

The Contact Lens Rule and the Evolving Contact Lens

We are acting as the patient's agent, just like a pharmacy might call on a patient's behalf. After the call is placed, if the prescriber tells us that the customer is not their patient, or the

JENNIFERSOMMER: Correct.

BETH DELANEY: And faxes are still being used?

JENNIFERSOMMER: Yes. I'll give you a little content--

BETH DELANEY: Let me get this on the record that faxes are still being used.

JENNIFERSOMMER: Let me give you some context for that. So it has been just recently that, obviously, our vision centers are in a larger part of our store. We're a mass merchandiser. And it's been recently that we've actually opened it up to where our hourly associates can receive attachments via email. And that didn't have anything to do with the vision center itself. But obviously, we have a number of hourly associates in a typical super.cent

And so we didn't want them to receive attachments. That would inhibit the ability to receive a prescription via email. We've also found it's more secure, especially with the prevalence of privacy concerns and data security concerns. And Walmart being a very large corporation, we found that fax is much more efficient. It's the same process that we use in our pharmacies. So we have approximately 5,000 pharmacies across the country. And so we still do use fax, which makes it better for our patients. Besawwe know that their data is being secured during that transmission.

BETH DELANEY: OK. Great. So what I'm going to do now is just ask both of you kind of a follow up question. So what I'm wondering is, from a business standpoint, does it matter to-- mean, you've kind of almost answered this. You would like to get the copy of the prescription. That's ideal.

CINDY WILLIAMS: Absolutely.

BETH DELANEY: OK.

CINDY WILLIAMS: We think the consumer gets their lenses faster. And there's more burden involved for both sides.

BETH DELANEY: OK. And so when you get the copy from and the same for Walmart?

JENNIFERSOMMER: Abs

But again, that's an inconvenience for the patient. So we've undertaken that education effort to make sure that they understand they really need to have that prescription in hand.

BETH DELANEY: Cindy, do you have any anything to add with what 1-800 does to incentivize?

CINDY WILLIAMS: Well, absolutely, Beth. We are always trying to get prescriptions from consumers. And during the ordering process alone, we ask them at the beginning to upload their prescription. If they don't have it at the beginning, we ask them again at the end to upload it. And then as soon as their order is processed, within two minutes, they're getting their order confirmation that they got their lenses.

And we're telling them, if you didn't use prescription this time, please give it to us now for your next order. Because it's going to make it faster for you. So we have alcatg7 -2.32 Y6(y2s)-1(. 1w)2(e)4 prescripti0(a)((f)y2s)-1(. 1 [(c)4(ons)-1.32 Y(um)-2(e)4(r)3(s)-1(. S)-4, 6(f)3(or)3goi)-23(s)-1(t)-2(a)4(consumersattheirc1(t)-2(a)c ateus prescri1ption.

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So there's a big difference. But it's way too high. I even polled my colleagues at the Cleveland Clinic Cole Eye Institute. I don't work there. But I polled them. And I asked them to look at their site and look at verification requests there. It's about a 90% rate there.

DAVID COCKRELL: On top of that, I think it needs to be a two way street. We need to know that re- we need to know that whatever it is we sent is received. We need to be able to contact whoever the seller is immediately. We can't even leave a message on most of them, let alone not be able to contact them. So with no verification, and just as these ones that we reject, like Dr. Steinemann was talking about, yesterday, day before yesterday when I was in my office, we had three immediately from three different online resellers for the same patient for two different prescriptions, two of the three.

So the patient is clearly shopping to see who will fill it or will miss it. And we have no idea if they got it filled or not. There's absolutely no response from the reseller to let us know, we received your rejection. We did not fill his prescription. If we really want to look after patient health care, I think it's important.

I'd like to correct one other thing that I heard this morning. Since she mentioned it earlier. I took moment over lunch to look at what the American Academy of Ophthalmology actually says in terms of contact lens examination.

BETH DELANEY: I joined you, right?

TIM STEINEMANN: Let me speak to that.

BETH DELANEY: OK, OK. You can, OK, Dr. Steinemann, I want it really quick though. Because we need to move on with verification, too.

TIM STEINEMANN: That was quoted out of context, five to 10 years applies to people who are young, under age 40 and have no risk for eye health problem.

BETH DELANEY: OK.

TIM STEINEMANN: Contact lens

BETH DELANEY: Guidelines-

TIM STEINEMANN: There is always a risk for eye health.

BETH DELANEY: It's not listed in the guidelines. It is in the AOA guidelines. But contact lens use is not listed as a risk factor, ~~ought~~, in the-

TIM STEINEMANN: Please look at the preferred practice patterns of the American Academy of Ophthalmology, annual exam, contact lens exam.

BETH DELANEY: OK.

TIM STEINEMANN: Annual exam for contact lens wearers.

BETH DELANEY: OK. So this is a-

TIM STEINEMANN: Please look at the EyeSmart website, annual exam for contact lens wearers.

BETH DELANEY: Well, this is a factual issue that we can clear up. But I did want to have we've a little bit more time before we switch over to Shauri. So have a question. So taking into account the things that we've heard today so far, in terms of what the factors are, which are overwearing your contact lenses, some hygiene issues. If the biggest percentage of problematic verification requests are expired prescriptions, but we also have data that shows that it seems like contact lens consumers are going back fairly frequently, I think from Steve, his data showed that 80% seemed to indicate that they had an exam in the last year.

And if you bump that up to two years, it was 94%. So how do those data points translate into your concern? So, do you know what I'm saying. Like, if people are going back and there is maybe somebody is ordering a couple of months at the end of their prescription, is that a health risk?

TIM STEINEMANN: Sure.

BETH DELANEY: I mean- so, yeah.

TIM STEINEMANN: Sure, it's related to a health risk. Why? Because people don't come back.

2 - Or they may not know it. And nothing can replace a face-to-face exam. C726(e)-13 Tc 0 oo 0.02 Tw 0

prescribers are very aggressively setting price. And they often are benchmarking it off of the online retailers. Because they know the consumer can open their phone standing there in the office and find the same exact product available at a stated price online.

So LensFerry allows a doctor to set their own price. We don't dictate price through LensFerry. And then the doctor, what we do find, is the doctor is often benchmarking that off of the industry standards that are out there. And there are additional features and capabilities in there for negotiations or other set pricing or price matching or other things like that for specials and that sort of thing. It opens up a convenient way for the patient to be able to access products from their prescriber without having to go through some of the steps that they might have to go through otherwise.

BETH DELANEY: So we're going to hear more about another subscription model later in the day. But so LensFerry, you're kind of acting as an intermediary between the sale of the contacts and the doctor?

SHAUN SCHOOLEY: That's right.

BETH DELANEY: And then are there any particular technology challenges with setting an interface with the doctor's offices? They have different ones or do you just bring that all to the table?

SHAUN SCHOOLEY: Yeah. It's probably an oversimplification to say we just pull the data across from their practice management systems or EHRs. Somebody had mentioned it earlier there. The catalog, the contact lens product catalog is significant. There are 80,000 plus products. There are nearly 10 million active SKUs at any given point. In our product, some of the technology challenges that we face, and I think that the industry faces, and it's just you've got multiple manufacturers that all carry that many SKUs. Those SKUs need to be understood and be carried at a detailed level to be able to bring across prescriptions carefully.

You've got a dozen different practice management systems, or electronic health records systems, that are out there. Every system works a little bit differently. Fields are used differently. Even doctors use the fields differently. So there's a lot of customization to be able to pull data across correctly. But done correctly, it brings across the right prescription and gives the doctor a comfort level that, when they're selling a product to a patient, they're selling the product they prescribed and not something that's been switched or changed or it's not going to be healthy or the right product for them.

BETH DELANEY: And from the interface, can the patient pull down a copy of their prescription?

SHAUN SCHOOLEY: LensFerry is not the business model on LensFerry is a purchase model. It's a commerce model, right? It's meant to sell products and allow for simple access through a mobile device, browser, email. There are products out there in the marketplace that act as electronic health records or carry that sort of thing.

BETH DELANEY: Portal.

SHAUN SCHOOLEY: Or portal kind of capabilities. But that's really not LensFerry's model.

BETH DELANEY: OK, great. Does anybody have anything to add to that before we move on to our free-for-all portion of the panel? OK. You want to start with a

PAUL SPELLMAN: Sure, well, Dr. Steinemann, you've certainly identified invalid verification

CINDY WILLIAMS: Well, yes, especially related to your suggestion about the eight-hour window. 1-800's data that we presented to the FTC did not support expanding the eight hours to a longer period of time because our data says that when doctors do engage in the verification process, that they do so by calling our doctor service line within two hours of the time that the verification call was placed.

And then our records indicate that we then get back to the doctor in one hour. So that's a three-hour time period to get the entire transaction done so that when doctors engage, they have plenty of time to actually get it corrected or canceled if necessary. Also, I would say, if we can think about, and I know John Graham mentioned that earlier this morning, 1-800 being a pharmacy.

If you think about doctors and the Walgreens for a prescription, for instance. When you're in the doctor's office, your prescription is usually over there electronically at the Walgreens pharmacy before you even leave the doctor's office. So that, I think, also supports the idea that eight hours is plenty of time to be able to determine whether there's a prescription in the patient's file.

BETH DELANEY: So some commenters have said that they struggled to identify the correct patient when they get it can be a fax or it can be a phone call. Is there anything that any of you could suggest to is there a way to have a unique identifier or

TIM STEINEMANN: Tnd I knowtens the iscideni7c9h(i1dD 3 T-10(l)3(i)-)-20(2oTc 0 TDd-)-20(3(w)r

required field. So in many instances, we wouldn't have the date of birth to give to give as a unique identifier.

BETH DELANEY: OK. Can I ask, what percentage of the online market do you think you are, if you have that information handy?

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requests?

TIO STEINO ANN: Dain, it can't be done quickly. That's been our experience. It doesn't take two or three minutes. Give us extra time.

process because we've developed a best in class phone system. And just to address some of the issues with the call, we immediately identify that 800 is the person calling. It's easy to understand. We abandoned text speech for all but the parameters.

It takes just two minutes of time and can be shortened down to 1 minute and 45 seconds if the doctors are getting regular calls and they utilize the IVR aspect. We allow the prescribers and their staff to pause, to replay, or to get a callback at a later time. And we did all this without being required to do so, without a rule, without a regulation, without a law being passed. Because we thought that was best for our customers and for the doctors. So at this point we believe that the prescriber should be motivated to listen to the call because it's in the best interest of their patient.

PAUL SPELLMAN: The Rule currently requires that prescribers release a copy of a patient prescription to a designated third party. This is the actual prescription itself, not just a verification request. If the FTC were to impose a timeframe for responding to such requests, because currently there's no frame like the eight hour verification timeframe, how do you think that that would impact the number of verification requests? I mean, could it possibly reduce the number of verification requests? And do you think it would impact the use of passive verification?

CINDY WILLIAMS: We think, at 1800 that a timeframe would be very beneficial that it would

CINDY WILLIAMS: That's correct.

BETH DELANEY: OK.

CINDY WILLIAMS: It's to have it on file for the next order that the consumer would be coming to actually obtain.

BETH DELANEY: OK. And then if you get a copy of the prescription, you have a copy that has an expiration date on it.

CINDY WILLIAMS: Indeed.

BETH DELANEY: So then you ~~have~~ have a record. And then that's an enforceable problem for you if you're selling. You know now that it's expired. It's not a matter of passive verification happening and you don't know. You actually have a copy of the prescription and your foreclosed from selling.

CINDY WILLIAMS: I would be remiss if I didn't say that sometimes the issue date and expiration date are not on the prescription. But certainly when they are on there, you are absolutely correct. We're vested with that knowledge. And a sale ~~past that~~ past that would be a violation.

BETH DELANEY: So Dr. Steinemann, do you want to weigh in on--

TIM STEINEMANN: I'd like a follow up to that. Expiration date and total number of lenses allowed.

BETH DELANEY: Yeah. I don't that's an interesting point. I mean, I think when you look to the purpose of the ~~rule~~ rule, it's to give the patient portability. And it's for sale of lenses with a valid prescription. And I think part of the background for the ~~rule~~ rule was that some patients may wear their contact lenses faster. ~~And~~ when you have a risk factor, one of the major factors being somebody overwearing them, I think the quantity you know, we have to have empirical data. So when we have data that shows how many contacts people are buying, which is not ginormous amounts, and when we have data that shows that people are going back for annual exams, we

BETH DELANEY: There's been quite a bit of discussion in over, since 2008, about the intention of the Act and the Rule. And we continue to look at that. But I think when you look back at what the risk factors are, ~~that~~ we have to look at all the empirical data. And when we look at sales data, and when we look at health risks, and we look at when people are going for exams and when we look at the cost of contact lenses and I don't know how much evidence there is that people are stockpiling several years of contact lenses. If that's true, we would like to see it. I mean I know anecdotally it might happen. But I mean I make ~~a fair~~ amount of money as a lawyer and I never purchased a year's prescription. It was something could happen. My vision could get worse.

DAVID COCKRELL: I doubt seriously there's a single doctor in this room that doesn't have that problem I just described. And that's just this room with 70 or 80 doctors in it.

BETH DELANEY: Right. I agree, it might happen. But I guess we'd have to look at the percentage, 41 million contact lens wearers. We have to look ~~from~~ an empirical perspective not just anecdotal. But this is data that we want and we're inviting you to provide. But I did want to get back to Dr. Steinemann. Because I think the CLAO, which I know you're part of that organization, I think that they had, in their comment to the NPRM, had said two business days for this proposal would work.

TIM STEINEMANN: Yes.

BETH DELANEY: OK, great.

TIM STEINEMANN: Yes.

PAUL SPELLMAN: Jennifer, did you have any thoughts on that?

JENNIFER SOMMER: Like I stated ~~before~~ we've been pretty successful in getting a copy of the prescription within the same business day when we make that phone call to the doctor's office. So when I polled our vision center managers, they said, we don't believe that the FTC needs to weigh in on this unless there's other purpose. But they've been pretty successful without any type of requirement.

BETH DELANEY: OK. So just from a hypothetical perspective, I mean if each and every prescriber automatically released prescriptions to their ~~patient~~ would the verification framework still be necessary? So what I want to hear about mostly I guess from retailers is does verification serve a purpose, even if someone were to have a copy? What contingencies would require verification to still be there?

CINDY WILLIAMS: Well, if a person, actually the doctor released and they have their prescription, why would verification be needed under that circumstance?

BETH DELANEY: Right. If you had a perfect world where every patient got a copy of their prescription.

thing was. It's not, so no I don't think the FTC needs to get involved in that ~~scam~~ problem that you would need to come in to resolve.

PAUL SPELLMAN: I know that back in 2004 the AOA had actually recommended that the FTC create like a standard verification form. Do you have any thoughts on whether that might be helpful?

DAVID CO

Because that information could actually transfer with the prescription very similar to when you're transferring your prescription, maybe a chronic condition prescription. You know how many refills are left on that prescription. So I think it helps with that issue as well. And make sure that the patient has adequate supply but still goes back to their eyecare provider for the necessary exams.

BETH DELANEY: All right, Dr. Steinemann?

TIM STEINEMANN: Communication is key, not only two-way communication but communication of choice for the prescriber. And if I can close with a statement crafted by Dr. Jacobs, past president CLAO that the renewal of these prescriptions, and particularly expired prescriptions, which may be in the seller's interest and the consumer's immediate interest, but not in the interest of the consumers long-term eye health or in the public health. This is our major concern.

DAVID COCKRELL: I do have a comment. I would like to see the FTC not move forward with the proposed rule as you've laid it out right now. And the reason for that is, as we looked at the number of complaints the FTC received over the five-year period ~~effort~~ that we requested information from you, and if there really are 40 million contact lens patients a year and if they really do replace their prescriptions every 12 to 14 months, over the five-year period of time, that's any place between 160 million and 200 prescriptions. And on record, that would come out to the number of complaints you received a ~~6000006~~ 0.00006%.

My point in saying that is, if it was a real problem for patients, you would have an enormous number of complaints. It wouldn't be six zeros to the left of the period mark. And so as I look at that, I've really tried to decide, is this really a big issue for patients? Or is it an issue that retailers want to turn into an issue? I think in this case, it's not a big issue. Or you'd have a lot more complaints and just don't see them.