FTC – A clear look at the Eyeglass Rule

May 18th 2023

Sarah Botha:

Good morning, and welcome to A Clear Look at the Eyeglass Rule. I'm Sarah Botha, and I'm an attorney in the Division of Advertising Practices. On behalf of my colleagues, we're delighted to have you joining us, some in person as well as via the live webcast. Before our program begins, I'm going to give a few administrative details, primarily for those in person. Please silence any mobile phones and devices. If you need to use them during the workshop, just be respectful of the speakers and your fellow audience members. Please be aware if you need to leave the Constitution Center building for any reason during the workshop, you'll have to go through security again in order to come back in. Keep this in mind and plan ahead, especially if you're participating on a panel, so that we can remain on schedule.

The restrooms are in the hallway just outside the auditorium. As you may know, there's a cafeteria located inside the building, so you can visit that without going through security. The cafeteria is open until 11:00 AM, and then it has limited service until it reopens at 11:30, and it will be open until 1:00 PM. There's no food or drink allowed inside the auditorium except for water. Most of you have received a lanyard with a plastic FTC event badge on it. We use these for multiple events, so when you leave the building this afternoon, please just return it to security. If an emergency occurs that requires you to leave the auditorium but remain in the building, please follow the instructions provided over the PA system. If an emergency occurs that requires the evacuation of the building, an alarm will sound, and everyone should leave the building in an orderly manner through the main 7th Street exit. After leaving the building, turn left and proceed down 7th Street and across E Street to the FTC emergency assembly area. Remain there until instructed to return to the building.

Please be advised that this event may be photographed, and it is being webcast and recorded. By participating, you're agreeing that your image and anything you say or submit may be posted indefinitely on the FTC.gov website or any of the commission's publicly available social media sites. A video recording of the webcast and a transcript of these proceedings will be available on our workshop webpage shortly after the event to create a lasting record for everyone who's interested in these issues.

During each panel, we will be accepting audience questions through our dedicated email address, which is EyeglassWorkshop2023@FTC.gov, and that will appear on the slides during each panel so you don't have to memorize it. We'll also collect question cards from attendees in the room. You may have picked some up when you came in, but if not, just raise your hand, and we can distribute them to the people in the audience. Due to time constraints, we may not be able to get to all the questions, but we will review every question that we receive. We are also seeking public comment until June 20th. Please take a look at the event webpage for information on how to submit comments.

Lastly, I want to thank our panelists for taking part in today's workshop. We're very grateful for your time. Aside from the people you'll see on stage today, this event would not be possible without the great work of Pinar Gezgec, Bruce Jennings, Casmir Campos, James Murray, and Kristal Peters; our honors paralegals Jacob Frech and Nicholas Xu, who helped us with registration; our talented staff from Division of Consumer and Business Education, June Chang and Lesley Fair; Mitch Katz from the Office of Public Affairs; and the invaluable Bonnie McGregor from our Division of Advertising Practices. And now I have the great pleasure of introducing the director of our Bureau of Consumer Protection, Sam Levine,

who will deliver opening remarks. Sam oversees the Commission's attorneys, investigators, and administrative personnel working to protect consumers from unfair and deceptive practices in the marketplace. Sam previously served as an attorney advisor to Commissioner Rohit Chopra and as a staff attorney in our Midwest regional office, and prior to joining the FTC, he worked at the Illinois Attorney General. Welcome, Sam.

Samuel Levine:

Well, thank you Sarah, and good morning, everyone. I am Sam Levine, the director of the Bureau of Consumer Protection at the FTC. And I want to welcome you this morning and thank you for coming to our workshop, A Clear Look at the Eyeglass Rule. Thanks particularly to all our panelists for taking the time to participate. We're looking forward to hearing what you have to say. And thank you to everybody in the audience and to everyone watching the webcast. We hope that today's discussion will be lively and informative. And as a proud glasses wearer myself, I know I am looking forward to hearing from all of you.

As many of you probably know, the Eyeglass Rule has been in place since 1978, and since that time, the goal of the FTC in this space has been to promote competition in the eyeglass marketplace and to empower consumers to comparison shop for glasses by making sure they have a copy of their prescription in hand after their eye exam. We're holding this workshop because we have been taking a close look at the Eyeglass Rule and how it's working in practice, and we've proposed a few updates to the rule with the goal of improving compliance and increasing clarity around the rule's requirements.

While we've taken written comments from the public on our rule changes, we organized this event today so that we can have a dialogue about the rule. We want to hear from consumers, prescribers, opticians, eyeglass sellers, and others about how they think the rule is working and which if any of the proposed changes the FTC should adopt. So we'll have a series of conversations today. We will tease out some of the issues we've seen come up in the public comments, in consumer complaints, and in our discussions with prescribers when we've engaged in enforcement actions. We'll examine what effects the proposed rule changes might have in terms of promoting competition and increasing consumer choice, and whether there are burdens these changes might impose on prescribers. We'll also talk about the amendments to the Contact Lens Rule that were adopted in 2020. How have prescribers implemented these requirements? What challenges have they presented? And what does the consumer experience look like?

Our first panel is going to look at the prescription release requirement, which, of course, is the foundation of the Eyeglass Rule. We'll hear from one consumer about her experience as a lifelong wearer of prescription eyeglasses and contact lenses. We'll consider whether patients understand their right to receive their prescription, and how prescribers are complying with the rule. It's one thing to say prescribers must give patients a copy of their prescription, but how prescribers comply with the requirement can have a real impact on the rule's effectiveness. When are you giving patients their prescription? Is it right after the exam, or you making them wait until the next day or after you've already sold them a pair of eyeglasses? Are you giving out prescriptions to everyone or only to patients who ask for one? If you make your patients pay for your eye exam before you provide the prescription, are you making clear that the fee is for the exam and not for the prescription? Are you charging everyone, regardless of whether they ask for their prescription or need eyeglasses?

Our second and third panels are going to take a close look at the proposed amendments and will consider the feedback we've received on the amendments in the public comments. We heard some concerns about the potential burden of a confirmation requirement in the Eyeglass Rule, and also we heard support for the confirmation requirement as a way to improve compliance with the rule and help

consumers understand their rights. This proposal is identical to a requirement that's been in place in the Contact Lens Rule since 2020, and we want to hear about how prescribers have adapted to that new requirement. We're also going to have a presentation from a practicing optometrist, who will share some real-life examples about how the confirmation requirement has been implemented. And then we'll consider the possible impact of extending this confirmation requirement to eyeglass prescriptions, whether it makes sense to have matching requirements for eyeglasses and contacts, and whether there are ways that prescribers can comply with the rule while minimizing the burden.

We know, for example, that electronic health records and online portals are changing the way that medical practices maintain patient records and communicate with patients. The proposed rule changes provide options for prescribers to share prescriptions electronically, with consumer consent. Under these proposed changes, it'll be fine to put a prescription on a portal if the consumer knows that it's there, if it's easily accessible, and if the consumer has agreed to receive it in that fashion. It will not be okay if you don't tell the consumer how to access their prescription or if you wait days or weeks before uploading it. And some consumers, of course, may prefer or even need a paper copy, so that needs to remain an option for them.

Finally, today we will discuss two other proposed rule changes that are primarily technical amendments but are designed to help patients and prescribers understand the boundaries of the rule and ensure that their prescription release is effective. We have proposed changing the term "eye examination" to "refractive eye examination" to clarify that the prescription must be provided anytime a refraction is taken. We've also proposed adding a statement, one that already appears in the Contact Lens Rule, noting that presentation of proof of insurance coverage counts as payment for purposes of determining when a prescription must be provided. We've had some public comments on both of these proposed changes, and we'll discuss the possible effects that these clarifying amendments might produce.

I hope that today's discussion can help us have a better understanding of what consumers experience when visiting their eye care professional and when they shop for glasses. And I hope we also come away with a clear understanding of what the prescriber's experience is in terms of complying with the Eyeglass Rule and how the proposed amendments could affect their practice. We are keeping an open mind and we're counting on a productive discussion. We also encourage all interested parties to share their thoughts via written comments, which can be submitted through June 20th. Your input helps our agency reach the most informed decisions, and we're deeply grateful for your being here today. Thanks very much.

Paul Spelman:

Thank you very much. My name is Paul Spelman. I'm an attorney with the Division of Advertising Practices here at the Federal Trade Commission. We're going to start with the first panel, which is the need for and ongoing barriers to prescription release. I'm going to introduce the panelists. There are longer bios. I'm just going to present short bios, but there are longer bios in the program if you want to take a look at that and get more information about the panelists. We have some panelists who are here with us and some panelists who are appearing remotely. The first panelist, to my left, is Sara Brown. She's the director of government affairs for Prevent Blindness, one of the leading national organizations devoted to protecting and improving eye health care and safety. She's been at Prevent Blindness since 2017. Earlier on in her career, she represented the interests of medical group practice managers with the Medical Group Management Association, among other things.

Appearing remotely is Wallace or Wally Lovejoy. Mr. Lovejoy has a long history in the optical industry and has been a consultant to many of the major optical retailers and managed vision care companies in the United States. He now has his own firm, Lovejoy Eyecare Consulting, and he's also chair of the

National Association of Retail Optical Companies, a trade organization or trade association for retail optical companies with co-located eye care services. Way back before getting into the optical field, Wally was actually an attorney with us, the FTC. Further to my left is Dr. Jeffrey Michaels. He is the co-owner of a private optometry practice in Glen Allen, Virginia, near Richmond. He's currently the chair of the American Optometric Association's Federal and Regulatory Policy Communications and is past president of the Virginia Optometric Association. He's also been honored as Optometrist of the Year by the American Optometric Association and the Virginia Optometric Association, among other honors.

To his left is Dr. Andrew Stivers, the associate director in the antitrust practice of the National Economic Research Association's associates economic consulting, or NERA for short, who specializes in the economics of consumer protection and privacy. Prior to joining NERA, Dr. Stivers was also with us. He was the deputy director for consumer protection in the FTCs Bureau of Economics. Before serving in federal government, Dr. Stivers was an assistant professor of economics at Oregon State University. Last but not least, we have Felecia Neilly. She's appearing remotely. And Miss Neilly is a trade compliance manager with a business software firm in Georgia. But what we're interested in most today is her experience as an eyeglass and contact lens consumer, which is how we're going to start today's panel.

Miss Neilly asked that she could participate in the workshop today, and we thought it would be great to have an individual consumer to recount some of her experiences. We didn't pick her for any particular viewpoint, but she has worn corrective eyewear since she was a child and has been to multiple eye care providers over the years. We would not contend of course, that her experience represents all consumers, but regardless, it's certainly worth hearing a little bit about what she's experienced, to remind us that when we talk about eye care and patients getting their prescriptions and paying for eyeglasses, it's not something that's just abstract or theoretical. We're talking about real people, millions of them in America, who go to their eye doctor every year because they rely on glasses or contacts in order to see, and it's for these people that the Eyeglass Rule was created. So let me start with some questions. Miss Neilly, thank you for joining us. Let me ask you, how many times do you think you've been to an eye doctor for an examination over the years?

Felecia P. Neilly:

Since I was nine years old, at least once a year, so I would say at least 50, 50 or more times, 50 or 60 times I've been for an eye exam.

Paul Spelman:

What about your experience was it that made you want to participate in the forum today?

Felecia P. Neilly:

Because just the difficulty that I've encountered in getting the eyeglass prescription issued to me. Just in our conversations, I never knew that this Eyeglass Rule has been in effect since, I think someone mentioned the '70s. And it's only just recently that I've been requesting the prescriptions by my provider because I thought you always needed to get your eyeglasses from the provider as well. So I just always purchased them following the eye exam, not knowing that I had the option to receive the prescription.

Paul Spelman:

Did you always not receive your eyeglass prescription, or did sometimes you get some of the prescription or anything?

Felecia P. Neilly:

When I requested it, when I learned that I could request it and shop around and be more competitive in purchasing my eyeglasses, then I received it. But as I mentioned during our conversation, sometimes the prescriptions weren't complete. If I left the office without requesting it, most times it was difficult to get it mailed to me or sent to me after the fact, or sometimes, most times, the prescription was just not complete.

Paul Spelman:

Did this affect your ability to get eyeglasses?

Felecia P. Neilly:

Absolutely because then I would have to go back and tell them, "The diameter is missing," or one of the components of the prescription that's necessary for filling it was not included in the prescription. So then there was time and difficulty. It just always felt like there was a reluctance once I left and didn't purchase from provider. There was just always reluctance in getting the complete information needed to fill the prescription, always.

Paul Spelman:

And you said that you went to multiple providers over the years. Did you notice differences between them?

Felecia P. Neilly:

No. It was the same experience when getting a prescription. And I just feel if the rule has been in effect since the '70s, it should be a part of your checkout, so to speak. When you're leaving the office, they should give you the prescription, whether you request requested or not.

Paul Spelman:

Do you recall what you typically paid for eyewear? Or...

Felecia P. Neilly:

The average for eyeglass, if I remember correctly, is around 200 for a complete prescription, until I started online. [inaudible] shopping became an option, and there's some discount retailers out there, so it started to get significantly cheaper.

Paul Spelman:

So once you had the prescription and were able to go to online shoppers, it affected how much you would pay for the eyewear?

Felecia P. Neilly:

Mm-hmm. Absolutely.

Paul Spelman:

Why is this issue important to you, and what would you like to see change?

Felecia P. Neilly:

It's important to me because as a consumer of eyewear, it impacts me directly. And as I mentioned before, I think there should be some kind of database or something so that you don't even need a paper prescription. Once you walk out of the office, wherever you go, you should be able to access your prescription pretty much like your medical records. I think that would be a significant improvement.

Paul Spelman:

Okay. Well, thank you very much for recounting your experience. We really appreciate it.

Felecia P. Neilly:

You're welcome.

Paul Spelman:

Now, as we noted, Miss Neilly's experience is just that of one consumer. And as I said, we're not contending that every consumer has had the same experience. But the fact that she's had these experiences, when the Eyeglass Rule's prescription release requirement has been in effect since 1978, is, of course, a tad unsettling. And we've received comments from other consumers saying that the prescriptions are not always released, or they're released upon request. In fact, I talk to people all the time, and I've become annoying about asking them, when they tell me they've been to the eye doctor, whether they've received their prescriptions. And quite a number of times, I'm told that they didn't. As some of you may know, the FTC recently sent 37 cease and desist letters to eyeglass providers after receiving complaints that they hadn't provided patients with prescriptions. And in 2020, we sent 28 such letters, and a few years earlier we sent 45 similar letters to contact lens prescribers, and just recently in February, we sent another 24 letters.

Now, the American Optometric Association, among others, has noted that the numbers are very small in relation to the overall number of prescribers in the United States, which is true. That's certainly true. But we typically only pursue cease and desist letters when we get a complaint from a consumer, and we don't always get a lot of eyeglass complaints, or contact lens complaints, about not receiving prescriptions. However, we've also seen some consumer surveys indicating that a fairly high percentage of consumers, just under 50% in one survey and more than 50% in another survey, didn't get their eyeglass prescription given to them after their eye exam. Sometimes they got it after they asked the doctor for it. Sometimes they didn't get it at all. As we acknowledged in the Eyeglass Rule notice of proposed rulemaking, no survey is perfect, and some of these surveys were submitted by interested parties, but they were also performed by reputable polling firms, using generally accepted survey methodology. We also, and this is important, we haven't seen any consumer surveys that contradict these findings.

So all that said, we're faced with questions about why compliance with the Eyeglass Rules prescription release requirement has proven a challenge, what are some of the obstacles to compliance, and whether it's even important to ensure compliance. We can discuss the last aspect later on, but we'd like to start with, for the sake of argument, assuming that compliance with the automatic prescription release provision does matter. So if we could just start the panel by asking, what are some of the reasons that doctors may not provide prescriptions automatically? Is there, for instance, confusion about the requirement, or are there some other reasons? If I could start with Dr. Michaels, if you have any thoughts.

Dr. Jeffrey Michaels OD:

Sure. What I'll say is, in my experience, 100% of the prescriptions that are coming out of our offices are automatically uploaded electronically to a portal the very second that the prescription is finalized. And so one of the things that happened over the last several years, as electronic health records became more mandated and as the federal government mandated, through a program called MIPS, that patients were given online access... That was the most important piece of the MIPS program that Medicare had. It mandated that patients get access to their portals. And so, in our experience, the vast majority of our patients don't want paper copies of the prescription. They want electronic copies so that they can have access in their phone and access at 2:00 in the morning, whenever they want it. And so the vast majority of patients that are being seen today are being seen with electronic health records, and those prescriptions are being authorized the second that the prescription is signed. They have immediate access to it.

Paul Spelman:

So do you think they misunderstand, that they think they have not received their prescription when it has been delivered electronically?

Dr. Jeffrey Michaels OD:

I can't speak for what the patients are understanding. What I do know is that overwhelmingly, more patients want electronic access to their prescriptions. And the ability to have it electronic, be able to upload it into whatever vendor they want to purchase from, becomes a much more convenient opportunity for them. And so the vast majority of optometrists that I know are immediately giving access to that and protocols are in place to ensure that patients understand how to get onto their portal. The portals that are being created today are created by the electronic health record, and so we spend a lot of time in our office making sure that patients have access to their portal and have the understanding of how to get onto the electronic portals.

Paul Spelman:

Miss Brown, do you have any thoughts on whether it is a problem that some patients may either be not getting their prescriptions or think they're not getting their prescriptions?

Sara D. Brown MPA:

Well, overwhelmingly, it is very concerning that patients might not understand how to access their prescriptions. It's wonderful that patients are overwhelmingly, as Dr. Michaels has said, requesting or desiring these prescriptions to be available to them online. But from the Prevent Blindness perspective and the patient's perspective, not every single patient is the same. Not everybody has the same access. Not everybody has the same broadband capabilities, the same smartphone technologies. And a lot of patients lack health literacy that encourages us as a completely available use to, or available avenue for them to receive access to their prescriptions. So it is encouraging, but it seems to that there's a missed opportunity if patients can access their records digitally, but if they're not also given other means to access their prescriptions.

Paul Spelman:

Now, it's our understanding that a lot of times, it's not the doctor themselves who hands the prescription, but rather the staff. Is there anything that can be done to help the staff, encourage the staff to comply with the rule? Is there anything, training or anything that needs to be done in that respect?

Sara D. Brown MPA:

Question to me?

Paul Spelman:

Sure.

Sara D. Brown MPA:

I think that one simple question that can really help to steer the patient in the right way to get their prescriptions when they need them, as they should be able to receive them, is giving them preference over how to receive their prescriptions. Asking them, do they prefer it digitally? Do they prefer a paper copy? Do they prefer both? I think asking that simple question, and giving the patient options to decide what is the best for them and to make their own health care decisions, is the best way to achieve that.

Paul Spelman:

Dr. Michaels, do you have any thoughts on that?

Dr. Jeffrey Michaels OD:

I do. I think that if you talk to any optometrist or ophthalmologist today, the workforce is completely different today compared to pre-COVID, and staff turnover is at a much higher rate. So your question about should something be done from a staff training point of view, it's always an ongoing effort, and because the workforce is completely different, staff training on all of the different patient relationship, whether it's the prescription or just simply pretesting or whatever aspect is an ongoing issue in today's workforce, that's not a reason to not be giving a prescription. Again, your question was more about what is the workforce like, and the workforce is completely different today compared to pre-COVID.

Paul Spelman:

Do you think it matters, the difference between an automatic release and releasing upon request?

Dr. Jeffrey Michaels OD:

Do I think there's a difference?

Paul Spelman:

Do you think it matters? Do you think-

Dr. Jeffrey Michaels OD:

I think that the automatic release has been so ingrained since the 1970s that it's not really a part of the conversation. It's a part of the norm. And so to hear today from the guest speaker to say that there were pieces of her prescription that are incomplete, from an electronic health record point of view or from a writing a prescription point of view, I don't actually understand what that means because a prescription for contact lenses is pretty standard. And so I expect that automatic release is just anybody who graduated today or within the last 20 years has been a part of that process.

Paul Spelman:

One of the issues-

Dr. Jeffrey Michaels OD:

Last 30 years.

Paul Spelman:

One of the issues that has come up is the reluctance of some people to ask for their prescription. What are some of the reasons you think that some groups, particularly some disadvantaged groups, might be reluctant to ask for a prescription if it's not automatically provided? Miss Brown, do you have any thoughts?

Sara D. Brown MPA:

I think with respect to whether the prescription is released automatically or not, doesn't necessarily mean that the patient understands that and understands what to do with that information and understands what their options are to receive the eyeglasses that are best appropriate for them. I would just point to that.

Paul Spelman:

How about the burden? How much of a burden is it to provide a prescription? I mean, the requirement has been around since the '70s, and yet we still hear comments that it is a burden to have to provide this to consumers. Does anyone have thoughts on that?

Dr. Jeffrey Michaels OD:

I don't think that it's a burden to provide the prescription. Where I see the burden is to ask for paperwork, to say, "Sign this piece of paper acknowledging that we've already given you a prescription." There's a lot of time, effort, discussion around that. I think that that is something that is greatly underestimated in terms of how long it takes and how much effort it takes to go through that process.

Paul Spelman:

We also understand that there's sometimes confusion on patients' part about what an exam was for, that there are different exams for eye health and then also for a refraction. And so if you get an eye health exam, you wouldn't be entitled to a prescription, and yet you might think that you were. Have you encountered that at all, Dr. Michaels?

Dr. Jeffrey Michaels OD:

Sure. Well, I think what's important to understand, if you look at how Medicare addresses an eye exam, they divide out the refraction from the eye health component. I think that the vast majority of people who are receiving a primary eye care eye examination today are expecting that they're going to have an eye health evaluation along with a glasses evaluation or contact lens evaluation. The vast majority of people would expect of that it's all inclusive together. I think Mr. Lovejoy has a question.

Paul Spelman:

Sure. Can we go to you, Mr. Lovejoy?

Wallace W. Lovejoy:

I wanted to clarify with Dr. Michaels and perhaps others about access to portals versus electronic health records. I have seen a great growth in the use of electronic health records by optometrists. Last report I

saw was perhaps 70, almost 75%, and that was a couple of years ago, so it's probably higher than that now. But the existence of electronic health records doesn't automatically, in my opinion, mean that you have access to a portal to get a copy of your prescription. But if I'm mistaken, I'd like to clarify that.

Dr. Jeffrey Michaels OD:

I can only speak from my experience, and every patient that we have is given their access to their online information. I'm not speaking for every electronic health record. I'm speaking for the electronic health record that I have.

Wallace W. Lovejoy:

Well, thank you.

Dr. Jeffrey Michaels OD:

I thought [inaudible].

Wallace W. Lovejoy:

Yeah. My personal experience has been that I usually get a paper copy. I consider myself an informed consumer, and yet it's been frustrating because I can't link my electronic health records from my optometrist to my primary care physician. But that may be because it's a small, private practice optometrist that doesn't have the same extent of an electronic health record as may be available to larger practices. But I think also, what you've described sounds like it would not be difficult to have a record of the patient receiving access to their prescription through your portal, so that would not seem like a significant burden.

Paul Spelman:

Let me ask a question about compliance. What do you think the optimal approach for the FTC or for any other agency, for that matter, for improving compliance would be? And let me go to Dr. Stivers since he has remained relatively quiet so far. Dr. Stivers, do you have any thoughts on that?

Dr. Andrew Stivers PhD:

Sure, and just a brief point about electronic health records, interoperability is a much wider, much more difficult problem in the medical field broadly. But in terms of compliance, for me, the question always comes back down to what the benefit of compliance is. I think it's really important to try to wind this back and remain sort of patient-centered and ask what is their experience, what is the benefit to them of additional requirements, having a paperwork requirement? I think one of the issues that Dr. Michaels raised, I think all of us experience when we go to any kind of medical professional where we're handed a stack of papers or an electronic stack of documents and asked to read and sign them. I would suggest that most of us sign them without reading them, so does handing an additional piece of paper to patients really accomplish anything in the broader context of all of the information that the patient is trying to absorb in that kind of environment? With the suggestion that perhaps there is some confusion about what kind of exam am I getting, other sorts of things that the patient really should be concentrating on and thinking about. That's to me, the real question about compliance is what is the additional benefit, including the burden to the consumer, of having one more piece of paper to sign or acknowledge?

Paul Spelman:

That touches on compliance in that respect but it doesn't touch as much on what the FTC's role should be. Do either of you have any thoughts on what the FTCs role should be in trying to ensure compliance with this rule that's been around for so long?

Dr. Andrew Stivers PhD:

Just briefly, let me add to that. Sorry, I got away from your specific question. The FTC has a really broad and powerful authority to go after deceptive and unfair practices. I think one of the values of that is that it can go into very contextual, very specific kinds of violations or alleged violations and go after miscreants that have violated the law or deceived or had unfair practice on consumers. The, I think, lure of a regulation is you can say, "Oh, okay, well we have passed this rule that it sort of applies everywhere," seems to provide a level playing field for everybody, there's a clear standard. But the downside of that is it's actually, if you look at the NPRM, it's quite lengthy, it requires hiring potentially expensive people like myself, attorneys, to evaluate what those things are. I think in terms of the FTC's compliance or the FTC's efforts to get folks to comply, they have to be aware of the burden on the vast majority of practitioners or businesses in general that are absolutely law abiding, are really working hard to make sure that their patients are served.

Paul Spelman:

Ms. Brown and Dr. Michaels, do you have any thoughts on that?

Sara D. Brown MPA:

As far as the compliance and what FTC is wanting to do, I think in terms of how it's actually implemented, thinking again of what patients are going to do this information, what they understand about it, I think including something that indicates, "This is why you are receiving this, here's what your rights are going to be about this. Here's how you can access this. If somehow your email gets hacked, you lose your password, there's a whole number of things that can happen in a digital space or if you lose the piece of paper that we give to you at the end of your appointment in addition to your bill and everything else that you are being handed." I think the more that you give patients information about what the information that they're receiving is and how it benefits them, I think that's where you get the compliance issue, right? At least for the patients.

Paul Spelman:

Dr. Michaels, do you have any thoughts?

Dr. Jeffrey Michaels OD:

Well, we heard that there were 30-some-odd letters out of 55,000 doctors who prescribe and so is the goal of the FTC to find that 0.00% or is it to create a policy that 100% of the people have to abide by extra paperwork? Because there was the point, I don't know what the math is 0.01%?

Paul Spelman:

I think that's a fair point. On the other hand, we have a long experience at the FTC with the fact that most consumers don't complain even when they have been treated unfairly or deceptively. I forget what the statistics are, but the percentage of people who complain, even when they have been fraudulently deceived and taken advantage of is minuscule. So we see complaints as not irrelevant. Certainly we see them as relevant, but as kind of the tip of the iceberg generally.

But let me move on to Dr. Stivers's comment to that that he submitted, which made the interesting argument that because of the changing marketplace, the rules prescription requirement, the automatic prescription release requirement might not be necessary to begin with. Dr. Stivers, would you like to sort of expound on that a little bit?

Dr. Andrew Stivers PhD:

Sure. Going back to 1978 where this actually didn't start, it started in the sixties with some initial guidance from the FTC, but going back to 1978, there was a fair amount of research that was being done to show that at the time the eyeglass market was experiencing relatively high prices and that that was tied to the lack of advertising in this space and the lack of the ability of consumers in that world, pre-internet world, to be clear. They just weren't able to price shop very well. There were actual restrictions, state level restrictions on substantive price advertising. The FTC really based its initial determination, it really kind of founded the premise for the initial eyeglass rule, on that lack of price competition. That sort of continued throughout the seventies and the second kind of eyeglass rule effort in the eighties.

Today, we have seen some profound changes in the marketplace. The one that I'll focus on, there's been a big shift in sort of the retailing environment. We all know the rise of Walmart and Sam's Club and the mass merchandisers have radically changed the offline and now online retail environment. But the big thing that has really changed is the ability of consumers to find prices, to shop to find competitors, before they even leave their house. Before the internet, before good information availability, really the only way to price compare, if there was also these advertising restrictions was to actually go to the establishment. Once you go to the establishment, you've got the exam, you're kind of there and there is potentially a problem of somebody being stuck. They don't know what the prices are across town, it would cost them time and money to go across town. With any other barriers in place to prevent people from comparison shopping, it's going to potentially have a substantial effect on price and consumer outcomes.

That is really not the kind of shopping experience that we have today. People, before they even go to their eye exam, can understand what the prices are, what the availability of other lenses are, what their other options are, and choose a provider and understand what their sort of reservation price as economists call it, would be if the actual examiner maybe has prices that are too high. They can say, "You know what? I'm going to go somewhere else." I think that's really the fundamental change is that how we shop and the availability of information and that shift really has, I think, undermined the initial premise for why there needed to be at that time regulation in this space.

Paul Spelman:

Let me ask you, a lot of that change seems to be about the ability to purchase the eyewear itself, which is sort of the second half of the equation rather than the changing before you get your prescription in the first place, the need to get the prescription is still the same and it's pretty difficult to comparison shop if you don't have the prescription. How does the change in the marketplace, the ability, where you buy the glasses, change the need for the prescription to be given in the first place?

Dr. Andrew Stivers PhD:

I think people should have the choice to shop where they want. There's a question of awareness of the other choices, the awareness that you have the right to get your prescription, and reach those other choices. I think there's a distinction being made, first of all, between the contact lens situation and eyeglasses. Eyeglass shopping is much more sort of visible. We all have seen storefronts full of

eyeglasses. We know that there are a lot of options out there. Contact lenses, not necessarily the same shopping experience so I want to make that distinction.

The other thing that I would say is that if you go to an eye exam and you're going to get contact lenses or eyeglasses, right? You don't just go recreationally, just say, "Oh, let me see what my eye eyes are like," so before you even go to that eye exam that you're going to be purchasing glasses, which means you're going to be thinking about, "Where do I want to purchase glasses? What kind of glasses do I want? What's my budget for those glasses?" and being aware of mass merchandisers, the online options that your examiner is probably going to have a selection of glasses for you to look at with the knowledge of all those different options and frankly all the different options for where you would get your eye exam. That allows you, even before you go to that exam, to understand what your relative choices are and go into it with some understanding that you have choice and that you ought to be able to get your prescription and take it elsewhere, which means that any sort of benefit of automatically offering it or even more attenuated requiring documentation that you've automatically offered it is really going to be attenuated and it's not clear that there's going to be a big benefit associated with that.

Paul Spelman:

Ms. Brown?

Dr. Jeffrey Michaels OD:

Can I make a just one point? I just wanted to say a comment to Dr. Stivers that many people do elect to recreationally get an eye health examination without the need for glasses and context because of all of the different diseases that can be detected through a comprehensive eye exam in well checks.

Dr. Andrew Stivers PhD:

Thank you.

Paul Spelman:

Ms. Brown, if I could ask you, how do you think if we didn't have the automatic release requirement, how do you think that that would affect consumers in general and particularly those who might not know about that they had even the right to request it?

Sara D. Brown MPA:

I think not having it would make a major impact on patient access. As I've shared, not every single patient has the same level of access, can't afford the very same things, there's different levels of health literacy, different kinds of insurance. I would point out that the CDC data shows that over 8 million Americans in this country cannot afford eyeglasses even though they need them and around 40% of adults in the United States have still not had an eye exam within the past year. Anything that gives them that kind of information to shop for what is the best for them under their own circumstances and make their own personal health decisions, I think not having automatic release would be detrimental to that. But I would also underscore that there's an opportunity for patient education at the point of the provider and the patient relationship to help them understand what this is about, what they can do with this information, and how they can ultimately make the best choice for themselves.

Paul Spelman:

Dr. Michaels, do you think that it's common for consumers to decide where they're going to purchase their eyeglasses before they even visit the eye doctor?

Dr. Jeffrey Michaels OD:

I think that whether you're purchasing eyeglasses or a phone or a car, I think that most patients today are evaluating their options before they wind up in a brick and mortar.

Paul Spelman:

Do you think then that there is less need for the automatic release?

Dr. Jeffrey Michaels OD:

I think that the automatic release has been around for so long that I think that it's just a part of what doctors do, and clearly we can find 30 people across the country who may not have complied or the letter response that I read back to the FTC from one of the people who received a letter was that they actually were complying and that it was a misunderstanding from the patient. So I think that the automatic compliance with this is so ingrained in optometrists and ophthalmologists that it's just a normal part of the day.

Wallace W. Lovejoy:

If I could add a comment, I saw some statistics from The Vision Council that suggested that there's maybe a dichotomy. Some people have made their mind up, they want to get an eye exam and buy eyewear and people in their survey at the Vision Council that had an eye exam in the last three months at the end of the year, this is at the end of 2022, and then also purchased prescription eyewear in the last three months, almost 80% of those bought their eyewear from their exam provider. But if you look only at people who had eye exams and distinguished whether or not they purchased eyewear, people who had an eye exam, all of the people who had an eye exam in the last three months without regard to whether they purchased eyewear were only 38% were likely to or did purchase eyewear from their exam provider. So twice as many people, or rather twice as high a percentage, were likely to buy from their provider at the same time. But then there's a significant number of people who get an eye exam and wait to shop and go somewhere else.

It's useful to have the prescription released and I would agree that the automatic release seems to make most sense. Why get a prescription if the doctor's not going to give it to you? It seems to me that doctors have an ethical responsibility to provide their patients with their prescription. I don't think there's any disagreement about the nature of whether or not patients should get their prescription. I think the question back to what Dr. Michaels was referring to is what's the burden of providing it to them and how can the FTC ensure that there is some evidence that patients in fact got their prescription?

Paul Spelman:

Let me follow up with that with as far as statistics. Do you have any indication as to whether the marketplace has changed in terms of the percentage of eye doctors who also sell glasses or are associated with a retail outlet? Is that pretty much the same as it was when the rule was first created or has that changed as far as you know?

Wallace W. Lovejoy:

Well, the rule led to the ability of organizations like Dr. Stivers was mentioning, Walmart, America's Best, Lens Crafters, Vision Works. They were able to grow because of both the ability to advertise, which was made unnecessary by the commercial free speech rulings of the Supreme Court and the prescription release, but the two go hand in hand. The ability to advertise doesn't matter if you don't get a copy of your prescription so the market has changed in that sense and the competition has grown as the FTC hoped, but it still appears that there's a significant number of people who aren't getting their prescriptions automatically. I think that the competition is more evident in the contact lens market, partly because of the contact lens rule, but also because of the fungibility of contact lenses. Once you have your prescription, you don't need to get further measurement, you're not selecting fashion and frame design so it makes it easier and there's a much higher percentage of people who buy their contact lenses online than there are people who buy eyeglasses for those reasons and maybe also some of the eyeglass fitting requirements that often have to be done in person. So yes, the market has changed significantly thanks to the FTC.

Paul Spelman:

Now, Congress and the commission have both said in the past that one of the reasons for the rule is because there's an inherent conflict of interest in terms of doctors selling what they prescribe. The American Optometric Association has pointed out that it's not a unique situation, that there are other prescribers who sell what they prescribe in other industries such as, for instance, veterinary care. Although I think it may be unique in terms of the percentage of revenue that doctors receive, but is that still the case and should that be considered? Dr. Stivers, do you have any thoughts on that?

Dr. Andrew Stivers PhD:

Sure. It's not unique to this industry, and I think in many industry, we can abstract a little bit and think about sometimes a brick and mortar location is a place for consumers to gather information. If you are the proprietor of such a business, say Circuit City, RIP, then you really want people to buy stuff there. You're providing information and you want to be able to benefit directly from the information that's being provided. Circuit City, of course, didn't charge for the information that they provided. It was a lot less technical perhaps, but it's basically the same kind of thing where you provide some information, you also want to be able to sell whatever kind of follow on products are associated with, rely on that information. I don't think it's unique here.

I think that eyeglass examiners have the same kind of incentives of sort of intention of every other retailer where you want to make a profit, but you also want to keep your customers happy because when they come back, you make more profit. If you give an exam to somebody every year, if they're happy with you, if they recommend you to their friends, that's going to be a benefit to you that you have to think about, "Well, do I want to be a real sharp operator and try to extract as much surplus as profit from this consumer at this particular moment," as opposed to thinking about the relationship. I recognize that in some industries, and at some times, there's going to be more or less sort of norm about how profits are made, but I don't think the incentives are that different in the eyeglass market as they are in most consumer markets where the information is important to the purchase of some physical related product.

Dr. Jeffrey Michaels OD:

I think if you look back at when the eyeglass rule went into effect, the emphasis on glasses might have been a lot higher in the doctor industry. But if you look at what eye health and vision care is today, the emphasis is today on medical care, not glasses care, I think that if you look back at, and I'll just speak

from my own perspective, if you looked at every Google review that a patient gave to our office, it's usually not the glasses were the reason. It's that this level of care that's being provided to me in a medical setting is exceptional.

Paul Spelman:

Some-

Dr. Jeffrey Michaels OD:

I think Ms. Neilly has a question.

Paul Spelman:

I'm sorry, what was that?

Dr. Jeffrey Michaels OD:

I think Ms. Neilly has her hand up.

Paul Spelman:

Oh, I'm sorry. Ms. Neilly, did you have something you wanted to say?

Dr. Jeffrey Michaels OD:

You're muted.

Paul Spelman:

You're muted.

Felecia P. Neilly:

I'm sorry. I was just curious from a consumer perspective, where is Dr. Michael's office located? What state?

Paul Spelman:

Virginia.

Felecia P. Neilly:

Okay. All right. Because I'm just really shocked. Before I got this notification from the FTC, I wasn't even aware of an eyeglass rule and I think there are some private practices here in Georgia and Alabama, which is where I've had most of my examinations, they aren't aware of the eyeglass rule either. The lack of information, and even I think that correlates with the complaints that the FTC is saying that their office receives. If people aren't even aware that there's a rule when a potential violation, there's just a lot of just lack of information and people are just not, and that might impact the number of complaints that you're getting because people don't even know there's an eyeglass rule.

Paul Spelman:

I think that's a good point. In fact, some consumer surveys have found that between 40 and 66% of consumers didn't even realize that they have a right to their prescription.

Felecia P. Neilly:

Exactly.

Paul Spelman:

Which raises the question, what can we do about that? Ms. Brown, do you have any thoughts?

Sara D. Brown MPA:

I agree. That's an excellent point that Ms. Neilly has brought up. Again, there was a question that was earlier about why don't patients ask for this information? Because they don't know. There was also an earlier question about what can be done to ensure that patients do know or get this information in a way that's accessible to them? It's once again asking, "What is your preference to get this information? You have a right to your prescriptions, here's what you can do with this. How do you prefer to receive that?" I think that's the best way to ensure that patients understand their rights to their own prescriptions and understand what their vision prescription means in the context of their overall eye health and their ability to see clearly.

Paul Spelman:

Dr. Michaels or Dr. Stivers, do you have any thoughts on that?

Dr. Andrew Stivers PhD:

I think consumer information is always something that can be improved in any market and often the question is what's the best way to do that? Is it regulation? Is it consumer education? Given the limited resources of the FTC, one of those questions is what are the most impactful areas to focus those resources on to improve consumers' outcomes across all of the thousands and thousands of products that you folks are trying to help consumers get the best price and most competitive markets out of?

Paul Spelman:

In terms of examining where we go with the rule, do you think that the current rate of compliance or non-compliance matters? Is that something that should be considered? For instance, often speed limits people drive a about 10 miles over the speed limit, and if you raise the speed limit, then they'll still drive 10 miles over the speed limit. If there has been a history of non-compliance, is that something that should be taken into account when we're considering how to amend the rule?

Dr. Andrew Stivers PhD:

I think it's a really interesting example. One of the questions that I think traffic engineers really try to ask is, what is a safe speed limit for given road? Taking into account that whatever speed limit they set, it's going to probably be 10 miles an hour faster than that. I think that the law enforcement also takes that into consideration and typically the folk knowledge that people have in terms of speed limits is we're not going to have a really strict enforcement. If somebody whips past the officer at 66 miles an hour, they're not going to pull them over and give them a ticket. If they whip past at 80 miles an hour, it becomes a lot more likely. That's just the reality of law enforcement. The question of how much compliance there is and how egregious that compliance is, that's the other side of it. It's not just how much compliance, it's how impactful that compliance or lack of compliance is on consumers.

Paul Spelman:

Dr. Michaels, do you have any thoughts on that?

Dr. Jeffrey Michaels OD:

Well, my only thought is what is the number or the percentage that the FTC would view as successful? If 99.9% of the prescriptions are automatically given out, is that successful enough for the FTC or do we go after the 0.001% because it wasn't at a 100%? Where does the FTC stand with the thought process?

Paul Spelman:

Well, you raised the 99%, but as I've noted, we have consumer surveys showing sometimes as much as 50% of patients don't automatically receive their prescription. You can debate the validity of those surveys, but it would seem to be more than just 1%.

Dr. Andrew Stivers PhD:

Well, the other side of that, of course, is how many of those folks actually did receive their prescriptions in some form? Obviously as we've heard from Ms. Neilly, not everyone does in every case, but the question is how are consumers impacted by a failure or a lack of overall 100% compliance? Some of the consumers that might not have automatically got their prescription wouldn't have shopped somewhere else anyway, they were already going to shop where they shopped. Some of those consumers asked if they really wanted it. Other consumers would eventually get it from some other fashion. Again, the question is how harmed are consumers by whatever level of compliance there is? It goes back to this question of, okay, is squeaking out that last 0.01%, whatever it is, really important? It's not just tied to what percentage of people automatically or didn't automatically get their prescription? It's what percent of people didn't automatically get their prescription that would've shopped elsewhere and benefited from that release? I think we don't have data for that, but given that the evidence we do have of compliance, compliance is quite widespread, and the FTC had done a survey back in the eighties, in the early days that suggested that everybody knew, almost everybody, 94% of people knew that they had a right to get their prescription and that compliance was actually relatively widespread even 30, 40 years ago.

Paul Spelman:

Let me ask you, if we went to a situation where patients didn't automatically receive a copy of their prescription, and even if the patient had decided ahead of time they were going to get their eyeglasses from that doctor, and then later on, say six months later, they decide to get a pair of prescription sunglasses, what would be the process for them if they wanted to now have their prescription so they could shop online? For the contact lens rule, we have a verification requirement. We don't have that for the eyeglass rule, but if patients weren't receiving their prescriptions automatically, then would you envision some situation where the prescription sunglass seller could call up the doctor and say, "Give me the prescription," and they would be required to do that?

Dr. Andrew Stivers PhD:

In my experience, and again, my experience is not necessarily representative, but my experience is that I immediately lose the piece of paper that I get from my examiner, and I have called back six months later and gotten a prescription either emailed or ...

Paul Spelman:

You think that the burden would be relatively small on the consumer in that respect?

Dr. Andrew Stivers PhD:

I think the burden would be relatively small on the consumer. Again, the difference between what the outcomes would be, and as Dr. Michael suggested, the automatic prescription is sort of built into the practice point, so I'm not sure that I would really argue that it's necessary or unnecessary, but I think the outcome for consumers of getting it automatically versus not getting it automatic, because again, a lot of people are going to have gotten it and lost it or gotten it and forgotten that they had it, et cetera, et cetera. How many people benefit from getting it six months a year earlier versus not? I don't think we know.

Paul Spelman:

Ms. Brown, do you have any thoughts on that?

Sara D. Brown MPA:

I'm thinking the person who does that is the ideal eye care patient. That's somebody who understands what their risk is, understands. Time to go between vision care needs. I would just encourage the FTC to, as far as the compliance effort goes, take some time to understand how the patient can be informed of their rights in this situation in receiving their prescription and what they can actually do with that. I think that's ultimately the way to bring patients to the table to understand that they can access this information and if the FTC is interested in compliance, looking at how to actually find out if the problem is occurring and how patients are responding and how providers are also responding in this too.

Paul Spelman:

Mr. Lovejoy, do you have your hand raised?

Wallace W. Lovejoy:

I do. Thank you. Just a couple of comments. I do think that optometry is unique among the healthcare professions in the amount of revenue, the percentage of the total revenue that comes from product sales, the products that they prescribe. The surveys that I've seen and information over the years shows it consistently staying over 50%, maybe as high as 55 or 60% of gross revenue comes from product sales in the practitioners that are dispensing optometrists. There are significant number of optometrists that are affiliated with optical dispensers, and they typically are not financially rewarded by the sale of product. The concern about financial interests or the conflict of interest, as you mentioned, it's significant enough in the healthcare professions broadly to have led to the anti-kickback statutes and the stark statutes. There's a unique exemption for in-office sales of product that optometry has been able to take advantage of. But that doesn't mean that there aren't still significant financial interests on the part of the prescriber and making sure that the consumer has access to their prescription, whether it's automatic release or I would suspect most optometrists as was suggested I think by Dr. Michaels, release a prescription, or provide multiple copies of a prescription upon request, but not all do. And I think that's what the FTC rule is focused on. So I think that encouraging some sort of record keeping that the prescription was in fact delivered to the patient is appropriate given the unique nature of the market and a significant amount of financial interest on the part of prescribing and dispensing optometrists.

Paul Spelman:

We are almost out of time. I don't know if we have any questions. Okay. I've been told we do have a couple of questions either from audience members or from someone watching online.

Sarah Botha:

One quick question that we had for Dr. Stivers related to the comment I believe about people can comparison shop before selecting a prescriber. Do you know of any survey evidence that consumers do this, that consumers' comparison shop before selecting their prescriber?

Dr. Andrew Stivers PhD:

I'm not aware of any published data on that, no.

Sarah Botha:

And we also have a question about educating patients about their rights, which I know is a topic you've discussed somewhat. The question asks, wouldn't the best possible way to educate the patient about their rights at a given practice be to simply give them a document detailing the office's policy and procedure? This could be given to each patient in each visit as a take home reference on how to obtain their prescription for glasses or contact lenses, such as via a portal or a printed copy, and also help the consumer to specify the option that works best for them. It would avoid the burden on both the patient and the provider, but more importantly, the patient would have a copy of their rights rather than the office having a signed copy that, as Dr. Stivers pointed out, most patients don't read, let alone understand.

Paul Spelman:

Does anyone want to tackle that question?

Dr. Andrew Stivers PhD:

I'll just say that I think that patient education is very, consumer education, more broadly even is very important. And the question of how best to inform patients and consumers is a much more complicated one than I would like. Ideally, we would be able to just provide a fact sheet to consumers across all of the kind of contested industries that the FTC is concerned about, but it turns out to be a little bit more nuanced than that. But a patient education campaign of some sort may be a useful endeavor here.

Paul Spelman:

Are there any more questions?

Wallace W. Lovejoy:

If I might add a point. There's a concept I think that runs throughout the healthcare professions of patient informed consent. And so I've seen recently legislation that if a patient, for example, is going to get an eye exam using telemedicine, that state law requires that the patient provide informed consent to using that process. So the question exists, what kind of documentation of that consent is appropriate?

And I think the same question exists with respect to consumer awareness of their rights to have a prescription. Is it adequate for the professional, for the optometrist or the ophthalmologist to make a note in the record that the patient was advised that they have a right to their prescription or were given their prescription or both? Or is it necessary to have a signed acknowledgement that they had received that information? Much like some of the state laws require a patient signature for informed consent, and that's not just about telemedicine, it's about surgical procedures or other medical procedures. So it

seems logical that record keeping should be required. I think a bigger question is exactly what form of record keeping and how can it be done with minimal intrusion for the maximum benefit. Thanks.

Paul Spelman:

Are there other questions? No. Okay. So we're essentially out of time, but let me just ask one last question to the panelists. This is the question that I asked Ms. Neilly earlier, which is basically what do you hope to come out of this rule review? And so if I could ask Ms. Brown and Dr. Michaels this question, what are your thoughts? What are you optimistic or hopeful for?

Sara D. Brown MPA:

Excuse me. From the patient perspective, would love to see more patients understanding their rights and how to access their prescription and understanding that this is part of the process when they see their eyecare provider. I think ultimately that's the best outcome, but also to do that in a way that, excuse me, I've seem to have I lost my voice. In a way that it meets the patient's needs. It meets them where they are in their health literacy journey, in their own healthcare journey and in a way that they prefer, so that they can be empowered with the information that they have to make their own healthcare decisions.

Paul Spelman:

Dr. Michaels?

Dr. Jeffrey Michaels OD:

Well, since Sarah took the patient perspective, I'll take the doctor perspective. I think that it's important for the FTC to have an open ear to what the burdens are, weighing where the needs are, and showing through data what is the metric that's being used to make the decisions.

Paul Spelman:

Okay. Well, thank you very much. That's going to conclude our first panel. We'll take a short break and then we'll have a presentation. Thank you.

Alysa Bernstein:

Welcome back. My name is Alysa Bernstein and I'm an attorney in the Bureau of Consumer Protection at the Federal Trade Commission. We will now hear from Dr. Stephen Montaquila, who is a practicing optometrist at and current president of West Bay Eye Associates in Warwick, Rhode Island. Dr. Montaquila is a fellow in the American Academy of Optometry and a diplomate of the American Board of Optometry. He practices full scope primary eye care, and serves as a clinical investigator for ophthalmic drug and device companies, as well as an industry advisor. Dr. Montaquila is appearing today the suggestion of the American Optometric Association, and we're glad to have him here.

We asked him to talk today about implementing the contact lens rule confirmation requirement. I'm sure Dr. Montaquila's presentation will provide valuable information that we can take into our next panel. On that panel, Dr. Montaquila and others, who I'll introduce shortly will discuss how any lessons learned in implementing the contact lens rule signed confirmation requirement may inform our similar proposal for the eyeglass rule. Thank you, Dr. Montaquila.

Dr. Stephen M. Montaquila OD:

Good morning, and thank you to the FTC for the opportunity to be here today. I've been asked to provide an overview of how doctors across the country are complying with the 2020 amendments made to the contact lens rule, specifically the requirement to obtain and retain confirmation that the prescription was provided to the patient. I'd like to take a few minutes to review each of the options for compliance that were provided to eyecare providers and also some learnings from my colleagues on how this process has played out. I feel that you'll be surprised that it may not be exactly as the FTC had envisioned it to be. Next slide.

Doctors using a range of approaches to comply with the updated rules. The options that were provided in the guidance were one, patients can sign a signed statement confirming receipt of their contact lens prescription. Two, patients can sign a prescriber retained copy of the contact lens prescription that contains a statement confirming that they received it. Three, patients can sign a prescriber retained copy of the receipt for the examination that contains an additional statement, confirm a receipt of the contact lens prescription. And four, doctors can provide prescriptions electronically if the patient provides verifiable affirmative consent to receive the prescription in that manner. Next slide.

Here you can see an example of a form that many doctors use that is an acknowledgement of receipt of the prescription. It's a flexible option, but can be cumbersome given the need for this form at the end of each fitting, and because it can generate more paperwork outside of electronic health record. Also, of course, storage is a challenge over time, it creates additional steps, which of course, as we know increases the opportunities for error. Next slide.

The second option, using a carbon copy prescription pad. The AOA does make available a prescription pad for doctors, which includes a carbon copy that can be retained and that carbon copy has the patient acknowledgement on it. According to healthit.gov, as of 2021, 88% of office-based physicians have transitioned to electronic health records, 88%. Handwriting prescriptions after generating one in an electronic format increases time and cost, and is not risk-free. Researchers at Weill Cornell Medical College found error rates of 30 per 100 written prescriptions, and only seven per 100 electronic prescriptions. Now, that of course was from medications, but I would propose that contact lenses are no less complex when written on a sheet of paper. Next slide.

Here's an example of a prescription that's printed out of an EHR that includes a confirmation statement that the patient can sign and the doctor can then copy and scan or retain this copy of the prescription, which includes the acknowledgement. While this approach addresses some of the concerns that exist with carbon copy handwritten methods, you do trade one set of problems for another. With this approach, the prescription is printed from the electronic health record system, but once signed by the patient, the office staff or doctor needs to take that prescription back, copy and perhaps scan it and then retain that for three years.

So to review those steps, we must print the prescription from the EHR. We must explain the process to the patient. We must re-explain why the patient needs to sign this form in the first place. We have to obtain their signature copy and or scan, name that document, store that document properly, deliver the prescription back to the patient and ensure that it's been properly stored from the doctor perspective, making sure our staff has done the job. Of course, this is all being done while the patient is checking out. Our staff is explaining their insurance coverage. The patient is paying their examination co-payment. They're making follow-up appointments. Arrangements are being made for laboratory studies. Staff is coordinating referral to a specialist. A communication is being sent to the patient's primary care physician, the referring doctor, et cetera. So what could possibly go wrong with that scenario? Next slide.

There's the option of keeping a signed examination receipt containing the authorization that they have received their prescription. I have not found any of my colleagues who have a system in place that

allows for this. Most of these receipts come from electronic health record systems or practice management systems, and those systems are simply not flexible enough from what I've been told to add these statements in and to have them signed. Next slide.

Finally, the doctor can provide the prescription electronically as long as the patient consents to receiving the prescription in that manner. Displayed here is an example of one form that's used across many practices in several states, which notes that patients can get their prescription on the patient portal, but also indicates the prescription's available on paper. The electronic approach can take many forms depending on the resources available to the practice. For the approach on screen, the consent is obtained on paper, but then other practices will use an electronic means to collect that signature.

This approach is not without challenges. The method requires many steps and a secure system for data transmission. Additionally, some electronic health record systems cannot automatically transmit the eyeglass or contact lens prescription to the patient portal. So when a patient requests an electronic copy of their prescription in those scenarios, the doctor must first print the prescription, attach it to an email, and then send it to the patient. For storage, it is possible to attach the information to the patient's medical record, but colleagues report that some electronic health record systems impose costs to store data over time. So using this method for them would increase the doctor's cost in perpetuity.

I think that one thing that I must say that is really concerning to the optometry community is that the FTC has decided that it's not enough for a patient to be given the prescription electronically or in their portal. The FTC went a step further and said that doctors have to receive the verifiable affirmative consent to provide the prescription electronically. In the rulemaking, there were actually accusations that doctors would try to make their patient portals challenging to access so that patients would not be able to obtain their prescriptions. And while the FTC noted in the footnotes of the rule that there's no evidence to suggest this is actually happening in any practice across the country, the rule change went forward with this requirement for verifiable affirmative consent to provide their prescription electronically. So doctors are unable to seek this consent verbally and document that in their medical record. The FTC did also indicate that doctors could record their patient giving consent. And I'll just be frank, the idea of pulling out a recorder and asking a patient to consent on tape is really incredibly demeaning to the physician or their staff.

A survey of my colleagues found that none of them used this method, but the primary reason they gave me was actually surprising. It was that they could not find any system that could securely obtain and store this data. So it's not that it wasn't looked into, it's just that there's just nothing on the market that can help them. Another complicating wrinkle to this is that in 11 states, you're prohibited from recording a conversation without both parties consent. So if you live in California, Delaware, Florida, Illinois, Maryland, Massachusetts, Montana, Nevada, New Hampshire, Pennsylvania, or Washington, the doctor would need a trained staff understanding the nuances of the law and the legal ramifications of collecting this information to ensure that they've done it right. It just doesn't seem like it's a viable method to obtain consent, and I could not imagine, at least in my office, that conversation between me or my staff and a patient. Next slide.

So the FTC estimates there are approximately 120 million more eyeglass than contact lens wearers in the United States. They further estimate that it takes a minute and a half to complete this entire process. I've done this assessment in my office. It takes my very best staff about four minutes to complete this process, from explaining why we're doing it to the patient, providing them with their prescription, making the copies, providing their prescription back to them, and ultimately storing it. I have further assessed the cost to comply, and it's difficult to tease this number out from compliance in general, but I can tell you that right now we devote about 1.5 FTE to all of our compliance issues, and

that's a cost of about $70,000 per year, not including any additional cost. That's just salary. Adding more rules will only increase this cost to the practice and to the already stressed healthcare delivery system.

So in closing, my experience and that are my colleagues, challenging as a mild descriptor. Compliance is costly to the patient and the doctor. While the FTC has offered options for compliance, all of them have challenges. One of them is virtually impossible given the available technology, and others put doctors in jeopardy of possibly violating other state laws. Experience has shown that patients are confused. Every colleague I speak with relates stories of widespread patient confusion as to why they are signing a prescription, signing a copy of something that they've just received. They don't understand the process, they don't understand why it's happening. So it speaks to the previous panel where patient education really seems to be at the core of what we're trying to get at here.

I had a patient, actually, as I was discussing, I had to move patients to be able to be here. And as I was discussing with a patient yesterday why I was not going to be in the office today, I told him what was going on here and he looked at me and said, "So I'm going to have to sign up a release that I received my eyeglass prescription, but you could write me a prescription for a narcotics and I don't have to sign a release for that?" And I thought that was poignant.

Staff is stressed. Our staff is kind of overloaded right now, and we're adding more stressors to them and we're trying to get them to help us to comply. And I think doctors are deeply concerned. Every colleague that I speak with expresses to me that they're doing everything they can to comply with all of these rules and regulations. They're trying their best, and in spite of their best. There are a lot of pitfalls. There's a lot of ways that things could go wrong during the course of a day, as I described earlier. So my request then, I guess, relates more to transparency in this discussion. Let's really truly convene a group of healthcare consumers, healthcare providers, and the FTC to find the best possible solution that puts the patient's needs first. Thank you.

Alysa Bernstein:

I think seeing real world examples of confirmations is really helpful to jumpstart our conversation and some of the information you provided is very useful as well to helping us have an informed discussion. I'm going to now introduce our panelists. Do we have Joe Neville on the webcast.

Joseph B. Neville:

I am on, yes.

Alysa Bernstein:

Okay, great. If we could change that camera. Oh, okay. Is your camera on, Joe?

Joseph B. Neville:

I think so. That's what I'm working on. Okay.

Alysa Bernstein:

Well, I'm going to go ahead and introduce the panelists while we get that squared away, I'll introduce I guess, who's in the room first. We have Dr. Stephen M. Montaquila, who you've already met. Then we have Dr. Mahsa Masoudi, who is an optometrist with the Marietta Eye Clinic in the Atlanta area. Dr. Masoudi is a member of the American Optometric Association Education Center Committee, and serves as the Secretary Treasurer for the Optometry Cares Foundation Board of Trustees. Then we have Dr. Michael Repka. He's a professor of ophthalmology and pediatrics at the Johns Hopkins University School

of Medicine. He is also the medical director for government Affairs for the American Academy of Ophthalmology.

Next to him is Pete Sepp, who is the president of the National Taxpayers Union and leads the organization's government affairs, public relations and development activities. And now on the screen, which was great news, we have Joseph Neville, who's the Executive Director of the National Association of Retail Optical Companies. NAROC is a nationwide organization representing the retail optical industry, whose members offer the availability of eye exams co-located with optical dispensaries.

On behalf of myself and the panelists, I'd like to note that the views we express today are our own and do not necessarily reflect the views of the commission or of any one particular organization or company. We'll try to incorporate questions we receive from audience members as well as viewers of the webcast toward the end of the panel. And you can submit those questions to eyeglassworkshop2023@ftc.gov. Or if you're in the room, you can raise your hand or someone will be walking around and you can get a question card.

In this panel, we're going to focus on the proposed requirement that prescribers ask patients to sign a statement confirming they received a copy of their eyeglass prescription. Patients would confirm by signing an acknowledgement of receipt, a prescriber retained copy of an eyeglass prescription or a prescriber retained copy of the exam receipt, and prescribers would need to keep those confirmations for at least three years. In considering this proposal, we're fortunate to be able to look to the confirmation requirement currently in effect for the contact lens rule, which was that requirement was implemented in late 2020, and doctor's offices have had a little over two years to get accustomed to the requirement. So we want to use this panel to explore how things are going with respect to confirmations for contact lens prescriptions, including the burden and the benefits involved with obtaining confirmations, the ways in which prescribers are complying.

And we'll also take a look at issues that are coming up for both prescribers and patients related to compliance. I wanted to start off by discussing the burden, which Dr. Montaquila definitely mentioned. Some of the comments we received in the NPRM discussed the burdens that offices may face with respect to the proposed confirmation requirement for the eyeglass rule, specifically the burden of obtaining signed confirmations and storing the confirmations. And we can look to the burden for the similar requirement of the contact lens rule already in place.

From the NRPM, we state in the NPRM, the primary drawback to requiring a signed confirmation is the increased record keeping burden imposed on prescribers since they would have to provide the piece of paper and retain the signed form for at least three years. And of course, this is, unless they choose to offer the digital copy of the prescription. In that case, the prescriber would have to retain the evidence of verifiable affirmative consent to the digital delivery. So I just want to get into a discussion of the burden. We've heard that there are some staffing shortages, increased costs and things like that happening in prescriber's offices. So how have prescriber's offices handled these burdens imposed by the confirmation requirement and how have they adapted in such circumstances to comply with the contact lens rule?

And maybe what we can do is if you want to turn your question card, if I have a question and you'd like to speak, you can turn your name tag, that would be helpful.

Dr. Michael Repka MD MBA:

Well, I'm delighted to start.

Alysa Bernstein:

Thank you, Dr. Repka.

Dr. Michael Repka MD MBA:

Because that's an easy question to answer. The burdens are clearly there. The manpower issues that were brought up are clearly there, not just for this, but many other compliance issues. The EMRs are not designed to take the FTCs rule into account, or they haven't developed the software platform to do that.

So today, with a contact lens rule, you have to have a signature, you have to have the form signed, you print twice, of course. And then if a patient gets it in the portal, which in our portal is simple, they just go on if they have it, they can download it. They don't actually need to provide a signature. So we send a note asking for a signature, and we never get those returned because the patient doesn't have to. And the modules aren't set up in the EMR to be compliant with that. So they get a notification. If they happen to send it back, of course they have to print it, sign it, scan it, and then figure out how to upload it into the portal. And then the staff have to actually take it from the portal and put it into the right record so that it can be retained.

Alysa Bernstein:

Dr. Montaquila's presentation mentioned that 88% of office spaces have transitioned to electronic health records, but what percent of consumers are using portals, and maybe certain segments of the population are more inclined to use those portals than others?

Dr. Stephen M. Montaquila OD:

Well, so I think what you're describing is the biggest challenge we have as practitioners, not just for this but for everything we do, is we keep the data electronically. Patients request the data in the format that makes most sense for them. It's challenging it to say the least in our practice because the information, just like Dr. Michael described, it goes automatically to their portal. It's in there. But we have to then teach them, if they want to use the portal, how to find it. They have to go in, they have to log in, they have to download it. It's not that difficult to do, but they still need the education as you would for any new system you'd use. But then we have plenty of patients who say, "I'm not electronic, just give me a copy." And then we have other patients who don't understand any of this and say, "Don't give me a copy because I'm going to lose it before I leave the office. I know you have it on record, I'll call you when I need it." And we have to try to force them to take a piece of paper.

So I think that the challenge for us is this really is not a consumer-friendly process in that the consumer can't elect the way they want to receive the information because we have to give them a copy, which again, as was said earlier, that's ingrained in us. We give them a copy. But patients oftentimes make the ultimate decision and leave it on the counter. They walk away without it. We hand it to them every time, but do they actually take it or have they lost it before the time they need it? And so I think that it's unfortunate, but there's not going to be one rule that's always going to be functional in every practice setting, nor to every patient in any practice setting. So it's not so much that we have 88% acceptance of electronic health records, it's that we don't have 100% of patients who think one way.

Alysa Bernstein:

I guess I would just say, and I appreciate that it's ingrained in some, perhaps many, but going back to the data that we have on the record, there does appear to be a real issue of compliance. So I appreciate that we're having this discussion today because there's some consumers who are just still not getting their prescriptions. Yes. Pete, did you want to speak to the burden?

Pete Sepp:

There's a rather interesting dichotomy here in the way that EHRs don't seem to be as adaptable to changing government rules and regulations as other systems. For example, in preparation for this session, I found no fewer than seven firms that provide tax software for the optometry industry to help to account for the horrendous sales tax burdens when you have, for example, tax-exempt prescription eyewear on the premises. But Lord help you if you sell an eyeglass case. Suddenly, you are in the sales tax compliance system, which is a tremendous burden on small businesses.

Yet, they do have an adaptability and a capability of keeping up and providing backend record keeping for those changes. Why aren't EHRs able to do that? I'm not asking that in an accusatory manner, but rather, that's an important question that I think FTCs should be able to explore and say, what is the challenge here in the existing systems and the portals, given the drop in costs for memory, dramatic, given the fact that I saw recent surveys that large medical practices spend an average of about $9,000 on EHR, not counting the employee costs, which are considerable. But knowing that, what's the problem here with the technology, and is it evolving?

Alysa Bernstein:

Dr. Masoudi?

Dr. Mahsa Masoudi OD:

So you ask about burdens and burdens, obviously, financial is a big one. But time is money too. And I don't just mean time for the doctors or the dispensing opticians, but time for the patient too. I can think of one repeated burden in our practice is where patients want the flexibility with their contacts if they're trying out a new modality, whether they're doing multifocals, which is where you see distancing them close together in one pair, or if they're doing something special for the first time where they're trying to get a special pair of contacts that they can wear for computer at work so that they can see as crisp as possible and et cetera, something else for later.

They take a few trials home with them and they don't want the burden of coming back to tell us, "I like this one more. I don't like this one. This brand was slightly more comfortable." So we give them a few trials after we make sure that it fits well with the expectation that they will go home, be in communication with us and let us know which one they would like finalized. Now, are we asking them to come, "Okay, drive all the way back here and then we can give you that prescription and sign this form," because as soon as we do finalize it, yes, our office too, it goes online immediately. But it's a burden for the patient to come back and explain to them why they need to come back.

Alysa Bernstein:

I think that's, to some extent in the prescriber's court and also the consumer, because the prescriber can have the consumer elect to receive their prescription via email. And it's so that's a different consideration too, I think especially with respect for contact lenses where there's often more than one exam, the fitting isn't complete. So I think that is somewhat specialized for the contact lens arena.

Go ahead. Did someone wish to speak? So I want to take it back to the specific statement that you made, Dr. Montaquila, that it takes about four minutes to complete the process. And I want to understand if that's what others are seeing too. And maybe we can get Joe in here to speak about maybe what NAROC members see in terms of burden. But are most consumers asking? Are all consumers asking, what is this? Why are you making me sign it? Is it an occasional consumer? Just want to understand that a little bit better.

Dr. Stephen M. Montaquila OD:

Because when the rule went into effect was just two years ago, so we haven't even seen, and of course, then there was the pandemic. So patients are just starting to come back in. So this is the first time they're experiencing where they have to sign a sheet of paper to receive their prescription. So it has to be explained.

Honestly, I don't feel comfortable just putting papers in front of them and asking them to sign them. Our staff has to explain, "You're signing this for this reason." So maybe that's just us, and maybe we're just slow at the process. But it seems to me that they need to be educated as to why I'm handing them a sheet of paper. And then invariably, they kind of tip their head, "But you just handed me the prescription. Why am I signing to say that I received it? I know I received, it's right here." So I think it may just be the way we do things in our process, but I'd be curious to see if anyone has a better system than I do.

Dr. Michael Repka MD MBA:

I won't say, I'm sure we don't have a good system for that because it's difficult. The question, Pete asked was why the EMR companies haven't followed? Well, the new rule, it takes time to get a consumer base or a user base that goes and asks the big company to prioritize that development over 500 other development requests that they get. I think we clearly need one because a signature pad or a checkoff box, which just rolled out in Epic for procedure consents would make this easier. But who knows how long that will ever take to be in this space.

Pete Sepp:

Yeah, I certainly agree with that. But there is the separate operational question of adaptability. What is wrong at the base of the system whereby that matrix can't be easily adaptable to a new record keeping requirement versus a system where you have tax compliance or labor compliance and it is readily adaptable? Software companies in the tax space can update software that's consumer facing literally two weeks after an IRS rate goes into effect or when congress passes a law. Now, this has not gone into effect, but one would think the speed of development would be quicker.

Alysa Bernstein:

Well, in a way, it is in effect for the contact lens rule, and it has been. It's not that new anymore. So you raise a really interesting question, the fact that it has been around, but we're not seeing what some technological advances that could make the burden less for prescribers. It's a really good question there. I'd like to get Joe in on the conversation. I know your comment to the NPRM, it seems that your members are not facing the same kind of burdens perhaps that we're hearing from other providers.

Joseph B. Neville:

Well, that's what I was going to comment. And I'm interested in Dr. Montaquila's information. It's useful. I'll take it back to our members because it will aid in our discussion. But yeah, our members, we've been talking about this for the last two years, with the assumption that an acknowledgement requirement would come into play as a part of changes to the rule. And quite honestly, our member said they're not having problems with the contact lens rule. Well, I don't prefer to throw out anecdotes. I've personally witnessed a couple of situations where the process for contact lenses seemed very easy. The doctor pushed the button to have the prescription printed out at the front desk, the prescription was handed over at the front desk by the staff person, and the staff person may be a bit simplistically said, "We'd like

to ask you to sign this receipt for your prescription. We're required to get your signature acknowledging that you've received it."

And a couple of people, and again, anecdotes here that I witnessed on this just said, "Okay, fine, thank you." And that was the way it worked. In talking to our members, it seems that a good number of them are paper-based. And so perhaps the anecdote that I just mentioned happens frequently in a lot of our members' locations. But as they have talked to their affiliated doctors, the comments that they've gotten back is, no, we're not having any particular problem with this. It has turned out to be relatively easy. And I understand Dr. Montaquila's points and again, want to follow up on those with my folks. But our folks just have not had a difficult experience with compliance in the contact lens arena.

Alysa Bernstein:

And I guess I'll also throw out there that to the extent that it is a relatively new requirement for contact lens rule, if it is taking longer to explain to consumers, then over time, then one would think that the burden would be reduced as they go in for their second, their third, their fourth, it just becomes something that they're used to.

We've talked about, there's already a confirmation requirement in place for contact lens prescriptions. It's the law. It would seem to make the burden of a new requirement for eyeglass prescriptions a lot lower if doctors already have mechanisms in place to obtain and store the confirmations and staff is already trained to provide them. Some could argue that it's a lot less confusing for patients and medical staff to have a single uniform requirement rather than getting confirmation of receipt for one prescription but not for another. Does anyone want to comment on that?

Dr. Stephen M. Montaquila OD:

That's the first thing I would say is volume. By FTCs estimates, I think they came up with 45ish million contact lens wearers versus about 165 million eyeglass wearers. The other thing that, as I think about, go through the course of my day and what would I do with these patients who need these eyeglass prescriptions, there are cases where a prescription is released, I guess the right word to be unexpectedly. I saw a patient on Monday who had a side effect of a drug that she actually, we had to get in touch with her primary care physician immediately who prescribed the drug. She also said, and as she was walking out the door, "And my contacts have been very uncomfortable, I have to go get a pair of glasses very quickly. Can I have a copy of my prescription?" That wasn't what she was there for.

But now we have to stop our flow. We have a patient who has an urgent concern, medical concern that has to be dealt with. And I thought to myself, could I imagine my front desk staff after making contact with her primary care physician, the primary care physician ask her to come right to my office and then say, "Wait, don't leave yet. You have to sign this piece of paper so that we can prove that we gave you a copy of your eyeglass prescription today." And I think in the world of contact lenses, it's very different because most of those patients are coming in specifically because they're updating their prescription for their contacts, they're getting a new fitting, they're having problem seeing, needing an adjustment. Eyeglass wears, as the FTC said, 165 million of them, so four to five times the number, come in all shapes and sizes for all different reasons. And I just think that that would be a challenge, to put a system in place, more challenging than for contact lens wearers in my practice anyway.

Dr. Mahsa Masoudi OD:

And you say 165 million. And then I want to go back and echo again. Some patients have variable needs. That's the first thing I have asked when I walk into a room is, "What do you do? How do you use your eyes?" And sometimes they need two different prescriptions. Sometimes they need three, if they have a

hobby that entails something more specific. So now are we getting an acknowledgement for each of the three different eyeglass prescriptions? And then each of those three have to be scanned? So that one 65 million could be times multiple depending on how many eyeglass prescriptions they're getting.

Alysa Bernstein:

I think you would just need, depends how your office is collecting acknowledgements, but it could be done in one statement.

Dr. Michael Repka MD MBA:

One other thing I could add here. I think of contact lenses as being ordered for an interim or an interval and the patients have set up their prescription. On the other hand, glasses sometimes are a time of exam purchase. But maybe at multiple times during the ensuing valid period of that prescription at different optical stores or at other vendors, and they may or may not have a copy or retained a copy of their original prescription. And so each of these new vendors are going to require a prescription to dispense the glasses, which is then going to require a phone call or a portal access or more phone calls to get a copy. And then the same signature of process probably is in place.

Alysa Bernstein:

The eyeglass rule covers the prescription release after the eyeglass exam. We have not elected to add requirements that prescribers provide additional copies of prescription. But to be honest, we were not finding necessarily the level of non-compliance we would need to put a rule to that into effect. So we're just hoping from a consumer patient friendly standpoint, providers are providing those additional copies.

Dr. Michael Repka MD MBA:

You have to make sure you give it at the first-

Alysa Bernstein:

At the time of the... Well, if there's a subsequent exam, that's separate. But I think you're talking about just a subsequent need arises for the consumer.

Joseph B. Neville:

Question.

Alysa Bernstein:

Yes.

Joseph B. Neville:

So I'm trying to understand a little better, the numbers that were just discussed, the number of contact lens wearers versus the number of eyeglass wearers. Any sense of what percentage of those contact lens wearers also get an eyeglass prescription at the same time? Is it really the difference between 45 million and 125 million, as opposed to maybe only 80 million eyeglass wearers because so many contact lens wearers have already received their eyeglasses script? Again, just trying to understand the numbers.

Alysa Bernstein:

Right. And I'll add to that too, that I think, do people see their prescribers more often for contact lens exams? Like they'll go every year as opposed to someone who may just want an eyeglass exam? I think our data shows they go every two years, I think is what the data showed. Go ahead, Pete.

Pete Sepp:

Once again, taking somewhat bigger picture view. When you do studies of regulatory burden, there's an important concept called the marginal or additive effect on the perceptions of those being regulated. You find this in labor tax, small businesses down the line, and you see them in the comments that were provided to FTC. I count that there were not a lot, but eight providers who identified themselves, either anonymous commenters or those who used their titles. Half of them were opposing this rule because they said, "I already have enough things to comply with." So it's always important to pull back and ask the question, is this rule the thing that is the problem complying with, or is it the overall burden that this thing adds to? That's the real issue. FTC can't do anything about tax compliance burdens, but taking that into account helps us to measure the burden more accurately and weigh it against the consumer benefits.

Alysa Bernstein:

And I think your comment did that quite artfully, Pete. I wanted to move on to discuss the benefit. In addition to discussing the burden of having the confirmation, it makes sense to balance the burden against any possible benefits to consumers, prescribers, online retailers of having the confirmation. Some of the things we mentioned in the NPRM, and feel free to push back on them, the potential benefit of increasing the number of patients in possession of their eyeglass prescriptions is substantial, namely, increased flexibility choice for consumers, a reduced likelihood of errors associated with incorrect, invalid and expired prescriptions, and consequently improved safety. And an improved ability for the commission to enforce and monitor prescriber compliance with the rules, prescription released requirements. The proposal would also, we talked about how it would also align the contact lens rule with the eyeglass rule, which might reduce confusion for consumers and maybe office staff as well. So are you seeing any of the benefits I just mentioned come to pass or what do you see as the benefits to assigned acknowledgement?

Dr. Mahsa Masoudi OD:

I'll give you one pro. I did survey my colleagues just to see if I was thinking alone in my thoughts. And I did have one person who did share with me that at her practice, they added just an extra question at the bottom of the acknowledgement form, "Do you plan on purchasing today or would you like to shop around first?" Which is totally in their right. And they don't have to answer it, it's optional. But it's on the form. And so it did help them keep track a little bit of their own ability to keep patients with them and loyal versus and price match and so that they could make sure that they could keep them forever, or if they wanted to shop around and why. "Oh, are we too expensive?" So it gave them an opportunity to work on their own practice and learn more about why patients are leaving and if they could meet them there. So I won't say it's absolutely without a pro, but it is a burden.

Dr. Stephen M. Montaquila OD:

And I can say that in my practice, I just haven't seen much difference. I find that for contact lenses, patients who intend to get them from a source are going to get them from that source. And oftentimes, they tell me when they come in. In fact, with eyeglasses, they're bombarded if they use the internet in

any way with resources of where they can purchase eyeglasses, whether it's the mass retailers. There's one large company that has many outlets around the country and they do a lot of advertising. They have a large advertising budget. Patients are aware of that. So it's not that patients come in ignorant of what their options are. And in fact, a lot of patients will ask, "I have a friend who got them online. What do you think? Should I get them there?" If your friend is happy, and you trust your friend's advice then sure.

But it just seems to me that more and more, which I think happened in the contact lens market as well, patients are realizing based on probably advertising and word of mouth, that there are all of these other resources. And most of them ask me. They come in at the outset of their exam, "I'm going to get my glasses or contacts at." Okay, they're going to get their prescription either way. But in most cases, they are voicing that to me that they're planning to get them somewhere. So in my head, they've already shopped, they already understand what their choices are. Someone has advised them, whether it's advertisement or a friend or what have you, and they're going to go to that resource. So I don't know that them signing a sheet of paper changes that paradigm in any way. But I don't know what happens on the retail side other than when that patient doesn't come to me first and has a copy at home, I can't answer that. But I'm just finding more and more patients are more informed as to what their options are.

Pete Sepp:

But there's also the impact in retail studies of an increasing shift between those who look and gather data online, but don't make the purchase online and come back to a place where they can palpably touch the product or examine the product. I would think that in the eyeglass market, big box retailers, small businesses, might actually have an advantage in that respect. I would not necessarily view the internet as a threat in that way. People might make price comparisons online, but then they would say, "Yeah, but I want to see what that frame really looks like on my face, and I don't want to have to ship packages back and forth for things I don't like." Maybe this isn't necessarily a threat, regulatorily.

Dr. Michael Repka MD MBA:

I'm sorry. I was going to say from a big ophthalmology optometry department, I don't think we've noticed any change of a benefit here from the consumer perspective on the contact lens space. I think that, just as was mentioned, I think it's really about that space evolving and it's in the public understanding what's going on. And I think that your comment about product is a contact lens in a box is a contact lens in a box, and whoever you get it from makes it an easier push. In any case, I don't think that there's been an advantage from our provider perspective.

Alysa Bernstein:

I think what would be helpful is if we would understand whether there's been greater compliance with automatic prescription release of contact lens since the signed acknowledgement requirement has been in effect. And I'm not sure we have that data, but I think that, that would be, to be able to have that data, if we're talking among perhaps prescribers who've always complied versus we've seen a lot of non-compliance. And so if we had a different group that was speaking candidly, we might get some different answers. I don't want to leave you out there, Joe. Did you have anything else to add on the benefits before we kind of move along?

Joseph B. Neville:

Well, the primary benefit that we see with this, is patient education. And I realize from previous conversation that there is a bit of a burden in explaining some of this to consumers. But nonetheless, it

feels like a way that the prescriber's office can explain, you have a right. There's an awful lot of articles out there about how doctors can keep their patients, and that's good. None of them say don't give them their script. But they have creative ways for keeping people in the office to buy glasses. But it feels to our association like this is a good educational tool, a quick educational tool the way we see it. I'm going to throw something out there that everybody may scoff at, but as a former litigator, somebody who worked for optical companies and dealt with optometrists who either came under board investigation or malpractice cases. One of my concerns always was documentation. And I found, and I suspect it's changed in the last 15 years, I found that a lot of doctors aren't very good at documentation. This is an opportunity to get them to document something that they've done. If the FTC is going to enforce more regularly and is going to do it by essentially accepting the complaint as true, then the doctor needs some proof that they actually complied. And the acknowledgement requirement, in my way of thinking, is some good evidence for the doctor to avoid the fistfight between did you or didn't you? And being able to demonstrate your compliance.

Alysa Bernstein:

And I would say, we've talked to some prescribers to whom we've sent some cease and desist letters, and some of them are insistent, "I provided it, I provided it. You know what, I'm just going to do what I do for the contact lens rule and I'm going to get a signed confirmation." And that's without the requirement being in effect. So that definitely speaks to what you were talking about, Joe.

Pete Sepp:

Well, and I certainly wouldn't scoff at that at all. It's affirmative regulatory defense. It's a common practice across quite a number of industries. But here's where there might be a problem that FTC can help to solve, and that is in many regulatory spheres, there is the concept of the safe harbor, whereby you're not just using this information to say, "We're going to go out and enforce the law with it." You use the information to say, "Businesses that gather this and do several other things have a safe harbor from regulatory prosecution."

And this may elicit the scoffs from everybody on the panel, but what if FTC were to issue something like a safe harbor in this area and say, "If you provide this kind of release, if you show this training video that's 30 minutes to your FTE, who handles this, if you retain the records for three years, you're good. You're compliant." Making that affirmative statement rather than saying, well, doing it on the sly and saying, "We still reserve the right to go after you." There are different ways to get compliance with the law instead of just straight enforcement.

Alysa Bernstein:

So I definitely can't speak to the safe harbor idea, but I can say that we are definitely, at the FTC, not looking for one-off problems with compliance. We're not looking for, "Oh, you messed up once, but every other time you comply."

Pete Sepp:

Yeah. You can't possibly.

Alysa Bernstein:

That's certainly not what we're...

Pete Sepp:

Yeah.

Alysa Bernstein:

I mean, technically, every time you don't give a prescription or for contact lenses, get a signed confirmation, it's a civil penalty violation.

Pete Sepp:

Right.

Alysa Bernstein:

But that's not what we're looking to do.

Pete Sepp:

Right.

Alysa Bernstein:

So I want to move along, just aware of the time, and talk about an exception that's in the rule, the contact lens rule, and that's being considered for the eyeglass rule. The contact lens rule doesn't require prescribers without a direct or indirect interest in the sale of ophthalmic goods to request confirmation from their patients, excuse me. Direct or indirect interest include, but are not limited to, through an association, affiliation or co-location with a prescription eyewear seller.

Our guidance indicates if you're in doubt, err on the side of asking for confirmations of prescription. And I just wanted to understand if anyone had wanted to add anything on whether the exemption is appropriate, is there a confusion as to who's covered under the language? And I don't know if anybody wants to speak to that issue? And if not, we can move on.

Joseph B. Neville:

I'll just jump in real quick. With the contact lens rule, we suggested that doctors who were affiliated in a co-location situation should be exempt. And that suggestion was soundly rejected. I think members of our association, it's a mixed bag between the optometrists who do sell the contact lenses and those who don't sell contact lenses, or quite frankly, anything else. They provide the clinical services. In this situation where an optical company leases space to an eye doctor, the eye doctor simply does not sell the eyeglasses.

And in my experience with talking to counsel as to the relationship between the optical company and the optometrist, any incentive that's given to the optometrist related to the sale of eyeglasses would violate the law. We've not promoted the idea that doctors next to retail optical companies get an exemption here, but it does seem to fit a little closer. We understand the rationale for not applying it in this case, and support what the FTC is proposing in this regard as the people who really are just involved in clinical and not connected in any way with sales.

Alysa Bernstein:

Let's talk a little bit about... Earlier, we talked about how there's a lot of compliance with the contact lens rule confirmation in the digital. But let's talk about the paper options. And I know Dr. Montaquila, you mentioned that one of them isn't being used at all. So let me mention the options. The prescriber can obtain patient confirmation in one of three ways, by signing a statement confirming receipt of the

prescription, by signing a prescriber retained copy of the prescription that has a statement confirming receipt of the prescription, or sign a prescriber retained copy of the receipt for an exam that has an statement confirming receipt of the prescription.

So that third option, I think, is what you said wasn't being used at all? So this is helpful for us to understand and know what, of the other two options, what's being used, what's easiest, what's the least burdensome. I will also throw out, we have some language that providers can use if they choose to use it. That was in the NPRM, my eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting. And so, is this language being used? So that's a lot of questions out there, but who would like to talk about the different paper options?

Dr. Mahsa Masoudi OD:

I'm just imagining my patients that I had before when I was at a community health clinic, or patients that don't have someone with them all the time to break through language barriers. Trying to explain to them at the end when all they know is they need to pull out their card for their co-payment to pay for something, and then try to sign a receipt and have the front desk person who's not trained in every language try to communicate with them the importance of why they're required to sign this form. There's so many other steps to it because of language barriers, and then multiply whatever patient education time might be a pro for that, but then it goes right back to a burden because that time has to be doubled.

Alysa Bernstein:

And I imagine that's true for privacy policies and HIPAA policies and all the other requirements that are...

Dr. Stephen M. Montaquila OD:

Well, I think the challenge there though is the HIPAA policy has to be signed once, when the patient first starts with your practice, and then only again if you change your policy. This is not that. If this was like that, it would make it much easier for all of us to implement because we could educate them as to what the office policy is, whether that's paper or electronic or a combination thereof.

It could happen at the outset when they first establish their relationship with us and only if we change policy or they make a request, because the patients could understand, "I know your policy and I'm happy with it." Or, "I'm not happy with it, I want it done a different way." And that could all be documented when we first meet them or at any time at time their choosing. So putting it in the patient's hands to have control.

Alysa Bernstein:

A little bit of devil's advocate, but if you explain it to the patient once, then hopefully the next time they come, they would understand.

Dr. Stephen M. Montaquila OD:

I mean, it's worked with HIPAA. Patients seem to know what their HIPAA rights are.

Alysa Bernstein:

Yeah.

Joseph B. Neville:

And I think this was addressed in panel number one, if I remember correctly. I think Mr. Lovejoy may have touched on this a little bit. The idea that you educate on the front end, and then perhaps, as Dr. Montaquila says, get that acknowledged at that point as a possibility. We had proposed educational materials as part of the contact lens rule, so it might fit into that category in this case.

Dr. Michael Repka MD MBA:

Could I add, if possible, if you look at additionals, it still seems to me that the EMRs of the future will be able to accept this as an electronic signature, that it will store in some fashion other than necessarily on a paper that says any of the three things that you've had there. So that if there's an option to do that, it would be nice. If you still needed it to be on a printable PDF, then not as convenient.

Alysa Bernstein:

No, and that's a question they had is do we need to make education more clear on that? Because the person can sign in writing on the piece of paper, but the person can also sign on a digital keypad that's automatically taken into whatever system the prescriber is using. And I think there was some confusion on that, so that's definitely something I wanted to hear back if people think we need to do greater education on that or it's a misunderstanding there, because yeah, a keypad signature makes complete sense.

Dr. Michael Repka MD MBA:

Right. If I could say, I think the understanding is whatever we did two and a half years ago is sort of where it stopped evolving. Whatever the solution somebody did before they actually did it is probably what they still do.

Dr. Stephen M. Montaquila OD:

And I would agree with that. It's true. Well, look, take HIPAA as your example. People are still doing whatever they did when HIPAA went into effect. And by and large, those documents have not changed unless that office had to change, and their processes have not changed. And whether that's out of necessity because our staff has to learn whatever compliance policies we have in place or whether it's just because it works, and maybe it still works for that practice.

But I think you're right. There's a challenge when you start to say, "Here's the ways you can comply." What happens when something new happens? You mentioned Epic. I worked with one of the first Epic implementations in the country, believe it or not, way back. And they have a really good system with a signature pad. The system I use now has an iPad. You can open up, they can sign on the iPad. But I am talking to other colleagues who say that their EHR system has no option similar to this. All of them are probably moving in the same direction, right?

Alysa Bernstein:

Well, in a way it's good. I mean, we get to look at these issues, again, obviously through the eyeglass lens instead of the contact lens lens. But, so it's good that we are able to explore some of these issues. I wanted to turn a little bit, talk about pre-appointment paperwork. We have seen patients being given paperwork in advance of their appointment for a contact lens exam. Maybe it's via email several days in advance, and the paperwork is intake paperwork and it can be several pages covering many subjects. Insurance information, medical and ocular history, maybe an annual contact lens review. And in some

instances, we've seen the paperwork contain language that says, "I have received my contact lens prescription if it was finalized", and there's a signature line for the patient at the bottom of all this information, and they're expected to complete the forms in advance of the appointment.

Clearly, this is a problem, right? We're asking patients to acknowledge receipt of their prescription prior to actually receiving their prescription or even having the exam. Doesn't comply with the rule and wouldn't be considered a valid acknowledgement. So as a result of seeing these examples, we issued public guidance on the subject. But I want to, that's a pretty black and white example of a problem, right? But I want to talk about maybe acknowledgement forms that are kind of at the right time, but they may contain other language in them that isn't relevant to the confirmation. So I want to understand here, are we getting real acknowledgement from consumers that they have in fact received their prescription?

Is it sometimes being buried with a bunch of other different things? And I'll point out that in the contact lens arena, in one of the notices for public comment, we got something from consumer action that recommended that any signed acknowledgement be on a separate standalone document. So what problems, if any, exist from the use of acknowledgement forms that contain unrelated information? Why might a prescriber legitimately be combining different subjects onto one form? And would it take much time for prescribers to obtain a separate signature for the contact lens acknowledgement apart from, say, prescriber practices or other things of that nature?

Dr. Stephen M. Montaquila OD:

I think, I don't know of anyone who's combining multiple signature or multiple documents together, although I can certainly see the benefit from the patient perspective, because there are multiple studies on what happens when a patient's overwhelmed with information at the point of care and how it impacts their care in general. So here we are trying to take care of their healthcare concerns, educating them about whatever they have in their healthcare, whether it's their history or whether they have signs of a disease that needs to be followed up on, why we need to see them in a certain period of time, that we're trying to set an appropriate follow up for them to provide proper healthcare. "Oh, and by the way, sign the sheet of paper." After we've just given them a ton of information about, let's say, macular degeneration or glaucoma, or we've made a referral for cataract surgery because it's the next best thing for them.

We give them information about all of this and a sheet of paper to sign, and do they know what that sheet of paper is? I'm also, as you say this, I'm thinking back to the last mortgage that I signed, and for anyone who has a mortgage, you put your initials at the bottom of 80 pages of documents, and eventually sign the last one. All of those pages had relevance, all those pages were important. You initialed them all and you bought your house. Here, I'm giving them a lot of important information and I'm giving them a bunch of sheets of paper. Imagine if it was all separate.

"You have to sign that I told you about glaucoma. You have to sign that I told you about your family history, macular degeneration. You have to sign that I'm referring you for cataract surgery. Oh, and sign this. I'm giving you a pair of eyeglass prescription. And you sometimes wear a contacts, sign this one too." So I think that the more we can do to reduce the confusion to the patient, the better we're taking care of our patients. And I think the patient should be first.

Dr. Michael Repka MD MBA:

Listening to that comment makes me think about another difference between the contact lens rule and the eyeglasses rule, and that's the age range. In fact, where the median age is going to be for this rule is

going to be way older than that for the contact lens rule. And I think it's fair to say that's a population that may be more easily stunned or worried about lots of signature lines.

Alysa Bernstein:

Can anybody see an issue that may arise though if the consumer doesn't know, again, if you're a prescriber who is actually who is providing the prescription. But if there's a non-compliant prescriber out there, you could see a problem. If they have a bunch of language on a form and the consumer just signs the bottom and it says, "I got my prescription." And then the FTC looks into it and the consumer's like, "I did not get it. I did not get it." I mean, just pushing the other way.

Dr. Michael Repka MD MBA:

I agree, I think it just lengthens the process.

Alysa Bernstein:

Yeah. Fair. If anyone else has something on that, I think we'd better see if there are any questions before we run out of time.

Paul Spelman:

Yeah. The question we have, actually, is something that I can answer. We had a question about the reference in the last panel to the survey on non-compliance and whether the FTC can share the source of this data. And the answer is that all the surveys are cited in the notice of proposed rulemaking for the eyeglass rule, as well as the previous contact lens rule. So those surveys can be looked at through those citations.

Well, we don't have any other questions.

Alysa Bernstein:

Okay. Well, I have another subject to discuss. I wanted to discuss enforcement. We've still been seeing reports of non-compliance with the contact lens rule automatic release requirement. In February 2023, we announced that we sent 24 cease and desist letters to prescribers informing them of the contact lens rules' requirements. We also sent 37 cease and desist letters regarding the eyeglass rule in April. We've provided guidance on the amendments and we've updated that guidance as needed. But my question is, should the FTC be doing more publicly on the enforcement front in addition to sending cease and desist letters? And if so, what would you like to see us do?

Dr. Mahsa Masoudi OD:

I wish I had an exact solution for you, but to reference something else from the earlier panel, if the FTC for example, like Mr. Spelman had said, was responsible for raising the speed limit because everyone was speeding, but then they're just going to go 10 miles over, why would the doctors, the eye care providers, why would they be more responsible for educating patients on their rights? Isn't that what the FTC should do? I don't know how, but I am thinking of when the FBI had their anti-piracy slide at the beginning of every single movie, that was in every audience member's face. They all got the memo. So why are we not helping Ms. Neely's of the world? Why are we not able to let them know before they even walk in our door what their rights are?

And I'm a Georgia girl. I always got my prescription when I was there, but I didn't know I needed it. I just got it. I was just a teenager, I didn't know. But seeing the changes of the contact lens rule while I was still

in optometry school, and having patients that came to that clinic forever and all of a sudden now having to sign an acknowledgement form, it was really different for them. And it was really different for me. I was a student, I have so many things to juggle, and now that I'm a doctor, I'm still a young doctor, I'm still trying to juggle all the different forms and make sure I cross all my T's and dot my I's. There's a lot out there, there's a lot to cover. So can the FTC do anything else preemptively to educate the public?

Alysa Bernstein:

I will, of course, say that we've done a lot of outreach with our division of consumer and business education. We do put out blogs and letters and information. But that is a question, what else should we be doing enforcement-wise or education-wise?

Pete Sepp:

There are many systems of notices to regulated parties that FTC could model more closely. Right now, Internal Revenue Services ramping up its capacity to send regular notices to taxpayers. Right now, the electronic capacity is something like six a year. They hope to be able to ramp that up to over 100, creating regular channels of communication, not just to the public, but to providers, of expectations would be a relatively inexpensive course. You could also take the more holistic view that perhaps there are neighborhood or community organizations concerned with health that could benefit from being able to advise members of their organizations about patient's rights with prescription release and the topics we're discussing here.

Alysa Bernstein:

Sure. We don't have much time, but I do have one quick question about, is anyone seeing patients refusing to sign the confirmations of prescription release?

Dr. Stephen M. Montaquila OD:

Yes.

Dr. Michael Repka MD MBA:

Yes.

Dr. Stephen M. Montaquila OD:

Patients refuse to sign. Patients, in many cases, won't even let us take their picture for their medical record. That patient's not going to sign anything. They don't absolutely have to sign. They'll sign their credit card receipt, but that's about it. So they're reticent. Some people, for whatever reason, are reticent to get involved in anything like that. So if I can't get a picture of them for their electronic health record, which helps to ensure that I'm taking care of the right patient and helps to ensure that I recognize that patient when a phone call comes in with respect to them, I can't get them to sign anything.

I mean, that's, to me, far more important that we don't make a medical mistake with who we're taking care of than having them sign any sheet of paper, and they won't let us take a picture even after we explain the importance of that to them. So that very same person oftentimes won't sign, or is in too much of a hurry to sign. I mean, in many cases, we have a busy office. I'd love to say we're always on time. It doesn't always happen. And there are some cases where patients are rushing to get out, to get to some other event, and we've actually had people who have said, "Email me my prescriptions." Right?

"I don't have time. I got to run." What do I do? Now I'm not in compliance. So we're in jeopardy because of that, but it's the patient's needs that have to come first.

Alysa Bernstein:

I guess, we've heard some, maybe many prescribers get permission to email prescriptions in the front end. But, yeah. And the refusal to sign, I mean, we can't and we don't make prescribers get a signature if someone doesn't want to sign. You just note it in the record.

Joseph B. Neville:

But that's...

Alysa Bernstein:

Oh, go ahead, please.

Joseph B. Neville:

I was just going to say, that was our suggestion early on in the process. That's something that we picked up from HIPAA where the office is allowed to write in, "Patient refused to sign", and while, I guess, it's possible that that could be abused, I think people are generally trying to comply. And so, something along those lines made sense to us.

Alysa Bernstein:

We're almost out of time, so I have just one last question. Are there any other compliance issues that have arisen with respect to the contact lens rule that we haven't discussed that may be relevant to the eyeglass rule? Or anything else on this subject that you wanted to add in the last time we have here? Do you think we've covered it all?

Pete Sepp:

I would just add very quickly that there are many, many other federal agencies capable of making contributions about compliance burden. Here as a supporter of this rule, my organization is nonetheless very cognizant of business tax and regulatory burdens. We can measure this. It's not easy. I think the results would show that compliance with this particular section might not be quite as burdensome, but there are existing burdens that make this a marginal problem, and we need to consider that.

Alysa Bernstein:

You mean existing burdens from other regulations?

Pete Sepp:

Yes, and that some of them even belong in FTC's wheelhouse. And so we need to take a look at the overall regulatory budget, which is tremendous on this industry and others.

Alysa Bernstein:

Okay. Thank you to all the panelists today. I really appreciate it very much, and that's all the time we have today.

Pete Sepp:

You're welcome.

Alysa Bernstein:

So we have a 15-minute break before the next panel.

Sarah Botha:

We're going to be discussing three other proposed amendments to the eyeglass rule that were included in our notice of proposed rulemaking back in January, and I'll introduce my panelists today. We have Dr. Aarlan Aceto, who's Board of Director and also Chair of the Legislative Committee for the Opticians Association of America. Dr. Aceto is also President of the National Federation of Opticianry Schools and is Program Coordinator and an associate professor of ophthalmic design and dispensing program at Middlesex Community College in Connecticut.

Dr. Artis Beatty, who has been the chief medical officer of MyEyeDr since 2017 where he sets both current and future clinical direction for the MyEyeDr practices. Dr. Beatty was previously part of a regional optometry practice in North Carolina for nearly 10 years. And Rebecca Hyder, who's Vice President of Governmental Affairs for the American Academy of Ophthalmology, where she leads the division responsible for advancing federal, state and health policy advocacy priorities on behalf of 18,000 US-based ophthalmologists. And joining us again virtually is Wallace Lovejoy. Thanks for coming back to join us. He was also on Panel One and he is the chair of the National Association of Retail Optical Companies, also known as NAROC. So thank you very much.

Just to mention what Alyssa mentioned on Panel Two, the views expressed today are our own, don't necessarily reflect the views of the commission or any one particular organization or company. Toward the end of our discussion, we'll try to incorporate audience questions either in the audience here today or from the virtual audience. You can submit those questions to EyeglassWorkshop2023@ftc.gov. Or if you're in your room, you can raise your hand. Someone will come around with a question card.

So again, we're going to discuss each of the three proposed amendments in turn. I am going to describe them briefly and then we can discuss possible questions that they present. For each amendment, we're interested in discussing possible benefits to consumers, prescribers, and other retailers, the possible burden to prescribers, and what factors we should take into account when we're determining whether the amendment would help us achieve the goals of the eyeglass rule, which is to promote competition in the eyeglass marketplace and enable consumers to shop around for their eyeglasses.

The first change that we're going to discuss is the proposal to allow prescribers with a patient's verifiable affirmative consent to provide the patient with a digital copy of a prescription such as by text message, email, or online patient portal in lieu of a paper copy. We've talked about this on the prior panel. I know it's in use. It was added to the contact lens rule in 2020, and some prescribers are already giving digital prescriptions for eyeglasses as well.

So we are proposing to include this in the rule to provide greater clarity and also explain the parameters that we would like the digital prescription to be released. Namely, verifiable affirmative consent means that a patient must have provided consent in a way that can be later confirmed, so that if we do need to go back and figure out if a patient has received their prescription, the prescriber would be able to provide some documentation that they consented to get it virtually. The consent also must specify the specific method of electronic delivery to be used, whether that's email, text, or online portal. Because it's possible patients may prefer one method but not others, and the patient should be able to make an informed choice.

The provision requires prescribers to keep a record of the consent to digital prescription release, and I think this might have been something that was touched upon in the prior panel and maybe there's some confusion. If you get the consent upfront to provide the prescription electronically, the rule as it's written in the contact lens rule and as it's proposed for the eyeglass rule, does not then require additional collection of confirmation. So you're kind of getting the agreement upfront and keeping a record of that agreement. But then after that, the provision of the prescription digitally is kind of its own record that it's been given out. You don't need to, I think it came up on the prior panel, print out a confirmation, get the person to sign it, or email them the confirmation, get them to sign it, send it back. That isn't what is proposed or currently required under the contact lens rule.

The only other thing I'll note is that it's important that this provision would not change the requirement to provide the prescription immediately after the exam. And it's something we can discuss as we talk about some of the compliance issues we've seen where it's not adequate to put it on the portal, just like it's not adequate to give it in person at a later date or the next day or the next week.

So for this proposal, we generally received positive feedback. Commenters on our NPRM noted that it was keeping pace with technology and it would help patients understand their rights. I'm interested in hearing from you all how you think having this option for digital delivery impacts the burden of having to prescribe the prescription and keeping a record that it's been provided. Do you want to start, Dr Aceto?

Dr. Aarlan Aceto OD:

Sure, sure. I think that I speak for a lot of folks. And from the optician standpoint and those who fill the prescription, it's sort of brilliant. Because again, we're keeping up with our current status of technology. It helps people, it's an all about an access type thing, and I think that that's a really, really good option. My only concern with this is not everybody, as we talked about with different clientele and different patients and different modalities, not everybody's as well versed. So I think this is a good start. And so anything that we can do to encourage this because of the access, because of the understanding, because of the technology that we're going through with the EHRs, this is almost a no-brainer. I think this is just a really, really good in step direction for having the doctors be able to be in compliance, having opticians have access to, have the patients have access to. I think this is good for a number of different parties. So I think this is a very good option.

Sarah Botha:

Okay. Dr. Beatty?

Dr. Artis Beatty OD:

I would agree with that. I think we do have to be careful with how we consider that delivery though. Requirements for that delivery to include all of the methods, including SMS and MMS, would or could actually produce new burden. Not everyone who delivers these things electronically has access to an SMS system or an MMS system. And so we'd want to be able to provide the possibility of delivering them electronically, but also allow for the provider to have the choice of how the electronic delivery would occur. And then the patient to consent to whether they want that electronic delivery or if they would prefer to have a paper version, rather than to require providers to be able to deliver it through those three different methods [inaudible].

Sarah Botha:

Do you think, just to follow up on that, Dr. Beatty, I believe we currently acknowledge sort of email, text, patient portal. Are there other methods that we may not be aware of that doctors are using?

Dr. Artis Beatty OD:

There are other configurable methods including websites that are specifically designed for prescription delivery that are not quite patient portals. So patient does not have full access to all of their exam information, but specifically their prescription. I think to some of the earlier points, it is a way of making things a little bit more simple for patients. So if a portal could possibly be confusing, having a website where the patient can enter rudimentary data and then get back just the prescription information that they were looking for should be acceptable too.

Sarah Botha:

Did you have anything to add, Ms. Hyder?

Rebecca Hyder:

Yes, I would say that we're supportive of giving the option for digital prescriptions. But again, we would agree with not mandating that every type of digital option be available.

Sarah Botha:

Okay. And Mr. Lovejoy, did you have anything that you wanted to add?

Wallace W. Lovejoy:

Just a question for clarification on the part of the FTC. Would the verifiable affirmative consent be acknowledged appropriately just by staff notation that the patient had been provided that? You're not requiring a patient's signature for that, are you?

Sarah Botha:

I believe that currently we say it has to be a way that can be later confirmed, such as through a signed consent form, or audio recording I know was discussed on the prior panel as being difficult. So I think that what is under consideration there is a signed consent by the patient because... But that is something we can consider, we're taking comment now to consider that.

Dr. Aarlan Aceto OD:

So being part of optical, I get to look at different portals and different offices. And not all of them, as we had mentioned, are as functional as others with signature pads. But when we are filling out our patient information, our insurance, like through an online portal which we can use now, our previous experience, our family history, those types of things, social medical history, some of these have a checkbox at the very beginning saying, "Here's some of our policies." Would, for the FTC, instead of a signature pad specifically could in that introductory have a check in the initial portal in the signup in the patient history form, say, "I am taking this," check, check, check. 'Cause I think more of them have that capability than have a signature pad specifically. So I'm just curious because I think that would be more functional for some of these EHRs potentially.

Sarah Botha:

Well, this is helpful information, this is why we're having this conversation so that we can get a better understanding of what things look like in practice. We also have to balance against that the consumer understanding and needs. I think one of the issues that we're concerned with is that consumers are aware of where their prescription can be found, understand how to access it and have really been given

that opportunity, as you said, to consent to whether they're receiving it through one of these digital methods or on paper.

One of the issues we've seen, I can jump to some of the compliance considerations that we've run into as we've been sending out some of these cease and desist letters. We're having conversations with prescribers and learning about their practices. We've seen forms where there's not a separate signature about digital consent. We've also seen forms where the information is included in an intake form among a lot of other information that the patient may not see. And in some cases the specific method of electronic delivery is not necessarily identified. It may say, "We will provide you with your prescription digitally either by text, email, or portal." So what do we think are the best practices for communicating with patients so that they understand how they're going to be receiving their prescription, have a chance to agree to that, and then know where to find it after the appointment?

Dr. Artis Beatty OD:

Well, I think from the earlier discussion, intake is a very complex thing. Yeah, I think we're going to talk a little bit about third party and insurance and how that complicates the patient's entrance into an exam. While I think there are things that can be coupled together to decrease the amount of forms that a patient is having to sign, I do think that there are certain aspects of that intake process that should be separate so that we can make sure that the patient is acknowledging things appropriately.

And that may be from if you have a service that is subsequently not covered, as an example, then you may need to think about paying for that service. Or in this case, whether or not we separate the acknowledgement for the availability of the prescription. I think that making sure that patients are adequately reading those forms is a challenge. And to the point earlier about the mortgage signing, you at some point are signing things because you know you have to sign them and you cannot have the money until you do. And I think there are patients who really want to have their eye exam or any of their medical exams and they are signing things because they know that they need to. And so it becomes a question of making sure that that patient is adequately acknowledging and not just signing.

Sarah Botha:

Does anyone else have any thoughts? I guess again, getting to what's the best practice for making sure the patient understands where they're going to get their prescription? If it's going to be provided digitally, if they're not going to be handed a copy, a physical copy when they leave the office, is it a matter of training office staff to remind the patient as they're leaving, " You can get your prescription on the portal or it will be emailed to you." How do you think that this is being accomplished or what consideration should go into that?

Dr. Artis Beatty OD:

In our practices, in our form helps the patient understand where that prescription's going to be available to them and how they can access it as well as the provision of paper copies should they prefer to have those copies. And thinking about that as the definition of how you have that acknowledgement for that patient probably helps to solve some of that.

Sarah Botha:

Any other thoughts? Do you all think that having this option to provide the prescription digitally is increasing compliance with the prescription release requirement? I know we have opinions that... Certainly the prescribers we're hearing from today feel that there is not a problem with prescription release, although that's something that we have seen through consumer complaints and survey data.

But just wondering if offering this option is helping make things easier for prescribers to comply or encouraging them to comply?

Wallace W. Lovejoy:

Well, I do think it is easier, excuse me, if a patient can get a prescription through email either directly of the prescription itself or to a link to a website or a portal where they can obtain it. And anecdotally I've heard reports of being able to be standing at the office desk checking out and having the prescription emailed to you before you leave the office. It's in your iPad or your iPhone and ready to be used wherever you might want to use it.

The NAROC members have affiliated doctors typically that absolutely have an incentive to deliver the prescription to the patient, because the doctors themselves are not selling the eyewear. And the patient is going to take that prescription, perhaps leave to shop someplace else, perhaps shop there at the location where the exam takes place. And more and more we're seeing some of those prescriptions being written after a telemedicine eye exam where the doctor and the patient are in a real time communication, but the doctor's remote. And the only way for the doctor to prescribe and get the prescription to the patient is electronically. It can be then printed out at the office and the patient can use it either there at the location or take it someplace else, but the patient then has access to it electronically as well.

Rebecca Hyder:

I would say that it gives providers more ability to comply, but I can't say that we have data to show that it improves compliance. Because again, I think our doctors are complying with the requirements. I also think it depends on the patients. I think, as Dr. Repka indicated, ophthalmology patients who are older... digital option, they may not even want or have any idea of how to access. So it's good to have the option, but I don't know that we have data to show that it has improved compliance.

Sarah Botha:

And so for those patients who may want or need a paper copy, do you think that by having this digital option, which is intended to be an opt-in versus an opt-out but may sometimes function the other way, do you think there's a burden placed on patients to obtain a copy of their prescription? For example, saying in the paperwork, "You're consenting to get electronic delivery, but you can ask for a paper copy." Do you think that there are circumstances where that's reasonable to tell the patient they need to ask for it, or do you think they should be given that choice upfront?

Dr. Aarlan Aceto OD:

So I will ask, it's sort of along those lines. And I will say sort of introductory to this is no group has probably benefited more from the eyeglass release than the opticians. We're feeling, we've had a lot of discussion with the people who prescribe and the burdens and understandably. But I will say that a good amount of the time that we spend oftentimes as opticians is sometimes calling for verification. But I do worry that some of these other burdensome regulations like the affirmative consent, for example, isn't going to change that. Because if they forget it at home, if they don't have it, we end up calling. And I don't know that it's that much of a burden to them. Because as we've called optometrist's office and ophthalmologist's office, I will tell you that without fail because of the great work of the FTC since 1978, there hasn't been as much pushback as before those rules were instigated.

And I was actually having a discussion with our OAA executive director in his 12 years. One of the comments he made is we were asking, is there really an issue about access to the prescriptions? Are we

having trouble getting them? And he said in his 10 years, he's never had an optician call him and say a doctor didn't release the prescription. So I think part of it is are they getting it, keeping, but the core of the spirit is are they having access to it? And I think from a burden from the patient's office, if they're going to say an optician's office, if we can call or verify or online if there's multiple different ways, I don't see that there's quite as much of a burden on the patients that way personally.

Sarah Botha:

Okay.

Dr. Artis Beatty OD:

Yeah, I actually would agree with that. I mean, I think that the number of patients who are issued a paper prescription only, to just not have it when they need it is relatively high. And so a simple request from the patient to have a paper copy should they need one I think is a really simple request on their side and not really burdensome. I think that as long as that prescription is issued at the request and there's an electronic version available to that patient, then it should be ample.

Dr. Aarlan Aceto OD:

And one other thing along those, I have had some folks and some doctors be slightly more reticent. Not because they don't want to let go of the prescription or they're not willing to share, it's the potential compliance with other federal laws and regulations. Like HIPAA for example. Like, "Well hold on, are you really the person asking? Do I have this random person asking me?" And so I think there's sometimes a lack of clarity for do they have to do it? Do they have to have the patient request? Is it in the care of the patient? And I think that some of the potential not allowing or sometimes, not initial reticence, is, "Am I violating HIPAA by giving the prescription by somebody who didn't have authority to ask for the prescription?" Is sometimes a concern potentially.

But again, I will tell you that by and large, at least where we practice and from the outreach from the OAA that we've heard or lack thereof, the optometrist and the ophthalmologists who are prescribing are generally very, very, very... If, God forbid, they weren't doing it initially, there doesn't seem to be a huge issue and a burden in us asking for it and them sharing it.

Sarah Botha:

Okay. Any other thoughts before we move on to the next proposed amendment?

Wallace W. Lovejoy:

Just one comment that it's important to remember that eyeglass prescriptions are different from both pharmaceutical and contact lens prescriptions in the sense that they can be used multiple times for a variety of both functional and fashion reasons. And unlike filling a drug prescription where you have a certain limited number of specific pills or tablets or injections, or even contact lens prescriptions where you might be able to use it more than once during the year that it was valid. But most people don't buy more contact lenses than they intend to use. In fact, it's hard to get patients to buy enough contact lenses. I think that making it easy for patients to get a copy later is something that most doctors are willing to do. But as I understand it, this rule does not require a future release of a prescription, that is optional on the part of the provider or prescriber. Is that correct?

Sarah Botha:

It's not mandated currently and it's not one of the proposed amendments that we're considering today, to mandate the duplicate copy.

Okay. So let's move on to talk about the second proposed change to the eyeglass rule. As you know, the eyeglass rule states that the prescription has to be released immediately after the exam. But it has a provision that allows prescribers to first require payment for the eye exam if they require immediate payment from all patients regardless of whether they require ophthalmic goods such as glasses or contacts. The notice of proposed rulemaking proposes to clarify that a patient's proof of insurance coverage will be deemed to be a payment for the purposes of determining when the prescription must be provided.

This is another provision that does appear in the contact lens rule. It originally came from Congress in the Fairness to Contact Lens Consumers Act. We've received questions about this issue, about whether it also applies in the eyeglass rule. We believe it's a common sense and should apply and we want to bring the rules into conformity to eliminate unnecessary confusion. We did have just a few comments on our notice of proposed rulemaking addressing this proposed change.

We had NAROC commented that it would generally increase compliance with the rule's requirement to receive the prescription at the completion of the exam. And we did have a concern, I think from the American Academy of Ophthalmology, that it should be where patients are eligible for insurance coverage. I think the concern was maybe in some cases patients have already used their benefit, is it available to them? And so I guess I wanted to start the conversation with a question about that, about how difficult is it at the time of the appointment or before the appointment to confirm whether there is insurance coverage so that the prescription can be released?

Rebecca Hyder:

Well, insurance is complex and I think sometimes it can be a challenge to confirm whether or not the coverage is available for a patient. Sometimes you don't take that patient's insurance or you may be on a different plan than what the patient has. So all of those things make it difficult sometimes to determine at the time of service that the patient actually had coverage for the benefit that they were seeing.

Sarah Botha:

Is that typically ascertained via a phone call to their insurance provider, or how do you go about confirming coverage?

Rebecca Hyder:

I think there can be different ways that our members can confirm that. Sometimes I think it can be done electronically. I think sometimes they do need to call. I was actually in a eyecare provider this weekend and they were calling for some patients, and other patients they seem to be able to verify it electronically.

Sarah Botha:

Okay.

Dr. Artis Beatty OD:

Yeah, I think in my experience you do have various ways of verifying eligibility between phone calls and electronic means. I think the issue is that being eligible, so verifying eligibility does not necessarily

guarantee benefit at the time of service or that the payment will be made at the time that the claim is filed. And so while I think that gap that some patients would have is not prohibitive and probably does not prevent people from complying with the rule, I do think there is a real issue between a patient who today shows eligibility for whatever plan that was verified, but by the time the claim is filed, no longer has that eligibility or was shown to be eligible in error, which can happen with determining which plans you are able to accept, what plan the patient is actually on, or the timing of the services.

Sarah Botha:

In our... Oh, I'm sorry, Wally, go ahead.

Wallace W. Lovejoy:

I was just going to add that while we think that this would likely increase compliance, we're not aware of really any significant number of instances where prescribers have been refusing to automatically provide the prescription until they got paid by the insurance company. It's the first we've heard of it. I think most of the affiliated optometrists with NAROC companies will wait to do the eye exam until they've received some sort of confirmation of eligibility of benefits. That doesn't mean they always get paid, but usually they will get paid and the proof of insurance coverage requirement here would not be a problem.

Sarah Botha:

Yeah, in some of our recent rule compliance we have come into a couple of different scenarios where we have learned of insurance playing a part in a consumer being denied a copy of their prescription. For example, we heard of a prescriber who withheld the prescription for up to 30 days while they waited for that payment to come through, which if they have confirmation of coverage probably shouldn't be happening. But are there circumstances where that could be appropriate? For example, one issue that's come up with some of the prescribers we've spoken with is Medicaid coverage and that Medicaid coverage can be particularly difficult to confirm upfront. Or other types of unique insurance coverage situations where it's not possible to get that confirmation. So trying to determine, again, what are the best practices, what would be covered by this proposed amendment to say you have to provide it after you determine coverage? Or do you think it's reasonable for the prescriber to wait until they receive payment?

Rebecca Hyder:

I don't know that our members are waiting to give the prescription until they get paid, I don't think that's what our members are doing. I do think they are providing the prescription at the time of service. I do think we are running into issues where patients are confused by what a free prescription or what [inaudible] it means.

Sarah Botha:

Yes.

Rebecca Hyder:

And that, I think that could be where some of the confusion is. That they think they shouldn't be charged for the service of getting the prescription because it's supposed to be free. And I think that is where the FTC could help clarify that, because I think that is a big issue.

Sarah Botha:

Yeah. And, well, we can touch upon that right now, and I also plan to talk about that a little bit for the final proposed rule change. But yes, I think what you're saying is the rule prohibits the prescriber from charging a fee specifically for releasing the prescription. In some cases, when we've talked to prescribers we've been told that the consumer was confused and the charge was actually for the eye exam, not the prescription. I think some of the challenges we're seeing is terminology being used, possibly by the office staff saying, "Oh, well if you want your prescription, it's going to be a charge." Not explaining to them that it's a charge for the eye exam.

The other side to that is also that we have spoken with prescribers who have indicated that that charge has only been requested, the fee has only been requested of the consumer, after they requested a copy of their prescription. So, for example, they've done the eye exam, they weren't going to charge them the separate refraction fee, which we understand in some cases is not covered by insurance. But that when the patient asked for a copy of the prescription, at that point they were told, "Oh, well there was a fee for that and here it is." So in a scenario like that, does that, in effect, turn into a prescription fee if it's not being applied evenly?

Wallace W. Lovejoy:

Can I ask for clarification, Sarah?

Sarah Botha:

Yes.

Wallace W. Lovejoy:

This may be more for ophthalmologists, although as more and more optometrists are doing medical eye exams, it likely relates to them as well. If a patient comes in and their chief complaint isn't about poor vision or refractive error, the doctor is likely, I think, and I'll ask the doctors to comment, to want to do a measure of whether or not there is a refractive error to help with the medical diagnosis, but may not want to write a prescription at the end of that because that's not what the chief complaint is about and they don't see a need for the patient to have a prescription for corrective eyewear.

But if the patient, at the end of this exam, asks for a prescription, then they would probably write one, but if it was a medical eye exam not being covered by a vision plan, there would be a charge for the refraction. The medical care, Medicare, most medical plans don't cover refraction if it is a medical exam. I think I've got that right, but I'm going to ask the doctors to comment. But that might be an instance where it would be appropriate to say, "Of course we can write you a prescription. There is a charge for a refraction."

Dr. Artis Beatty OD:

Yeah, so I think there's probably two separate issues that are being raised. The issue of charging patients unfairly is probably more of a compliance issue outside of the scope of the rule and that those providers should be addressed from a compliance with billing and coding appropriately for patient care. Wally, to your point, I think there's a distinction between using refraction as a diagnostic tool and using refraction to deliver a proper prescription that the patient is expected to see well from. And so you really should go into the examination and predetermine whether or not the deliverable at the end of that exam is going to qualify as a prescription, and then that should actually determine what you're going to charge that patient. So as an example, if I have a patient who's presenting with blurred vision and I suspect that that blurred vision is from a cataract, then I'm going to use my refraction as a tool to understand how far that cataract has impacted the vision.

But ultimately the diagnosis will be around the cataract and in those particular cases, you're not generating a prescription for that patient to go and fill with the expectation that they're going to get better vision. And so my exam would be based on the cataract finding and I would not be charging for a refraction nor would I be delivering a prescription that that patient would go and get a new pair of glasses from. And so I think you have to be able to do some of those things in the exam lane to determine what the intent of the exam is and what the intent, or what the outcome should be in order to clarify and make sure that you are being compliant with billing purposes.

Sarah Botha:

That's very helpful, and I think we'll want to touch upon that in a few more minutes as well when we discuss the terminology question because I think that's very relevant. Yes.

Dr. Aarlan Aceto OD:

Well, I know a few ophthalmologists that do the MI area that practice like that, and they'll do the refraction, but if you don't ask for the prescription, they don't charge you for the 92015 refraction. To me, and this is just my personal, it's almost like they say an eyeglass consumer, if you said that's not right, everybody has to be charged, it seems like the overall cost of healthcare would go up because you'd be charging... And let's say only 20% ask for their prescription and they only charge the 20%, then you paid for what you asked for. But those actually, the other 80% that didn't ask, now just save the refraction fee of $50 or $80. I don't think that that's a bad thing if, on whole, more people are saving money that the doctor did something but they didn't ask and they didn't deliver.

They're not charging for the prescription, they're charging for what they did, but they opted not to charge if you weren't going to benefit from it. But if they did, you are paying for the service you would have asked, but they're comping out to people who are not going to make use of it. It's almost, it seems beneficial in aggregate to the entire, let's say there's a hundred patients, 80% didn't have to pay. If we change it to everyone has to pay in that particular aspect, the overall cost that was out of pocket is going to go up, it seems to me. And that's just my observation and if I'm understanding how some ophthalmologists do it and some may potentially, other practitioners and other optometrists do it.

Sarah Botha:

Okay. Did you want to add anything? Okay, so just getting back to this consumer confusion over the fees, we have seen an example of a form a prescriber's office provides before the exam that explains to the patient upfront that a refraction is sometimes not covered by insurance and the patient will be asked to pay for it. If such a form is used, do you think that could resolve some of the consumer confusion or what other methods do you think could be helpful for helping consumers understand that being asked to pay an exam fee is not a violation of the rule and they're still entitled to their prescription once they pay that.

Rebecca Hyder:

I know in talking to some of our providers who've called us after they've had a patient say that you're not allowed to charge me for my refraction, and the FTC says you can't charge me. So I think part of it is that there needs to be something that states in the rule that refraction services are different than the cost of a prescription.

Sarah Botha:

So actually adding language in the rule itself as opposed to in consumer guidance about that? Any other thoughts?

Wallace W. Lovejoy:

I believe there may be instances that would be similar to what Dr. Beatty was talking about where the doctor might, in their medical judgment, decide that a prescription wasn't appropriate, that it was not going to solve the vision problem, for example cataracts, and so they would choose not to write a prescription. I think that's a legitimate use of professional judgment and there would not be a requirement to release a prescription even if a refraction had been done. Whether or not... Well, obviously if they're going to charge for the refraction, I assume that that means they're writing a prescription, but maybe the doctors can advise me on that too.

Dr. Artis Beatty OD:

And I agree with that a hundred percent. Right, and it goes back to determining what level of testing you're going to do and what is part of your diagnostic testing versus what is producing a result that then gives the patient that prescription and making that determination. And to your point, having that conversation upfront so that you can then determine who's going to be charged appropriately, I think is fair.

Sarah Botha:

Yes.

Dr. Aarlan Aceto OD:

In Washington, could you ask the Centers for Medicare services to start paying for a refraction and then that would solve a lot of these problems.

Sarah Botha:

Don't ask me.

Dr. Aarlan Aceto OD:

There may be a connection in there for them.

Sarah Botha:

So again, I think we're going to cover this in just a minute when we talk about the eye examination definition and terminology because I think that clarity could be helpful. But just finishing up with respect to this provision in the rule that allows you to withhold the prescription pending payment, or in this case will be insurance coverage. Do you feel it's sufficiently clear and do you feel prescribers understand that if you are withholding a copy of the prescription pending payment, you can't then sell eyeglasses to the patient until you've given them their prescription?

Because we have had some instances where the patient doesn't get the prescription until after they've made the purchase. And in the rule, the whole purpose of the rule is to separate examination from dispensing, and so the patient needs that prescription first.

Dr. Aarlan Aceto OD:

That's one concern that some of our optician members have had some concerns with, and that is at the end of the actual doctor's exam, oftentimes they're directed to the dispensary just as a matter of course, and they purchase at the end of the actual... And the copays, the exam fees, the glasses are all taken. Then they said, here's your eyeglass prescription. And some of our members have asked, is there a way that we could clarify that the prescription should come to them at the end of the doctor's experience? And most of them, quite frankly, 80% are going to purchase where they're prescribed anyway, that's understandable. But for the folks that potentially won't, as long as it's in their hand, that will spark the, "Well, I'm either going to stay here because this is where I intended to." Or that may be one of those areas where your point to the FTC's concern about knowing what the options are, having that be a little bit more clear cut as opposed at the end of an entire transaction and bundling.

Sarah Botha:

So is this an area where potentially the language of the rule could be more explicit rather than just saying “immediately after the exam,” saying “and before offering to sell,” something of that?

Dr. Aarlan Aceto OD:

On the spot, I couldn't tell you, but at least it's worthy of a discussion of some sort with all the parties involved.

Dr. Artis Beatty OD:

I would think that it goes back to the electronic acknowledgement. So being able to acknowledge that you are going to have access to your prescription as soon as your prescription is final, which occurs at the end of the exam is probably appropriate. Making it super complex is that you've got, their patients have their insurance that may cover their exam, they have insurance that may cover any materials. Most patients prefer, when they can, not to have to swipe two or three times during a transaction. And so having to break it into pieces can make it a little bit more confusing for patients from an insurance perspective. As long as they are aware, and to Wally's other point, in our practices, when the EMR finalizes the prescription, the patient gets pinged with, "Your prescription is available," and so that should suffice for them to have access to that before they are into the optical experience.

Sarah Botha:

Mm-hmm. Right. Okay-

Wallace W. Lovejoy:

I suppose there is a slim chance that patients could walk out without paying if they were given their prescription and decided not to shop at the affiliated optical dispensary. I say that as a chance, but I'm not aware that that happens very often. I note that the rule would require prescription release, but could wait until the patient's paid for the exam, but only if the optometrist would've required immediate payment had the exam revealed that no ophthalmic goods were required. I think that every time there is no prescription, the doctor would immediately charge for the exam. So I'm not sure what that language adds. What was that intended to clarify?

Sarah Botha:

I believe that language is intended to prevent a situation we were discussing before, where a patient is only charged once they ask for their prescription so that it doesn't in essence become a prescription fee. Either that charge is being applied to the patients generally, or if the doctors don't typically charge for

that service, then I think the rule is contemplating that they shouldn't just be charged because they're getting a copy of the prescription. But again, we welcome feedback and further information about the processes, how this interacts with insurance. On our open docket it's always helpful to have more information and a better understanding of how these things work in practice.

Rebecca Hyder:

I was just going to say something based on my own personal experience as somebody who's worn glasses almost my entire life. I know when I've been seen by a physician or an optometrist and they are writing a paper prescription, I tend to get that while I'm still sitting in a chair. If it's coming from the EHMR, I tend to get that when I'm checking out because it's being printed someplace other than the exam room. So that might also be something to you consider.

Sarah Botha:

Right, right. But is it being provided before then they're led into the dispensary, I think was the question.

Wallace W. Lovejoy:

Another question, Sarah. It's not your intention though, or the commission's intention to require a two-step process for payment. In a dispensing optometrist's office do they have to charge for the eye exam before they charge for the eyeglasses should the patient choose to shop there?

Sarah Botha:

Well, we don't have anything in the rule that mandates when patients should be charged. It's more about when patients should receive their prescription. So it's really up to the practice how it wants to proceed. But I think it is problematic if, as Dr. Beatty, I think, was explaining, there may be a resistance to wanting to do two separate transactions, but if then you're holding onto the prescription until after you've already made a sale, I don't think that that would be compliant or certainly within the spirit of the rule, which is designed to give consumers a choice of where they shop and they may not know they have that choice if they don't have their prescription in hand. I do want to get to talking about this third, which I think is related to this whole conversation that we've been having, the proposal to change the term in the rule from eye examination to refractive eye examination. This change was proposed based on comments that the commission received in response to the advanced notice of proposed rulemaking, which was how we initiated this rulemaking back in 2015.

We kind of put this on pause while we were updating the contact lens rule and then restarted it. But back in 2015, we had several comments that we then, in addition to some compliance issues which we can discuss, decided to propose, well, will this help to, instead of saying eye examination the rule, we say refractive eye examination? And to just provide the definition at issue, the rule requires that the prescription be immediately released after the end of the eye examination. And “eye examination” is defined in the rule as “the process of determining the refractive condition of a person's eyes or the presence of any visual anomaly by the use of objective or subjective tests.” So in 2015, the AOA and others, individual prescribers, commented to us that this definition, as it is written in the rule, for when the prescription has to be released, more accurately describes refractive services rather than the full scope of an eye examination.

And the comments we received were that it would help alleviate consumer confusion about when the prescription is due if we made it clear that we're talking about a refractive examination, not the other services that may be provided as part of a more comprehensive eye examination. And just additionally, in some of our compliance efforts that we've undertaken when we're talking to prescribers, there does

appear to be some confusion about when do they have to give the prescription? Is it just an annual vision check versus a more comprehensive exam versus a medical exam by an ophthalmologist? In what circumstances is it due? And given the definition in the rule as that it's due whenever they've determined the refractive condition of a person's eye or the presence of any visual anomaly, it seems that it may be owed every time a refraction is taken, with the caveat of the medical determination that a prescription may not be advisable in that particular scenario. But wanted to get your feedback because when we proposed this change, the comments that we received now here in 2023, we had some concerns both from the Opticians Association and the AOA about continuing confusion about this. And so we want to understand what those concerns are, if you all are able to speak to them and explain.

Dr. Artis Beatty OD:

My, how times have changed. So in 2015, we did not have the advent of mobile and online refractions, which are addressing a need that's different than the traditional eye exam. I can speak for our practices and I'm sure it's going to be similar for your members as well. Generally speaking, patients don't come in, consumers don't come in and receive only a refraction whenever they're having an eye exam. And it goes back to what we were discussing before. The two components are really intertwined. So any health assessment that we do really starts with an assessment of the visual function, and then from that you move into understanding any refractive error and creating a prescription. But then you follow that with understanding for the final prescription, are there any things in the eye from a health perspective that subjectively change what you need to prescribe for that patient and so they are really put together.

And since there really doesn't exist right now a decoupling where a patient is going to come into a practice and receive solely a refraction, it could get a little bit more confusing because effectively the online type of refraction is essentially a decoupling where it is purely the visual piece. And so I think that labeling it a refractive exam really starts to confuse patients as to what the value is for having a full eye exam and can start to make that feel the same as having some exam that you are getting online without the presence of the doctor.

Sarah Botha:

So a couple of questions I have is we have this definition, there's a question of the term that we use for the definition, and then there's the definition itself. So is the definition currently a clear and accurate way of describing a refraction? Does it describe something else? Is it incomplete? And then what would the appropriate term be to correspond with that definition? And not to put you on the spot if you haven't thought these issues through, but I think it would be helpful to us as we are reworking the rule. Is the definition itself clear? Is the term that we're using clear to make prescribers and consumers understand when they should be receiving their prescription?

Wallace W. Lovejoy:

One alternative might be to talk about the doctor's thought process. If the doctor has diagnosed refractive error and determined that a prescription for corrective eyewear is an appropriate treatment plan, that is what should trigger the prescription release. And whether or not there was a refraction only done, if that's permitted by state law, or comprehensive exam was done. You don't have to confuse the consumer with the FTC rule. There may be state laws that require minimum eye exams. There may be disclosures required if it is something less than a comprehensive eye exam. But the issue for consumers ought to be if the doctor has determined I need a prescription for corrective eyewear to address my refractive error, then I should get that prescription.

Sarah Botha:

Any other thoughts or any ways that it could be potentially more objective so the consumer has a clearer line of understanding?

Dr. Aarlan Aceto OD:

I was going to say, I think potentially, when you have some of the patients or doctors that are arguing about, "I didn't do a refraction or I didn't charge them," or some of the doctors, maybe there's just a simple two-step litmus test. Did they use a phoropter and did they charge a 92015? If those two are met, if they charge for refraction they did that, you're entitled to a prescription. If they didn't do it or they didn't charge you for it, they didn't do that procedure, then that would eliminate some of the confusion. Potentially it's just a two-step litmus test. If they did the phoropter and they charged a 92015, which is the diagnosis code for a refraction, you're entitled to a prescription. If they didn't, you didn't pay for it, you don't get it. It seems pretty straightforward I would imagine. Potentially.

Dr. Artis Beatty OD:

Potentially.

Dr. Aarlan Aceto OD:

Yeah, potentially.

Wallace W. Lovejoy:

But one issue with that is the online vision tests that are not comprehensive eye exams don't charge anybody for a 92015. They may charge for the prescription, but I'm not sure that there's a coding issue involved. They're not billing anyone other than the patient.

Sarah Botha:

Right, and then we've discussed these situations where maybe the refraction was taken in a medical exam, but only given upon request. And we've had patients contact us concerned about that because they are wanting their prescription from their provider in those instances and there's a lack of clarity as to whether they're entitled to receive it. So I think it would be helpful to us to understand, one, again, is the current definition, the language that we use currently in the eyeglass rule, does that accurately define a refraction or is anything missing? And is it appropriate to call it a refraction rather than calling it an eye exam, which covers a lot more potential services.

Dr. Artis Beatty OD:

So when you think about it from an objective standpoint, the words that are used to describe a refraction are accurate. The issue is that a prescription is rarely, if ever, a refraction. So when you're delivering a prescription for a patient, it is not necessarily the same thing that was refracted. And there is professional judgment, there's some artistry in producing that prescription. And it takes into account all of the factors that we talked about before from the age of that patient to the health of that patient's eye, to the other factors about what that patient does or how they use their eyes. And so to the earlier point, if the phoropter is used and you're billing for it, in my mind that means that you've taken all those things into consideration. You've come up with the subjective number that you're going to use and you're confident that you're going to make some sort of difference or improvement in that patient's vision. And together that gives you a prescription that's used.

So if the question is that, if it's objectively that the words are right, yes they are. But I don't think that practitioners use the language the same way because they're very rarely doing just the objective part in handing a person a prescription. And so I think FTC should consider that piece as well.

Wallace W. Lovejoy:

And I do think there ought to be an exemption when the doctor uses his or her professional judgment to not write a prescription that if they simply indicate that in the medical records, that's adequate, or that there's no need to release a prescription if the doctor has determined that a prescription need not be or should not be written.

Sarah Botha:

So Wally, are you suggesting that that should be explicitly stated in the rule?

Wallace W. Lovejoy:

Yes.

Dr. Artis Beatty OD:

Okay.

Sarah Botha:

We've also heard about the AMAs CPT codes, current procedural terminology codes for billing outpatient. I think this is what you're talking about a little bit with billing the refractive exam separately. But as we're thinking about changing the terminology, how can we be sure not to be creating complications with respect to the CPT codes?

Dr. Artis Beatty OD:

I would think that the CPT codes in general describe explicitly the procedure and its billable reference. It doesn't necessarily define the pieces or the individual components of that procedure. And so when we think about refractions as an example, a refraction can be as simple as giving you two choices or as complex as making you see double to bring you back to one. There's not necessarily a definition within the CPT for what has to happen during that refraction, and so I think those two things would be independent.

Wallace W. Lovejoy:

I think what's really at issue here is whether or not a consumer goes from being a patient to a purchaser of eyewear with the option to take the prescription for eyewear, which is required in every state, to someplace other than the prescriber. And so if a person is not becoming a prescriber because they have not written a prescription for corrective eyewear, then the rule doesn't apply to them. And we need to maybe think about how to make that clear in the rule itself. And consumers may want a prescription when they shouldn't have one, and the potential prescriber, the physician or optometrist, ought to have the ability to say, "No, I'm not prescribing eyewear for you for the following reasons." And make a note of that in the record.

Sarah Botha:

And if they do that, if they decide that they're not going to provide the prescription in their medical judgment, is it then appropriate that they do not sell eyewear to that patient?

Wallace W. Lovejoy:

Absolutely.

Dr. Aarlan Aceto OD:

Absolutely.

Dr. Artis Beatty OD:

Absolutely.

Sarah Botha:

Okay. Do we have any questions? No questions from our audience members. In the few minutes remaining, I'll just ask, we've covered three different proposed changes and some of them are interconnected. So I wanted to give you all a chance if you had other thoughts that have come to your mind as we've been having this conversation that you wanted to share.

Dr. Artis Beatty OD:

So I've had thoughts that part of this conversation and really some of the other ones from earlier today, we've talked a lot about protecting the consumer, protecting the patient. And we've talked about their freedom of choice, but we haven't talked a lot about educating them on what they get from folks that maybe don't fall within this rule. So Wally just brought up, if you're going to have an online refraction, you're not necessarily a part of this rule. Or you can have glasses delivered from an online resource, it's not clear that those retailers don't necessarily have the ability to adjust those products or service those products for that patient. If there's an error in the creation of that product, what is their recourse? And so as we think about protecting the patient and the consumer, we should also consider, outside of giving them a prescription, once they have it, how do we make sure that the product they get actually delivers what the expectation was from that prescription as well.

Sarah Botha:

Just to touch on what you were saying about these online prescription options, the rule covers optometrists and ophthalmologists. Is it possible that the provider in that case is falling outside of those categories or is there usually an optometrist involved?

Dr. Artis Beatty OD:

It is still gray. And while there are no FDA approved de novo refraction products today, there are FDA-approved acuity verification products. And because of the approval of those prescriptions, it could be within ophthalmology, it could be within optometry, depending on the state. But then the patient is getting this product and going out to shop for glasses at another retailer who may or may not have responsibility for the outcome.

Sarah Botha:

Any other thoughts?

Dr. Aarlan Aceto OD:

Along that line, and again, that's where the importance of the licensed educated folks like the optometrist, ophthalmologists or opticians, verifying and protecting the public in that regards, freedom of choice isn't good if the choice is potentially rife with potential error. And that's where I agree there that there has to be some mechanism for... Unfortunately that's a different discussion for a different day.

Sarah Botha:

Ms. Hyder or Wally, either of you want to have a final word?

Wallace W. Lovejoy:

Just a reminder of some of the other comments that we've heard today about the role of the FTC in helping the industry identify, and maybe this is an information sharing process, what are the most efficient compliance methods? And as you work with prescribers, how can you help other prescribers learn how to comply with the rule in the simplest, most efficient way? And then also, I've heard suggestions on helping lead the development of guidelines for consumer information, consumer education about rights and responsibilities. Not that the FTC ought to necessarily be doing advertising, but giving people some guidelines on how to educate their own customers and making sure that that message is consistent throughout the industry.

And then I think it'd be great for the commission to report on a regular basis. And I'm not sure what the right frequency would be, I think that depends on your budget, but how you use the access to records that would be required by the rule to demonstrate compliance. What are you learning? How often are you using it? Do you audit? And what feedback should the industry and profession be getting?

Sarah Botha:

Right. Great.

Rebecca Hyder:

And I would just say that again, getting back to the point of making it clear to both the providers and the consumer of what exactly they're entitled to, the prescription, and that the services are separate.

Sarah Botha:

Thank you. Well, I'd like to thank all of you on my panel as well as all of the previous panelists. It's been a really great discussion. I do want to note that this docket is open until June 20th. We welcome further comment. We would appreciate data, if you have it, to support the information that you provide to us. That is very helpful to us. So please feel free if there's something you've heard today that you want to share more information about or respond to, that is open until June 20th. And thank you all. I think we're done for the day. Thank you so much.

Dr. Artis Beatty OD:

Thank you.

Dr. Aarlan Aceto OD:

Thank you so much. Appreciate everything.

Rebecca Hyder:
[inaudible] Yeah.