



Senate Fiscal Agency  
P. O. Box 30036  
Lansing, Michigan 48909-7536



Telephone: (517) 373-5383  
Fax: (517) 373-1986

Senate Bill 853 (as enacted)  
Sponsor: Senator Rick Jones  
Senate Committee: Health Policy  
First House Committee: Regulatory Reform  
Second House Committee: Health Policy

**PUBLIC ACT 269 of 2014**

Date Completed: 9-19-14

**RATIONALE**

Across the nation, self-service kiosks that offer health and wellness screenings and information to customers have been placed in some retail establishments. Evidently, some of the machines in other states employ automated technology for the purpose of identifying vision problems, and some consumers use the information they receive from the kiosks to purchase glasses or contact lenses. Without an examination and diagnosis by a qualified physician or optometrist, however, serious eye problems can go undetected or users might purchase glasses or contacts that are inappropriate for their individual circumstances, potentially leading to further compromised vision. To protect public health, it was suggested that vision screening and the use of automated equipment for that purpose be restricted to certain health professionals, that a valid prescription be required for the sale and dispensing of glasses and contacts, and that the Department of Licensing and Regulatory Affairs be authorized to investigate and take action against individuals who perform vision screening without the proper qualifications and supply glasses or contacts without a prescription.

**CONTENT**

**The bill adds Part 55A (Eye Care Consumer Protection) to the Public Health Code to regulate contact lenses and corrective spectacles (glasses) as medical devices for consumer protection purposes. Specifically, the bill does the following:**

- **Prohibits a person other than a licensee (a licensed physician specializing in eye care or a licensed optometrist) or a person performing under a licensee's supervision from using certain means to make a determination about the human eye.**
- **Prohibits a person other than a licensee from prescribing glasses or contact lenses based on that determination.**
- **Requires a valid prescription for the dispensing, giving, or selling of glasses and contact lenses.**
- **Prohibits the use of certain automated testing devices to generate objective refractive data without the supervision of a licensee.**
- **Designates the Department of Licensing and Regulatory Affairs (LARA) as the entity responsible for the administration and enforcement of Part 55A, and allows LARA to promulgate rules.**
- **Authorizes LARA to investigate a violation of Part 55A, order a person to cease and desist from a violation, and assess costs related to the investigation.**
- **Authorizes LARA to refer a case for further enforcement action against a person who fails to comply with a cease and desist order.**
- **Authorizes LARA to file a civil action to enforce Part 55A.**
- **Authorizes a court to impose a civil fine of at least \$5,000 per violation, as well as the costs of an investigation and attorney fees.**

**-- Makes it a misdemeanor to violate Part 55A or a cease and desist order, and prescribes penalties.**

Part 55A may be referred to as the "Eye Care Consumer Protection Law". The bill will take effect on September 30, 2014.

Scope of Part 55A; Definitions

The bill specifies that, except as otherwise provided, spectacles and contact lenses are medical devices and are subject to the requirements of Part 55A for the protection of consumers.

Part 55A does not apply to a diagnostic contact lens that is used by a licensee during an examination and evaluation, an optical instrument or device that is not intended to correct or enhance vision, or an optical instrument or device that is not made, designed, or sold specifically for a particular individual.

"Spectacles" means an optical instrument or device worn or used by an individual that has at least one lens designed to correct or enhance vision to address the visual needs of the individual wearer and commonly known as glasses, including spectacles that may be adjusted by the wearer to achieve different types or levels of visual correction or enhancement.

"Contact lens" means a lens placed directly on the surface of the eye, regardless of whether it is intended to correct a visual defect. The term includes a cosmetic, therapeutic, or corrective lens. "Diagnostic contact lens" means a contact lens used to determine a proper contact lens fit.

"Licensee" means either of the following:

- A physician who is licensed or otherwise authorized to engage in the practice of medicine under Part 170 (Medicine) or Part 175 (Osteopathic Medicine and Surgery) of the Code and who specializes in eye care.
- An optometrist who is licensed or otherwise authorized to engage in the practice of optometry under Part 174 (Optometry).

For the purpose of writing a valid prescription, "examination and evaluation" means an assessment of the ocular health and visual status of a patient that does not consist solely of objective refractive data or information generated by an automated refracting device or other automated testing device. "Valid prescription" means a written or electronic order by a licensee who has conducted an examination and evaluation of a patient. A prescription also must meet a number of other conditions in order to be valid.

Prohibited Conduct

Part 55A prohibits a person from doing any of the following:

- Employing objective or subjective physical means to determine the accommodative or refractive condition or range of power of vision or muscular equilibrium of the human eye unless that activity is performed by a licensee or under the supervision of a licensee.
- Prescribing glasses or contact lenses based on that determination unless that activity is performed by a licensee.
- Dispensing, giving, or selling glasses or contacts except pursuant to a valid prescription.
- Using an automated refractor or other automated testing device to generate objective refractive data unless that use is by a licensee or under the supervision of a licensee.

("Supervision" means that term as defined in Section 16109 of the Code. Under that section, "supervision" means the overseeing of or participation in the work of another individual by a licensed health professional in circumstances in which at least all of the following conditions exist:

- The continuous availability of direct communication in person or by radio, telephone, or telecommunication between the supervised individual and a licensed health professional.
- The availability of a licensed health professional on a regularly scheduled basis to review the practice of and provide consultation to the supervised individual, to review records, and to further educate the supervised individual in the performance of his or her functions.
- The provision by the supervising health professional of predetermined procedures and drug protocol.)

### Enforcement & Administration

Except as otherwise provided, the administration and enforcement of Part 55A are the responsibility of LARA. The Department may promulgate rules under the Administrative Procedures Act (APA) that it determines necessary to implement, administer, and enforce Part 55A.

### Violations & Sanctions

A person or governmental entity that believes that a violation of Part 55A or a rule promulgated under it has occurred or has been attempted may make a written allegation of that fact to LARA. Upon reviewing an allegation, if LARA determines there is a reasonable basis to believe that a violation or attempted violation exists, the Department must investigate. The Department may hold hearings, administer oaths, and order testimony to be taken at a hearing or by deposition conducted pursuant to the APA. The Department does not have to wait until harm to human health occurs to initiate an investigation.

After determining that a violation has occurred, LARA may order a person to cease and desist from the violation. A person ordered to cease and desist is entitled to a hearing before LARA if a written request for a hearing is filed within 30 days after the order's effective date.

The Department may assess costs related to the investigation of a violation, and may issue an order for these costs after a hearing held in compliance with the APA. The Department may refer a case for further enforcement action against a person who fails to comply with a cease and desist order that is not contested or that is upheld following a hearing. The Department is not required to issue a cease and desist order before taking action as described below.

The Department may file a civil action seeking an injunction or other appropriate relief to enforce Part 55A or a rule promulgated under it. The court may impose a civil fine of at least \$5,000 for each violation or attempted violation of Part 55A or a related rule. The court also may award costs of an investigation and attorney fees from the violator or attempted violator.

A person who violates Part 55A, a rule, or a cease and desist order is guilty of a misdemeanor punishable by imprisonment for up to one year and/or a fine of at least \$5,000 but not more than \$25,000. If successful in obtaining a conviction, the agency prosecuting the case is entitled to actual costs and attorney fees from the defendant.

MCL 333.5551-333.5571

## **ARGUMENTS**

*(Please note: The arguments contained in this analysis originate from sources outside the Senate Fiscal Agency. The Senate Fiscal Agency neither supports nor opposes legislation.)*

### **Supporting Argument**

The emergence of eye exam kiosks presents a number of risks to the public. Reportedly, the purpose of such kiosks is to provide free exams to people who typically do not see a doctor, so that they might seek care from a qualified eye care professional if any vision problems are identified. Some people, however, view the self-service exam as a replacement for a comprehensive eye exam from a doctor. This is of concern because there are serious eye conditions or underlying health problems that such a machine cannot identify, such as glaucoma.

Left untreated, certain diseases or conditions can lead to further vision loss and in some cases warrant removal of the eyeball. Additionally, a kiosk might provide inaccurate screening results, leading consumers to purchase glasses or contacts that cause blurred vision, eyestrain, fatigue, or discomfort. For contact lenses, even those meant purely for cosmetic purposes, it is necessary that a proper fit is ensured and that the patient is given guidance regarding wear and necessary follow-up care in order to avoid eye injury and disease. In any case, it is critical that the results of a vision test be interpreted by a doctor specializing in the eye. The bill will protect consumers from the potential dangers by prohibiting vision determinations and the use of automated eye exam equipment by anyone other than an appropriate licensed health professional, and by requiring a valid prescription for the sale or dispensing of glasses and contact lenses.

In addition, the bill will protect public health and safety by defining "valid prescription". Currently, the Public Health Code authorizes ophthalmologists and optometrists to prescribe glasses and contact lenses, but does not state explicitly that *only* these licensed professionals may do so. Furthermore, the Code does not require a prescription for glasses or contacts. Federal law treats all contact lenses as medical devices, and the Food and Drug Administration requires a prescription for them but does not specify defining criteria, leaving states to determine for themselves what constitutes a legitimate prescription. Due to Michigan's lack of clearly defined eye care prescription requirements, LARA's ability to protect the public had been limited. The bill's definition of "valid prescription" will close a gap in the law by overtly requiring that a licensee who has examined and evaluated the patient write the prescription, and establishing other regulations. This definition, together with the bill's enforcement and penalty provisions, will provide LARA with an effective oversight mechanism.

While self-service eye exam kiosks have not been a problem in Michigan thus far, it is prudent to enact the statutory framework to prevent their appearance in the State. The legislation is a proactive measure to protect the public from injury, disease, and vision loss.

Legislative Analyst: Julie Cassidy

### **FISCAL IMPACT**

The bill will have an indeterminate, but likely negative, fiscal impact on the Department of Licensing and Regulatory Affairs, and no fiscal impact on local units of government. Under the bill, LARA will be responsible for implementation, administration, and enforcement of Part 55A. Other than revenue from any administrative fines received from people who violate Part 55A, existing resources will have to support any costs incurred.

Fiscal Analyst: Josh Sefton

A1314\853ea

This analysis was prepared by nonpartisan Senate staff for use by the Senate in its deliberations and does not constitute an official statement of legislative intent.