

From: Dr. Keith Poindexter
Sent: Thursday, March 11, 2004 12:42 PM
To: CONTACTLENSRULE
Cc:
Subject: Contact Lens Rule, Project No. R411002

To whom it may concern:

To first answer your questions from Section IX.

General questions:

4. a) The definition of business hour could be further expounded to include which 9 a.m.-5 p.m. is correct. In other words, does this time period apply to the seller's time zone or the prescriber's time zone? b) Many prescribers are only open 3.5 or 4 days per week. Assuming a prescriber is closed every Friday, if a verification was faxed on Thursday at 8 pm, then the prescriber would not receive it until he/she arrived in the office again at 9 am on Monday, at which time the eight hours would have expired without a chance to verify or deny the rx. The cost to the prescriber now increases, as the prescriber now must have a staff member come in on those days (non weekend, non federal holidays) that the office is normally closed just to check for these faxes, in order to comply with the rule. c) Medically necessary follow-up should not be further defined, as that is in the eyes of the prescriber. Any further restrictions between doctor and patient could interfere with proper care.

5. c) No, the definition of contact lens prescription should not necessarily include the prescriber's email address, as some may not have such.

6. "Contact lenses" should be defined, and must include any lens, whether designed to correct vision or not, which is intended to be placed directly upon the eye, including "Plano" lenses intended solely for cosmetic purposes and lenses intended for therapeutic purposes. Each of these are, in fact, contact lenses, and an essential reason for requiring a prescription from a licensed professional for contact lenses -- the potential for adverse effects on the health of the eye -- is equally true whether the lens corrects vision or not.

7. The definition of "Direct Communication" is unworkable with respect to email and fax transmissions. A communication is not "completed" until received by the recipient. Thus, until an email or fax is read, or a message heard, the communication is not completed. There is no way for the sender to know when these forms of communication have been completed or IF they have been completed. Email messages can be "lost in cyberspace" or inadvertently deleted or blocked by spam blocking software, which may occur at the ISP level or by the recipient's system. A fax may be "lost" by a paper jam, an ink failure, or held in a fax machines memory, if, for instance, the machine runs out of paper, and then lost upon a power outage before it is printed. The only viable means of communication, where all interested parties can and will know that the communication has been completed, is a telephone call from a person, answered by a person.

8. a) Yes c) The issue date should have no bearing on the expiration date. For instance, a patient could have had their last exam in March 01, 2003. The rx expires on March 01, 2004. If a seller requests the prescription on Feb 2004, then the issue date would be Feb 2004. However, according to the Act and Rule, the expiration date MUST be a year from the "issue date". In this case, a patient would thus be allowed to, in essence, extend their prescription by another year. If the doctor wrote the issue date for Feb 2004, and the expiration date March 01, 2004, he would be violating the letter (but probably not the intent/spirit) of the law.

Prescriber Verification

17. d) Not necessarily. See comment above regarding definition of 8 business hours. The other dilemma is... what happens if inclement weather prevents the prescriber from being in the office within the defined 8 business hours?

18. c) Extending the "time as defined by the FTC" to three business days would help solve many of the above issues. Given that most contact lenses are for two weeks or greater wear time, and the fact most wearers would probably initiate a sale from sellers when they opened their last pair of lenses, not to mention the speed of delivery of product (in most cases overnight or second day air), this should not limit the expedient delivery of lenses to patients (doctor term)/consumers (seller term).

21. c) Sellers should also be required to maintain all requests for prescription verification, including the duplicate requests they send. It is not uncommon to receive duplicate requests for verification for the same patient, of which the prescriber is required to keep both. Neither party should share unequal (read double for prescriber and single for seller) burden.

22. a) The prescription is defined to expire in one year from the issue date. What happens if the issue date (date the patient is given the prescription) is just a few days prior to the original expiration date. See 8c above.

23. c) Reasons to set expiration dates of less than one year include, but are not limited too, neovascularization of the cornea, history of extended wear, history of corneal ulcer, diabetes (corneal hypoesthesia), new contact lens wearer (to monitor for early signs of contact lens complications), young age (possible sudden refractive changes, also tendency for children to be less compliant with wear and disinfection regimens), corneal degenerations (i.e. keratoconus), giant papillary conjunctivitis, or monocular vision (vision in only one eye). e) Prescribers currently retain medical records for all patients according to state law, which is usually 7 years.

Now for some more generic comments...

The time for verification defined by the FTC does need to be addressed. Several situations come to mind where 8 business hours is not enough. As mentioned above, times when the office is closed that don't fall on Federal holidays or weekends (i.e. for vacations, some offices are open only part time, inclement weather, etc.). If so, it should read "eight business hours after the prescriber receives (or is confirmed to have received) the verification request". Even less than eight hours under that definition would more than likely be acceptable. Also, there is no interpretation as to the protocol for situations when a verification is incorrect/invalid, but the prescriber did not receive the request until after the 8 business hours have elapsed. How to deal with prescriptions that were already filled, but were invalid/inaccurate?

The issue date should be defined as the "date the contact lens prescription was finalized", not "the date the patient receives a copy of the prescription". The prescription could be finalized on 02-04-04 and given to the patient with an expiration date of a year. If the patient then requests another copy 364 days later, on 02-03-05 (the new issue date), then, by rule, the expiration date is automatically extended yet another year. This makes no sense.

Direct communication "includes a completed communication" [section 315.2]. "The Act states that a seller cannot sell contact lenses to a customer unless the seller has obtained a copy of the patient's contact lens prescription or verified the prescription through a direct communication [completed communication] with the prescriber." [section 315.5]. Then Section 315.5 c claims "a prescription is verified if ... (3) the prescriber fails to communicate with the seller within 8 business hours (or a similar time period) after receiving a proper verification request from the seller". Many events could lead to either the prescriber not receiving the verification request within that time frame or receiving it at all, especially when it comes to fax and email delivery. On the contrary, many events could also lead to the seller not receiving the prescriber verification in a timely manner (or at all) either. Since direct communication "includes a completed communication", but this is not always a guarantee with fax and e-mail (for reasons previously identified), it would seem one section of the rule contradicts the other.

Section 315.5 f asks for comments on the costs of maintain such records for three years. In our office, the cost of maintaining the records is negligible. However, paperwork reduction act calculation you mentioned is incorrect. To create a contact lens prescription, it usurps about ____ minutes of our staff time. This includes 40+ seconds to complete the prescription itself with 30+ seconds to scan the copy into our electronic medical records. This does not account for the time involved on a routine basis for ordering the CL prescription forms, nor the costs associated with the generation of said forms. Nor does this account for the typical patient, who tends to misplace the original prescription. When this happens, it takes another 40+ seconds to field the phone call request from the patient requesting a second copy. Another minute of staff time to complete the prescription, and then either fax or mail the copy (again) to the patient. So for these initial prescriptions, a minute of time is almost correct. But for the ~25% of patients who need repeat release of prescription (not mentioning those who have sellers attempt to obtain this information for the patient), the total time involved is almost three minutes. As you can see, this process in our office, and I am sure many others, involves more than "merely writing a few pieces of information onto a slip of paper and handing it to the the patient."

Section 315.5(f) is illogical with passive verification. To reduce costs, it would be advantageous for sellers to "lose/misplace" prescriber's verification responses, such that they could fill the prescription and not have to worry about more paperwork. In other words, why would a seller keep this documentation if the seller can just as easily claim they never received it while still complying with passive verification? In 315.5(f)(2), "confirmation of the completed communication of that request" should be further defined. Does this mean a report showing the fax was sent without difficulty? Or a confirmation from the recipient (prescriber) stating that he/she indeed received the request?

In Section VII, you request modifications to the rule that could minimize the burden on small entities. You could put some impetus/responsibility on the patient/consumer and sellers. For instance, once a prescription has been released the first time, assuming this prescription is for an entire years supply (time and quantity), do not require the prescriber to release it again. Or at least limit the number of verifications/releases small entities prescribers must complete. This duplicate/triplicate work does increase the burden, and would be akin to asking a primary care physician to repeatedly create drug prescriptions for the same patient. It would be even better if we had some type of national database that the prescriber could communicate (either via their electronic medical records, or direct data input) with all sellers to reduce the burden on all involved. This would help assure compliance with the prescription. I don't know the exact costs involved if this were undertaken, but a good contact source for a possible answer is www.patientwire.com.

Thanks for listening to my concerns, and feel free to contact me if you need anything further...

Keith Poindexter