in complying with their recordkeeping obligations under the Act. Such technologies may help reduce the burden of information collection imposed by the Act. For example, contact lens sellers who seek verification of prescriptions via facsimile and/or email, may use information technology to create and/or retain those records as required by the Rule, and thereby reduce the time it may take to produce and maintain verification requests. In addition, nothing in the Act or Rule prohibits regulated entities from using the least burdensome information technology to reduce compliance burdens. Moreover, in its Notice of Rulemaking,² the Commission specifically sought comments on ways to minimize the burden of the Rule's collections of information through the use of information technology.

Consistent with the Government Paperwork Reduction Elimination Act, Pub L. No. 105-227, Title XVII, 112 Stat. 2681-749, nothing in the Rule prescribes that the disclosures be made, records be filed or kept, or signatures be executed, on paper or in any particular format that would preclude the use of electronic methods to comply with the Rule's requirements.

(4) Efforts to Identify Duplication

The Rule's disclosure and recordkeeping requirements do not duplicate any other information collection requirements imposed by the Commission. To the extent some state laws may already require prescription release, and/or recordkeeping, similar to that required by the Act, prescribers and sellers likely can comply with both requirements through a single release or record-keeping system, thereby avoiding duplication.

(5) Efforts to Minimize Burden on Small Organizations

The Rule's disclosure and recordkeeping requirements are designed to impose the minimum burden on all affected members of the industry, regardless of size. The Act itself does not allow the Commission any latitude to treat small businesses differently, such as by exempting a particular category of firm or setting forth a lesser standard of compliance for any category of firm.

² 69 Fed. Reg. 5,440 (February 4, 2004).

However, staff believes that the burdens imposed by the Rule on small businesses will be relatively low. Based on staff's knowledge of the eyewear industry, the small businesses affected by the Rule primarily will consist of contact lens prescribers in solo or small practices. Their burdens under the Rule primarily entail providing contact lens prescriptions to patients or their agents, documenting in exceptional cases the medical reasons for setting a contact lens prescription date of less than one year, and verifying prescriptions for some of their patients who seek to purchase their contact lenses from another seller. The Rule permits some limitation on prescription release and verification. For example, the Rule does not require prescribers to provide additional copies of prescriptions to patients after the initial release upon completion of a contact lens fitting, although the Rule does not prohibit this practice.

(6) Consequences of Conducting the Collection Less Frequently

Less frequent "collection" would violate the express statutory language of the Fairness to Contact Lens Consumers Act, 15 U.S.C. §§ 7601 *et seq.* Specifically, the Act's requirements that prescribers release contact lens prescriptions to their patients upon completion of a contact lens fitting, and document the medical reasons for setting a contact lens prescription expiration date shorter than one year, do not permit less frequent disclosure.³ Similarly, the Act's requirement that contact lens sellers retain records of all direct communications involved in obtaining prescription verification does not permit less frequent collection of information.⁴

The Commission's Rule requires that sellers retain the required records for a period of three years. Staff believes that a record retention period that is shorter than three years would hamper the Commission's ability to verify contact lens prescribers' and sellers' compliance with the Rule, because the statute of limitations applicable to Commission rule violations is three years.⁵

(7) Circumstances Requiring Collection Inconsistent With Guidelines

The collection of information in the Rule is consistent with all applicable guidelines contained in 5 C.F.R. § 1320.5(d)(2).

(8) Public Comments/Consultation Outside the Agency

On February 8, 2013, the FTC sought public comment on the Rule's information collection requirements and on the associated estimates of PRA burden. 78 Fed. Reg. 9,391. The American Optometric Association ("AOA") submitted a comment on April 9, 2013. That comment stated that the majority of the information collected by the FTC is accurate; however, it provided alternate figures for some data, expressed disfavor of passive verification, and sought more effective enforcement of the Rule. Data provided by the AOA are addressed further in our response to Specification 12 (Estimated Annual Hours and Labor Cost Burden) below.

³ See 15 U.S.C. §§ 7601, 7604.

⁴ See 15 U.S.C. § 7603(b).

⁵ See Section 19(d) of the FTC Act, 15 U.S.C. 57b(d).

Pursuant to the OMB regulations that implement the PRA (5 C.F.R. Part 1320), the FTC is providing a second opportunity for public comment while seeking OMB approval to extend the existing paperwork clearance for the Rule.

(9) Payments and Gifts to Respondents

Not applicable.

(10) Assurances of Confidentiality

Not applicable. No assurance of confidentiality is necessary because although the Contact Lens Rule requires regulated entities to disclose and/or maintain records, it does not require the submission of any such records to the agency. Thus, to the extent, if any, that the agency may require production of such records for law enforcement purposes in specific proceedings, such production would not constitute an information collection activity within the meaning of the Paperwork Reduction Act. In any event, in such proceedings, records would be protected by law from mandatory public disclosure.⁶

(11) Matters of a Sensitive Nature

Not applicable. The Contact Lens Rule does not require the disclosure or production of sensitive or confidential information to the Commission. To the extent that confidential information covered by a recordkeeping requirement is collected by the Commission for law enforcement purposes, the confidentiality provisions of Section 21 of the FTC Act, 15 U.S.C. 57b-2, will apply.

(12) Estimated Annual Hours and Labor Cost Burden

Estimated total annual hours burden: 1,594,981 hours.

This figure is derived by adding 685,514 hours for contact lens prescribers to 909,467 hours for contact lens sellers, for a combined industry total of 1,594,981 hours. This is higher than the estimates submitted to OMB in 2009 (the similar figure was 850,000 hours in 2009). The higher estimate is due to (1) an increase in the estimated number of contact lens wearers from 34 million (2008) to 38 million (2012); (2) staff's belief that the percentage of sales in the industry that require obtaining or verifying a prescription is currently higher than what was previously estimated; and (3) the addition of time for hours that prescribers' offices spend responding to verification requests.

1. Prescribers

⁶ See, e.g., Section 21 of the FTC Act, 15 U.S.C. 57b-2; Exemption 6 of the Freedom of Information Act, 5 U.S.C. 552(b)(6).

The Rule requires prescribers to make disclosures in two ways. Upon completing a contact lens fitting, the Rule requires that prescribers (1) provide a copy of the contact lens prescription to the patient, and (2) as directed by any person designated to act on behalf of the patient, provide or verify the contact lens prescription.

As noted above, the number of contact lens wearers in the United States is estimated to be approximately 38 million.⁷ Therefore, assuming an annual contact lens exam for each contact lens wearer, approximately 38 million people would receive a copy of their prescription each year under the Rule. AOA suggests that the number of wearers is closer to 40 million, but it was unable to identify a source for this number. AOA also commented that the actual exam cycle is closer to 18 months. However, because most prescriptions are valid a minimum of one year under the Rule, and use of the commenter's exam cycle would lead to an estimate of a lower number of exams, we continue to estimate that patients seek exams annually.

At an estimated one minute per prescription, the annual time spent by prescribers complying with the requirement to release prescriptions to patients would be approximately 633,333 hours. [(38 million × 1 minute)/60 minutes = 633,333.33 hours.] The AOA comments that prescribers spend three to five minutes providing a prescription to a patient. However, we believe that this estimate does not take into account that the OMB regulation implementing the PRA defines "burden" to exclude any effort that would be expended regardless of a regulatory requirement.⁸ In most instances the doctor is only copying a prescription that is already in the patient's file, thus we continue to use our estimate of one minute.

As stated above, prescribers may also be required to provide or verify contact lens prescriptions to sellers. According to recent survey data, approximately 40% of contact lens purchases are from a source other than the prescriber.⁹ Assuming that each of the 38 million contact lens wearers in the U.S. makes one purchase per year, this means that about 13,642,000 contact lens purchases (38 million x 35.9%) are made from sellers other than the prescriber.

Recent data from industry indicate that approximately 75% of sales to non-prescriber sellers require verification and that prescribers correct or decline the prescription received for approximately 5.1% of those verification requests. Additionally, some prescribers may voluntarily confirm prescriptions. Because correcting or declining incorrect prescriptions is mandated by the Rule and occurs in response to only 5.1% of requests, staff assumes that

⁷ See Jason J. Nichols, Annual Report: Contact Lenses 2012, Contact Lens Spectrum, Jan. 2013, at 24.

⁸ 5 CFR 1320.3(b)(2).

⁹ See VisionWatch, The Vision Council, Contact Lenses, 11A–C (March 2012) (Research Report); VisionWatch, The Vision Council, Contact Lenses, 11A–C (Sept. 2012) (Research Report). The average of the figures given for each six-month period is 35.9%. The AOA's comment indicated that only 33% of consumers get their contact lenses from a third party, as opposed to 35.9%. However, we continue to use 35.9%, a similar but slightly higher figure, in our estimate to ensure that we are not underestimating the burden.

prescribers voluntarily confirm prescriptions less often and confirm no more than an additional 5.1% of prescriptions. Using a combined response rate of 10.2%, the FTC estimates that prescribers' offices respond to approximately 1,043,613 requests annually. [(13,642,000 x 75%) x 10.2% = 1,043,613 responses]

The AOA comments that responding to verification requests requires three minutes per request. Using that data, we estimate that these responses require an additional 52,181 hours annually. [(1,043,613 × 3 minutes)/60 minutes = 52,181 hours.]

Combining these hours with the hours spent disclosing prescriptions to consumers, we estimate a total of 685,513.98 disclosure hours for contact lens prescribers. [633,333 + 52,181 = 685,514 hours.]

Lastly, as required by the FCLCA, the Rule also imposes a recordkeeping requirement on prescribers. They must document the specific medical reasons for setting a contact lens prescription expiration date shorter than the one-year minimum established by the FCLCA. This burden is likely to be nil because the requirement applies only in cases when the prescriber invokes the medical judgment exception, which is expected to occur infrequently, and prescribers are likely to record this information in the ordinary course of business as part of their patients' medical records. As mentioned previously, the OMB regulation that implements the PRA defines "burden" to exclude any effort that would be expended regardless of a regulatory requirement.¹⁰

2. Sellers

As noted above, a seller may sell contact lenses only in accordance with a prescription that the seller (a) has received from the patient or prescriber, or (b) has verified through direct communication with the prescriber. The FCLCA also requires sellers to retain prescriptions and records of communications with prescribers relating to prescription verification for three years.

Staff believes that the burden of complying with these requirements is low. As stated previously, there are approximately 13,642,000 sales by non-prescriber sellers annually and approximately 75% of those sales require verification. Therefore, sellers verify approximately 10,231,500 orders annually and retain two records for such sales: the verification request and any response from the prescriber. Staff estimates that sellers' verification and recordkeeping for those orders will entail a maximum of five minutes per sale. At an estimated five minutes per sale to each of the approximately 10,231,500 orders, contact lens sellers will spend a total of 852,625 burden hours complying with this portion of the requirement. [(10,231,500 orders × 5 minutes)/60 minutes = 852,625 hours.]

This means that approximately 25% of the remaining sales to non-prescriber sellers do not require verification and require the seller to keep only the prescription provided. Staff estimates that this recordkeeping burden requires at most one minute per order for 3,410,500

¹⁰ 5 CFR 1320.3(b)(2).

orders, resulting in 56,842 burden hours. $[(3,410,500 \text{ orders} \times 1 \text{ minute})/60 \text{ minutes} = 56,842 \text{ hours.}]$

Combining burden hours for all orders, staff estimates a total of 909,467 hours for contact lens sellers. This estimate likely overstates the actual burden because it includes the time spent by sellers who already keep records pertaining to contact lens sales in the ordinary course of business. In addition, the estimate may overstate the time spent by sellers to the extent that records (e.g., verification requests) are generated and stored automatically and electronically, which staff understands is the case for some online sellers.

Estimated total labor cost burden: \$48,991,000 (rounded to the nearest thousand).

Commission staff derived labor costs by applying appropriate hourly cost figures to the burden hours described above. Based on information from the industry, staff estimates that optometrists account for approximately 85% of prescribers. Consequently, for simplicity, staff will focus on their average hourly wage in estimating prescribers' labor cost burden.

According to Bureau of Labor Statistics from May 2012, salaried optometrists earn an average wage of \$52.80 per hour and general office clerks earn an average wage of \$14.07 per hour.¹¹

Assuming that optometrists are performing the brunt of the labor for prescribers and office clerks are performing the labor for non-prescriber sellers, estimated total labor cost attributable to the Rule would be approximately \$49 million. $[(\$52.80 \times 685,514 \text{ hours}) + (\$14.07 \times 909,467 \text{ hours}) = \$48,991,340.]$

The contact lens market is a multibillion dollar market. One recent survey estimates that contact lens sales in the U.S. totaled \$4,025,500,000 at the retail level between September 2011 and September 2012.¹² The total labor cost burden estimate of \$48,991,340 represents approximately 1.22% of the overall retail market.

(13) Capital and Other Non-Labor Costs

Estimated annual non-labor cost burden: \$0 or minimal.

¹¹ We have updated these figures since our 60-Day notice, using 2012 data that became available in March 2013. Press Release, Bureau of Labor Statistics, United States Department of Labor, Occupational Employment and Wages - May 2012, Table 1 (Mar. 29, 2013), *available at* <http://www.bls.gov/news.release/ocwage.htm>.

¹² The Vision Council, Consumer Barometer, 2 (Sept. 2012) (Research Report). The market may, in fact, be larger; this number does not include dollars spent by consumers 17 years of age and younger. AOA's comment provided smaller numbers for the size of the contact lens market. However, the numbers provided by the AOA appear to be at the manufacturing level, and do not appear to be as recent as the number relied on by the FTC.

Staff believes that the Rule's disclosure and recordkeeping requirements impose negligible capital or other non-labor costs, as the affected entities are likely to have the necessary supplies and/or equipment already (*e.g.*, prescription pads, patients' medical charts, facsimile machines and paper, telephones, and recordkeeping facilities such as filing cabinets or other storage).

(14) Estimated Cost to the Federal Government

Staff estimates that the fiscal year cost to the FTC of enforcing the Rule's requirements will be approximately \$52,000 per year. This estimate is based on the assumption that 15-20% of one Attorney work year, 2.5% of one Economist work year, 15% of one Investigator work year, and 15% of one Paralegal work year will be expended to enforce the Rule's requirements.

(15) Program Changes or Adjustments

There are no program changes since the FTC's prior clearance renewal in 2010. The increased estimates for burden hours and labor costs from that prior clearance request are due to an increase in the estimated number of contact lens wearers, staff's belief that the percentage of sales in the industry that requires obtaining or verifying a prescription is currently higher than what was previously estimated, and the inclusion into the estimate of time that prescribers' offices expend responding to verification requests from other sellers.

(16) Statistical Use of Information/Publication of Results

Not applicable. There are no plans to publish for statistical use any information required by the Rule.

(17) Requested Permission Not to Display the Expiration Date for OMB Approval

This is not applicable, since the Commission will display the expiration date of the clearance.

(18) Exceptions to the "Certification for Paperwork Reduction Act Submissions"

Not applicable.