Title: Section 76.934(e), Petitions for Extension of Time.

Form Number: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; and State, local, or tribal governments.

Number of Respondents and Responses: 20 respondents; 10 responses.

Frequency of Response: On occasion reporting requirement; Third party disclosure requirement.

Estimated Time per Response: 4 hours.

Total Annual Burden: 80 hours.

Total Annual Cost: None.

Needs and Uses: The information collection requirements contained under 47 CFR 76.934(e) states that small cable systems may obtain an extension of time to establish compliance with rate regulations provided that they can demonstrate that timely compliance would result in severe economic hardship. Requests for the extension of time should be addressed to the local franchising authorities (''LFAs'') concerning rates for basic service tiers.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–27902 Filed 12–19–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meetings

TIME AND DATE: 2 p.m. on December 20, 2023.

PLACE: This Board meeting will be open to public observation only by webcast. Visit *https://www.fdic.gov/news/board-matters/video.html* for a link to the webcast. FDIC Board Members and staff will participate from FDIC Headquarters, 550 17th Street NW, Washington, DC.

Observers requiring auxiliary aids (*e.g.,* sign language interpretation) for this meeting should email *DisabilityProgram@fdic.gov* to make necessary arrangements.

STATUS: Open to public observation via webcast.

MATTERS TO BE CONSIDERED: The Federal Deposit Insurance Corporation's Board of Directors will meet to consider the following matters:

Discussion Agenda

Memorandum and resolution re: Proposed 2024 FDIC Operating Budget.

Memorandum and resolution re: Final Rule on FDIC Official Signs and Advertising Requirements, False Advertising, Misrepresentation of Insured Status, and Misuse of the FDIC's Name or Logo.

Summary Agenda

No substantive discussion of the following items is anticipated. The Board will resolve these matters with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Disposition of Minutes of a Board of Directors' Meeting Previously Distributed.

Summary reports, status reports, and reports of actions taken pursuant to authority delegated by the Board of Directors.

CONTACT PERSON FOR MORE INFORMATION: Direct requests for further information concerning the meeting to Debra A. Decker, Executive Secretary of the Corporation, at 202–898–8748.

Authority: 5 U.S.C. 552b.

Dated at Washington, DC, on December 14, 2023.

Federal Deposit Insurance Corporation.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2023–28157 Filed 12–18–23; 4:15 pm]

BILLING CODE 6714–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments, relevant information, or documents regarding the agreements to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, 800 North Capitol Street, Washington, DC 20573. Comments will be most helpful to the Commission if received within 12 days of the date this notice appears in the **Federal Register**, and the Commission requests that comments be submitted within 7 days on agreements that request expedited review. Copies of agreements are available through the Commission's website (*www.fmc.gov*) or by contacting the Office of Agreements at (202) 523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 201325–001.

Agreement Name: Sealand/Network Space Charter Agreement.

Parties: Maersk A/S; Network Shipping, Ltd.

Filing Party: Wayne Rohde; Cozen O'Connor.

Synopsis: The Amendment changes the name of the agreement and deletes Panama, El Salvador, Nicaragua and Mexico from the geographic scope of the agreement. The Amendment changes the authority that Maersk had to charter space to Network to now authorizing Network to charter space to Maersk. The Amendment deletes obsolete language from the agreement and adds new language, revises the notice for termination and updates the persons to whom the notice is to be provided. The Amendment also restates the Agreement.

Proposed Effective Date: 1/26/2024.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/25450.

Dated: December 15, 2023.

Carl Savoy,

Federal Register Alternate Liaison Officer.

[FR Doc. 2023–27959 Filed 12–19–23; 8:45 am]

BILLING CODE 6730–02–P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension

AGENCY: Federal Trade Commission.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Federal Trade Commission (FTC or Commission) is seeking public comment on its proposal to extend for an additional three years the Office of Management and Budget clearance for the Contact Lens Rule (the Rule). The current clearance expires on December 31, 2023.

DATES: Comments must be filed by January 19, 2024.

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. The *reginfo.gov* web link is a United States Government website produced by the Office of Management and Budget (OMB) and the General Services Administration (GSA). Under PRA requirements, OMB's Office of Information and Regulatory Affairs (OIRA) reviews Federal information collections.

FOR FURTHER INFORMATION CONTACT: Paul Spelman, Attorney, Division of Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission, (202) 326–2889, *pspelman@ftc.gov.*

SUPPLEMENTARY INFORMATION:

Title: Contact Lens Rule (Rule), 16 CFR part 315.

OMB Control Number: 3084–0127.

Type of Review: Extension of a currently approved collection.

The Rule was promulgated by the FTC pursuant to the Fairness to Contact Lens Consumers Act (FCLCA), Public Law 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, and was most recently amended in 2020.[1] 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. Additional provisions in the Rule that constitute collections of information as defined by 5 CFR 1320.3(c) require that sellers who use calls containing automated verification messages record the entire call, and preserve such recordings for at least three years. In addition, the Rule requires that prescribers either: (a) obtain from patients, and maintain for a period of not less than three years, a signed confirmation of prescription release on a separate stand-alone document; (b) obtain from patients, and maintain for a period of not less than three years, a patient's signature on a confirmation of prescription release included on a copy of a patient's prescription; (c) obtain from patients, and maintain for a period of not less than three years, a patient's signature on a confirmation of prescription release included on a copy of a patient's contact lens fitting sales receipt; or (d) provide each patient with a copy of the prescription via online portal, electronic mail, or text message, and for three years retain evidence that such prescription was sent, received, or, if provided via an online-patient portal, made accessible, downloadable, and printable by the patient. For prescribers who choose to offer an electronic method of prescription delivery, the Rule requires that such prescribers maintain records or evidence of affirmative consent by patients to such digital delivery for three years. The Rule also requires prescribers to document in their records the medical reasons for setting a contact lens prescription expiration date of less than one year, and 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.

Likely Respondents: Contact lens prescribers and contact lens sellers.

Estimated Annual Labor Hours Burden: 3,104,050 hours (derived from 2,045,650 contact lens prescriber hours + 1,058,400 contact lens seller hours).

- *Contact Lens Prescribers:* 750,000 hours (45 million contact lens wearers × 1 minute per prescription release/60 minutes) + 187,500 hours (33,750,000 contact lens wearers × 20 seconds per confirmation of prescription release) + 62,500 hours (11,250,000 contact lens wearers × 20 seconds per affirmative consent to electronic prescription delivery) + 295,650 hours (3,547,800 verification requests × 5 minutes per response/60 minutes) + 750,000 hours recordkeeping = 2,045,650 hours.
- *Contact Lens Sellers:* 985,500 hours (11,826,000 orders × 5 minutes per verification/60 minutes) + 72,900 burden hours (4,374,000 orders × 1 minute recordkeeping/60 minutes) = 1,058,400 hours.

Estimated Total Labor Cost Burden: Approximately $117,606,598 (derived from ($63.99 × 888,803 optometrist hours) + ($127.62 × 156,848 ophthalmologist hours) + ($19.78 × 1,000,000 prescribers' office clerk hours) + ($19.78 × 1,058,400 sellers' office clerk hours).

Estimated Total Non-Labor Cost Burden: $591,300 (11,826,000 × $.05 per automated message recording).

Estimated Total Annual Cost Burden: $120,764,786 ($117,606,598 labor cost + $591,300 non-labor cost).

Request for Comment:

On August 14, 2023, the FTC sought public comment on the information collection requirements associated with the Rule. 88 FR 55044. The FTC received one comment germane to the issues that the agency sought comment on pursuant to the PRA renewal request. That comment was from the American Optometric Association (''AOA''), an organization representing more than 50,000 optometrists and optometric professionals. In its comment, the AOA contends that the 2020 Rule amendment requiring that prescribers obtain a signed confirmation-of-prescription has created a greater compliance burden than previously projected by the FTC.[2]

As noted above, the 2020 Rule amendments require that upon completion of a contact lens fitting, the prescriber must request that a patient sign a statement confirming receipt of their contact lens prescription (unless a digital copy of a prescription is provided to the patient via portal, email, or text message).[3] The prescriber may, but is not required to, use the one-sentence confirmation statement, ''My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting'' to satisfy the requirement, and such statement can be on a stand-alone document or included on a contact lens prescription or exam receipt.[4]

In approving the Rule amendments in 2020, the FTC estimated that the time required to collect a patient signature and confirmation of prescription takes ten seconds on average.[5] The FTC's estimate of ten seconds was derived from two sources. The first was a similar previously-approved patient-acknowledgment-requirement under HIPAA, the Health Insurance Portability and Accountability Act, which requires, among other things, that each health provider obtain a patient signature confirming receipt of that provider's HIPAA Notice of Privacy Practices.[6] The

[1] Final Rule, 85 FR 50668 (Aug. 17, 2020).

[2] American Optometric Association (PRA Comment #7) *available at https://www.regulations.gov/comment/FTC-2023-0049-0007.*

[3] 16 CFR 315.3(c). In order to provide digital copies of prescriptions, the prescriber must first obtain a single signed consent-to-electronic-delivery from each patient.

[4] 16 CFR 315.3(c)(ii).

[5] 85 FR 50709.

[6] Standards for Privacy of Individually Identifiable Health Information, 67 FR 53182, 53261

Continued

HIPAA acknowledgment requirement,[7] which has been in effect for more than 20 years, faced objections prior to implementation over concerns it would be burdensome and costly to implement.[8] The U.S. Department of Health and Human Services rejected those contentions and determined that its signed acknowledgment would require just ten seconds to hand out and ten seconds to obtain a patient's signature.[9]

The second source for the FTC's estimate of 10 seconds was a consumer survey by the polling firm Survey Sampling International (''SSI'') of how long it took consumers to read a proposed two-sentence statement, ''My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting. I understand I am free to purchase contact lenses from the seller of my choice.'' The survey found that it took consumers, on average, twelve seconds to review those two sentences, and 90% of respondents read it in 20 seconds or less.[10] Additionally, 90% of consumers surveyed indicated they understood the proposed acknowledgement statement, and 94% indicated that they had no follow-up questions.[11] The Commission's Final Rule did not include the second sentence of the surveyed confirmation statement, thereby shortening the final confirmation statement by nearly half, with the expected result that it might only take six or seven seconds for consumers to read and comprehend. Based on the survey average of 12 seconds to read the previously-proposed two-sentence statement, and on the approved HHS signed-acknowledgment estimate, the Commission, in its Rule amendments of 2020, estimated ten seconds to read and provide a signature for the Rule's one-sentence confirmation-of-prescription-release statement.[12]

In its new PRA comment, however, the AOA contends that the FTC ''significantly underestimated'' how long it would take to confirm prescription releases.[13] According to the AOA, a 2023 survey it conducted of some of its member optometrists found that 84.8% indicate it takes 30 seconds or more to obtain the patient's signed confirmation, not counting additional time necessary to address patient questions about the form they are signing, and 69.9% of prescribers said patients ''typically'' have questions regarding the acknowledgment.[14]

AOA's comment accords with some written and verbal comments provided to the Commission during an ongoing review of the Eyeglass Rule,[15] which includes a proposal to add a similar confirmation-of-prescription-release requirement. The Commission's Eyeglass Rule review has examined, among other things, the burden arising from the existing Contact Lens Rule's confirmation-of-prescription-release requirement, and thus some of the comments received during the Eyeglass Rule review pertain to the Rule burden discussed herein. For instance, at a 2023 FTC workshop on the Eyeglass Rule,[16] panelist Dr. Stephen Montaquila, a Rhode Island optometrist, estimated that it takes his staff four minutes to complete the entire Contact Lens Rule process of printing out a patient's prescription, handing it to the patient, explaining why it needs to be signed, having the patient sign it, making a copy of it, and storing the signed copy as a record.[17] Dr. Montaquila did not break down his estimate by task, so it is unclear how long he estimates it takes for a consumer to simply read and sign the confirmation statement, as opposed to the time it takes for his staff to print out the prescription and confirmation and store the confirmation as a record. As detailed in this submission, the Commission has allowed for one minute for prescribers to print out the prescription, and an additional minute for staff to store the signed confirmation.

In addition, the National Taxpayers Union, an Alexandria, Virginia-based advocacy organization, submitted a comment to the Eyeglass Rule review stating that while it generally supports the confirmation requirement, ''[G]iven the various reading speeds of customers who may be elderly or have limited proficiency in English, the 10 second estimate [used for the Contact Lens Rule's confirmation requirement] could prove low.'' [18]

Some commenters, however, disagreed that it takes a significant amount of time to obtain a patient's signed confirmation. The National Association of Retail Optical Companies (''NAROC''), a trade association comprised of retail optical companies with co-located eye care services (such as LensCrafters, Costco Optical, and Walmart Vision Center), commented that thousands of optometrists affiliated in co-location with NAROC member companies ''regularly comply with [Contact Lens Rule requirements] with little or no added cost or other burden on the eye care practice.'' [19] According to NAROC representative and Eyeglass Rule Workshop panelist Joseph Neville, ''I've personally witnessed a couple of situations where the process for contact lenses seemed very easy. . . . the Rx was handed over at the front desk by the staff person, and the staff person maybe a bit simplistically said, ''We'd like to ask you to sign this receipt for your

(Aug. 14, 2002) (implementing 45 CFR 164.520(c)(2)(ii)).

[7] 45 CFR 164.520(c)(2)(ii).

[8] Standards for Privacy of Individually Identifiable Health Information, 67 FR 53182, 53240–43 (Aug. 14, 2002) (implementing 45 CFR 164.520(c)(2)(ii)).

[9] *Id.* at 53240–43, 53260–61. HHS also calculated three cents per signed acknowledgment for the cost some doctors might incur for the paper. *Id.* at 53256. Since 2018, HHS has been considering a proposal to eliminate its signed-acknowledgment requirement as no longer necessary to compel providers to distribute Notices of Privacy Practices to patients, but HHS has not determined that the 10-second time estimate for obtaining a patient signature is inaccurate. Request for Information on Modifying HIPAA Rules to Improve Coordinated Care, 83 FR 64302, 64302–03 (2018), *https://www.govinfo.gov/content/pkg/FR-2018-12-14/pdf/2018-27162.pdf#page=1.* For a more fulsome discussion about the HHS proposal to eliminate its signed acknowledgment, and why this has little relevance with respect to the Contact Lens Rule, *see* CLR Final Rule, 85 FR 50684–85, footnotes and accompanying text.

[10] 1–800 CONTACTS (Contact Lens Rule Workshop Comment #3207); Laurence C. Baker, ''Analysis of Costs and Benefits of the FTC Proposed Patient Acknowledgment and Recordkeeping Amendment to the Contact Lens Rule,'' 11 (2017), *https://www.ftc.gov/system/files/summaries/initiatives/677/10192017_meeting_summary_from_mko_for_the_contact_lens_rule_rulemaking_proceeding.pdf* (SSI online survey of 500 respondents). Twelve seconds was the average, the median was 10 seconds.

[11] *Id.* at 18.

[12] 84 FR 24693.

[13] AOA (PRA Comment #7), *supra* note 9.

[14] *Id.* According to AOA, the survey was conducted in-house by its Health Policy Institute and Research Departments, and distributed to member optometrists via AOA's weekly email newsletter with a link and invite to the survey titled ''Voice your concerns by Oct. 9: Complying with the FTC Contact Lens Rule.'' Of members who responded to the AOA's link request, 327 completed the survey.

[15] This is officially the Ophthalmic Practice Rules, 16 CFR part 456.

[16] ''A Clear Look at the Eyeglass Rule,'' Public Workshop (May 18, 2023), transcript *available at https://www.ftc.gov/news-events/events/2023/05/clear-look-eyeglass-rule* [hereinafter ER Workshop Transcript].

[17] Montaquila, ER Workshop Transcript at 23–24.

[18] National Taxpayers Union (ER NPRM Comment #28) *available at https://www.regulations.gov/comment/FTC-2023-0001-0028. See also* Prine (ER Workshop Comment #38) (simply stated that having patients sign a receipt of their prescription and then scan that into their chart ''took a lot of extra time'') *available at https://www.regulations.gov/comment/FTC-2023-0001-0038;* Michaels, ER Workshop Transcript at 9 (stating, ''There's a lot of time, effort, discussion around [the confirmation requirement]. I think that is something that is greatly underestimated in terms of how long it takes and how effort it takes to go through that process.'').

[19] NAROC (ER NPRM Comment #24) *available at https://www.regulations.gov/comment/FTC-2023-0001-0024. See also* Consumer Action (ER NPRM Comment #26) (''we do not believe it is a burden on providers to obtain, document, and retain a consumer's affirmative receipt of their prescription.'').

prescription. We're required to get your signature acknowledging that you've received it.'' And a couple of people, and again, anecdotes here that I witnessed on this, just said, ''Okay, fine, thank you.'' [20]

Discussion of the Comments and Evidence Regarding the Time Required

In considering how much time it takes to complete the confirmation-of-prescription-release requirement for this Paperwork Reduction Act purpose, the Commission has evaluated the evidence in the record, including the previously-approved HHS estimate for a similar signed-acknowledgment, the comments in response to the PRA request for comment in the 60-Day **Federal Register** notice and the Contact Lens Rule and Eyeglass Rule rulemakings, and the two surveys mentioned above, one of consumer read-times and the other of prescriber-estimates for staff time.

The Commission finds none of the comments, and neither survey, dispositive in and of itself. The surveys, in particular, are suggestive but not determinative. The SSI survey of consumer read-times on a computer monitor is helpful, but may not take into account elderly patients or those for whom English is not their first language. It also does not take into account the time it takes for prescribers' staff to hand a paper confirmation document to the patient and for the patient to sign it and hand it back. The AOA survey, meanwhile, very likely overestimates the time necessary to obtain a confirmation because of the manner in which the survey solicited its respondents. The prescribers were self-selected in response to an AOA invitation to ''Voice your concerns'' about complying with the Contact Lens Rule. Because the poll only included prescribers who responded to this invitation, its findings may not be representative of the average prescriber. In fact, it is probable that a large number of those who responded were prescribers who *have* concerns about the patient-confirmation requirement and the time it takes to obtain a confirmation, while prescribers who do not have concerns, or have fewer concerns, did not bother to respond. By framing the survey as an invitation to voice concerns about complying with the Rule, the survey has been transformed from a disinterested information-gathering tool into a motivating call to action. So while it is possible that prescribers who did not respond to the survey also share the concerns raised by survey respondents, that cannot be concluded from the survey.[21]

The Commission also has concerns that some of the time prescribers ascribe to patients reading and signing the confirmation is, in fact, due to non-mandated choices by prescribers with respect to the design of the confirmation statement. As noted above, the Rule merely requires that patients read and sign a simple statement confirming receipt of their prescription, and the Commission allowed that the one-sentence statement, ''My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting,'' would fully satisfy the requirement. According to the AOA survey, nearly 60% of prescribers use a separate form with a statement confirming receipt (as opposed to obtaining a patient signature on a prescription copy or sales receipt), but the survey did not specify or ask prescribers what confirmation statement they used on their form, making it difficult to determine the true average time it takes to comply with the confirmation-of-prescription-release requirement. Moreover, the AOA has supplied its members with a model template confirmation form that includes four additional paragraphs consisting of ''important information to review prior to receiving your contact lens prescription.'' [22] This information includes various recommendations from the Centers for Disease Control and the Food and Drug Administration about healthy contact lens use (such as ''Take out your contacts and call your eye doctor if you have eye pain, discomfort, redness, or blurry vision'') as well as five bullet points listing some of the symptoms for an eye infection (''Irritated, red eyes, worsening pain in or around the eyes,'' etc.).[23] While the document is titled ''Contact Lens Prescription Acknowledgment Form,'' only at the very end is there a statement, ''Sign below to acknowledge that you were provided a copy of your contact lens prescription at the completion of your contact lens fitting.''

According to Workshop Panelist Dr. Montaquila, the AOA template is a common form used to obtain patient confirmations.[24] If this is indeed the case, the Commission is not surprised that many prescribers report it takes patients 30 seconds or longer to read and sign, nor that patients might have questions, or be confused, as to why they now have to sign and acknowledge not just receipt of their prescription, but that they read these recommendations from the CDC and FDA. The additional information from these two other federal agencies may be useful for patients, but is not required by the Rule, nor considered part of the PRA burden of compliance.

Despite the aforementioned concerns about the reliability of the AOA survey in establishing the time it takes for a patient confirmation, the Commission does not discount the survey altogether, and views it as suggestive, and an additional indication that many prescribers sincerely believe the 10-second estimate does not accurately reflect the time required to obtain a patient's signed confirmation. The Commission has therefore decided to increase the estimated time to obtain a patient confirmation signature (and the time to collect an affirmative consent to electronic delivery, in instances where the prescription is provided digitally rather than in paper) from 10 to 20 seconds. The Commission believes that 20 seconds may better reflect the time required for a patient to not just read a one-sentence confirmation, but also to physically sign and return the document to staff, and for any staff explanation as to why the patient's signature is required. The 20-second estimate may also better align with the original HIPAA estimate, which accorded 10 seconds to hand out the acknowledgment and another ten seconds to obtain a patient's signature and collect the document.[25]

Pursuant to OMB regulations, 5 CFR part 1320, that implement the PRA, 44 U.S.C. 3501 *et seq.,* the FTC is providing this second opportunity for public comment while seeking OMB approval to renew the pre-existing clearance for the Rule.

Estimated Annual Hours and Labor Cost Burden

Estimated annual hours burden: 3,104,050 hours.

This figure is derived by adding disclosure and recordkeeping-hours for contact lens prescribers to

[20] Neville, ER Workshop Transcript at 28–29.

[21] The Commission also notes that while the AOA states that it represents some 50,000 optometric professionals, only 327 members responded to AOA's invitation and completed the survey, which could indicate that most AOA members do not have concerns about complying with the Contact Lens Rule. However, there could be other reasons for the relatively small number of prescribers (in proportion to the total membership) who responded, so the Commission will not draw any inferences from the low response rate.

[22] *See* AOA Contact Lens Rule Compliance Toolkit, sample template, 8, available at *https://documents.aoa.org/Documents/CLCS/Contact-Lens-Rule-Compliance-Toolkit.pdf.*

[23] *Id.*

[24] Montaquila, ER Workshop transcript at 23.

[25] *See supra* notes 15–16.

recordkeeping hours for contact lens sellers.

1. Prescribers and Their Office Staff

The Rule requires prescribers to collect information and make disclosures in three ways. Upon completing a contact lens fitting, the Rule requires that prescribers (1) provide a copy of the contact lens prescription to the patient,[26] (2) collect a patient's signature on either a Confirmation of Prescription Release or a consent-to-electronic-prescription-release and preserve such record, and (3) 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 estimated by the Centers for Disease Control to be approximately 45 million.[27] 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 and be required to either sign a Confirmation of Prescription Release or consent to electronic delivery of their prescription.[28]

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 million × 1 minute)/60 minutes = 750,000 hours]. Since the Rule requires that prescriptions be released automatically at completion of a fitting, the Commission—for purposes of calculating the PRA burden—assumes that prescription releases to patients are handled by the prescriber rather than the prescriber's office staff.[29] 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. Furthermore, this estimate allocates the same time for both paper and electronic delivery of prescriptions, even though the latter likely takes less time for the prescriber.[30]

The time required to collect a signature from a patient confirming release of a prescription is estimated at twenty seconds, as discussed above. It is estimated that 25% of patients would opt for electronic delivery of their prescriptions and thus would not need to sign a Confirmation of Prescription Release. Based on our knowledge of the industry and how the medical field operates, the Commission believes most signed patient confirmations are obtained by prescribers' office staff rather than by the prescribers themselves.[31] The time spent by prescribers' staff complying with the requirement to obtain signed confirmations from the other 75% of patients is approximately 187,500 hours annually [(75% × 45 million prescriptions yearly × 20 seconds) = 187,500 hours].

As noted above, it is estimated that approximately 25% of patients would opt for electronic delivery of their prescriptions. In order to opt for electronic delivery, patients are required to sign an affirmative consent to receive their prescription via email, text, or patient portal. The time required to collect an affirmative consent signature is estimated at twenty seconds, and the annual time spent complying with the requirement to obtain such signatures is approximately 62,500 hours [(25% × 45 million prescriptions yearly × 20 seconds) = 62,500 hours]. Based on our knowledge of the industry and how the medical field operates, the Commission believes most signed patient consents are obtained by prescribers' office staff rather than by the prescribers themselves.[32]

As stated above, prescribers may also be required to provide or verify contact lens prescriptions to sellers. According to survey data, approximately 36% of contact lens purchases are from a source other than the prescriber.[33] 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 × 36% = 16,200,000) 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 purchases × 73%) × 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

[26] The 2020 amendments to the Contact Lens Rule altered the definition of ''provide to the patient a copy'' of the contact lens prescription to include electronic delivery of the prescription, such as via email, text, or by uploading it to a patient portal. In order to avail themselves of this option, prescribers must obtain and maintain evidence of the patients' affirmative consent to electronic delivery for three years.

[27] Centers for Disease Control, Healthy Contact Lens Wear and Care, Fast Facts, *https://www.cdc.gov/contactlenses/fast-facts.html. See also* U.S. Food & Drug Administration, Focusing on Contact Lens Safety, *https://www.fda.gov/consumers/consumer-updates/focusing-contact-lens-safety.*

[28] 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 adherence to the Rule will provide the best estimate of the Rule's contemplated burden, even if, in practical terms, it overestimates the burden.

[29] This assumption may be incorrect, particularly in instances where a contact lens fitting is not completed during the prescriber's examination itself, but rather after the patient tests out the lenses for a few days. Nonetheless, the Commission does not have information as to what percentage of prescriptions are released by prescribers or by prescribers' staff, and thus will calculate the PRA with the assumption that they are all released by the prescriber.

[30] *See* Michaels, Workshop Transcript at 18 (noting that in his office, prescriptions are automatically uploaded to a patient portal ''the very second the prescription is finalized.'')

[31] In prior PRA submissions, the task of collecting a patient signature on a confirmation-of-prescription-receipt was attributed to prescribers, but based on more recent conversations with prescribers and others in the industry, the Commission now believes that this task is more appropriately designated as performed by prescribers' office staff. This is further supported by comments during the Eyeglass Rule Workshop, such as that of panelist Dr. Montaquila, who noted that his staff completes the process ''from explaining why we're doing it to the patient, providing them with their prescription, making copies, providing their prescription back to them, and ultimately storing it. . . . Our staff has to explain, 'You're signing this for this reason.'' Montaquila, ER Workshop Transcript at 22, 28. *See also* Neville, ER Workshop Transcript at 28 (commenting that he has observed situations where the doctor pushed a button to have the prescription printed out at the front desk, the prescription was handed over at the desk by the staff person, and the staff person obtained the patient's signature on the confirmation.); AOA Report for Complying with the FTC Contact Lens Rule, (survey to prescribers, Question 3, ''Have you experienced challenges in training staff on the new requirements for the Contact Lens Rule?''; Question 9 ''How much time per day does your staff spend on addressing patient questions with the acknowledgment form and process?'').

[32] *See supra* note 40.

[33] Jason J. Nichols & Deborah Fisher, ''2018 Annual Report,'' Contact Lens Spectrum, Jan. 1, 2019, *https://www.clspectrum.com/issues/2019/january-2019.*

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 prior industry comments,[34] 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 × 5 minutes)/60 minutes = 295,650 hours]. Based on investigations and anecdotal comments, FTC staff is aware that many verification requests are handled by office staff rather than by the prescribers themselves. FTC staff, however, does not possess reliable information as to what percentage of verification requests are performed by prescribers or their staff, and thus will allocate all such time to prescribers.

Lastly, the Rule and FCLCA also impose recordkeeping requirements on prescribers' offices. First, they must maintain signed confirmations, or signed consent to electronic prescription delivery and proof that such prescriptions were delivered via email, text, or patient portal, for a period of three years. For purposes of PRA analysis, the Commission has used the assumption that all prescriber offices require a full minute to store and maintain each confirmation record, and a full minute to store and maintain each consent to electronic prescription delivery and proof of electronic prescription delivery.[35] The Commission thus allots an additional 750,000 annual hours for prescribers' offices to store and maintain records of patient confirmations and consents. The Commission believes these labor hours are most likely performed by prescribers' office staff.

The Rule also requires prescribers to 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.

Combining all hours spent annually disclosing prescriptions to consumers, obtaining confirmations of prescription release from consumers, obtaining affirmative consent to electronic prescription delivery from consumers, responding to verification requests, and maintaining records as required by the Rule, we estimate a total of 2,045,650 hours for all contact lens prescribers to comply with the Rule [750,000 prescription-release hours + 187,500 confirmation-collection hours + 62,500 electronic-delivery-consent-collection hours + 295,650 verification-response hours + 750,000 recordkeeping hours = 2,045,650 hours]. Of this total, we estimate 1,045,650 are prescriber labor hours, and 1,000,000 are labor hours performed by prescribers' clerical office staff.

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.

As stated previously, there are approximately 16,200,000 sales by non-prescriber sellers annually and approximately 73% of such 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 × 5 minutes)/60 minutes = 985,500 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 truth, 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 recordkeeping 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 $117,606,598.

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 $84,548,448 labor cost estimate submitted to OMB in 2019 due to new information collection and recordkeeping requirements in the Rule, and to wage increases for optometrists, ophthalmologists, and office staff.

According to Bureau of Labor Statistics (BLS), salaried optometrists earn an average wage of $63.99 per hour, ophthalmologists—which are listed by BLS under ''surgeons''—earn an average wage of $127.62 per hour, and general office clerks earn an average wage of $19.78 per hour.[36] Based on our knowledge of the industry and the number of optometrists and ophthalmologists in the United States, we assume that of the 1,045,650 prescriber labor hours relating to the Rule, optometrists are performing 85% of such hours and ophthalmologists are performing the remaining 15% of prescriber hours.[37] We credit general office clerks for performing the remaining hours, both for prescribers' offices (1,000,000 hours) and for non-prescriber sellers (1,058,400 hours). Based on these assumptions and

[34] Notice and Request for Comment, 81 FR 62501 (Sept. 9, 2016).

[35] 85 FR 5709.

[36] Press Release, Bureau of Labor Statistics, United States Department of Labor, Occupational Employment and Wage Statistics—May 2022, *https://www.bls.gov/news.release/ocwage.t01.htm.* Median salaries for prescribers and clerks are slightly 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 salary outliers that can distort the average. Salaries can also vary significantly by region. However, since Contact Lens Rule PRA submissions have historically used national salary averages to estimate the burden, the FTC will continue to do so for this submission.

[37] *See* Proposed Collection Request, 81 FR 31938, 31940 (May 20, 2016); Proposed Collection Request, 84 FR 32170, 32172 (July 5, 2019).

estimates above, the estimated total labor cost attributable to the Rule is approximately $117,606,597 [($63.99 × 888,803 optometrist hours = $56,874,504) + ($127.62 × 156,848 ophthalmologist hours = $20,016,942) + ($19.78 × 1,000,000 prescribers' office clerk hours = $19,780,000) + ($19.78 × 1,058,400 sellers' office clerk hours = $20,935,152) = $117,606,598].

Capital and Other Non-Labor Costs

Estimated annual non-labor cost burden: $591,300.

Staff believes that the Rule's disclosure and recordkeeping requirements described above 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) to perform those requirements. The 2020 Rule amendments, however, modified the Rule to require that sellers who use automated verification messages record the calls and preserve the recordings for three years. The Commission does not believe that requiring sellers who use automated messages for verification to record the calls and preserve them will create a substantial burden. The requirement will not require additional labor time, since the calls will be for the same duration as they were previously, but may require capital and other non-labor costs to record the calls and store them electronically. Based on comments supplied during the Rule modification process, the Commission estimates the cost to record each verification call at five cents apiece.[38]

Based on survey data, approximately 36% of contact lens purchases are from a source other than the prescriber. Assuming that each of the 45 million contact lens wearers in the U.S. makes on purchase per year, this would mean that approximately 16,200,000 contact lens purchases are made annually from sellers other than the prescribers. And since approximately 73% of sales by non-prescriber sellers require verification, this means that approximately 11,826,000 contact lens purchases would require verification calls, faxes, or emails. The Commission does not possess information as to the percentage of verifications completed by telephone versus fax or email, and thus for purposes of this analysis will assume that all verifications are performed via phone and deliver automated messages that are subject to the call-recording requirement. Based on the aforementioned assumptions, the Commission estimates that the requirement to record automated telephone verification messages will cost sellers, in aggregate, $591,300 (11,826,000 × $.05).

Total Costs to the Industry (Including Labor and Non-Labor Costs)

Combining the annual labor cost burden with the non-labor cost burden, the total cost burden of the Rule is estimated at $118,197,898 ($117,606,598 + $591,300 = $118,197,898).

This burden is not insubstantial, but to put it in perspective, a recent survey estimated the value of the U.S. contact lens market at approximately $9.6 billion (not counting examination revenue).[39] Therefore, the total cost burden estimate of $118,197,898, imposed by the Rule, represents a cost of approximately 1.2% of the overall retail revenue generated through the sale of contact lenses.

Your comment—including your name and your state—will be placed on the public record of this proceeding. Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as anyone'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.

Josephine Liu,

Assistant General Counsel for Legal Counsel.

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[38] 85 FR 50711. It is possible this would be a one-time expense for sellers to invest in recording equipment, as opposed to an annual outlay. But in the absence of information as to how sellers manage such recordings, the Commission will assume, for the purpose of this PRA analysis, that recording expense is a recurring annual cost burden.

[39] *See https://www.globenewswire.com/en/news-release/2022/09/05/2509723/0/en/Contact-Lenses-Market-Size-Will-Achieve-USD-17-4-Billion-by-2030-growing-at-6-9-CAGR-Exclusive-Report-by-Acumen-Research-and-Consulting.html.* Some estimates already put the U.S. contact lens market as high as $17 billion, *see https://www.visionmonday.com/business/article/us-optical-retail-market-estimated-at-765-billion-in-the-vision-councils-first-comprehensive-market-insights-report/.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to 5 U.S.C. 1009(d), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended, and the Determination of the Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)–PAR 20–280, Cooperative Research Agreements Related to the World Trade Center Health Program (U01); RFA–OH–24–002, Exploratory/Developmental Grants on Lifestyle Medicine Research Related to the World Trade Center Health Program (R21); RFA–OH–24–003, Exploratory/Developmental Grants Related to the World Trade Center Survivors (R21–No Applications with Responders Accepted); and RFA–OH–24–004, World Trade Center Health Program Mentored Research Scientist Career Development Award (K01).

Dates: March 19–21, 2024.

Times: 11 a.m.–6 p.m., EDT.

Place: Video-Assisted Meeting.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Laurel Garrison, M.P.H., Scientific Review Officer, Office of Extramural Programs, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 5555 Ridge Avenue, Cincinnati, Ohio 45213. Telephone: (513) 533–8324; Email: *LGarrison@cdc.gov*.

The Director, Office of Strategic Business Initiatives, Office of the Chief