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STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2018

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A N A C T

RELATING TO HEALTH AND SAFETY -- THE CONSUMER PROTECTION IN EYE CARE
ACT

Introduced By: Senators Ciccone, Lombardi, Gallo, and Goodwin

Date Introduced: February 15, 2018

Referred To: Senate Health & Human Services

It is enacted by the General Assembly as follows:

1 SECTION 1. Title 23 of the General Laws entitled "HEALTH AND SAFETY" is hereby
2 amended by adding thereto the following chapter:

3 CHAPTER 95

4 THE CONSUMER PROTECTION IN EYE CARE ACT

5 **23-95-1. Short title.**

6 This act shall be known and may be cited as the "Consumer Protection in Eye Care Act".

7 **23-95-2. Definitions.**

8 As used in this chapter:

9 (1) "Automated computer program" means automated equipment or application designed
10 to be used on a telephone, a computer, or an Internet-accessible device that can be used either in
11 person or remotely to conduct an eye assessment.

12 (2) "Contact lens" means any lens placed directly on the surface of the eye, regardless of
13 whether or not it is intended to correct a visual defect. Contact lenses are medical devices and
14 include, but are not limited to any cosmetic, therapeutic, or corrective lenses.

15 (3) "Delegate" means a person tasked by a provider to assist in the examination of the
16 eyes and adnexa or in the development of a prescription for spectacles and/or contact lenses as
17 part of a provider's utilization of an automated computer program or other eye examination
18 equipment.

- 1 (4) "Department" means the Rhode Island department of health.
- 2 (5) "Dispense" means the act of furnishing spectacles or contact lenses to a patient.
- 3 (6) "Established treatment site" means a location where a patient shall seek care where
4 there is a provider present and sufficient technology and equipment to allow for an adequate
5 physical evaluation as appropriate for the patient's presenting complaint, and requires a provider
6 in-person patient relationship.
- 7 (7) "Eye examination" means a physical assessment of the ocular health and visual or
8 refractive status of a patient that does not consist solely of objective refractive data or information
9 generated by an automated testing device, including an autorefractor, in order to establish a
10 medical or refractive diagnosis or for the correction of vision disorders.
- 11 (8) "Eye examination equipment" means computerized or manual medical devices used to
12 measure refractive status and/or ocular health of the patient, including, but not limited to,
13 Internet-based or local computer programs, automated examination equipment, manual
14 examination equipment, cameras, scanning lasers, automated refracting devices, non-contact or
15 contact tonometers.
- 16 (9) "In-person evaluation" means a patient evaluation conducted by a provider who is at
17 the same physical location as the location of the patient.
- 18 (10) "Prescription" means a provider's handwritten or electronic order for spectacles or
19 contact lenses based on an eye examination.
- 20 (11) "Provider" is a health care professional licensed under chapter 35.1 or 37 of title 5.
- 21 (12) "Spectacles" means an optical instrument or device worn or used by an individual
22 that has one or more lenses designed to correct or enhance vision addressing the visual needs of
23 the individual wearer, commonly known as "glasses" or "eyeglasses", including spectacles that
24 may be adjusted by the wearer to achieve different types or levels of visual correction or
25 enhancement. Spectacles does not include an optical instrument or device that is not intended to
26 correct or enhance vision or is sold without consideration of the visual status of the individual
27 who will use the optical instrument or device.
- 28 (13) "Supervision" means overseeing the utilization of a delegated automated computer
29 program or other eye examination equipment shall be provided by a provider. The utilization of
30 an automated computer program or other eye examination equipment by a delegate may be
31 performed if the examination has been delegated and the delegating provider provides appropriate
32 on-site supervision and the delegate has met necessary training requirements.

33 **23-95-3. Purpose.**

34 The purpose of this chapter is to provide for the development, establishment, and

1 enforcement of standards:

2 (1) To ensure and protect quality eye care for individuals receiving eye care in the state of
3 Rhode Island; and

4 (2) For the encouragement of quality maintenance and improvement in all aspects of eye
5 care delivered to individuals in the state.

6 **23-95-4. Dispensing; Prescriptions.**

7 (a) Except as provided for by § 5-35.1-10, no person may dispense contact lenses or
8 spectacles in this state to a patient without a valid prescription from a provider.

9 (b) A valid prescription for spectacles or contact lenses:

10 (1) Shall contain an expiration date of not less than one year from the date of the eye
11 examination, unless the provider determines that it is medically appropriate for the prescription to
12 expire sooner. If the expiration date is less than one year from the date of the eye examination, the
13 provider shall inform the patient of the reasoning, and document the reasoning in the provider's
14 medical records for the patient.

15 (2) Shall not be made based solely on information about the human eye generated by an
16 automated computer program.

17 (3) Shall take into consideration any medical findings and any refractive error discovered
18 during the eye examination.

19 (4) Shall consider all contact lenses used in the determination of a contact lens
20 prescription to be diagnostic lenses.

21 (c) After the diagnostic period and the contact lenses have been adequately fitted and the
22 patient is released from immediate follow-up care by persons licensed and regulated by the
23 department, the prescribing provider shall, at no cost, provide a prescription to the patient. A
24 person shall not dispense or adapt contact lenses or spectacles without first receiving
25 authorization to do so by a prescription, except when authorized orally by a provider. Patients
26 who comply with such fitting and follow-up requirements as may be established by the
27 prescribing provider may obtain contact lenses until the expiration date listed on the prescription
28 from a person who may lawfully dispense contact lenses under this chapter.

29 (d) No contact lenses may be sold or dispensed in this state except pursuant to a
30 prescription which:

31 (1) Conforms to state and federal regulations governing such forms and includes the
32 name, address, and state licensure number of a prescribing practitioner;

33 (2) Explicitly states the number of refills; provided, however, that the number of refills
34 shall be sufficient for, and not excessive of, the provision of the requisite number of contact

1 lenses under normal use until the expiration date of the prescription;

2 (3) Explicitly states that it is for contact lenses and indicates the lens brand name and
3 type, including all specifications necessary for the ordering or fabrication of lenses; and

4 (4) Is kept on file by the person selling or dispensing the contact lenses for at least
5 twenty-four (24) months after the prescription is filled.

6 (e) Anyone who fills a prescription bears the full responsibility of the accuracy of the
7 contact lenses or spectacles provided under the prescription.

8 (f) At no time, without the direction of a prescriber, shall any changes or substitutions be
9 made in the brand or type of lenses the prescription calls for with the exceptions of tint change if
10 requested by the patient. However, if a prescription specifies "only" a specific color or tinted lens,
11 those instructions shall be observed.

12 (g) All sales of and prescriptions for contact lenses in this state shall conform to the
13 federal Fairness to Contact Lens Consumers Act, Pub .L. 108-164, 15 U.S.C. § 7601, et seq. The
14 provisions of this chapter shall be construed in aid of and in conformity with said federal act.
15 Civil proceedings to enforce the provisions of this chapter may be brought by any board created
16 under the Rhode Island department of health or by any other interested person through injunction
17 or other appropriate remedy.

18 **23-95-5. Emergent technologies.**

19 No person shall operate an automated computer program or other eye examination
20 equipment to conduct an eye assessment or to generate a prescription for contact lenses or
21 spectacles, unless:

22 (1) Diagnostic information and data, including photographs and scans, gathered by the
23 automated computer program are read and interpreted by a provider;

24 (2) The provider who reads and interprets the diagnostic information and data, including
25 photographs and scans, gathered by the automated computer program and/or delegate, has an
26 established doctor-patient relationship with the patient, and has performed at least one in-person
27 evaluation of the patient that includes the state mandated required elements for an eye
28 examination as provided for in § 5-35.1-16 and the rules and regulations promulgated by the
29 department thereunder, at an established treatment site;

30 (3) The provider can verify the identity of the patient requesting treatment via the
31 automated computer program or other eye examination equipment;

32 (4) The automated computer program or other eye examination equipment is approved by
33 the federal Food and Drug Administration for the intended use;

34 (5) The automated computer program or other eye examination equipment is designed

1 and operated in a manner that provides any applicable accommodation required by the federal
2 Americans with Disabilities Act of 1990, codified at 42 U.S.C. § 12101 et seq., as amended;

3 (6) The automated computer program or other eye examination equipment is used for the
4 collection and transmission of information and data, including photographs and scans, gather and
5 transmits protected health information in compliance with the federal Health Insurance Portability
6 and Accountability Act of 1996, Pub .L. 104-191, codified at 42 U.S.C. § 300(gg), 29 U.S.C. §
7 1181 et seq., and 42 U.S.C. § 1320(d) et seq.;

8 (7) The procedure for which the automated computer program or other eye examination
9 equipment is used has a recognized current procedural terminology code maintained by the
10 American Medical Association;

11 (8) The automated computer program or other eye examination equipment prominently
12 displays the name, state license number and physical location of the provider who will read and
13 interpret the diagnostic information and data, including photographs and scans as well as non-
14 urgent and emergency contact information of said provider;

15 (9) The owner or lessee of the automated computer program or other eye examination
16 equipment maintains liability insurance in an amount adequate to cover claims made by
17 individuals diagnosed or treated based on information and data, including photographs and scans,
18 generated by the service and/or automated computer program; and

19 (10) There is simultaneous interaction between the provider via director two (2) way
20 communication with any delegate at all times, whereby the provider shall be immediately
21 available to respond promptly to any question or problem that may arise as a result of the service
22 being provided and shall be immediately available to respond promptly to any question or
23 problem that may arise as a result of the service being provided.

24 **23-95-6. Delegation; Written protocol; Supervision; Training.**

25 (a) Prior to delegating the performance of eye care services, including, but not limited to,
26 refractive eye care services, the provider shall perform an in-person initial evaluation of the
27 patient. The delegating provider is responsible for ensuring the delegate performing the service
28 has demonstrated sufficient proficiency for the services to be provided. Prior to performing the
29 services, the delegating provider shall inform the patient about the training and qualifications of
30 who will perform the services.

31 (b) A provider may delegate the performance of eye care services through use of a
32 written protocol. The written protocol shall be reviewed annually by the provider and the delegate
33 and updated as necessary, be provided to the department or to any patient upon request, and
34 provide;

1 (1) Identification of the device being used to perform the service and its inherent
2 limitations;

3 (2) Description of appropriate care and proper follow up, including a plan to ensure that
4 the service meets nationally recognized standards of care;

5 (3) A quality assurance plan for ongoing management of the patient; and

6 (4) A method for maintaining medical records for the service provided.

7 (c) A delegate may only perform those services delegated by and under the supervision of
8 a provider. Supervision requires that the provider have direct two-way communication with the
9 delegate at all times, and the provider shall be immediately available to respond promptly to any
10 question or problem that may arise as a result of the service being provided.

11 (d) A provider who delegates performance of eye care services shall provide, upon
12 request by the department, documentation of a delegate's completion of appropriate training in the
13 safe and effective use of all components and capabilities of an automated computer program; and
14 for each service being provided, it is the responsibility of the delegating provider to ensure that
15 the delegate is appropriately trained in the indications, appropriate use, accurate data collection,
16 and contraindications involved in the service being provided.

17 **23-95-7. Informed consent.**

18 It is the responsibility of the provider prior to performing remotely administered eye care
19 services, including, but not limited to, vision correction services, to clearly inform the patient as
20 to the indications and limitations of the technology to be used as well as alternative evaluation
21 and treatment options. This information shall be provided, in writing, to the patient and an
22 acknowledgement of receipt, signed by the patient, shall be maintained by the provider for a
23 period of two (2) years, and a copy shall be provided to the patient prior to the services being
24 rendered.

25 **23-95-8. Age minimum.**

26 No person shall operate an automated computer program or attempt to provide remote
27 vision correction services, or to conduct an eye assessment to generate a spectacle or contact lens
28 prescription for anyone under the age of eighteen (18) years old.

29 **23-95-9. Standard of care.**

30 Evaluation, treatment, and consultation recommendations made by a provider utilizing an
31 automated computer program, including issuing a prescription via electronic means, shall be held
32 to the same standards of appropriate practice as those in traditional in-person clinical settings.

33 **23-95-10. Violations; Penalty; Private right of action.**

34 (a) Any person who believes a violation of this chapter or the rules and regulation

1 adopted pursuant thereto has occurred or been attempted may file a complaint with the
2 department in writing. If, upon reviewing the complaint, the department determines there is a
3 reasonable basis to believe a violation or attempted violation has occurred, the department shall
4 investigate. The department may, on its own initiative or otherwise, initiate an investigation if it
5 has a reasonable basis to believe a violation of the act or the rules and regulations has occurred or
6 been attempted. Nothing in this chapter shall be deemed to require the department to wait until
7 human harm has occurred to initiate an investigation of a violation of this chapter. As part of the
8 investigation under this section, the department may hold hearings, administer oaths, and take
9 testimony in person or by deposition. Such hearings shall be conducted pursuant to the
10 administrative procedures act, chapter 35 of title 42. The findings of the investigation and any
11 hearings held pursuant to the investigation shall be in writing.

12 (b) If, as a result of an investigation pursuant to this section the department finds that a
13 person has violated or attempted to violate this chapter, it may impose a civil penalty of not more
14 than ten thousand dollars (\$10,000) for each violation. If the department finds that a violation or
15 attempted violation occurred and did not result in significant harm to human health, the
16 department may issue a warning instead of imposing a civil penalty. Any civil penalty imposed
17 pursuant to this section may be collected as provided in such section. At the request of the
18 department, the attorney general may file a civil action seeking an injunction or other appropriate
19 relief to enforce this chapter and the rules and regulations adopted and promulgated thereunder.

20 (c) In addition to any remedies under this chapter, the rules and regulations adopted
21 thereunder, or other provisions of state or federal law, a person adversely affected by a violation
22 of this chapter may bring action for injunctive relief and, upon prevailing, in addition to such
23 injunctive relief, shall recover monetary damages of no more than one thousand dollars (\$1,000)
24 for each day found to be in violation plus attorneys' fees and costs.

25 **23-95-11. Rules and regulations.**

26 The department, in conjunction with the boards established by §§ 5-35.1-13 and 5-37-1.1,
27 may adopt and promulgate reasonable rules and regulations to carry out the provisions of this
28 chapter.

29 SECTION 2. This act shall take effect upon passage.

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EXPLANATION
BY THE LEGISLATIVE COUNCIL
OF

A N A C T

RELATING TO HEALTH AND SAFETY -- THE CONSUMER PROTECTION IN EYE CARE
ACT

1 This act would provide for consumer protection in eye care services by developing
2 standards and enforcement protocols related to the utilization of emergent technologies in the
3 provision of eye care services, as well as for the delegation of eye care services by providers.

4 This act would take effect upon passage.

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