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Part III

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16 CFR Parts 315 and 456
Contact Lens Rule; Final Rule

FEDERAL TRADE COMMISSION

16 CFR Parts 315 and 456

RIN 3084–AA95

Contact Lens Rule

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Trade Commission (the ''Commission'') issues a Final Rule implementing the Fairness to Contact Lens Consumers Act (the ''Act''), 15 U.S.C. 7601 *et seq.*, which provides for the availability of contact lens prescriptions to patients and the verification of contact lens prescriptions by prescribers. This document also implements two clerical amendments to the Commission's Ophthalmic Practices Rules to clarify the distinction between those Ophthalmic Practices Rules and the Contact Lens Rule.

DATES: *Effective Date:* The Rule will become effective on August 2, 2004.

ADDRESSES: Requests for copies of the Rule and the Statement of Basis and Purpose should be sent to the Commission's Public Reference Branch, Room 130, Federal Trade Commission, 600 Pennsylvania Avenue, NW., Washington, DC 20580. The complete record of this proceeding is also available at that address. Relevant portions of the proceeding, including the Rule and Statement of Basis and Purpose, are also available at the Commission's Web site, *http://www.ftc.gov.*

FOR FURTHER INFORMATION CONTACT: Division of Advertising Practices, Thomas Pahl or Char Pagar [(202) 326–3528], Federal Trade Commission, Bureau of Consumer Protection, Division of Advertising Practices, 600 Pennsylvania Avenue, NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: The Contact Lens Rule (''the Rule'') implements the requirements of the Fairness to Contact Lens Consumers Act (''the Act''), 15 U.S.C. 7601–7610. Specifically, the Rule: (1) Requires prescribers (such as optometrists and ophthalmologists) to provide patients with a copy of their contact lens prescription immediately upon completion of a contact lens fitting; (2) requires prescribers to provide or verify contact lens prescriptions to any third party designated by a patient; (3) prohibits prescribers from placing certain conditions on the release or verification of a contact lens prescription; (4) limits the circumstances under which a provider can require payment for an eye exam prior to releasing a contact lens prescription to a patient; (5) requires contact lens sellers to either obtain a copy of a patient's prescription or verify the prescription before selling contact lenses; (6) addresses the issue of private label contact lenses; (7) sets minimum expiration dates for contact lens prescriptions; (8) prohibits representations that contact lenses may be obtained without a prescription; (9) prohibits prescribers from using or requiring patients to sign any waiver or disclaimer of liability for the accuracy of an eye examination; (10) defines relevant terms; (11) establishes that violations of the proposed Rule will be treated as violations of a rule defining an unfair or deceptive act or practice under section 18 of the Federal Trade Commission Act; and (12) provides that State and local laws and regulations are preempted under certain circumstances.

Statement of Basis and Purpose

I. Introduction

On December 6, 2003, President Bush signed the Act into law.[1] Among other things, the Act requires that prescribers, including optometrists and ophthalmologists, provide contact lens prescriptions to their patients upon the completion of a contact lens fitting.[2] The Act also mandates that prescribers verify contact lens prescriptions to third-party contact lens sellers who are authorized by consumers to seek such verification.[3] The Act directs the Commission to prescribe implementing rules.[4] Any violation of the Act or its implementing rules constitutes a violation of a rule under Section 18 of the Federal Trade Commission Act, 15 U.S.C. 57a, regarding unfair or deceptive acts or practices.[5] The Act authorizes the Commission to investigate and enforce the Act in the same manner, by the same means, and with the same jurisdiction, powers, and duties, as a trade regulation rule under the Federal Trade Commission Act.[6]

The Commission published a Notice of Proposed Rulemaking and Request for Public Comment (''NPRM'') in the **Federal Register** on February 4, 2004,[7] and the 60-day comment period closed on April 5, 2004. The Commission received more than 7,000 comments. The commenters included nearly 6,000 individual consumers as well as prescribers, their State and national trade associations, contact lens sellers, State attorneys general, and others. Based on the rulemaking record, including the comments received, the Commission has modified the proposed Rule published in the NPRM and now promulgates a final rule as described in this Statement of Basis and Purpose.

In addition, the Commission enforces the Ophthalmic Practice Rules,[8] which primarily require the release of eyeglass prescriptions to patients at the completion of an eye examination, and prohibit eye care practitioners from placing certain conditions on such release. The Commission today implements two clerical amendments, set forth in section III below, to clarify the relationship between the Ophthalmic Practices Rules and the Contact Lens Rule.

II. The Rule

As noted above, the Commission published the proposed rule and accompanying analysis in the **Federal Register** on February 4, 2004.[9] Unless specifically modified herein, all of the analysis accompanying the proposed rule in the NPRM is adopted and incorporated into this Statement of Basis and Purpose for the final rule.

A. Section 315.1: Scope of Regulations

Section 315.1 of the proposed Rule described the basis for, and the general scope of, the regulations in part 315—the ''Contact Lens Rule''—which implements the Fairness to Contact Lens Consumers Act. The Commission received no comments on this provision and adopts it without modification.

B. Section 315.2: Definitions

1. Definition of ''Business Hour''

Congress recognized that consumers may be harmed if they face undue delays in receiving their contact lenses from a seller. Congress also acknowledged that consumers may be harmed if a seller provides contact lenses to a consumer based on an expired, inaccurate, or otherwise invalid prescription. Congress balanced these considerations in section 4(d)(3) of the Act by allowing a seller to treat a prescription as ''verified'' and sell contact lenses to a consumer if a prescriber has not notified the seller ''within eight (8) business hours, or a similar time as defined by the Commission,'' that a prescription is expired, inaccurate, or otherwise invalid.[10]

[1] 15 U.S.C. 7601–7610 (Pub. L. 108–164).

[2] *Id.* at 7601.

[3] *Id.* at 7601, 7603.

[4] *Id.* at 7607.

[5] *Id.* at 7608.

[6] *Id.*

[7] 69 FR 5440 (Feb. 4, 2004).

[8] 16 CFR part 456.

[9] 69 FR 5440 (Feb. 4, 2004).

[10] 15 U.S.C. 7603(d)(3).

The Act does not define ''business hour'' or set forth how to calculate ''eight business hours.'' The purpose of the verification period established under the Act, however, is to give prescribers an opportunity to determine whether prescriptions are expired, inaccurate, or otherwise invalid. Because prescribers make this determination during the hours that they are open, Congress apparently intended prescribers to have eight hours during which they are open for business to respond to a verification request.

Accordingly, in the proposed Rule, the Commission defined ''business hour'' as an hour between 9 a.m. and 5 p.m., during a weekday excluding Federal holidays. The definition further specified that for verification requests received between 9 a.m. and 5 p.m., ''eight (8) business hours'' would be calculated from the first business hour that occurs after the seller provides the prescription verification request to the prescriber, and conclude after eight business hours have elapsed. For verification requests received by a prescriber during non-business hours, the calculation of eight business hours would begin at 9 a.m. on the next weekday that is not a Federal holiday, and would end at 9 a.m. on the following weekday.

For the reasons discussed below, the Commission retains the definition of ''business hour'' as an hour between 9 a.m. and 5 p.m., during a non-holiday weekday. However, the Commission has revised the rule to provide sellers with the option of counting a prescriber's regular business hours on Saturdays, so long as the seller has actual knowledge of these hours. In addition, the Commission has revised the calculation of ''eight (8) business hours'' so that the verification period ends—and a seller may sell contact lenses—as soon as eight business hours have elapsed. Finally, the Commission clarifies that business hours are to be determined based on the time zone of the prescriber.

a. Actual Hours

The Commission's proposed definition of ''business hour'' generated a substantial number of public comments. A number of comments sought a definition that reflects prescribers' actual business hours. For example, one large Internet-based contact lens seller urged that sellers should have the option of determining the actual business hours of a particular prescriber and using those as an alternative to the Rule's ''default'' business hours.[11]

A number of prescribers and their trade associations also sought a definition of ''business hours'' that reflects actual business hours. These commenters, however, explained that the Commission's proposed definition did not take into account days when a prescriber's office is closed and the prescriber cannot respond to a verification request within eight business hours. These commenters sought various exceptions or extensions to the business hour definition to accommodate circumstances such as days the prescriber's office is regularly closed; days the prescriber is performing surgery; and days a prescriber is out of the office for continuing education, illness, vacation, or inclement weather.[12] Many commenters also sought an exception for so-called ''satellite offices,'' described as prescriber offices commonly located in rural areas and open only one or two days per week.[13] Other commenters emphasized generally that actual prescriber business hours vary from those of other retail and Internet businesses, and urged the Commission to craft a rule that ''serves the best interests and safety of the consumers, not just those of contact lens sellers.''[14]

Few of the voluminous comments received on this issue proposed a means of accommodating the requested exceptions. Some suggested providing a longer verification period generally,[15] while others suggested that the prescriber's office be permitted to inform the seller of the prescriber's return date, or the date on which the office would next be open, at which time the eight business hour verification period would commence.[16] One commenter suggested that, prior to requesting verification, a seller should first have to determine that the prescriber's office is open and that the prescriber will be present in the office during the next eight hours.[17]

Having considered these comments, the Commission declines to adopt an actual hours or other prescriber-specific approach to business hours. Evidence in the record indicates that there are more than 50,000 prescribers in the United

[11] 1–800 CONTACTS (Comment #1140). The Mercatus Center at George Mason University (Regulatory Studies Program) (Comment #1087) made a similar proposal.

[12] *E.g.,* American Optometric Association (Comment #1149) (citing continuing education, vacation and illness); American Academy of Ophthalmology (Comment #1057) (9–5 Monday through Friday does not address realities of ophthalmologic practice; approximately 40% of its members are solo practitioners; Rule should make exceptions for surgery days, continuing education, a weekday when the office is regularly closed, State or religious holidays, solo practitioner illness and/or vacation days, and for local, State, or federally mandated jury duty); New Jersey Academy of Ophthalmology (Comment #1126) (most physicians are closed one day per week and close for vacation several weeks per year; requiring coverage from 9–5 every Monday through Friday is unrealistic and unduly burdensome); Nebraska Optometric Association (Comment #1083) (seeking ''reasonable extensions'' of eight-hour rule when doctor is absent for continuing education, vacation, or illness); Ohio Optometric Association (Comment # 1151) (same, citing continuing education obligations, illness, vacation, periods of unplanned practice interruptions); New Mexico Optometric Association (Comment # 1081) (continuing education, vacation and illness); C. Lesko, M.D., FACS (Comment #960) (performs surgery two days a week); Kansas Optometric Association (Comment #1153) (citing continuing education (24 hours per year in Kansas), vacation and illness); American Society of Cataract and Refractive Surgery (Comment #1148); E. Lamp, O.D. (Comment #714).

[13] *E.g.,* Kansas Optometric Association (Comment #1153) (citing approximately 60 satellite offices in State); Kentucky Optometric Association (Comment #1101); Colorado Optometric Association (Comment #1067); American Optometric Association (Comment #1149); Nebraska Optometric Association (Comment #1083) (seeking ''reasonable extension'' of eight-hour rule for verifications sent to satellite offices); Pennsylvania Optometric Association (Comment #959); Ohio Optometric Association (Comment # 1151); New Mexico Optometric Association (Comment # 1081); B.L.Whitesell, O.D. (Comment #1115); S. Wagner, M.D. (Comment #928). A number of these commenters explained that the records for patients of satellite offices are often kept at the satellite office and thus, on days the office is not open, are not readily accessible for verification during an eight-hour window.

[14] A.L. Warner (Comment #706).

[15] *E.g.,* Texas Ophthalmological Association (Comment #1117).

[16] *E.g.,* American Optometric Association (Comment #1149); Ohio Optometric Association (Comment # 1151); American Society of Cataract and Refractive Surgery (Comment #1148) (prescriber could be required to leave information on answering service, voicemail, or answering machine); B.L. Whitesell, O.D. (Comment #1115) (willing to tell sellers what his hours are); K. Driver, O.D. (Comment #273) (same); S. Wagner, M.D. (Comment #928) (Rule should allow prescriber to respond within eight hours to a faxed request to a satellite office, providing a specific statement that the records are in a remote location and will be available for review on a certain date). *See also* Pennsylvania Optometric Association (Comment #959) (stating some of its members have contacted seller and asked them to fax verification request to the main office but seller refused).

[17] Tupelo Eye Clinic/Chappell (Comment #11). Other commenters made similar suggestions. *E.g.,* New Jersey Academy of Ophthalmology (Comment #1126) (suggesting physicians be permitted extra time beyond the eight business hours to comply, or exempting from liability physicians who could not verify a prescription due to office closure); Your Family Eye Doctors, Inc. (Comment #705) (recommending 24 business hours for verification rather than eight, to accommodate satellite offices); G. Lozada (Comment #1063) and Opticians Association of Ohio (Comment #1156) (also suggesting 24 hours); American Academy of Ophthalmology (Comment #1057) (suggesting time period for verification begin at 9:00 a.m. on the next business weekday that the office is open).

States,[18] and that actual business hours vary widely among them.[19] It likely would be difficult and burdensome—perhaps impossible—for some sellers to determine and keep track of the actual hours of 50,000 prescribers.[20] By contrast, a general rule using a uniform definition of business hours for all prescribers provides clarity and relative ease of compliance and enforcement. Moreover, there does not appear to be any practical way to accommodate the myriad circumstances during which the offices of 50,000 individual prescribers may be closed or otherwise not able to respond to a prescription verification request.[21]

In addition, several commenters, including optometric associations and one State board, voiced support for the proposed definition, particularly its limitation to weekdays and non-holidays.[22] One commenter stated that ''it would be impractical for the Commission to craft store- or prescriber-specific rules.'' [23] Similarly, other commenters opposed exceptions or extensions for days a prescriber's office may be closed for vacation, State or local holidays, or other reasons. These commenters argued that making such exceptions would impose undue burdens on small sellers to keep track of such closures, thereby harming their ability to compete with larger sellers. These commenters also argued that it would unreasonably delay delivery of contact lenses to consumers.[24]

b. General Rule

Having determined that a general rule using uniform business hours is preferable to an actual hours standard, the Commission discusses below the remaining comments received on its proposed definition and the revisions the Commission has made to the Rule in response.

1. Monday Through Friday

A number of commenters offered alternative definitions of business hours. A few commenters, including the California Board of Optometry, urged the Commission to consider adopting a verification time period that tracks California State law.[25] Under California's prescription release law, a prescription is verified if the prescriber does not respond by or before the same time on the next business day after the seller requested verification, or by 2 p.m. the next business day, whichever is earlier.[26]

One contact lens seller, Wal-Mart, proposed a ''24-hour'' rule, somewhat similar to California's, under which the verification period would expire at the same time on the next business day after the prescriber received the verification request.[27]

Another seller, 1–800 CONTACTS, proposed defining ''business hours'' as 9 a.m. to 6:30 p.m., Monday through Friday, and 9 a.m. to 4 p.m. on Saturday, based on a survey of actual prescriber business hours.[28] The survey itself concluded that a ''standardized work week'' for optical goods retailers is 9 a.m. to 6:15 p.m. Monday through Thursday, 9 a.m. to 6 p.m. Friday, and 9 a.m. to 4:15 p.m. Saturday.[29]

Finally, a group of 34 State Attorneys General commented that the proposed definition was too narrow because many prescribers are open longer hours and on weekends.[30] The Attorneys General offered three alternatives, with a preference for a definition that would allow the eight-hour verification period to end when the eight business hours elapse, not at the start of the next business hour.[31]

[18] *See, e.g.*, American Optometric Association (Comment #1137) (representing some 33,000 members). In addition, the American Academy of Ophthalmology has represented to Commission staff that it represents approximately 17,000 members.

[19] *See, e.g.*, comments discussed *supra*; 1–800 CONTACTS (Comment #1140) at attachment 32 (survey of prescribers' actual hours).

[20] *Cf.* AC Lens (Comment # 974) (arguing that Rule should not exclude State or local holidays as business days because doing so would put unreasonable burden on smaller entities in other States that have no practical way to track down such holidays in all 50 States).

[21] The suggestion that a prescriber's staff be permitted to contact the seller and inform them of the prescriber's absence—and thereby obtain an extension to the eight hour verification period—is simply not practical. Such a system would work only if prescribers' offices were staffed on the relevant day, and the public comments made clear that in many cases the office is simply closed—*e.g.*, because it is a satellite office, the office is regularly closed on a certain weekday, or due to inclement weather.

[22] *E.g.,* Florida Board of Optometry (Comment #1100); National Association of Optometrists and Opticians (Comment #1146) (supporting limitation to weekdays and non-holidays); American Optometric Association (Comment #1149) (supporting proposed definition because it ''recognizes the fact that while some offices are open on some Saturdays, most are not open every Saturday, and many are not open any Saturday'').

[23] National Association of Optometrists and Opticians (Comment #1146).

[24] AC Lens (Comment # 974); R.Weigner (Comment #1118) (information about State and local holidays is not available to national mail order and internet firms; even if it were available, it would be cost-prohibitive to implement and would stifle competition).

[25] *E.g.,* California Board of Optometry (Comment #21); Hon. Jim Matheson, U.S. House of Rep. (Comment #1237); L. Correa, California Assembly Rep. (Comment #1142); Citizens for a Sound Economy (Comment #1108) (noting the California law ''has been in place for over a year, and has worked well''); William F. Shughart, II, Ph.D. (Comment #975) (on behalf of 1–800–CONTACTS).

[26] California's statute took effect in January 2003, just over one year before the Fairness to Contact Lens Consumers Act took effect.

[27] Wal-Mart Optical Division (Comment #1070).

[28] 1–800 CONTACTS (Comment #1140). The survey, submitted as part of the record in this proceeding, was prepared by Synovate, a market research firm, and consisted of 300 telephone interviews for each of four retail channels—independent optometrists, ophthalmologists, optical retail chains (*e.g.*, LensCrafters, Pearle Vision), and mass merchandisers (*e.g.*, Wal-Mart, Target, Costco)—asking about store business hours. *See* Comment #1140, attachment 32. From the interview results, average opening and closing times were determined for each day of the week for each retail channel as follows:

Mass merchandisers: approximately 9:15 a.m. to 8:35 p.m. Monday through Friday, Saturday 8:45 a.m. to 7:25 p.m., Sunday 11:25 a.m. to 5:05 p.m.

Retail optical chains: approximately 9:45 a.m. to 7:25 p.m. Monday through Thursday, Friday 9:40 a.m. to 7:15 p.m., Saturday 9:40 a.m. to 6:05 p.m., Sunday 11:35 a.m. to 5:15 p.m. (49% are closed Sunday).

Independent optometrists: approximately 9 a.m. to 5:50 p.m. Monday, Tuesday, Thursday, Wednesday 9 a.m. to 5:35 p.m., Friday 8:50 a.m. to 5:20 p.m., Saturday 9 a.m. to 2:40 p.m. (39% are closed Saturday, 91% are closed Sunday).

Ophthalmologists: approximately 8:35 a.m. to 5:10 p.m. Monday through Thursday, Friday 8:30 a.m. to 4:35 p.m., Saturday 8:40 a.m. to 1:25 p.m. (75% are closed Saturday, 98% are closed Sunday).

[For purposes of simplicity, the Commission has rounded off some of the averages set forth in the survey results to the closest 5-minute increment.] Then, final average daily opening and closing times—combining all four channels—were determined by weighting each channel's average to match the actual incidence of lenses dispensed among the four channels.

[29] *See* Comment #1140, attachment 32.

[30] State Attorneys General (Comment #1114). This comment represented the views of the Attorneys General representing Alabama, Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Iowa, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nevada, New York, North Dakota, Commonwealth of the Northern Mariana Islands, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Utah, Virginia, Washington, West Virginia, Wisconsin, and Wyoming. The Attorney General of Idaho filed a separate comment (Comment #1176) joining the other States.

The Independent Women's Forum (Comment #1236) raised many of the same arguments as the State Attorneys General, and argued that the proposed definition of ''business hours'' would ''seriously undermine[] women's autonomy by reversing the conveniences that have been created, in part, to support working women and mothers.'' *See also* Hon. J. Sensenbrenner (Comment # 1246) (arguing proposed definition ''bears no relation to the way either consumers or retailers behave''); Progressive Policy Institute (Comment #1141) (recommending broader definition of business hour because eye care providers can sell contact lenses to consumers any time they are open but would only have to verify prescriptions between 9–5 on weekdays); Americans for Prosperity (Comment #1145) (proposed definition is not grounded in actual practices of the eye care industry).

[31] The other alternatives were: (1) Using an ''actual hours'' standard under which sellers would be obligated to know the actual business hours of each prescriber, and would be permitted to presume verification (and ship an order) after the prescriber had received the request and been open for eight

The Commission addresses the commenters' specific proposals in detail below. However, having considered the comments, the Commission has decided to retain the proposed definition of ''business hour'' as an hour between 9 a.m. to 5 p.m. on a non-holiday weekday. Evidence in the record clearly indicates that the 50,000 prescribers in the United States vary as to their actual business hours—in some cases widely. However, the Act clearly contemplates that prescribers should have a reasonable opportunity when they are open to respond to verification requests. The evidence indicates that most prescribers are open Monday through Friday, and that most are open for at least eight hours per day. Some appear to open earlier than 9 a.m., and some appear to be open after 5 p.m., but a 9 a.m. to 5 p.m. rule generally should provide these prescribers eight hours during which they are actually open to respond to prescription verification requests.[32] Moreover, such a general rule should be easy for sellers and prescribers to apply, because eight business hours would usually end at the exact same time on the following business day. For example, if a verification request is received at 2 p.m. on a Tuesday, the prescriber would have until 2 p.m. on Wednesday to respond.

2. Saturday

Several commenters urged the Commission to include Saturday business hours in the Rule's definition of ''business hours.'' [33] Sellers argued that many prescribers are, in fact, open on Saturdays, and that current retail operations in the United States typically include Saturday business hours.[34] The California Board of Optometry noted that California's prescription release law recognizes Saturday as a business day—''to accommodate the operational needs of contact lens sellers''—and argued this model has proven successful.[35]

Other commenters, however, pointed out that many prescribers are *not* open on Saturdays.[36] The evidence in the record supports this argument, indicating that a significant number of prescribers are not regularly open on Saturdays. Survey data indicates that 39% of optometrists and 75% of ophthalmologists are closed on Saturday,[37] and that these groups issue a substantial majority of contact lens prescriptions. This conclusion is generally consistent with the estimates that some prescribers made in their comments.[38]

Based on the comments and evidence, the Commission has revised the Rule to give sellers the *option* of determining whether an individual prescriber in fact has regular Saturday business hours, and, if so, to include those hours in the eight-hour verification period prescribed in section 315.5(c)(3). A rule requiring that Saturday hours be counted as business hours would deny many prescribers who are not open a reasonable opportunity to respond to prescription verification requests. At the same time, not counting Saturdays at all would deny consumers the opportunity to have their prescriptions verified by those prescribers who *are* open, and to receive their lenses more quickly.

Because it may be burdensome for some sellers to obtain actual knowledge of prescribers' Saturday business hours,[39] the Commission concludes that the Rule should provide sellers the option of counting those hours, rather than requiring them to do so. This approach will enable a consumer whose prescriber is open on Saturday, and who wants to receive lenses as quickly as possible, to find a seller that will determine the prescriber's Saturday hours. In addition, this approach should be easy for prescribers to implement, because only those that are open will have to respond to verification requests on Saturdays.

To facilitate the use of Saturday business hours, the final Rule incorporates two related revisions to the proposed Rule. First, a seller that exercises its option to count a prescriber's regular Saturday business hours must state those hours clearly on the verification request.[40] This requirement will alert the prescriber that the seller is in fact counting Saturday hours—so that the prescriber can respond appropriately—and also provide an opportunity for the prescriber to notify the seller if the seller uses the wrong hours. Second, a seller exercising its option to count a prescriber's regular Saturday business hours must maintain a record of those hours and the basis for the seller's actual knowledge of what those hours are—*i.e.*, how the seller determined the hours.[41] These related provisions are intended to promote accuracy by sellers and facilitate enforcement.

3. Sunday

The proposed definition of ''business hour'' excluded Sundays. The Commission did not receive any comments advocating the inclusion of Sundays in business hours. The evidence in the record also suggests that most prescribers are closed that day.[42] Accordingly, the Commission retains the exclusion of Sundays from the definition of business hour.

4. Federal Holidays

The Commission's proposed definition of ''business hour'' did not count Federal holidays. One commenter suggested that the definition should include all Federal holidays except the ''major'' ones—*i.e.*, Christmas, New Year's Day, and Thanksgiving—because ''most businesses'' are open on the other Federal holidays.[43] The record in this

business hours; and (2) allowing sellers the option of using the 9 a.m. to 5 p.m. non-holiday weekday definition or the actual prescriber business hours. *See* Comments ##1114, 1176.

[32] The Commission notes that this rule has a similar practical effect as the California model and the ''24-hour rule'' promoted by a number of commenters. In many cases, the verification period will expire at the same time, on the next business day, after the prescriber receives the request, regardless of which model is utilized. For example, a request received at 10 a.m. on a Tuesday would be deemed verified at 10 a.m. on Wednesday under the Commission's definition, the California model, or the 24-hour rule. In some instances, the Commission's Rule will result in quicker verification than under other proposed models; for requests received prior to 9 a.m. on a Monday through Friday, the prescription will be verified at 5 p.m. that same day rather than at 9 a.m. the following business day under the California model or the 24-hour rule.

[33] *E.g.,* California Board of Optometry (Comment #21); AC Lens (Comment # 974); Costco Wholesale Corporation (Comment #1061); 1–800 CONTACTS (Comment #1140); Wal-Mart Optical Division (Comment #1070); Citizens for a Sound Economy (Comment #1108).

[34] *E.g.,* 1–800 CONTACTS (Comment #1140); Costco Wholesale Corporation (Comment #1061); *See also* Wal-Mart (Comment #1070) (arguing that many working people can only shop in the evening, and that ''contact lens prescribers should be presumed to work normal business hours on days when most other people work, whether or not they actually do so'').

[35] California Board of Optometry (Comment #21). By contrast, however, the California Optometric Association argued against including Saturday business hours. *See* Comment #1158.

[36] *E.g.,* National Association of Optometrists and Opticians (Comment #1146); American Optometric Association (Comment #1149).

[37] *See* 1–800 CONTACTS (Comment #1140) at attachment 32.

[38] National Association of Optometrists and Opticians (Comment #1146) (estimating more than half practitioners are not open on Saturdays; supporting limitation to non-holiday weekdays); American Optometric Association (Comment #1149) (supporting proposed definition of business hours because it ''recognizes the fact that while some offices are open on some Saturdays, most are not open every Saturday, and many are not open any Saturday'').

[39] *Cf.* AC Lens (Comment # 974) (arguing that Rule should not exclude State or local holidays as business days because doing so would put unreasonable burden on smaller entities in other States that have no practical way to track down such holidays in all 50 States).

[40] *See* discussion of section 315.5(b) *infra.*

[41] *See* discussion of section 315.5(g) *infra.*

[42] *See, e.g.,* 1–800 CONTACTS (Comment #1140) at attachment 32 (indicating 49% of retail optical chains, 91% of independent optometrists, and 98% of ophthalmologists are closed on Sunday).

[43] Wal-Mart Optical Division (Comment #1070). *See also* AC Lens (Comment #974) (arguing that

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proceeding, however, does not provide evidence indicating that most prescribers are open on the other Federal holidays. Because the Act is intended to give prescribers eight business hours during which they are open to respond to a verification request, the Commission declines to count ''non-major'' Federal holidays in the definition of business hour and, accordingly, retains the proposed definition of ''business hour'' as excluding Federal holidays.

c. Calculation of Eight Business Hours

The Commission received a number of comments on its proposed method of calculating eight business hours, some of which are discussed above. Under the proposed Rule, the eight-hour verification period would have expired—and a seller could ship a customer's order—at the start of the next business hour *after* eight such hours had elapsed. Overall, these comments objected to the ''eight-hours-plus-one-day'' verification period that would result in some circumstances.[44] For example, the State Attorneys General argued that the eight hours should not exceed one business day; otherwise, it would undermine the Act's intent to increase consumer choice and convenience.[45] They pointed out that the Act deems a prescription verified if the prescriber does not respond ''within'' eight hours. The proposed Rule's requirement that seller wait longer than those eight hours—and often an extra day—before shipping is not justified and likely will have anticompetitive effects.[46]

The Commission recognizes that its proposed method of calculation would have imposed significant delays on sellers and consumers under some limited circumstances. For example, a verification request received after 5 p.m. on a Tuesday would not be deemed verified until 9 a.m. on Thursday. In addition, a request received after 5 p.m. on a Friday would not be deemed verified until 9 a.m. the following Tuesday—or at 9 a.m. the following Wednesday if Monday were a Federal holiday. Although the latter scenario would not occur frequently, such delay would have been significant.

Accordingly, the Commission has clarified in the final Rule that the eight-hour verification period ends—and a seller may sell contact lenses—*when* eight business hours have elapsed. Thus, for example, if a prescriber receives a proper verification request before 9 a.m., the seller may ship a customer's order at 5:01 p.m. if the prescriber has not responded that the prescription is expired, inaccurate, or otherwise invalid. Under this approach, prescribers will have a reasonable opportunity to respond to verification requests, and consumers will obtain the benefits from expeditious verification.

In addition, the Commission has clarified that the time period is calculated from the time the *prescriber receives* a proper verification request from a seller, rather than when the seller provides the request to the prescriber as stated in the proposed Rule.[47] That is, if a prescriber receives a verification request during business hours (as defined in the final Rule), the eight-hour verification period begins immediately; if a prescriber receives a request during non-business hours, the eight hours begins at the start of the next business hour. This clarification is necessary to harmonize the definition of ''business hour'' with section 4(d)(3) of the Act, which provides that a prescription is verified if the prescriber fails to communicate ''within eight (8) business hours after receiving from the seller'' the information required to make a verification request.[48]

d. Time Zone

A number of prescribers, as well as national and state optometric associations, commented that the Rule should specify that business hours are calculated based on the prescriber's time zone, not the seller's.[49] The Commission agrees that the Rule should make clear which time zone applies. Given that Congress intended to give prescribers eight business hours during which they are open to verify prescriptions,[50] the Commission concludes that ''business hour'' should be determined based on the prescriber's time zone, and has revised the Rule accordingly.

2. Definition of ''Commission'

The proposed Rule defined ''Commission'' to mean the Federal Trade Commission.[51] The Commission received no comments on this definition and adopts it, without modification, in the final Rule.

3. Definition of ''Contact Lens''

The Act does not define the term ''contact lens.'' In the NPRM, the Commission asked whether the Rule should define the term and, if so, whether the definition should include non-corrective (*e.g.*, decorative) lenses.[52]

The Commission received a number of comments on this issue. Most commenters recommended defining the term, and most urged the Commission to specifically include ''cosmetic,'' ''decorative,'' or ''non-corrective'' lenses, or otherwise explicitly state that the Rule applies to *all* contact lenses.[53] The primary reason stated was that both corrective and non-corrective lenses pose health risks to consumers and therefore a prescription should be required to obtain them. One commenter also stated that Congress did not draw any distinction in the Act between different types of lenses, and therefore the definition in the Rule should not.[54]

Two commenters noted, however, that some cosmetic lenses currently are available without a prescription.[55] To

Federal holidays should only be the major ones when majority of retail businesses are closed).

[44] *E.g.,* Hon. J. Sensenbrenner (Comment # 1246) (objecting to the eight-hours-plus-one-day calculation of eight business hours).

[45] State Attorneys General (Comments ##1114, 1176).

[46] *See also* The Independent Women's Forum (Comment #1236) (objecting to ''eight-hours-plus-one-day'' calculation); Hon. J. Sensenbrenner (Comment #1246) (same). In addition, hundreds of consumers stated that an eight-hour-plus-one-day verification period was too long. *See, e.g.,* Comments #142, 143, 431, 463, 555, 571, 602–05, 616, 617, 620, 629, 631–36, 638, 640, 641, 644–47, 649, 670, 674, 680, 682, 685, 690, 691, 697, 709, 710, 726, 727, 731, 732, 746–51, 753, 754, 755, 760, 763, 766, 777, 779, 782, 787–89, 799, 803.

[47] The proposed Rule had stated that eight business hours would begin ''at the time that the seller provides the prescription verification request to the prescriber.'' 69 FR at 5441.

[48] 15 U.S.C. 7603(d).

[49] *E.g.,* M. Spittler (Comment #158); Wheaton Eye Clinic (Comment #416); C.W. Kissling, O.D. (Comment #452); E. Attaya (Comment #952); Pennsylvania Optometric Association (Comment #959); Olathe Family Vision (Comment #971); Kansas Optometric Association (Comment #1153); Colorado Optometric Association (Comment #1067); New Mexico Optometric Association (Comment #1081); Kentucky Optometric Association (Comment #1101); National Association of Optometrists and Opticians (Comment #1146); American Optometric Association (Comment #1149); Ohio Optometric Association (Comment #1151); California Optometric Association (Comment #1158). Two other commenters more generally asked the Commission to specify which time zone applies. K. Poindexter (Comment #260); E. Lamp, O.D. (Comment #714).

[50] 15 U.S.C. 7603(d).

[51] *See* 69 FR at 5448.

[52] 69 FR at 5447.

[53] K. Green (Comment #4); C. Smith (Comment #6); M. Davis (Comment #8); M. Walker (Comment #10); W. Lindahl (Comment #16); W. West (Comment #126); Poindexter (Comment #260); Illinois Optometric Association (Comment #1005); Kansas Board of Examiners in Optometry (Comment #1007); American Optometric Association (Comment #1149); Kansas Optometric Association (Comment #1153); New Mexico Optometry Association (Comment #1081); Ohio Optometric Association (Comment # 1151); California Optometric Association (Comment #1158).

[54] American Optometric Association (Comment #1149).

[55] American Society for Cataract and Refractive Surgery (Comment #1148); Mercatus Center at

avoid ambiguity about the Rule's applicability to such lenses, one of these commenters recommended that the Commission define ''contact lens'' as ''any contact lens for which state or federal law requires a prescription.'' [56]

The Act focuses on the release and verification of contact lens prescriptions. The Act also prohibits advertising that contact lenses ''may be obtained without a prescription.'' [57] The Commission thus concludes that Congress intended the Act and implementing Rule to cover only contact lenses for which a prescription is required. Accordingly, the Commission has decided to add the following definition to the Rule: ''For purposes of the Rule, 'contact lens' means any contact lens for which state or federal law requires a prescription.''

4. Definition of ''Contact Lens Fitting''

Section 11(1) of the Act defines a ''contact lens fitting'' as ''the process that begins after an initial eye examination for contact lenses and ends when a successful fit has been achieved or, in the case of a renewal prescription, ends when the prescriber determines that no change in the existing prescription is required.'' [58] The Act states that the fitting process ''may include—(a) an examination to determine lens specifications; (b) except in the case of a renewal of a contact lens prescription, an initial evaluation of the fit of the contact lens on the eye; and (c) medically necessary follow-up examinations.'' [59] The definition of ''contact lens fitting'' in the proposed Rule was taken verbatim from the Act.[60] For the reasons set forth below, the Commission adopts this definition without modification in the final Rule.

A number of commenters suggested that the term ''medically necessary follow-up examinations'' be defined specifically in the final Rule.[61] Based on the record, the Commission lacks the expertise to define this term; moreover, it seems unlikely that even medical professionals could list in advance all circumstances in which there are valid medical reasons for a follow-up examination. Accordingly, the Commission declines to define that term in the final Rule at this time. The Commission, however, expects prescribers to exercise sound professional judgment when determining if follow-up exams are ''medically necessary'' based on appropriate and objective standards of medical care.

5. Definition of ''Contact Lens Prescription''

Section 11(3) of the Act defines a ''contact lens prescription'' as ''a prescription, issued in accordance with State and Federal law, that contains sufficient information for the complete and accurate filling of a prescription for contact lenses, including the following: (a) The name of the patient; (b) the date of examination; (c) the issue date and expiration date of prescription; (d) the name, postal address, telephone number, and facsimile telephone number of prescriber; (e) the power, material or manufacturer or both of the prescribed contact lens; (f) the base curve or appropriate designation of the prescribed contact lens; (g) the diameter, when appropriate, of the prescribed contact lens; and (h) in the case of a private label contact lens, the name of the manufacturer, trade name of the private label brand, and, if applicable, trade name of equivalent brand name.'' [62] The definition of ''contact lens prescription'' in the proposed Rule was taken verbatim from Section 11(3) of the Act.[63] For the reasons set forth below, the Commission adopts the proposed definition without modification in the final Rule.

a. Number of Lenses Prescribed

Several prescriber trade associations,[64] one state optometry board,[65] and numerous individual prescribers [66] recommended that the Commission revise the definition to require the inclusion on the prescription of the number of lenses or refills allowed. Many of these commenters expressed concerned that the absence of such information would allow patients to circumvent the prescription expiration date by purchasing additional quantities of lenses before the prescription expires.[67] One of these commenters pointed out that the Act contemplates that quantity limits are appropriate because it mandates that sellers include the quantity ordered in their verification requests.[68]

Sellers, in contrast, noted that the Act does not provide for prescribers to limit the number of boxes or units dispensed so long as the prescription is current.[69] The sellers further argued that such restrictions could be used to impose expiration dates shorter than those contemplated under the Act. Moreover, an academic ophthalmologist commented that allowing prescribers to limit the number of refills might encourage patients to overwear contact lenses in order to ''stretch'' their prescriptions to the end of the expiration period.[70] The same commenter noted that, if quantity limits are imposed, patients who tear or lose their lenses or who have to replace lenses more frequently may have prescriptions that run out before they expire. In addition, one seller contended that patients may choose to replace lenses more frequently than recommended by their prescriber, and that such potentially healthier choices could be precluded if prescriptions limit

George Mason University (Regulatory Studies Program) (Comment #1087).

[56] Mercatus Center at George Mason University (Regulatory Studies Program) (Comment #1087).

[57] 15 U.S.C. 7605.

[58] *Id.* at 7610(1).

[59] *Id.*

[60] *See* 69 FR at 5448.

[61] Consumers Union (Comment #1139) (recommending that follow-up examinations must be medically indicated and occur within 30 days of the original fitting exam); R. Weigner (Comment #1118) (follow-up examination should be ''more strictly defined so it cannot extend indefinitely''); American Society for Cataract and Refractive Surgery (Comment #1148) (opposing a Commission-determined standard, but recommending the Rule expressly state ''as reasonably determined by the prescriber''); Illinois Optometric Association (Comment #1005) (seeking a broader definition such as ''medically necessary follow-up examinations and/or sufficient follow up and lens parameter adjustment to minimize the risks of contact lens complications as much as clinically possible''); Dr. K. Poindexter (Comment #260).

One trade association also requested a clarification that the initial evaluation includes giving a patient a pair of lenses to wear on a trial basis, and that the fitting is not complete until the prescriber settles on the final prescription. American Society for Cataract and Refractive Surgery (Comment #1148). The Commission believes that the proposed definition of ''contact lens fitting'' clearly and sufficiently indicates that a contact lens fitting may include an initial evaluation of the fit of the contact lens on the eye (except in the case of renewals) as well as any medically necessary follow-up exams.

[62] 15 U.S.C. 7610(3).

[63] *See* 69 FR at 5488.

[64] American Optometric Association (Comment #1149); Illinois Optometric Association (Comment #1005); Kentucky Optometric Association (Comment #1101).

[65] Kansas Board of Examiners in Optometry (Comment #1007).

[66] *E.g.,* E. Attaya (Comment #952); G. Barker (Comment #125); S. Carlson, O.D. (Comment #906); M. R. Carter (Comment #3); M. Dean (Comment #457); D. Deeds (Comment #13); K. Green (Comment #4); W. Lindahl (Comment #16); M. Palermo, O.D. (Comment #22); M. Walker (Comment #165); Your Family Eye Doctors, Inc. (Comment #705).

[67] *E.g.,* Kansas Board of Examiners in Optometry (Comment #1007); W. Lindahl (Comment #16).

[68] American Optometric Association (Comment #1149).

[69] AC Lens (Comment #974); William F. Shughart, II, Ph.D., on behalf of 1–800-CONTACTS (Comment #975) .

[70] P.S. D'Arienzo, M.D. (Comment #1056).

the number of lenses that can be dispensed.[71]

After reviewing the comments, the Commission has decided not to modify the definition of contact lens prescription to require the inclusion of the quantity of lenses or refills allowed. The Act does not require the inclusion of quantity information on the prescription. In addition, if the quantity of lenses is included on the prescription, then prescribers may use quantity limits to impose prescription expiration dates that are effectively shorter than the one-year period imposed under the Act. Moreover, it is not necessary to include the quantity of lenses on the prescription to limit patients' ability to circumvent the expiration date. Section 315.5(b) requires verification requests to contain the quantity of lenses ordered, and as discussed below in section 315.5(d), the quantity ordered may be a legitimate basis for a prescriber to treat a request for verification of a prescription as ''inaccurate.'' The verification process itself thus generally allows prescribers to prevent patients from ordering excessive contact lenses.

The Commission recognizes that some State laws or regulations may require prescribers to include such information on the prescription. Prescribers in States without such requirements may also choose to include such information on the prescription.

The Commission, however, emphasizes that prescribers may not use quantity limits to frustrate the prescription expiration requirements imposed by section 315.6 of the final Rule. The quantity of lenses or refills specified in the prescription must be sufficient to last through the prescription's expiration date, which typically will be one year after the issue date. If a lesser quantity of lenses or refills is specified in the prescription, the prescriber must have a legitimate medical reason for doing so, and the requirements imposed by section 315.6(b) of the final Rule on writing a prescription for less than one year must be met.

b. Private Label Lenses

A few sellers commented on the Rule provision regarding private label lenses.[72] This provision requires prescriptions for private label contact lenses to identify ''the name of the manufacturer, trade name of the private label brand, and, if applicable, trade name of equivalent brand name.''[73] Two sellers recommended that the Rule be revised to require manufacturers of private label lenses to provide information to prescribers regarding all equivalent brands, so that this information can be included on the prescription.[74] One of the sellers stated that prescribers and sellers may not know which private label lenses have equivalent brands, so there is currently no mechanism by which sellers and prescribers can comply with subsection (8) of the proposed definition.[75] Nothing in the Act or its legislative history, however, indicates that Congress intended to require contact lens manufacturers to inform prescribers of brand names of equivalent lenses. Consequently, the Commission has concluded that imposing such disclosure requirements on manufacturers would exceed the mandate of the Act.

Another seller suggested that the definition be modified to require those who prescribe private label contact lenses to identify on the prescription the ''trade name of a brand name sold to alternative sellers.''[76] Section 11(3)(H) of the Act requires that prescriptions for private label contact lenses include the name of the manufacturer, the private label brand name, and, if applicable, the ''trade name of an equivalent brand name.''[77–78] Although the Act thus expressly requires that ''equivalent brand name'' contact lenses be identified in prescriptions for private label lenses, it does not require that such ''equivalent brand name'' contact lenses be sold to alternative sellers. The Commission has therefore concluded that requiring prescribers to identify the ''trade name of a brand name sold to alternative sellers'' would go beyond the requirements of the Act.[79]

c. Other Suggested Additions

A few prescribers recommended that a contact lens wearing schedule be required on the prescription.[80] A contact lens wearing schedule outlines how often the contact lenses should be removed and/or replaced. After reviewing these comments, the Commission has determined that the record does not contain sufficient evidence to justify the imposition of such a requirement in the final Rule. The Commission notes, however, that the Rule does not prohibit a prescriber from including such information on the prescription.

One commenter suggested that the Commission modify the proposed definition to require prescribers to include an e-mail address on prescriptions for verification purposes, presumably to facilitate communications between sellers and prescribers.[81] Other commenters recommended that an email address be allowed, but not required, on a contact lens prescription because some prescribers may not use e-mail.[82] One such commenter pointed out that e-mail addresses are likely to change frequently, particularly in rural areas.[83] After reviewing these comments, the Commission has decided not to revise the Rule to require the inclusion of an e-mail address, because the record contains no evidence regarding the extent to which prescribers use e-mail to communicate. Although not required, a prescriber may choose to include his or her e-mail address on a contact lens prescription, to facilitate efficient communication between prescribers and patients as well as between prescribers and sellers.

One prescribers' trade association recommended that the Rule expressly allow contact lens prescriptions to include language underscoring that there should be no substitutions.[84] The

[71] AC Lens (Comment #974).

[72] Costco Wholesale Corporation (Comment #1061); AC Lens (Comment #974); 1–800 CONTACTS (Comment #1140).

[73] 69 FR at 5488.

[74] Costco Wholesale Corporation (Comment #1061); AC Lens (Comment #974).

[75] Costco Wholesale Corporation (Comment #1061).

[76] 1–800 CONTACTS (Comment #1140). This commenter was also concerned about ''doctor exclusive lenses,'' which it described as contact lenses sold by manufacturers only to eye care providers and for which there are no available substitutes sold to alternative sellers. The commenter suggested that the Rule require prescribers who prescribe such ''doctor exclusive lenses'' to specify on the prescription a brand name for lenses that are similar, but not identical, to the prescribed lenses, and are sold to alternative sellers. The Act requires disclosure only when lenses identical to the prescribed lenses are sold under different private label brand names. The imposition of a disclosure requirement for other lenses is beyond the mandate of the Act.

[77] [78] 15 U.S.C. 7610(3)(H).

[79] In addition, one prescriber trade association recommended that subsection (8) of the definition be revised to state ''trade name of identical brand name'' rather than ''trade name of equivalent brand name'' to emphasize that prescription alteration is not allowed. Illinois Optometric Association (Comment #1005). Because the phrase ''trade name of equivalent brand name'' was taken directly from the Act, and there is no evidence in the record indicating that the phrase is inappropriate, the Commission has decided not to make the requested change.

[80] *E.g.,* M. Walker (Comment #165); R. Carter (Comment #3).

[81] R.Weigner (Comment #1118).

[82] American Society for Cataract and Refractive Surgery (Comment #1148); K. Poindexter (Comment #260); Illinois Optometric Association (Comment #1005).

[83] Illinois Optometric Association (Comment #1005).

[84] American Optometric Association (Comment #1149). A prescriber expressed a similar concern that contact lens sellers ''notoriously switch patients into what they see as equal or identical

Act, however, permits substitution of identical contact lenses for private label lenses.[85] Consequently, the Commission has concluded that this recommendation would be inconsistent with the Act.

6. Definition of ''Direct Communication''

The proposed Rule defined ''direct communication'' to mean a ''completed communication by telephone, facsimile, or electronic mail.'' [86] In its NPRM, the Commission explained that, under this definition, direct communication by telephone would require reaching and speaking with the intended recipient, or leaving a voice message on the telephone answering machine of the intended recipient; and direct communication by facsimile or electronic mail would require that the intended recipient actually receive the facsimile or electronic mail message.[87] For the reasons set forth below, the Commission adopts this definition without modification in the final Rule.

a. Automated Telephone Systems

The Commission received a substantial number of comments objecting to sellers' use of automated telephone systems to convey verification requests to prescribers. Most of these commenters were individual prescribers or prescriber trade associations, a number of whom argued that automated requests do not constitute direct communication and should be expressly prohibited under the Rule.[88] Some commenters bluntly stated that the automated systems currently in use simply ''don't work.'' [89] Other commenters explained that so-called ''binary'' automated systems—which ask prescribers to press 1 to verify or press 2 if not willing to verify—are inadequate. Binary automated systems do not provide prescribers an option to correct any inaccuracy; require an immediate response and thus do not allow the prescriber eight business hours to verify; and do not provide the option of speaking with the seller.[90]

Other commenters stated that automated systems often malfunction [91] or begin imparting information as soon as the prescriber's telephone answering system picks up (*e.g.*, for after-hours calls), which frequently results in all or part of the message being cut off or not recorded at all.[92] Two prescribers objected that automated verification systems are ''cumbersome'' and ''time-consuming'' for staff who must respond to the verification request in real time while patients are in their office waiting for service.[93]

The Commission recognizes that automated telephone systems may create communication problems as described in the comments received. Nevertheless, we decline to revise the definition of ''direct communication'' to prohibit the use of automated telephone verification requests. The Act expressly authorizes sellers to send verification requests by telephone,[94] which is commonly understood to include automated telephone systems. It would thus seem to be contrary to Congressional intent to prohibit the use of this technology.

Nevertheless, the Commission emphasizes that calls from automated telephone systems must fully comply with all applicable Rule requirements. For example, any automated verification request must (1) provide complete verification request information as required under section 315.5(b), and this information must be either received by a person on the telephone or otherwise received in full (*e.g.*, all of the requisite information left on a telephone answering machine), and (2) allow eight business hours for the prescriber to respond. If these and other applicable requirements are not met, the automated verification request is not valid.

In addition, the Commission will continue to monitor whether full, valid requests for verification of a prescription are being made through the use of automated telephone systems. If evidence demonstrates that sellers are not making valid verification requests but are providing consumers with contact lenses despite deficient requests, the Commission may revisit this issue.

b. Technologies Used for ''Direct Communication''

Other commenters argued that the Commission should alter the scope of technologies that may be used to achieve direct communication between sellers and prescribers. Some commenters urged the Commission to define ''direct communication'' more broadly than originally proposed. For example, one seller suggested the term include the existing technologies currently specified—facsimile, telephone, and e-mail—plus any ''substantially equivalent communication technology,'' so as to specifically embrace future technologies.[95] Other commenters sought a narrower definition that would permit verification only through a person-to-person telephone call;[96] one commenter recommended that the Rule permit only fax and e-mail communication, and not telephone.[97]

The Act plainly states that ''direct communication'' includes communication by telephone, facsimile, or electronic mail.'' [98] Accordingly, the

contact lens [prescriptions]'' and added that ''this practice should be stopped.'' S. Wexler, O.D. (Comment #375).

[85] Section 4(e) of the Act, 15 U.S.C. 7603(f).

[86] 69 FR at 5448.

[87] *See id.* at 5441.

[88] *E.g.,* American Optometric Association (Comment #1149); Nebraska Optometric Association (Comment #1083); Arizona Optometric Association (Comment #1072); Arizona Medical Association (Comment #1130); Ohio Optometric Association (Comment # 1151); Kansas Optometric Association (Comment #1153); Kentucky Optometric Association (Comment #1101); K. Driver, O.D. (Comment #273); Wheaton Eye Clinic (Comment #416); S. Bryant, O.D. (Comment #1127); J. B. Rogers, O.D. (Comment #1119); B. Oppenheim (Comment #1).

[89] *E.g.,* Olathe Family Vision (Comment #971); Your Family Eye Doctors, Inc. (Comment #705); Drs. Odom and Coburn (Comment #958); *see also* A. Lee (Comment #1096) (''automatic calling by [a] robot is worthless''); R. Garfield (Comment #19) (citing numerous problems with automated phone verification); M. Przybylowski (Comment #9) (same); S. Carpenter (Comment #182).

[90] *E.g.,* Texas Ophthalmological Association (Comment #1117); North Carolina State Optometric Society (Comment #1074); Oklahoma Association of Optometric Physicians (Comment #1125); American Academy of Ophthalmology (Comment #1057); Illinois Optometric Association (Comment #1005).

[91] *E.g.,* Ohio Optometric Association (Comment #1151); Oklahoma Association of Optometric Physicians (Comment #1125).

[92] *E.g.,* National Association of Optometrists and Opticians (Comment #1146); Colorado Optometric Association (Comment #1067) (noting some recordings shut off automatically before the message is complete); Kansas Optometric Association (Comment #1153) (noting that some optometrists' offices do not record incoming messages at all).

[93] J. Sawyer (Comment #814); D. Ball (Comment #849).

[94] *See* 15 U.S.C. 7603(a)(2) (permitting prescription verification by ''direct communication''), 7603(g) (defining ''direct communication'' to include communication by telephone).

[95] 1–800 CONTACTS (Comment #1140). *See also* Mercatus Center at George Mason University (Regulatory Studies Program) (Comment #1087) (suggesting more open-ended definition—such as adding ''or other electronic means''—rather than enumerating all permissible communication options).

[96] *E.g.,* K. Poindexter (Comment #260) (arguing that communication by fax and e-mail are not workable because seller has no way to know when prescriber receives it and thus when the communication was ''completed''); M. Walker (Comment #10) (same); M. Davis (Comment #8) (same); Catherine Smith (Comment #6) (same); K. Green (Comment #4) (citing problems with fax—*e.g.*, paper jam, no paper, no toner, memory failure—and e-mail—*e.g.* blocked by anti-spam software or by ISP); J. Maurillo (Comment #172) (suggesting that person-to-person call be followed by a faxed confirmation); H. Cerri, M.D. (Comment #1129) (verification should occur by recorded telephone call).

[97] C.F. Ford, O.D. (Comment #969).

[98] 15 U.S.C. 7603(g).

Commission cannot eliminate by rule any of the three specified methods. As for expanding the definition to specifically reference ''future'' or ''substantially equivalent'' technology, Congress's use of the term ''includes'' contemplates that additional methods of communication may develop that sellers and prescribers could use in the verification process. There is no evidence in the record, however, of specific additional technologies that sellers and prescribers currently use or are likely to use in the verification process. Moreover, the Commission cannot determine how the verification process would work, or how recordkeeping requirements would apply, with respect to as-yet-unknown technologies. If such other technologies develop, the Commission may consider revising the Rule to permit those technologies to be used in direct communication.

c. ''Completed'' Communication by Telephone, Facsimile or Electronic Mail

Commenters also asked the Commission to define or clarify when a ''completed'' communication by telephone, facsimile or electronic mail has occurred. One Internet-based contact lens seller proposed an expansive definition that would include either (a) affirmative evidence that a communication was completed, (b) evidence that a fax or e-mail or substantially equivalent communication technology had been attempted twice, or (c) evidence that live telephone verification had been attempted.[99] Another seller suggested that electronic confirmation of a successful facsimile transmission, or the absence of notification that an e-mail was undeliverable, should be sufficient evidence of completed communication by those means.[100]

A number of prescribers sought narrower definitions of ''completed'' communications or more stringent requirements on sellers, such as the receipt of a confirmation of successful fax transmission and confirmation that someone was available in the prescriber's office within the eight-hour time period to respond.[101] Similarly, one commenter sought a requirement that sellers call prescribers to verify that the fax or e-mail verification request was in fact received, if the prescriber does not respond within eight hours.[102] One optometrist argued that the Rule requires that the prescriber must ''receive'' the verification request, and the only way to ensure this is to require some type of receipt or positive response from the prescriber.[103]

The specific question of whether a message left on an answering machine or voicemail constitutes a ''completed'' communication generated a number of comments. Most of these comments—primarily from prescribers and one of their trade associations—argued that the Rule should not permit voice messages.[104] These commenters stated, for example, that they often had difficulty transcribing the messages, thus increasing the potential for error,[105] and that sellers should not be allowed to leave confidential patient information on an answering machine.[106] Other commenters, however, favored allowing messages on answering machines.[107] One commenter argued that allowing voicemail messages helps avoid extended ''phone tag,'' while another stated that prohibiting such messages would impose a significant burden on smaller sellers who are located in the Eastern time zone and are trying to communicate with offices of prescribers in Western time zones.[108]

The language of the Act does not specifically define when a seller's communication of verification information is completed. Legislative history is instructive on the issue of what constitutes a completed communication, however. In its Report, the House Committee made clear that it intended direct communication to mean ''a message [that] has been both sent and received.''[109]

Having considered the comments, the Commission declines to further define what constitutes a ''completed'' communication in the Rule. However, the Commission confirms, as explained in the NPRM, that a communication is ''completed'' when all of the required information is received by the recipient. For example, direct communication by telephone would require reaching and speaking with the intended recipient, or clearly leaving a voice message on the telephone answering machine of the intended recipient setting forth all of the required information. Direct communication by facsimile or electronic mail similarly would require that the intended recipient receive the facsimile or electronic mail message. A facsimile confirmation will usually provide a sufficient basis to conclude that a facsimile communication was successfully received. E-mails are typically received almost instantaneously after they are sent, so confirmation that an e-mail was sent will generally constitute a sufficient basis to conclude that the e-mail was received.[110]

It is incumbent upon the party initiating the communication to use a method that enables the recipient to receive all the information being communicated, and the eight-business-hour verification period does not begin until such receipt occurs. Moreover, sellers must document the communications as provided in part 315.5(f) of the final Rule.

The Commission also declines to impose additional requirements on sellers to confirm receipt of communications by prescribers. The Act reveals no indication that Congress intended to impose different standards when sellers communicate with prescribers than when prescribers communicate with sellers. The record

[99] 1–800 CONTACTS (Comment #1140).

[100] AC Lens (Comment #974) (Rule should not require active acknowledgment of receipt by recipient, as that would be contrary to the Act's passive verification scheme). *See also* Mercatus Center at George Mason University (Regulatory Studies Program) (Comment #1087) (urging Commission not to define ''completed'' communication too restrictively because the Act's intent appears to tolerate some errors, such as e-mails lost in cyberspace or a prescriber's fax machine running out of paper).

[101] Staff (Comment #131). *See also* C. Lesko, M.D. FACS (Comment #960) (seller should have to verify that fax was actually sent to and received by the appropriate prescriber's office, so that consumers do not use fake prescriber names and fax numbers).

[102] American Society for Cataract and Refractive Surgery (Comment #1148) (but proposing that fax confirmation and no error e-mail notice (or notification that addressee has received and/or read an e-mail) would be sufficient evidence of completion for communications by prescriber to seller).

[103] E. Lamp, O.D. (Comment #714).

[104] *E.g.,* Kansas Board of Examiners in Optometry (Comment #1007) (arguing seller has no way to know when prescriber receives message, and thus when eight-hour verification period begins and ends); C.F. Ford, O.D. (Comment #969); A.L. Warner (Comment #706); Wheaton Eye Clinic (Comment #416); E. Lamp, O.D. (Comment #714).

[105] American Optometric Association (Comment #1149) (suggesting at a minimum that prescribers be allowed to opt out of telephone verification); E. Attaya (Comment #952) (recordings are confusing and at times impossible to understand). *See also* Drs. Odom and Coburn (Comment #958) (citing difficulties with answering machine messages).

[106] Staff (Comment #131).

[107] *E.g.,* R. Weigner (Comment #1118); Wal-Mart Optical Division (Comment #1070) (arguing that it is reasonable to presume that prescribers listen to their messages).

[108] American Society of Cataract and Refractive Surgery (Comment #1148); AC Lens (Comment #974) (noting that message would include full information required by Act).

[109] H. Rep. No. 108–318, at 10 (2003).

[110] However, if the sender has reason to believe that an e-mail was not transmitted instantly (*e.g.,* receiving an electronic notification stating that the e-mail transmission was not successful) or that a facsimile was not transmitted, then the communication is not completed until it is actually received by the recipient.

also does not provide sufficient evidence to warrant such a revision to the Rule.[111]

7. Definition of ''Issue Date''

Section 5(c) of the Act defines the ''issue date'' as ''the date on which the patient receives a copy of the prescription.'' [112] The definition of ''issue date'' in the proposed Rule was taken verbatim from the Act.[113] Under section 315.6 of the Rule, contact lens prescriptions may not expire less than one year after the ''issue date'' unless medically necessary.

Several commenters suggested that the definition be modified to make clear that the ''issue date'' is the date on which the prescriber provides the patient with the prescription at the completion of the examination or fitting.[114] Most of these commenters indicated that a prescriber giving an additional copy of a prescription to a patient at some later date should not constitute another ''issue date.'' If it did, the expiration date for the prescription could be extended one year from the new issue date.[115]

Section 2(a)(1) of the Act requires a prescriber to provide a copy of the prescription to the patient when the prescriber ''completes a contact lens fitting.'' [116] The Commission does not believe Congress intended to allow patients to extend the prescription issue date—and thereby extend the prescription expiration date—by obtaining additional copies of prescriptions from prescribers subsequent to the completion of the contact lens fitting. The Commission has therefore concluded that the definition of ''issue date'' should be revised to clarify that it is ''the date on which the patient receives a copy of the prescription *at the completion of a contact lens fitting.*''

8. Definition of ''Ophthalmic Goods''

The proposed Rule defined ''ophthalmic goods'' to mean contact lenses, eyeglasses, or any component of eyeglasses.[117] The Commission received no comments on this definition, and adopts it without modification in the final Rule.

9. Definition of ''Ophthalmic Services''

The proposed Rule defined ''ophthalmic services'' to mean the measuring, fitting, and adjusting of ophthalmic goods subsequent to an eye examination.[118] The Commission received no comments on this definition, and adopts it without modification in the final Rule.

10. Definition of ''Prescriber''

The Commission's proposed Rule defined ''prescriber'' to mean, with respect to contact lens prescriptions, an ophthalmologist, optometrist, or other person permitted under State law to issue prescriptions for contact lenses in compliance with any applicable requirements established by the Food and Drug Administration.[119] This definition tracked the language of the Act verbatim.[120]

The Commission received a number of comments on this proposed definition, most of which related to the application of this definition to licensed opticians currently permitted under State law to fit contact lenses. According to the commenters, these opticians—sometimes referred to as ''dispensing opticians''—may perform a contact lens fitting based on an eyeglass prescription that contains a notation from the prescriber that the patient is ''OK for contact lenses'' or similar language.[121]

Several commenters, including the Opticians Association of America, urged the Commission to make clear in the Rule that licensed dispensing opticians must release contact lens prescriptions to their patients at the end of a contact lens fitting.[122] The California Association of Dispensing Opticians noted that California law currently requires dispensing opticians to release prescriptions to patients.[123]

Having reviewed the comments, the Commission has concluded that, to the extent dispensing opticians are authorized under state law to issue prescriptions, they are ''prescribers'' under the Act and are required to release contact lens prescriptions at the completion of a contact lens fitting just like other prescribers. The Commission believes that such a requirement is both consistent with, and necessary to fully effectuate, Congress's intent to provide consumers with their prescriptions. Accordingly, the Commission's final Rule defines ''prescriber'' to include opticians authorized or permitted under state law to perform contact lens fitting services who also are permitted to issue contact lens prescriptions.[124]

11. Definition of ''Private Label Contact Lenses''

Section 315.2 of the proposed Rule defines ''private label contact lenses'' as ''contact lenses that are sold under the label of a seller where the contact lenses are identical to lenses made by the same manufacturer but sold under the labels of other sellers.'' [125] This proposed definition was derived from Section 4(f) of the Act.[126] The Commission received no comments on the proposed definition, and therefore adopts it without modification in the final Rule.

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[111] The Commission also declines to allow the presumption of a ''completed'' communication based merely on evidence that a fax or e-mail had been attempted twice, or evidence that live telephone verification had been attempted, as one commenter suggested. The Act requires that prescribers actually receive a verification request for a direct communication to occur.

[112] 15 U.S.C. 7604(c).

[113] *See* 69 FR at 5448.

[114] American Optometric Association (Comment #1149); Dr. K. Poindexter (Comment #260); W. West, O.D. (Comment #126); W. Barr, O.D. (Comment #1068); Arizona Optometric Association (Comment #1072) (suggesting that prescription expiration period begin when prescriber determines contact lens parameters); 1–800 CONTACTS (Comment #1140) (suggesting ''the date on which the patient, *or any person designated to act on behalf of the patient, first* receives a copy of the prescription'').

[115] A few commenters suggested that the ''issue date'' be defined as the date the prescriber writes the prescription or as some earlier date. *E.g.,* American Society for Cataract and Refractive Surgery (Comment #1148) (suggesting the date the prescriber writes the prescription); R. Weigner (Comment #1118) (suggesting the actual date on which the prescription was written, and recommending that pre- or post-dating of prescriptions be expressly disallowed); S.J. St. Marie, O.D. (Comment #1121) (suggesting that the issue date be earlier than the release date when the prescriber requires the patient to use the lenses on a diagnostic trial basis). Section 5(c) of the Act mandates the ''patient receipt'' standard contained in the proposed Rule. Consequently, the Commission declines to implement the requested changes in the final Rule.

[116] 15 U.S.C. 7601(a)(1).

[117] *See* 69 FR at 5449.

[118] *See* 69 FR at 5449.

[119] *See* 69 FR at 5449.

[120] 15 U.S.C. 7610(2).

[121] *E.g.,* K. Green (Comment #4); D. Acosta (Comment #14).

[122] K. Green (Comment #4); Opticians Association of America (Comment #1059); California Association of Dispensing Opticians (Comment #1104).

[123] Comment #1104.

[124] One commenter also recommended that the Commission revise the definition of ''contact lens prescription'' to include ''an eyeglass prescription and the notation 'OK for contact lenses' or similar language on the prescription provided there are no contraindications for contact lenses.'' D. Acosta (Comment #14). The Commission believes the revised definition of ''prescriber'' adequately addresses this comment.

Another commenter recommended that the Rule prohibit anyone from fitting and dispensing contact lenses unless that person is properly licensed to write a prescription. Kentucky Optometric Association (Comment #1101). *See also* Ohio Optometric Association (Comment #1151) (urging Commission to state in the Rule that contact lens ''fitting'' may be initiated and directed only by a licensed optometrist or ophthalmologist). The question of who is authorized to fit contact lenses is beyond the scope of the Act; it is a question that is properly resolved as a matter of State law.

[125] 69 FR at 5448.

[126] 15 U.S.C. 7603(f).

C. Section 315.3: Availability of Contact Lens Prescriptions to Patients

1. 315.3(a)—In general

a. The Prescription Release Requirement

Section 2(a)(1) of the Act requires that ''when a prescriber completes a contact lens fitting, the prescriber—(1) whether or not requested by the patient, shall provide a copy of the contact lens prescription to the patient.'' [127] Section 315.3(a)(1) of the proposed Rule tracks the language of the Act verbatim.[128] For the reasons set forth below, the Commission adopts this provision without modification in the final Rule.

As an initial matter, the Commission notes that thousands of consumers submitted comments expressing strong support for the Act and proposed Rule's prescription release requirement.[129] Many of these commenters felt strongly that the contact lens prescription belongs to the consumer.[130] Others stated that contact lens consumers should have the same prescription release rights as eyeglasses wearers.[131]

The State Attorneys General expressed hope that the prescription release requirement will accelerate the frequency with which patients provide an actual copy of the prescription to a non-prescribing seller.[132] The State Attorneys General noted that elimination of the need for verification under such circumstances will allow the seller to ship the lenses immediately. House Judiciary Committee Chairman Sensenbrenner, a co-sponsor of the Act, pointed out that the intent of the Act is ''to allow consumers to receive their contact lens prescriptions so they can easily shop around to buy their lenses from any number of suppliers.'' [133]

A few prescribers expressed concern about the health implications of the immediate prescription release obligation imposed by section 315.3(a)(1).[134] Section 2(a)(1) of the Act,[135] however, expressly requires prescribers to release contact lens prescriptions to patients when the ''prescriber completes a contact lens fitting,'' not at some later date.

Several commenters expressed the concern that prescribers may pressure consumers to purchase contact lenses from them if, prior to releasing the written prescription, prescribers can try to persuade consumers to make such a purchase. These commenters urge the Commission to require that prescribers release the written prescription immediately following the contact lens fitting and before attempting to sell and dispense contact lenses.[136] The Act does not impose any such restriction on prescribers. Moreover, because the Act and the Rule provide that prescribers may not require the patient to purchase contact lenses from them or from another person, *see* 15 U.S.C. 7601(b) and section 315.3(b)(1) of the Rule, consumers already have protection against pressure to purchase from the prescriber. The Commission therefore has determined not to require that prescribers release the written prescription immediately following the contact lens fitting and before attempting to sell and dispense contact lenses.

A few commenters suggested that the prescriber be given the option to not release the prescription or to release it for ''informational purposes only'' if the patient has purchased a full year's supply of contact lenses at the time of the eye examination.[137] Because such an exception would be contrary to the Act's express requirement that consumers receive a copy of their prescription at the completion of a contact lens fitting, it is not included in the final Rule.

Two commenters recommended that the prescription release obligation be limited to one release per patient.[138] Section 2(a)(1) of the Act mandates the release of the patient's contact lens prescription to the patient at the completion of the contact lens fitting.[139] The Act neither requires prescribers to, nor prohibits them from, releasing additional copies of the prescription. The Commission declines to require or prohibit by Rule the release of additional copies of the prescription.

Finally, a number of prescribers suggested that custom-designed soft lenses and rigid gas permeable lenses be exempt from the release requirement because such lenses require significant interaction between the prescriber and the manufacturer as well as proper follow-up and medical management.[140] In contrast, one seller recommended that the Commission not make an exception for rigid gas permeable and other specialized made-to-order lenses, because it supplies such lenses to consumers more conveniently and at significant savings compared to prescribers.[141] Section 2(a)(1) of the Act mandates simply that the prescriber ''provide to the patient a copy of the contact lens prescription.'' [142] The Act thus does not permit the Commission by rule to grant an exception to the release requirement for custom-designed soft and rigid gas permeable lenses. Moreover, the record indicates that some sellers (other than prescribers) can supply such lenses to consumers. Consequently, the creation of an exception to the release requirement for custom-designed soft and rigid gas

[127] 15 U.S.C. 7601(a)(1).

[128] *See* 69 FR at 5449.

[129] *E.g.,* Consumers (Comments ##28, 29, 30, 31, 32, 33, 34, 36, 38, 40, 43, 44, 45, 48, 49, 51, 54, 56, 57, 59, 60, 64, 69, 71, 72, 73, 74, 75, 78, 79, 82, 83, 84, 87, 89, 90, 91, 92, 93, 94, 96, 97, 98, 100, 102, 105, 106, 107, 108, 109, 110, 111, 114, 115, 118, 119, 120, 121, 122, 123, 124, 132, 147, 152, 153, 155, 159, 163, 166, 169, 170, 171, 173, 174, 176, 178, 179, 181, 183, 184, 186, 187, 189, 190, 191, 192, 195, 198, 199, 201, 202, 203, 204, 205, 206, 207, 209, 210, 212, 213, 215, 217, 218, 219, 220, 222, 223, 226, 227, 228, 229, 230, 231, 232, 234, 235, 238, 240, 241, 242, 245, 246, 247, 248, 249, 250, 253, 255, 256, 257, 258, 259, 262, 263, 264, 265, 267, 272, 276, 281, 287, 289, 290, 292, 308, 315, 326, 327, 337, 342, 349, 358, 364, 380, 441, 451, 455, 465, 514, 519, 521, 539, 624, 653, 698, 726, 740, 761, 762, 765, 772, 775, 776, 777, 790, 793, 795, 798, 802, 806, 807, 808, 809, 813, 816, 820, 824, 825, 830, 836, 837, 841, 845, 848, 853, 859, 871, 873, 875, 878, 879, 880, 881, 892, 895, 897, 898, 922, 923, 936, 955, 967, 994, 1008, 1069, 1098, 1099, 1131, 1186, 1215, 1216, 1220, 1222, 1235).

[130] *E.g.,* Consumers [Comment ##1201 (''I have the undeniable right to have a copy of my Rx for my records, whether I choose to do anything with it or not''); Comment #1221 (''my prescription belongs to me, not the doctor to hold for ransom'')].

[131] *E.g.,* Consumers (Comments ##27, 43, 45, 65, 66, 70, 85, 86, 101, 105, 160, 209, 222, 225, 246, 255, 259, 266, 274, 293, 295, 301, 303, 310, 314, 321, 336, 344, 370, 384, 396, 402, 414, 432, 449, 493, 496, 497, 652, 656, 664, 693, 772, 798, 805, 806, 833, 873, 881, 895, 898, 921, 939, 950, 956, 988, 1004, 1182, 1193, 1194, 1214, 1216, 1220, 1226).

[132] State Attorneys General (Comments ##1114, 1176).

[133] Hon. F. James Sensenbrenner, Jr., U.S. House of Rep. (Comment #1246).

[134] A. Richards (Comment #2) (recommending that release not be required until the patient has safely worn the contact lenses for 6 months, and noting that it often takes several weeks before corneal problems are manifested); D. Pao (Comment #139) (noting that the proper prescription is typically not decided at the initial fitting visit, but normally, at the follow-up visit in 1–2 weeks, and in most cases by 4–6 weeks). One prescriber was concerned that the release obligation is not in the best interest of the consumer because contact lens sellers have no knowledge of preventative care. A.D. Adins, O.D. (Comment #1133).

[135] 15 U.S.C. 7601(a)(1).

[136] 1–800 CONTACTS (Comment #1140); William F. Shughart, II, Ph.D., on behalf of 1–800–CONTACTS (Comment #975); The Independent Women's Forum (Comment #1236); Americans for Prosperity (Comment #1145). *See also* discussion of section 315.3(b)(2), *infra*, concerning the ability of prescribers to offer a bundled package of an eye examination and contact lenses.

[137] North Carolina State Optometric Society (Comment #1074); M. Walker (Comment #165).

[138] Nebraska Optometric Association (Comment #1083); Dr. K. Poindexter (Comment #260).

[139] 15 U.S.C. 7601(a)(1).

[140] American Society for Cataract and Refractive Surgery (Comment #1148); Colorado Optometric Association (Comment #1067); California State Board of Optometry (Comment #21) (requesting exception for rigid gas permeable, bitoric gas permeable, bifocal gas permeable, keratoconus and custom lenses); Wheaton Eye Clinic (Comment #416); S. Carlson, O.D. (Comment #906); G. Lozada (Comment # 1063).

[141] AC Lens (Comment #974).

[142] 15 U.S.C. 7601(a)(1).

permeable lenses would be inconsistent with the Act's goal of meaningful prescription portability and increased consumer choice. The final Rule accordingly includes no such exception.

b. The Prescription Verification Requirement

Section 2(a)(2) of the Act requires that, when a prescriber completes a contact lens fitting, the prescriber ''shall, as directed by any person designated to act on behalf of the patient, provide or verify the contact lens prescription by electronic or other means.'' [143] Section 315.3(a)(2) of the proposed Rule tracks the language of the Act verbatim.[144] For the reasons set forth below, the Commission adopts the proposed provision without modification in the final Rule.

Prescriber trade associations recommended that sellers be required to obtain written proof of authority to act on the patient's behalf.[145] In contrast, one seller urged the Commission to clarify in the final Rule that sellers or other agents are not required to have a written agency agreement to act on a patient's behalf, because the Act allows for verification by telephone.[146]

After reviewing the comments, the Commission has not included in the final Rule the requirement that sellers present written proof that they are agents of consumers. Section 4(g) of the Act expressly includes communications by telephone as a means of ''direct communication'' that sellers can use to submit verification information to prescribers.[147] The Act therefore clearly contemplates that the entire verification process can be conducted by telephone, which implicitly precludes requiring written proof that a seller is an agent of a consumer.[148]

A few prescribers commented that the Rule does not state how many times a prescriber is required to verify a prescription.[149] These commenters were concerned that prescribers must bear the burden of verification requests from multiple sellers, even though the patient has already received a copy of the prescription. The Act clearly imposes two separate obligations upon prescribers at the completion of a contact lens fitting. First, prescribers must provide a copy of the prescription to the patient.[150] Second, prescribers must provide or verify the prescription as directed by any person designated to act on behalf of the patient.[151] Consequently, the Act itself mandates that prescribers may have to respond to verification requests from multiple sellers.

2. 315.3(b)—Limitations

Section 315.3(b) of the proposed Rule would prohibit prescribers from imposing certain conditions on the release or verification of a contact lens prescription.[152] Specifically, a prescriber may not (1) require a patient to purchase contact lenses from the prescriber or from another person, (2) require payment in addition to, or as part of, the fee for an eye examination, fitting, and evaluation, or (3) sign a waiver or release of liability, as a condition of release or verification.[153] The proposed Rule tracked the Act almost verbatim,[154] and, as discussed below, the Commission adopts this provision without modification in the final Rule.

a. Section 315.3(b)(1)

The Commission received numerous comments relating to the prohibition against prescribers' requiring the purchase of contact lenses as a condition of prescription release. Most of these commenters urged the agency to add an exception in the Rule for ''specialty'' or ''custom'' lenses—such as rigid gas permeable and toric lenses—which are manufactured specifically for an individual patient and for which manufacturers do not provide free trial pairs.[155] According to these commenters, such lenses include lenses to treat kerataconus, high and irregular astigmatic lenses, and lenses used for orthokeratology. A prescriber must purchase these lenses from the manufacturer—at a typical cost in the range of $150 per pair—to conduct the fitting process, and the prescriber may not be able to return the lenses to the manufacturer.[156] The commenters contend that prescribers should be permitted to require their patients to pay for these lenses prior to releasing the contact lens prescription. Otherwise, the prescriber would have to absorb the cost of these lenses if a patient takes the prescription and fills it elsewhere.[157] One trade association estimated that such lenses account for a very small percentage of contact lens sales—less than 5% for its members—and that non-prescribers (*i.e.*, mail order and mass merchant sellers) do not typically sell these lenses anyway.[158]

The Act expressly prohibits prescribers from conditioning prescription release on the purchase of contact lenses. The Commission thus does not have the authority to grant an exception to that prohibition. Moreover, the record indicates that some sellers (other than prescribers) can supply custom-designed soft and rigid gas permeable lenses to consumers. Consequently, the creation of an exception for custom-designed soft and rigid gas permeable lenses would be inconsistent with the Act's goal of meaningful prescription portability and increased consumer choice. The final Rule accordingly includes no such exception.

Nevertheless, as the commenters explained, ''speciality'' or custom-made lenses are sometimes necessary to complete the fitting process. To the extent these lenses are necessary to complete the fitting process, prescribers may charge patients for such lenses as part of the cost of the fitting process,[159] and as such may condition the release of a contact lens prescription on payment of the fitting fee.

[143] 15 U.S.C. 7601(a)(2).

[144] *See* 69 FR at 5449.

[145] American Society for Cataract and Refractive Surgery (Comment #1148); New York State Optometric Association (Comment #1073); Florida Board of Optometry (Comment #1100). Two of these commenters also expressed concern about state professional responsibility rules that may prohibit the release of patient information without written consent. New York State Optometric Association (Comment #1073); Florida Board of Optometry (Comment #1100).

[146] 1–800 CONTACTS (Comment #1140).

[147] 15 U.S.C. 7603(g).

[148] Moreover, the consumer must provide his or her prescription information to the seller to begin the verification process, which itself is probative as to whether the seller is the consumer's agent.

[149] Staff (Comment #131); E. Attaya (Comment #952).

[150] 15 U.S.C. 7603(a)(1).

[151] 15 U.S.C. 7603(a)(2).

[152] *See* 69 FR at 5449.

[153] *Id.*

[154] 15 U.S.C. 7601(b).

[155] *E.g.*, D. Hughes (Comment #712); National Association of Optometrists and Opticians (Comment #1146); American Optometric Association (Comment #1149); Illinois Optometric Association (Comment #1005); W. Lindahl (Comment #7); K. Green (Comment #4); J. Owen (Comment #154). *See also* Texas Ophthalmological Association (Comment #1117) (prescribers should be able to charge for lenses necessary to complete the fitting process); California Optometric Association (Comment #1158) (same); Arizona Optometric Association (Comment #1072) (Rule should address specialty lenses); Arizona Medical Association (Comment #1130) (same).

[156] National Association of Optometrists and Opticians (Comment #1146) (historically patients have been required to pay for these lenses in conjunction with the fitting, typically in the range of $150 per pair).

[157] Notably, these commenters did not object to releasing the prescription to the patient at the completion of the fitting process. *E.g.,* American Optometric Association (Comment #1149).

[158] National Association of Optometrists and Opticians (Comment #1146).

[159] One commenter suggested that the cost of such lenses be incorporated into the contact lens fitting fee. A.L. Warner (Comment #706). Another commenter advised against ''bundling'' the cost of the lenses into the fitting fee itself, because the prices of such lenses vary. Texas Ophthalmological Association (Comment #1117).

b. Section 315.3(b)(2)

This provision of the proposed Rule prohibits prescribers from requiring payment in addition to, or as part of, the fee for an eye examination, fitting, and evaluation, as a condition of prescription release or verification. The Commission received few comments on this provision and adopts it without modification in the final Rule.

One commenter recommended that prescribers be allowed to charge a reasonable fee for providing verification services to their competition.[160] The Act expressly prohibits such a fee. Another commenter sought clarification that prescribers may bill patients for a contact lens fitting and medically necessary follow-up exams, in addition to a regular eye exam.[161] Section 315.3(b)(2) of the Rule expressly permits prescribers to charge for these services, consistent with section 315.4, as a condition of releasing a contact lens prescription.

Another commenter asked the Commission to clarify that the Rule prohibits prescribers from requiring payment for ''service agreements'' or similar follow-up exams beyond the contact lens fitting.[162] According to this commenter, a survey conducted in Texas in October 2000 showed that prescribers charged customers for a ''service agreement'' covering follow-up visits, which tie the patient to that prescriber's office. If such follow-up visits are not part of the contact lens fitting process—*i.e.*, medically necessary—then the Act expressly prohibits requiring payment for them as a condition of prescription release or verification.

On a similar point, a few commenters raised the issue of whether section 315.3(b) permits ''bundling'' practices by prescribers. One commenter asked the Commission to clarify that this section does not prohibit prescribers from offering a ''package deal'' on an exam and the initial set of diagnostic lenses used to establish proper fit, medical suitability for contact lens wear, etc.[163] This commenter argued that practitioners should be able to compete with other contact lens providers by offering services in a bundled package, so long as they do not charge an extra fee for providing the prescription.

Other commenters complained about the practice of bundling.[164] For example, one contact lens seller expressed concern that section 315.3(b) permits bundling and therefore allows prescribers to coerce consumers into buying contact lenses from them, before releasing the contact lens prescription.[165]

The Act does not prohibit a prescriber from offering a bundled package of an eye examination and contact lenses, provided that consumers have the option to purchase the eye examination separately and still receive their prescription. The Commission thus clarifies that bundling of the eye examination and contact lenses is not a per se violation of the Act or the final Rule.

In its NPRM, the Commission specifically asked for comment about whether prescribers itemize charges and fees in a manner that distinguishes the amount the patient is paying for an eye examination, fitting, and evaluation from the amount he or she is paying for contact lenses.[166] One commenter indicated that a patient's receipt typically itemizes the charges into accepted insurance codes, and suggested that no further itemization is necessary.[167] Another commenter reported that prescribers commonly use package deals as means of avoiding itemizing charges and fees, and suggested that the Rule require itemization of all charges and fees presented to the patient for payment at the end of a contact lens fitting.[168] The Commission concludes that the record does not contain sufficient evidence to warrant a requirement that prescribers itemize their charges on a patient's bill.

Finally, one commenter asked the Commission to prohibit additional conduct by prescribers that undermines prescription portability and the intent of the Act.[169] For example, this commenter recommended that the Rule prohibit prescribers from discussing the purchase of contact lenses prior to releasing the consumer's prescription. The commenter also asked that the Rule require prescribers to inform consumers in writing, before the fitting process begins, of their right under the Act to receive their prescription. The Act does not address such prescriber conduct, and the Commission has determined not to incorporate any restrictions on such conduct into the final Rule.[170]

c. Section 315.3(b)(3)

This provision of the proposed Rule prohibited prescribers from requiring a patient to sign a waiver or release as a condition of releasing or verifying a prescription.[171] The Commission received no comments on this provision, and adopts it without modification in the final Rule.

D. Section 315.4: Limits on Requiring Immediate Payment

Section 315.4 of the proposed Rule states that a ''prescriber may require payment of fees for an eye examination, fitting, and evaluation before the release of a contact lens prescription, but only if the prescriber requires immediate payment in the case of an examination that reveals no requirement for ophthalmic goods.''[172] The provision further states that ''for purposes of the preceding sentence, presentation of proof of insurance coverage for that service shall be deemed to be a payment.''[173] The language in the proposed Rule tracks section 3 of the Act verbatim.[174] For the reasons set forth below, the Commission adopts the proposed provision without modification in the final Rule.

One prescribers' trade association stated that some of its members have misinterpreted this provision as prohibiting them from requiring payment of fees for an eye exam, fitting and evaluation before the release of a contact lens prescription.[175] The Commission believes that the language of the proposed Rule is clear that requiring payment of fees for an eye exam, fitting and evaluation before the release of a contact lens prescription is permissible, but only if the prescriber also requires immediate payment in the case of an examination that reveals no

[160] D.S. Dwyer, M.D. (Comment #1071).

[161] S. Wagner (Comment #1107); see also Illinois Optometric Association (Comment #1005) (seeking clarification that a prescriber may require a comprehensive eye exam before performing a contact lens fitting and releasing the contact lens prescription). S. Wagner (Comment #1107) also asked the Commission to clarify that prescribers may charge a fee for verifying a contact lens fitting originally performed by another prescriber—*i.e.*, to confirm, for a new patient, that a previous fit is still valid and correct. If the service described by this commenter effectively constitutes a ''contact lens fitting,'' the prescriber may charge the consumer for this service as it would for any contact lens fitting.

[162] Consumers Union (Comment #1139).

[163] American Academy of Ophthalmology (Comment #1057).

[164] *E.g.*, Consumers Union (Comment #1139).

[165] 1–800 CONTACTS (Comment #1140).

[166] 69 FR at 5447.

[167] Illinois Optometric Association (Comment #1005).

[168] Consumers Union (Comment #1139).

[169] 1–800 CONTACTS (Comment # 1140).

[170] The same commenter also recommended that the Commission add a provision to the Rule prohibiting prescribers from using a seller's verification request to interfere with a pending contact lens sale. *See id.* The Commission believes that adding such a provision would exceed the mandate of the Act.

[171] *See* 69 FR at 5449.

[172] *Id.*

[173] *Id.*

[174] *See* 15 U.S.C. 7602.

[175] American Society for Cataract and Refractive Surgery (Comment #1148).

need for contact lenses or other ophthalmic goods.

Another prescribers' trade association asked the Commission to clarify that insurance coverage must be ''current'' and ''valid'' to ensure that patients do not attempt to defraud providers.[171] A few commenters also asked the Commission to clarify that this provision of the Rule does not require a prescriber to accept as payment proof of insurance from an insurance plan in which the prescriber does not participate.[172] In response, the Commission notes that the Act and the proposed Rule require that prescribers accept ''proof of insurance coverage'' as a form of payment. Clearly, to be a form of payment, the policy must cover the patient, be current, and be accepted by the prescriber. The Commission does not believe that any changes to the proposed Rule are needed to address the meaning of ''proof of insurance coverage.''[173] Regulating insurance plans or their discount policies is beyond the scope of the Act.

E. Section 315.5: Prescriber Verification

1. 315.5(a)—Prescription Requirement

Section 315.5(a) of the proposed Rule stated that a ''seller may sell contact lenses only in accordance with a contact lens prescription for the patient that is: (1) presented to the seller by the patient or prescriber directly or by facsimile; or (2) verified by direct communication.''[174] This provision was taken verbatim from the Act.[175] For the reasons set forth below, the Commission retains the same language in the final Rule.

a. Use of Copies

A number of individual prescribers and state optometric associations recommended that the Rule be revised to require the seller to obtain the original prescription and prohibit the use of copies.[176] These commenters expressed concern that patients may use copies of the prescription to circumvent either the prescription expiration period or the number of refills allowed. One seller, in contrast, asked the Commission to clarify that the seller is not required to have the original prescription to sell contact lenses.[177] The Commission notes that section 4(a)(1) of the Act states expressly that a prescription may be presented to a seller ''directly or by facsimile.''[178] A requirement that the seller obtain the original prescription would directly conflict with the phrase ''by facsimile'' in the statute. The Commission has therefore decided not to revise the Rule to require the seller to obtain the original prescription.

b. Presentation of Prescriptions ''Directly or by Facsimile''

A few commenters requested that the Commission broadly interpret the phrase ''directly or by facsimile'' in Section 4(a)(1) of the Act[179] and section 315.5(a)(1) of the Rule. One seller suggested that the Rule expressly permit prescription information to be provided to the seller in person or by telephone, facsimile, electronic mail or a substantially equivalent future technology.[180] The State Attorneys General commented that a patient should be able to deliver a digital image of a prescription (*i.e.*, a scanned copy) directly to the seller via electronic mail.[181]

The Commission has concluded that a patient or a prescriber may present the prescription to a seller in person, by mail, by facsimile, or through a digital image of the prescription that is sent via electronic mail.[182] All of these communication mechanisms allow the seller to view either the original or an exact copy of the prescription that was written by the prescriber. Consequently, these communication mechanisms allow the patient or prescriber to present the prescription ''directly or by facsimile'' to the seller under section 4(a)(1) of the Act and section 315.5(a)(1) of the Rule.

Furthermore, the Commission has concluded that the provision of prescription information from the consumer to the seller by telephone or by e-mail (other than an e-mail containing a digital image of the prescription, as discussed above) does not meet the ''directly or by facsimile'' standard imposed by section 4(a)(1) of the Act.[183] Telephone or e-mail communications are not expressly referenced in section 4(a)(1) of the Act, which addresses direct presentation requirements. In contrast, Section 4(g) of the Act states that a direct communication for verification purposes can be sent by ''telephone, facsimile or electronic mail.''[184] Thus, Congress expressly allowed telephone and e-mail communications for verification purposes in section 4(g) of the Act, but did not similarly allow telephone and e-mail communications for direct presentation purposes in section 4(a)(1) of the Act. Unlike the verification process, the direct presentation process may occur without the prescriber's involvement. Accordingly, the Act imposes a heightened level of scrutiny by requiring the seller to obtain the prescription ''directly or by facsimile.'' Consequently, if the patient reads the prescription information to the seller on the telephone or provides prescription information (as opposed to a digital image of the prescription) to the seller via e-mail or other electronic means, the prescription must be verified pursuant to section 315.5(d) of the Rule before the seller may supply lenses to the patient.

The Commission has further decided not to include ''substantially equivalent future technologies'' within the scope of acceptable direct presentation mechanisms. Section 4(a)(1) of the Act does not expressly reference or contemplate future technologies, and the Commission is not aware of other technologies which meet the statutory standard. The Commission therefore declines to include future technologies that do not involve an exact copy of the prescription within the scope of acceptable direct presentation mechanisms at this time.

c. Delegation of Verification Obligations

A few commenters recommended that the Rule be revised to provide prescribers with the ability to delegate

[171] American Academy of Ophthalmology (Comment #1057).

[172] American Academy of Ophthalmology (Comment #1057); American Society for Cataract and Refractive Surgery (Comment #1148); K. Green (Comment #4).

[173] One seller noted that some insurance plans provide discounts on lens purchases only if the patient purchases lenses from the same prescriber who provided the exam, and recommended that the Rule prohibit such practices in insurance or pricing policies. 1–800 CONTACTS (Comment #1140).

[174] 69 FR at 5449.

[175] *See* 5 U.S.C. 7603(a).

[176] Illinois Optometric Association (Comment #1005); Colorado Optometric Association (Comment #1067); Nebraska Optometric Association (Comment #1083); M. Palermo (Comment #22); M. Dean (Comment #148); J. Barnes (Comment #239); D. Hughes (Comment #712); S. Carlson, O.D. (Comment #906); D.S. Dwyer, M.D. (Comment #1071); J.L.Walters, O.D. (Comment #1109); S. Wagner (Comment #1107).

[177] Wal-Mart Optical Division (Comment #1070).

[178] 15 U.S.C. 7603(a)(1).

[179] 15 U.S.C. 7603(a)(1).

[180] 1–800 CONTACTS (Comment #1140).

[181] State Attorneys General (Comments ##1114 and 1176).

[182] One definition of ''facsimile'' is ''an exact copy.'' Merriam-Webster New Collegiate Dictionary 410 (1977). The Commission has concluded that a digital image of a prescription that is sent via electronic mail is ''an exact copy'' of the actual prescription, and therefore meets the ''directly or by facsimile'' standard set forth in section 4(a)(1) of the Act.

[183] The Commission's Rule is not intended to prohibit prescribers from using such mechanisms to issue contact lens prescriptions or orders to the extent authorized by other applicable law, however. *See, e.g.,* 21 CFR 801.109(a)(2).

[184] *See* 15 U.S.C. 7603(g).

their verification obligations to specific individuals in their offices.[185] The Commission declines to make the requested revision, and notes that neither the Act nor the Rule prohibits a prescriber from delegating the authority to respond to verification requests. The prescriber, however, remains responsible for ensuring that such staff members acting on his or her behalf comply with the Act and the Rule.

2. 315.5(b)—Information for Verification

Section 315.5(b) of the proposed Rule sets forth the information that a seller must provide the prescriber through direct communication when the seller is seeking to verify a contact lens prescription.[186] The proposed Rule required the seller to provide the prescriber with the following specific information: (1) The patient's full name and address; (2) the contact lens power, manufacturer, base curve or appropriate designation, and diameter when appropriate; (3) the quantity of lenses ordered; (4) the date of patient request; (5) the date and time of verification request; (6) the name of a contact person at the seller's company, including facsimile and telephone numbers.[187] This provision of the proposed Rule was taken verbatim from section 4(c) of the Act.[188]

a. Saturday Business Hours

As discussed above, the Commission has modified the definition of ''business hour'' in section 315.2 of the final Rule to ''include, at the seller's option, a prescriber's regular business hours on Saturdays, provided that the seller has actual knowledge of these hours.'' To facilitate the use of Saturday business hours, the Commission has revised section 315.5(b) of the final Rule to require sellers who opt to count such hours to state the prescriber's Saturday business hours in the verification request. Specifically, section 315.5(b)(7) of the final Rule provides that ''if the seller opts to include the prescriber's regular business hours on Saturdays as ''business hours'' for purposes of paragraph (c)(3) of this section,'' the verification request must include ''a clear statement of the prescriber's regular Saturday business hours.'' This information must be included in the verification request to alert the prescriber in case the seller is relying upon inaccurate information regarding the prescriber's regular Saturday business hours.[189]

b. Format of Required Information

Numerous commenters requested that the Commission either revise the Rule to require a standard verification request form or publish a model verification request form.[190] The Commission has decided not to modify the Rule to require the use of a standard verification form. Each seller thus retains flexibility to develop the best form for its verification requests. Nevertheless, the Commission emphasizes that any verification form used must provide prescribers with all of the required prescription verification information and should also provide prescribers with sufficient opportunity (*e.g.*, space on a form) to indicate that a particular prescription is expired, not the prescriber's patient, inaccurate, or otherwise invalid.[191]

A number of prescriber groups and individual prescribers submitted comments expressing concern that verification requests from sellers often do not contain required information, including the date and time of the request.[192] Inclusion of such information on verification requests is central to the Rule's effective operation. The Commission emphasizes that the sale of contact lenses based on a verification request which does not contain all of the required information constitutes a Rule violation.

c. Additional Information in Verification Requests

One prescriber trade association and an individual prescriber suggested that the verification request include additional information, such as the patient's telephone number and the patient's date of birth, which prescribers can use to search their records for the patient's file and to ensure that verification requests for individuals with the same name and same address do not create confusion.[193] However, the commenters did not provide any evidence suggesting that the verification information required by section 315.5(b) of the proposed Rule would be insufficient to allow prescribers to search their patient files. Moreover, the commenters did not provide evidence regarding the frequency with which the ''same name, same address'' problem actually arises. Absent such evidence, the Commission declines to implement the requested change.

A State optometry association requested that the verification request contain the prescription's expiration date as well as the number of refills prescribed.[194] Regarding the prescription expiration date, the Commission notes that prescribers should have this information because they issued the prescription and specified any expiration date of less than one year. Indeed, section 4(e) of the Act clearly places the burden on the prescriber to notify the seller if a prescription is expired.[195] With respect to the number of refills prescribed, the Commission notes that the Act does not require contact lens prescriptions to include such information. Moreover, there is no reason to believe or evidence to suggest that a seller who is attempting to verify a prescription would necessarily have information as to the number of refills prescribed.[196] For these reasons, the Commission declines to impose the requested changes.

Another state optometric association recommended that the seller be required to provide its e-mail address on the

[185] *E.g.*, Wal-Mart Optical Division (Comment #1070); American Society for Cataract and Refractive Surgery (Comment #1148).

[186] *See* 69 FR at 5449.

[187] *Id.*

[188] 15 U.S.C. 7603(c).

[189] One seller recommended that sellers be required to include this type of information in verification requests. 1–800 CONTACTS (Comment #1140).

[190] American Optometric Association (Comment #1149) (requesting model form); North Carolina State Optometric Society (Comment #1074); Oklahoma Association of Optometric Physicians (Comment #1125); Kansas Optometric Association (Comment #1153); Nebraska Optometric Association (Comment #1083); D. Ball (Comment #849); M. Spittler (Comment #158); New Mexico Optometric Assoc (Comment # 1081); Kentucky Optometric Association (Comment #1101); Arizona Optometric Association (Comment #1072); Ohio Optometric Association (Comment # 1151); K. Driver, O.D., Optometrist, P.A. (Comment #273); Olathe Family Vision (Comment #971); S. Bryant, O.D. (Comment #1127).

[191] Prescribers and prescribers' trade associations have submitted comments indicating that sellers' current verification response forms do not contain an ''expired'' option or do not provide options fitting typical situations. *E.g.*, Wisconsin Optometric Association (Comment #1086); D. Tabak (Comment #23); M. Spittler (Comment #158); Dr. G.S. Leekha (Comment #24).

[192] American Optometric Association (Comment #1149); Colorado Optometric Association (Comment #1067); Staff (Comment #131); Your Family Eye Doctors, Inc. (Comment #705); D. Hughes (Comment #712).

[193] National Association of Optometrists and Opticians (Comment #1146)(telephone number and date of birth); C.W. Kissling, O.D. (Comment #452) (date of birth).

[194] New York State Optometric Association (Comment #1073). This commenter also suggested that the verification request include the number of refills requested. In response, the Commission notes that section 315.5(b)(3) requires the seller to list the quantity of lenses ordered on the verification request.

[195] 15 U.S.C. 7603(e).

[196] For example, a seller would not have this information if the consumer had used a different seller in the past to refill a prescription.

verification form.[197] In response, the Commission notes that the Act allows the use of e-mail for direct communications between sellers and prescribers. Nothing in the Act, however, forces either sellers or prescribers to use e-mail as a means of communicating. Consequently, because sellers are not required to accept responses to verification requests by e-mail, the Commission declines to require that the e-mail address of sellers be included on the verification form.

A few prescribers requested that the seller be required to verify or confirm that the prescriber who is being asked to verify the prescription is the prescriber who fitted the contact lenses in question.[198] Otherwise, these commenters stated, a verification request that is sent to the wrong prescriber may be filled via passive verification because the prescriber neglects to respond to it. The Commission declines to implement the requested change because prescribers have the ability to respond that such verification requests are ''invalid'' under section 315.5(d) of the Rule. In addition, a verification request sent to the wrong prescriber does not conform with the requirements of the Act and section 315.5(b) of the Rule, and thus does not commence the eight-business-hour verification period.

d. Contact Person at the Seller's Company

Regarding the requirement in section 315.5(b)(6) of the Rule that the verification request include the name of a contact person at the seller's company, one prescribers' trade association commented that the person whose name is provided should be accessible to the prescriber and actually be handling the verification request.[199] This provision of the Rule is intended to ensure that the prescriber is able to reach a responsible person at the seller's company rather than requiring that the prescriber be able to reach the specific person who is handling the verification request. The Commission thus agrees that the seller's listed contact person or, if that contact person is unavailable, an alternate person who is familiar with the verification request and is authorized to respond to the prescriber, must be reasonably accessible to the prescriber. However, the person whose name is provided on the verification form need not personally handle the verification request because such a requirement would be impractical.

In comparison, one seller recommended that the contact name disclosure requirement in section 315.5(b)(6) be eliminated because the verification process already anticipates that the prescriber has a means of direct communication with the seller.[200] The Commission declines to implement the requested change because the contact name disclosure requirement stems directly from section 4(c)(6) of the Act and the evidence in the record contains insufficient evidence to justify its elimination.

e. Selection of Communication Mechanism

A few State optometric associations recommended that prescribers be allowed to determine the communication mechanism that sellers must use to submit a verification request to the prescriber (*i.e.*, by telephone, fax or online).[201] Section 4(g) of the Act expressly defines ''direct communication'' as including three different communication mechanisms that sellers may use: telephone, facsimile or electronic mail.[202] The Act therefore does not permit prescribers to limit the communications mechanisms sellers may use to submit verification requests.[203]

3. 315.5(c)—Verification Events

Section 315.5(c) of the proposed Rule states that a ''prescription is verified under paragraph (a)(2) of this section only if one of the following occurs: (1) the prescriber confirms the prescription is accurate by direct communication with the seller; (2) the prescriber informs the seller through direct communication that the prescription is inaccurate and provides the accurate prescription; or (3) the prescriber fails to communicate with the seller within eight (8) business hours after receiving from the seller the information described in paragraph (b) of this section.''[204] This provision was derived from section 4(d) of the Act.[205] For the reasons discussed below, the Commission adopts this provision without modification in the final Rule.

Many prescribers either opposed or expressed significant concern about the passive verification system imposed by this section of the Rule.[206] A few prescribers' trade associations also expressed significant concern about the use of a passive verification system in connection with a restricted medical device such as contact lenses.[207] Because Congress has decided to impose a passive verification system through the Act, whether to adopt a passive verification system is not at issue in this rulemaking proceeding.

a. The Start of the Prescription Verification Period

A few prescribers' trade associations requested that the Commission clarify that, for purposes of section 315.5(c)(3), ''eight business hours'' begins when the prescriber receives a *complete* verification request from the seller.[208] In contrast, one seller argued that if a prescriber receives an incomplete verification request, the prescriber should be required to treat the request as an ''inaccurate'' one under section 315.5(d) of the Rule and should be required to provide the seller with corrected information within eight business hours.[209] Another seller commented that, as long as the verification request provides the prescriber sufficient information to locate the patient's record, the Rule should explicitly require the prescriber to provide the seller with the missing information from the prescriber's records.[210]

After reviewing these comments, the Commission has concluded that the prescription verification period begins when the prescriber receives a *complete* verification request. Section 4(d)(3) of the Act states clearly that a prescription

[197] California Optometric Association (Comment #1158).

[198] Smith/Eye Care of Ellensburg (Comment #12); G. Barker (Comment #125).

[199] National Association of Optometrists and Opticians (Comment #1146).

[200] Costco Wholesale Corporation (Comment #1061).

[201] Kansas Optometric Association (Comment #1153); New Mexico Optometric Association (Comment #1081); Ohio Optometric Association (Comment # 1151).

[202] 15 U.S.C. 7603(g).

[203] Nevertheless, nothing in the Act prohibits prescribers from informing sellers of their preferred mode of communication and nothing prohibits sellers from accommodating such requests.

[204] 69 FR at 5449.

[205] *See* 15 U.S.C. 7603(d).

[206] J. Rubin (Comment #699); N. Silverstein, M.D. and R. Silverstein, M.D. (Comment #930); J. Owen (Comment #154); Dr. J. Pingel (Comment #962); C.F. Ford, O.D. (Comment # 969); S. Renner, O.D. (Comment #850); J.L.Walters, O.D. (Comment #1109); Jackson & Baalman (Comment #1084); D. D'Alessandro (Comment #1138); M.Turner, O.D. (Comment #1106); A. Lee (Comment #1096); R. Purnell (Comment #1075); D.S. Dwyer, M.D. (Comment #1071); E. Goodlaw (Comment #18); M.Turner, O.D. (Comment #1058) (recommending that personal, non-automated call or mail from seller be required if seller does not hear from the provider to confirm that the provider received the verification request).

[207] AAO (Comment #1057); American Society for Cataract and Refractive Surgery (Comment #1148); Wisconsin Optometric Association (Comment # 1086).

[208] American Optometric Association (Comment #1149); National Association of Optometrists and Opticians (Comment #1146).

[209] Wal-Mart Optical Division (Comment #1070).

[210] 1–800 CONTACTS (Comment #1140).

is verified only if the prescriber fails to communicate with the seller within eight business hours ''after receiving from the seller the information'' required to be provided by the Act.[211] Thus, the eight-business-hour period to verify only begins to run when the seller provides *all* of the required information to the prescriber.

The Rule does not expressly require prescribers to notify sellers of incomplete requests. If the seller is not informed that a verification request is incomplete, however, a sale based on an expired, inaccurate or otherwise invalid prescription may occur after eight business hours. Because this may pose health risks to patients, the Commission encourages prescribers to inform sellers if they receive incomplete verification requests. In addition, the Commission notes that the Rule does not require prescribers to complete incomplete verification requests, but does not prohibit prescribers from doing so.

b. The Length of the Prescription Verification Period

Section 4(d)(3) of the Act states that the prescription verification period is ''8 business hours or a similar time as defined by the Federal Trade Commission.'' [212] The Act therefore authorizes the Commission to impose a prescription verification period of either ''eight business hours'' or a ''similar time.'' Section 315.5(c)(3) of the proposed Rule contained an ''eight business hour'' prescription verification period.[213] For the reasons set forth below, the Commission retains this provision in the final Rule and adds a requirement that, during the eight-business-hour period, sellers provide a ''reasonable opportunity'' for prescribers to communicate with sellers regarding verification requests.

Many commenters specifically addressed the length of the prescription verification period. For example, one seller indicated that the prescription verification period contained in section 315.5(c)(3) of the proposed Rule of eight business hours is too long, and recommended shortening it to five hours from the time the seller makes the verification request, and to two hours if a live agent of the seller is able to communicate with a live agent of the prescriber by telephone.[214] This commenter pointed out that California's prescription verification period (the earlier of 24 hours or 2 p.m. the next business day) is shorter than the verification period in the proposed Rule, and problems have not been reported in that State.

In addition, numerous consumers voiced their support for little or no delay in the shipping of contact lenses.[215] These consumers explained that their busy lives require the ease and convenience of immediate shipping.[216] A number of the consumers pointed out that quick or overnight shipments are especially important in emergency situations if contact lenses have been lost or torn.[217] Many consumers also commented that they oppose a delay period that prevents them from ordering contact lenses from their preferred sources.[218]

In contrast, numerous prescriber groups and individual prescribers argued that the prescription verification period in the proposed Rule should be extended because it is too short to account for prescribers' busy schedules, illness, multiple location practices, vacations, professional conferences, and/or other absences from the office.[219]

After reviewing the comments, the Commission has decided to retain the ''eight business hour'' standard in the final Rule. The ''eight business hour'' standard was taken directly from the Act, and the Commission has concluded that there is insufficient evidence in the record to justify a modification of the statutory standard.

The Commission recognizes that any verification period requires patients to wait to receive their contact lenses from non-prescriber sources. However, Congress expressly required the Commission to impose a verification period of ''eight business hours or a similar time'' in Section 4(d)(3) of the Act.

The Commission has decided not to implement a verification period shorter than the ''eight business hour'' period contained in the proposed Rule. The California standard, which is cited by one proponent of a shorter verification period, involves a verification period that may be as long as 24 hours or as short as approximately five business hours. The California experience therefore does not support the imposition of a blanket five-hour verification period, and, for the reasons discussed in detail above in the definition of ''business hour'' under section 315.2 of the Rule, the Commission has decided not to adopt the California approach. In addition, the Commission notes that the record contains no evidence to support the two-hour verification period proposed for situations in which a live agent of the seller is able to contact a live agent of the buyer. There is no reason to believe that a prescriber will be able (or should be required) to respond to a verification request more quickly simply because someone in the prescriber's office is able to answer the telephone when it rings.

[211] 15 U.S.C. 7603(d)(3).

[212] 15 U.S.C. 7603(d)(3).

[213] *See* 69 FR at 5449.

[214] 1–800 CONTACTS (Comment #1140).

[215] *E.g.*, Comments #135, 136, 137, 138, 141, 142, 143, 144, 145, 146, 481, 575, 583, 596, 597, 623, 738.

[216] *E.g.*, Comments #144, 145, 385, 386, 409, 410, 419, 423, 424, 425, 427, 430, 438, 439, 442, 443, 445, 446, 450, 454, 456, 466, 467, 468, 471, 473, 474, 477, 479, 480, 484, 489, 532, 533, 536, 548, 550, 554, 557, 558, 560, 562, 565, 567, 569, 570, 579, 587, 589, 590, 592, 595, 598, 600, 601, 606, 609, 610, 611, 612, 613, 625, 626, 628, 629, 632, 633, 634, 641, 642, 649, 650, 652, 654, 655, 658, 659, 661, 662, 663, 672, 673, 675, 676, 678, 679, 680, 681, 685, 690, 693, 694, 695, 697, 701, 719, 759, 777, 786, 791, 809, 810, 826, 834, 845, 852, 871, 873, 877, 881, 882, 883, 885, 892, 895, 905, 907, 908, 909, 915, 916, 924, 927, 949, 953, 981, 986, 988, 1065, 1082, 1110, 1169, 1214, 1215, 1216, 1220, 1222, 1223, 1224, 1225, 1226, 1227, 1229, 1230, 1234.

[217] *E.g.*, Comments #140, 146, 388, 389, 390, 391, 393, 415, 421, 428, 433, 434, 444, 458, 460, 461, 475, 482, 526, 535, 541, 543, 545, 546, 564, 568, 578, 580, 581, 582, 585, 586, 591, 593, 594, 599, 621, 627, 628, 648, 688, 728, 731, 746, 749, 753, 782, 873, 888, 979, 1020, 1226.

[218] *E.g.*, Comments #142, 143, 431, 463, 555, 571, 602, 603, 604, 605, 616, 617, 620, 629, 631, 632, 633, 634, 635, 636, 638, 640, 641, 644, 645, 646, 647, 649, 670, 674, 680, 682, 685, 690, 691, 697, 709, 710, 726, 727, 731, 732, 746, 747, 748, 749, 750, 751, 753, 754, 755, 760, 763, 766, 777, 779, 782, 787, 788, 789, 799, 803, 825, 832, 835, 857, 858, 862, 866, 889, 901, 904, 911, 921, 957, 970, 979, 996, 1000, 1012, 1015, 1016, 1018, 1019, 1020, 1022, 1023, 1024, 1025, 1026, 1027, 1028, 1029, 1030, 1031, 1032, 1033, 1034, 1035, 1036, 1037, 1039, 1040, 1043, 1044, 1046, 1048, 1051, 1052, 1089, 1099, 1103, 1111, 1170, 1172, 1177, 1198, 1206, 1207.

[219] American Optometric Association (Comment #1149) (proposing a minimum of 12 business hours); Association of Regulatory Boards of Optometry (Comment #1154); Texas Optometric Association (Comment #977) (24 hours or actual prescriber business hours); American Society for Cataract and Refractive Surgery (Comment #1148); Illinois Optometric Association (Comment #1005) (48 hours); North Carolina State Optometric Society (Comment #1074) (24 or 16 business hours); E. Attaya (Comment #952); R. Scharfman, M.D. (Comment #890) (either more than an eight-hour response time or require seller to have secure 24-hour accessible means for receiving prescriber responses); Slusher (Comment #15) (16 hours); R. Graham (Comment #162); A. Henley (Comment #151); Wheaton Eye Clinic (Comment #416) (3 days); Morgantown Eye Associates, PLLC (Comment #925) (72 hours); Poindexter (Comment #260) (3 business days); K. Green (Comment #4) (six working days); S. Carpenter (Comment #182); B. Athwal (Comment #188) (one month); T. Vail (Comment #211); A.D. Dorfman, M.D. (Comment #304); S. Wexler, O.D. (Comment #375) (one day or three days); C. Lesko, M.D., FACS (Comment #960); D. Emrich, O.D. (Comment #973) (48 hours); Your Family Eye Doctors, Inc. (Comment #705) (24 hours); B.L.Whitesell, O.D. (Comment #1115); G. Lozada (Comment #1063) (24 hours, excluding weekends and holidays and making provisions for docs who are ill or out of town); O. Merdiuszew (Comment #1055); R. Purnell (Comment #1075); D.S. Dwyer, M.D. (Comment #1071); Jackson & Baalman (Comment #1084).

Moreover, as noted above, any alternative verification period must be ''similar'' to the eight-business-hour period contained in the Act.[220] The commenter's proposed five-hour/two-hour standard would result in a verification period which is significantly shorter than the eight-business-hour period contained in the Act. Consequently, the Commission has concluded that the commenter's suggested verification period is not sufficiently ''similar'' to the eight-business-hour period contained in the Act to warrant adoption.

The Commission also declines to implement a prescription verification period longer than ''eight business hours'' because the evidence in the record does not support such a change. As noted above in the discussion of the definition of ''business hours'' under section 315.2 of the Rule, survey evidence indicates that most prescribers' offices are open at least eight hours a day from Monday to Friday.[221] In addition, under the final Rule, Saturday hours will not count as part of the prescription verification period for those prescribers who are not regularly open for business on Saturdays. Several prescribers commented that a longer verification period would reduce their compliance burden under the Rule,[222] but they did not provide data demonstrating that prescribers will not be able to comply with the eight-business-hour verification period.

Moreover, as noted above, the Act requires that any alternative verification period be ''similar'' to the eight-business-hour period contained in the Act.[223] The commenters' suggested verification periods ranged from 12 business hours to one month.[224] Such verification periods would significantly exceed the eight-business-hour period contained in the Act. Consequently, the Commission has concluded that the commenters' proposed standards are not sufficiently ''similar'' to the eight-business-hour period contained in the Act to warrant adoption.

c. The Verification Process

Communication between prescribers and sellers forms the foundation for section 315.5(c) of the Rule. However, a number of prescribers' trade associations and individual prescribers commented that prescribers regularly have difficulty communicating with sellers because sellers' telephone and fax lines are busy.[225] Several of these commenters recommended that the Rule expressly require sellers to maintain sufficient telephone and fax lines to communicate with prescribers.[226] A few commenters further requested that sellers be required to provide toll-free telephone and fax lines to receive communications from prescribers, although one seller argued against such a requirement.[227]

The Act implies that prescribers will have an opportunity to respond to verification requests. The Commission declines to articulate with specificity the equipment or personnel that sellers must have to handle verification requests, so that they will have flexibility in determining the most effective and efficient means of providing this opportunity.[228] Instead, the final Rule mandates that sellers provide prescribers a ''reasonable opportunity'' for the prescriber to communicate with the seller regarding such requests.[229]

Several prescriber trade associations and at least one prescriber suggested that prescribers be allowed to respond to a verification request by submitting a copy of the patient's prescription to the seller.[230] The Commission agrees that the prescriber may provide the seller with a copy of the actual prescription in response to a verification request. However, to be considered a valid response to a verification request, the prescription must include all of the information necessary to correct any inaccuracies contained in the verification request, as required by section 315.5(d) of the Rule.

One prescriber suggested that a national database of contact lens prescriptions be created to allow prescribers and sellers to communicate.[231] The creation of such a database is beyond the mandate of the Act.

d. Pre-Verification Obligations

Several State optometric associations suggested that patients should be required to certify that they have had an eye examination in the past one or two years or, alternatively, should be asked by the seller if they have had an eye exam in the past one or two years.[232] The Act does not impose either a certification obligation on patients or a notification obligation on sellers. Moreover, the evidence in the record is not sufficient to determine whether such requirements would benefit consumers. The Commission therefore declines to include such requirements in the final Rule.

e. Post-Verification Obligations

A significant number of prescriber trade associations and individual prescribers suggested that the Rule be modified to require sellers to notify prescribers when the seller fills a patient's contact lens order and to include in that notification the quantity of contact lenses it supplied to the patient.[233] Some commenters pointed

[220] *See* 15 U.S.C. 7603(d)(3).

[221] 1–800 CONTACTS, Inc. (Comment #1140).

[222] *See, e.g.,* A. Henley (Comment #151); T. Vail (Comment #211); C. Lesko, M.D., FACS (Comment #960); Your Family Eye Doctors, Inc. (Comment #705).

[223] *See* 15 U.S.C. 7603(d)(3).

[224] *E.g.* American Optometric Association (Comment #1149) (proposing a minimum of 12 business hours); B. Athwal (Comment #188) (suggesting one month).

[225] National Association of Optometrists and Opticians (Comment #1146); American Optometric Association (Comment #1149); Kansas Board of Examiners in Optometry (Comment #1007); Kentucky Optometric Association (Comment #1101); Ohio Optometric Association (Comment #1151); Pennsylvania Optometric Association (Comment #959); P. Suscavage (Comment #20); D. Deeds (Comment #13); T. Vail (Comment #211); W. West (Comment #126); W.G. Wilde, O.D., P.C. (Comment #284); C.J. Jensen, O.D., F.A.A.O. (Comment #305).

[226] *E.g.,* National Association of Optometrists and Opticians (Comment #1146); American Optometric Association (Comment #1149); Kansas Board of Examiners in Optometry (Comment #1007); Kentucky Optometric Association (Comment #1101); Ohio Optometric Association (Comment #1151) (recommending that 90% of first time calls should not reach a busy signal and that sellers provide evidence of adequate communications access to the Commission through periodic phone/Internet provider audit confirmation); Wheaton Eye Clinic (Comment #416).

[227] *E.g.,* Kentucky Optometric Association (Comment #1101) (in favor of toll-free lines); W. West (Comment #126) (in favor of toll-free lines); Wal-Mart Optical Division (Comment #1070) (against toll-free lines).

[228] Some other consumer protection statutes that the Commission enforces expressly address the issue of how a business must respond to requests. *E.g.,* Fair Credit Reporting Act, 15 U.S.C. 1581g(c)(1)(B) (requiring nationwide consumer reporting agencies to provide ''a toll-free telephone number established by the agency at which personnel are accessible to consumers during normal business hours'').

[229] Moreover, nothing in the Act or Rule prohibits sellers from establishing toll-free lines to facilitate communications with prescribers.

[230] Kansas Optometric Association (Comment #1153); New Mexico Optometric Assoc (Comment #1081); Ohio Optometric Association (Comment #1151); J.B. Rogers, O.D. (Comment #1119).

[231] K. Poindexter (Comment #260).

[232] Kansas Optometric Association (Comment #1153); New Mexico Optometric Association (Comment #1081); Arizona Optometric Association (Comment #1072); Ohio Optometric Association (Comment #1151).

[233] American Optometric Association (Comment #1149); Nebraska Optometric Association (Comment #1083); New York State Optometric Association (Comment #1073); Oklahoma Assoc of Optometric Physicians (Comment #1125); Kansas Optometric Association (Comment #1153); New Mexico Optometric Association (Comment #1081); Kentucky Optometric Association (Comment #1101); Arizona Optometric Association. (Comment #1072); Ohio Optometric Association (Comment #1151); K. Driver, O.D. (Comment #273); C. Lesko,

Continued

out that such notification would be especially important for orders verified under the passive verification mechanism.[234] The commenters argued that, without notification, a patient may be able to evade the prescription's expiration date by ordering from multiple sellers [235] or by ordering more refills than allowed by the prescription.[236] A few prescribers suggested that the seller be required to notify the patient when the patient's contact lens prescription is filled via passive verification,[237] and one State optometry board suggested that the seller be required to notify the patient if the prescriber refuses to verify a prescription.[238]

In contrast to the prescribers, sellers argued that any attempt by prescribers to limit the quantity of contact lenses supplied to patients under a current prescription would be unwarranted under the Act.[239] An academic ophthalmologist commented that, if quantity limits are imposed, patients who tear or lose their lenses or who have to replace lenses more frequently may have prescriptions that run out before they expire.[240] One seller also pointed out that patients may choose to replace lenses more frequently than recommended by their prescriber, and that such choices may be potentially healthier for patients.[241]

After reviewing the comments, the Commission has decided not to require contact lens sellers to notify prescribers or patients when contact lenses are supplied to patients or when a prescriber refuses to verify a prescription. The Act does not impose such notification requirements. Moreover, although the Act creates a prescription release and verification system for contact lenses, it does not impose any post-verification obligations (other than recordkeeping requirements) on sellers, prescribers, or patients. Consequently, the Commission has concluded that the imposition of the suggested post-verification notification obligation upon sellers would be beyond the mandate of the Act.

One seller commented that if passive verification has occurred under section 315.5(c)(3) of the Rule and the seller does not know the prescription expiration date,[242] the seller should presume that the prescription is valid for only 30 days and supply lenses accordingly.[243] The Commission has concluded that such a 30-day presumed expiration date falls outside the mandate of the Act. The Act creates a regulatory regime which, aside from recordkeeping obligations, ends once passive verification has occurred. Although the Act does not require sellers to presume such a 30-day expiration date, it also does not prohibit them from doing so.

One State optometry board recommended that the seller be prohibited from shipping contact lenses or shipping additional contact lenses to a patient if the prescriber notifies the seller that the prescription is inaccurate, invalid or expired after the eight-business-hour period has passed.[244] One seller similarly recommended that the seller be required to notify the patient and permit the patient to return the unused lenses to the seller if the prescriber's negative response is received after the eight-business-hour period has passed.[245] The Commission believes that, aside from recordkeeping obligations, the statutory regime imposed by the Act ends when the eight-business-hour period has passed. Consequently, the requested changes fall outside the requirements of the Act. Nevertheless, the Commission notes that nothing in the statute or the Rule prohibits a prescriber from submitting such notifications to the seller or the seller from acting upon such notifications. It would likely be in the best interest of their common customer, the patient, for them to do so.

One prescribers' trade association recommended that a seller be required to document that a prescriber is licensed whenever it fills a prescription via passive verification.[246] The commenter indicated that such a requirement would prevent patients from using fictional prescriber contact information to obtain contact lenses through passive verification. The Act does not impose such a requirement. Furthermore, the Commission notes that the record does not contain any data regarding patients' submission of fictional prescriber contact information to sellers. Absent such information, the Commission cannot determine whether the license verification obligation suggested would benefit consumers. The Commission thus has not included a license verification requirement in the final Rule.

Another prescribers' trade association recommended that sellers provide a written message [''Warning: If you are having any of the following symptoms, remove your contact lenses immediately and consult your eye care practitioner before wearing your lenses again: unexplained eye discomfort, watering, vision change or redness.''] whenever lenses are supplied to a patient.[247] The commenter pointed out that its State law imposes such a notification requirement. Because the Act does not require such a warning, and the record does not contain sufficient evidence to determine whether such a requirement would benefit consumers, the Commission has not included such a requirement in the final Rule. Nevertheless, except as discussed below in the preemption section, the Commission notes that the Act does not alter the obligation to comply with applicable State law.

f. The Verification Process and HIPAA

In the NPRM, the Commission asked whether the Health Insurance Portability and Accountability Act of 1996 (''HIPAA'')[248] limits or otherwise affects prescribers'' ability to respond to a verification request under the Act.[249] Among other things, HIPAA and its implementing Privacy Rule (entitled ''Standards for Privacy of Individually

M.D., FACS (Comment #960); Olathe Family Vision (Comment #971); S. Bryant, O.D. (Comment #1127); R. Jackson (O.D. (Comment #963); G. Lozada (Comment #1063); M. Turner, O.D. (Comment #1058); Jackson & Baalman (Comment #1084); S.J. St. Marie, O.D. (Comment #1121); J. B. Rogers, O.D. (Comment #1119) (prescriber should be notified of all passive verification sales); S. Carpenter (Comment #182); W. Vietti, O.D. (Comment #127).

[234] *E.g.,* Nebraska Optometric Association (Comment #1083); New Mexico Optometric Assoc (Comment #1081); Ohio Optometric Association (Comment #1151); C. Lesko, M.D., FACS (Comment #960); M. Turner, O.D. (Comment #1058); J.B. Rogers, O.D. (Comment #1119).

[235] *E.g.,* American Optometric Association (Comment #1149); Nebraska Optometric Association (Comment #1083); New York State Optometric Assoc (Comment #1073); S.J. St. Marie, O.D. (Comment #1121). Several additional commenters did not propose a refill notification mechanism, but expressed concern about patients who order from multiple sellers in order to evade expiration dates and other prescription limitations. *E.g.,* E. Attaya (Comment #952); M. Dean (Comment #457); D. Howard, O.D. (Comment #987); Your Family Eye Doctors, Inc. (Comment #705); A. Lee (Comment #1096).

[236] *E.g.,* Nebraska Optometric Association (Comment #1083); K. Driver, O.D. (Comment #273).

[237] D. Pao (Comment #139); E. Lamp, O.D. (Comment #174).

[238] Kansas Board of Examiners in Optometry (Comment #1007).

[239] AC Lens (Comment #974); William F. Shughart, II, Ph.D., on behalf of 1–800–CONTACTS (Comment #975).

[240] P.S. D'Arienzo, M.D. (Comment #1056).

[241] AC Lens (Comment #974); P.S. D'Arienzo, M.D. (Comment #1056).

[242] Although passive verification cannot occur if the verification request is incomplete, neither the Act nor the final Rule requires sellers to include an expiration date in such a request. *See* 15 U.S.C. 7603(c); Section 315.5(b) of final Rule.

[243] Wal-Mart Optical Division (Comment #1070).

[244] Kansas Board of Examiners in Optometry (Comment #1007).

[245] 1–800 CONTACTS (Comment #1140).

[246] Texas Ophthalmological Association (Comment #1117).

[247] Kentucky Optometric Association (Comment #1101).

[248] Pub. L. 104–191 (Aug. 21, 1996).

[249] *See* 69 FR at 5447.

Identifiable Health Information'')[250] limit the circumstances under which a covered entity may disclose individually identifiable health information without prior written authorization from the patient. The Act itself did not expressly address HIPAA, but the Commission sought comment on the issue because verification of a patient's contact lens prescription information may entail the disclosure of individually identifiable health information protected by the Privacy Rule.

The majority of the commenters on this question agreed that the Privacy Rule permits eye care providers to provide contact lens prescription verification information to an authorized third-party seller without the patient's written authorization.[251]

One commenter noted that the preamble to the HIPAA Privacy Rule specifically indicates that disclosure of protected health information by an eye doctor to a distributor of contact lenses for the purpose of confirming a contact lens prescription is considered ''treatment,'' and Section 164.506 of the HIPAA Privacy Rule permits disclosure under such circumstances.[252] Another commenter recommended that the Commission include language in the final Rule clarifying that contact lens sellers are ''health care providers'' under the Privacy Rule when selling or dispensing lenses pursuant to a prescription, and thus the ''treatment'' provision permits prescribers to verify prescription information to such sellers.[253]

A few commenters disagreed, stating that a prescription verification request should be accompanied by a signed authorization from the patient to release the medical information.[254]

The Commission does not believe that the HIPAA Privacy Rule limits prescribers' ability to verify contact lens prescriptions under the Contact Lens Rule. First, the HIPAA Privacy Rule permits a ''covered entity'' to use or disclose protected health information without patient authorization ''for treatment, payment, or health care operations.'' [255] Providing, confirming or correcting a prescription for contact lenses to a seller designated by the patient constitutes ''treatment'' under the Privacy Rule.[256] Second, the HIPAA Privacy Rule allows ''covered entities'' to use or disclose protected health information without patient authorization if the use or disclosure is ''required by law.'' [257] To the extent the disclosure of protected health information needed to provide, confirm, or verify a contact lens prescription is required under the Act and the Rule, such disclosure constitutes a disclosure required by law under the HIPAA Privacy Rule.[258] Accordingly, the Commission does not believe it needs to revise the proposed Rule to address HIPAA-related issues.

4. 315.5(d)—Invalid Prescription

Section 315.5(d) of the proposed Rule states that if ''a prescriber informs a seller before the deadline under paragraph (c)(3) of this section that the contact lens prescription is inaccurate, expired, or otherwise invalid, the seller shall not fill the prescription. The prescriber shall specify the basis for the inaccuracy or invalidity of the prescription. If the prescription communicated by the seller to the prescriber is inaccurate, the prescriber shall correct it, and the prescription shall then be deemed verified under paragraph (c)(2) of this section.'' [259] This provision was derived from Section 4(e) of the Act.[260] For the reasons discussed below, the Commission adopts this provision without modification in the final Rule.

a. Inaccurate Prescriptions

If some of the information on a verification request is incorrect, but can be corrected, the prescription is ''inaccurate'' for purposes of section 315.5(d) of the Rule. Several commenters addressed the issue of inaccurate prescriptions. A few State optometric associations requested that the eight-business-hour prescription verification period be extended or treated as a new request when a prescriber notifies the seller that a correction is required.[261] In contrast, one seller indicated that the Rule should expressly state that a prescriber must provide accurate prescription information at the same time that the prescriber informs the seller that the prescription is inaccurate.[262] After reviewing the comments, the Commission has concluded that the prescriber must provide the correct information at the same time that the prescriber informs the seller that the prescription is inaccurate. Nothing in the Act indicates that Congress intended to extend the prescription verification period (including triggering a new eight-business-hour period) if the prescriber has determined that a prescription is inaccurate.

One State optometric association suggested that sellers be required to verify receipt of corrections submitted by prescribers.[263] The Commission declines to make the requested change because nothing in the Act contemplates the imposition of such a notification requirement on sellers.

The Commission also has concluded that the quantity ordered may be a legitimate basis for a prescriber to treat a request for verification of a prescription as ''inaccurate,'' because Congress indicated in section 4(c) of the Act that the quantity of lenses ordered is relevant information by requiring sellers to include the quantity ordered in prescription verification requests.[264] For example, if a verification request indicates that a patient seeks to purchase a nine-month supply of lenses only one month before the prescription expires, the prescriber may treat the

[250] 45 CFR Parts 160, 164.

[251] *E.g.,* AC Lens (Comment #974); American Academy of Ophthalmology (Comment #1057); Wal-Mart Optical Division (Comment #1070); 1–800 CONTACTS (Comment #1140); American Society for Cataract and Refractive Surgery (Comment #1148).

[252] American Society for Cataract and Refractive Surgery (Comment #1148) (citing preamble to HIPAA Privacy Rule, 67 FR 53219 (Aug. 14, 2002)). *See also* AC Lens (Comment #974) (stating disclosure of prescription information is permitted as ''treatment'' under 45 CFR 164.506); 1–800 CONTACTS (Comment #1140) (same).

[253] American Academy of Ophthalmology (Comment #1057). This commenter also urged the Commission to examine HIPAA's small business exemptions to determine whether they are applicable to the proposed rule or in conflict with it. The Commission is not aware of any such exemptions.

[254] Tupelo Eye Clinic (Comment #11); S. Carpenter (Comment #182); D. Dwyer, M.D. (Comment #275); Association of Regulatory Boards of Optometry (Comment #1154).

[255] *See* 45 CFR 164.506.

[256] *See* 67 FR 53219 (Aug. 14, 2002). See also the FAQ on the HHS Office for Civil Rights HIPAA Privacy Web site at *http://www.hhs.gov/ocr/hipaa,* entitled ''Does the HIPAA Privacy Rule permit an eye doctor to confirm a contact [lens] prescription received by a mail-order contact company?'' (Answer ID #270). Answer: ''Yes. The disclosure of protected health information by an eye doctor to a distributor of contact lenses for the purpose of confirming a contact lens prescription is a treatment disclosure, and is permitted under the Privacy Rule at 45 CFR 164.506.''

[257] *See* 45 CFR 164.512(a).

[258] For example, a prescriber is required by the Act and Rule to provide a contact lens prescription to a designated contact lens seller. *See* 15 U.S.C. 7601(a)(2); 16 CFR 315.3(a)(2). In addition, a prescriber who responds to a seller's prescription verification request and states that the prescription information is inaccurate must provide the correct information. *See* 15 U.S.C. 7603(e); 16 CFR 315.5(d).

[259] 69 FR at 5449.

[260] *See* 15 U.S.C. 7603(e).

[261] Ohio Optometric Association (Comment # 1151); Kansas Optometric Association (Comment #1153); New Mexico Optometric Association (Comment #1081).

[262] Wal-Mart Optical Division (Comment #1070).

[263] Nebraska Optometric Association (Comment #1083).

[264] *See* 15 U.S.C. 7603(c)(3).

verification request as inaccurate. Under such circumstances, the prescriber would be required to provide the seller with information regarding the basis for the inaccuracy as well as to correct the prescription by specifying an appropriate number of lenses to be dispensed.[265]

b. Expired Prescriptions

If a seller seeks verification of a prescription for which the expiration date has passed, the prescription is ''expired'' for purposes of section 315.5(d) of the Rule. Numerous commenters addressed prescribers' obligations with respect to expired prescriptions. One seller recommended that the Rule explicitly require prescribers to provide sellers the examination date and prescription issue date when reporting that a prescription has expired.[266] This seller was concerned that, without such an obligation, prescribers may use the ''expired'' option to avoid complying with prescription verification obligations. Numerous prescriber groups and prescribers, in contrast, commented that sellers are either not honoring prescribers' responses that a prescription is expired or are not honoring such responses unless the prescriber provides additional information regarding the expired prescription.[267]

The Commission has concluded that prescribers should be allowed to respond that a prescription is ''expired'' without providing additional information to the seller. Section 4(e) of the Act establishes three categories of invalid prescriptions (*i.e.*, inaccurate, expired, and otherwise invalid).[268] Section 4(e) then requires prescribers to ''specify the basis for the inaccuracy or invalidity'' only if a particular prescription is designated as inaccurate or invalid.[269] The Act does not impose a similar additional information requirement for expired prescriptions. Consequently, the Commission has decided not to require prescribers to provide additional information, such as the examination date or the prescription issue date, when they respond that a prescription is expired, although they may choose to do so.[270]

A number of prescribers indicated that a prescription should be deemed expired for purposes of section 315.5(d) of the Rule when the prescribed number of refills has been filled.[271] For the reasons provided above in the discussion of ''inaccurate'' prescriptions, the Commission has concluded that prescribers may treat a verification request as ''inaccurate'' rather than as ''expired'' based on the relationship between the quantity of lenses ordered (as indicated in the verification request) and the expiration date of the prescription. In such situations, the prescriber must provide corrected information to the seller as to the quantity of lenses that may be ordered under an accurate verification request.

c. Invalid Prescriptions

An ''otherwise invalid'' prescription under section 315.5(d) of the Rule includes, for example, situations where the verification request does not contain sufficient information to allow the prescriber to identify the patient, identifies a person who is not the prescriber's patient, or identifies a patient who has developed a medical condition which prohibits the use of contact lenses.

One seller requested that the Commission expressly define an invalid prescription as one that has expired or does not apply to the buyer.[272] The seller argued that prescribers should not be able to define ''invalid'' in a subjective manner, and that the prescriber's burden to correct an invalid prescription should be the same as the prescriber's burden to correct an inaccurate prescription. The Commission declines to make the requested changes because Section 4(e) of the Act clearly identifies three categories of invalid prescriptions (inaccurate, expired, and otherwise invalid) with different obligations imposed on prescribers for each category.[273] The Commission notes, however, that section 315.5(d) of the final Rule requires a prescriber who designates a prescription as invalid to specify the basis for the invalidity.

d. Multiple Verification Requests

Several prescriber trade associations and prescribers stated that prescribers regularly receive multiple verification requests for the same patient from a seller, even after the prescriber has responded to the original verification request.[274] Some trade associations specifically recommended that the Commission sanction sellers who submit multiple or frivolous verification requests.[275] Under the Act and the Rule, a seller may send one verification request via direct communication to the prescriber.[276] Unless a subsequent request contains additional or revised information, a seller may not resend another verification request to the prescriber.

5. 315.5(e)—No Alteration of Prescription

Section 315.5(e) of the proposed Rule prohibits the alteration of prescriptions by stating that a ''seller may not alter a contact lens prescription. Notwithstanding the preceding sentence, a seller may substitute for private label contact lenses specified on a prescription identical contact lenses that the same company manufactures and sells under different labels.''[277] This provision is derived from section 4(f) of the Act,[278] and the Commission has decided to adopt the proposed provision without modification in the final Rule.

A number of prescribers and prescriber trade associations

[265] A few prescribers commented that they are amenable to such an approach. M. Walker (Comment #165) (would like the right to limit the number of boxes prescribed to the time remaining on the prescription before expiration); D. Hughes (Comment #712) (prescriber should be allowed to approve a verification request but limit the number of boxes consistent with the prescription expiration date).

[266] 1–800 CONTACTS (Comment #1140).

[267] American Academy of Ophthalmology (Comment #1057); National Association of Optometrists and Opticians (Comment #1146); Wisconsin Optometric Association (Comment #1086); P. Butler (Comment #730); Pennsylvania Optometric Association (Comment #959); F. Aulicino (Comment #167); Family Vision Care (Comments ##130, 397); T. Pierzchala (Comment #243); K.S. Aldridge, DO (Comment #1106); M. Malone (Comment #1123); Low Country Vision Center (Comment ##406, 1183); T. Copelovitch (Comment #214); D. Ball (Comment #849); D. Tabak (Comment #23); M. Spittler (Comment #158).

[268] *See* 15 U.S.C. 7603(e).

[269] *Ibid.*

[270] When a prescriber responds to a verification request by indicating that a patient's prescription has ''expired,'' the seller may not ship lenses to that patient.

[271] New York State Optometric Association (Comment #1073); Oklahoma Association of Optometric Physicians (Comment #1125); Kansas Optometric Association (Comment #1153); New Mexico Optometric Association (Comment #1081); M. Dean (Comment #457).

[272] Wal-Mart Optical Division (Comment #1070).

[273] *See* 15 U.S.C. 7603(e).

[274] American Optometric Association (Comment #1149); National Association of Optometrists and Opticians (Comment #1146); Nebraska Optometric Association (Comment #1083); Illinois Optometric Association (Comment #1005); Pennsylvania Optometric Association (Comment #959); M. Onyon (Comment #161); H.G. Schneider, M.D. (Comment #1006); E. Attaya (Comment #952); Silverdale Eyecare Center (Comment #1054) (recommending that seller not be allowed to make multiple verification requests without confirming the prescriber's information with the patient ordering the lenses); Jackson & Baalman (Comment #1084).

[275] American Optometric Association (Comment #1149); Illinois Optometric Association (Comment #1005).

[276] If the verification request does not meet the ''direct communication'' standard set forth in section 315.2 of the Rule because the communication was not completed, the seller may resend the verification request.

[277] 69 FR at 5449.

[278] *See* 15 U.S.C. 7603(f).

commented that sellers have been providing patients with lenses that are substantially different from the ones prescribed by the prescriber.[279] Some commenters provided anecdotal examples in which sellers altered patients' prescriptions by supplying patients with tinted lenses, generic lenses or extended wear lenses even though such lenses had not been prescribed for the patient's use.[280] The Commission notes that section 315.5(e) of the Rule expressly prohibits sellers from substituting contact lenses unless the substitution involves the replacement of private label lenses with identical lenses made by the same manufacturer but sold under the labels of other sellers.[281]

One seller commented that the Act is based on the assumption that sellers can easily obtain equivalent national brands for private label lenses, but, the seller argued, this assumption is incorrect.[282] According to the seller, manufacturers have cut off entities who supply such lenses to alternative sellers. The seller suggested that the Rule require prescribers who prescribe private label brands to include on the prescription the name of a brand sold directly to alternative sellers. Nothing in the Act contemplates the imposition of such a disclosure requirement on prescribers.

6. 315.5(f)—Recordkeeping for Verification Requests

In accordance with the Act,[283] section 315.5(f) of the proposed Rule would require sellers to maintain, for a period of at least three years, records of all direct communications relating to prescription verification, as well as any prescriptions they receive from patients or prescribers.[284] As stated in the NPRM, the purpose of these recordkeeping requirements is to allow the Commission to investigate whether there has been a rule violation and to seek civil penalties for any such violations.[285] The Commission has slightly revised this provision as discussed below.

a. Copies of Prescriptions

Paragraph 315.5(f)(1) of the proposed Rule would require that sellers keep copies of prescriptions (including an e-mail containing a digital image of the prescription) or fax copies of prescriptions they receive directly from a patient or a prescriber.[286] The Commission received no comments on this provision, and adopts it without modification in the final Rule.

b. Documentation of Verification Requests

Paragraphs 315.5(f)(2) and (3) of the proposed Rule specified the documentation sellers would have to maintain relating to verification requests.[287] The required recordkeeping would vary based on the means of direct communication used by the seller or prescriber. If a seller communicates through facsimile or e-mail, it would have to maintain a copy of the verification request and a confirmation of the completed communication of that request. If the seller communicates through telephone, it would have to maintain a telephone log describing the information that the seller provided to the prescriber (*e.g.*, noting that the seller read the required prescription information to the prescriber); recording the date and time the telephone call was completed; and indicating how the call was completed (*e.g.*, by speaking with someone directly (and if so whom) or by leaving a message).[288] In addition, for communications by telephone, the seller would have to retain copies of its telephone bills.[289] Required records of communications from prescribers would be similar.[290]

The Commission received several comments on its proposed recordkeeping provision. Some commenters agreed with the provision generally.[291] Some commenters suggested the Rule also require, for telephone communications, the name of the person at the prescriber's office with whom the seller spoke, as well as the person calling on behalf of the seller.[292] Two sellers suggested eliminating the requirement that they preserve telephone bills, arguing that the requirement is burdensome and the bills can be obtained from the telephone company if necessary.[293] Also, two commenters requested that the Rule allow the seller to keep the required telephone logs in electronic format.[294] Finally, some commenters sought clarification of what constitutes the required confirmation of a completed verification request.[295]

Having considered the comments, the Commission has revised the proposed Rule to: (1) Require records of telephone communications to include the names of the individuals who participated in the call; (2) eliminate the requirement that sellers retain telephone bills; and (3) permit electronic storage of logs and other records. The Commission believes these revisions will further the recordkeeping requirements' purpose of facilitating investigation of whether a rule violation has occurred, and also reduce the burden on sellers of maintaining documents.

7. 315.5(g)—Recordkeeping for Saturday Business Hours

As set forth above in the Commission's discussion of the

[279] American Optometric Association (Comment #1149); Kansas Optometric Association (Comment #1153); Wheaton Eye Clinic (Comment #416); P. Beale, O.D. (Comment #1090, 1064); M. Malone (Comment #1123); D.K. Boltz (Comment #175).

[280] *E.g.,* Wheaton Eye Clinic (Comment #416) (tinted lenses); P. Beale, O.D., FAAO (Comment #1090, 1064) (generic lenses); D. K. Boltz (Comment #175) (switching patient from daily wear to extended wear lenses). In comparison, however, one State optometric association pointed out that its State law allows sellers to change the color of a contact lens without penalty, and noted that the experience in that State has not resulted in any problems. California Optometric Association (Comment # 1158).

[281] Some prescribers suggested that sellers be prohibited from supplying a brand of lens other than the one prescribed by the seller. *E.g.*, D.L. Rodrigue (Comment #1102); B.L.Whitesell, O.D. (Comment #1115); A. Lee (Comment #1096); M. Malone (Comment #1123). The Commission notes that Section 4(f) of the Act, 15 U.S.C. 7603(f), expressly exempts private label lenses from the general ban on contact lens substitutions. If a seller's substitution of one lens brand for another lens brand qualifies as a private label substitution under the Rule, the substitution would not violate the Rule's requirements.

[282] 1–800 CONTACTS (Comment #1140).

[283] *See* 15 U.S.C. 7603(b).

[284] 69 FR at 5449.

[285] 69 FR at 5442.

[286] *See* 69 FR at 5449.

[287] *See* 69 FR at 5449.

[288] *See* 69 FR at 5443, 5449.

[289] *See* 69 FR at 5443.

[290] Section 315.5(f)(3) of the proposed Rule would require a seller to maintain a copy of any fax or e-mail communication from a prescriber, and a record of the time and date it was received; for a telephone communication, the seller would maintain a telephone log describing the information communicated and the date and time it was received.

[291] *E.g.,* AC Lens (Comment #974) (recordkeeping requirements are reasonable); Kansas Board of Examiners in Optometry (Comment #1007) (preservation of confirmation that a facsimile or e-mail communication was successful will be crucial for enforcement: ''Because the seller will be entrusted with determining when the eight business hour period expires, it is important the seller have verification the request has been received.''); K. Poindexter (Comment #260) (seller should have to keep copies of all verification requests sent).

[292] *E.g.*, American Optometric Association (Comment #1149); Kansas Board of Examiners in Optometry (Comment #1007) (names of person(s) involved in the communication is key for investigating complaints and will foster accountability).

[293] Costco Wholesale Corporation (Comment #1061); Wal-Mart Optical Division (Comment #1070).

[294] Wal-Mart Optical Division (Comment #1070); AC Lens (Comment #974).

[295] *E.g.*, K. Poindexter (Comment #260); *see also* Wal-Mart Optical Division (Comment #1070) (for e-mails, saving the e-mail should be sufficient; seller should not have to verify that e-mail was received but should save notice of nondelivery if received). The Commission has addressed this issue in its discussion of the definition of ''direct communication'' elsewhere in this notice.

definition of ''business hour,'' the final Rule gives contact lens sellers the option to include a prescriber's regular Saturday business hours in the eight-hour verification period, if the seller has actual knowledge of those hours. In addition, the final Rule incorporates a new provision—section 315.5(g)—which requires that a seller exercising this option must maintain a record of the prescriber's regular Saturday business hours and the basis for the seller's actual knowledge thereof—*i.e.*, how the seller determined the hours. This new provision is intended to ensure that sellers have a sound basis for their actual knowledge, and to facilitate review by the Commission of seller's practices in using Saturday business hours for prescription verification.[296]

F. Section 315.6: Expiration of Contact Lens Prescriptions

Section 315.6 of the Commission's proposed Rule addresses expiration dates for contact lens prescriptions and closely tracks the requirements set forth in the Act.[297] Specifically, the proposed Rule provides that a contact lens prescription expires: (1) On the date specified by State law, if that date is one year or more after the issue date of the prescription; (2) not less than one year after the issue date if the expiration date under State law is less than one year after its issue date, or the State law does not specify an expiration date; or (3) on a different expiration date based on a prescriber's medical judgment with respect to the ocular health of the particular patient. If a prescriber specifies an expiration date of less than one year from the issue date, the prescriber must document the relevant medical reasons in the patient's medical record with sufficient detail to allow a qualified medical professional to determine the reasonableness of the shorter expiration date, and must retain such documentation for at least three years. As noted in the NPRM, the purpose of establishing a minimum expiration date as a matter of Federal law is to prevent prescribers from selecting a short expiration date for a prescription that unduly limits the ability of consumers to purchase contact lenses from other sellers, unless legitimate medical reasons justify setting such an expiration date.[298]

The Commission received several comments on this provision of the proposed Rule. For the reasons set forth below, the Commission has retained this provision as originally proposed.

1. One Year Minimum Expiration Period

With respect to the general rule that a prescription shall expire not less than one year after its issue date, some commenters agreed with the minimum and wanted State laws specifying short expiration periods to be preempted.[299] Other commenters stated that the minimum expiration date should be extended to two years rather than one,[300] while another commenter asked the Commission to strike ''not less than'' and thereby set a definitive expiration date of one year.[301] Based on the Act, the Commission concludes that Congress intended to defer to applicable state law except where such law establishes an expiration period of less than one year.

2. Medical Judgment for an Expiration Date of Less Than One Year

In its NPRM, the Commission specifically sought comment on what circumstances would provide a legitimate medical reason for setting an expiration date of less than one year.[302] Commenters cited circumstances including neovascularization of the cornea, hypoxia, diabetes, corneal degenerations (*i.e.*, keratoconus), history of frequent conjunctivitis, history of non-compliance with wearing schedules, and new contact lens wearers.[303] The Commission's Rule is premised on the expectation that prescribers will use applicable standards of care in determining whether medical reasons necessitate a prescription expiration period of less than one year.

The Commission received several other comments relating to the ''medical judgment'' exception. One commenter urged the Commission to recognize that setting a prescription expiration date of less than one year should occur ''only in exceptional circumstances.''[304] Based on the express language of the Act,[305] the Commission concludes that Congress intended to establish a general rule governing prescription expiration—namely, State law or one year from issue date, whichever is longer—and to provide an exception to that general rule to allow for cases in which a shorter expiration date is medically necessary. As such, the Commission anticipates that prescriptions shorter than one year in fact will be the exception, not the rule.

With respect to prescriptions of less than one year, section 315.6(b) of the proposed Rule would require prescribers to document the medical reasons ''with sufficient detail to allow for review by a qualified professional in the field.'' One commenter asked the Commission to clarify the applicable standard of review.[306] The Commission anticipates that such review would be conducted by a qualified professional comparable to the prescriber, such as an ophthalmologist reviewing documentation created by an ophthalmologist. The Commission does not believe it is necessary to further define the term.

G. Section 315.7: Content of Advertisements and Other Representations

Section 315.7 of the proposed Rule would prohibit any person that engages in the manufacture, processing, assembly, sale, offering for sale, or distribution of contact lenses from representing, by advertisement, sales presentation, or otherwise, that contact lenses may be obtained without a prescription.[307] This provision was taken verbatim from the Act.[308] The Commission did not receive any comments directly addressing this prohibition, and the Commission adopts it without modification in the final Rule.

Several commenters, primarily prescribers and some of their trade

[296] This optional recordkeeping requirement is not a substantive or material modification to the collection of information that the Office of Management and Budget has approved under the Paperwork Reduction Act. *See* 5 CFR 1320.5(g). Moreover, the Commission believes that only a few contact lens sellers will use the option of including a prescriber's regular Saturday hours in the eight hour verification period. Therefore, any increase in burden under the PRA will not be significant, and in any event would be offset by the decrease in burden that results from the changes in the recordkeeping requirements that are applicable to all sellers.

[297] *See* 69 FR at 5449–5450; 15 U.S.C. 7604.

[298] 69 FR at 5443.

[299] *E.g.*, Wal-Mart Optical Division (Comment #1070).

[300] S. Cutter (Comment #184) (one year is too short); R.Weigner (Comment #1118) (HMOs pay for eye exams every two years).

[301] K. Green (Comment #4) (stating that the standard of care calls for an annual contact lens follow-up exam—or less if medically indicated—and that the Commission should not dictate medical standard of care).

[302] 69 FR at 5448.

[303] American Optometric Association (Comment #1149); K. Poindexter (Comment #260).

[304] 1–800 CONTACTS (Comment #1140).

[305] 15 U.S.C. 7604.

[306] American Society for Cataract and Refractive Surgery (Comment #1148) (noting that the preamble to the proposed Rule referred to a ''qualified medical professional'' rather than a ''qualified professional in the field''). This commenter also noted that the phrase ''with sufficient detail'' is not in the Act. Such a requirement is necessary so that the Commission can review the reasons for an expiration date of less than one year. The inability to conduct such a review could significantly compromise the Commission's ability to enforce this provision.

[307] 69 FR at 5450.

[308] 15 U.S.C. 7605.

associations, urged the Commission to add another provision to the Rule which would prohibit false or misleading advertisements regarding the Act or Rule.[309] A number of commenters also suggested that the Rule specifically prohibit false or misleading ads regarding the amount a customer can save by purchasing contact lenses from a particular seller.[310] Other commenters more generally urged the Commission to scrutinize sellers' advertising for deceptive claims.[311] The Act addressed only one specific type of deceptive claim. Section 5 of the Commission Act already provides sufficient authority for the Commission to address other deceptive claims in advertising for contact lenses, and so there is no need to address them in the Rule.

H. Section 315.8: Prohibition of Waivers

Subsection 315.8 of the proposed Rule stated that a ''prescriber may not place on a prescription, or require the patient to sign, or deliver to the patient, a form or notice waiving or disclaiming the liability or responsibility of the prescriber for the accuracy of the eye examination.'' [312] The provision further stated that the ''preceding sentence does not impose liability on a prescriber for the ophthalmic goods and services dispensed by another seller pursuant to the prescriber's correctly verified prescription.'' [313] This provision was taken verbatim from Section 7 of the Act.[314] The Commission has decided to adopt this provision without modification in the Final Rule.

The Commission received one comment from a prescriber who voiced his support for the provision.[315] A few prescribers were concerned about their liability in the event that contact lenses sold to a patient via passive verification eventually lead to a lawsuit against the prescriber.[316] Traditionally, such liability issues are determined by state law. Moreover, the language of the Act does not indicate that Congress intended to address liability issues aside from the specific matters covered by Section 7 of the Act.

I. Section 315.9: Enforcement

Section 315.9 of the proposed Rule addressed the Commission's enforcement of the Rule.[317] Section 315.9 provided that a violation of the Rule ''shall be treated as a violation of a rule under Section 18 of the Federal Trade Commission Act, 15 U.S.C. 57a,'' and also stated that ''the Commission will enforce this Rule in the same manner, by the same means, and with the same jurisdiction, powers, and duties as are available to it pursuant to the Federal Trade Commission Act, 15 U.S.C. 41 *et seq.*'' [318] Commenters did not suggest any changes to the language of this enforcement provision; the Commission is adopting it without modification.

J. Section 315.10: Severability

Section 315.10 of the proposed Rule stated that the provisions of the Contact Lens Rule are separate and severable from one another, and that if any provision is stayed or determined to be invalid, it is the Commission's intention that the remaining provisions shall continue in effect. The Commission received no comments on this provision and retains it.

K. Section 315.11: Preemption

A number of comments asked that the Commission clarify to what extent the final Rule preempts State law. For example, some commenters urged the Commission to clarify that the Rule preempts State laws on issues such as prescription expiration dates, the substitution of equivalent brand contact lenses, and other allegedly ''anti-competitive'' State laws.[319] One commenter sought guidance about whether the Act or the Rule would preempt existing State law relating to the release of personally identifiable information.[320] Finally, other commenters asked the Commission to define the term ''seller'' to preempt current State laws that may seek to limit or place conditions on who may sell contact lenses, such as State licensing and registration requirements.[321]

A Federal law may preempt State law either through (1) express statutory preemption; (2) implied preemption where the intent of the Federal law is to occupy the field exclusively; or (3) implied preemption where State and Federal law actually conflict.[322] A conflict may arise where the language of Federal and State laws is inconsistent.[323] A conflict also may arise if State law ''stand[s] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'' [324]

The Act does not expressly state that it preempts any State laws. The language of the Act, however, appears to be inconsistent with the language of some State laws. For example, the Act sets an expiration date for contact lens prescriptions of ''not less than one year after the issue date of the prescription if * * * State law specifies * * * a date that is less than one year after the issue date.'' [325] Consequently, the Act preempts any State laws that establish a prescription expiration date of less than one year.[326]

In addition, certain State laws regarding prescription release and verification requirements appear to be an obstacle to the accomplishment of the purposes and objectives of the Act. The Act was intended to create ''[a] uniform national standard for prescription release and verification * * *.'' [327] The House committee

[309] *E.g.,* Nebraska Optometric Association (Comment #1083) (also seeking prohibition against sellers falsely informing patients of prescribers' refusal to verify prescriptions, or for encouraging patients to file false complaints against prescribers); Ohio Optometric Association (Comment #1151) (same).

[310] *E.g.,* North Carolina State Optometric Society (Comment #1074); Kansas Optometric Association (Comment #1153); New Mexico Optometric Association (Comment #1081); Ohio Optometric Association (Comment #1151); M. Dean (Comment #148).

[311] *E.g.*, Arizona Optometric Association. (Comment #1072); W. West (Comment #126).

[312] 69 FR at 5450.

[313] *Id.*

[314] 15 U.S.C. 7606.

[315] D. Pao (Comment #139).

[316] Tupelo Eye Clinic/Chappell (Comment #11); J.B. Rogers, O.D. (Comment #1119).

[317] *See* 69 FR at 5450.

[318] *Id.*

[319] Costco Wholesale Corporation (Comment #1061) (Rule should make clear that State law prohibiting substitution of equivalent brand name lenses are superceded by Act and Rule); Wal-Mart Optical Division (Comment #1070) (Rule should preempt any State law setting prescription expiration less than one year, and any other anti-competitive State laws); Hon. J. Sensenbrenner, U.S. House of Rep. (Comment #1246) (Act intended to preempt States from erecting regulatory or other barriers intended to artificially restrict or limit consumers' ability to purchase contact lenses from third-party sellers).

[320] New York State Optometric Association (Comment #1073) (citing New York State Education Department ruling that the release of personally identifiable information without patient's prior written consent constitutes unprofessional conduct potentially subject to professional discipline; noting that HIPAA allows State privacy rules to be more restrictive than Federal requirements). Another commenter raised a similar issue, stating that Florida law prohibits optometrists from releasing patient information without patient consent. Florida Board of Optometry (Comment #1100).

[321] Wal-Mart Optical Division (Comment #1070); 1–800 CONTACTS (Comment #1140).

[322] *See Lorillard Tobacco Co.* v. *Reilly*, 533 U.S. 525, 121 S. Ct. 2404, 2414 (2001); *Crosby* v. *National Foreign Trade Council*, 530 U.S. 363, 372–73 (2000); *English* v. *General Elec. Co.*, 496 U.S. 72, 78–79 (1990).

[323] *See English*, 496 U.S. at 79.

[324] *Freightliner Corp.* v. *Myrick*, 514 U.S. 280, 287 (1995); *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941).

[325] *See* 15 U.S.C. 7604(a)(2).

[326] There may be other direct conflicts between the Act and State laws, including, for example, State laws conflicting with the Act's provision allowing the substitution of equivalent brand contact lenses under certain circumstances, and State laws requiring written authorization from a patient as a condition of verifying contact lens prescription information. To the extent that such State laws actually conflict with the Act, they would also be preempted.

[327] H. Rep. No. 108–318, at 5 (2003).

report stated that such a standard would ''best serve the consumer'' because it ''promotes competition, consumer choice, and lower prices by extending to contact lens wearers the same automatic right to copies of their own prescriptions and allows consumers to purchase contact lenses from the provider of their choice.[328]

The Commission believes that State laws or regulations restricting prescription release or requiring ''active'' prescription verification—that is, prescribers actually must confirm and verify all prescriptions to sellers—would frustrate the purpose of the Act. Congress clearly intended to allow consumers greater freedom to choose the seller from whom they purchase their contact lenses. To further this goal, the Act requires that consumers receive their prescriptions at the end of the contact lens fitting process. It also provides that a seller may ship if a prescriber has not verified a prescription within a defined period of time, thereby preventing prescribers from failing to respond to a verification request to preclude consumers from buying contact lenses from a different seller. Consequently, the Commission concludes that the Act preempts any State laws or regulations that restrict prescription release or require active verification, because they would undermine Congress's purpose of giving consumers greater freedom in their choice of sellers from whom they purchase their contact lenses.[329]

Accordingly, the Commission has added part 315.11 to the final Rule that explicitly preempts State and local laws and regulations that establish a prescription expiration date of less than one year or that restrict prescription release or require active verification. In addition, part 315.11 also preempts any other State or local laws or regulations that are inconsistent with the Act or this part but only to the extent of the inconsistency.

III. Clerical Amendments to the Ophthalmic Practice Rules (16 CFR Part 456)

In its NPRM, the Commission also proposed two clerical amendments to the Ophthalmic Practice Rules designed to clarify the relationship between those Rules and the Contact Lens Rule. First, the Commission proposed changing the title of the Ophthalmic Practices Rules to ''Ophthalmic Practice Rules (Eyeglass Rule).'' Second, the Commission proposed adding to the Ophthalmic Practice Rules a cross-reference to the Contact Lens Rule, similar to the reference contained in section 315.1 of the Contact Lens Rule. The Commission received no comments on these proposed amendments and adopts them without modification.[330]

IV. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act, as amended, 44 U.S.C. 3501 *et seq.* (''PRA''), the Commission submitted the proposed Rule to the Office of Management and Budget (''OMB'') for review. The OMB has approved the Rule's information collection requirements.[331] The Commission did not receive any comments that necessitated modifying its original burden estimates for the Rule's information collection requirements.

Disclosures: As set forth in the NPRM, the Rule imposes certain disclosure requirements on contact lens prescribers, as required by the Act. Specifically, prescribers must provide a copy of a patient's contact lens prescription to the patient or an authorized third party upon completion of a contact lens fitting.[332]

A few commenters confirmed that the Commission estimate of one minute is an appropriate estimation of the time it takes prescribers to provide a copy of a contact lens prescription to a patient at the completion of a contact lens fitting.[333] The Commission did not receive comments on its estimates of the burden of providing a copy of the prescription to an authorized third party.

Several commenters—primarily prescribers—stated that responding to verification requests from sellers takes more than one minute.[334] Some of these commenters noted that the verification process may entail a number of steps, including answering the telephone, recording the verification request information, pulling the patient's chart, providing the information to the prescriber, reviewing the information and making a decision about the request, communicating information to the seller, and refiling the chart.[335]

Responding to a verification request does not impose a paperwork burden under the PRA, however, because the Rule does not require the prescriber to provide information to a third party. Rather, under the Rule, the prescriber determines whether to respond to a verification request, and, if so, what information to provide to the seller. If, for example, the prescription information contained in a verification request is not expired, inaccurate or otherwise invalid, the prescriber need not respond at all. Thus, depending on the particular circumstances of a particular verification request, the prescriber may or may not disclose information. Accordingly, these comments do not necessitate revising the Commission's original burden estimate.

Recordkeeping: The proposed Rule also would impose recordkeeping requirements on both prescribers and sellers. Prescribers, as required by the Act, must document in their patients'

[328] *Id.*

[329] The House Committee that passed the Act reached the same conclusion: ''The Committee believes that any State law with an active or positive contact lens prescription verification system would stand as an obstacle to the accomplishment of the full purposes and objectives of this Act. Practically, it would be impossible to comply with the terms of this Act and an active verification scheme. Therefore, it is the intent of the Committee that the passive verification system in section 4(d) preempt any conflicting State laws that use active or positive contact lens prescription verification systems.'' *Id.* at 9–10.

[330] One commenter asked the Commission to add a new provision to the Eyeglass Rule which would allow sellers to request eyeglass prescriptions from prescribers on behalf of patients. Wal-Mart Optical Division (Comment #1070). This suggestion is outside the scope of the Contact Lens Rule rulemaking and would constitute a substantive change to the Eyeglass Rule requiring a full rulemaking proceeding, which the Commission declines to undertake.

[331] The assigned OMB control number is 3084–0127.

[332] *See* 69 FR at 5444; *see also* 15 U.S.C. 7601(a). The Commission has retained in the relevant Rule provision as originally proposed.

[333] *E.g.*, American Society for Cataract and Refractive Surgery (Comment #1148); Poindexter (Comment #260); E. Lamp, O.D. (Comment #714). One commenter noted that the time is increased to approximately three (3) minutes, however, if a patient subsequently requests another copy of the prescription. Poindexter (Comment #260). *See also* American Society for Cataract and Refractive Surgery (Comment #1148) (noting that providing subsequent copies of prescriptions will take more than one minute, because staff must pull chart, provide to prescriber, prepare prescription, etc.). Because the Rule does not require prescribers to provide such additional copies, this comment does not necessitate modification of the Commission's original burden estimate.

[334] *E.g.*, Tupelo Eye Clinic/Chappell (Comment #11) (suggesting amending the Commission's cost factor to more accurately reflect the true cost, but not providing alternate time estimate); W. West (Comment #126) (estimating one minute of prescriber and five minutes of staff time); Staff (Comment #131); American Society for Cataract and Refractive Surgery (Comment #1148); E. Lamp, O.D. (Comment #714) (estimating one minute for staff and one minute for prescriber for each verification request); H.G. Schneider, M.D. (Comment #1006) (estimating minimum of 20 minutes for telephone verification); S. Renner, O.D. (Comment #850) (estimating 45 minutes to deal with automated verification request).

[335] *E.g.*, Tupelo Eye Clinic/Chappell (Comment #11); American Society for Cataract and Refractive Surgery (Comment #1148).

records the medical reasons for setting a contact lens prescription expiration date of less than one year.[336] The Commission did not receive any comments on its burden estimates for this requirement.

Contact lens sellers must 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 consumers or prescribers.[337] One contact lens seller asked the Commission to specify in the Rule that an electronic entry—in lieu of maintaining actual telephone bills—would satisfy the requirement that sellers maintain records of direct communication occurring via telephone.[338] The Commission already has deleted from the final Rule the requirement that sellers maintain telephone bills, and clarified that electronic storage of telephone log information is permitted. Accordingly, this comment does not necessitate an increase in the Commission's original burden estimate.[339]

V. Regulatory Flexibility Act

The Regulatory Flexibility Act (''RFA''), 5 U.S.C. 601–612, requires an agency to provide an Initial Regulatory Flexibility Analysis (''IRFA'') with a proposed rule and a Final Regulatory Flexibility Analysis (''FRFA'') with the final rule, if any, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. *See* 5 U.S.C. 603–605.

In its NPRM, the Commission stated its expectation that the proposed Rule would not have a significant economic impact on a substantial number of small entities.[340] The Commission noted that the Act [341] expressly mandates most, if not all, of the Rule's requirements. It thus accounts for most, if not all, of the economic impact of the proposed Rule.[342] Further, the Commission estimated that the burdens most likely to be imposed on small entities (such as many contact lens prescribers) were likely to be relatively small: providing contact lens prescriptions to patients or their agents, recording the medical reasons for setting prescription expiration dates of less than one year, and verifying prescription information.[343] Finally, the Commission estimated that the Rule's more significant recordkeeping burdens likely would fall primarily on larger sellers of contact lenses, the entities more likely to seek verification of prescriptions and thus trigger those requirements.[344]

For those reasons, the Commission deemed the NPRM as notice to the Small Business Administration of the agency's certification of no effect.[345] Nonetheless, the Commission determined that it was appropriate to publish an IRFA in order to inquire into the impact of the proposed Rule on small entities. Having received only a small number of comments on the IRFA, the Commission has prepared the following FRFA, and confirms its certification of no effect.

A. Need for and Objectives of the Final Rule

The Act directs the Commission to prescribe rules implementing the Act not later than 180 days after the Act takes effect on February 4, 2004.[346] Accordingly, the Commission issued a proposed Contact Lens Rule on February 4, 2004, and announces its final Rule in this document. The objectives of the Rule are to implement the Act and effectuate its intent to provide for the availability of contact lens prescriptions to consumers.

B. Significant Issues Raised by Public Comments, Summary of Agency's Assessment of These Issues, and Changes, If Any, Made in Response

The Commission received very few comments on its IRFA. These comments generally challenged the Commission's expectation that the Act and Rule will not have a significant economic impact on a substantial number of small entities. One comment stated that, ''[w]hile we agree that most of these burdens are mandated by the Act, they will nonetheless be quite substantial,'' and, as the Commission acknowledged in its NPRM, ''most of the prescribers affected by this statute will be small entities.'' [347] In particular, the comments argued that the burden imposed on small entities by the Act's verification requirement is substantial, as responding to verification requests takes significant time and many prescribers receive multiple requests per day.[348] To reduce this burden, one comment suggested that the Rule limit the number of verifications and prescription releases that small business prescribers must perform for a particular customer.[349]

The Commission recognizes the Rule imposes burdens on small entities, and the Commission has addressed some of these burdens in the context of the Paperwork Reduction Act in above. However, these burdens are mandated by the Act. Moreover, some of these burdens are minimal, relative to prescribers' overall business costs. For example, the Commission has estimated—and commenters agree—that prescription release will require approximately one minute per patient, and that documenting medical reasons for setting prescription expiration dates shorter than one year likely already occurs in the ordinary course of business. The obligation to verify prescriptions imposes more burden, but the evidence in the record suggests it also is relatively small as compared to overall business costs: although one commenter indicated that some prescribers receive multiple verification requests per day, other evidence in the record suggests that prescribers receive, on average, just under two (2) verification requests per week—a significantly smaller burden.[350]

Furthermore, as discussed earlier, the Commission has made certain revisions in the final Rule to reduce the burdens on businesses regardless of size—*e.g.*, permitting electronic recordkeeping of certain direct communications and eliminating the proposed requirement to maintain telephone bills. In addition, the final Rule permits some limitation on prescription release and verification. For example, the Commission has indicated that the Rule does not require prescribers to provide additional copies of prescriptions to patients after the initial release upon completion of a contact lens fitting, although the Rule

[336] *See* 69 FR at 5444; *see also* 15 U.S.C. 7604(b)(1).

[337] *See* 69 FR at 5444; *see also* 15 U.S.C. 7603(b).

[338] Wal-Mart Optical Division (Comment #1070). Wal-Mart did not specifically invoke the Commission's PRA estimates, but commented generally on the recordkeeping provisions of the proposed Rule. Nonetheless, the Commission has considered these comments as relevant to its PRA estimates.

[339] As discussed *supra*, the new provision in the final rule, that concerns recordkeeping for those sellers who choose to count a prescriber's regular Saturday business hours in the eight hour verification period, is not a substantive or material modification to the collection of information.

[340] *See* 69 FR at 5445.

[341] 15 U.S.C. 7601–7610.

[342] See 59 FR at 5445.

[343] *Id.*

[344] *Id.*

[345] *Id.*

[346] 15 U.S.C. 7607.

[347] American Society for Cataract and Refractive Surgery (Comment #1148).

[348] American Academy of Ophthalmology (Comment #1057) (stating that responding to a high volume of requests requires significant resources, assuming five minutes per request); American Society for Cataract and Refractive Surgery (Comment #1148) (burden of verifying likely to be substantial).

[349] K. Poindexter (Comment #260).

[350] *See* American Academy of Ophthalmology (Comment #1057) (up to 10 per day is not uncommon); 1–800 CONTACTS (Comment #1140) at 55.

does not prohibit this practice either.[351] Moreover, the Commission expects that, in time, as prescribers and sellers gain experience in the verification process and become more efficient, the burdens imposed on small businesses will decrease. Accordingly, the Commission does not believe the burdens imposed by the Rule on small entities are significant, and has not made any changes to the Rule in response to the comments received on its IRFA.

C. Description and an Estimate of the Number of Small Entities to Which the Final Rule Will Apply, or Explanation Why No Estimate Is Available

The Rule applies to both ''prescribers'' and ''sellers'' of contact lenses. As stated in the NPRM,[352] the Commission staff believes that many prescribers will fall into the category of small entities (*e.g.*, Offices of Optometrists less than $6 million in size), but that, for the most part, sellers subject to the Rule's recordkeeping requirements likely will be larger businesses.[353] Determining a precise estimate of the number of small entities covered by the Rule's disclosure and recordkeeping requirements is not readily feasible, and the Commission did not receive comments providing this information. However, the Commission generally estimates that the Rule will affect approximately 50,000 prescribers, many of whom are likely to be small businesses; some comments confirm that the Rule will likely impact a large number of small businesses.[354]

D. Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Final Rule, Including an Estimate of the Classes of Small Entities That Will Be Subject to the Requirements, and the Type of Professional Skills That Will Be Necessary To Comply

As mandated by the Act, the Rule imposes disclosure and recordkeeping requirements, within the meaning of the Paperwork Reduction Act, on contact lens prescribers and sellers. With respect to disclosure, section 315.3(a) the Rule requires prescribers to provide patients with a copy of their contact lens prescription upon completion of a contact lens fitting, and to provide such prescriptions to third parties authorized to act on behalf of patients.

The Rule also implements several recordkeeping requirements. First, if a prescriber sets a contact lens prescription expiration date shorter than one year, section 315.6(b) of the Rule requires the prescriber to document the medical reasons justifying the shorter expiration date and maintain that record for three years. Second, section 315.5(g) of the Rule requires sellers to maintain records of all direct communications relating to prescription verification. The specific records a seller must retain vary depending on the manner of communication.

The Commission has obtained clearance from the Office of Management and Budget (''OMB'') for these requirements.[355] The Commission staff estimated that the proposed Rule's disclosure and recordkeeping requirements referenced above would impose an average annual burden of 600,000 hours on prescribers—primarily consisting of time spent by prescribers writing and providing prescriptions to their patients—for a total annual labor cost of $25.2 million. For sellers, the staff estimated that the proposed Rule would impose an average annual burden of 300,000 hours—primarily consisting of time spent by clerical staff performing recordkeeping—for a total annual labor cost of $3 million.

E. Steps the Agency Has Taken in the Final Rule To Minimize any Significant Economic Impact of the Final Rule on Small Entities, Consistent With Applicable Statutory Objectives, Including the Factual and Legal Bases for the Alternatives Adopted and Those Rejected

The final Rule's disclosure and recordkeeping requirements are designed to impose the minimum burden on all affected members of the industry, regardless of size. The Act itself does not allow the Commission any latitude to treat small businesses differently, such as by exempting a particular category of firm or setting forth a lesser standard of compliance for any category of firm. Thus, although the Commission recognizes that the Rule imposes some burden on small entities, it does not believe the burden will be significant, and, in any event, the Commission is largely constrained by the fact that the Act mandates those burdens.

Nonetheless, the Commission has indicated above that the Rule permits some limitation on prescription release and verification by prescribers. Moreover, in time, as prescribers and sellers gain experience and efficiency in the verification process, the Commission expects that the burdens imposed on small businesses will decrease. Accordingly, the Commission confirms its initial certification of no effect.

VI. Final Rule

List of Subjects in 16 CFR Parts 315 and 456

Advertising, Medical devices, Ophthalmic goods and services, Trade practices.

■ Accordingly, for the reasons stated in the preamble, the Federal Trade Commission amends 16 CFR chapter I as follows:

■ 1. Add a new part 315 to read as follows:

PART 315—CONTACT LENS RULE

Sec.
315.1 Scope of regulations in this part.
315.2 Definitions.
315.3 Availability of contact lens prescriptions to patients.
315.4 Limits on requiring immediate payment.
315.5 Prescriber verification.
315.6 Expiration of contact lens prescriptions.
315.7 Content of advertisements and other representations.
315.8 Prohibition of certain waivers.
315.9 Enforcement.
315.10 Severability.
315.11 Effect on state and local laws.

Authority: Pub. L. 108–164, secs. 1–12; 117 Stat. 2024 (15 U.S.C. 7601–7610).

§ 315.1 Scope of regulations in this part.

This part, which shall be called the ''Contact Lens Rule,'' implements the Fairness to Contact Lens Consumers Act, codified at 15 U.S.C. 7601–7610, which requires that rules be issued to address the release, verification, and sale of contact lens prescriptions. This part specifically governs contact lens prescriptions and related issues. Part 456 of Title 16 governs the availability of eyeglass prescriptions and related issues (the Ophthalmic Practice Rules (Eyeglass Rule)).

§ 315.2 Definitions.

For purposes of this part, the following definitions shall apply:

Business hour means an hour between 9 a.m. and 5 p.m., during a weekday (Monday through Friday), excluding Federal holidays. ''Business hour'' also may include, at the seller's option, a prescriber's regular business hours on Saturdays, provided that the seller has actual knowledge of these hours.

[351] *See* discussion of section 315.5, *supra.*

[352] *See* 69 FR at 5445.

[353] *See* 12 CFR Part 121.201 (Small Business Administration's Table of Small Business Size Standards).

[354] *E.g.*, American Society for Cataract and Refractive Surgery (Comment #1148); American Academy of Ophthalmology (Comment #1057) (approximately 40% of AAO members are solo practitioners with very small staffs).

[355] The assigned OMB clearance number is 3084–0127.

''Business hour'' shall be determined based on the time zone of the prescriber.

''Eight (8) business hours'' shall be calculated from the time the prescriber receives the prescription verification information from the seller, and shall conclude when eight (8) business hours have elapsed. For verification requests received by a prescriber during non-business hours, the calculation of ''eight (8) business hours'' shall begin at 9 a.m. on the next weekday that is not a Federal holiday or, if applicable, on Saturday at the beginning of the prescriber's actual business hours.

Commission means the Federal Trade Commission.

Contact lens means any contact lens for which State or Federal law requires a prescription.

Contact lens fitting means the process that begins after an initial eye examination for contact lenses and ends when a successful fit has been achieved or, in the case of a renewal prescription, ends when the prescriber determines that no change in the existing prescription is required, and such term may include:

(1) An examination to determine lens specifications;

(2) Except in the case of a renewal of a contact lens prescription, an initial evaluation of the fit of the contact lens on the eye; and

(3) Medically necessary follow-up examinations.

Contact lens prescription means a prescription, issued in accordance with State and Federal law, that contains sufficient information for the complete and accurate filling of a prescription for contact lenses, including the following:

(1) The name of the patient;

(2) The date of examination;

(3) The issue date and expiration date of prescription;

(4) The name, postal address, telephone number, and facsimile telephone number of prescriber;

(5) The power, material or manufacturer or both of the prescribed contact lens;

(6) The base curve or appropriate designation of the prescribed contact lens;

(7) The diameter, when appropriate, of the prescribed contact lens; and

(8) In the case of a private label contact lens, the name of the manufacturer, trade name of the private label brand, and, if applicable, trade name of equivalent brand name.

Direct communication means completed communication by telephone, facsimile, or electronic mail.

Issue date means the date on which the patient receives a copy of the prescription at the completion of a contact lens fitting.

Ophthalmic goods are contact lenses, eyeglasses, or any component of eyeglasses.

Ophthalmic services are the measuring, fitting, and adjusting of ophthalmic goods subsequent to an eye examination.

Prescriber means, with respect to contact lens prescriptions, an ophthalmologist, optometrist, or other person permitted under State law to issue prescriptions for contact lenses in compliance with any applicable requirements established by the Food and Drug Administration. ''Other person,'' for purposes of this definition, includes a dispensing optician who is permitted under State law to issue prescriptions and who is authorized or permitted under State law to perform contact lens fitting services.

Private label contact lenses mean contact lenses that are sold under the label of a seller where the contact lenses are identical to lenses made by the same manufacturer but sold under the labels of other sellers.

§ 315.3 Availability of contact lens prescriptions to patients.

(a) *In general.* When a prescriber completes a contact lens fitting, the prescriber:

(1) Whether or not requested by the patient, shall provide to the patient a copy of the contact lens prescription; and

(2) Shall, as directed by any person designated to act on behalf of the patient, provide or verify the contact lens prescription by electronic or other means.

(b) *Limitations.* A prescriber may not:

(1) Require the purchase of contact lenses from the prescriber or from another person as a condition of providing a copy of a prescription under paragraph (a)(1) or (a)(2) of this section or as a condition of verification of a prescription under paragraph (a)(2) of this section;

(2) Require payment in addition to, or as part of, the fee for an eye examination, fitting, and evaluation as a condition of providing a copy of a prescription under paragraph (a)(1) or (a)(2) of this section or as a condition of verification of a prescription under paragraph (a)(2) of this section; or

(3) Require the patient to sign a waiver or release as a condition of releasing or verifying a prescription under paragraph (a)(1) or (a)(2) of this section.

§ 315.4 Limits on requiring immediate payment.

A prescriber may require payment of fees for an eye examination, fitting, and evaluation before the release of a contact lens prescription, but only if the prescriber requires immediate payment in the case of an examination that reveals no requirement for ophthalmic goods. For purposes of the preceding sentence, presentation of proof of insurance coverage for that service shall be deemed to be a payment.

§ 315.5 Prescriber verification.

(a) *Prescription requirement.* A seller may sell contact lenses only in accordance with a contact lens prescription for the patient that is:

(1) Presented to the seller by the patient or prescriber directly or by facsimile; or

(2) Verified by direct communication.

(b) *Information for verification.* When seeking verification of a contact lens prescription, a seller shall provide the prescriber with the following information through direct communication:

(1) The patient's full name and address;

(2) The contact lens power, manufacturer, base curve or appropriate designation, and diameter when appropriate;

(3) The quantity of lenses ordered;

(4) The date of patient request;

(5) The date and time of verification request;

(6) The name of a contact person at the seller's company, including facsimile and telephone numbers; and

(7) If the seller opts to include the prescriber's regular business hours on Saturdays as ''business hours'' for purposes of paragraph (c)(3) of this section, a clear statement of the prescriber's regular Saturday business hours.

(c) *Verification events.* A prescription is verified under paragraph (a)(2) of this section only if one of the following occurs:

(1) The prescriber confirms the prescription is accurate by direct communication with the seller;

(2) The prescriber informs the seller through direct communication that the prescription is inaccurate and provides the accurate prescription; or

(3) The prescriber fails to communicate with the seller within eight (8) business hours after receiving from the seller the information described in paragraph (b) of this section. During these eight (8) business hours, the seller shall provide a reasonable opportunity for the prescriber to communicate with the seller concerning the verification request.

(d) *Invalid prescription.* If a prescriber informs a seller before the deadline

under paragraph (c)(3) of this section that the contact lens prescription is inaccurate, expired, or otherwise invalid, the seller shall not fill the prescription. The prescriber shall specify the basis for the inaccuracy or invalidity of the prescription. If the prescription communicated by the seller to the prescriber is inaccurate, the prescriber shall correct it, and the prescription shall then be deemed verified under paragraph (c)(2) of this section.

(e) *No alteration of prescription.* A seller may not alter a contact lens prescription. Notwithstanding the preceding sentence, a seller may substitute for private label contact lenses specified on a prescription identical contact lenses that the same company manufactures and sells under different labels.

(f) *Recordkeeping requirement—verification requests.* A seller shall maintain a record of all direct communications referred to in paragraph (a) of this section. Such record shall consist of the following:

(1) For prescriptions presented to the seller: the prescription itself, or the facsimile version thereof (including an email containing a digital image of the prescription), that was presented to the seller by the patient or prescriber.

(2) For verification requests by the seller:

(i) If the communication occurs via facsimile or e-mail, a copy of the verification request, including the information provided to the prescriber pursuant to paragraph (b) of this section, and confirmation of the completed transmission thereof, including a record of the date and time the request was made;

(ii) If the communication occurs via telephone, a log:

(A) Describing the information provided pursuant to paragraph (b) of this section,

(B) Setting forth the date and time the request was made,

(C) Indicating how the call was completed, and

(D) Listing the names of the individuals who participated in the call.

(3) For communications from the prescriber, including prescription verifications:

(i) If the communication occurs via facsimile or e-mail, a copy of the communication and a record of the time and date it was received;

(ii) If the communication occurs via telephone, a log describing the information communicated, the date and time that the information was received, and the names of the individuals who participated in the call.

(4) The records required to be maintained under this section shall be maintained for a period of not less than three years, and these records must be available for inspection by the Federal Trade Commission, its employees, and its representatives.

(g) *Recordkeeping requirement—Saturday business hours.* A seller that exercises its option to include a prescriber's regular Saturday business hours in the time period for verification specified in §315.5(c)(3) shall maintain a record of the prescriber's regular Saturday business hours and the basis for the seller's actual knowledge thereof. Such records shall be maintained for a period of not less than three years, and these records must be available for inspection by the Federal Trade Commission, its employees, and its representatives.

§ 315.6 Expiration of contact lens prescriptions.

(a) *In general.* A contact lens prescription shall expire:

(1) On the date specified by the law of the State in which the prescription was written, if that date is one year or more after the issue date of the prescription;

(2) Not less than one year after the issue date of the prescription if such State law specifies no date or specifies a date that is less than one year after the issue date of the prescription; or

(3) Notwithstanding paragraphs (a)(1) and (a)(2) of this section, on the date specified by the prescriber, if that date is based on the medical judgment of the prescriber with respect to the ocular health of the patient.

(b) *Special rules for prescriptions of less than one year.*

(1) If a prescription expires in less than one year, the specific reasons for the medical judgment referred to in paragraph (a)(3) of this section shall be documented in the patient's medical record with sufficient detail to allow for review by a qualified professional in the field.

(2) The documentation described in the paragraph above shall be maintained for a period of not less than three years, and it must be available for inspection by the Federal Trade Commission, its employees, and its representatives.

(3) No prescriber shall include an expiration date on a prescription that is less than the period of time that he or she recommends for a reexamination of the patient that is medically necessary.

§ 315.7 Content of advertisements and other representations.

Any person who engages in the manufacture, processing, assembly, sale, offering for sale, or distribution of contact lenses may not represent, by advertisement, sales presentation, or otherwise, that contact lenses may be obtained without a prescription.

§ 315.8 Prohibition of certain waivers.

A prescriber may not place on a prescription, or require the patient to sign, or deliver to the patient, a form or notice waiving or disclaiming the liability or responsibility of the prescriber for the accuracy of the eye examination. The preceding sentence does not impose liability on a prescriber for the ophthalmic goods and services dispensed by another seller pursuant to the prescriber's correctly verified prescription.

§ 315.9 Enforcement.

Any violation of this Rule shall be treated as a violation of a rule under section 18 of the Federal Trade Commission Act, 15 U.S.C. 57a, regarding unfair or deceptive acts or practices, and the Commission will enforce this Rule in the same manner, by the same means, and with the same jurisdiction, powers, and duties as are available to it pursuant to the Federal Trade Commission Act, 15 U.S.C. 41 *et seq.*

§ 315.10 Severability.

The provisions of this part are separate and severable from one another. If any provision is stayed or determined to be invalid, it is the Commission's intention that the remaining provisions shall continue in effect.

§ 315.11 Effect on state and local laws.

(a) State and local laws and regulations that establish a prescription expiration date of less than one year or that restrict prescription release or require active verification are preempted.

(b) Any other State or local laws or regulations that are inconsistent with the Act or this part are preempted to the extent of the inconsistency.

PART 456—[AMENDED]

■ 2. The authority citation for part 456 continues to read as follows:

Authority: 15 U.S.C. 57a; 5 U.S.C. 552.

■ 3. Revise the title of part 456 to read as follows:

PART 456—OPHTHALMIC PRACTICE RULES (EYEGLASS RULE)

■ 4. Add a new § 456.5 to read as follows:

§ 456.5 Rules applicable to prescriptions for contact lenses and related issues.

Rules applicable to prescriptions for contact lenses and related issues may be found at 16 CFR part 315 (Contact Lens Rule).

By direction of the Commission.

Donald S. Clark,

Secretary.

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