CENTER FOR HEALTH INFORMATION AND ANALYSIS

MANDATED BENEFIT REVIEW OF H.B. 903: AN ACT RELATIVE TO PRESCRIPTION EYE DROPS

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BENEFIT MANDATE OVERVIEW H.B. 903: AN ACT RELATIVE TO PRESCRIPTION EYE DROPS

HISTORY OF THE BILL

The Joint Committee on Financial Services referred House Bill (H.B.) 903, "An Act relative to prescription eye drops," sponsored by Rep. Farley-Bouvier of Pittsfield in the 188th General Court (and submitted as H.B. 841 in the 189th General Court), to the Center for Health Information and Analysis (CHIA) for review. Massachusetts General Laws, chapter 3, section 38C requires CHIA to review and evaluate the potential fiscal impact of each mandated benefit bill referred to the agency by a legislative committee.

WHAT DOES THE BILL PROPOSE?

H.B. 903 requires health insurance plans to cover "a refill of prescription eye drops in accordance with guidance for early refills of topical ophthalmic products provided to medicare part D plan sponsors..." This guidance from the Centers for Medicare and Medicaid Services instructs insurers that best practice is to allow early refills at 70 percent of predicted days of use (e.g., allow a medication with a predicted use of 30 days to be refilled at 21 days), and to allow the same refill allowances whether the prescription is filled at a retail pharmacy or through mail-order.

MEDICAL EFFICACY OF EARLY REFILLS FOR EYE DROPS

Prescription eye drops, or topical ophthalmic solutions, are effective in treating a wide variety of conditions. H.B. 903, if enacted, would provide coverage for more frequent refills, affecting prescriptions most often used in treatments for chronic conditions such as glaucoma, uveitis, chronic dry eye, allergies, and amblyopia. This analysis uncovered no research specifically addressing how insurance coverage for early refills affects patient outcomes. However, some patients have difficulty administering eye drops as directed, and may use more drops than intended, thereby exhausting their supply before the expected days of use reflected in the prescription. Insurance benefit rules may discourage the early refill of these prescriptions, thereby making adherence to eye disease treatment regimens more difficult for some patients. Studies have shown that gaps in treatment can negatively impact patient outcomes, and for some conditions such as glaucoma, increases the patient's risk of vision loss and/or blindness.

CURRENT COVERAGE

In a survey of the ten largest insurance carriers in Massachusetts conducted for this review, all report coverage for early refills of prescription eye drops at between 70 and 85 percent of expected days of use, with some imposing limits on the number of early refills allowed.

The 188th General Court of the Commonwealth of Massachusetts, House Bill 903, "An Act relative to prescription eye drops". Accessed 6 February 2015: https://malegislature.gov/Bills/188/House/H903. In the 189th General Court of the Commonwealth of Massachusetts, House Bill 841; accessed 16 March 2015: https://malegislature.gov/Bills/189/House/H841.



COST OF IMPLEMENTING THE BILL

Because insurance carriers already provide coverage for early refills to at least some degree, the potential effect of this proposed mandate on fully-insured commercial insurance premiums is very small. It would result in an average annual increase, over five years, to the typical member's monthly health insurance premiums of between \$0.002 (0.0004%) and \$0.003 (0.0006%) per year.

The Massachusetts Division of Insurance in consultation with the Health Connector will need to be consulted to provide an analysis of estimated state liability associated with a given proposed mandated benefit bill.

PLANS AFFECTED BY THE PROPOSED BENEFIT MANDATE

Individual and group accident and sickness insurance policies, corporate group insurance policies, and HMO coverage issued pursuant to Massachusetts General Laws, as well as plans, self- and fully-insured, provided by the Group Insurance Commission (GIC) for public employees and their dependents, would be subject to this proposed mandate. The proposed benefit mandate is assumed to apply to members covered under the relevant plans, regardless of whether they reside within the Commonwealth or merely have their principal place of employment in the Commonwealth.

PLANS NOT AFFECTED BY THE PROPOSED BENEFIT MANDATE

Self-insured plans (i.e., where the employer or policyholder retains the risk for medical expenses and uses a third-party administrator or an insurer only to provide administrative functions), except for those managed under the GIC, are not subject to state-level health insurance benefit mandates. State health benefit mandates do not apply to Medicare and Medicare Advantage plans whose benefits are qualified by Medicare; consequently this analysis excludes members of fully-insured commercial plans over 64 years of age. This mandate also does not apply to federally-funded plans including TRICARE (covering military personnel and dependents), the Veterans Administration, and the Federal Employee's Health Benefit Plan. This bill does not apply to Medicaid/MassHealth.



MEDICAL EFFICACY ASSESSMENT: EARLY REFILLS FOR PRESCRIPTION EYE DROPS

Massachusetts House Bill (H.B.) 903, as drafted for the 188th General Court (and submitted as H.B. 841 in the 189th General Court), requires health insurance plans to cover "a refill of prescription eye drops in accordance with guidance for early refills of topical ophthalmic products provided to medicare part D plan sponsors..." This guidance from the Centers for Medicare and Medicaid Services instructs insurers that best practice is to allow early refills at 70 percent of predicted days of use (e.g., allow a medication with a predicted use of 30 days to be refilled at 21 days), sooner for certain beneficiaries, and to permit the same refill allowances whether the prescription is filled at a retail pharmacy or through mail-order.²

M.G.L. c. 3 § 38C charges the Massachusetts Center for Health Information and Analysis (CHIA) with reviewing the medical efficacy of proposed mandated health insurance benefits. Medical efficacy reviews summarize current literature on the effectiveness and use of the mandated treatment or service, and describe the potential impact of a mandated benefit on the quality of patient care and the health status of the population.

PRESCRIPTION EYE DROPS

Prescription eye drops, or topical ophthalmic solutions, are used to treat a wide variety of conditions, both acute and chronic. However, this mandate impacts only prescriptions for which patients require refills. Most often these are treatments for chronic conditions, including, for example, glaucoma, uveitis, chronic dry eye (keratoconjunctivitis sicca), allergic conjunctivitis, corneal transplants, certain eye surgeries, and amblyopia.³ Understanding the nature of conditions often treated with eye drops is useful in understanding the value of maintaining prescribed treatment regimens; several of these conditions are described below.

- Glaucoma is "a group of eye disorders leading to progressive damage to the optic nerve, and is characterized by loss of nerve tissue resulting in loss of vision." In the United States, glaucoma is the leading cause of preventable blindness and the second leading cause of blindness overall; at least three million people have the disease. Of those with glaucoma, over 62 percent are over age 65, and approximately 37 percent are aged 40 to 65. The most common form of the disease is associated with increased fluid pressure in the eye that may result in vision loss. According to the American Glaucoma Society (AGS), "[w]hile glaucoma may develop in individuals with or without elevated eye pressure, reducing the pressure in the eye is the only proven way to stop or slow glaucoma. The condition is chronic, and can be controlled but not cured through medication compliance and regular physician visits. Currently available treatments include medications and laser and conventional surgery. Of these, eye drops and sometimes other medications are the most commonly used, typically prescribed to reduce intraocular pressure to prevent further damage to the optic nerve.
- Uveitis is the swelling and/or irritation of the middle layer of the eye, or uvea, which supplies blood to the retina. ¹⁴ Approximately 38 people per 100,000 in the U.S. have the condition. ¹⁵ While the average age of onset is 30.7 years, approximately 5 to 10 percent of cases occur in children under age 16. ¹⁶ Uveitis is the third leading cause of blindness in developed countries, and is estimated to be the cause of 10 to 20 percent of cases of blindness in the United States. ¹⁷ Symptoms of uveitis include pain, redness, blurred vision, floating spots, and sensitivity to light. The condition can result from several causes, including certain autoimmune diseases, trauma, infections, and toxins. ¹⁸ Uveitis can cause glaucoma, cataracts, retinal detachment, and permanent vision damage or loss. ¹⁹ It is often treated with steroid eye drops, as well as drops to dilate the pupils and relieve pain. ²⁰



- Chronic dry eye syndrome is a condition in which the eye does not produce tears properly, or the tears evaporate quickly and are not of the correct consistency.²¹ The prevalence of dry eye in the United States is estimated to be 7 percent for women and 4 percent for men over the age of 50.^{22,23} The condition stems from a variety of causes, and can be accompanied by inflammation of the eye surface.²⁴ Chronic dry eye syndrome can lead to ulcers, pain, scarring on the eye surface, and potentially some vision loss, although permanent loss is not common.²⁵ Currently, the anti-inflammatory drug cyclosporine is the only prescription medication specifically approved to treat dry eye, and is used to decrease corneal damage, increase tear production, and reduce symptoms.²⁶ Other prescription drops or ointments, such as antibiotics or corticosteroids, can be used in certain cases.²⁷
- Allergic conjunctivitis is an allergic reaction, often to common irritants such as pollen, in which the body produces antibodies that in turn triggers mast cells in the mucous linings of the eyes and airways to release inflammatory substances such as histamines.²⁸ One study estimated the prevalence of the condition at 15 to 20 percent of the population, although the study authors suspect the rate could be significantly higher and recommend additional research.²⁹ Symptoms include tearing, inflammation, and intense itching of the eyes.³⁰ Treatment is most often with allergy eye drops and/or corticosteroids.³¹

EARLY REFILLS FOR PRESCRIPTION EYE DROPS

H.B. 903 does not require coverage for prescription eye drops in general, and in fact almost all are already covered by insurers. Instead it addresses terms and conditions of coverage, specifically the availability of early refills. Therefore, this review will not address the efficacy of prescription eye drops, but assumes that these FDA-approved treatments are effective for the conditions for which they are prescribed. Instead, the research presented summarizes studies measuring patient eye drop prescription adherence, or patients' ability to use the volume of the prescribed medication as directed, the potential adverse outcomes of non-adherence, and the relationship between patient adherence and insurance coverage rules regarding refills.

Administration of eye drops

Some patients have difficulty administering eye drops in their own eyes; these patients may not instill the correct number of drops successfully in the eye, or they may dispense too many drops at one time. One study of patients instilling eye drops to treat glaucoma found that, while most patients claim to have no problems using the drops correctly, less than one-third were able to actually do so.³² A more recent study found these problems persist even with patients who have significant experience in using drops.³³

Potential adverse outcomes of non-adherence

According to a study that assessed patient self-efficacy with general glaucoma medication adherence and eye drop technique, patients less adherent to their glaucoma medication regimen, including those less able to administer their eye drops effectively, are "significantly more likely" to experience more severe outcomes. This may include irreversible vision impairment and/or blindness, or an increased likelihood that surgical intervention will be needed. A report published by the California Health Benefits Review Program stated that "in advanced cases of glaucoma or uveitis, lapses in therapy of only 2 to 3 days could result in further vision loss." This result aligned with other research that found poor patient compliance increased the occurrence of blindness for glaucoma patients.



The relationship between adherence and coverage rules for refills

For patients with coverage for prescription medications, the time interval between refills is often set by their insurance carrier or the insurance carrier's contracted pharmacy benefit management company. Clinicians have indicated these restrictions can prohibit patients who have difficulty administering eye drops from obtaining early refills when they have prematurely exhausted their medication supply, making adherence to their treatment regimens more difficult. Recording to a joint statement by the American Academy of Ophthalmology and the American Glaucoma Society, [o]phthalmologists are increasingly aware that restrictions on medication availability are a component of poor outcomes in glaucoma treatment. In the first study of its kind, a recently-published analysis attempted to measure how often patients ran out of glaucoma eye drops prior to a scheduled refill, finding that 5 percent of survey respondents routinely ran out of their prescription medication between refills, and 25 percent reported this "early exhaustion" at least once per year. The researchers' survey data suggests that "[o]ne barrier to patient adherence... is an inadequate amount of medication available between prescription refills."

In response to this problem and to complaints filed by patients and providers, in 2010 the Centers for Medicare and Medicaid Services issued a guidance memo for Medicare Part D (pharmacy) plan sponsors, advising them of best practice policy for their Medicare Part D prescription plans. The guidance stated that:

CMS recognizes that early refill edits are an important utilization management tool used to promote compliance and prevent waste. However, it is equally important that Part D sponsors implement such edits in a manner that does not unreasonably put beneficiaries at risk of interruptions in drug therapy that potentially have serious consequences.⁴⁴

The memo goes on to state that refill schedules set for tablets and capsules "are not necessarily appropriate for other dosage forms for which administration is not as easily measured and controlled." CMS advised insurers to allow refills at 70 percent of predicted days of use for both retail and mail-order prescriptions and to allow physicians to authorize even earlier refills for specific patients who may need them. This guidance is not a directive, however, and CMS has not conducted research on the impact of its implementation by Medicare carriers.

Although most insurance carriers have adopted these recommendations on behalf of their Medicare patients, Medicare covers only about half of glaucoma patients. Beyond this, as of March 2015, ten states have enacted prescription eye drops early refill legislation.⁴⁸ In a survey of the ten largest insurance carriers in Massachusetts conducted for this review, all report coverage for early refills of prescription eye drops at between 70 and 85 percent of expected days of use for all fully-insured commercial patients, with some imposing limits on the number of early refills allowed.

The effect of eye drop refill coverage on outcomes

This analysis uncovered no specific research outlining the impact on patient outcomes of insurance coverage for early refills of eye drops. However, glaucoma is a chronic disease, and the leading cause of preventable blindness in the United States. The main treatment for the disease is the consistent and correct use of eye drops to maintain intraocular pressure. If a patient does not use the drops correctly or consistently, the risk of blindness or vision loss increases. Treatment outcomes of other eye conditions are likewise dependent on the correct and consistent use of eye drops.

Eye drops are more difficult to administer consistently than other medication types, such as pills. There is evidence some patients have difficulty instilling eye drops as directed, often using more drops than intended and exhausting their supply before the prescribed expected days of use. Based on insurance administrative rules, patients may then have to wait to obtain additional medication, thereby disrupting their treatment. This treatment gap can negatively impact patient outcomes, and in the case of glaucoma, increases the patient's risk of vision loss and/or blindness.



ENDNOTES

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APPENDIX

Actuarial Assessment of House Bill 903 Submitted to the 188th General Court: "An Act relative to prescription eye drops"

Prepared for Commonwealth of Massachusetts Center for Health Information and Analysis

April 2015

Prepared by Compass Health Analytics, Inc.



Actuarial Assessment of House Bill 903 Submitted to the 188th General Court: "An Act relative to prescription eye drops"

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Actuarial Assessment of House Bill 903: "An Act relative to prescription eye drops"

Executive Summary

Massachusetts House Bill (H.B.) 903, as drafted for the 188th General Court (and submitted as H.B. 841 in the 189th General Court), would require commercial health insurance plans to "provide coverage for a refill of prescription eye drops in accordance with guidance for early refills of topical ophthalmic products provided to medicare part D plan sponsors..." This guidance from the Centers for Medicare and Medicaid Services instructs insurers that best practice is to allow early refills at 70 percent of predicted days of use (e.g., allow a medication with a predicted use of 30 days to refill at 21 days), sooner for certain beneficiaries, and to permit the same refill allowances whether the prescription is filled at either a retail pharmacy or through mail-order.²

Massachusetts General Laws (M.G.L.) c. 3 § 38C charges the Massachusetts Center for Health Information and Analysis (CHIA) with reviewing the potential impact of proposed mandated health care insurance benefits on the premiums paid by businesses and consumers. CHIA has engaged Compass Health Analytics, Inc. to provide an actuarial estimate of the effect the proposed mandate would have on the cost of health insurance in Massachusetts.

Background

Prescription eye drops, or topical ophthalmic solutions, are effective in treating a wide variety of conditions. H.B. 903, if enacted, would provide coverage for more frequent refills, affecting prescriptions most often used in treatments for chronic conditions such as glaucoma, uveitis, chronic dry eye, allergies, and amblyopia.³ However, some patients have difficulty administering eye drops as directed, and may dispense more drops than intended, thereby exhausting their supply before the prescribed expected days of use.

The key provision of H.B. 903 requires commercial carriers to provide prescription eye drop refills in accordance with early refill guidance provided to Medicare Part D plan sponsors by the Centers for Medicare and Medicaid Services (CMS), described above.

In a recent survey of ten of the largest insurance carriers in Massachusetts, all reported coverage for early refills of prescription eye drops. The proposed mandate would require carriers to cover refills for eye drop prescriptions at any time on or after 70 percent of the expected days of use as reflected in the prescription (e.g., as early as day 21 of a 30-day prescription). The carriers report coverage for early refills at between 70 and 85 percent of the prescribed days of use.

Analysis

The incremental impact on premiums of the proposed legislation will stem from the difference between Medicare Part D guidelines and current carrier practice and the extent to which earlier

refills generate increased utilization of prescription eye drop refills by patients. Compass estimated the impact on premiums by executing the following steps:

- Construct a historical baseline profile of prescription eye drop products broken into claims, utilization, and average unit cost, using the Massachusetts All Payer Claim Database (APCD).
- Calculate the distribution of refills per patient (user) to estimate the number of additional refills under the proposed mandate. Note that only users with a prescription for more than one month of drops may need early refills.
- Summarize current carrier coverage for prescription eye drop early refills and compare it to the coverage proposed by H.B. 903.
- Using available literature on the number of patients likely to need early prescription refills, develop an estimated range of increased utilization due to the mandated coverage adjusted for current coverage levels.
- Apply estimated incremental utilization to the baseline claim cost to calculate incremental spending, dividing by the corresponding membership to derive per member per month (PMPM) costs.
- Estimate the impact of insurer retention (administrative costs and profit) on premiums.
- Estimate the fully-insured Massachusetts population under age 65, projected for the next five years (2016 to 2020).
- Project the estimated cost over the next five years.

Factors affecting the analysis

The utilization estimate includes some uncertainty due to limited information regarding the proportion of the population needing early refills. While there is substantial evidence that patients often incur wastage and therefore need more drops per dose than prescribed, the extent to which this necessitates early refills is not certain. Because eye drop bottles allow for some waste, and the amount of waste varies among patients, it is difficult to predict the additional utilization resulting from covering earlier refills.

In addition, confusion on the part of members and pharmacists surrounding differing levels of coverage between commercial carriers creates uncertainty. Some patients may do without eye drops until the next scheduled refill date, even if their coverage allows for early refills. Standardizing coverage among commercial carriers could mitigate this effect, thus increasing utilization.

This uncertainty is addressed by modeling a reasonable range of assumptions based on judgment. To the extent that the increased utilization is greater or less than assumed, the impact of the legislation may differ slightly from that presented in this analysis, but the difference is not likely to be material given the very low dollar impact of the mandate when viewed at the level of the overall fully-insured commercial market.

Summary results

Table ES-1 summarizes the effect of H.B. 903 on premiums for fully-insured plans, averaged over five years. Note that the effective date of the relevant provisions is assumed to be January 1, 2016.

This analysis estimates that the proposed mandate, if enacted, would increase fully-insured premiums by as much as .0006 percent on average over the five years following the effective date. The low proportion (around 0.1 percent) of the population that uses prescription eye drops with multiple fills in conjunction with the level of coverage for early refills currently provided by commercial carriers produces a minor incremental cost stemming from the proposed mandate.

Finally, the impact of the proposed mandate on any one individual, employer-group, or carrier may vary from the overall results depending on the current level of benefits each receives or provides, and on how the benefits will change under the mandate.

Table ES-1: Summary Results

						Weighted	
	2016	2017	2018	2019	2020	Average	5 Yr Total
Members (000s)	2,329	2,305	2,279	2,253	2,226		
Medical Expense Low (\$000s)	\$33	\$47	\$49	\$51	\$53	\$50	\$233
Medical Expense Mid (\$000s)	\$38	\$55	\$57	\$60	\$62	\$58	\$273
Medical Expense High (\$000s)	\$44	\$64	\$67	\$69	\$72	\$67	\$316
Premium Low (\$000s)	\$36	\$53	\$54	\$56	\$59	\$55	\$258
Premium Mid (\$000s)	\$42	\$61	\$64	\$66	\$69	\$64	\$302
Premium High (\$000s)	\$49	\$71	\$74	\$77	\$80	\$75	\$350
PMPM Low	\$0.002	\$0.002	\$0.002	\$0.002	\$0.002	\$0.002	\$0.002
PMPM Mid	\$0.002	\$0.002	\$0.002	\$0.002	\$0.003	\$0.002	\$0.002
PMPM High	\$0.002	\$0.003	\$0.003	\$0.003	\$0.003	\$0.003	\$0.003
Estimated Monthly Premium	\$473	\$487	\$501	\$515	\$530	\$487	\$487
Premium % Rise Low	0.0004%	0.0004%	0.0004%	0.0004%	0.0004%	0.0004%	0.0004%
Premium % Rise Mid	0.0005%	0.0005%	0.0005%	0.0005%	0.0005%	0.0005%	0.0005%
Premium % Rise High	0.0005%	0.0005%	0.0005%	0.0005%	0.0006%	0.0006%	0.0006%

Executive Summary Endnotes

¹ The 188th General Court of the Commonwealth of Massachusetts, House Bill 903, "An Act relative to prescription eye drops". Accessed 6 February 2015: https://malegislature.gov/Bills/188/House/H903. In the 189th General Court of the Commonwealth of Massachusetts, House Bill 841; accessed 16 March 2015: https://malegislature.gov/Bills/189/House/H841.

² Tudor CG, Kelman J. Early Refill Edits on Topical Ophthalmic Products [Memorandum]. Centers for Medicare and Medicaid Services (CMS), Center for Medicare to All Part D Plan Sponsors. Released 2 June 2010; accessed 29 January 2015: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoEarlyRefillOpth 060210.pdf.

³ Interview with Cynthia Mattox, MD, Vice President, American Glaucoma Society; Vice Chair for Clinical Services, Department of Ophthalmology; Director, Glaucoma and Cataract Service; Director, New England Eye Center at Steward St. Elizabeth's Medical Center; Co-Director, Glaucoma Fellowship; Vice Chair of Ophthalmology; Assistant Professor, Tufts University School of Medicine; 9 January 2015. https://www.tuftsmedicalcenter.org/PhysicianDirectory/Cynthia-Mattox.aspx.

Actuarial Assessment of House Bill 903: "An Act relative to prescription eye drops"

1. Introduction

Massachusetts House Bill (H.B.) 903, as drafted for the 188th General Court (and submitted as H.B. 841 in the 189th General Court), would require in part that commercial health insurance plans "shall provide coverage for a refill of prescription eye drops in accordance with guidance for early refills of topical ophthalmic products provided to medicare part D plan sponsors..." This guidance from the Centers for Medicare and Medicaid Services instructs insurers that best practice is to allow early refills at 70 percent of predicted days of use (e.g. allow a medication with a predicted use of 30 days to refill at 21 days), sooner for certain beneficiaries, and to permit the same refill allowances whether the prescription is filled at a retail pharmacy or through mail-order.² Massachusetts General Laws (M.G.L.) c. 3 § 38C charges the Massachusetts Center for Health Information and Analysis (CHIA) with reviewing the potential impact of proposed mandated health insurance benefits on the premiums paid by businesses and consumers. CHIA has engaged Compass Health Analytics, Inc. to provide an actuarial estimate of the effect the proposed mandate would have on the cost of health insurance in Massachusetts.

Assessing the impact of this proposed mandate on premiums entails analyzing its incremental effect on spending by insurance plans. This in turn requires comparing spending under its provisions to spending under current statutes and current benefit plans for the relevant services.

Section 2 of this analysis outlines the provisions of the proposed mandate. Section 3 summarizes the methodology used for the estimate. Section 4 discusses important considerations in translating the mandate's language into estimates of its incremental impact on health care costs and steps through the calculations. Section 5 summarizes the results.

2. Interpretation of H.B. 903

The following subsections describe the provisions of H.B. 903, as drafted for the 188th General Court, related to coverage for prescription eye drops.

2.1. Plans affected by the proposed mandate

If enacted, H.B. 903 would amend M.G.L. chapter 1760, Health Insurance Consumer Protections, which affects plans offered by health insurance carriers directly governed by other statutory chapters, specifically accident and sickness insurance policies (governed by c. 175), hospital service corporations (c. 176A), medical service corporations (c. 176B), and HMOs (c. 176G).³ Based on the sponsor's responses to questions on the intent of the bill, this analysis also assumes the bill was intended to apply to all plans, fully-insured and self-insured, offered by the Group Insurance Commission for the benefit of state and local employees and their dependents.

This analysis assumes the bill requires coverage for members under the relevant Massachusetts-licensed plans regardless of whether they reside within the Commonwealth or merely have their principal place of employment in the Commonwealth.

Self-insured plans, except for those managed by the GIC, are not subject to state-level health insurance benefit mandates. State mandates do not apply to Medicare or Medicare Advantage plans, and this analysis does not address any potential effect of the bill on Medicare supplement plans even to the extent they are regulated by state law. This analysis does not apply to Medicaid/MassHealth.

This analysis assumes the proposed legislation, if enacted, would be effective for policies issued or renewed on or after January 1, 2016.

2.2. Covered services

Prescription eye drops, or topical ophthalmic solutions, are effective in treating a wide variety of conditions. H.B. 903, if enacted, would provide coverage for more frequent refills, affecting prescriptions most often used in treatments for chronic conditions such as glaucoma, uveitis, chronic dry eye, allergies, and amblyopia.⁴ However, some patients have difficulty administering eye drops as directed, and may dispense more drops than intended, thereby exhausting their supply before the prescribed expected days of use.

For patients with insurance coverage for prescription medications, the time interval between refills is often set by their insurance carrier or the insurer's contracted pharmacy benefits management company. Clinicians have indicated that these restrictions often prohibit patients who have difficulty administering eye drops from obtaining early refills when they have prematurely exhausted their medication supplies, creating a barrier to treatment adherence.^{5,6,7}

In response to this problem and to complaints filed by patients and providers, in 2010 the Centers for Medicare and Medicaid Services (CMS) issued a guidance memo for Medicare Part D (pharmacy) plan sponsors, advising them of best practice policy for their Medicare Part D prescription plans. The memo states that refill schedules set for tablets and capsules "are not necessarily appropriate for other dosage forms for which administration is not as easily measured and controlled." CMS advised insurers to allow refills of topical ophthalmic products at 70 percent of predicted days of use for both retail and mail-order prescriptions, and flexibility for physicians to authorize even earlier refills for specific patients who may need them.

The key provision of H.B. 903 requires commercial carriers to provide prescription eye drop refills in accordance with early refill guidance provided to Medicare Part D plan sponsors by CMS. The three components of the CMS guidance that would affect the commercial market as a result of this mandate are:

• The effect of H.B. 903 on pharmacy edits for early refills. Medicare Part D guidance recommends that sponsors "Permit refills at 70% of the predicted days of use. By way of an example, for a prescribed medication with an expected duration of 30 days of use,

the refills would be permitted at day 21."¹⁰ H.B. 903 would require commercial insurers to cover refills following the guidance that applies to these Medicare sponsors.

- Consistent refill practice for retail and mail order prescriptions. Medicare part D guidance recommends sponsors "ensure that the refill allowances are the same regardless of purchase through retail or mail-order sources." H.B. 903 would require insurers to apply the same early refill rules to both retail and mail prescriptions.
- Exceptions to early refill edits. Medicare part D guidance recognizes that the suggested edits will not meet the needs of all patients and significant wastage could occur, requiring some patients to request refills even prior to the time allowed in the edits above. The Medicare Part D guidance permits "physicians to authorize earlier refills than 70% days of use for particular beneficiaries who continue to have difficulty with inadvertent wastage." H.B. 903 would require insurers to cover refills when a prescriber authorizes them for a patient who needs them even earlier than at 70 percent days of expected use.

These Medicare Part D provisions are each considered below in an analysis of their impact on the Massachusetts fully-insured commercial market.

2.3. Current coverage

In a recent survey of ten of the largest insurance carriers in Massachusetts, all reported coverage for early refills of prescription eye drops. The proposed mandate would require carriers to cover refills for eye drop prescriptions at any time on or after 70 percent of the expected days of use as reflected in the prescription (e.g., as early as day 21 of a 30-day prescription). The carriers report coverage of early refills at between 70 and 85 percent of the prescribed days of use. Most carriers apply the same early refill percentage to both retail and mail-order prescriptions. The weighted average of current coverage across all carriers and types of prescriptions allows for early refills at about 77 percent of the expected days' supply.

2.4. Existing laws affecting the cost of H.B. 903

This analysis has uncovered no current Massachusetts insurance mandates regarding insurance coverage for prescription eye drop refills. No existing federal mandates related to the specific subject matter of this bill and applicable to commercial insurance have been identified.

3. Methodology

3.1. Overview

As described above, the proposed legislation would require commercial carriers to provide prescription eye drop refills in accordance with early refill guidance provided to Medicare Part D plan sponsors by CMS. Based on a survey of Massachusetts health insurance carriers, early refills

for prescription eye drops are covered by all carriers, but some carriers cover refills only after more than the 70 percent of expected days of use suggested by the CMS guidance and required by the proposed mandate. The incremental impact on premiums of the proposed legislation would stem from the difference between Medicare Part D guidelines and current carrier practice and how that difference translated into increased utilization of prescription eye drop refills by patients.

3.2. Steps in the analysis

The general approach outlined above was executed in the following steps.

Analyze the impact of the proposed mandate on service delivery

- Construct a historical baseline profile of prescription eye drop products broken into claims, utilization, and average unit cost, using the Massachusetts All Payer Claim Database (APCD).
- Calculate the distribution of refills per patient (user) to estimate the number of additional refills under the proposed mandate. Note that only users with a prescription for more than one month of drops may need early refills.
- Summarize current carrier coverage for prescription eye drop early refills and compare that to the coverage required by H.B. 903.
- Using available literature on the number of patients likely to need early prescription refills, develop an estimated range of increased utilization due to the mandated coverage adjusted for current coverage levels.

Calculate the impact of projected spending on insurance premiums

- Apply estimated incremental utilization to the baseline claim cost to calculate incremental spending, dividing by the corresponding membership to derive per member per month (PMPM) costs.
- Estimate the impact of insurer retention (administrative costs and profit) on premiums.
- Estimate the fully-insured Massachusetts population under age 65, projected for the next five years (2016 to 2020).
- Project the estimated cost over the next five years.

Section 4 describes these specific steps in more detail.

3.3. Potential cost and utilization impacts of the proposed mandate

Because prescription eye drop refills are currently covered by carriers at a level fairly close to the level of coverage proposed by H.B. 903, the expected impact of the proposed mandate on premiums is small. As discussed previously, the weighted average of current coverage across all carriers and types of prescriptions allows for early refills at approximately 77 percent of the expected days

supply vs. the 70 percent required by this mandate. As a result only a small increase in utilization is expected.

However, the level of coverage varies by commercial carrier. When an eye drop supply is exhausted, carriers allow a range of coverage of early refills at between 70 and 85 percent of the prescribed days of use. In addition to this range, criteria for obtaining a refill are administered differently among the carriers. For example, some require that the pharmacist call the carrier with the reason for the early refill. Some carriers include limits to the number of early refills allowed in a calendar year; one carrier allows only one early refill every six months. These differences make it difficult for physicians and pharmacists to advise patients about their coverage, and may result in some patients not taking advantage of the coverage they have. Creating a standard coverage level across all carriers will improve access to early refills for all patients, which will in turn expand the expected increase in utilization.

In estimating the impact on premiums under different assumptions, it is also important to understand the member's own awareness and use of his or her current benefit levels. Patient confusion about benefits may make an early refill request by the patient less likely. To the extent this is occurring it depresses current utilization, and therefore standardization of the benefit may provide another source of utilization increase.

This analysis models different degrees of patient awareness of current coverage levels in the low, medium, and high cost scenarios.

3.4. Data sources

The primary data sources used in the analysis were:

- Information from clinicians, cited as appropriate.
- Information from a survey administered to private health insurance carriers in Massachusetts.
- Academic literature, published reports, and population data cited as appropriate.
- Massachusetts insurer claim data from CHIA's Massachusetts All Payer Claim Database (APCD) for calendar year 2012, for plans covering the majority of the under-65 fully insured population subject to the mandate.

The more detailed step-by-step description of the estimation process described below addresses limitations in some of these sources and uncertainties they contribute to the cost estimate.

3.5. Limitations

This analysis relies primarily on an assessment of the need for additional refills for prescription eye drops under the provisions of H.B. 903. The estimates draw on 2012 statewide data on prescription eye drops and their paid claim costs.

The utilization estimate includes some uncertainty due to limited information regarding the proportion of the population needing early refills. While there is substantial evidence that patients often incur wastage and therefore use more than the specified dose per administration, the extent to which that would necessitate early refills is not certain. Because eye drop bottles allow for some waste, and the amount of waste varies among patients, it is difficult to predict the additional utilization resulting from covering earlier refills.

In addition, the confusion surrounding differing levels of coverage between commercial carriers, as described in section 3.3, creates uncertainty when attempting to measure current utilization. Some patients may do without drops until the next scheduled refill date even if their coverage would allow for the earlier refill. Standardizing the coverage among commercial carriers could mitigate this effect and increase utilization.

This uncertainty is addressed by modeling a reasonable range of assumptions based on judgment. To the extent that the increased utilization is greater or less than assumed, the impact of the legislation may differ slightly from that presented in this analysis, but the difference is not likely to be material given the very low dollar impact of the mandate when viewed at the level of the overall fully-insured commercial market.

4. Analysis

This section describes the actual calculations outlined in the previous section in more detail. The analysis includes development of a best estimate "middle-cost" scenario, as well as a low-cost scenario using assumptions that produced a lower estimate, and a high-cost scenario using more conservative assumptions that produced a higher estimated impact.

Section 4.1 below describes the steps used to calculate the baseline cost used in the estimation of incremental cost. Sections 4.2 and 4.3 describe current coverage and the estimated impact on utilization of enacting the bill. Sections 4.4 to 4.7 discuss the incremental cost calculation and the projection over the reporting period. The analysis drew on observed prescription eye drop claim cost from 2012 data, and developed increased utilization assumptions and calculations for the projection period as described in the sub-sections that follow. The incremental spending was projected for the period January 1, 2016 to December 31, 2020 using an annual pharmacy inflation rate from a CMS study; 13 trends are in the range of 0.0 percent to 7.6 percent, averaging 4.6 percent.

4.1. Baseline: average costs for prescription eye drops

The impact of H.B. 903 on premiums stems from requiring carriers to cover early refills for topical ophthalmic products. To establish a baseline expense level for products affected by the mandate, Compass calculated total allowed and paid claim costs for prescriptions eye drops and corresponding eligible membership levels for 2012 using the Massachusetts APCD. Allowed claims include all claim dollars (before member cost sharing) covered by the commercial carriers. Paid claims are allowed claims less member cost sharing (co-pays, deductibles, coinsurance, etc.) and represent the commercial carrier's cost. The early refill requirement would apply to prescriptions

with additional quantities allowed on the original prescription (refillable prescriptions). To estimate the increased utilization stemming from early refills, prescription eye drop utilization was restricted to prescriptions with refills or multiple fills. Since this analysis measures the incremental cost of the mandate incurred by the commercial carriers, paid claims were used for the baseline. Table 1 shows the cost of prescription eye drop claims for total allowed dollars, total paid dollars, and paid dollars for prescription eye drops with refills. Table 1 also displays the corresponding member months and the resulting PMPM costs.

Table 1: Per Member per Month Allowed and Paid Costs

	<u>Claims</u>	Member Months	<u>PMPM</u>
All Eye drops Allowed Claims	\$10,447,485	17,064,716	\$0.61
All Eye Drops Paid Claims	\$6,588,697	17,064,716	\$0.39
Eye Drops with Refills Paid Claims	\$3,341,549	17,064,716	\$0.20

In 2012, prescriptions with refills accounted for about 51 percent of all prescription eye drop claim dollars. This subset of prescriptions represents the baseline costs from which the incremental cost of early refills was calculated.

4.2. Summary of carriers' current coverage

As discussed previously, responses to a survey of the ten largest Massachusetts commercial health insurance carriers indicated that early refills of eye drops are covered at between 70 and 85 percent of the prescribed days of use, with a weighted average coverage of about 77 percent of the prescribed days of use. H.B. 903 proposes that when eye drops supplies are exhausted at 70 percent of the prescribed days of use commercial carriers must cover early refills. Based on an interview with a Massachusetts pharmacist, early refills are rarely denied by commercial carriers. However, because current coverage varies by carrier, this analysis anticipates that patients may not always take advantage of their current coverage. Creating a standard and somewhat improved level of coverage across all carriers is expected to have some impact on utilization, as discussed in the next section.

4.3. Increased utilization from early refills

Section 4.1 developed the baseline cost to which the analysis will apply the expected increase in the rate of utilization resulting from the change in coverage for early refills. The impact on carrier spending due to the proposed mandate will be driven by additional utilization by those members currently paying for early refills out of pocket or going without their medication.

It is common for patients to incur a certain amount of wastage when administering eye drop medication. According to the American Academy of Ophthalmology "53-61% of regular eye drop patients administer more than one drop and 80% with visual co morbidities administer more than one drop."¹⁴ However, the Academy does not quantify the number of patients that need an early refill. Based upon input from a practicing ophthalmologist, prescription eye drop prescriptions

allow for a certain amount of waste, so not all patients that incur wastage need early refills. To estimate the expected increase Compass reviewed a recent published study examining glaucoma patients and their need to refill their prescriptions early, and the prevalence of self-reported early eye drop bottle exhaustion. The results showed that about 25 percent of the patients reported problems with early exhaustion of eye drop bottles. Five percent reported that they either "often" (5 to 7 times per year), "usually" (8 to 11 times per year), or "always" ran out of eye drops prior to a scheduled refill.¹⁵

Taking into account the days' supply and the above-cited portion of the population requiring an early refill, Compass calculated two measures of increased utilization. The first compared the rate of early prescription exhaustion from the glaucoma study to that expected with coverage as reported by the commercial carriers from the carrier survey, resulting in an estimated increase in overall utilization of between 0.4 and 0.6 percent. The second compared the early exhaustion rate from the glaucoma study to a scenario with no coverage for early refills. In this case the increase in overall utilization is between 3.2 and 4.1 percent.

As discussed in Section 3, the increase in utilization from this proposed mandate will depend on two things: (i) the change from the current coverage with commercial carriers to the coverage required under the mandate, and (ii) the extent that current coverage is under-utilized due to confusion around existing coverage and administrative burdens. Discussions with practicing pharmacists suggest that obtaining early refills in accordance with carrier coverage may be somewhat burdensome but does not result in claim denials or patients paying out of pocket; however, some patients might not attempt to obtain early refills when needed.

As noted above, the effect of item (i) is between 0.4 and 0.6 percent. Assuming item (ii) – the percentage of the time an early refill that would have been covered by the carriers is not requested by the patient – is 10 percent, the increased utilization from that effect would be between 0.3 and 0.4 percent (the result of multiplying the 10 percent patient deterrence factor by the 3.2 to 4.1 utilization increase estimated above for the no-early-refills scenario). Combining the effects of these two sources of increased utilization results in an increased utilization range of 0.7 to 1.0 percent.

Based on these assumptions, Table 2 displays the projected increase in utilization of eye drop prescriptions under the provisions of H.B. 903.

Table 2: Impact to Overall Utilization as a Result of Additional Early Refills

	<u>Utilization</u>
	<u>Increase</u>
Low Scenario	0.7%
Mid Scenario	0.8%
High Scenario	1.0%

4.4. Incremental cost calculation

The effect of the proposed mandate on insurer medical expense was derived by applying the estimated incremental utilization from Table 2 to the baseline paid claim cost for prescriptions with early refills (\$0.20 PMPM from Table 1). The incremental cost was then divided by the total members (member months) in the 2012 base data, yielding the incremental PMPM cost in Table 3.

Table 3: Estimate of PMPM Increase in Carrier Spending

Low Scenario	\$0.001
Mid Scenario	\$0.002
High Scenario	\$0.002

4.5. Carrier retention and increase in premium

Assuming an average retention rate of 9.7 percent, based on CHIA's analysis of administrative cost and profit in Massachusetts, the increase in medical expense was adjusted upward to approximate the total impact on premiums. Table 4 shows the result.

Table 4: Estimate of Increase in Carrier Spending with Retention

Low Scenario	\$0.002
Mid Scenario	\$0.002
High Scenario	\$0.002

4.6. Projected fully-insured population in Massachusetts

Table 5 shows the fully-insured population in Massachusetts ages 0 to 64 projected for the next five years. Appendix A describes the sources of these values.

Table 5: Projected Fully-Insured Population in Massachusetts, Ages 0-64

Year	Total (0-64)
2016	2,329,040
2017	2,304,658
2018	2,279,367
2019	2,253,405
2020	2,226,328

Projecting the five-year impact of the proposed mandate requires projecting the 2012 baseline PMPM cost forward to the same 2016-2020 period, discussed next.

4.7. Projection

The incremental PMPM premium from Section 4.5 was multiplied by the member months from Section 4.6 to estimate projected incremental costs. The results are presented in the next section.

5. Results

The estimated impact of the proposed mandate is outlined below. The analysis includes a best estimate "mid-level" scenario, as well as a low-level scenario using assumptions that produced a lower estimate, and a high-level scenario using more conservative assumptions.

5.1. Five-year estimated impact

For each year in the five-year analysis period, Table 6 displays the projected net impact on medical expense and premiums using projected fully-insured membership. Note that H.B. 903 is assumed effective for policies issued or renewed on or after January 1, 2016.¹⁶

This analysis estimates the mandate, if enacted, would increase fully-insured premiums by as much as .0006 percent on average over the five years following the effective date. The low proportion (around 0.1 percent) of the population that uses prescription eye drops with multiple fills in conjunction with the level of coverage for early refills currently provided by commercial carriers produces a minor incremental effect.

Finally, the impact of the proposed mandate on any one individual, employer-group, or carrier may vary from the overall results depending on the current level of benefits each receives or provides, and on how the benefits will change under the mandate.

Table 6: Summary Results

						Weighted	
	2016	2017	2018	2019	2020	Average	5 Yr Total
Members (000s)	2,329	2,305	2,279	2,253	2,226		
Medical Expense Low (\$000s)	\$33	\$47	\$49	\$51	\$53	\$50	\$233
Medical Expense Mid (\$000s)	\$38	\$55	\$57	\$60	\$62	\$58	\$273
Medical Expense High (\$000s)	\$44	\$64	\$67	\$69	\$72	\$67	\$316
Premium Low (\$000s)	\$36	\$53	\$54	\$56	\$59	\$55	\$258
Premium Mid (\$000s)	\$42	\$61	\$64	\$66	\$69	\$64	\$302
Premium High (\$000s)	\$49	\$71	\$74	\$77	\$80	\$75	\$350
PMPM Low	\$0.002	\$0.002	\$0.002	\$0.002	\$0.002	\$0.002	\$0.002
PMPM Mid	\$0.002	\$0.002	\$0.002	\$0.002	\$0.003	\$0.002	\$0.002
PMPM High	\$0.002	\$0.003	\$0.003	\$0.003	\$0.003	\$0.003	\$0.003
Estimated Monthly Premium	\$473	\$487	\$501	\$515	\$530	\$487	\$487
Premium % Rise Low	0.0004%	0.0004%	0.0004%	0.0004%	0.0004%	0.0004%	0.0004%
Premium % Rise Mid	0.0005%	0.0005%	0.0005%	0.0005%	0.0005%	0.0005%	0.0005%
Premium % Rise High	0.0005%	0.0005%	0.0005%	0.0005%	0.0006%	0.0006%	0.0006%

5.2. Impact on the GIC

The proposed mandate is assumed to apply to both fully-insured and self-insured plans operated for state and local employees by the Group Insurance Commission (GIC), with an effective date for all GIC policies on July 1, 2016.

The benefit offerings of GIC plans are similar to those of most other commercial plans in Massachusetts. However, based on data from the 2012 Massachusetts APCD, the GIC's utilization for prescription eye drops (per thousand members) is about 44 percent higher than that of the general fully-insured population. As a result, the estimated effect of the proposed mandate on GIC early refill of prescription eye drop expense is expected to be about 44 percent higher than that estimated for the other fully-insured plans in Massachusetts. It is important to note approximately 30 percent of the GIC membership was identifiable in the APCD, and the utilization estimate assumes the available portion represents a reasonable sample of the overall GIC membership. To estimate the medical expense separately for the GIC, the PMPM medical expense for the general fully-insured population was applied to the GIC membership and increased by 44 percent starting in July of 2016.

Table 7 breaks out the GIC-only fully-insured membership and the GIC self-insured membership and the corresponding incremental medical expense and premium. Note that the total medical expense and premium values for the general fully-insured membership displayed in Table 6 also include the GIC fully-insured membership. Finally, the proposed mandate is assumed to require the GIC to implement the provisions on July 1, 2016; therefore, the results in 2016 represent approximately one half of an annual value.

Table 7:
GIC Self-Insured Summary Results

						Weighted	
	2016	2017	2018	2019	2020	Average	5 Yr Total
GIC Fully-Insured							
Members (000s)	59	59	59	59	59		
Medical Expense Low (\$000s)	\$1	\$2	\$2	\$2	\$2	\$2	\$8
Medical Expense Mid (\$000s)	\$1	\$2	\$2	\$2	\$2	\$2	\$10
Medical Expense High (\$000s)	\$1	\$2	\$2	\$3	\$3	\$3	\$11
Premium Low (\$000s)	\$1	\$2	\$2	\$2	\$2	\$2	\$9
Premium Mid (\$000s)	\$1	\$2	\$2	\$2	\$3	\$2	\$11
Premium High (\$000s)	\$1	\$3	\$3	\$3	\$3	\$3	\$13
GIC Self-Insured							
Members (000s)	263,430	263,158	262,793	262,352	261,763		
Medical Expense Low (\$000s)	\$4	\$8	\$8	\$9	\$9	\$8	\$37
Medical Expense Mid (\$000s)	\$4	\$9	\$10	\$10	\$11	\$10	\$44
Medical Expense High (\$000s)	\$5	\$11	\$11	\$12	\$12	\$11	\$51

Appendix A: Membership Affected by the Mandate

Membership potentially affected by a proposed mandate may include Massachusetts residents with fully-insured employer-sponsored health insurance (including through the GIC), non-residents with fully-insured employer-sponsored insurance issued in Massachusetts, Massachusetts residents with individual (direct) health insurance coverage, and, in some cases, lives covered by GIC self-insured coverage. Membership projections for 2016 to 2020 are derived from the following sources.

Total Massachusetts population estimates for 2012, 2013, and 2014 from U. S. Census Bureau data¹⁷ form the base for the projections. Distributions by gender and age, also from the Census Bureau,¹⁸ were applied to these totals. Projected growth rates for each gender/age category were estimated from Census Bureau population projections to 2030.¹⁹ The resulting growth rates were then applied to the base amounts to project the total Massachusetts population for 2016 to 2020.

The number of Massachusetts residents with employer-sponsored or individual (direct) health insurance coverage was estimated using Census Bureau data on health insurance coverage status and type of coverage²⁰ applied to the population projections.

To estimate the number of Massachusetts residents with fully-insured employer-sponsored coverage, projected estimates of the percentage of employer-based coverage that is fully-insured were developed using historical data from the Medical Expenditure Panel Survey Insurance Component Tables.²¹

To estimate the number of non-residents covered by a Massachusetts policy – typically cases in which a non-resident works for a Massachusetts employer offering employer-sponsored coverage – the number of lives with fully-insured employer-sponsored coverage was increased by the ratio of the total number of individual tax returns filed in Massachusetts by residents²³ and non-residents²³ to the total number of individual tax returns filed in Massachusetts by residents.

The number of residents with individual (direct) coverage was adjusted further to subtract the estimated number of people previously covered by Commonwealth Care who moved into MassHealth due to expanded Medicaid eligibility under the Affordable Care Act.²⁴

Projections for the GIC self-insured lives were developed using GIC base data for 2012²⁵, 2013,²⁶ and 2014²⁷ and the same projected growth rates from the Census Bureau that were used for the Massachusetts population. Breakdowns of the GIC self-insured lives by gender and age were based on the Census Bureau distributions.

Endnotes

¹ The 188th General Court of the Commonwealth of Massachusetts, House Bill 903, "An Act relative to prescription eye drops". Accessed 6 February 2015: https://malegislature.gov/Bills/188/House/H903. In the 189th General Court of the Commonwealth of Massachusetts, House Bill 841; accessed 16 March 2015: https://malegislature.gov/Bills/189/House/H841.

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² Tudor CG, Kelman J. Early Refill Edits on Topical Ophthalmic Products [Memorandum]. Centers for Medicare and Medicaid Services (CMS), Center for Medicare to All Part D Plan Sponsors. Released 2 June 2010; accessed 29 January 2015: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoEarlyRefillOpth 060210.pdf.

³ See M.G.L. c. 1760, § 1 for the definition of "carrier" for that chapter. https://malegislature.gov/Laws/GeneralLaws/Partl/TitleXXII/Chapter1760/Section1.

⁴ Interview with Cynthia Mattox, MD, Vice President, American Glaucoma Society; Vice Chair for Clinical Services, Department of Ophthalmology; Director, Glaucoma and Cataract Service; Director, New England Eye Center at Steward St. Elizabeth's Medical Center; Co-Director, Glaucoma Fellowship; Vice Chair of Ophthalmology; Assistant Professor, Tufts University School of Medicine; 9 January 2015. https://www.tuftsmedicalcenter.org/PhysicianDirectory/Cynthia-Mattox.aspx.

⁵ Op. cit. Interview with Cynthia Mattox, MD; 9 January 2015.

⁶ Moore DB, Walton C, Moeller KL, et. al. Prevalence of self-reported early glaucoma eye drop bottle exhaustion and associated risk factors: a patient survey. BMC Ophthalmol. 2014 Jun 13;14:79. Accessed 30 January 2015: http://www.ncbi.nlm.nih.gov/pubmed/24927769.

⁷ Op. cit. AAO and AGS joint Position Statement on Glaucoma Eye Drop Availability.

⁸ Op. cit. Tudor CG, Kelman J. Early Refill Edits on Topical Ophthalmic Products [Memorandum].

⁹ Ibid.

¹⁰ M.G.L. c. 17, § 13. https://malegislature.gov/Laws/GeneralLaws/PartI/TitleII/Chapter17/Section13.

¹¹ Ibid.

¹² Ibid.

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