SENATE . . . . . No. 2512

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

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In the One Hundred and Eighty-Ninth General Court
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SECTION 1. Chapter 32A of the General Laws is hereby amended by inserting after section 17O the following section:-

Section 17P. Coverage offered by the commission to an active or retired employee of the commonwealth insured through the group insurance commission 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 (iii) the prescription eye drops prescribed by the health care practitioner are a covered benefit under the policy or contract of the insured.

SECTION 2. Section 1 of chapter 94C of the General Laws is hereby amended by striking out, in line 286, as appearing in the 2014 Official Edition, the words "sections 66 and 66B" and inserting in place thereof the following words:- section 66 and section 66B or 66C.

SECTION 3. Section 7 of said chapter 94C is hereby amended by striking out, in line 212, as so appearing, the words "sections 66 and 66B" and inserting in place thereof the following words:- section 66 and section 66B or 66C.

SECTION 4. Section 9 of said chapter 94C, as so appearing, is hereby amended by striking out, in line 2, the words "sections 66 and 66B" and inserting in place thereof the following words:- section 66 and section 66B or 66C.

SECTION 5. Said section 9 of said chapter 94C, as so appearing, is hereby further amended by inserting after the word "podiatrist", in line 69, the following word:- , optometrist.

SECTION 6. Chapter 112 of the General Laws is hereby amended by inserting after section 12FF the following section:-

Section 12GG. (a) A pharmacist may dispense a 90-day supply for a prescribed topical ophthalmic product when: (i) the practitioner prescribed an initial 30-day prescription for the topical ophthalmic product; (ii) the patient completed the initial 30-day prescription; (iii) the practitioner did not indicate on the original prescription that dispensing the prescription in a specific amount with periodic refills is medically necessary; and (iv) the total quantity of dosage units dispensed, including refills, does not exceed the total quantity of dosage units indicated by the practitioner on the prescription.

(b) Subsection (a) shall not apply to initial prescriptions for topical ophthalmic products that are prescribed for a 90-day supply.

(c) A pharmacist shall not dispense a prescription refill pursuant to this section in excess of the initial prescribed amount if the practitioner instructs otherwise, either orally or in writing.

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

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

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

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

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

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

SECTION 10. Section 66B of said chapter 112, as so appearing, is hereby amended by inserting after the word "injection", in line 14, the second time it appears, the following words:-

except for the administration of epinephrine, adrenaline or other agents used in the percutaneous treatment of anaphylaxis.

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

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

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

(f) An insurer or risk management organization that provides insurance to an optometrist licensed pursuant to this chapter shall make an annual report to the Betsy Lehman center for patient safety and medical error reduction. The report shall provide the 10 most common categories of losses, claims or actions for damages for personal injuries alleged to have been caused by error, omission or negligence in optometrists' performance of services that the

company incurred during the previous calendar year. The report shall include completed cases and settlements only and shall not include information identifying providers or patients. The report shall be provided to the Betsy Lehman center for patient safety and medical errors reduction board at the center's request under annual timelines and reporting requirements established by the center with the input of the patient safety and medical errors reduction board established in subsection (c) of said section 15 of said chapter 12C. The center shall use this information in the development of evidence-based best practices to reduce errors and enhance patient safety as required by subsection (e) of said section 15 of said chapter 12C to increase awareness of error prevention strategies through public and professional education.

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

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

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

SECTION 13. Chapter 175 of the General Laws is hereby amended by inserting after 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

(iii) the prescription eye drops prescribed by the health care practitioner are a covered benefit 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:-

Section 8LL. A contract between a subscriber and the corporation under an individual or group hospital service plan which is 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 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 (iii) the prescription eye drops prescribed by the health care practitioner are a covered benefit under the policy or contract of the insured.

SECTION 15. Chapter 176B of the General Laws is hereby amended by inserting after 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:-

Section 4DD. An individual or group health maintenance contract 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 (iii) the prescription eye drops prescribed by the health care practitioner are a covered benefit under the policy or contract of the insured.

SECTION 17. Not more than 180 days after the effective date of this act, the department of public health and the board of registration in optometry shall promulgate the rules and regulations required by sections 7 and 9 of chapter 94C of the General Laws and sections 66A, 66B, 66C and 68C of chapter 112 of the General Laws.