



BILLING CODE: 6750-01-S

**FEDERAL TRADE COMMISSION
Agency Information Collection Activities;
Proposed Collection; Comment Request**

AGENCY: Federal Trade Commission (FTC or Commission).

ACTION: Notice.

SUMMARY: The FTC plans to ask the Office of Management and Budget (OMB) to extend for an additional three years the current Paperwork Reduction Act (PRA) clearance for information collection requirements contained in the Contact Lens Rule (or Rule). The current clearance expires on October 31, 2019.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Request for Comments part of the SUPPLEMENTARY INFORMATION section below. Write "Paperwork Reduction Act: FTC File No. P072108" on your comment, and file your comment online at <https://www.regulations.gov> by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Paul Spelman, Attorney, Division of Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Mail Drop CC-10528, Washington, DC 20580, at (202) 326-2487.

SUPPLEMENTARY INFORMATION: The Rule was promulgated by the FTC pursuant to

the Fairness to Contact Lens Consumers Act (FCLCA), Pub. L. 108-164 (Dec. 6, 2003), which was enacted to enable consumers to purchase contact lenses from the seller of their choice. The Rule became effective on August 2, 2004. As mandated by the FCLCA, the Rule requires the release and verification of contact lens prescriptions which are generally valid for one year and contains recordkeeping requirements applying to both prescribers and sellers of contact lenses.

Specifically, the Rule requires that prescribers provide a copy of the prescription to the consumer upon the completion of a contact lens fitting, even if the patient does not request it, and verify or provide prescriptions to authorized third parties. The Rule also mandates 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 through direct communication with the prescriber. In addition, the Rule imposes recordkeeping requirements on contact lens prescribers and sellers. For example, the Rule requires prescribers to document in their patients' records the medical reasons for setting a contact lens prescription expiration date of less than one year. The Rule requires contact lens sellers to maintain records for three years of all direct communications involved in obtaining verification of a contact lens prescription, as well as prescriptions, or copies thereof, which they receive directly from customers or prescribers.

The information retained under the Rule's recordkeeping requirements is used by the Commission to substantiate 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 either to ensure that entities are complying with the Rule's requirements or to bring enforcement actions based on violations of the Rule.

No substantive provisions in the Rule have been amended or changed since staff's prior submission and OMB clearance in 2016.¹ Thus, the Rule's disclosure and recordkeeping requirements remain the same.

Under the PRA, 44 U.S.C. 3501-3521, Federal agencies must get OMB approval for each collection of information they conduct or sponsor. "Collection of information" includes agency requests or requirements to submit reports, keep records, or provide information to a third party. 44 U.S.C. 3502(3); 5 CFR 1320.3(c). The FTC is seeking renewed clearance for the information collection requirements associated with the Commission's Contact Lens Rule, 16 CFR Part 315 (OMB Control Number 3084-0127).

Burden Statement

Estimated annual hours burden: 2,104,050 hours.

This figure is derived by adding 1,045,650 disclosure hours for contact lens prescribers to 1,058,400 recordkeeping hours for contact lens sellers, for a combined industry total of 2,104,050 hours. This estimate is an increase from the 1,903,315 annual burden hours submitted to OMB in 2016. The higher estimate is due to an increase in the estimated number of contact lens wearers in the United States from 41 million to 45 million.²

1. Prescribers

¹ OMB clearance for the current Rule expires October 31, 2019. On May 28, 2019, the FTC published a Supplemental Notice of Proposed Rulemaking ("SNPRM") (84 FR 24664) which proposes amendments to the Rule, and the FTC is separately seeking OMB's approval for the information-collection requirements associated with those amendments. Because the SNPRM was drafted prior to this Comment Request, some of the data and estimates may differ in the two documents. Should the Commission adopt the proposed amendments in the SNPRM, it could alter or render moot the assumptions, conclusions, and estimates put forth in this notice based on the current Rule.

² Centers for Disease Control, Healthy Contact Lens Wear and Care, Fast Facts, <https://www.cdc.gov/contactlenses/fast-facts.html>.

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. Prescribers can verify a prescription either by responding affirmatively to a request for verification, or by not responding at all, in which case the prescription will be “passively verified” after eight business hours. Prescribers are also required to correct an incorrect prescription submitted by a seller, and notify a seller if the prescription submitted for verification is expired or otherwise invalid. Staff believes that the burden of complying with these requirements is relatively low.

The number of contact lens wearers in the United States is now estimated by the Centers for Disease Control to be approximately 45 million.³ Therefore, assuming an annual contact lens exam for each contact lens wearer, approximately 45 million people would receive a copy of their prescription each year under the Rule.⁴

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 750,000 hours. $[(45 \text{ million} \times 1 \text{ minute})/60 \text{ minutes} = 750,000 \text{ hours}]$. In all likelihood, this estimate overstates the actual burden because it includes the time spent by prescribers who already release prescriptions to patients in the ordinary course of business.

As stated above, prescribers may also be required to provide or verify contact lens prescriptions to sellers. According to recent survey data, approximately 36% of contact lens

³ *Id.*

⁴ In the past, some commentators have suggested that typical contact lens wearers obtain annual exams every 18 months or so, not every year. However, because prescriptions under the Rule are valid for a minimum of one year, we continue to estimate that patients seek exams every 12 months. Staff believes a calculation that assumes compliance with the Rule will provide the best estimate of the Rule’s contemplated burden.

purchases are from a source other than the prescriber.⁵ Assuming that each of the 45 million contact lens wearers in the U.S. makes one purchase per year, this means that approximately 16,200,000 contact lens purchases (45 million x 36%) are made from sellers other than the prescriber.

Based on prior discussions with industry, approximately 73% of sales by non-prescriber sellers require verification, and prescribers affirmatively respond (by notifying the seller that the prescription is invalid or incorrect) to approximately 15% of those verification requests. Using a response rate of 15%, the FTC therefore estimates that prescribers' offices respond to approximately 1,773,900 verification requests annually [(16,200,000 x 73%) x 15% = 1,773,900 responses]. Additionally, some prescribers may voluntarily respond to verification requests and confirm prescriptions (as opposed to simply letting the prescription passively verify). Because correcting or declining incorrect prescriptions is mandated by the Rule and occurs in response to approximately 15% of requests, staff assumes that prescribers voluntarily confirm prescriptions less often, and confirm at most an additional 15% of prescriptions (and, in all likelihood, significantly less). Using a combined response rate of 30%, the FTC estimates that prescribers' offices respond to approximately 3,547,800 requests annually.

According to the industry comments to the 2016 PRA submission, responding to verification requests requires approximately five minutes per request. Using that data, we estimate that these responses require an additional 295,650 hours annually. [(3,547,800 x 5 minutes)/60 minutes = 295,650 hours]. Combining these hours with the hours spent disclosing prescriptions to consumers, we estimate a total of 1,045,650 hours for all contact lens prescribers to comply with the Rule. [750,000 hours + 295,650 hours = 1,045,650 hours].

⁵ Jason J. Nichols & Deborah Fisher, "2018 Annual Report," Contact Lens Spectrum, Jan. 1, 2019, <https://www.clspectrum.com/issues/2019/january-2019>.

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.

2. *Sellers*

As noted above, a seller may sell contact lenses only in accordance with a valid prescription that the seller has (a) received from the patient or prescriber, or (b) 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 relatively low.

As stated previously, there are approximately 16,200,000 sales by non-prescriber sellers annually and approximately 73% of those sales require verification. Therefore, sellers verify approximately 11,826,000 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 11,826,000 orders, contact lens sellers will spend a total of 985,500 burden hours complying with this portion of the requirement.

$[(11,826,000 \times 5 \text{ minutes})/60 \text{ minutes} = 985,500 \text{ hours}]$.

Approximately 27% of sales to non-prescriber sellers do not require verification and thus require only that the seller retain the prescription provided. Staff estimates that this recordkeeping burden requires at most one minute per order (in many cases, this retention is electronic and automatic and will not require any time) for 4,374,000 orders [16,200,000 sales × 27%], resulting in 72,900 burden hours. [(4,374,000 orders × 1 minute)/60 minutes = 72,900 hours].

Combining burden hours for all orders [985,500 hours + 72,900 hours], staff estimates a total of 1,058,400 hours for contact lens sellers. It is likely that this estimate 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, and those whose records are generated and preserved automatically when a customer orders online, which staff believes is the case for many online sellers.

Estimated total labor cost burden: Approximately \$84,548,448.

This figure is derived from applying hourly wage figures for optometrists, ophthalmologists, and office clerical staff to the burden hours described above. This estimate is higher than the \$73,082,912 labor cost estimate submitted to OMB in 2016 due to an increase in the estimated number of contact lens wearers in the United States and wage increases for optometrists, ophthalmologists, and office staff.

According to Bureau of Labor Statistics, salaried optometrists earn an average wage of \$57.68 per hour, other physicians and surgeons—such as ophthalmologists—earn an average wage of \$98.02 per hour, and general office clerks earn an average wage of \$16.92 per hour.⁶

⁶ Press Release, Bureau of Labor Statistics, United States Department of Labor, Occupational Employment Statistics – May 2018, <https://www.bls.gov/news.release/ocwage.t01.htm>. Median salaries for prescribers and clerks (\$53.75 for optometrists, \$96.58 for other physicians and

Assuming that optometrists are performing 85% of the labor hours and ophthalmologists are performing 15% the labor hours for prescribers, and office clerks are performing the labor for non-prescriber sellers, estimated total labor cost attributable to the Rule would total approximately \$84,548,448. [$\$66,640,319$ prescriber hours ($\$57.68 \times 888,802.5$ optometrist hours = $\$51,266,128$) + ($\$98.02 \times 156,847.5$ ophthalmologist hours = $\$15,374,192$) + $\$14,618,765$ for seller hours ($\$16.92 \times 1,058,400$ office clerk hours = $\$17,908,128$) = $\$84,548,448$.]

A recent survey estimated that the U.S. contact lens market revenue is approximately \$5,012,800,000 (not counting examination revenue) in 2017.⁷ Therefore, the total labor cost burden estimate of \$84,548,448 imposed by the Rule represents a cost of approximately 1.69% of the overall retail revenue generated.

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

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

surgeons, and \$15.74 for general office clerks) are lower than average salaries and, consequently, would result in a lower overall burden imposed by the Rule. It is possible that medians are more representative since they do not include outliers that can distort the mean. Salaries can also vary by region. The average hourly wage for optometrists in New Mexico, for instance, is \$41.76 per hour, whereas optometrists in North Dakota earn an average of \$84.18 per hour. *Id.*

<https://www.bls.gov/oes/current/oes291041.htm>. However, since Contact Lens Rule PRA submissions have historically used national mean salaries to estimate the burden, the FTC will continue to do so for this submission.

⁷ "Vision Markets See Continued Growth in 2017, VisionWatch Says," Vision Monday, March 20, 2018, <http://www.visionmonday.com/business/research-and-stats/article/vision-markets-see-continued-growth-in-2017-visionwatch-says/>. See also, Steve Kodey, US Optical Market Eyewear Overview, 4, https://www.ftc.gov/sites/default/files/filefield_paths/steve_kodey_ppt_presentation.pdf. The FTC does not possess market data for 2018.

machines and paper, telephones, and recordkeeping facilities such as filing cabinets or other storage).

Request for Comments

The FTC invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information. In particular, the FTC invites comments on (5) what percentage of sales by non-prescriber sellers require verification; (6) what percentage of verification requests are affirmatively responded to by prescribers (either by notifying the seller that the prescription is valid, or by notifying the seller that the prescription is invalid or incorrect); (7) what percentage of contact lens prescriptions are written by ophthalmologists as opposed to optometrists or other medical specialties; (8) what percentage of verification requests received by optometrists' offices are handled by optometrists and what percentage are handled by office staff; (9) what percentage of verification requests received by ophthalmologists' offices are handled by ophthalmologists and what percentage are handled by office staff; and (10) whether the FTC should rely on mean wage data or median wage data in calculating the Rule's burden.

You can file a comment online or on paper. For the FTC to consider your comment, we must receive it on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Write "Paperwork Reduction Act: FTC File No. P072108" on your comment. Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online, or to send

them to the Commission by courier or overnight service. To make sure that the Commission considers your online comment, you must file it through the <https://www.regulations.gov> website by following the instructions on the web-based form. Your comment -- including your name and your state -- will be placed on the public record of this proceeding, including the <https://www.regulations.gov> website. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on www.regulations.gov.

If you file your comment on paper, write "Paperwork Reduction Act: FTC File No. P072108" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible FTC Website at www.regulations.gov, you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any "trade secret or any commercial or financial information which . . . is privileged or confidential" -- as provided by Section 6(f)

of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2) – including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled “Confidential,” and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record.⁸ Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted publicly at www.regulations.gov, we cannot redact or remove your comment unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. You can find more information, including routine uses permitted by the Privacy Act, in the Commission’s privacy policy, at <https://www.ftc.gov/site-information/privacy-policy>.

Heather Hipsley
Deputy General Counsel.

⁸ See FTC Rule 4.9(c).

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