

Federal Trade Commission (FTC) Contact Lens Rule Update **For Prescribers**

Topic / Issue	Our Stance	Actual 2020 Final Rule Outcome	Action Required For Prescribers	
Manufacturer inclusion on contact lens prescription (Rx)	Johnson & Johnson Vision Care, Inc. (JJV) urged FTC to preserve manufacturer / brand as part of Rx	Manufacturer / brand retained as key element of Rx	✓ No change from original Contact Lens (CL) Rule	
Prescription expiration	JJV reiterated importance of 1 year Rx minimum	Kept the current 1 year Rx expiration	✓ No change from original CL Rule ✓ Consult your state board laws	
Confirmation of prescription release (e.g. Signed acknowledgement)	JJV is a top level member of Health Care Alliance for Patient Safety (APS) which urged FTC to implement a less intrusive means to educate consumers (e.g. signage) of their rights to freely receive their prescriptions.	Pulled back on initial proposal that was more onerous—instead adding flexibility to required methods for obtaining confirmation of Rx release (e.g. digital portability) Note: Following the FTC CL Rule announcement on June 23, APS asked Congress to delay implementation of new rule requirements including signed acknowledgment	Do nothing	Prescribers who do not have a direct or indirect financial interest in the sale of contact lenses are exempt from new prescription release requirement
			Need to implement	Prescribers who have financial interest in sale of contact lenses have several options to implement new requirement
			Other notable items	If patient refuses to sign a confirmation, prescribers must document and retain on file
				Must provide additional copy of CL Rx to patient or designated agent within 40 business hours of request

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This is not intended to constitute legal advice. Consult your attorney to ensure compliance with applicable laws, regulations, and other considerations.

Confirmation of Prescription Release (e.g. Signed Acknowledgment)

Prescribers who have financial interest in sale of contact lenses have several options to implement new requirement

Hard Copy



- ✓ A patient signs separate confirmation statement or prescriber retained copy of CL Rx or sales receipt containing confirmation statement
- ✓ Must keep signed confirmation statement on file for 3 years

Sample Confirmation Statement

My eye doctor provided me with a copy of my contact lens prescription at the completion of my contact lens fitting

[Patient signature]

or

Digital Copy



- ✓ Provide digital copy and retain evidence it was sent, received, made accessible, downloadable, or printable
- ✓ Must obtain patient consent for providing digital copy and indicate method of electronic delivery
- ✓ May obtain e-signature (ESIGN compliant)
- ✓ Must keep digital consent on file for 3 years

Sample Digital Consent

I authorize my eye doctor to provide me with a digital copy of my contact lens prescription by [insert method email, text, online portal, etc.] at the completion of my contact lens fitting

[Patient signature or e-signature]

FTC Contact Lens Rule Update **For Sellers**

Topic / Issue	Our Stance	Actual 2020 Final Rule Outcome	Action Required For Sellers
<p>Prescription alteration</p> <p>“Private label” lenses (Marketed under different names but same lens)</p>	<p>Johnson & Johnson Vision Care, Inc. (JJV) urged FTC to reinforce that Rx alteration remains illegal and preserve private label distinction</p>	<p>Explicitly stated altering manufacturer / brand is illegal</p> <p>Substitution is only permitted when contact lenses are made by same manufacturer, under same conditions</p>	<ul style="list-style-type: none"> ✓ A seller may not alter a contact lens prescription including manufacturer/ brand. ✓ For private label contact lenses, a seller may substitute a contact lens prescription (Rx) <u>only when identical</u> contact lenses are made by same manufacturer that is recorded on Rx and are marketed under different brand names
<p>Prescription verification / automated “robocalls”</p>	<p>JJV urged FTC to ban robocalls, and if not, add more requirements to how these calls must be made</p> <p>Note: JJV continues its advocacy efforts on H.R. 3975 which would prohibit sellers from using robocalls to verify CL Rx.</p>	<p>Requires automated calls to be clear & comprehensible, option to repeat, provide ‘paper trail’ by maintaining call on file for 3 years</p>	<ul style="list-style-type: none"> ✓ Sellers must record entire call and preserve complete recording ✓ Start call by identifying it is a prescription verification request in accordance with CL Rule ✓ Deliver message in slow deliberate manner and at volume prescriber can understand ✓ Make message repeatable at the prescriber’s option ✓ Must maintain recording on file for 3 years
<p>Prescription Presentation</p>	<p>JJV supported FTC for adding this requirement, which promotes a clear prescription “paper trail”, reduce sellers’ reliance on the passive verification process, and contributes to more error-free prescription fulfillment</p>	<p>Requires mechanism for patients to directly upload and share their prescriptions</p>	<ul style="list-style-type: none"> ✓ Sellers must make prominently available a way for consumers to present their prescriptions, and must clearly disclose that method ✓ The method of presentation (e-mail, text message, file upload, etc.) and related disclosure must be provided before requesting the prescriber’s contact information to verify the prescription