Actuarial Analysis of the Drug Formulary Commission's Abuse-Deterrent Drug Formulary under Chapter 258 of the Acts of 2014 "An Act to increase opportunities for long-term substance abuse recovery"

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Prepared by
Compass Health Analytics, Inc.

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This report was prepared by Amy Raslevich, MPP, MBA, Valerie Hamilton, RN, MHA, JD, Andrea Clark, MS, Jeffrey Stock, FSA, MAAA, Jennifer Elwood, FSA, MAAA, and James Highland, PhD.

Actuarial Analysis of the Drug Formulary Commission's Abuse-Deterrent Drug Formulary

Executive Summary

Chapter 258 of the Acts of 2014[1] was signed by Governor Deval Patrick on August 6, 2014. The new law amended the statute establishing the Drug Formulary Commission (the Commission) in the Department of Public Health (DPH), charging the Commission with preparing a drug formulary of chemically-equivalent substitutions for Schedule II and III non-abuse-deterrent opioids that the Commission determined to have a heightened level of public health risk (HPHR) due to the drugs' potential for abuse and misuse. Except in cases where the practitioner has indicated "no substitution," the new law requires pharmacists to dispense an interchangeable abuse-deterrent opioid (ADO) product, if one exists, or if none exists, a less expensive, reasonably available, interchangeable drug product as allowed by the most current formulary or supplement thereof.[2] Abuse-deterrent drug products are manufactured with physical, chemical, or other barriers that make abuse more difficult or less attractive or rewarding.

Chapter 258 provides that coverage for the abuse-deterrent drug products listed on the formulary of chemically-equivalent substitutions shall be on a basis not less favorable than non-abuse-deterrent opioid drug products, and an increase in patient cost sharing shall not be allowed. The effect of this requirement, in addition to the changes to the pharmacy substitution procedure, is to encourage a shift to abuse-deterrent opioids while insulating patients from the increased cost.

Section 4 of Chapter 258 provided that the Commission may request an insurance benefit review by the Massachusetts Center for Health Information and Analysis (CHIA). Insurance benefit reviews analyze the potential impact of mandated health care insurance benefits on the premiums paid by businesses and consumers. The Commission requested such a review, and CHIA engaged Compass Health Analytics, Inc. (Compass) to provide an actuarial estimate of the effect implementation of a draft formulary of abuse-deterrent substitutes, prepared pursuant to Chapter 258, would have on the cost of health insurance in Massachusetts.

Background

Prescription opioids are powerful pain-reducing medications that include prescription oxycodone (e.g., Oxycontin®, Percocet®), hydrocodone (e.g., Vicodin®) and morphine (e.g., Kadian®, Avinza®, MS Contin®), among others, and have both benefits as well as potentially serious risks.[3,4] Prescription opioids can help to manage moderate to severe pain when properly prescribed and used.[5,6] They reduce the intensity of pain signals reaching the brain and affect the brain areas controlling emotion, diminishing the effects of a painful stimulus.[7] When opioids are misused or abused, they can cause serious harm, including opioid use disorder,[8] overdose, and death.[9,10]

The Centers for Disease Control and Prevention (CDC) refers to the rising number of deaths by prescription overdose as an epidemic.[11] Since 1999, deaths involving opioids (including prescription opioid pain medications and heroin) in the United States have quadrupled, and during

the same time period, the amount of prescription opioids sold in the United States nearly quadrupled.[12] At least half of all opioid deaths involve a prescription opioid.[13] In response to these statistics, the federal and state governments have launched numerous initiatives, and abuse deterrent opioid formulations have been developed.

Provisions of the law pertaining to abuse-deterrent opioids

Prior to the enactment of Chapter 258, Massachusetts law required pharmacists to dispense a less expensive, reasonably available, interchangeable drug product for all prescriptions as allowed by the most current formulary or supplement thereof, except in cases where the practitioner indicated "no substitution." Chapter 258 of the Acts of 2014, amends this requirement in the case of certain prescriptions with a heightened level of public health risk (HPHR) due to the drugs' potential for abuse and misuse and provides that, except in cases where the prescriber has indicated "no substitution," the pharmacist shall dispense a chemically-equivalent abuse-deterrent product if one exists on the Commission's formulary of chemically-equivalent substitutions; or if none exists, a less expensive, reasonably available, interchangeable drug product as allowed by the current formulary.

Other sections of Chapter 258 direct carriers to cover ADOs listed on the formulary developed by the commission on a basis not less favorable than that for non-abuse-deterrent opioid drug products.

Analysis

Compass estimated the impact of the Chapter 258 drug formulary substitution requirement by analyzing:

- The utilization of each relevant drug in the draft formulary in the absence of the substitution requirement
- The utilization of each relevant formulary drug accounting for the substitution requirement
- The cost of the relevant formulary drugs

Compass then aggregated these components and projected them forward over the next two years (2017 to 2018) for the fully-insured Massachusetts population under age 65, forecasting medical inflation and adding insurer retention (administrative cost and profit) to arrive at an estimate of the bill's effect on premiums.

This analysis relies on estimates of the percent of utilization of the HPHR opioids that would be replaced by ADOs. This uncertainty is addressed by modeling a range of assumptions within reasonable judgment-based limits, and producing a range of incremental impact estimates based on varying these parameters.

Summary results

This analysis estimates that the drug formulary substitution requirement would increase fully-insured premiums by as much as 0.05 percent on average over the next two years; a more likely

increase is in the range of 0.04 percent, equivalent to an average annual expenditure of $4.1 million over the period 2017 to 2018. While the utilization of opioids may decrease in response to numerous state and federal initiatives, the cost of the mandate is driven by the comparatively higher cost of the brand name ADOs substituted for generic HPHR opioids, which currently comprise the vast majority of utilization for all of the relevant formulary drugs.

Table ES-1: Summary Results

	2017	2018	Average	2 Yr Total
Members (000s)	2,159	2,156		
Medical Expense Low ($000s)	$2,032	$2,982	$2,507	$5,014
Medical Expense Mid ($000s)	$2,988	$4,383	$3,685	$7,371
Medical Expense High ($000s)	$4,024	$5,904	$4,964	$9,928
Premium Low ($000s)	$2,284	$3,350	$2,817	$5,634
Premium Mid ($000s)	$3,357	$4,925	$4,141	$8,282
Premium High ($000s)	$4,521	$6,634	$5,578	$11,155
PMPM Low	$0.12	$0.13	$0.13	$0.13
PMPM Mid	$0.18	$0.19	$0.19	$0.19
PMPM High	$0.24	$0.26	$0.25	$0.25
Estimated Monthly Premium	$463	$473	$468	$468
Premium % Rise Low	0.03%	0.03%	0.03%	0.03%
Premium % Rise Mid	0.04%	0.04%	0.04%	0.04%
Premium % Rise High	0.05%	0.05%	0.05%	0.05%

Executive Summary Endnotes

[1] Chapter 258 of the Massachusetts Acts of 2014: "An Act to increase opportunities for long-term substance abuse recovery." Accessed 1 September 2016: https://malegislature.gov/Laws/SessionLaws/Acts/2014/Chapter258.

[2] U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER). Approved Drug Products with Therapeutic Equivalence Evaluations, 36th Edition: Orange Book Preface. Accessed 4 October 2016: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm.

Many prescribers, pharmacists, and carriers rely on therapeutic equivalent drugs to substitute generic form medications for brand form medications. One reference most often used in selecting substitutes is the U.S. Food and Drug Administration (FDA) Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book).

> The publication, Approved Drug Products with Therapeutic Equivalence Evaluations (the List, commonly known as the Orange Book), identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Drugs on the market approved only on the basis of safety (covered by the ongoing Drug Efficacy Study Implementation [DESI] review [e.g., Donnatal® Tablets and Librax® Capsules] or pre-1938 drugs [e.g., Phenobarbital Tablets]) are not included in this publication. The main criterion for the inclusion of any product is that the product is the subject of an application with an effective approval that has not been withdrawn for safety or efficacy reasons. Inclusion of products on the List is independent of any current regulatory action through administrative or judicial means against a drug product. In addition, the List contains therapeutic equivalence evaluations for approved multisource prescription drug products. These evaluations have been prepared to serve as public information and advice to state health agencies, prescribers, and pharmacists to promote public education in the area of drug product selection and to foster containment of health care costs. Therapeutic equivalence evaluations in this publication are not official FDA actions affecting the legal status of products under the FD&C Act.

[3] FDA. Drugs. Opioid Medications. Accessed 15 August 2016: http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm.

[4] National Institute on Drug Abuse (NIDA). Research Report Series. Prescription Drugs: Abuse and Addiction. Accessed 6 September 2016: https://www.drugabuse.gov/sites/default/files/rrprescription.pdf.

[5] *Op. cit.* FDA. Drugs. Opioid Medications.

[6] *Op. cit.* NIDA, Research Report Series. Prescription Drugs: Abuse and Addiction.

[7] *Op. cit.* NIDA, Research Report Series. Prescription Drugs: Abuse and Addiction.

[8] U.S. Substance Abuse and Mental Services Administration (SAMHSA). Mental and Substance Abuse Disorders. Substance Use Disorders. Accessed 1 September 2016: http://www.samhsa.gov/disorders/substance-use.

> Symptoms of opioid use disorder include a strong desire for opioids, inability to control or reduce use, continued use despite interference with major obligation or social functioning, use of larger amounts over time, development of tolerance, spending a great deal of time to obtain and use opioids, and withdrawal symptoms that occur after stopping or reducing use, such as negative mood, nausea or vomiting, muscle aches, diarrhea, fever, and insomnia.

[9] *Op. cit.* FDA, Drugs. Opioid Medications.

[10] *Op. cit.* SAMHSA, Mental and Substance Use Disorders. Substance Use Disorders.

[11] U.S. Centers for Disease Control and Prevention (CDC). Injury Prevention & Control: Opioid Overdose. Understanding the Epidemic. Last reviewed and updated June 21, 2016. Accessed 14 September 2016: https://www.cdc.gov/drugoverdose/epidemic/.

[12] *Op. cit.*CDC. Injury Prevention & Control: Opioid Overdose. Understanding the Epidemic.

[13] *Op. cit.*CDC. Injury Prevention & Control: Opioid Overdose. Understanding the Epidemic.

Actuarial Analysis of the Drug Formulary Commission's Abuse-Deterrent Drug Formulary

1. Introduction

Chapter 258 of the Acts of 2014[1] was signed by Governor Deval Patrick on August 6, 2014. Section 4 of the new law charged the Drug Formulary Commission (the Commission) in the Department of Public Health (DPH) with:

- Determining a list of drugs that are opiates[2], as defined in section 1 of chapter 94C, and contained in schedule II[3] or III[4] of section 3 of chapter 94C, that have a heightened level of public health risk (HPHR) due to the drugs' potential for abuse and misuse
- Preparing a drug formulary of chemically-equivalent[5] substitutions for drugs on this list that incorporate abuse-deterrent properties (described below)

Except in cases where the practitioner has indicated "no substitution," Section 17 of the new law requires pharmacists to dispense a chemically-equivalent abuse-deterrent opioid (ADO) drug product, if one exists; or if none exists, a less expensive, reasonably available, interchangeable drug product as allowed by the most current formulary or supplement thereof.[6] A given substituted ADO might be more expensive than the originally-prescribed drug, resulting in increased cost to health insurance carriers.

Chapter 258 provides that coverage for the ADOs listed on the formulary shall be on a basis not less favorable than that for non-abuse-deterrent opioid drug products, and an increase in patient cost sharing shall not be allowed. The effect of this requirement, on top of the changes to pharmacy substitution procedure, is to encourage a shift to abuse-deterrent opioids, while insulating patients from potential increases in cost.

In July 2016, the Commission completed analysis of a draft drug formulary[i] that included seven interchangeable abuse-deterrent drug products, as outlined in Appendix A.[7] Two of the interchangeable ADOs, Embeda® and Hysingla ER®, are chemically-equivalent substitutions for identified heightened public health risk (HPHR) opioid drug products. The Commission did not identify equivalent HPHR opioid drug products for the following five ADOs on the draft list: Nucynta ER® (tapentadol extended release tablet), Oxaydo® (oxycodone immediate-release tablet), Oxycodone extended-release tablet[8], Oxycontin® (oxyocodone extended-release tablet) and Xtampza ER® (oxycodone extended-release tablet). The focus of this analysis is on the impact of the substitution requirement; therefore, the five ADOs without equivalent HPHR opioids are not included in the calculations.

As provided in Section 4 of the law, the Commission requested an insurance benefit review by the Massachusetts Center for Health Information and Analysis (CHIA). Insurance benefit reviews

[i] The drug formulary becomes final only upon promulgation of 105 CMR 720, as amended, which is expected in 2017.

analyze the potential impact of mandated benefits on the health insurance premiums paid by businesses and consumers. The Commission requested such a review, and CHIA engaged Compass Health Analytics, Inc. (Compass) to provide an actuarial estimate of the effect implementation of the draft formulary would have on the cost of health insurance in Massachusetts.

2. Interpretation

2.1. Opioid abuse and abuse-deterrent opioids

The Centers for Disease Control and Prevention (CDC) refers to the rising number of deaths by prescription overdose as an epidemic.[9] Since 1999, deaths involving opioids (including prescription opioid pain medications and heroin) in the United States have quadrupled, and during the same time period, the amount of prescription opioids sold in the U.S. nearly quadrupled.[10] At least half of all opioid deaths involve a prescription opioid.[11] From 1999 to 2014, more than 165,000 individuals in the United States died from opioid pain medication overdose.[12] In 2015, the estimated rate of unintentional opioid-related (including heroin, opioid pain medications, and other opioids) overdose deaths in Massachusetts was 24.6 per 100,000 residents.[13] In response to these statistics, the federal and state governments have launched numerous initiatives.

Prescription opioids are available as immediate-release (IR) or extended release/long-acting (ER/LA) formulations. Although misuse or abuse of any opioid formulation can lead to serious side effects, including overdose and death, the risk is significantly higher for the ER/LA formulations.[14] This is because these formulations contain a greater amount of opioid, and tampering can transform an ER/LA formulation into an IR formulation.[15,16] To intensify their experience, some patients modify the route of administration (e.g., snorting or injecting them).[17] These types of tampering behaviors increase the risk of serious medical complications, including overdose and death.[18]

Abuse-deterrent opioid drug products (ADOs) are intended to thwart efforts to modify the route of administration, and are manufactured with physical, chemical, or other barriers that make abuse more difficult or less attractive or rewarding.[19] The science of abuse-deterrence is relatively new, and the analytical, clinical, and statistical methods for evaluating ADO technologies are rapidly evolving.[20] The United States Food and Drug Administration (FDA) currently approves seven extended-release (ER) opioid products with abuse-deterrent properties,[21] but to date, the FDA has not approved any such abuse-deterrent labeling for Immediate Release (IR) opioids.[22]

In July 2016, the Commission completed a draft drug formulary of chemically-equivalent substitutions for schedule II and III opioids that were determined to have a HPHR due to the drugs' potential for abuse and misuse, and incorporated one of the following (see Appendix A):

1. A physical or chemical barrier that (i) prevents chewing, crushing, cutting, grating, grinding, melting or other physical manipulations that enable abuse or (ii) resists extraction of the opioid by common solvents such as water, alcohol or other organic solvents

2. An agonist or antagonist combination that interferes with, reduces or defeats the euphoria associated with abuse
3. An aversion quality that produces an unpleasant effect if the dosage form is manipulated or altered or a higher dose than directed is used
4. A delivery system that, under FDA guidance, offers resistance to abuse
5. A prodrug[23] technique that limits opioid activity until transformed in the gastrointestinal tract
6. Any other technique, as may be identified or recommended by the FDA, that offers significant abuse deterrence

When considering whether a drug is a chemically-equivalent substitution, Chapter 258 instructed the Commission to consider:

- The accessibility of the drug and its proposed substitute
- Whether the drug's substitute is cost prohibitive
- The effectiveness of the substitution
- Whether, based upon the current patterns of abuse and misuse, the drug's substitute incorporates abuse-deterrent technology that will be an effective deterrent to such abuse and misuse

Based on these criteria, the Commission approved the following definition:

> Chemically Equivalent Substitution, for the purpose of creating a formulary of drugs with abuse deterrent properties that the commission has determined may be appropriately substituted for opioids that have been determined to have a heightened public health risk due to the drugs' potential for abuse and misuse, shall mean drug products which contain the same active ingredients, and are equivalent in strength or concentration, dosage form, and route of administration, and produce a comparable biological effect. Prodrugs or ingredients without analgesic effect that are used solely for abuse deterrent formulations need not be equivalent.[24]

2.2. Provisions of Chapter 258 pertaining to ADOs

The following paragraphs outline the provisions of Chapter 258 relevant to this analysis.

Default substitution of ADOs for HPHR opioids by pharmacists

Prior to enactment of Chapter 258, Massachusetts law required pharmacists to dispense a less expensive, reasonably available, interchangeable drug product for all prescriptions as allowed by the Commission's current formulary, except in cases where the practitioner indicated "no substitution."[25] In the case of a prescription for an HPHR opioid, Chapter 258 requires pharmacists to dispense an interchangeable abuse-deterrent product if one exists, or if none exists, a less expensive, reasonably available, interchangeable drug product as allowed by the most current formulary or supplement thereof, as was required prior to the enactment of Chapter 258.

The Commission's minutes show evidence of questions raised about the legality under federal law of the default substitution requirement for the specified ADOs.[26] This analysis assumes the default substitution of ADO's for HPHR opioids is permissible under federal law.

Coverage of ADOs on a basis not less favorable than that for HPHR opioids

Chapter 258 requires health insurance plans to provide coverage for ADO drug products "on a basis not less favorable" than coverage for HPHR drug products covered by the plan. An increase in patient cost sharing is not allowed to achieve compliance with this section.

Because most ADO formulations are relatively new and under patent protection, they are often more expensive than HPHR opioid formulations that might be older and available in generic form. Carriers often assign expensive drugs to classes (tiers) that require relatively higher copayments. Chapter 258 would forbid carriers from assigning substituted ADOs to higher copayment tiers.

The effect of this parity requirement, on top of the changes to the default pharmacy substitution procedures described above, is to encourage a shift to abuse-deterrent opioids defined in the formulary while insulating patients from the increased cost of doing so.

2.3. Plans affected by Chapter 258

Chapter 258's requirement for default substitution of a chemically-equivalent substitution applies to all HPHR opioid prescriptions dispensed in the Commonwealth regardless of what entity (commercial insurance, Medicare, Medicaid, the patient, etc.) pays for the dispensed drug. However, the separate requirement to cover the ADO on a basis not less favorable than that for HPHR opioids applies only to the health insurance plans specified in Chapter 258. This analysis addresses the costs to those plans.[ii]

Chapter 258 amended the statutes regulating entities providing health insurance in Massachusetts to require they cover the substituted ADOs on a basis not less favorable than that for non-abuse deterrent opioids. The following five sections of the law each address a type of health insurance policy:

- Section 9: Insurance for persons in service of the Commonwealth, administered by the Group Insurance Commission (GIC) (creating M.G.L. c. 32A, §17L)
- Section 21: Accident and sickness insurance policies (creating M.G.L. c. 175, §47EE)
- Section 23: Contracts with non-profit hospital service corporations (creating M.G.L. c. 176A, §8GG)
- Section 25: Certificates under medical service agreements (creating M.G.L. c. 176B, §4GG)
- Section 27: Health maintenance contracts (creating M.G.L. c. 176G, §4Y)

[ii] This is consistent with the scope of most insurance benefit reviews conducted by CHIA. Section 4 of Chapter 258, in referring to the Commission's authority to ask CHIA for assistance, specifically refers to an "insurance benefit review".

The law requires coverage for members under the relevant plans, regardless of whether they reside within the Commonwealth or merely have their principal place of employment in the Commonwealth. Note that health benefit plan mandates do not apply to plans that cover Massachusetts residents but are issued in other states (although prescriptions for these residents will be affected by the substitution requirement along with everyone else's).

Self-insured plans, other than those administered by the GIC (see above) are not subject to state-level health insurance benefit mandates. State mandates do not apply to Medicare, and this analysis assumes that this mandate does not affect Medicare extension/supplement plans even to the extent they are regulated by state law. This analysis does not apply to Medicaid/MassHealth.

2.4. Other existing laws affecting ADOs

Chapter 52 of the Acts of 2016 was signed into law March 14, 2016. It has multiple provisions that regulate opioid prescriptions. The law imposes a seven-day limit on prescribing non-abuse-deterrent opioid drug products, excluding certain circumstances (except for minors for whom the seven-day limit always applies). It requires use of the Prescription Monitoring Program (PMP) by prescribers, and establishes a benchmark mechanism to monitor prescriber opioid prescription practices.[27] It requires certain patient evaluations and pain management agreements between prescribers of opioid drug products and their patients. The law also charges the Commission with identifying and publishing a list of non-opioid drug products approved by the FDA that are effective pain management alternatives and have a lesser potential for abuse than an opioid drug product contained in Schedules II and III. The intent of these provisions is to encourage more judicious prescribing potentially leading to a reduction in the use of non-abuse-deterrent opioid products.[28]

On July 22, 2016, President Obama signed into law the Comprehensive Addiction and Recovery Act (CARA)[29] impacting opioid abuse prevention, treatment, recovery, law enforcement, criminal justice reform, and overdose reversal. While this law does not address ADOs directly, several of its provisions may lead to a reduction in the use and misuse of opioid products.

3. Methodology

3.1. Overview

Projecting the impact of the proposed formulary on premiums requires estimating the volume of HPHR opioid prescriptions that would be converted to ADOs, both in the absence of the default substitution requirement and in response to that requirement. Combining these components, and accounting for carrier retention, results in a baseline estimate of the proposed formulary's incremental effect on premiums, which is then projected over the two years following the assumed January 1, 2017 effective date of the formulary.

3.2. Data sources

The primary data sources used in the analysis were:

- Utilization data for long-acting opioids for January 2014 to June 2016 from the Massachusetts Prescription Monitoring Program (PMP)
- Wholesale Acquisition Cost (WAC) per unit for ADOs and HPHR opioids provided by the Department of Public Health (DPH)
- Carrier claim data from the Massachusetts All Payer Claim Database (MA-APCD) for calendar year 2014, for plans covering the majority of the under-65 fully-insured population subject to the coverage requirements of Chapter 258
- Consumer Price Index prescription drug information for 2013 to 2016
- Information from the DPH Drug Formulary Commission and clinical providers

3.3. Steps in the analysis

The following steps summarize the analysis.

Estimate the utilization of HPHR opioids and ADOs in the absence of the substitution requirement

- Determine utilization of HPHR opioids in the draft formulary for relevant population from 2014 MA-APCD.
- Calculate utilization changes for 2014 through June 2016 from PMP data to estimate 2016 baseline HPHR opioid utilization.
- Estimate 2016 baseline utilization of ADOs for relevant population using PMP 2016 data.

Estimate the cost of HPHR opioids and ADOs in the absence of the substitution requirement

- Determine price for each HPHR opioid using paid cost per unit for relevant population from 2014 MA-APCD.
- Estimate price for each ADO using paid cost per unit from PMP 2015 WAC.
- Estimate 2016 baseline price per unit for ADOs and HPHR opioids.
- Project price increase per unit for all relevant drugs to 2016 baseline based on Consumer Price Index for prescription drugs.[30]
- Multiply utilization by price per unit to calculate total cost of HPHR opioids and ADOs for the relevant population in the absence of the substitution requirement.

Estimate the utilization and cost of HPHR opioids that would convert to ADOs due to substitution

- Determine drug conversion ratio for each HPHR opioid dosage level to equivalent ADO.
- Develop low-, mid-, and high-scenario estimates of utilization by drug and form that would convert from HPHR to ADO due to the substitution requirement.

- Multiply converted utilization under each scenario by price per unit to estimate baseline annual costs.

Estimate the marginal cost of HPHR opioids that would convert to ADOs due to substitution

- Subtract cost of HPHR opioids and ADOs in the absence of substitution from costs under low, mid, and high conversion scenarios to estimate the incremental cost of the substitution requirement.
- Divide the annual incremental cost by the corresponding membership to calculate baseline per member per month (PMPM) costs.
- Project PMPM costs through projection period based on price increase per unit using the three-year average prescription drug CPI.

Calculate the impact of projected increases in medical expense on insurance premiums

- Estimate the impact of carrier retention (administrative costs and profit) on premiums.
- Estimate the fully-insured Massachusetts population under age 65, projected for the next two years (2017 to 2018).
- Multiply the PMPM costs for each scenario by the corresponding membership to get annual incremental cost.

Estimate the impact of potential changes in utilization of these drugs on the PMPM costs

Section 4 describes these steps in more detail.

3.4. Limitations

This analysis is limited to the drugs specifically outlined by the Drug Formulary Commission in its draft as components of chemically-equivalent substitutions, including four HPHR opioids and two ADOs. Many more opioid products are prescribed in general, including other ADOs the Commission did not pair with chemically-equivalent HPHR opioid products. However, this analysis does not consider utilization of these other drugs, nor does it include estimation of utilization changes from these drugs to other opioids that may be identified by the Commission as ADOs but are not identified as components of a substitution or that may be introduced to the market in the future.

This analysis is focused on the substitution of ADOs for chemically-equivalent HPHRs only. The impact on drug prices and utilization of the law existing before enactment of Chapter 258, requiring pharmacists to dispense a less-expensive drug product for prescriptions, is assumed to already be reflected in the baseline data.

All MA-APCD information used in this study to generate PMPM costs is based on data from the largest three health insurance carriers in the Massachusetts commercial market.[31] Aggregate dollar cost estimates contained in this report assume that the PMPM costs obtained from the MA-APCD sample data are representative of the overall fully-insured commercial under-65 population.

One significant limitation of this study is that no single available data set includes complete information about the relevant draft formulary drugs for the study population over time. Therefore, both MA-APCD and PMP data were used to construct a projection model for ADO and HPHR opioid use through 2018. Below is a description of the relevant data elements and the limitations in each database.

	APCD	PMP
Time period available	2014 was available for this analysis	2014 – June 2016
Population	Fully-insured membership ages 0-64	All prescriptions (for entire population)
Price	Paid and Allowed amounts	Wholesale Acquisition Cost (WAC)
Limitations	- 2015 data unavailable - Relevant ADO drugs not released until 2015 - Data used from top 3 carriers only	- Unable to analyze relevant population as payer data is unavailable - WAC is not reflective of drug prices paid by carriers

The ADOs analyzed in this study were introduced to the market in 2015, meaning that available data about the use of these drugs over time is very limited. The expectation of the Commission is that more ADOs will be approved by the FDA in the near future, which will further disrupt patterns of utilization for all opioids. Likewise, a variety of public health and other efforts beyond this substitution requirement have been and are being implemented to limit the use and misuse of opioids overall; these programs are intended to decrease the utilization of opioids generally. If effective, opioid use, and the cost impact of the substitution requirement on insurance premiums, may fall below the estimates included in this projection. However, no available historical data adequately captures all of these variables over time, and the number of variables that continues to change and impact opioid use makes projections less stable than is typical in other studies of the effect of legislation on insurance costs.

These uncertainties are addressed by modeling a range of assumptions within reasonable judgment-based limits, and producing a range of estimates of incremental cost by varying these parameters. The more detailed step-by-step description of the estimation process outlined in the next sections addresses these uncertainties further.

4. Analysis

This section describes the 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.

Chapter 258 requires pharmacists to substitute an ADO for a prescribed chemically-equivalent HPHR opioid, adhering to substitutions defined by the Commission, unless the prescriber overrides it. The marginal cost of the requirement is calculated for the Massachusetts fully-insured population under age 65 by estimating the differences between the utilization of these drugs under

various conversion scenarios and the utilization estimated in the absence of the requirement. Costs are then adjusted to account for drug price inflation and carrier retention.

4.1. Utilization of formulary opioids in the absence of substitution

Assuming the Commission's draft formulary, the substitution requirement applies to four HPHR opioids and two ADOs, each with varying dosage and generic-form availability, outlined in Table 1. One drug, Avinza, was taken off the market in brand-name form in July 2015, though the generic form is still available. Zohydro, Embeda, and Hysingla were all introduced to the market in 2015; none are available in generic form.

The underlying calculations for these projections were based on each of the drug/dosage and generic/brand combinations (over 60 combinations). For simplicity, this report will summarize these calculations variously by drug, drug category (HPHR, ADO), drug form (generic, brand), or in total.

Table 1:
Draft Drug Formulary HPHR Opioids and ADOs

HPHR Opioids	Dosage levels (mg)	Generic?	Notes
Avinza	30, 45, 60, 75, 90, 120	Yes	Brand only discontinued 7/15
Kadian	10, 20, 30, 40, 50, 60, 70, 80, 100, 130, 150, 200	Yes	
MS Contin	15, 30, 60, 100, 200	Yes	
Zohydro	10, 15, 20, 30, 40, 50	No	Entered market 2015
ADO	Dosage levels (mg)	Generic?	Notes
Embeda	20, 30, 50, 60, 80, 100	No	Entered market 2015
Hysingla	20, 30, 40, 60, 80, 100, 120	No	Entered market 2015

This analysis is intended to project costs of the substitution requirement for the fully-insured population ages 0-64 in Massachusetts. This requires analyzing utilization by patients covered by specific insurance types, which is available through MA-APCD data. However, MA-APCD claims available for this analysis are current through only calendar year 2014, and four of the proposed formulary drugs either entered the market or significantly changed in availability in 2015, including the only two ADOs on the list. Therefore, the analysis relied on information from the PMP to augment MA-APCD data. As described previously, the PMP could not be used to provide baseline utilization data, as in the past that database did not collect data on patient health insurance coverage, and reflected merely whether or not a patient paid for the drug out-of-pocket.

As a first step, utilization data for relevant drugs available in 2014 was pulled from the MA-APCD. For drugs introduced in 2015 and not in the MA-APCD, 2016 PMP utilization data serves as a basis, and is adjusted downward to capture only the relevant population of fully-insured commercial patients by applying the ratio of 2014 MA-APCD to 2014 PMP utilization, which averaged 14.3 percent for the proposed formulary drugs. This data was adjusted based on trends by drug, form, and dosage calculated from PMP data for January 2014 through June 2016. These calculations

resulted in a 2016 baseline of utilization based on quantity dispensed, which Table 2 summarizes by drug and form.

Table 2:
2016 Baseline Draft Formulary Drug Utilization by Quantity Dispensed

	Brand	Generic	Total
HPHR Opioids	24,756	809,834	834,591
Avinza	0	2,385	2,385
Kadian	1,361	41,021	42,382
MS Contin	4,692	766,429	771,121
Zohydro	18,703	0	18,703
ADOs	9,294	0	9,294
Embeda	5,904	0	5,904
Hysingla	3,390	0	3,390
Total	34,050	809,834	843,884

4.2. Cost of draft formulary opioids in the absence of substitution

As with utilization data, use of both the MA-APCD and PMP was necessary to estimate the per-unit cost of each formulary drug and dosage by form. To appropriately reflect actual costs paid in the relevant Massachusetts health insurance market, MA-APCD data was used where available. For drugs not introduced until 2015, 2015 Wholesale Acquisition Costs (WAC) by dosage and form were used, and adjusted downward based on the average ratio of 2015 PMP to 2014 MA-APCD unit costs, a factor of 1.58. WAC is one of several available drug pricing estimates available for purchase, but does not reflect actual transaction costs for a given drug.[32]

To then adjust 2014 prices to the 2016 baseline year, the Consumer Price Index (CPI) for prescription drugs was applied for each respective year.[33] Table 3 reflects these values.

Table 3:
Opioid Drug Price Inflation Estimates

	2014-15	2015-16
Prescription Drug CPI	2.4%	5.0%

Prices for each drug by form and dosage level were projected for each year of the report; Table 4 averages these prices by drug and form.

Table 4:
2016 Opioid Drug Price per Unit Estimates

	Brand	Generic
HPHR Opioids	$8.95	$5.79
Avinza	N/A	$9.76
Kadian	$12.09	$5.33
MS Contin	$9.09	$2.27
Zohydro	$5.67	N/A
ADOs	$11.79	N/A
Embeda	$9.42	N/A
Hysingla	$14.16	N/A
Average	$10.09	$5.79

Prices for each drug, dosage, and form were then multiplied by the corresponding estimated utilization for the baseline year. Table 5 summarizes the total cost of the formulary drugs in the absence of the substitution requirement for baseline year 2016.

Table 5:
2016 Baseline Draft Formulary Drug Cost

	Brand	Generic	Total
HPHR Opioids	$159,188	$1,153,235	$1,312,424
Avinza	$0	$21,005	$21,005
Kadian	$10,500	$314,079	$324,579
MS Contin	$46,163	$818,152	$864,315
Zohydro	$102,525	$0	$102,525
ADOs	$76,107	$0	$76,107
Embeda	$42,908	$0	$42,908
Hysingla	$33,199	$0	$33,199
Total	$235,295	$1,153,235	$1,388,530

4.3. Estimated conversion from HPHR opioids to ADOs

Chapter 258 requires that, "[e]xcept in cases where the practitioner has indicated "no substitution", the pharmacist shall dispense: an interchangeable abuse-deterrent product if one exists."[34] Table 6 outlines the drug conversions to be used under the terms of the substitution requirement, as defined by the Commission.

Table 6:
Drug Formulary Commission HPHR to ADO Chemical Equivalents

HPHR Opioids	ADO Equivalent
Avinza	
Kadian	Embeda
MS Contin	
Zohydro	Hysingla

Chemical equivalence is determined in part by the dosage of opioid in each drug; in other words, the new ADO drug must have a dose of opioid identical to that of the replaced HPHR drug. Three different scenarios may occur in this dosage conversion. First, and most straightforward, the equivalent ADO drug is offered in the exact same dosage as the HPHR opioid. Second, equivalent dosage levels are not available in a single ADO pill, and two ADO pills are used to replace a single pill of the HPHR opioid to reach chemical equivalence.[35] Third, some HPHR opioids are available in dosages below the lowest dosage level of ADO available. In these cases, an ADO substitution cannot be made for the HPHR opioid, as ADOs may not be cut or split to achieve a lower dosage level, as such alteration may eliminate or diminish the abuse-deterrent properties of the product.[36]

This analysis makes two assumptions about these conversions. First, where the HPHR dosage is below the lowest available ADO dosage, patients are assumed to remain on the HPHR opioid. Second, where two ADO pills must be combined to achieve the chemically-equivalent dose of the HPHR dose, the analysis assumes that the least expensive combined option is provided to the patient. Table 7 outlines the drug conversions used in the model.

Table 7:
HPHR to ADO Chemical Dosage Equivalents

	HPHR Mg	ADO Mg
Avinza to Embeda	30	30
	45	N/A
	60	60
	75	N/A
	90	30+60
	120	2x60
MS Contin to Embeda	15	N/A
	30	30
	60	60
	100	100
	200	2x100
Zohydro to Hysingla	10	N/A
	15	N/A
	20	20
	30	30
	40	40
	50	20+30

	HPHR Mg	ADO Mg
Kadian to Embeda	10	N/A
	20	20
	30	30
	40	2x20
	50	50
	60	60
	70	20+50
	80	80
	100	100
	130	30+100
	150	50+100
	200	2x100

It is unknown what percent of patients will convert from their current dosage of HPHR opioid to an ADO chemical equivalent as a result of the substitution requirement, as prescribers have the ability to indicate "no substitution" on a patient's prescription. Therefore, the model developed three scenarios for such conversions, which are outlined in Table 8.

Table 8:
Patients converting from HPHR opioid to ADO due to the substitution requirement

	Conversion rate
Low Scenario	50%
Mid Scenario	70%
High Scenario	90%

Two items of note arise regarding drug conversions. First, as described previously, some patients will not be able to convert to the ADO because the chemically-equivalent dose is not available at this time; these patients and their costs do not impact the marginal results in the model. Second, some providers may switch patients to the chemically-equivalent ADO regardless of the substitution requirement for clinical reasons, which may overestimate the impact of the requirement generally.

4.4. Estimated change to utilization of HPHR opioids and ADOs

Using the baseline utilization outlined in Table 2 and the conversion rates listed in Table 8, utilization of each drug by form was calculated, as outlined in Tables 9, 10, and 11. By far the largest impact on utilization in each scenario is the conversion of generic MS Contin to brand name Embeda. Each 20 percent increase in conversion to ADOs, which are only available in brand name form, results in approximately 100,000 doses of generic MS Contin converted. Note that not all HPHR opioids can convert to ADOs due to dosage availability, and that the totals under each scenario are not equal, as some conversions require an increase from one to two pills to achieve chemical equivalence. Both of these issues are explained in more detail in previous sections.

Table 9:
Draft Formulary Drug Utilization by Quantity Dispensed
for Brand Name Drugs

		Conversion Rate		
	No Formulary	50%	70%	90%
HPHR Opioids	24,756	17,869	15,115	12,360
Avinza	0	0	0	0
Kadian	1,361	719	463	206
MS Contin	4,692	2,558	1,705	852
Zohydro	18,703	14,592	12,947	11,303
ADOs	9,294	292,884	406,320	519,756
Embeda	5,904	285,367	397,153	508,938
Hysingla	3,390	7,516	9,167	10,818
Total	34,050	310,753	421,435	532,116

Table 10:
Formulary Drug Utilization by Quantity Dispensed for Generic Drugs

		Conversion Rate		
	No Formulary	50%	70%	90%
HPHR Opioids	809,834	541,504	434,169	326,834
Avinza	2,385	1,399	1,001	604
Kadian	41,021	21,752	14,045	6,338
MS Contin	766,429	518,353	419,122	319,892
Zohydro	0	0	0	0
ADOs	0	0	0	0
Embeda	0	0	0	0
Hysingla	0	0	0	0
Total	809,834	541,504	434,169	326,834

Table 11:
Utilization by Quantity Dispensed for All Draft Formulary Drugs

		Conversion Rate		
	No Formulary	50%	70%	90%
HPHR Opioids	834,591	559,373	449,284	339,194
Avinza	2,385	1,399	1,001	604
Kadian	42,382	22,472	14,508	6,544
MS Contin	771,121	520,911	420,827	320,744
Zohydro	18,703	14,592	12,947	11,303
ADOs	9,294	292,884	406,320	519,756
Embeda	5,904	285,367	397,153	508,938
Hysingla	3,390	7,516	9,167	10,818
Total	843,884	852,257	855,603	858,950

4.5. Estimated change to total cost of HPHR opioids and ADOs

Opioid drug prices were multiplied by estimated utilization for each drug, form, and dosage in the model to calculate formulary drug costs by quantity dispensed under each scenario. These costs are summarized by drug form in Tables 12 through 14.

Table 12:
Total Draft Formulary Drug Costs by Quantity Dispensed for Brand Name Drugs

		Conversion Rate		
	No Formulary	50%	70%	90%
HPHR Opioids	$159,188	$106,949	$86,053	$65,158
Avinza	$0	$0	$0	$0
Kadian	$10,500	$5,458	$3,441	$1,424
MS Contin	$46,163	$23,379	$14,265	$5,151
Zohydro	$102,525	$78,113	$68,348	$58,583
ADOs	$76,107	$2,489,476	$3,454,824	$4,420,171
Embeda	$42,908	$2,426,301	$3,379,658	$4,333,015
Hysingla	$33,199	$63,175	$75,165	$87,156
Total	$235,295	$2,596,425	$3,540,877	$4,485,329

Table 13:
Total Draft Formulary Drug Costs by Quantity Dispensed for Generic Drugs

		Conversion Rate		
	No Formulary	50%	70%	90%
HPHR Opioids	$1,153,235	$635,252	$428,058	$220,865
Avinza	$21,005	$11,583	$7,814	$4,045
Kadian	$314,079	$161,717	$100,772	$39,828
MS Contin	$818,152	$461,952	$319,472	$176,993
Zohydro	$0	$0	$0	$0
ADOs	$0	$0	$0	$0
Embeda	$0	$0	$0	$0
Hysingla	$0	$0	$0	$0
Total	$1,153,235	$635,252	$428,058	$220,865

Table 14:
Total Draft Formulary Drug Costs by Quantity Dispensed for All Formulary Drugs

		Conversion Rate		
	No Formulary	50%	70%	90%
HPHR Opioids	$1,312,424	$742,201	$514,112	$286,022
Avinza	$21,005	$11,583	$7,814	$4,045
Kadian	$324,579	$167,175	$104,213	$41,252
MS Contin	$864,315	$485,331	$333,737	$182,143
Zohydro	$102,525	$78,113	$68,348	$58,583
ADOs	$76,107	$2,489,476	$3,454,824	$4,420,171
Embeda	$42,908	$2,426,301	$3,379,658	$4,333,015
Hysingla	$33,199	$63,175	$75,165	$87,156
Total	$1,388,530	$3,231,677	$3,968,935	$4,706,193

4.6. Estimated marginal cost and PMPM of HPHR opioids and ADOs

The marginal cost of the substitution requirement is calculated by subtracting the total formulary drug costs in the absence of the requirement from the total costs under each scenario. Table 15 displays the results.

Table 15:
Marginal Costs by Quantity Dispensed
for All Draft Formulary Drugs

	Conversion Rate		
	50%	70%	90%
HPHR Opioids	$(570,223)	$(798,312)	$(1,026,402)
Avinza	$(9,423)	$(13,192)	$(16,961)
Kadian	$(157,404)	$(220,366)	$(283,327)
MS Contin	$(378,984)	$(530,578)	$(682,172)
Zohydro	$(24,412)	$(34,177)	$(43,942)
ADOs	$2,413,369	$3,378,717	$4,344,065
Embeda	$2,383,393	$3,336,751	$4,290,108
Hysingla	$29,976	$41,966	$53,957
Total	$1,843,146	$2,580,405	$3,317,663

Marginal cost by scenario is then divided by the 2016 corresponding fully-insured pharmacy membership from the MA-APCD, and by 12 months to calculate the estimated baseline PMPM incremental cost attributable to the requirement.

Table 16:
Total and PMPM Baseline Marginal Cost
of Substitution Requirement

	Total Annual Cost	Baseline PMPM cost
Low Scenario	$ 1,843,146	$ 0.11
Mid Scenario	$ 2,580,405	$ 0.15
High Scenario	$ 3,317,663	$ 0.19

4.7. Projected PMPM cost of substitution requirement

Chapter 258 prohibits substitution of an ADO for an HPHR opioid from imposing additional cost-sharing requirements on patients, meaning that deductibles, copayments, and coinsurance amounts may not increase based on the substituted drug. This analysis estimates that 96 percent of patients used a generic form of one of the formulary drugs in the baseline period. Unless the physician indicates that no substitution is allowed, the law requires that these patients be switched to an ADO, each of which is a brand-name drug. Where patient cost sharing is lower for generic drugs than for brand-name drugs, this cost sharing may not change due to the substitution. No data was available to assess the degree to which cost-sharing levels were higher for brand name ADOs

relative to generic HPHR opioids, but it is likely that cost sharing is greater for the brand name products. This may result in increased carrier costs and premiums, as carriers will need to cover the increased cost of the brand-name drugs without the typical offsetting higher patient cost sharing those drugs usually require.

The baseline PMPM cost from Table 16 was varied under several scenarios to estimate the increase in costs due to the constraints on changes to cost-sharing, based on the paid and allowed costs for the relevant drugs. Specifically, it was assumed that cost sharing would not increase in the low scenario, but would increase 5 percent in the mid scenario and 10 percent in the high. The resulting PMPM costs then projected from 2016 through the end of the study period, increasing the cost per unit by an average of 4.6 percent annually, based on a three-year average of CPI for prescription drugs.[37] Table 17 shows these results.

Table 17:
Estimated Marginal PMPM Cost of Substitution Requirement
Projected for Study Period

	Cost Increase	2016	2017	2018
Low Scenario	0%	$0.11	$0.11	$0.12
Mid Scenario	5%	$0.15	$0.16	$0.17
High Scenario	10%	$0.21	$0.22	$0.23

4.8. Carrier retention and increase in premium

Assuming an average annual retention rate of 11.0 percent based on CHIA's analysis of administrative costs and profit in Massachusetts,[38] the increase in medical expense was adjusted upward to approximate the total impact on premiums. Table 18 shows the result.

Table 18:
Estimated Increase in PMPM Premium Due to Substitution Requirement
Projected for Study Period

	2017	2018
Low Scenario	$0.12	$0.13
Mid Scenario	$0.18	$0.19
High Scenario	$0.24	$0.26

While 11 percent is the standard carrier retention in the Massachusetts fully-insured commercial marketplace, this figure may underestimate the cost of administration to carriers for this specific substitution requirement. As carriers will need to modify their administrative systems and work with PBMs and pharmacies to ensure that the brand-name ADO drugs are included in the generic drug tier for purposes of collecting cost-sharing from patients, additional costs to the carriers, and corresponding increases in plan premiums, may result.

4.9. Projected fully-insured population in Massachusetts

Table 19 shows the fully-insured population in Massachusetts age 0 to 64 projected for the next two years. Appendix B describes the sources of these values.

Table 19:
Projected Fully-Insured Population in Massachusetts, Ages 0-64

Year	Total (0-64)
2017	2,159,380
2018	2,157,070

4.10. Total incremental medical expense and increase in premium

Multiplying the total estimated PMPM cost from Table 17 by the projected fully-insured membership over the analysis period yields the total medical expense associated with the substitution requirement, shown in Table 20. This analysis assumes the formulary would be effective January 1, 2017.[39]

Table 20:
Estimated Marginal Cost of Draft Drug Formulary Substitution Requirement

	2017	2018
Low Scenario	$2,032,376	$2,981,826
Mid Scenario	$2,987,592	$4,383,284
High Scenario	$4,024,104	$5,904,015

Multiplying the estimated increase in PMPM premiums from Table 18 by the projected fully-insured membership over the analysis period yields the total impact on premiums, including carrier retention, associated with the substitution requirement, shown in Table 21.

Table 21:
Estimate of Increase in Premiums

	2017	2018
Low Scenario	$2,283,568	$3,350,366
Mid Scenario	$3,356,845	$4,925,038
High Scenario	$4,521,465	$6,633,725

4.11. Projected utilization changes for draft formulary opioids without the substitution requirement

Projecting utilization of various opioids into the future is exceptionally complex given the number of variables impacting the use of these drugs. On one hand, many public health, governmental, and other efforts are currently directed at decreasing the use and misuse of these drugs, including increased use of the Massachusetts Prescription Monitoring Program by more prescribers,[40] new guidelines released by the CDC for prescribing opioids for chronic pain,[41] and various projects

coordinated by the Massachusetts Opioid Abuse Prevention Collaborative.[42] In reviewing utilization data from the PMP for January 2014 through June 2016, the overall average utilization of these opioids has decreased by 6.7 percent. On the other hand, as previously stated, new drugs, dosages, and forms are frequently introduced to the market, while others are removed. New drug introductions are often accompanied by increased utilization in the market. Both of these competing factors will continue into the foreseeable future, and may offset each other.

For simplicity throughout this report, the analysis assumed utilization changes through the projection period were zero. However, additional calculations found that every 5 percent change in utilization yielded a corresponding 8.0 percent change in medical expense PMPM and in total PMPM premium impact when carrier retention is included.

5. Results

The estimated impact of the proposed formulary on medical expense and premiums appears in Table 22. The analysis includes development of 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 that produced a higher estimated impact.

The impact on premiums is based primarily on estimates of the quantity of HPHR opioids that will be replaced with ADOs during the projection period. More pointedly, the majority of HPHR opioids currently dispensed are in generic form, while all convertible ADOs are available only in brand-name form. The vast majority of utilization of HPHR opioids is now generic MS Contin, which comprises over 90 percent of utilization for the drugs relevant to the study, but totals slightly under 59 percent of costs for these formulary drugs. The price in the baseline period for generic MS Contin is estimated at $2.27 per unit dispensed, while its equivalent ADO, Embeda, is estimated at $9.42 per unit dispensed. The result of this conversion from generic MS Contin to brand name Embeda is that costs across scenarios increase by approximately 30 to 40 percent for each 20 percent of drugs converted from HPHR to available ADO. Moreover, carriers will have even higher costs as a result of the reduced patient cost sharing for those patients who will switch from generic HPHR opioids to brand-name ADOs, estimated to further increase carrier costs by up to 10 percent.

A variety of factors will affect these estimates, including any significant adjustments to the drug prices for opioids in the Massachusetts fully-insured market, changes to overall opioid utilization resulting from public health efforts, the approval of new opioids for patient use, and the addition of any more ADOs as chemically-equivalent substitutions for HPHRs to the Drug Formulary Commission list.

Starting in 2020, the federal Affordable Care Act will impose an excise tax, commonly known as the "Cadillac Tax", on expenditures on health insurance premiums and other relevant items (health savings account contributions, etc.) that exceed specified thresholds. To the extent that relevant expenditures exceed those thresholds (in 2020), the substitution requirement, by increasing premiums, has the potential of creating liability for additional amounts under the tax. Estimating the amount of potential tax liability requires information on the extent to which premiums,

notwithstanding the effect of this requirement, will exceed or approach the thresholds is beyond the scope of this analysis.

5.1. Two-year estimated impact

For each year in the two-year analysis period, Table 22 displays the projected net impact of the substitution requirement on medical expense and premiums using a projection of Massachusetts fully-insured membership. Note that the proposed formulary is assumed effective January 1, 2017.

The low scenario impact is $2.8 million per year on average, and is due to the lower estimates of the number of HPHR opioids that will convert to ADOs. The high scenario has an average cost of $5.6 million per year, and reflects higher assumptions for this variable. The middle scenario has average annual costs of $4.1 million, or an average of 0.04 percent of premium.

Finally, the impact of the proposed formulary 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 substitution requirement.

Table 22: Summary Results

	2017	2018	Average	2 Yr Total
Members (000s)	2,159	2,156		
Medical Expense Low ($000s)	$2,032	$2,982	$2,507	$5,014
Medical Expense Mid ($000s)	$2,988	$4,383	$3,685	$7,371
Medical Expense High ($000s)	$4,024	$5,904	$4,964	$9,928
Premium Low ($000s)	$2,284	$3,350	$2,817	$5,634
Premium Mid ($000s)	$3,357	$4,925	$4,141	$8,282
Premium High ($000s)	$4,521	$6,634	$5,578	$11,155
PMPM Low	$0.12	$0.13	$0.13	$0.13
PMPM Mid	$0.18	$0.19	$0.19	$0.19
PMPM High	$0.24	$0.26	$0.25	$0.25
Estimated Monthly Premium	$463	$473	$468	$468
Premium % Rise Low	0.03%	0.03%	0.03%	0.03%
Premium % Rise Mid	0.04%	0.04%	0.04%	0.04%
Premium % Rise High	0.05%	0.05%	0.05%	0.05%

5.2. Impact on the GIC

The proposed formulary is assumed to apply to both fully-insured and self-insured plans operated for state and local employees by the GIC, with an effective date for all GIC policies on July 1, 2017.

Because the benefit offerings of GIC plans are often similar to those of most other commercial plans in Massachusetts, the estimated PMPM effect of the proposed formulary on GIC medical expense is not expected to differ from that calculated for the other fully-insured plans in Massachusetts. 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 starting in July of 2017.

Table 23 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 22 also include the GIC fully-insured membership. Finally, the proposed formulary is assumed to require the GIC to implement the provisions on July 1, 2017; therefore, the results in 2017 are approximately one-half of an annual value.

Table 23: GIC Summary Results

	2017	2018	Average	2 Yr Total
GIC Fully-Insured				
Members (000s)	54	54		
Medical Expense Low ($000s)	$36	$75	$55	$110
Medical Expense Mid ($000s)	$52	$110	$81	$162
Medical Expense High ($000s)	$71	$148	$109	$219
Premium Low ($000s)	$40	$84	$62	$124
Premium Mid ($000s)	$59	$123	$91	$182
Premium High ($000s)	$79	$166	$123	$246
GIC Self-Insured				
Members (000s)	270	270		
Medical Expense Low ($000s)	$178	$373	$276	$552
Medical Expense Mid ($000s)	$262	$549	$405	$811
Medical Expense High ($000s)	$353	$739	$546	$1,092

Appendix A: Draft Formulary of Substitutions for Opioids with Heightened Public Health Risk

HPHR Opioid	Interchangeable Abuse-deterrent Drug Product	Commercially Available Strengths	Dosing Frequency	ADP Efficacy Category[43]
Kadian® (morphine ER capsules)	**Embeda®** (morphine sulfate extended-release/ naltrexone capsule)	20 mg/0.8 mg	Every 24 hours or every 12 hours	Category II
Morphine ER 12 or 24 hour capsules (generic Kadian®)		30 mg/1.2 mg		
Morphine ER 24 hour capsules (generic Avinza®)		50 mg/2 mg		
Morphine ER tablet (generic MS Contin®)		60 mg/2.4 mg		
MS Contin (morphine ER tablet)		80 mg/3.2 mg		
Zohydro ER (hydrocodone ER capsule)	**Hysingla ER®** (hydrocodone extended-release tablet)	20 mg	Every 24 hours	Category II
		30 mg		
		40 mg		
		60 mg		
		80 mg		
		100 mg		
		120 mg		

HPHR Opioid	Interchangeable Abuse-deterrent Drug Product	Commercially Available Strengths	Dosing Frequency	ADP Efficacy Category[43]
No equivalent HPHR opioid identified	**Nucynta ER®** (tapentadol extended release tablet)	50 mg 100 mg 150 mg 200 mg 250 mg	Every 12 hours	Category II
No equivalent HPHR opioid identified	**Oxaydo®** (oxycodone immediate-release tablet)	5 mg 7.5 mg	Every 4-6 hours	Category III
No equivalent HPHR opioid identified	**Oxycodone** extended release tablet	10 mg 15 mg 20 mg 30 mg 40 mg 60 mg 80 mg	Every 12 hours or every 8 hours	Category II
No equivalent HPHR opioid identified	**Oxycontin®** (oxycodone extended-release tablet)	10 mg 15 mg 20 mg 30 mg 40 mg 60 mg 80 mg	Every 12 hours or every 8 hours	Category II
No equivalent HPHR opioid identified	**Xtampza ER® (oxycodone ER capsule)**	9 mg 13.5 mg 18 mg 27 mg 36 mg	Every 12 hours with food	Category II

Appendix B: Membership Affected by the Proposed Formulary

Membership potentially affected by a proposed mandate may include Massachusetts residents with fully-insured employer-sponsored health insurance issued by a Massachusetts licensed company (including through the GIC), non-residents with fully-insured employer-sponsored insurance issued in Massachusetts, Massachusetts residents with individual (direct) health insurance coverage, and lives covered by GIC self-insured coverage. Membership projections for 2017 to 2021 are derived from the following sources.

The 2014 Massachusetts All Payer Claim Database (MA-APCD) formed the base for the projections. The APCD provided fully-insured and self-insured membership by insurance carrier. The APCD was also used to estimate the number of non-residents covered by a Massachusetts policy. These are typically cases in which a non-resident works for a Massachusetts employer offering employer-sponsored coverage.

The Massachusetts Center for Health Information and Analysis (CHIA) uses supplemental information, beyond the data in the MA-APCD, to develop enrollment trend reports and provided information on where they sourced the data in their report (MA-APCD and supplemental carrier information). We adjusted our membership estimates for the data not in the MA-APCD where appropriate.

The 2014 combined membership projection by carrier was compared to Massachusetts Division of Insurance (DOI) reports estimating fully-insured covered members by insurance carrier. The membership projections were increased to include insurance carriers reported by the DOI but not in the MA-APCD or CHIA supplementary report. These were typically insurance carriers with small membership in the state.

The distribution of members by age and gender was estimated using MA-APCD population distribution ratios and was checked for reasonableness and validated against the U.S. Census.[44] Membership was projected forward from the 2014 base year through 2021 using Census Bureau population growth rate estimates by age and gender.[45]

Projections for the GIC self-insured lives were developed using GIC base data for 2013,[46] 2014,[47] and 2015,[48] 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.

Appendix C: Comparison to DPH Drug Formulary Commission Cost Estimates

As part of its work in developing the opioid drug formulary in Massachusetts, the Department of Public Health presented initial estimates of the costs of substitution for HPHR opioids and ADOs, as outlined in the substitution requirement. While the precise methodology used for the DPH report is not known, several important differences between this analysis and the DPH report exist that explain in part the different conclusions of the two evaluations.

1) The DPH report is based on data captured in the Prescription Monitoring Program database, which comprises all patients of all ages in Massachusetts, inclusive of all public and private health insurance members, as well as the uninsured. Conversely, the CHIA report excludes MassHealth (Medicaid), Medicare, TRICARE (health insurance for uniformed U.S. military service members and their families), uninsured, and self-insured group members from its analysis, and includes instead only fully-insured commercial members ages 0 to 64. In terms of population, the CHIA report represents only 21 percent of the population reflected in the DPH analysis. Moreover, utilization patterns between the two groups are vastly different. In comparing total quantity dispensed units in 2014, the MA-APCD data used by CHIA was less than 10 percent of the units in the PMP.

2) DPH estimated drug prices in its analysis based on 2015 Wholesale Acquisition Cost data obtained from First Databank. These prices are provided to First Databank by drug manufacturers and do not reflect actual prices paid in the Massachusetts health insurance marketplace, which may include substantial discounts negotiated by health insurance carriers, their pharmacy benefits managers (PBMs), and the pharmacies from which the drugs are obtained by patients. MA-APCD paid amounts are calculated based on allowed payments less patient cost-sharing divided by units dispensed. In comparing 2015 WAC data used by DPH to 2014 cost data available in the MA-APCD used by CHIA, WAC prices were almost 40 percent higher than paid per unit amounts reflected in the MA-APCD.

3) In its cost evaluations, DPH focused only on conversions where a single ADO dose is used to replace a single HPHR opioid dose (e.g. 30 mg Embeda is substituted for 30 mg Kadian). That analysis did not include instances where two ADO pills can be combined to reach a chemically-equivalent dose of an HPHR opioid (e.g. two 100 mg Embeda are substituted for one 100 mg Kadian). Per input of the DPH Formulary Commission, these multi-pill chemically-equivalent substitutions will be subject to this substitution requirement, and are thus included in the CHIA analysis. Section 4.3 provides more detail on these substitutions.

Endnotes

[1] Chapter 258 of the Massachusetts Acts of 2014: "An Act to increase opportunities for long-term substance abuse recovery." Accessed 14 September 2016: https://malegislature.gov/Laws/SessionLaws/Acts/2014/Chapter258.

[2] An opiate is any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion in to a drug having addiction-forming or addiction-sustaining liability. See M.G.L. c. 94C §1.

[3] Schedule II: The drug or other substance has a high potential for abuse. The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. Abuse of the drug or other substances may lead to severe psychological or physical dependence. 21 U.S.C. 812. Accessed 14 September 2016: http://www.deadiversion.usdoj.gov/21cfr/21usc/812.htm.

[4] Schedule III: The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I or II. The drug or other substance has a currently accepted medical use in treatment in the United States. Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence. 21 U.S.C. § 812.

[5] Massachusetts Department of Public Health, Drug Formulary Commission (DPH-DFC). Minutes from 17 March 2016 and meeting presentation 7 April 2016. Accessed 14 September 2016: http://www.mass.gov/eohhs/docs/dph/quality/drugcontrol/drug-formulary/2016-meetings/dfc-minutes-031716.pdf

> "Chemically Equivalent Substitution, for the purpose of creating a formulary of drugs with abuse deterrent properties that the commission has determined may be appropriately substituted for opioids that have been determined to have a heightened public health risk due to the drugs' potential for abuse and misuse, shall mean drug products which contain the same active ingredients, and are equivalent in strength or concentration, dosage form, and route of administration, and produce a comparable biological effect. Prodrugs or ingredients without analgesic effect that are used solely for abuse deterrent formulations need not be equivalent."

[6] U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER). Approved Drug Products with Therapeutic Equivalence Evaluations, 36th Edition: Orange Book Preface. Accessed 4 October 2016: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm.

Many prescribers, pharmacists, and carriers rely on therapeutic equivalent drugs to substitute generic form medications for brand form medications. One reference most often used in selecting substitutes is the U.S. Food and Drug Administration (FDA) Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book).

> The publication, Approved Drug Products with Therapeutic Equivalence Evaluations (the List, commonly known as the Orange Book), identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Drugs on the market approved only on the basis of safety (covered by the ongoing Drug Efficacy Study Implementation [DESI] review [e.g., Donnatal® Tablets and Librax® Capsules] or pre-1938 drugs [e.g., Phenobarbital Tablets]) are not included in this publication. The main criterion for the inclusion of any product is that the product is the subject of an application with an effective approval that has not been withdrawn for safety or efficacy reasons. Inclusion of products on the List is independent of any current regulatory action through administrative or judicial means against a drug product. In addition, the List contains therapeutic equivalence evaluations for approved multisource prescription drug products. These evaluations have been prepared to serve as public information and advice to state health agencies, prescribers, and pharmacists to promote public education in the area of drug product selection and to foster containment of health care costs. Therapeutic equivalence evaluations in this publication are not official FDA actions affecting the legal status of products under the FD&C Act.

[7] More information about the work of the Massachusetts Drug Formulary Commission may be found at http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/drug-control/drug-formulary-commission.html.

[8] Oxycodone extended-release tablet is an authorized generic for OxyContin® (oxycodone extended-release tablet), exhibits identical properties, and is considered a chemically equivalent substitute).

[9] U.S. Centers for Disease Control and Prevention (CDC). Injury Prevention & Control: Opioid Overdose. Understanding the Epidemic. Last reviewed and updated June 21, 2016. Accessed 14 September 2016: https://www.cdc.gov/drugoverdose/epidemic/.

[10] *Op. cit.* CDC, Injury Prevention & Control: Opioid Overdose. Understanding the Epidemic.

[11] *Op. Cit.* CDC, Injury Prevention & Control: Opioid Overdose. Understanding the Epidemic.

[12] CDC. Injury Prevention & Control: Opioid Overdose. Prescription Opioid Overdose Data. Accessed 14 September 2016. Accessed 14 September 2016: http://www.cdc.gov/drugoverdose/data/overdose.html.

[13] Massachusetts Department of Public Health. Data Brief: Opioid-related Overdose Deaths Among Massachusetts Residents. Posted: August 2016. Accessed 13 September 2016: http://www.mass.gov/eohhs/docs/dph/quality/drugcontrol/county-level-pmp/opioid-related-overdose-deaths-among-ma-residents-august-2016.pdf.

[14] Bond M, Malamut R. Routes of abuse of prescription opioid analgesics: a review and assessment of the potential impact of abuse-deterrent formulations. Accessed 2 September 2016: http://www.tandfonline.com/doi/full/10.1080/00325481.2016.1120642?scroll=top&needAccess=true.

[15] *Op. cit.* Bond M, Malamut R, Routes of abuse of prescription opioid analgesics: a review and assessment of the potential impact of abuse-deterrent formulations.

[16] Argoff CE, Silvershein DI. A Comparison of Long- and Short-Acting Opioids for the Treatment of Chronic Noncancer Pain: Tailoring Therapy to Meet Patient Needs. Mayo Clinic Proceedings. Mayo Clin Proc. 2009 Jul; 84(7): 602-612. Accessed 13 September 2016: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2704132/.

[17] U.S. Substance Abuse and Mental Services Administration (SAMHSA). Mental and Substance Abuse Disorders. Substance Use Disorders. Accessed 1 September 2016: http://www.samhsa.gov/disorders/substance-use.

[18] *Op. cit.* SAMHSA, Substance Use Disorders.

[19] FDA Center for Drug Evaluation and Research (FDA-CDER). Abuse-Deterrent Opioids-Evaluation and Labeling: Guidance for Industry. Accessed 2 September 2016: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm334743.pdf.

[20] FDA. FDA Facts: Abuse-Deterrent Opioid Medications. Accessed 27 August 2016: http://www.fda.gov/NewsEvents/Newsroom/FactSheets/ucm514939.htm.

[21] *Op. cit.* FDA, FDA Facts: Abuse Deterrent Opioid Medications.

FDA approved extended-release/long-acting abuse deterrent opioids include OxyContin, Targiniq ER, Embeda, Hysingla ER, MorphaBond, Xtampaza ER, Troxca ER.

[22] *Op. cit.* FDA, FDA Facts: Abuse Deterrent Opioid Medications.

[23] Wermuth CG, Ganellin CR, Lindberg P, et. al. Glossary of Terms Used in Medicinal Chemistry; IUPAC Recommendations 1998. International Union of Pure and Applied Chemistry, Chemistry and Human Health Division, Medicinal Chemistry Section. Pure & App Chem. 1998;70(5):1129-43. Accessed 19 September 2016: https://www.iupac.org/publications/pac/1998/pdf/7005x1129.pdf.

> Prodrug: A prodrug is any compound that undergoes biotransformation before exhibiting its pharmacological effects. Prodrugs can thus be viewed as drugs containing specialized non-toxic protective groups used in a transient manner to alter or to eliminate undesirable properties in the parent molecule.

[24] *Op. cit.* Massachusetts Department of Public Health, Drug Formulary Commission (DPH-DFC), Minutes from 17 March 2016 and meeting presentation 7 April 2016.

[25] M.G.L. c. 112 §12D.

[26] Massachusetts Department of Public Health, Drug Formulary Commission (DPH-DFC). Minutes from 15 October 2016. Accessed 14 September 2016: http://www.mass.gov/eohhs/docs/dph/quality/drugcontrol/drug-formulary/dfc-minutes-101515.doc.

[27] DPH, Massachusetts Prescription Monitoring Program (MA-PMP). Accessed 15 September 2016: http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/drug-control/pmp/.

> The MA PMP collects dispensing information on Massachusetts Schedule II through V controlled substances dispensed pursuant to a prescription. Schedules II through V consist of those prescription drug products with recognized potential for abuse or dependence (e.g., narcotics, stimulants, sedatives). Consequently they are among those most sought for illicit and non-medical use. The Drug Control Program (DCP) analyzes the PMP data to determine prescribing and dispensing trends; provide patient prescription history information to prescribers and dispensers; provide educational information to health care providers and the public; and to provide case information to regulatory and law enforcement agencies concerning drug distribution and diversion.
>
> The Department of Public Health's DCP established the MA PMP in 1992 pursuant to joint regulations (105 CMR 700.012) with the Board of Registration in Pharmacy (247 CMR 5.04). The prescription information is reported electronically to the PMP at least every 24 hours, or next business day, from all Massachusetts community, hospital outpatient and clinic pharmacies as well as from out-of-state mail order pharmacies that deliver to patients in Massachusetts.

[28] Massachusetts Executive Office of Health and Human Services (MA EOHHS). Letter from Eric Sheehan, J.D., Bureau Director, Bureau of Health Care Safety and Quality; and Chair Designee, Massachusetts Drug Formulary Commission to Massachusetts prescribers. Letter dated 26 August 2016. Accessed 4 October 2016: http://www.mass.gov/eohhs/docs/dph/quality/drugcontrol/drug-formulary/non-opioid-drug-list-and-letter-july2016.pdf.

[29] P.L. 114-198, "Comprehensive Addiction and Recovery Act of 2016." Accessed 1 September 2016: https://www.congress.gov/114/plaws/publ198/PLAW-114publ198.pdf.

[30] U.S. Department of Labor, Bureau of Labor Statistics (BLS). Consumer Price Index. CPI Detailed Report, Data for July 2016: Table 25. Historical Consumer Price Index for All Urban Consumers (CPI-U): U.S. city average, by commodity and service group and detailed expenditure categories. Accessed 7 September 2016: http://www.bls.gov/cpi/cpid1607.pdf.

[31] The allowed amount and paid claims PMPM estimates developed from claim data for the present study drew upon calendar year 2014 data from CHIA's Massachusetts All Payer Claim Database (MA-APCD) Release 4.0. CHIA collects and manages data from commercial carriers, third party administrators, and public programs. CHIA works with each carrier to conduct a quality control process on the MA-APCD data, and "clears" data through this process on a carrier-by-carrier basis as this process is complete. The MA-APCD quality-controlled pharmacy claim data sample includes the three largest commercial carriers in the Commonwealth and MassHealth. The quality-controlled sample of three commercial carriers comprises approximately 60 percent of total commercial fully-insured and GIC primary pharmacy membership under age 65 in the Commonwealth. Compass relied upon this quality-controlled data sample after verifying basic reasonableness checks on membership and expenses. Cost estimates contained in this report assume that the PMPM costs obtained from the MA-APCD sample data are representative of the overall fully-insured commercial under-65 population.

[32] First Data Bank (FDB). Drug Pricing Policy. Accessed 8 September 2016: http://www.fdbhealth.com/policies/drug-pricing-policy/.

> Wholesale Acquisition Cost (WAC): as published by FDB represents the manufacturer's (for purposes of this Drug Price Policy, the term "manufacturer" includes manufacturers, repackagers, private labelers and other suppliers) published catalog or list price for a drug product to wholesalers as reported to First Databank by the manufacturer. WAC does not represent actual transaction prices and does not include prompt pay or other discounts, rebates or reductions in price. First Databank does not perform any independent investigation or analysis of actual transaction prices for purposes of reporting WAC. First Databank relies on manufacturers to report or otherwise make available the values for the WAC data field.

[33] *Op. cit.* BLS, Consumer Price Index. CPI Detailed Report, Data for July 2016: Table 25.

[34] Chapter 258 of the Massachusetts Acts of 2014: "An Act to increase opportunities for long-term substance abuse recovery." Accessed 1 September 2016: https://malegislature.gov/Laws/SessionLaws/Acts/2014/Chapter258.

[35] In its cost evaluations, DPH focused only on conversions where a single ADO dose is used to replace a single HPHR opioid dose, and did not include ADO pills combined to reach a chemically-equivalent dose of an HPHR opioid.

[36] *Op. cit.* FDA-CDER, Abuse-Deterrent Opioids: Evaluation and Labeling, Guidance for Industry.

[37] *Op. cit.* BLS, Consumer Price Index. CPI Detailed Report, Data for July 2016: Table 25.

[38] Massachusetts Center for Health Information and Analysis. (MA-CHIA). Annual Report on the Massachusetts Health Care System, September 2016. Accessed 12 September 2016: http://www.chiamass.gov/assets/2016-annual-report/2016-Annual-Report.pdf.

[39] The analysis assumes the mandate would be effective for policies issued and renewed on or after January 1, 2017. The impact of the mandate on cost in 2017 was estimated at 71.3 percent of the annual cost, using an assumed renewal distribution by month, by market segment, and by the Massachusetts market segment composition.

[40] Massachusetts Executive Office of Health and Human Services (MA-EOHHS). State Health Officials Announce Open Registration for New Online PMP System [Press Release]. Released 14 July 2016; accessed 8 September 2016: http://www.mass.gov/eohhs/gov/newsroom/press-releases/dph/new-online-pmp-system.html.

[41] Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. Accessed 8 September 2016: http://dx.doi.org/10.15585/mmwr.rr6501e1.

[42] MA-EOHHS. Opioid Overdose Prevention. Accessed 8 September 2016: http://www.mass.gov/eohhs/gov/departments/dph/programs/substance-abuse/prevention/opioid-overdose-prevention.html#MassachusettsOpioidAbusePreventionCollaborative.

[43] Category 1: Laboratory-based in vitro manipulation and extraction studies. Category 2: Pharmacokinetic studies (the study of the time course of drug absorption, distribution, metabolism, and excretion). Category 3: Clinical abuse potential studies.

[44] U.S. Census Bureau. Annual Estimates of the Resident Population for the United States, Regions, States, and Puerto Rico: April 1, 2010 to July 1, 2015. Accessed 28 April 2016: http://www.census.gov/popest/data/state/totals/2015/index.html.

[45] *Op. cit.* U.S. Census Bureau, Annual Estimates of the Population for the United States, Regions, States, and Puerto Rico: April 1, 2010 to July 1, 2015.

[46] Group Insurance Commission. GIC Health Plan Membership by Insured Status FY2013. Accessed 28 March 2016: http://www.mass.gov/anf/docs/gic/annual-report/annualreportfy2013.pdf.

[47] Group Insurance Commission. GIC Health Plan Membership by Insured Status FY2014. Accessed 28 March 2016: http://www.mass.gov/anf/docs/gic/annual-report/fy2014annual-report.pdf.

[48] Group Insurance Commission, Group Insurance Commission Fiscal Year 2015 Annual Report. Accessed 25 January 2016: http://www.mass.gov/anf/docs/gic/annual-report/gic-annual-reportfy15.pdf.