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Contact Lens Policy

The following items are insurance and governmentally mandated forms, as well as, industry and practice guidelines that **directly** affect you as a patient and a consumer. These items are important, PLEASE READ THEM THOROUGHLY. By signing below, you provide consent to all forms, as illustrated below and acknowledge receipt of the patient information package. You may revoke any or all of this consent at any time, unless we have relied upon your consent, but it must be in writing. If you have questions please do not hesitate to ask the doctor or the staff.

1. The “Fairness to Contact Lens Act” – “signature on file”
2. Informed Consent – “signature on file”
3. Guidelines for Contact Lenses and Contact Lens Wear – “signature on file”
4. Cornea and contact lens evaluation – “signature on file”
 - a. Definition
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 - a. Contents
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 - e. Contact Lens Progress Evaluation

WHILE WEARING CONTACT LENSES: NO SLEEPING, NO SWIMMING, NO SHOWERS, AND NO TANNING BEDS.

REMOVE YOUR CONTACT LENSES IMMEDIATELY AND CALL US IF: 1) YOU DEVELOP UNUSUAL REDNESS OR PAIN 2) YOU EXPERIENCE AN UNUSUAL DECREASE IN VISION 3) YOU SUSPECT SOMETHING WRONG.

Signed _____ Date _____

1. The “Fairness to Contact Lens Consumers Act”

2. Informed Consent

a. Contact lenses are medical devices that are designed to fit on the anterior surface of the eye (or cornea) and correct (not cure) refractive conditions such as nearsightedness, farsightedness, astigmatism and presbyopia, as well as, ocular pathology.

b. Contact lenses can cause significant vision loss and blindness. Inappropriate treatment of contact lenses increases and enhances the risks of contact lenses causing significant vision loss and blindness. Infectious and non-infectious contact lens complications can be painful, create the necessity for permanent discontinuance of contact lens wear, reduce visual acuity and cause permanent corneal damage resulting in permanent vision loss and blindness.

3. Guidelines for Contact Lens and Contact Lens Wear

a. Guidelines for appropriate use of contact lenses:

- i. Daily wear of contact lenses with appropriate replacement schedule.
- ii. Limiting the wear of the contact lenses while monitoring for any changes in the quality of the contact lenses in the way the contact lenses fit the eye, and/or comfort or any ocular tissue or the contact lenses, and/or any alteration of the vision of the contact lenses.
- iii. Limiting the wear of contact lenses while monitoring for any changes in the ocular health of the patient’s eyes and systemic health of the patient.
- iv. Only using FDA approved contact lenses, contact lens cleaning and disinfection supplies, and contact lens care and handling procedures.
- v. While wearing the contact lenses, no sleeping, no swimming, no showers and no tanning beds. Remove immediately your contact lenses and callus if:
 - (a) you develop unusual redness or pain.
 - (b) you experience an unusual decrease in vision.
 - (c) you suspect something wrong.

b. Guidelines for inappropriate use of contact lenses:

- i. Extended wear or sleeping in contact lenses.
- ii. Contact lens wear in while performing high risk activities such as:
 - (a) any work related activity (i.e. occupational hazards such as exposure to Chemicals, dust, dirt, hazardous compounds, wearing contact lenses in violation or regulations, rules or policies (governmental or private), wearing contact lenses in situations where contact lenses are, would be or should be contraindicated,
 - (b) any water-related activity that would allow the contact lens to come in Contact with water (i.e. showers, swimming, spas, tap water, any other non-sterilized water),
 - (c) any recreational activities that could lead to damage to the eye or surrounding tissues.

(d) any activity that could lead to inflammation, swelling or edema of the eye or surrounding tissues (i.e. tanning beds, welding, direct sunlight or any other activity that could cause the eye to inflame, swell or promote edema).

CONTACT LENSES DO NOT PROTECT AGAINST DAMAGE TO THE EYES OR SURROUNDING TISSUES. CONTACT LENSES ARE NOT PROPER SUBSTITUTES FOR PROPER EYEWEAR. APPROPRIATE PROTECTIVE EYEWEAR MUST BE UTILIZED FOR PROTECTION.

- c. Guidelines for ocular and systemic complications.
 - i. Any illness (systemic or ocular) such as bacterial, viral, fungal, or parasitic infections will increase and enhance the risks associated with contact lenses and contact lens wear. Contact lens must not be worn.
 - ii. Contact lens wear must be discontinued after the patient perceives that there is a problem with the eye or the contact lenses.
 - iii. Certain medications (ocular or systemic) can increase or enhance the risks associated with contact lenses and contact lens wear. Please discuss any medication use with the eye doctor.
 - iv. Physical changes within the body or to the eye or ocular surfaces will increase or enhance the risks associated with contact lenses and contact lens wear.
 - v. Numerous ocular conditions (ocular surface, ocular adnexa, and surrounding tissues) such as decreased ocular lubrication (dry eye), lid malformations, blinking problems, anterior segment pathologies (ocular allergies such as Giant Papillary Conjunctivitis) and corneal pathologies (anterior and posterior basement membrane diseases) can increase or enhance the risks associated with contact lenses and contact lens wear.

- d. Guidelines for insertion and removal of contact lenses.
 - i. Insertion and removal of the contact lens increases and enhances the risk associated with contact lens and contact lens wear.
 - ii. Proper insertion and removal of contact lenses limit's the risks associated with contact lenses and contact lens wear.
 - iii. Patients are instructed in proper insertion and removal procedures, as well as, sanitary procedures. A level of efficiency in contact lens procedures must be obtained before a patient may leave the office with diagnostic lens.
 - iv. Proper care and/or handling of contact lenses limit's the risks associated with contact lens and contact lens wear.
 - v. Always utilize sanitary procedures during the insertion and removal of contact lenses (such as hand washing and FDA approved contact lens solutions).

- e. Guidelines for cleaning and disinfection procedures.
 - i. The use of contact lenses enhances the risk of ocular infection. Numerous studies have found pathological bacteria, viruses fungus and parasites around the eyes, in the eyes, on contact lenses, in contact lens solutions, and contact lens cases.
 - ii. It is important to utilize proper procedures for hand washing, cleaning of area the eyes and eyelids/eyelashes, cleaning of contact lenses and cleaning of

- contact lens cases.
- iii. Only FDA approved contact lens solutions that are labeled for must be used to clean or disinfect the contact lenses. Contact lens cases should be cleaned and exchanged when necessary.
 - iv. Contact lens wear must be discontinued after the patient perceives that there is a problem with the eye or the contact lenses.
 - (a) redness of the eye or the surrounding tissues.
 - (b) pain, irritation or discomfort of the eye or the surrounding tissues.
 - (c) reduced vision in any manner including blurry vision, altered vision, hazy vision or poor vision.
 - v. If the contact lens becomes contaminated, the solutions become contaminated or if the patient suspects that the contact lens or solutions have become contaminated, throw away the contact lenses and solutions immediately.
- f. Guidelines for minor contact lens wearers.
- i. Minors may not elect contact lens wear without the approval of a parent or legal guardian in recognition of the risks associated with contact lens wear.
 - ii. Both the parent or legal guardian and the minor will understand the risks associated, as indicated in these guidelines, with contact lens and contact lens wear before they approve of the minor contact lens wear.
 - iii. The parent or legal guardian, if contact lens wear is approved for the minor will support the minor in the care and handling of the contact lenses.
 - iv. Minor will understand how to handle and care for the contact lenses on their own abilities after the parent or legal guardian has agreed to support and give approval for contact lens wear.
 - v. Minor will show competence with the contact lenses before they will be able to leave the office with the contact lenses.
- g. Guidelines for contact lens evaluations, progress evaluations, and release of patient.
- i. Numerous procedures are utilized to determine the appropriate type contact lens, mode of contact lens wear, appropriate schedule of contact lens wear, and care regimen.
 - ii. Certain types of contact lens and contact lens wear can produce difficulty with vision, problems with depth perception, problems with focusing and they may require a period of time for adjustment before wearing them for daily activities. Examples include:
 - (a) toric contact lenses may rotate causing blurry vision.
 - (b) bifocal contact lenses may cause difficulty in distance vision.
 - (c) mono-vision contact lenses may cause difficulty in distance vision.
 - (d) rigid gas permeable contact lenses may cause sensitivity to light, as well as, a foreign body sensation, causing difficulty in distance vision.
 - iii. If the patient feels that the contact lenses need any further adjustment, or enhancement, or the contact lens does not feel comfortable, the patient is instructed to remove the contact lens immediately and contact the office for assistance. All contact lens patients must have a back up pair of eyewear suitable for vision purposes available to them.
 - iv. All contact lens patients have a one week progress evaluation designed to

- answer any additional questions, evaluate any patient concerns or complaints.
- v. If the patient is ready to be discharged, the contact lens patient is released.
- h. Guidelines for Contact Lens Emergencies.
- i. Contact lens wear increases the risk of corneal injury. Contact lens can create contact lens emergencies resulting in pain, corneal damage and vision loss, as well as, blindness.
 - ii. Any departure from practice guidelines, industry standards, and governmental regulations will increase the risks associated with contact lens wear and create a contact lens emergency.
 - iii. During business hours, the patient is to remove the contact lens immediately in a contact lens emergency and contact the office immediately. Proceed to the office immediately.
 - iv. During non-business hours, the patient is to remove the contact lens immediately in a contact lens emergency and contact the office immediately leaving a message for the office. Proceed to a local emergency room for treatment and referral to our office.
 - v. All Contact lens emergencies are seen immediately.

THE ABOVE GUIDELINES FOR CONTACT LENSES AND CONTACT LENS WEAR ARE GUIDELINES ONLY FOR THE PATIENT'S USE OF CONTACT LENSES. IF YOU HAVE ANY QUESTIONS CONCERNING ANY ASPECT OF CONTACT LENS AND/OR CONTACT LENS WEAR AND/OR THE CORNEAL EVALUATION, THE APPROPRIATE USE OF CONTACT LENSES, OR THE CARE AND/OR HANDLING OF CONTACT LENSES. AT ANY TIME, THE PATIENT MAY, AT THEIR OPTION, DISCONTINUE THE CORNEAL AND CONTACT LENS EVALUATION AND/OR CONTACT LENS WEAR. PLEASE ASK THE DOCTOR OR THE STAFF.

4. Corneal and contact lens evaluation.
- a. Definition- contact lenses are medical devices that are placed on the anterior surface of the cornea. The following information may be utilized by your eyecare professional to evaluate and determine the vision and eye health aspects of the contact lenses, as well as, corneal tissue.
 - b. Contents
 - i. biomicroscopic evaluation of the eyelids, conjunctiva, cornea and dynamics of the blink
 - ii. tear flow evaluation for quality, quantity, punctal function and surface irregularities
 - iii. tear quality evaluation for the three layers (i.e. oil, water, mucin)
 - iv. corneal integrity evaluation for epithelial and endothelial defects, limbal vessel encroachment, eyelid position and corneal sensitivity
 - v. corneal curvature evaluation for measurement, shape and toricity
 - vi. eyelid evaluation for eyelid position, edge characteristics, aperture size and eyelash complications.
 - vii. medical condition evaluation for ocular versus systemic prescription

medications concerning type, amount and time, as well as, affect on ocular tissue and contact lenses.

- viii. medical condition evaluation for ocular versus systemic over-the-counter medications concerning type, amount and time, as well as, affect on ocular tissue and contact lenses.
- ix. allergy evaluation for type, severity, location and utilization of ocular and systemic prescription and over-the-counter medications.
- x. needs analysis: vision, ranges, occupation, sports and recreation activities

5. All contact lens prescriptions will be release after the cornea and contact lens Evaluation.

- a. Contents – per the “Fairness to Contact Lens Consumers Act” the contact lens prescription will contain the following information:
 - i. name of patient
 - ii. date of examination
 - iii. issue date and expiration date of prescription
 - iv. name, postal address, telephone number and facsimile telephone number of prescriber
 - v. power, material or manufacturer or both
 - vi. base curve or appropriate designation
 - vii. diameter when appropriate
 - viii. in the case of a private label contact lens, name of manufacturer, trade name of private label brand and if applicable trade name of equivalent brand name
- b. Expiration – All contact lens prescriptions expire in one year unless the following:
- c. “Medical necessity” expiration – under the special rules section a prescription may be less than one year if, under medical judgment, it is determined that the ocular health of the patient is at risk.

6. Contact lens office policies – all patients will be advised of their contact lenses options.

- a. Types – numerous types of contact lenses are available.
 - i. category 1 – spherical contact lenses, clear or opaque
 - ii. category 2 – toric contact lenses (soft annual and planned replacement), bifocal (soft annual or planned replacement)
 - iii. category 3 – rigid gas permeable, custom toric (soft and rgp), “medically necessary” contact lenses.
- b. Mode – all contact lens prescriptions are for daily wear contact lenses (i.e. removed every night) with the appropriate replacement schedule.
- c. Replacement Schedule – various replacement schedules may be utilized including daily, two weeks, monthly, quarterly and annual replacement.
- d. Care and Handling – all patients are instructed in the proper care and wear of

contact lenses.

- i. Contact Lens Care and Handling Form – includes care system, wearing schedule, replacement schedule, and notices.
- e. Contact lens progress evaluations – all patients have a one week follow-up evaluation.

SECTION 1. SHORT TITLE.

This Act may be cited as the ‘Fairness t Contact Lens Consumers Act’.

SEC. 2. AVAILABILITY OF CONTACT LENS PRESCRIPTIONS TO PATIENTS.

(a) IN GENERAL – When a prescriber completes a contact lens fitting, the prescriber—

- (1) whether or not requested by the patient, shall provide to the patient a copy of the contact lens prescription; and
- (2) shall, as directed by any person designated to act on behalf of the patient, provide or verify the contact lens prescription by electronic or means.

(b) LIMITATIONS – A prescriber may not—

- (1) require purchase of contact lenses from the prescriber or from another person as a condition of providing a copy of a prescription under subsection (a)(1) or (a)(2) or verification of a prescription under subsection (a)(2);
- (2) require payment in addition to, or as part of, the fee for an eye examination, fitting, and evaluation as a condition of providing a copy of prescription under subsection (a)(1) or (a)(2) or verification of a prescription under subsection (a)(2); or
- (3) require the patient to sign a waiver or release as a condition of verifying or releasing a prescription.

SEC. 3 IMMEDIATE PAYMENT OF FEES IN LIMITED CIRCUMSTANCES.

A prescriber may require payment of fees for an eye examination, fitting, and evaluation before the release of a contact lens prescription, but only if the prescriber requires immediate payment in the case of an examination that reveals no requirement for ophthalmic goods. For purposes of the preceding sentence, presentation, of proof of insurance coverage for that service shall be deemed to be a payment.

SEC. 4 PRESCRIBER VERIFICATION.

(a) PRESCRIPTION REQUIREMENT - A seller may sell contact lenses only in accordance with a contact lens prescription for the patient that is—

- (1) presented to the seller by the patient or prescriber directly or by facsimile; or
- (2) verified by direct communication.

(b) RECORD REQUIREMENT – A seller shall maintain a record of all direct communications referred to in subsection (a).

(c) INFORMATION – When seeking verification of a contact lens prescription, a seller shall provide the prescriber with the following information:

- (1) Patient's full name and address.
 - (2) Contact lens power, manufacturer, base curve or appropriate designation, and diameter when appropriate.
 - (3) Quantity of lenses ordered.
 - (4) Date of patient request
 - (5) Date and time of verification request.
 - (6) Name of contact person at seller's company, including facsimile and telephone number.
- (d) VERIFICATION EVENTS – A prescription is verified under this Act only if one of the following occurs:
- (1) The prescriber confirms the prescription is accurate by direct communication with the seller.
 - (2) The prescriber informs the seller that the prescription is inaccurate and provides the accurate prescription.
 - (3) The prescriber fails to communicate with the seller within 8 business hours, or a similar time as defined by the Federal Trade Commission, after receiving from the seller the information described in subsection (c).
- (e) INVALID PRESCRIPTION – If a prescriber informs a seller before the deadline under subsection (d)(3) that the contact lens prescription is inaccurate, expired, or otherwise invalid, the seller shall not fill the prescription. The prescriber shall specify the basis for the inaccuracy or invalidity of the prescription. If the prescription communicated by the seller to the prescriber is inaccurate, the prescriber shall correct it.
- (f) NO ALTERATION – A seller may not alter a contact lens prescription. Notwithstanding the preceding sentence, if the same contact lens is manufactured by the same company and sold under multiple labels to individual providers, the seller may fill the prescription with a contact lens manufactured by that company under another label.
- (g) DIRECT COMMUNICATION – As used in this section, the term 'direct communication' includes communication by telephone, facsimile, or electronic mail.

SEC. 5 EXPIRATION OF CONTACT LENS PRESCRIPTIONS.

- (a) IN GENERAL - A contact lens prescription shall expire—
- (1) on the date specified by the law of the State in which the prescription was written, if that date is one year or more after the issue date of the prescription;
 - (2) not less than one year after the issue date of the prescription if such State law specifies no date or a date that is less than one year after the issue date of the prescription; or
 - (3) notwithstanding paragraphs (1) and (2), on the date specified by the Prescriber, if that date is based on the medical judgment of the prescriber With respect to the ocular health of the patient.
- (b) Special Rules for Prescriptions of Less Than 1 Year – If a prescription expires in less than 1 year, the reasons for the judgment referred to in subsection (a)(3) shall be documented in the patient's medical record. In no

circumstance shall the prescription expiration date be less than the period of time recommended by the prescriber for a reexamination of the patient that is medically necessary.

(c) DEFINITION – As used in this section, the term ‘issue date’ means the date on which the patient receives a copy of the prescription.

SEC. 6. CONTENT OF ADVERTISEMENTS AND OTHER REPRESENTATIONS.

Any person that engages in the manufacture, processing, assembly, sale, offering for sale, or distribution of contact lenses may not represent, by advertisement, sales presentation, or otherwise, that contact lenses may be obtained without a prescription.

SEC. 7. PROHIBITION OF CERTAIN WAIVERS.

A prescriber may not place on the prescription, or require the patient to sign, or deliver to the patient a form or notice waiving or disclaiming the liability or responsibility of the prescriber for the accuracy of the eye examination. The preceding sentence does not impose liability on a prescriber for the ophthalmic goods and serviced dispensed by another seller pursuant to the prescriber’s correctly verified prescription.

SEC. 8. RULEMAKING BY FEDERAL TRADE COMMISSION.

The Federal Trade Commission shall prescribe rules pursuant to section 18 of the Federal Trade Commission Act (15 U.S.C. 57a) to carry out this Act. Rules so prescribed shall be exempt from the requirements of the Magnuson-Moss Warranty--Federal Trade Commission Improvement Act (15 U.S.C. 2301 et seq.). Any such regulations shall be issued in accordance with section 553 of title 5, United States Code. The first rules under this section shall take effect not later than 180 days after the effective date of this Act.

SEC. 9. VIOLATIONS.

(a) IN GENERAL - Any violation of this Act or the rules required under section 8 shall be treated as a violation of a rule under section 18 of the Federal Trade Commission Act (15 U.S.C. 57a) regarding unfair or deceptive acts or practices.

(b) ACTIONS BY THE COMMISSION – The Federal Trade Commission shall enforce this Act in the same manner, by the same means, and with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) were incorporated into and made a part of this Act.

SEC 10. STUDY AND REPORT.

(a) **STUDY** – The Federal Trade Commission shall undertake a study to examine the strength of competition in the sale of prescription contact lenses.

The study shall include an examination of the following issues:

(1) Incidence of exclusive relationships between prescribers or sellers and contact lens manufacturers and the impact of such relationships on competition.

(2) Difference between online and offline sellers of contact lenses, including price, access, and availability.

(3) Incidence, if any, of contact lens prescriptions that specify brand name or custom labeled contact lenses, the reason for the incidence, and the effect on consumers and competition.

(4) The impact of the Federal Trade Commission eyeglasses rule (16 CFR 456 et seq.) on competition, the nature of the enforcement of the rule, and how such enforcement has impacted competition.

(5) Any other issue that has an impact on competition in the sale of prescription contact lenses.

(b) **REPORT** – Not later than 12 months after the effective date of this Act, the Chairman of the Federal Trade Commission shall submit to the Congress a report of the study required by subsection (a).

SEC 11. DEFINITIONS.

As used in this Act:

(1) **CONTACT LENS FITTING** – The term ‘contact lens fitting’ means the process that begins after the initial eye examination and ends when a successful fit has been achieved or, in the case of a renewal prescription, ends when the prescriber determines that no change in prescription is required, and such term may include--

(A) an examination to determine lens specifications;

(B) except in the case of a renewal of a prescription, an initial evaluation of the fit of the lens on the eye; and

(C) medically necessary follow up examinations.

(2) **PRESCRIBER** – The term ‘prescriber’ means, with respect to contact lens prescriptions, an ophthalmologist, optometrist, or other person permitted under State law to issue prescriptions for contact lenses in compliance with any applicable requirements established by the Food and Drug Administration.

(3) **CONTACT LENS PRESCRIPTION** – The term ‘contact lens prescription’ means a prescription, issued in accordance with State and Federal law, that contains sufficient information for the complete and accurate filling of a prescription, including the following:

(A) Name of the patient.

(B) Date of examination.

(C) Issue date and expiration date of prescription.

- (D) Name, postal address, telephone number, and facsimile telephone number of prescriber.
- (E) Power, material or manufacturer or both.
- (F) Base curve or appropriate designation.
- (G) Diameter, when appropriate.
- (H) In the case of a private label brand, and if applicable, trade name of equivalent brand name.

SEC 12. EFFECTIVE DATE.

This Act shall take effect 60 days after the date of the enactment of this Act.