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BILL ANALYSIS

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Senate Bill 853 (as introduced 3-6-14)
Sponsor: Senator Rick Jones
Committee: Health Policy

Date Completed: 3-20-14

CONTENT

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

- **Prohibit a person other than a licensee (a licensed physician specializing in eye care or a licensed optometrist) from using certain means to make a determination about the human eye, or prescribing spectacles or contact lenses based on that determination.**
- **Require a valid prescription for the dispensing, giving, or selling of spectacles and contact lenses.**
- **Prohibit the use of certain automated testing devices to generate objective refractive data without the supervision of a licensee.**
- **Designate the Department of Licensing and Regulatory Affairs (LARA) as the entity responsible for the administration and enforcement of proposed Part 55A, and allow LARA to promulgate rules.**
- **Authorize LARA to investigate a violation of Part 55A, and require the Department to report its findings to the LARA Director.**
- **Authorize the Director to impose an administrative fine or, under certain circumstances, issue a warning for a violation.**
- **Require the Director to advise the Attorney General if a person failed to pay an administrative fine, and allow the Attorney General to bring an action for the failure.**
- **At the Director's request, allow the Attorney General to file a civil action seeking an injunction or other appropriate relief to enforce Part 55A.**
- **Authorize a court to impose a civil fine of up to $5,000 for each violation and order additional equitable or injunctive relief to ensure compliance.**
- **Allow the Attorney General to bring an action to recover the reasonable costs of the investigation from a violator.**

Part 55A could be referred to as the "Eye Care Consumer Protection Law".

Scope of Part 55A; Definitions

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

Part 55A would not apply to a diagnostic contact lens that was used by a licensee during an examination and evaluation, an optical instrument or device that was not intended to

correct or enhance vision, or an optical instrument or device that was sold without consideration of the visual status of the individual who would use it.

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

"Licensee" would mean any 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" would mean 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" would mean a written or electronic order by a licensee who has conducted an examination and evaluation of a patient. A prescription also would have to meet a number of other conditions in order to be valid.

Prohibited Conduct

Part 55A would prohibit 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 or prescribing spectacles or contact lenses based on that determination unless that activity were performed by a licensee.
-- Dispensing, giving, or selling spectacles or contact lenses except pursuant to a valid prescription.
-- Using an automated refractor or other automated testing device to generate objective refractive data unless that use were under the supervision of a licensee.

("Supervision" would mean 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 where 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 proposed Part 55A would be the responsibility of LARA. The Department could promulgate rules under the Administrative Procedures Act (APA) that it determined necessary to implement, administer, and enforce Part 55A.

Violations & Sanctions

A person or governmental entity that believed that a violation of Part 55A or a rule promulgated under it had occurred or had been attempted could make a written allegation of that fact to LARA. Upon reviewing an allegation, if LARA determined there was a reasonable basis to believe the existence of a violation or attempted violation, the Department could investigate. The Department could hold hearings, administer oaths, and order testimony to be taken at a hearing or by deposition conducted pursuant to the APA, and would have to report its findings to the LARA Director. The Department would not have to wait until harm to human health occurred to initiate an investigation.

If the Director determined that a violation had occurred, he or she could proceed as described below.

Upon finding after notice and an opportunity for a hearing that a person had violated or attempted to violate Part 55A or a related rule, the Director could impose an administrative fine of a maximum of $1,000 for each violation or attempted violation. If the Director found that a violation or attempted violation did not result in significant harm to human health, he or she could issue a warning instead of imposing a fine.

The Director would have to advise the Attorney General of a person's failure to pay an administrative fine. The Attorney General could bring an action in a court of competent jurisdiction for the failure to pay the fine.

At the Director's request, the Attorney General could file a civil action seeking an injunction or other appropriate relief in the name of the people of the State to enforce Part 55A and the rules promulgated under it. The court could impose on a violator or attempted violator a maximum civil fine of $5,000 for each violation or attempted violation and could order additional equitable or injunctive relief to ensure compliance with Part 55A. In addition, the Attorney General could bring an action in circuit court to recover the reasonable costs of the investigation from a violator or attempted violator.

Proposed MCL 333.5551-333.5567 Legislative Analyst: Julie Cassidy

FISCAL IMPACT

The bill would 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 would be responsible for implementation, administration, and enforcement of proposed Part 55a. Other than revenue from any administrative fines received from people who violated Part 55a, existing resources would have to support any costs incurred.

Fiscal Analyst: Josh Sefton

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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.