# THE EVOLUTION OF THE CONTACT LENS RULE AND TODAY'S CHALLENGES

The Federal Trade Commission (FTC) implemented the Fairness to Contact Lens Consumers Act (FCLCA) of 2003 as the Contact Lens Rule ("the Rule")—imposing requirements on contact lens prescribers and sellers to improve consumers' access to their lenses and ensure they receive those prescribed by their doctor, and promote patient eye health and safety.

## 2004

### Contact Lens Rule Implementation

**Prescription verification:** sellers must verify a patient's prescription with a provider if a copy of the prescription is not directly provided to them [including via fax, telephone, or email].

**Prescription release:** prescribers must provide a patient with a copy of their prescription.

**Prescription alteration:** sellers may not alter a prescription except in cases when substituting for their own "private label" lenses—those made by the same manufacturer, but sold under a different name.

**Prescription expiration:** contact lens prescriptions expire on the date specified by state law, as specified by the doctor, or at least one year after prescription is issued.

## 2016

### Proposed Update to the Rule

**Prescription release:** proposed to require that prescribers obtain copy of a patient's signed acknowledgement of prescription release to ensure they understand their prescription is portable.

**Prescription alteration:** proposed to remove the term "private label" from the Rule to ensure it is clear to sellers when permissible to substitute for their own private label lenses.

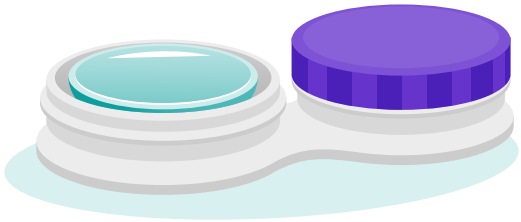
## 2019

### Supplemental Proposed Update to the Rule

**Prescription verification:** acknowledges some of the issues that robocalls present—but does not ban them as a permissible form of direct communication via telephone to verify patient prescriptions.

**Prescription release:** modifies its previous proposal allowing for greater flexibility around how a prescriber may obtain confirmation of prescription release, including through digital means.

**Prescription alteration:** expands the definition of prescription alteration to explicitly include instances where a seller provides a brand/manufacturer of lenses other than those prescribed; requires that sellers provide patients with a means to present them with their prescriptions.



## 2015

### 10 Year Review of the Rule and Public Feedback

**Challenges in the prescription verification process:** many stakeholders commented that loopholes in the prescription verification process compromise patients' access to their prescribed lenses.

- **Robocalls:** sellers' use of automated "robocalls" or recorded messages left for a provider's office for purposes of prescription verification that may be garbled or incomplete.
- **Prescription alteration:** sellers dispense lenses to patients other than those prescribed to them, which could potentially impact a patient's eye health and safety.

## 2018

### FTC Public Workshop

FTC holds public workshop examining Contact Lens Rule/marketplace and welcomes written comments. Many continued to express persistent issues with loopholes in the prescription verification process such as **robocalls and prescription alteration,** which FTC did not address in 2016.

## Looking Ahead: Opportunities to Promote Patient Health and Safety

There are still opportunities to improve the prescription verification process and better promote patient health and safety.

**Robocalls:** FTC indicated it believes robocalls fall within the definition of direct communication via telephone, consistent with the FCLCA. FTC proposed additional requirements for robocalls, but they will likely continue to present challenges to providers and compromise patients' access to their prescribed lenses.

Johnson & Johnson Vision Care Inc., will continue to work closely with the Federal Trade Commission (FTC) during its review of the Contact Lens Rule. We support a regulatory framework that prioritizes patient safety and eye health, and we remain committed to continuing to work with the eye care community, policymakers, and regulators to ensure patients' evolving needs are met today, and in the future.