

CONTACT LENS RULE, PROJECT NO. R411002

Question 3 - Definition of “business hour”: This term as defined is not sufficiently clear. It should not take into account any state and/or local holidays nor prescriber vacation days. It should take into account the “business hours” of weekend days for prescriptions from national chains. The impact of incorporating state and/or local holidays and prescriber vacation days into the definition of “business hour” would require information that is not available to national mail order and internet firms and even if it was would be cost prohibitive to implement and thus would stifle the competition this Rule seeks to enable.

Question 4 - Definition of “contact lens fitting”: This term as defined is not sufficiently clear. Yes a contact lens fitting commences at the end of the initial eye examination, however when does the “fitting” end. There should be a mandated period of time beyond which the “fitting” cannot extend and the prescription must be given to the patient. The term “medically necessary follow up examinations” also needs to be more strictly defined so it cannot extend indefinitely. The term “contact lens fitting” must be defined to include an initial pair of “trial” lenses and all costs associated with the fitting including all “medically necessary follow up examinations” to the point the patient is given a written prescription and allowed to purchase lenses from whomever the patient decides.

Question 5 - Definition of “contact lens prescription”: This term as defined is not sufficiently clear and is overly restrictive. To truly promote competition “contact lens prescription” should have the same definition under Federal and State laws or Federal law should take precedence if the prescription is being filled by an out of state company. The prescription should include all the information required in the Act, however often this information is missing, incomplete or incorrect either by accident or design. If some of the information missing can be corrected by the company filling the prescription it should not hinder that company from filling it without the necessity of further verification. For instance if the prescription includes the name of the lens and that lens has only one diameter, base curve, manufacturer or material and if this information is missing, incomplete or incorrect it should still be considered a valid prescription and the corrected prescription should be allowed to be filled. Date of the examination should be optional for it is meaningless for the purposes of the Act as the prescription date would take precedence. In the case of a prescription for “private label” lenses the inclusion of the “trade name” of the equivalent brand name should be mandatory to reduce consumer confusion and foster the competition the Act seeks to provide. The definition should require the inclusion of the prescriber’s email address for verification purposes.

Question 7 - Definition of “direct communication”: The term “direct communication” is not sufficiently clear and is overly restrictive. Direct Communication should extend to messages left on telephone answering machines. Direct communication should be further clarified to include the ability of the patient or someone designated by the patient to provide an original, copy or fax of the patients contact lens prescription to the person or company filling the prescription and should not require the person or company filling the prescription to have to additionally verify that prescription in any other way with the prescriber.

Currently if a doctor, nurse or employee of a doctor’s office calls in a drug prescription to a pharmacy that pharmacy does not need to have a written prescription at all, this option should extend to sellers of contact lenses.

Further if some of the information necessary to fill a drug prescription is either missing or illegible and can be corrected by the pharmacy filling the prescription without unnecessary calls to the doctor’s office the pharmacy can fill the prescription at its discretion. Likewise contact lens prescriptions are often incomplete or illegible and can usually be corrected without additional verification. For instance, if the prescription includes the name of the lens and that lens has only one diameter, base curve, manufacturer or material and if this information is missing, incomplete or incorrect it should still be considered a valid prescription and the corrected prescription should be allowed to be filled. Only if a contact lens prescription is not sufficiently clear should the contact lens supplier be required to call the prescriber.

It is obvious that anyone filling a prescription for contact lenses will want to dispense the correct lenses especially in today’s litigious society not to mention for the patients satisfaction. If there is a question regarding the prescription the person or company filling the prescription would be foolish to risk the ire of the patient, the expense of replacing incorrect lenses or a lawsuit by not calling the prescriber to verify the lenses are correct. Requiring contact lens suppliers to meet a higher standard than that reserved for pharmacies dispensing drugs which if incorrectly filled can cause immediate injury or death is patently absurd

The impact of complying with the term direct communication as presently defined on small businesses would be enormous. I anticipate a doubling of costs associated with this provision through time spent verifying with no benefit to the consumer whatsoever. Markup on contact lenses is already extremely low and this will drive many smaller companies out of business altogether. Costs will rise due to the smaller companies inability to compete and continuing industry consolidation, i.e. Drugstore.com’s recent purchase of Vision Direct. Consumers will have less choice and the industry will be dominated by two or three large mail order and internet companies and the largest retailers like WalMart, Sam’s Club, Costco and BJ’s who currently sell the most popular lenses below the best wholesale price available to small companies. I challenge anyone to find any documented cases where lenses as currently sold have caused harm to anyone because of the lenses the consumer has received. Injuries to consumers are almost always the result of incorrect hygienic practices by the consumer and nothing in this Act can or will prevent this from happening. At the very least small businesses should be exempt from verifying prescriptions unless there is an obvious problem with the prescription as presented.

Direct Communication should not expressly require for communication by email or facsimile the receipt of a confirmation the communication was successful as there is presently no way to do such verification.

Question 8 – Definition of “issue date”: The term issue date as presently described is not sufficiently clear. The term should be defined to specify the actual date the prescription was written and not allow either pre or postdating. Federal Law should take precedence over State law in this regard. The benefit to consumers will be to have the prescription valid as long as possible to prevent the unnecessary expense of more frequent office visits than is medically necessary.

Question 16 – Section 315 (a) Circumstances under which contact lens sellers may sell contact lenses to a patient: This provision is not sufficiently clear. This provision should be further clarified to include the ability of the patient or someone designated by the patient to provide an original, copy or fax of the patient's contact lens prescription to the person or company filling the prescription and should not require the person or company filling the prescription to have to additionally verify that prescription in any other way with the prescriber. Pharmacies may fill drug prescriptions with only a written prescription without having to call the prescriber to verify the prescription. Further if a doctor or employee of the doctor's office calls in a prescription to the pharmacy that pharmacy does not need to have a written prescription at all, this option should extend to sellers of contact lenses. Only if the prescription is not sufficiently clear does the pharmacy need to call the prescriber and then it is entirely at the discretion of the pharmacy.

There are no additional requirements the Commission should consider requiring as any additional requirements would add additional costs upon all involved without any justifiable benefits.

Question 22 – Minimum contact lens prescription expiration date: This provision is not sufficiently clear. For the purposes of the Act Federal law should take precedence over the various State laws which specify the minimum expiration date for contact lens prescriptions especially for prescriptions presented to out of state contact lens sellers. In addition any law relating to contact lens prescriptions should specify a minimum contact lens prescription expiration date of two years from the date the prescription was actually written, not from when the “fitting” was completed as this term is also not sufficiently clear.

The reasons for a two year expiration are:

1. All the major HMO's (including Cigna, Healthsouth and Blue Cross) pay only for an eye examination every two years. These HMO's have decided, no doubt after extensive research and experience that a yearly examination is not only a waste of their resources,

but is totally unnecessary as there is unlikely to be any change in prescription over a two year period.

2. Often there is pressure for the patient to purchase lenses from the prescribing doctor as well as manufacturer incentives such as rebates for the purchase of a years supply. Taken together these form a powerful inducement for the patient to purchase lenses from the doctor and by the time the lenses are used the original prescription will have expired, the patient will be forced to see the doctor and be subject to the same pressures.

The costs of defining “contact lens prescription” in Section 315.6(a) as stated are more than double what is medically necessary. Requiring an examination and prescription expiration every two years instead of one will save the consumer 50% of the cost of the examinations as well as saving up to 70% on the cost of obtaining lenses from an alternate supplier. The costs of defining “contact lens prescription” as stated in Section 315.6(a) will stifle consumer choice in the purchasing of lenses and prevent the savings from competition and the resulting lower prices the Act seeks to implement.

Respectfully submitted,
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