RECALLED

April 21, 2016

**H. 4728**

Introduced by Reps. Long, Erickson, Douglas, Ridgeway, Hixon, Jefferson, Whitmire, Tallon, Daning, Anthony, Hiott, Ballentine, Allison, Bowers, Spires, W.J. McLeod, Williams, Bales, Nanney, Knight, Southard, V.S. Moss, Gagnon, Willis, Huggins, Corley, Taylor, Herbkersman, King, Felder, Hicks, Loftis, Simrill, Pope, Riley, McCoy, Henderson, Hosey, D.C. Moss and Brannon

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Read the first time January 26, 2016.

**STATEMENT OF ESTIMATED FISCAL IMPACT**

**Fiscal Impact Summary**

This bill as amended would have no expenditure impact on the general fund, federal funds, or other funds.

**Explanation of Fiscal Impact**

**Explanation of Amendment by House Medical, Military, Public and Municipal Affairs on April 14, 2016**

**State Expenditure**

This amendment adds Chapter 24 to Title 40 and entitles the chapter Eye Care Consumer Protection. The amendment provides definitions related to prescriptive eye wear including the term kiosk. The amendment requires that a prescription for spectacles or contact lenses must take into account medical findings made and refractive error discovered during an eye examination. A prescription for eye wear may not be based solely on the refractive error of the eye or be generated by a kiosk. Violation of this section constitutes misconduct and a provider who violates this section is subject to disciplinary action by the licensee’s respective board as specified in Section 40-37-110 for optometrists and in Section 40-47-110 for medical examiners (ophthalmologists).

The Department of Labor, Licensing and Regulation reports that this bill would have no expenditure impact on the general fund, federal funds, or other funds.

**Explanation of Bill as Filed on January 26, 2016**

**State Expenditure**

This bill amends Title 44 by adding Chapter 45 known as the Eye Care Consumer Protection Law. The bill requires the Department of Health and Environmental Control to regulate the dispensing of prescription eyewear. The bill defines the term kiosk and specifies requirements for the proper use of automated visual diagnostic equipment. The bill requires the Department of Health and Environmental Control to enforce this Chapter through complaint investigations and hearing procedures. The bill specifies fines and other penalties for violations and provides that the violator’s licensing board shall retain all assessed fines and determine disciplinary actions.

**Department of Health and Environmental Control.** The department estimates that this new regulatory program would require one investigator, one administrative assistant, and one licensed practical nurse. First year costs are estimated at $185,440 (including $145,529 for salaries and fringes, $20,633 for operating costs, and $19,278 for the one-time purchase of office equipment and investigative training). Subsequently, annual operating expenditures are estimated at $166,162.

**Department of Labor, Licensing and Regulation.** The department reports that this bill would have no expenditure impact on the general fund, federal funds, or other funds. Minimal expenditures are anticipated but these would be absorbed using available resources.

Frank A. Rainwater, Executive Director

Revenue and Fiscal Affairs Office

**A** **BILL**

TO AMEND THE CODE OF LAWS OF SOUTH CAROLINA, 1976, BY ADDING CHAPTER 45 TO TITLE 44 TO ENACT THE “EYE CARE CONSUMER PROTECTION LAW” SO AS TO ESTABLISH REQUIREMENTS FOR A PERSON WHO SELLS SPECTACLES OR CONTACT LENSES USING REFRACTIVE DATA OR INFORMATION GENERATED BY AN AUTOMATED TESTING DEVICE.

Be it enacted by the General Assembly of the State of South Carolina:

SECTION 1. This chapter may be cited as the “Eye Care Consumer Protection Law”.

SECTION 2. Title 44 of the 1976 Code is amended by adding:

“CHAPTER 45

Eye Care Consumer Protection

Section 44‑45‑10. For purposes of this chapter, unless the context indicates otherwise:

(1) ‘Consumer’ or ‘patient’ means a person who submits to an eye examination or eye evaluation in this State.

(2) ‘Consumer disclosure’ means a written disclosure for the benefit and knowledge of a patient on a form approved by the department as to the incomplete nature of an eye exam that is limited to determining refractive error without a diagnosis or evaluation of any ocular or systemic pathologies.

(3) ‘Contact lenses’ means a lens placed directly on the surface of the eye, regardless of whether it is intended to correct a visual defect, and includes, but is not limited to, cosmetic, therapeutic, and corrective lenses.

(4) ‘Department’ means the South Carolina Department of Health and Environmental Control.

(5) ‘Dispense’ means the act of providing a pair of spectacles or contact lenses to a patient.

(6) ‘Eye examination’ or ‘eye evaluation’ means an assessment of all or a portion of the ocular health profile, which must include a complete written or electronic medical history, as well as an assessment of the visual status of a patient.

(7) ‘Kiosk’ means automated equipment or an automated application, which is designed to be used on a phone, computer, or internet‑based device that can be used in person or remotely to provide refractive data or information.

(8) ‘Licensing board’ means the provider’s licensing board established pursuant to Title 40.

(9) ‘Medical history’ means a complete collection, written and digital, of all material medical data and a medical profile as is customarily collected under the most recent year’s Current Procedural Terminology (CPT) code and which must be retained as part of the patient’s medical records in accordance with the provider’s professional licensing requirements.

(10) ‘Prescription’ means a provider’s handwritten or electronic order to correct refractive error that is based on an eye examination.

(11) ‘Provider’ means an individual licensed by the South Carolina Board of Examiners in Optometry or the South Carolina Board of Medical Examiners.

(12) ‘Spectacles’ means an optical instrument or device worn or used by an individual that has one or more lenses designed to correct or remediate vision deficits or needs of the individual wearer and are commonly known as glasses, including spectacles that may be adjusted by the wearer to achieve different types or levels of visual correction or enhancement, and excluding over‑the‑counter spectacles not intended to correct or enhance vision or sold without consideration of the visual status of the individual using the spectacles.

(13) ‘Visual status’ means the assessment of the visual acuity, accommodation, and ocular alignment of the eyes in an uncorrected state and the best corrected visual acuity achievable with the aid of a spectacle or contact lens prescription; however, the assessment must not be based solely on objective refractive data or information generated by an automated testing device, including an auto refractor or other electronic refractive‑only testing device, to provide a medical diagnosis or to establish a refractive error for a patient as part of an eye examination or eye evaluation.

Section 44‑45‑20. (A) A person in this State may not dispense spectacles or contact lenses to a patient without a valid prescription from a provider.

(B) To be valid, a prescription must contain an expiration date on spectacles or contact lenses of one year from the date of examination by the provider or a statement of the reasons why a shorter time is appropriate based on the medical needs of the patient. A provider may not refuse to issue a prescription for spectacles or contact lenses to a patient. The prescription must take into consideration medical findings made and refractive error discovered during the eye examination.

(C) A prescription for spectacles or contact lenses may not be based solely on the refractive eye error of the human eye or be generated by a kiosk.

Section 44‑45‑30. A person may not operate a kiosk in this State unless:

(1) the kiosk is approved by the United States Food and Drug Administration for the intended use;

(2) the kiosk is designed and operated in a manner that provides the accommodations required by the federal Americans with Disabilities Act;

(3) the kiosk and accompanying technology used for the collection and transmission of information and data, including photographs and scans, gathers and transmits protected health information in compliance with the federal Health Insurance Portability and Accountability Act;

(4) the procedure for which the kiosk is used has a recognized Current Procedural Terminology (CPT) code maintained by the American Medical Association;

(5) the physical location of the kiosk prominently displays the name and state professional license number of the individual provider who will read and interpret the diagnostic information and data, including photographs and scans;

(6) diagnostic information and data, including photographs and scans, gathered by the automated equipment is read and interpreted by a provider; and

(7) the owner or lessee of the automated equipment maintains liability insurance in an amount of not less than two million dollars per occurrence and four million dollars in the aggregate for claims made by individuals diagnosed or treated based on information and data, including photographs and scans generated by the automated equipment.

Section 44‑45‑40. (A) A provider who fails, without good cause, to comply with the requirements of this chapter must be assessed administrative and professional license penalties as follows:

(1) for a first violation, a fine of five hundred dollars, a warning letter, and notification to the provider’s licensing board;

(2) for a second violation, a fine of one thousand dollars and monthly reporting of compliance by the provider to the provider’s licensing board, under penalty of perjury, for twelve months;

(3) for a third violation, a fine of two thousand five hundred dollars and suspension of the provider’s license for ten days; and

(4) for more than three violations, a fine of five thousand dollars and suspension of the provider’s license for ninety days or more, as determined by the provider’s licensing board.

(B) The department within ten days of assessment shall notify the provider’s licensing board of any administrative and professional licensing penalty assessed. Each violation of this chapter constitutes a separate violation for purposes of assessing administrative and professional licensing penalties.

(C) The provider’s licensing board shall retain all fine monies assessed and collected pursuant to subsection (B).

(D) A professional licensing board may take disciplinary action against a provider in addition to assessing a penalty required pursuant to subsection (A).

Section 44‑45‑50. A person or governmental entity that believes there has been a violation or attempted violation of this chapter, or a regulation promulgated pursuant to this chapter, may submit the allegation to the department in writing. If, upon reviewing the written allegation, the department determines there is a reasonable basis for the allegation, the department shall investigate. Nothing in this chapter requires the department to wait until physical injury or other medical harm has occurred to initiate an investigation.

Section 44‑45‑60. The department, as part of investigating an allegation pursuant to Section 44‑45‑50, may hold hearings, administer oaths, and order testimony to be taken at a hearing or by deposition conducted pursuant to the South Carolina Administrative Procedures Act and shall report its findings to the provider’s licensing board for further disposition as to any possible disciplinary matters.

Section 44‑45‑70. A person or entity including, but not limited to, a corporation, limited liability company, limited partnership, general partnership, or other non‑individual entity, which aids or assists a provider in violating this chapter must be fined in the same amount as the provider whom the person or entity assisted or aided in violating this chapter. The person or entity also may be subject to civil action, including an action for temporary or permanent injunctive relief, in a court of competent jurisdiction as part of a cause of action filed by the South Carolina Attorney General, the department, or a private party for conduct found to constitute repeat violations of this chapter.”

SECTION 3. If any section, subsection, paragraph, subparagraph, sentence, clause, phrase, or word of this act is for any reason held to be unconstitutional or invalid, such holding shall not affect the constitutionality or validity of the remaining portions of this act, the General Assembly hereby declaring that it would have passed this act, and each and every section, subsection, paragraph, subparagraph, sentence, clause, phrase, and word thereof, irrespective of the fact that any one or more other sections, subsections, paragraphs, subparagraphs, sentences, clauses, phrases, or words hereof may be declared to be unconstitutional, invalid, or otherwise ineffective.

SECTION 4. This act takes effect upon approval by the Governor.

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