Supporting Statement
Proposed Amendments to the Contact Lens Rule
16 CFR § 315
(OMB Control # 3084-0127)

(1-2) Necessity for Collecting the Information/Use of the Information

The Federal Trade Commission promulgated the Contact Lens Rule ("Rule") pursuant to the Fairness to Contact Lens Consumers Act ("FCLCA"), Public Law 108-164 (December 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 contact lens prescribers to provide prescriptions to their patients upon the completion of a contact lens fitting, and provide or verify such prescriptions to authorized third parties, such as contact lens sellers. Sellers may provide contact lenses only in accordance with a valid prescription that is presented directly to the seller or verified with the prescriber.

Section 315.3(a)(1) of the Rule requires a prescriber to provide a copy of the contact lens prescription to the patient after completing a contact lens fitting, regardless of whether it was requested by the patient. Section 315.3(a)(1) of the Rule tracks the language of the Act verbatim.[1] This provision, referred to as automatic prescription release, was intended to empower consumers to comparison shop for contact lenses. Based on twelve years of experience enforcing the Rule and careful consideration of public comments during the rule review,[2] the Commission determined that compliance with the law's automatic prescription release provision could be substantially improved.[3] The Commission concluded that the potential benefits of increasing the number of patients in possession of their prescriptions were substantial: increased patient flexibility and choice in shopping for lenses; a reduced number of verification requests, which many prescribers find burdensome; a reduced likelihood of errors associated with incomplete or invalid prescriptions, which can jeopardize patient eye health; and a reduction in the number and complications of failed attempts at verification. Increasing prescription-release compliance also would likely spur competition and innovation among contact lens sellers and manufacturers, and reduce attempts by sellers to verify incorrect, expired, and invalid prescriptions, or to verify with the wrong prescriber. The Commission also determined that the cumulative effect of increased automatic-release compliance would thus be lower costs and improved convenience and flexibility for patients, sellers, and prescribers, as well as increased

[1] 15 U.S.C. 7601(a)(1).

[2] Contact Lens Rule, Request for Comment, 80 Fed. Reg. 53,272 (September 3, 2015) ("Request for Comment").

[3] In fact, the Commission has received evidence that a majority of consumers—between 56-65% —are not receiving their contact lens prescriptions automatically as required by law, and millions of consumers are not receiving them at all. Supplemental Notice of Proposed Rulemaking, 84 Fed. Reg. 24,664 (May 28, 2019) ("SNPRM").

accuracy of prescriptions presented to sellers, thereby reducing potential consumer harm.

In 2016, the Commission proposed to amend the Rule to require that prescribers obtain a signed acknowledgment after releasing a contact lens prescription and maintain each such acknowledgment for a period of not less than three years.[4] Requiring a signed acknowledgment would increase the Commission's ability to assess and verify compliance with the Rule.

After a subsequent review of additional public comments, workshop transcripts, and various empirical surveys and analyses,[5] the Commission is proposing to modify its prior proposal for a signed acknowledgment requirement by instituting a more flexible Confirmation of Prescription Release provision. The proposed modifications to the Rule would require that prescribers either (1) 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; (2) 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; (3) 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 (4) 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 was sent, received, or, if provided via an online-patient portal, made accessible, downloadable, and printable by the patient.

As discussed in the Supplemental Notice of Proposed Rulemaking ("SNPRM"), the Commission believes that this modified proposal will achieve the goals of the original proposal while imposing less of a burden on prescribers. Specifically, the modified proposal would improve compliance with the congressionally-mandated automatic prescription release requirement, and thereby benefit consumers and competition by ensuring that contact lens users have the ability to comparison shop for lenses. Furthermore, the modified proposal will provide much-needed improvements to the Commission's ability to evaluate and enforce compliance with this core provision of the Rule. Also, by allowing prescribers more options and flexibility, the proposed modification will impose even less of an overall burden on prescribers than the prior proposal, which the Commission had determined was relatively minimal.[6]

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[4] Notice of Proposed Rulemaking, 81 Fed. Reg. 88,526 (proposed Dec. 7, 2016) ("NPRM").

[5] Comments received in response to the NPRM are available at https://www.ftc.gov/policy/public-comments/2016/10/initiative-677. Comments received in connection with the workshop are available at https://www.ftc.gov/news-events/events-calendar/2018/03/contact-lens-rule-evolving-contact-lens-marketplace. *See also* Public Workshop Examining Contact Lens Marketplace and Analyzing Proposed Changes to the Contact Lens Rule, 82 Fed. Reg. 57,889 (Dec. 8, 2017).

[6] NPRM, 81 Fed. Reg. at 88,534, 88,557-58. The estimated Paperwork Reduction Act ("PRA") burden under the modified proposal is 597,917 hours for all prescribers and their staff, compared to 683,333 hours for the signed acknowledgment proposal, a decrease of approximately 13 percent. The total cost estimate,

The proposed requirement to collect patient signatures and the associated recordkeeping requirement would each constitute an information collection as defined by 5 CFR 1320.3(c). Accordingly, the Commission is providing PRA burden estimates for them, as set forth below.

(3) Consideration of Using Improved Technology to Reduce Burden

The proposed amendments permit the covered firms to use paper or electronic format to reduce the burden of information collection. Moreover, in its SNPRM, 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 proposed amendments 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 proposed 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 proposed 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.

While some contact lens prescribers subject to the Rule's requirements are small businesses, staff believes that everything consistent with the requirements of the Rule has been done to minimize the compliance burden. Although the Act requires the Rule to apply to all covered firms whether they are small entities or not, the Commission is seeking comment about minimizing impact on small businesses.

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however, is somewhat higher ($13,244,727 for the revised proposal compared to $10,475,495 for the prior proposal) due to increases in labor costs since 2016, and the fact that the PRA estimate for the original proposal did not include time required to obtain a patient's signature, whereas the new proposal assigns that time to prescribers (as opposed to office staff) and counts it as a PRA burden, in accordance with the feedback of many NPRM commenters.

(6) Consequences of Conducting the Collection Less Frequently

The proposed recordkeeping requirement would require that sellers retain the required records for a period of not less than three years. Staff believes that a record retention period shorter than this would hamper the Commission's ability to confirm contact lens prescribers' compliance with the Rule, because the statute of limitations applicable to Commission rule violations is three years.[7]

(7) Circumstances Requiring Collection Inconsistent With Guidelines

The proposed amendment's information collection requirements are consistent with all applicable guidelines contained in 5 C.F.R. § 1320.5(d)(2). Under the proposed rule amendments, the Commission's Rule would only require that covered entities maintain the form for three years. Instances where records are required to be maintained longer than three years are mandated by individual state laws.[8]

(8) Consultation Outside the Agency

On September 3, 2015, the Commission solicited comment on the Contact Lens Rule as part of its periodic review of its rules and guides.[9] As with other regulatory rule reviews, the Commission sought comment on whether there is a continuing need for the Rule as currently promulgated and about the Rule's costs and benefits. The comment period closed on October 26, 2015. The Commission reviewed the 660 comments received in response to the initial request for comments. Virtually all commenters agreed that there is a continuing need for the Rule and that it benefits consumers and competition. The majority of commenters recommended some modifications to the Rule in order to maximize the benefits to consumers and competition, decrease the burden on businesses, protect consumers' eye health, or improve overall compliance with the Rule's existing requirements. The Commission subsequently published an NPRM on December 7, 2016. The sixty-day comment period closed on January 30, 2017. In its NPRM, the Commission determined that the overall weight of the evidence demonstrated a need to improve compliance with the Rule's automatic prescription release requirement, as well as a need to create a mechanism for monitoring and enforcing that requirement. Accordingly, the NPRM proposed to

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[7] *See* Section 19(d) of the FTC Act, 15 U.S.C. 57b(d).

[8] *See, e.g.*, 246 Mass. Code Regs. § 3.02 (requiring optometrists to maintain patient records for at least seven years); Wash. Admin. Code § 246-851-290 (requiring optometrists to maintain records of eye exams and prescriptions for at least five years); Iowa Admin. Code r. 645-182.2(2) (requiring optometrists to maintain patient records for at least five years); Fla. Admin. Code r. 64B13-3.003(6) (requiring optometrists to maintain patient records for at least five years).

[9] 2015 Request for Comment. Comments received in response to this request are available at https://www.ftc.gov/policy/public-comments/2015/09/initiative-621.

amend the Rule to require that prescribers request that patients sign an acknowledgement form upon receiving a copy of their contact lens prescription, and maintain each such acknowledgement form for three years.[10] In response to the NPRM, the Commission received over 4,000 additional comments, many from prescribers concerned about the burden of the proposed signed acknowledgment requirement.[11]

In light of the comments received on the NPRM, the Commission determined that it would be beneficial to hold a public workshop on the Contact Lens Rule and the evolving contact lens marketplace to explore issues raised throughout the comment process as well as topics related to the evolution of the contact lens marketplace. On December 8, 2017, the Commission published a Federal Register Notice announcing the March 7, 2018 workshop[12] with a comment period closing on April 6, 2018. The workshop included six panels, covering issues relating to the overall contact lens marketplace, health and safety, competition, purchasing and verification, the proposed signed acknowledgment and consumer choice, and the future of contact lens prescribing and selling. In response to the Commission's comment request and workshop, the Commission received approximately 3,400 additional comments from a wide range of commenters, including numerous consumers and prescribers, as well as industry associations, state attorneys general, contact lens manufacturers, and retailers.[13]

After a thorough review of comments, workshop transcripts, and various empirical surveys and analyses, the Commission is now issuing a Supplemental Notice of Proposed Rulemaking, as opposed to implementing a Final Rule. Written comments must be received on or before July 29, 2019.

(9) Payments and Gifts to Respondents

Not applicable.

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[10] The Commission also proposed a technical amendment, to remove the words "private label" from Section 315.5(e) to conform the language of the Rule to that of the FCLCA. In addition to seeking comment on these proposals, the NPRM sought comment on the following issues: the provision of additional copies of prescriptions, the amount of time for a prescriber to respond to such a request, the use of patient portals to release prescriptions, and potential modifications to address concerns about automated telephone verification calls.

[11] Comments received in response to the NPRM are available at https://www.ftc.gov/policy/public-comments/2016/10/initiative-677.

[12] Public Workshop Examining Contact Lens Marketplace and Analyzing Proposed Changes to the Contact Lens Rule, 82 Fed. Reg. 57,889 (Dec. 8, 2017).

[13] Comments received in response to the workshop notice, as well as transcripts of, and materials from, the workshop, are available at https://www.ftc.gov/news-events/events-calendar/2018/03/contact-lens-rule-evolving-contact-lens-marketplace.

(10-11) Assurances of Confidentiality/Matters of a Sensitive Nature

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 PRA. In any event, in such proceedings, records would be protected by law from mandatory public disclosure.[14]

(12) Estimated Annual Hours Burden and Associated Labor Cost

Estimated Additional Annual Hours Burden: 597,917 hours (85,417 hours regarding signatures + 512,500 hours regarding their retention).

Commission staff estimates the PRA burden of the proposed modifications based on its knowledge of the eye-care industry. The staff believes there will be an additional burden on individual prescribers' offices to generate and present to patients the confirmations of prescription release, and to collect and maintain the confirmations of prescription release for a period of not less than three years.

The number of contact lens wearers in the United States is currently estimated to be approximately 41 million.[15] Therefore, assuming an annual contact lens exam for each contact lens wearer, approximately 41 million people would read and sign a confirmation of prescription release every year.[16]

The Commission believes that generating and presenting the confirmation of prescription release to patients will not require significant time. Creating the confirmation of prescription release should be relatively straightforward for prescribers since the Commission's proposal is flexible in that it allows any one of several different modalities and delivery methods to satisfy the requirement, including adding the confirmation to existing documents that prescribers routinely provide (sales receipts) or are already required to provide (prescriptions) to patients. The

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[14] *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).

[15] Jennifer R. Cope et al., "Contact Lens Wearer Demographics and Risk Behaviors for Contact Lens-Related Eye Infections—United States, 2014," Morb. Mortal. Wkly. Rep. 64(32):865-70, 866 (Aug. 21, 2015).

[16] In the past, some commenters have suggested that typical contact lens wearers obtain annual exams every 18 months or so, rather than one every year. Because most prescriptions are valid for a minimum of one year under the Rule, Commission staff will continue to assume conservatively for purposes of PRA burden estimation that patients seek exams every 12 months. However, as discussed *infra*, note 21 and accompanying text, prescription-confirmation releases would not be required under option § 315.5(c)(1)(iv).

Commission's proposal is also flexible in that it does not prescribe other details such as the precise content or language of the patient confirmation, but merely requires that, if provided to the patient in-person, the confirmation from the consumer must be in writing. At the same time, the Commission's proposal does not require that prescribers spend time generating their own content for the confirmation, since the Commission has provided draft language that prescribers are free to use to satisfy the requirement, if they so desire. Furthermore, the confirmation proposal is flexible enough to cover situations where a contact lens fitting is completed remotely, since a prescriber can readily satisfy the requirement by various methods, including email, text, or uploading the prescription to a patient portal.

The four proposed options for a prescriber to confirm a prescription release to a patient are set out in § 315.3(c). The first three options (§ 315.3(c)(1)(i), (ii), and (iii)), which direct a prescriber to provide information to a patient in the form of a confirmation of prescription release, are not disclosures constituting an information collection under the PRA because the FTC has supplied the prescriber with draft language the prescriber can use to satisfy this requirement.[17] However, as noted above, the collection of a patient's signature and the associated recordkeeping required constitutes an information collection as defined by OMB regulations that implement the PRA. Nonetheless, the Commission believes it will require minimal time for a patient to read the confirmation of prescription release and provide a signature. Based on a survey submitted in response to the NPRM, it would take consumers, on average, twelve seconds to read the two-sentence acknowledgment proposed by the Commission at the NPRM stage.[18] Since the new proposed confirmation of prescription release would be significantly shorter than the prior proposed acknowledgment, Commission staff expects that the time required to read and sign such confirmation would be less, perhaps half (six seconds). As noted above, a somewhat similar written acknowledgment requirement under HIPAA was estimated to require ten seconds for the consumer to complete.[19] Based on the consumer survey and prior estimate, the Commission allots ten seconds for the consumer to read and provide a signature.

The fourth option, § 315.3(c)(1)(iv), does not constitute an information collection under the PRA, since no new information is provided or requested of the patient. Excluding that from consideration and assuming the remaining three options are exercised with equal frequency, three-fourths or 75% of approximately 41 million annual prescription releases otherwise entail reading

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[17] "The public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public is not included within" the definition of "collection of information." 5 CFR 1320.3(c)(2).

[18] 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/meeting_summary_for_the_contact_lens_rulemaking_proceeding.pdf. The median was ten seconds.

[19] 67 FR at 53261.

and signing a confirmation statement. Thus, 85,417 hours, cumulatively (75% x 41 million prescriptions yearly x ten seconds each) would be devoted to those tasks.[20]

Maintaining those signed confirmations for a period of not less than three years should not impose substantial new burden on individual prescribers and their office staff. The majority of states already require that optometrists keep records of eye examinations for at least three years,[21] and thus many prescribers who opt to include the confirmation of prescription release on the prescription itself would be preserving that document, regardless. Similarly, most prescribers already retain customer sales receipts for financial recordkeeping purposes, and thus prescribers who opt to include the confirmation of prescription release on the sales receipt also could be retaining that document, regardless. Moreover, storing a one-page document per patient per year should not require more than a few seconds, and an inconsequential, or *de minimis*, amount of record space. As noted above, some prescribers might present the confirmation of prescription release electronically, and such format would allow the confirmation to be preserved without any additional burden. For other prescribers, the new recordkeeping requirement would likely require that office staff either preserve the confirmation in paper format or electronically scan the signed confirmation and save it as an electronic document. For prescribers who preserve the confirmation electronically, Commission staff estimates that scanning and saving the document would consume approximately one minute. Commission staff do not possess detailed information on the percentage of prescribers' offices that use paper forms, electronic forms, or that scan paper files and maintain them electronically. Thus, for purposes of this PRA analysis, Commission staff will conservatively assume that *all* prescriber offices require a full minute per confirmation for recordkeeping arising from the proposed modifications.

Excluding from PRA consideration the fourth option, §315.3(c)(1)(iv), as there is no signature to obtain or retain, and assuming that prescribers elect the remaining options three-fourths or 75% of the time, the recordkeeping burden for all prescribers to scan and save such confirmations would amount to 512,500 hours (75% x 41 million prescriptions yearly x one minute) per year. Thus, estimated incremental PRA recordkeeping burden for prescribers resulting from the proposed Rule modifications is 597,917 hours (85,417 hours regarding signatures + 512,500 hours regarding their retention).

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[20] The FTC has previously accounted for and retains active OMB clearance regarding its separate PRA burden estimates for prescriber release of prescriptions to patients (as opposed to the instant burden estimate for the time to read and sign a confirmation statement). Those previous estimates were one minute per prescriber and 683,333 hours, cumulative of the estimated 41 million prescriptions released annually. *See* 81 FR 31398, at 31939 (May 20, 2016); 81 FR 62501, at 62501 (Sept. 9, 2016).

[21] *See, e.g.*, 246 Mass. Code Regs. § 3.02 (requiring optometrists to maintain patient records for at least seven years); Wash. Admin. Code § 246-851-290 (requiring optometrists to maintain records of eye exams and prescriptions for at least five years); Iowa Admin. Code r. 645-182.2(2) (requiring optometrists to maintain patient records for at least five years); Fla. Admin. Code r. 64B13-3.003(6) (requiring optometrists to maintain patient records for at least five years).

Arguably, the overall burden of the Rule—including verification costs previously approved by the Office of Management and Budget[22]—could lessen (or not increase by as much as the incremental burden from the proposed Rule modifications), given potentially offsetting effects presented by the proposed modifications. As noted above, some commenters suggested that the increased burden from the proposed signed-acknowledgment requirement would be lessened or even outweighed by a reduced verification burden, because with more patients in possession of their prescriptions and able to present them to third-party sellers, fewer time-consuming verifications would be necessary.[23] Based on some commenter and Commission projections, a decrease of between 9%-23% in verifications could be sufficient to offset the entire cost of the signed-acknowledgment proposal.[24] Since the estimated burden for the confirmation of prescription release proposal is similar to that of the signed acknowledgment,[25] and would be expected to have the same offsetting effects, it is possible that the burden of the proposed modification would be offset to a great extent by a reduction in verifications. In the SNPRM, the Commission requests additional comment on whether and by how much a reduction in verifications would result from the confirmation of prescription proposal.

Since the Confirmation of Prescription Release proposal—in contrast to the Signed-Acknowledgment proposal—exempts prescribers who do not have a direct or indirect financial interest in the sale of contact lenses, this will also reduce the burden created by the new requirement. The Commission, however, does not currently possess information as to how many prescribers would qualify for the exemption due to a lack of financial interest in the sale of lenses. The Commission therefore has not reduced its PRA burden estimate accordingly. Instead, the

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[22] The Commission has estimated that prescribers' offices spend five minutes per verification request, based on information provided by the American Optometric Association. Agency Information Collection Activities; Submission for OMB Review, 81 FR 62501 (Sept. 9, 2016). The Commission has also estimated that sellers spend five minutes per verification request, and one minute on recordkeeping in non-verification circumstances (to preserve the prescription when presented by a patient); OMB Control No. 3084-0127.

[23] SNPRM at 24,678 [notes 183-190 and accompanying text].

[24] Based on the estimated burden for the Commission's prior signed-acknowledgment requirement proposal. SNPRM at 24,678 [note 186 and accompanying text].

[25] The estimated burden of the proposed confirmation requirement is lower than the signed-acknowledgment burden in terms of time required (597,917 hours for all prescribers and their staff compared to 683,333 hours for the signed-acknowledgment proposal, a decrease of approximately 13 percent). However, the estimated total financial burden is somewhat higher due to increases in average hourly wages for prescribers and staff since 2016, and due to the addition of time—now assigned to prescribers—to obtain a signature, in response to comments and information received subsequent to publication of the NPRM. Because of the higher overall cost, it might require a greater respective decrease in verifications to offset the financial burden. As noted, however, in the SNPRM at 24, 693 [note 352 and accompanying text], *none o*f the monetary burden-offset calculations takes into account the expected benefit to consumers of having their prescriptions and being able to choose from among competing providers; the savings consumers might achieve by purchasing lower-priced lenses; the improvements to health and safety due to a reduction in errors associated with invalid prescriptions currently verified through passive verification; and the Commission's improved ability to assess and verify compliance with the Rule.

SNPRM requests comment on the percentage of prescribers who would qualify for the proposed § 315.3(c)(3) exemption.

This PRA analysis also does not attempt to assess and estimate hours or cost burden for sellers regarding the proposed Rule modifications that would require those who use automated telephone messages, wholly or in part, to verify a prescription, to record the full call, among other steps associated with that proposed modification. As noted in the SNPRM's Section VIII.E. (Request for Comments/Automated Telephone Verification Messages), the Commission seeks comments to help inform such estimated burden, to the extent applicable.

Estimated Total Annual Labor Cost Burden: $13,244,727.

Commission staff derives labor costs by applying appropriate hourly cost figures to the burden hours described above. The prescriber task to obtain patient signed acknowledgments theoretically could be performed by medical professionals (e.g., optometrists, ophthalmologists) or support staff (e.g., dispensing opticians, ophthalmic medical technicians). To estimate associated labor costs, staff will conservatively assume that optometrists would perform the task.[26] Applying a mean hourly wage of $57.26[27] for optometrists to the above-noted estimate of 85,417 hours, resultant aggregate labor costs to obtain patient signatures would be $4,890,977.

Commission staff assumes that office clerks will typically perform the labor pertaining to the printing, scanning and storing of prescription release confirmations. Applying a mean hourly wage for office clerks of $16.30 per hour,[28] to the above-noted estimate of 512,500 hours, cumulative labor costs for those tasks would total $8,353,750.

Therefore, combining the aggregate labor costs for both prescribers and office staff to obtain patient signed acknowledgments and preserve the associated records, the Commission estimates the total labor burden of the confirmation of prescription release proposal to be $13,244,727.

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[26] It is not certain that this assumption is well-founded. *See* CLR Panel IV Tr., SNPRM at 24,674 [note 126, at 8] (statements of David Cockrell that, in his office, the staff handle all the verification calls). Many prescribers may use office staff to handle verification calls, which would result in a significantly lower burden calculation for prescribers' offices than what the Commission previously calculated. Without more empirical data as to who handles most verification requests, however, the Commission will continue to use the estimate for prescribers, even if it might overstate the actual burden.

[27] Economic News Release, U.S. Dep't of Labor, Bureau of Labor Statistics, Table 1. National employment and wage data from the Occupational Employment Statistics survey by occupation, May 2017: https://www.bls.gov/news.release/ocwage.t01.htm ("BLS Table 1").

[28] BLS Table 1.

(13) Estimated Annual Capital or Other Non-Labor Costs

The proposed recordkeeping requirements detailed above regarding prescribers impose negligible capital or other non-labor costs, as prescribers likely have already the necessary equipment and supplies (e.g., prescription pads, patients' medical charts, scanning devices, recordkeeping storage) to act upon those requirements.

(14) Estimated Cost to Federal Government

Staff believes that the cost to the FTC for administering the proposed Rule changes will be *de minimis*. Accordingly, Commission staff retains the previous estimate of $52,000 per year as the cost to the Government for implementing the Rule. 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/Adjustments

The proposed amendments will result in an estimated additional 597,917 burden hours, annualized, and cumulative of all affected manufacturers, $13,244,727 in associated labor costs, and negligible capital/non-labor costs.

(16) Plans for Tabulation and Publication

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.