

STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2017

A N A C T

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

Introduced By: Senators Ciccone, Lombardi, McCaffrey, Archambault, and Lombardo

Date Introduced: March 15, 2017

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 94

4 THE CONSUMER PROTECTION IN EYE CARE ACT

5 **23-94-1. Short title.**

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

7 **23-94-2. Definitions.**

8 (a) 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, Internet
13 based or local computer programs, automated examination equipment, manual examination
14 equipment, cameras, scanning lasers, automated refracting devices, non-contact or contact
15 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 glasses or
19 contact lenses based on an eye examination.
- 20 (11) "Provider" is a health care professional licensed under chapters 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 may
24 be adjusted by the wearer to achieve different types or levels of visual correction or enhancement.
25 Spectacles does not include an optical instrument or device that is not intended to correct or
26 enhance vision or sold without consideration of the visual status of the individual who will use
27 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 **23-94-3. Purpose.**

- 34 (a) 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;

3 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 **23-94-4. 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 by the provider or a statement by the provider of the reasons why a shorter time is
12 appropriate based on the medical needs of the patient.

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

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

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

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

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

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

32 (2) Explicitly states an expiration date of not more than twelve (12) months from the date
33 of the last prescribing contact lens examination;

34 (3) Explicitly states the number of refills;

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

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

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

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

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

17 **23-94-5. Emergent technologies.**

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

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

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

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

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

33 (5) The automated computer program or other eye examination equipment is designed
34 and operated in a manner that provides any applicable accommodation required by the federal

1 Americans with Disabilities Act of 1990, codified at 42 U.S.C. 12101 et seq., as amended;

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

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

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

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

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

23 **23-94-6. Delegation; written protocol; supervision; training.**

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

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

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

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

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

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

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

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

15 **23-94-7. Informed consent.**

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

23 **23-94-8. Age minimum.**

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

27 **23-94-9. Standard of care.**

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

31 **23-94-10. Violations; penalty; private right of action.**

32 (a) Any person who believes a violation of this chapter or the rules and regulation
33 adopted pursuant thereto has occurred or been attempted may file a complaint with the
34 department in writing. If, upon reviewing the complaint, the department determines there is a

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

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

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

23 **23-94-11. Rules and regulations.**

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

27 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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