The Commonwealth of Massachusetts

In the One Hundred and Eighty-Ninth General Court (2015-2016)

SENATE, Thursday, December 8, 2016

The committee on Rules to whom was referred the House Bill relative to prescription eye drops (House, No. 4195),- reports, that the matter be placed in the Orders of the Day with an amendment striking out all after the enacting clause and inserting in place thereof the text of Senate document numbered 2512; and by striking out the title and inserting in place thereof a new title "An Act relative to eye care".

For the committee, Mark C. Montigny

The Commonwealth of Massachusetts

In the One Hundred and Eighty-Ninth General Court (2015-2016)

1	SECTION 1. Chapter 32A of the General Laws is hereby amended by inserting after
2	section 170 the following section:-
3	Section 17P. Coverage offered by the commission to an active or retired employee of the
4	commonwealth insured through the group insurance commission that provides coverage for
5	prescription eye drops shall provide coverage for refills of prescription eye drops in accordance
6	with the Medicare Part D guidelines on early refills of topical ophthalmic products when: (i) the
7	prescribing health care practitioner indicates on the original prescription that additional
8	quantities of the prescription eye drops are needed; (ii) the refill requested by the insured does
9	not exceed the number of additional quantities indicated on the original prescription by the
10	prescribing health care practitioner; and (iii) the prescription eye drops prescribed by the health
11	care practitioner are a covered benefit under the policy or contract of the insured.
12	SECTION 2. Section 1 of chapter 94C of the General Laws is hereby amended by
13	striking out, in line 286, as appearing in the 2014 Official Edition, the words "sections 66 and
14	66B" and inserting in place thereof the following words:- section 66 and section 66B or 66C.

15	SECTION 3. Section 7 of said chapter 94C is hereby amended by striking out, in line
16	212, as so appearing, the words "sections 66 and 66B" and inserting in place thereof the
17	following words:- section 66 and section 66B or 66C.
18	SECTION 4. Section 9 of said chapter 94C, as so appearing, is hereby amended by
19	striking out, in line 2, the words "sections 66 and 66B" and inserting in place thereof the
20	following words:- section 66 and section 66B or 66C.
21	SECTION 5. Said section 9 of said chapter 94C, as so appearing, is hereby further
22	amended by inserting after the word "podiatrist", in line 69, the following word:-, optometrist.
23	SECTION 6. Chapter 112 of the General Laws is hereby amended by inserting after
24	section 12FF the following section:-
25	Section 12GG. (a) A pharmacist may dispense a 90-day supply for a prescribed topical
26	ophthalmic product when: (i) the practitioner prescribed an initial 30-day prescription for the
27	topical ophthalmic product; (ii) the patient completed the initial 30-day prescription; (iii) the
28	practitioner did not indicate on the original prescription that dispensing the prescription in a
29	specific amount with periodic refills is medically necessary; and (iv) the total quantity of dosage
30	units dispensed, including refills, does not exceed the total quantity of dosage units indicated by
31	the practitioner on the prescription.
32	(b) Subsection (a) shall not apply to initial prescriptions for topical ophthalmic products
33	that are prescribed for a 90-day supply.
34	(c) A pharmacist shall not dispense a prescription refill pursuant to this section in excess
35	of the initial prescribed amount if the practitioner instructs otherwise, either orally or in writing.

36 (d) Within a reasonable time following an increase of supply pursuant to this section, the
 37 dispensing pharmacist or the pharmacist's designee shall notify the prescribing practitioner of the
 38 increase.

39 (e) This section shall not apply to topical ophthalmic products that are controlled
40 substances as defined by the Controlled Substances Act, 21 U.S.C. 802, or section 1 of chapter
41 94C, except those classified as schedule VI prescription drugs.

42 (d) This section shall not apply to prescriptions dispensed in a hospital licensed pursuant
43 to section 51 of chapter 111. No retail pharmacy, however organized, shall be exempt from this
44 section.

45 SECTION 7. Section 66 of chapter 112 of the General Laws, as appearing in the 2014
46 Official Edition, is hereby amended by inserting after the word "utilization", in line 7, the
47 following words:- and prescription.

48 SECTION 8. Said section 66 of said chapter 112, as so appearing, is hereby further 49 amended by striking out, in lines 12 and 13, the words "and 66B" and inserting in place thereof 50 the following words:- , 66B and 66C.

51 SECTION 9. The first paragraph of section 66A of said chapter 112, as so appearing, is 52 hereby amended by adding the following sentence:- A registered optometrist may administer 53 epinephrine, adrenaline or other agents used in the percutaneous treatment of anaphylaxis.

54 SECTION 10. Section 66B of said chapter 112, as so appearing, is hereby amended by 55 inserting after the word "injection", in line 14, the second time it appears, the following words:-, second for the administration of epinephrine, adrenaline or other agents used in the percutaneoustreatment of anaphylaxis.

58 SECTION 11. Said chapter 112 is hereby further amended by inserting after section 66B
59 the following section:-

60 Section 66C. (a) A registered optometrist, qualified by an examination for practice 61 pursuant to section 68 after January 1, 2013, certified pursuant to section 68C and registered to 62 issue written prescriptions pursuant to subsection (h) of section 7 of chapter 94C, may utilize and 63 prescribe topical and oral therapeutic pharmaceutical agents used in the practice of optometry, as 64 defined in section 66 and described in 21 U.S.C. 812 or in said chapter 94C, including those 65 placed in schedules III, IV, V and VI by the commissioner pursuant to section 2 of said chapter 66 94C for the purpose of diagnosing, preventing, correcting, managing or treating ocular diseases, 67 including glaucoma and ocular abnormalities of the human eye and adjacent tissue and the 68 administration of epinephrine, adrenalin or other agents used in the percutaneous treatment of 69 anaphylaxis. Nothing in this section shall permit optometric utilization or prescription of: (i) 70 therapeutic pharmaceutical agents for the treatment of systemic diseases; (ii) invasive surgical 71 procedures; or (iii) pharmaceutical agents administered by subdermal injection, intramuscular 72 injection, intravenous injection, subcutaneous injection or retrobulbar injection, except as 73 authorized in this section for the percutaneous treatment of anaphylaxis. The pharmaceutical 74 agents from schedule III shall be limited to narcotic analgesics and shall not include the use of 75 hallucinogenic substances or anabolic steroids. Oral steroid treatment required beyond 14 days 76 shall be continued only in consultation with the patient's primary care provider and noted in a 77 patient's medical record.

(b) If an optometrist, during the course of examining or treating a patient with the aid of a diagnostic or therapeutic pharmaceutical agent, exercising professional judgment and the degree of expertise, care and knowledge ordinarily possessed and exercised by optometrists under like circumstances, determines the existence of the signs of previously unevaluated disease which requires treatment not included in the scope of optometric practice as provided in section 66, the optometrist shall refer the patient to a licensed physician or other qualified health care practitioner. Optometrists may utilize and prescribe nonlegend agents.

(c) Nothing in this section shall prevent an optometrist authorized pursuant to this section
from serving as an approved investigator in a clinical trial evaluating pharmaceutical agents
described in subsection (a).

(d) If a patient exam results in a diagnosis of congenital glaucoma or if, during the course
of examining, managing or treating a patient with glaucoma, surgical treatment is indicated, an
optometrist shall refer that patient to a qualified health care provider for treatment.

91 (e) Optometrists licensed pursuant to this chapter shall participate in relevant state and
92 federal reports or data collection efforts relative to patient safety and medical error reduction
93 coordinated by the Betsy Lehman center for patient safety and medical error reduction
94 established in section 15 of chapter 12C.

95 (f) An insurer or risk management organization that provides insurance to an optometrist 96 licensed pursuant to this chapter shall make an annual report to the Betsy Lehman center for 97 patient safety and medical error reduction. The report shall provide the 10 most common 98 categories of losses, claims or actions for damages for personal injuries alleged to have been 99 caused by error, omission or negligence in optometrists' performance of services that the 100 company incurred during the previous calendar year. The report shall include completed cases 101 and settlements only and shall not include information identifying providers or patients. The 102 report shall be provided to the Betsy Lehman center for patient safety and medical errors 103 reduction board at the center's request under annual timelines and reporting requirements 104 established by the center with the input of the patient safety and medical errors reduction board 105 established in subsection (c) of said section 15 of said chapter 12C. The center shall use this 106 information in the development of evidence-based best practices to reduce errors and enhance 107 patient safety as required by subsection (e) of said section 15 of said chapter 12C to increase 108 awareness of error prevention strategies through public and professional education.

SECTION 12. Said chapter 112 is hereby further amended by inserting after section 68Bthe following section:-

111 Section 68C. (a) The board of registration in optometry shall administer an examination 112 to permit the utilization and prescription of therapeutic pharmaceutical agents as defined in 113 section 66C. The examination shall: (i) be held in conjunction with examinations provided in 114 sections 68, 68A and 68B; and (ii) include any portion of the examination administered by the 115 National Board of Examiners in Optometry or other appropriate examinations covering the 116 subject matter of therapeutic pharmaceutical agents. The board may administer a single 117 examination to measure the qualifications necessary under said sections 68, 68A and 68B and 118 this section. The board shall only qualify for practice in accordance with said sections 68, 68A 119 and 68B and this section. An applicant who presents satisfactory evidence of graduation from a 120 school or college of optometry approved by the board subsequent to January 1, 2013 shall have 121 satisfied all the requirements of sections 68, 68A and 68B and this section.

122 (b) Examination for the utilization and prescription of therapeutic pharmaceutical agents 123 placed under schedules III, IV, V and VI by the commissioner pursuant to section 2 of chapter 124 94C and defined in section 66C shall, upon application, be open to an optometrist registered 125 pursuant to section 68, 68A or 68B and to any person who meets the qualifications for 126 examination under said sections 68, 68A and 68B. An applicant, registered as an optometrist 127 pursuant to said section 68, 68A or 68B, shall: (i) possess a current Massachusetts controlled 128 substances registration for the use of topical pharmaceutical agents described in section 66B and 129 placed under schedule VI by the commissioner pursuant to said section 2 of said chapter 94C; 130 and (ii) furnish to the board of registration in optometry evidence of the satisfactory completion 131 of 40 hours of didactic education and 20 hours of supervised clinical education relating to the 132 utilization and prescription of therapeutic pharmaceutical agents defined in said section 66C. 133 The education shall: (i) be administered by the Massachusetts Society of Optometrists, Inc.; (ii) 134 be accredited by a college of optometry or medicine; and (iii) meet guidelines and requirements 135 of the board of registration in optometry. The board of registration in optometry shall provide to 136 the department of public health and each successful applicant a certificate of qualification in the 137 utilization and prescription of all therapeutic pharmaceutical agents as defined in said section 138 66C.

(c) An optometrist licensed in another jurisdiction shall be considered an applicant under this section by the board of registration in optometry. An optometrist licensed in another jurisdiction may submit evidence to the board of registration in optometry of practice equivalent to that required in section 68, 68A or 68B and the board, at its discretion, may accept the evidence in order to satisfy any of the requirements of this section. An optometrist licensed in another jurisdiction to utilize and prescribe therapeutic pharmaceutical agents substantially equivalent to those placed under schedules III, IV, V and VI by the commissioner pursuant to
section 2 of chapter 94C and defined in subsection (a) of section 66C may submit evidence to the
board of registration in optometry of equivalent didactic and supervised clinical education in
order to satisfy all the requirements of this section.

(d) A licensed optometrist who has completed a post-graduate residency program
approved by the Accreditation Council on Optometric Education after July 31, 1997 may submit
an affidavit to the board of registration in optometry from the licensed optometrist's residency
supervisor or the director of residencies at the affiliated college of optometry attesting that an
equivalent level of instruction and supervision was completed in order to satisfy all the
requirements of this section.

(e) As a requirement of license renewal, an optometrist licensed pursuant to this section
shall submit to the board of registration in optometry evidence attesting to the completion of 3
hours of continuing education specific to glaucoma.

158 SECTION 13. Chapter 175 of the General Laws is hereby amended by inserting after
159 section 47II the following section:-

Section 47JJ. A policy, contract, agreement, plan or certificate of insurance issued, delivered or renewed within the commonwealth that provides coverage for prescription eye drops shall provide coverage for refills of prescription eye drops in accordance with the Medicare Part D guidelines on early refills of topical ophthalmic products when: (i) the prescribing health care practitioner indicates on the original prescription that additional quantities of the prescription eye drops are needed; (ii) the refill requested by the insured does not exceed the number of additional quantities indicated on the original prescription by the prescribing health care practitioner; and 167 (iii) the prescription eye drops prescribed by the health care practitioner are a covered benefit168 under the policy or contract of the insured.

SECTION 14. Chapter 176A of the General Laws is hereby amended by inserting after
section 8KK the following section:-

171 Section 8LL. A contract between a subscriber and the corporation under an individual or 172 group hospital service plan which is delivered, issued or renewed within the commonwealth that 173 provides coverage for prescription eye drops shall provide coverage for refills of prescription eye 174 drops in accordance with the Medicare Part D guidelines on early refills of topical ophthalmic 175 products when: (i) the prescribing health care practitioner indicates on the original prescription 176 that additional quantities of the prescription eye drops are needed; (ii) the refill requested by the 177 insured does not exceed the number of additional quantities indicated on the original prescription 178 by the prescribing health care practitioner; and (iii) the prescription eye drops prescribed by the 179 health care practitioner are a covered benefit under the policy or contract of the insured.

180 SECTION 15. Chapter 176B of the General Laws is hereby amended by inserting after 181 section 4KK the following section:-

Section 4LL. A subscription certificate under an individual or group medical service agreement delivered, issued or renewed within the commonwealth that provides coverage for prescription eye drops shall provide coverage for refills of prescription eye drops in accordance with the Medicare Part D guidelines of early refills of topical ophthalmic products when: (i) the prescribing health care practitioner indicates on the original prescription that additional quantities of the prescription eye drops are needed; (ii) the refill requested by the insured does not exceed the number of additional quantities indicated on the original prescription by the prescribing health care practitioner; and (iii) the prescription eye drops prescribed by the health care practitioner are a covered benefit under the policy or contract of the insured.

SECTION 16. Chapter 176G of the General Laws is hereby amended by inserting after
section 4CC the following section:-

193 Section 4DD. An individual or group health maintenance contract that provides coverage 194 for prescription eye drops shall provide coverage for refills of prescription eye drops in 195 accordance with the Medicare Part D guidelines on early refills of topical ophthalmic products 196 when: (i) the prescribing health care practitioner indicates on the original prescription that 197 additional quantities of the prescription eye drops are needed; (ii) the refill requested by the 198 insured does not exceed the number of additional quantities indicated on the original prescription 199 by the prescribing health care practitioner; and (iii) the prescription eye drops prescribed by the 200 health care practitioner are a covered benefit under the policy or contract of the insured. 201 SECTION 17. Not more than 180 days after the effective date of this act, the department 202 of public health and the board of registration in optometry shall promulgate the rules and 203 regulations required by sections 7 and 9 of chapter 94C of the General Laws and sections 66A, 204 66B, 66C and 68C of chapter 112 of the General Laws.