

LEGISLATOR Talking Points



SB 853: Eye Care Consumer Protection Act

Sponsor: Senator Rick Jones (R-Grand Ledge)



BACKGROUND:

SB 853 will amend 1978 PA 368 and create **Part 55A**, a new part of the Public Health Code, under Article 5, named Eyecare Consumer Protection Act. Part 55A would be one of a group of laws within the Public Health Code that are aimed at the "Prevention and Control of Diseases, Infections, and Disabilities." For example, Article 5 includes laws that address topics such as lead abatement and toxic substances in children's toys. **The rationale for the creation of the "Eye Care Consumer Protection Act" under Article 5 is because the law is intended to protect against injuries the public may sustain when they buy spectacles (glasses) or contact lenses without a prescription and without oversight of their medical eye care by their healthcare provider.**

WHY THE EYE CARE CONSUMER PROTECTION ACT IS IMPORTANT TO THE PUBLIC?

- ✓ The Public Health Code does not define what constitutes a prescription for glasses or contact lenses, or subject such prescriptions to appropriate regulation under Michigan law. There are federal laws that establish that prescription glasses and all contact lenses are medical devices, but those federal laws alone, and without supplemental state law, do not result in effective enforcement by state and local enforcement agencies to protect the public. While it is clear ophthalmologists (MDs and DOs licensed under Parts 170 and 175) and optometrists (ODs licensed under Part 174) can prescribe glasses and contact lenses, it is not clear that only these trained and licensed professionals can do so. Michigan law does not state that a prescription is required for the dispensing (sale) of contact lenses, including plano or cosmetic contact lenses, and glasses that correct vision. Nor does Michigan law define what constitutes a proper prescription for glasses and contact lenses to guide prescribers and dispensers (sellers); ensuring that prescriptions are dispensed as ordered for each individual patient.
- ✓ Each year ODs, MDs, and DOs specializing in the care of the eye see injuries in their patients attributable to the wearing of glasses and contact lenses dispensed in retail settings without the oversight of their medical eye care by ophthalmologists or optometrists. For instance, cosmetic contact lenses are often sold in costume shops in the weeks preceding Halloween without a prescription. Contact lenses that change eye color are also sometimes sold in retail stores. These lenses often have not been prescribed or fitted by professionals and wearing them may cause allergic reactions, corneal abrasions, infections, decreased vision, and even blindness.
- ✓ Similarly, there are retail stores that sell glasses with lenses that can adjust the level of vision correction, but are sold without a prescription. However, glasses or contact lenses that are not prescribed by licensed professionals can be inaccurate even if they are adjustable, negatively affecting visual perception. For example, individuals who drive or perform high-risk jobs wearing glasses or contact lenses dispensed with an inaccurate or expired prescription can pose a significant risk of injury to the wearer and others. In another example, a patient wearing glasses or contact lenses dispensed with an inaccurate or expired prescription may incorrectly read the dose or dosing schedule on a prescription bottle; subjecting them to possible serious injury. If the "kiosk exam" is to adhere to good public health principles, it will need to add a photo screener (strab), puff tonometry (glaucoma), an optic nerve head analyzer and a retinal camera with an accurate computer interpretation. Even with this added technology, a medical eye care professional must interpret the data to treat the patient.
- ✓ Without state law making it clear that a prescription is required to dispense contact lenses or glasses, and without state law clearly defining a proper prescription, the Department of Licensing And Regulatory Affairs (DLARA) has limited power to protect the public from injuries. By defining and regulating prescriptions for glasses and contact lenses DLARA will be able to take action against sales made without a prescription in order to protect the health and safety of state residents.
- ✓ The Federal Food, Drug, and Cosmetic Act (FDCA) treats all contact lenses as medical devices, including non-corrective or cosmetic contact lenses. The Food and Drug Administration (FDA) requires a prescription to dispense and use all contact lenses. The FDCA does not define what constitutes a prescription for contact lenses or glasses and the FDA has not promulgated a rule on the issue. **Rather, the FDA expressly decided to leave the issue to state law.** While the FDA does not have a definition for either prescription, the Federal Fairness To Contact Lens Consumers Act does provide a basic definition of a contact lens prescription in U.S.C.A. Title 15, Chapter 102 §7610(C) (available upon request); however this law also says that a contact lens prescription must include any additional information as may be required by State's law. The Federal Ophthalmic Practice Rules also defines eyeglasses prescriptions by deferring entirely to state law: C.F.R. Title 16, Part 456, 4561 (g) "A prescription is the written specifications for lenses for eyeglasses which are derived from an eye examination, including all of the information specified by state law, if any, necessary to obtain lenses for eyeglasses."

The Eye Care Consumer Protection Act includes these six important components that represent today's medical standard of eye care and will ensure the health and vision of the public is protected in our state:

1. A specific state definition of a valid prescription for contact lenses.
2. A specific state definition of a valid prescription for spectacles.
3. The affirmative requirement that all contact lenses and spectacles dispensed, given, or sold in Michigan may only occur with a valid prescription.
4. The prohibition against dispensing, giving, or selling contact lenses and spectacles without a valid prescription.
5. The prohibition against anyone other than an OD, MD or DO specializing in eye care who have the appropriate education, training and instrumentation to examine and diagnose diseases or conditions of the eye from writing a valid prescription.
6. The prohibition against a valid prescription relying only on data produced by an auto refractor or similar device.

U.S.C.A. Title 15, Chapter 102 §7610(C)

✓The Federal Food, Drug, and Cosmetic Act (FDCA) treats all contact lenses as medical devices, including non-corrective or cosmetic contact lenses. The Food and Drug Administration (FDA) requires a prescription to dispense and use all contact lenses. The FDCA does not define what constitutes a prescription for contact lenses or glasses and the FDA has not promulgated a rule on the issue. **Rather, the FDA expressly decided to leave the issue to state law.** While the FDA does not have a definition for either prescription, the Federal Fairness To Contact Lens Consumers Act does provide a basic definition of a contact lens prescription in U.S.C.A. Title 15, Chapter 102 §7610(C) (**available upon request**); however this law also says that a contact lens prescription must include any additional information as may be required by State's law. The Federal Ophthalmic Practice Rules defines eyeglasses prescriptions by deferring entirely to state law: C.F.R. Title 16, Part 456, 4561 (g) "*A prescription is the written specifications for lenses for eyeglasses which are derived from an eye examination, including all of the information specified by state law, if any, necessary to obtain lenses for eyeglasses.*"

U.S.C.A. Title 15, Chapter 102 § 7610. Definitions

(C) 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 contact lens, name of manufacturer, trade name of private label brand, and, if applicable, trade name of equivalent brand name.]

RISKS OF OBTAINING CONTACT LENSES OR A CONTACT LENS RX FROM AN UNLICENSED PROVIDER:

CONDITION	CAUSE	POTENTIAL RESULT
Acanthamoeba keratitis	Improper lens care guidance and follow up care	Partial to total loss of vision
Corneal ulcer	Incorrect lens fit, guidance and follow up care	Partial to total loss of vision
Anterior uveitis	Incorrect lens fit, guidance and follow up care	Partial loss of vision
Corneal edema	Incorrect lens fit, guidance and follow up care	Clouding of vision
Corneal abrasion	Incorrect lens fit, guidance and follow up care	Painful loss of vision; ulcer
Corneal warpage	Incorrect lens fit, guidance and follow up care	Partial loss of vision
Corneal neovascularization	Incorrect lens fit, guidance and follow up care	Corneal scarring, partial vision loss & inflammation
Contact lens keratopathy	Incorrect lens fit, guidance and follow up care	Partial loss of vision from corneal inflammation
Giant papillary conjunctivitis (GPC)	Incorrect lens fit, guidance and follow up care	Chronic irritation and inflammation of lids
Ocular toxicity	Incorrect lens care, guidance and follow up care	Partial loss of vision
Sterile corneal infiltrates	Incorrect lens fit, guidance and follow up care	Painful inflammation and partial loss of vision
Tight lens syndrome	Incorrect lens fit, guidance and follow up care	Painful, partial loss of vision

RISKS OF OBTAINING SPECTACLES OR SPECTACLE LENS RX FROM AN UNLICENSED PROVIDER:

SYMPTOMS OF EYE CARE CONSUMER	PERCEIVED CAUSE	POTENTIAL UNDIAGNOSED CAUSE PLACING THE EYE CARE CONSUMER AT RISK
Blurred vision	Need for new glasses	Cataracts, Diabetes, Glaucoma, Hypertension, Age-Related Macular Degeneration, Medications, Dry Eyes, Vitreous Degeneration, Retinal Degenerations or Detachment, Corneal Dystrophy, Posterior Uveitis, Binocular Vision Abnormality, Optic Nerve Disease, Ocular Tumor, Amblyopia and a Myriad of Ocular Manifestations of Systemic Disease Migraine
Eyestrain, Fatigue or Discomfort	Need for new glasses	Binocular Vision Imbalance or Abnormality, Dry Eye Syndrome, Retained Corneal or Conjunctival Foreign Body, Chronic Keratitis, Chronic Conjunctivitis, Sinus Congestion or Infection, Trichiasis, Thyroid Eye Disease, Anterior or Posterior Uveitis

RISKS OF USING AUTOMATED REFRACTION DEVICES TO DETERMINE A SPECTACLE LENS PRESCRIPTION BY AN UNLICENSED PROVIDER:

UNDIAGNOSED OCULAR CONDITION	POTENTIAL EFFECT ON SPECTACLE PRESCRIPTION PLACING THE EYE CARE CONSUMER AT RISK
Keratoconus	Highly inaccurate lens prescription causing blurred vision and risk of bodily injury
Cataracts, Corneal Dystrophies, Corneal Scarring, Small Pupil, Irregular Astigmatism	Inaccurate lens prescription causing blurred vision and risk of bodily injury
Pediatric Spasm of Accommodation	Inaccurate lens prescription causing loss of near vision functionality, missed diagnosis of amblyopia and risk of failure to achieve academically
Latent Hyperopia, Pseudomyopia	Inaccurate lens prescription causing blurred vision at near, eyestrain and loss of ability to perform near vision tasks at work or school