Mandated Benefit Review of House Bill 977:

An Act Relative to Providing for Care of Patients with Mitochondrial Disease

September 2013
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Benefit Mandate Overview:
Mitochondrial Disease

History of the Bill
Massachusetts General Laws, chapter 3, section 38C requires the Center for Health Information and Analysis (CHIA) to review and evaluate the potential fiscal impact of each benefit mandate bill referred to the agency by a legislative committee.

The Joint Committee on Financial Services referred House Bill (H.B.) 3641, “An act providing for care and treatment of patients with mitochondrial disease,” to the Division of Health Care Finance and Policy (DHCFP) on March 16, 2012 for review. When the new legislative session began on January 2, 2013, a similar bill – H.B. 977 – was filed, and the Committee requested that CHIA, successor agency to DHCFP, modify the scope of the review to reflect the revised bill.

What Does the Bill Propose?
H.B. 977 requires that health insurance plans, defined in the bill, provide “coverage for treatment of mitochondrial disease [including], but not limited to, the use of vitamin and nutritional supplements, such as CoEnzyme Q10, Vitamin E, Vitamin C, Vitamin B1, Vitamin B2, Vitamin K1 and L-Carnitine.”

H.B. 977 focuses on pharmacologic treatment for mitochondrial disease – specifically combinations of vitamin and nutritional supplements. These treatments may take the form of the mito-cocktail and require special ingredients or preparations – some classified as bulk chemicals or medical food, and sometimes requiring the services of a compounding pharmacy. A mito-cocktail may contain anywhere from two to 20 ingredients, of which those specified in H.B. 977 are among the most common.

What is Mitochondrial Disease?
Mitochondrial disease encompasses a group of metabolic disorders characterized by dysfunction of the mitochondria. Organ systems most reliant on oxygen (e.g., brain, muscle, heart) are more often affected by mitochondrial disease, but the illness can affect any cell or organ and presents in vastly different ways, from isolated muscle weakness to multi-systemic illness.

Many illnesses, including autism, ALS, chronic fatigue, muscular dystrophy, cardiomyopathy, epilepsy, cerebral palsy, diabetes, fibromyalgia, and Alzheimer’s, Parkinson’s, and Huntington’s diseases have been linked to mitochondrial disease.

Estimates of prevalence of mitochondrial disease vary, in part because it is difficult to diagnose due to its many possible presentations. However, a 2013 clinical resource that synthesized findings from several studies found an overall prevalence of primary mitochondrial defects of between 11.5 and 20 cases per 100,000.† There is currently no known cure for mitochondrial disease, and treatments at this time remain mostly supportive or palliative.

* In November 2012, under Massachusetts General Laws, chapter 224 of the Acts of 2012, the Division of Health Care Finance and Policy was re-named the Center for Health Information and Analysis, along with shifts in certain responsibilities.
Current Coverage

Six major Massachusetts health insurers surveyed by CHIA do not cover over-the-counter vitamins and supplements, which are included in most of the mito-cocktail therapies named in H.B. 977. Co-Enzyme Q10 was named as a covered benefit by one insurer and a potentially covered benefit by another insurer for patients diagnosed with mitochondrial disease. All insurance companies use a “medical necessity” guideline for coverage of the disease itself, and for treatments that may be required for its potential side effects, such as physical or occupational therapy or cochlear implants.

Cost of Implementing the Bill

Adding this benefit to fully-insured health plans would result in a low-end estimate of adding 2 cents (0.00 percent), and a high-end estimate of adding 14 cents to the typical member’s monthly health insurance premiums (0.03 percent) on average over the next five years.

Plans Affected by the Proposed Benefit Mandate

Individual and group accident and sickness insurance policies, corporate group insurance policies, and HMO policies issued pursuant to the Massachusetts General Laws, as well as the Group Insurance Commission (GIC) policies covering state employees and their dependents would be subject to this mandate.

The proposed benefit mandate laws would 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

Health insurance plans operated as self-insured entities (i.e., where the employer policyholder retains the risk for medical expenditures and uses the insurer to provide administrative functions) are subject to federal law and not to state-level mandates. State-mandated health benefits do not apply to Medicare and Medicare Advantage plans and their benefits are qualified by Medicare. Consequently this analysis excludes any members of commercial fully-insured plans over 64 years of age. These mandates also do not apply to federally-funded plans including TRICARE (covering military and dependents), Veterans Administration, the Federal Employees’ Health Benefit Plan, and Medicaid/MassHealth.

Implications of the Federal Affordable Care Act

While this fiscal impact review focuses on premiums in accordance with H.B. 977, Affordable Care Act (ACA) changes have since gone into effect. In accordance with §1311(d)(3)(B) of the ACA and as codified in CFR §155.170, the Commonwealth is required to offset the costs of benefit mandates not included in the state’s Essential Health Benefits (EHB) benchmark plan for individuals enrolled in Qualified Health Plans (QHPs) through the Health Connector, the state’s ACA-compliant Exchange, or outside of the Exchange. Specifically, the costs of these benefit mandates will need to be supported through the state’s operating budget or through other state resources. This would include the costs for any mandated benefits enacted on or after January 1, 2012.
As of September 2013, state benefit mandates enacted on or after January 1, 2012 (and therefore not included in the state’s EHB benchmark plan) include:

1. Cleft Palate and Cleft Lip
   (M.G.L. c. 175 § 47BB; M.G.L. c. 176A § 8EE; M.G.L. c. 176B § 4EE; and M.G.L. c. 176G § 4W)

2. Hearing Aids for Children
   (M.G.L. c. 175 § 47X(f); M.G.L. c. 176A § 8Y(f); M.G.L. c. 176B § 4EE; and M.G.L. c. 176G § 4N)

3. Oral Cancer Therapy
   (M.G.L. c. 175 § 47DD; M.G.L. c. 176A § 8FF; M.G.L. c. 176B § 4FF; and M.G.L. c. 176G § 4X)
Medical Efficacy Assessment: Mitochondrial Disease

Massachusetts H.B. 977 requires health insurance plans to cover the cost of treatment of persons diagnosed with mitochondrial disease including, but not limited to, the use of vitamin and nutritional supplements, such as CoEnzyme Q10, Vitamin E, Vitamin C, Vitamin B1, Vitamin B2, Vitamin K1 and L-Carnitine. M.G.L. c. 3 § 38C charges the Massachusetts Center for Health Information and Analysis (CHIA), formerly the Division of Health Care Finance and Policy, with reviewing the medical efficacy of mandating the benefit. Medical efficacy reports include the potential impact that each benefit could have on the quality of patient care and health status of the population as well as research results addressing the medical efficacy of the treatment or service compared to alternative treatments.

Evaluating treatment outcomes presents challenges. Patients may report feeling better without measurable evidence of improvement in function or disease status and vice versa. Patient-reported outcomes are increasingly being recognized as valuable data that may merit consideration even when below the threshold of statistical significance.

What is Mitochondrial Disease?

Mitochondrial disease refers to a group of diverse metabolic disorders characterized by dysfunction of the mitochondria.1 Mitochondria are organelles (cell sub-units with functions essential to the cell’s ability to process nutrients and produce energy) that are present in every cell of the body except red blood cells: they generate cells’ energy. With mitochondrial disease, mitochondria cannot efficiently turn sugar and oxygen into energy, so cells do not work correctly.2 Without sufficient energy, cells may become damaged or even die, and one or more bodily functions may become impaired.

While organ systems most reliant on aerobic metabolism (e.g., brain, muscle, heart) are more often affected by mitochondrial disease, the illness can affect any cell or organ and present with a wide range of clinical expression, from isolated muscle weakness to severe multi-systemic illness.3 Mitochondria also play a role in other cellular activities, from regulating cell processes that affect normal human development to producing cholesterol.4 Once thought to be relatively well-defined and quite rare, mitochondrial disease is being identified more frequently as diagnostic capabilities improve.5

Pathology

Mitochondrial disease can present at any age, from birth through adulthood, and affect almost any organ or body function.6 Severity ranges from fatal to essentially asymptomatic and discovered only as an incidental finding. Many of the most dramatic types tend to present in children and often carry a poor prognosis, but there is no typical course or prognosis. Some types develop into chronic and often progressively debilitating disease over the course of a lifetime.7 Presentation and clinical course can be variable and unpredictable – even among similar subgroups – for reasons still not entirely well understood.8

Some conditions related to mitochondrial disease have been defined as named syndromes such as MELAS (mitochondrial myopathy, encephalopathy, lactic acidosis, and stroke syndrome – a progressive neurodegenerative disorder) or CPEO (chronic progressive external ophthalmoplegia, an eye disorder characterized by progressive inability to move the eyes and eyebrows).9
Depending on which cells of the body are affected, symptoms of mitochondrial disease may include poor growth, muscle weakness, vision or hearing problems, developmental delays, learning disabilities, heart, liver or kidney disease, gastrointestinal disorders, respiratory disorders, diabetes, thyroid problems, increased risk of infection, seizures and other neurological problems, dementia and other psychiatric disorders.

**Diagnosis and Prevalence**

People with mitochondrial disorders not so severe as to be rapidly fatal in childhood often experience struggles over proper diagnosis and adequate treatment. Yet early diagnosis and treatment may offer the only hope of preventing poor outcomes. DNA analysis and muscle biopsy have been among the main tools for diagnosing a mitochondrial disorder, although newer and less invasive diagnostics are under development. Adult patients especially may be at risk for any number of misdiagnoses, from fibromyalgia to chronic obstructive pulmonary disease (COPD), if clinicians do not maintain a high index of suspicion for mitochondrial disease as the common root cause of seemingly unrelated problems. One clinical resource synthesized statistics from several studies in which different geographic areas and populations were sampled and found an overall prevalence of primary mitochondrial defects of at least 13.1:100,000. These statistics are likely underestimates of the true prevalence due to under-diagnosis.

**Potential Causes**

Mitochondrial diseases are believed to be inherited. They can occur at any age and involve one or more body systems. Most are the result of mutations (changes) in DNA located in the nucleus of the cell, or in the mitochondria of a cell. Some mitochondria become poorly functioning because of another disease process (including other chromosomal disorders), exposure to toxins or viruses, or other inherited genetic mutations that are not disease-causing until “triggered” by some other genetic factor.

**Treatments**

Despite significant advances in understanding mitochondrial disease, there is still no known cure, and treatment remains mainly supportive or palliative. Treatments are of necessity individualized because “no two people will respond to a particular treatment in a specific way even if they have the same disease.” The results of a recent survey on expert practice are currently being compiled in an attempt to continue to inform this process.

H.B. 977 focuses on pharmacologic treatment, specifically combinations of vitamin and nutritional supplements. Some of these vitamins and supplements may be available over-the-counter in forms and dosages suitable for use in mitochondrial patients who are able to swallow many pills, while others may not. These pharmacologic treatments may take the form of the mito-cocktail and require special ingredients or preparations, some classified as bulk chemicals or medical food, and sometimes requiring the services of a compounding pharmacy.
While some pharmacologic agents mandated by H.B. 977 appear to be beneficial in the treatment of mitochondrial disease or its side effects, none have demonstrated a long-term benefit for clinically important outcomes on a statistically significant, generalizable level. Vitamin and nutritional support for pathways known or suspected to be affected in mitochondrial disease seem to have become general practice despite the lack of strong evidence, specific guidelines, or expert consensus. Of note, secondary disorders such as diabetes or hearing loss may result from mitochondrial disease and should continue to be treated by the standard of care for those particular conditions.

For children, standard dosing is often weight-based and changes over time. Mitochondrial disease in children – especially the most severe variety – may be treated differently from those in adults. Prevention of avoidable complications is another important consideration of care.

**Treatments Specifically Named in H.B. 977:**

**Coenzyme Q10 (CoQ10)** (also called ubiquinone) is an essential cofactor in the mitochondrial respiratory chain as well as an antioxidant. It is the primary ingredient in most mito-cocktails. Supplementation is thought to enhance the activity of electron transport chain (cellular energy-generating process) enzymes when they are deficient, which is often considered to be the case in mitochondrial disease. Reduced fatigue, reduced muscle cramps, and isolated reports of clinical and metabolic improvement have been documented with the use of this supplement.

**Vitamin E** is an antioxidant. Antioxidants help to minimize the presence of “free radicals” that attack healthy cells. They may prevent further damage to the mitochondria and other parts of the cell caused by imbalances in other processes resulting from mitochondrial disease.

**Vitamin C** is another antioxidant that frequently appears among the most common components of the mito-cocktail. It is involved in neurotransmitter synthesis and increases iron absorption. Limited scientific data is available regarding its effectiveness in treating mitochondrial disease.

**Vitamin B1 (thiamine)** plays an important role in the health of the nervous system and other organs that may be affected by mitochondrial disease. One study reported isolated improvements in treating Kearns-Sayre Syndrome and other mitochondrial disorders with this supplement, but a larger and more recent study showed no significant effect.

**Vitamin B2 (riboflavin)** often forms the base preparation of a mito-cocktail along with CoQ10 because of its importance as a cofactor in the energy-generating process. Two early 1990s studies showed clinical and biochemical improvements in small groups of patients who received this supplement, but a larger study of 16 different patients failed to show a benefit.

**Vitamin K** rarely appears in the literature among the most frequently used supplements. It may stimulate oxygen utilization, but its role in treating mitochondrial disease is not well-established. It is unclear if its common form (K1) has benefit, however it does have contraindications and potentially serious adverse effects as it affects blood clotting.

**L-Carnitine (levocarnitine or carnitine)** is used to correct secondary biochemical deficits observed in patients with mitochondrial disease. Carnitine levels are decreased in these patients for reasons that are not yet well understood. One study showed that the use of carnitine supplements in patients who suffered from secondary carnitine deficiency and CPEO (a type of mitochondrial disease affecting the eyes and eyelid movement) resulted in improvements in isolated cases.
Other Established and Emerging Treatments
Symptomatic treatment has been the mainstay of mitochondrial disease therapy to date. Aerobic and resistance training exercise may also be beneficial and is often prescribed as it has been shown to increase oxidative capacity and mitochondrial volume. Other forms of physical, occupational and speech therapy may also be indicated. Medical equipment or surgical procedures such as cochlear implants, cardiac pacemakers and defibrillators, or organ transplantation may be essential to help alleviate the worsening of symptoms of mitochondrial disease.

Cost of Treatments
Mitochondrial disease is diagnosed via muscle biopsy (a test that can cost in excess of $10,000), but can sometimes be diagnosed from clinical symptoms or a positive blood test identifying a specific genetic mutation.

A mito-cocktail, which usually includes some or all of the treatments specifically named in H.B. 977, may contain anywhere from two to 20 ingredients, of which those specified in H.B. 977 are among the most common. According to Compass Health Analytics, the monthly cost to patients in Massachusetts has been estimated in the range of $300-$600. The most common component, CoQ10, contributes significantly to the cost range, as a one-month supply may cost $200 (per 400mg daily).
Endnotes


21. Interview with Katherine B. Sims, MD, Massachusetts General Hospital Director of the Neurogenetics Clinic; Mark Korson, MD, Associate Professor of Pediatrics, Genetics/Metabolism, Tufts Floating Hospital for Children; January 29, 2013.


27. The Mitochondrial Medicine Society. News and Updates detailed the latest MMS project: “The Mitochondrial Medicine Society has completed studying the state of clinical mitochondrial medicine in North America. The study surveyed 32 clinicians that direct mitochondrial disease clinics to assess how mitochondrial disease care is provided. The data has been compiled and we hope to present it to all of you soon.” Accessed March 23, 2013 at [mitosoc.org](http://mitosoc.org) (undated material). This study was also mentioned by Dr. Korson during the expert interview (cited endnote 28).


55 Ibid.

Acknowledgements
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Actuarial Assessment of House Bill 977: An Act providing for care and treatment of patients with mitochondrial disease

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Center for Health Information and Analysis

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Prepared by
Compass Health Analytics, Inc.
Actuarial Assessment of House Bill 977:
An Act providing for care and treatment of patients with mitochondrial disease

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Actuarial Assessment of House Bill 977:
An Act providing for care and treatment of patients with mitochondrial disease

Executive Summary

House Bill 977 requires health insurance plans to provide coverage and payment for the treatment of mitochondrial disease.¹ M.G.L. c.3 § 38C charges the Massachusetts Center for Health Information and Analysis (CHIA, formerly the Division of Health Care Finance and Policy) with, among other duties, reviewing the potential impact of proposed mandated health care insurance benefits on the premiums paid by employers and consumers. CHIA has engaged Compass Health Analytics, Inc. to provide an actuarial estimate of the effect enactment of the bill would have on the cost of health care insurance in Massachusetts.

Background

H.B. 977 requires that health insurance plans provide “coverage for treatment of mitochondrial disease. Said treatment shall include, but not be limited to, the use of vitamin and nutritional supplements, such as CoEnzyme Q10, Vitamin E, Vitamin C, Vitamin B1, Vitamin B2, Vitamin K1 and L-Carnitine.”

Mitochondrial disease is a group of disorders caused by a dysfunction in the mitochondrial respiratory chain in almost any cell of the body. The disease can affect virtually any organ or system at any age in a myriad of ways. Because of this wide variety in the presentation of the disease, it is difficult to diagnose, and the science and medicine surrounding mitochondrial disease is rapidly evolving. The most recent published data estimate that mitochondrial disease affects between 11.5 and 20 people per 100,000.

There is currently no cure for mitochondrial disease, and treatments are largely supportive. The treatment named in the proposed mandate, commonly known as the “mito-cocktail”, aims to keep patients healthy and delay progression of the disease by maximizing energy, eliminating and avoiding cellular toxins, and preventing or minimizing physiologic stresses like infections. Treatment with the mito-cocktail is on-going, and is estimated to cost on average between $3600 and $7200 per year per patient.

Coverage by health insurers for the mito-cocktail is highly variable between, and possibly even within, carriers. While most insurers explicitly do not pay for mito-cocktail treatment, some have made exceptions for certain individuals, most often children. More often, carriers deny payment

¹This bill was introduced into the 187th General Court (2011-2012) as House Bill 320. The bill has been re-introduced to the 188th General Court as House Bill 977. Our analysis will be guided by the intent as communicated to the Center by the sponsors in discussions about the bill and by the language of the re-submitted version.
based on the lack of scientific evidence proving the efficacy of mito-cocktail treatment. Researchers in the mitochondrial disease field confirm the lack of supportive evidence from controlled testing.

**Analysis**

Compass estimated the impact of H.B. 977 through the following steps:

- Estimate the populations covered by the mandate, projected for the coming five years.
- Estimate the prevalence rate of mitochondrial disease in the covered population.
- Estimate the number of patients who will be treated with the mito-cocktail.
- Estimate monthly costs for the mito-cocktail.
- Apply the monthly costs to the relevant treated patient population to calculate the incremental costs of the mandate.
- Calculate the proposed mandate’s incremental effect on carrier medical expense.
- Estimate the impact on premiums of insurers' retention (administrative costs and profit).
- Project the estimated cost over the next five years.

The rarity and heterogeneity of mitochondrial disease, and the variability inherent in the mito-cocktail treatment, has at least the following impacts on the analysis:

- Estimates of the prevalence rate of the disease are imprecise.
- No claim data are available for analysis, as diagnostic codes are not applied consistently by providers, and the mito-cocktail is not identifiable in pharmacy claim data.
- Randomized controlled studies designed to test the safety and efficacy of the mito-cocktail are rare and inconclusive.
- Existing insurance coverage for the mito-cocktail is inconsistent, which may affect the final estimate of the mandate’s marginal impact on carriers.

**Summary results**

Table ES-1 summarizes the effect of H.B. 977 on premium costs for fully-insured plans, averaged over five years. The final analysis estimates that the bill, if enacted, would increase fully-insured premiums by as much as 0.03 percent on average over the next five years, although the more likely range is closer to 0.01 percent.

The degree of precision achievable in this analysis is limited by the lack of empirical data about a rare condition and a highly heterogeneous treatment. But while the results have some variation measured by the ratio between low- and high-level scenarios, even the high-level estimate represents a small increase in overall premiums.
The impact of the bill 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, on how the benefits will change under the proposed mandate, and upon the disease prevalence in a specific population.

Table ES-1
Estimated Incremental Impact of H.B. 977 on Premium Costs

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Actuarial Assessment of House Bill 977:
An Act providing for care and treatment of
patients with mitochondrial disease

1. Introduction

House Bill 977 requires health insurance plans to provide coverage and payment for the treatment
of mitochondrial disease. M.G.L. c.3 § 38C charges the Massachusetts Center for Health
Information and Analysis (CHIA, formerly the Division of Health Care Finance and Policy) with,
among other duties, reviewing the potential impact of proposed mandated health care insurance
benefits on the premiums paid by employers and consumers. CHIA has engaged Compass Health
Analytics, Inc. to provide an actuarial estimate of the effect enactment of the bill would have on the
cost of health care insurance in Massachusetts.

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

Section 2 of this analysis outlines the provisions of the bill. Section 3 summarizes the methodology
used for the estimate. Section 4 discusses important considerations in translating the bill’s
language into estimates of its incremental impact on health care costs. Section 5 describes the
calculation of the estimate.

2. Interpretation of H.B. 977

The following subsections describe the provision of H.B. 977, as redrafted for the 188th General
Court.

2.1. Plans affected by the proposed mandate

The bill amends the statutes that regulate insurers providing health insurance in Massachusetts. It
has the following five sections, each addressing statutes dealing with a particular type of health
insurance policy:

- Section 1: Insurance for persons in service of the Commonwealth (creating M.G.L. c. 32A,
  § 17L)
- Section 2: Accident and sickness insurance policies (creating M.G.L. c. 175, § 47EE)

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2 This bill was introduced into the 187th General Court (2011-2012) as House Bill 320. The bill has been re-
introduced to the 188th General Court as House Bill 977. Our analysis will be guided by the intent as
communicated to the Center by the sponsors in discussions about the bill and by the language of the re-
submitted version.
Section 3: Contracts with non-profit hospital service corporations (creating M.G.L. c. 176a, § 8FF)

Section 4: Certificates under medical service agreements (creating M.G.L. c. 176B, § 4GG)

Section 5: Health maintenance contracts (creating M.G.L. c. 176G, § 4Y)

All sections mandate coverage for 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.

Health insurance plans operated as self-insured entities (i.e., where the employer policyholder retains the risk for medical expenditures and uses the insurer to provide administrative functions) are subject to federal law, and not to state-level mandates.

Section 1 of the bill directs the commissioners of the Commonwealth’s own largely self-insured employee plan (the Group Insurance Commission, or GIC) to provide coverage. While the bill reaches the GIC, CHIA has instructed Compass not to include it in this analysis.

State health benefit mandates do not apply to Medicare, and Medicare Advantage plans and their benefits are qualified by Medicare. Consequently this analysis excludes any members of commercial fully-insured plans over 64 years of age. Some might use Medicare supplement plans, but generally benefits in those plans mirror Medicare’s benefits (though “innovative” additional benefits might be offered in some cases) and the proposed mandate will likely not affect them. Such plans are typically excluded from mandate legislation. Finally, some employees over 64 have fully-insured plans through their employers, often with Medicare, which will be the primary payer for some and not others. We assume the number of people in this group suffering from this relatively rare condition is small enough that it will not significantly affect the results of this analysis.

2.2. Covered services

H.B. 977 requires that each of the targeted types of health insurance plans listed above provide “coverage for treatment of mitochondrial disease. Said treatment shall include, but not be limited to, the use of vitamin and nutritional supplements, such as CoEnzyme Q10, Vitamin E, Vitamin C, Vitamin B1, Vitamin B2, Vitamin K1 and L-Carnitine.”

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3 Note that the membership of any fully-insured plans sponsored by the GIC will be included in the membership estimate for the commercial, fully-insured plans that are the main focus of this analysis.

4 As noted elsewhere, mitochondrial disease is likely correlated with disability severe enough to keep sufferers out of the workforce; this is probably even more pronounced for people over 64, and relatively few sufferers over 64 are likely to work. Finally, some people over 64, generally certain resident aliens, might have commercial insurance without Medicare, but we assume the sufferers in this group are very few.
Mitochondria are the organelles in every human cell (except red blood cells) that generate the cell’s energy; they produce 90 percent of the energy needed by the human body.5 Mitochondrial disease is a group of disorders that result from dysfunction in the mitochondrial respiratory chain, and are “the most prevalent group of inherited neurometabolic diseases.”6

Associated conditions

Mitochondrial disease includes a set of associated, clinically heterogeneous conditions,7 and can be caused by nuclear or mitochondrial mutations (primary mitochondrial disease) or a genetic alteration that, when externally triggered, produces mitochondrial dysfunction (secondary mitochondrial disease).8 Sometimes mitochondrial disease affects a single organ, but most cases involve multiple organ systems and include neurologic and myopathic problems. The disease may present at any age, “and virtually any organ or tissue can be involved.”9 Some individuals exhibit clinical features that can be grouped into a single clinical syndrome, but the disease is extremely variable, and patients may not fall into one category of symptoms or syndromes.10

Mitochondrial disease, then, is not a single diagnosis. In fact, at least fifteen diagnosis codes11 can be applied to mitochondrial disease, yet their assignment is neither clear nor universally employed. The home page of the North American Mitochondrial Disease Consortium, part of the Rare Diseases Clinical Research Network at the National Institutes of Health, lists 29 separate disorders,12 and the United Mitochondrial Disease Foundation outlines 44 separate diseases on its website.13 Further, no single diagnostic method is used to establish the presence of the disease, making its

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10 According to Haas, et. al., “[c]ommon clinical features of mitochondrial disease include ptosis, external ophthalmoplegia, proximal myopathy and exercise intolerance, cardiomyopathy, sensorineural deafness, optic atrophy, pigmented retinopathy, and diabetes mellitus. Common central nervous system findings are fluctuating encephalopathy, seizures, dementia, migraine, stroke-like episodes, ataxia, and spasticity.” Ibid.
identification and analysis extremely challenging. The science and medicine surrounding the understanding of mitochondrial disease is dynamic and rapidly evolving.

Moreover, a host of other diseases have been linked to mitochondrial dysfunction. This category is extremely broad and includes such conditions as autism, ALS, chronic fatigue, muscular dystrophy, cardiomyopathy, epilepsy, cerebral palsy, diabetes, fibromyalgia, and Alzheimer’s, Parkinson’s, and Huntington’s diseases. However, while we recognize that the science of mitochondrial disorders is evolving rapidly, these diseases are generally not considered “mitochondrial disease” and therefore this analysis assumes they are not included in the term as used in the proposed mandate.

Treatments

Currently, the treatment and management of mitochondrial disease is largely supportive, and “the disorders progress relentlessly causing significant morbidity and premature death.” Given this, many treatments for mitochondrial disease patients are prescribed for symptoms related to the disease, and are not specific to mitochondrial disease itself. One example is cochlear implants, used to treat sensioneural hearing loss, which occurs in many mitochondrial disorders. For treating this type of loss, cochlear implants have been proven medically effective, and therefore, in general, health insurance would pay for such treatment. For the purposes of this analysis, we assumed that if scientific evidence exists to prove that specific treatments are medically necessary or effective to treat a diagnosed symptom or disease, that such treatment would already be covered by insurance, and therefore not impacted by the proposed mandate.

Aside from reducing the myriad of symptoms, treatment for mitochondrial disease itself generally focuses on keeping a patient healthy, delaying disease progression, maximizing energy, eliminating or avoiding cellular toxins that may further hamper mitochondrial function, and preventing or minimizing symptoms that accompany physiologic stresses like surgery, infections, etc. The most common treatments presently prescribed consist of dietary and exercise regimens.

Prescribed exercise may include physical, occupational, and/or speech therapy; these are not intended to “change the underlying mitochondrial disease, but to preserve and maximize strength,

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16 Pfeffer, op.cit.


18 Ibid.

mobility, and functioning.” In a survey of insurance carriers in the Commonwealth, all indicated that physical, occupational, and speech therapies are treatments currently covered by existing policies. Again, then, this analysis assumes costs for these types of treatments are not affected by the proposed mandate.

Instead, the focus of the mandate, and of this analysis, is on the prescribed use of combination nutraceuticals (or vitamin and nutritional supplements), often referred to as the “mito-cocktail.” These typically consist of a variety of antioxidants, and often include medical foods and over-the-counter vitamins and supplements. The intent of the mito-cocktail is to target the biochemical pathways in mitochondrial disease that reduce energy production and cause cellular stress.

However, no mito-cocktail treatment for mitochondrial disease has been proven effective through randomized controlled trials, the standard scientific basis upon which the safety and effectiveness of a clinical intervention is tested. This is due, in part, to the rarity of the diseases, the heterogeneity of the patient population and the clinical manifestations, and the “infinite number of potential combinations” possible in the creation of a patient-specific mito-cocktail.

Nonetheless, while H.B. 977 does not explicitly address the criteria that carriers may use in evaluating the medical necessity of a treatment, this analysis interprets the proposed mandate as requiring coverage for mito-cocktail therapy for patients with mitochondrial disease regardless of whether the carrier regards the treatment as experimental or not evidence-based.

Finally, we assume the bill makes no changes to general insurance policy requirements such as cost-sharing.

2.3. Existing laws affecting the cost of H.B. 977

Current Massachusetts statutes contain no mandates explicitly addressing mitochondrial disease. Even so, understanding of the disease and its connections with other conditions continues to evolve, and some of those connections might point to conditions addressed in existing mandates.

For example, Massachusetts law currently mandates “coverage for nonprescription enteral formulas [. . .] medically necessary for the treatment of malabsorption caused by Crohn’s disease,

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20 Parikh, op.cit.
22 Parikh, op.cit.
23 Tarnopolsky, op.cit.
26 Tarnopolsky, op.cit.
ulcerative colitis, gastroesophageal reflux, gastrointestinal motility, chronic intestinal pseudo-obstruction, and inherited diseases of amino acids and organic acids.” But according to the federal Recommended Uniform Screening Panel (RUSP), inherited diseases of amino acids and organic acids, listed in the Massachusetts statute, fall into a category of “metabolic disorders” along with “fatty acid oxidation disorders” (FAODs) some of which may be classified as mitochondrial diseases.

To the extent current law mandates treatment for some variants of mitochondrial disease, the net impact of proposed mandate would be reduced. However, responses to a survey of carriers about their coverage for treatment for mitochondrial disease indicated they saw no connection to existing statutes. Given that, and because FAODs are not specifically mentioned in current Massachusetts law, this analysis assumes existing mandates do not apply to mitochondrial disease as defined for the proposed mandate.

Further, existing state mandates require newborn screening for metabolic disorders, which would include the FAODs within the category of mitochondrial diseases. However, those mandates do not require coverage for the cost of treating any identified mitochondrial diseases.

Therefore, this analysis assumes no current federal or state mandates will affect the estimated cost of the proposed bill.

One point of note, however, is the potential for future changes to coverage that may be mandated at the federal level. In correspondence between the Secretary of Health and Human Services, and the Advisory Committee on Heritable Disorders in Newborns and Children, the Committee chair recommended that medical foods for the treatment of metabolic disorders identified through newborn screening, which would include some mitochondrial diseases, be uniformly covered for

27 M.G.L. c. 176G §4D

28 "Recommended Uniform Screening Panel of the Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children.” U.S. Department of Health and Human Services.
http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendedpanel/index.html (accessed March 06, 2013). These metabolic disorders include Carnitine uptake defect/carnitine transport defect (CUD); Medium-chain acyl-CoA dehydrogenase deficiency (MCAD); Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD); and Long-chain L-3 hydroxyacyl-CoA dehydrogenase deficiency (LCAD).

29 M.G.L. c. 176B §4C

30 According to the FDA, a medical food is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." U.S. Food and Drug Administration. "Regulatory Information: Orphan Drug Act.”

For further FDA guidance on the definition of medical food, see: U.S. Food and Drug Administration. "Guidance for Industry: Frequently Asked Questions about Medical Foods.”
adults and children through private and public insurance. In fact, L-Carnitine, specifically mentioned in H.B. 977, is recommended for the treatment of certain FAODs, and falls into the Committee’s recommendation for federally-mandated coverage. Further, these medical foods are currently under consideration to be included as an “Essential Health Benefit” as part of the Affordable Care Act. If, then, some mito-cocktails are defined to be medical foods for the treatment of metabolic disorders identified through newborn screening, and if these are included as essential health benefits under the Affordable Care Act, the incremental financial impact of this mandate on Massachusetts insurance carriers would be further diminished.

Finally, in accordance with §1311(d)(3)(B) of the federal Affordable Care Act (ACA) and as codified in CFR §155.170, the Commonwealth is required to offset the costs of mandated benefits not included in the state’s Essential Health Benefits (EHB) benchmark plan for individuals enrolled in Qualified Health Plans (QHPs) through the Health Connector, the state’s ACA-compliant Exchange, or outside of the Exchange. These include the costs of any mandated benefits enacted on or after January 1, 2012. The costs of these mandated benefits will need to be supported through the state’s operating budget or through other state resources. However, because the potential impact of H.B. 931 on state resources does not directly affect commercial premiums, CHIA has not requested an estimate of the magnitude of that impact in this analysis.

3. Methodology

3.1. Steps in the analysis

Compass estimated the impact of H.B. 977 through the following steps:

- Estimate the populations covered by the mandate, projected for the coming five years.
- Estimate the prevalence rate of mitochondrial disease in the covered population.
- Estimate the number of patients who will be treated with the mito-cocktail.
- Estimate monthly costs for the mito-cocktail.
- Apply the monthly costs to the relevant treated patient population to calculate the incremental costs of the mandate.

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• Calculate the proposed mandate’s incremental effect on carrier medical expense.
• Estimate the impact on premiums of insurers’ retention (administrative costs and profit).
• Project the estimated cost over the next five years.

3.2. Data sources
The primary data sources used in the analysis were:
• Interviews with legislative and CHIA staff regarding legislative intent.
• Interviews with clinical experts, including mitochondrial disease specialists.
• Interviews with compounding pharmacists specializing in the preparation and provision of the ‘mito-cocktail’ in Massachusetts.
• Academic literature, including population data, cited as appropriate.
• Responses to a survey sent to Massachusetts health insurance carriers with questions about their coverage for mitochondrial disease and mito-cocktails.

The step-by-step description of the estimation process that follows addresses limitations in some of these sources, and the uncertainties they contribute to the cost estimate.

4. Factors Affecting the Analysis
Some important issues arise when translating the provisions of H.B. 977 into an analysis of incremental cost. The rarity and heterogeneity of mitochondrial disease limits the availability of empirical data regarding treatment practices, costs, and coverage for the disease.

4.1. Prevalence of mitochondrial disease
Published estimates of the prevalence rate of mitochondrial disease range from approximately 11.5\textsuperscript{34} to 20\textsuperscript{35,36} per 100,000. However, the literature also reveals the complexity in making these statistical estimations, as the disease itself is not uniformly defined.\textsuperscript{37,38}

Because, as previously discussed, providers do not apply consistent diagnostic coding for mitochondrial disease, an analysis of commercial claim data would not provide an accurate estimate of the prevalence of the disease. Therefore, this analysis will rely on the published statistics, and estimate the prevalence rate range at 11.8 to 20 per 100,000, with the mid-point of 15.9 per 100,000.

The above prevalence values reflect the estimated number of people in the population with mitochondrial disease, and it would be unlikely, particularly given the challenges of defining the disease, that all people with the condition would be diagnosed and under active treatment. Still, we can at least assume the proportion of members actually diagnosed who get mito-cocktail treatment will be fairly high; according to interviews with several clinical experts, almost all patients diagnosed with mitochondrial disease receive prescriptions for some form of mito-cocktail. And based on information from these providers, we can assume that almost all patients would adhere to these prescriptions, while a few might not adhere because they would have difficulty tolerating the cocktail or maintaining the discipline necessary to follow the regimen (somewhat like the discipline necessary to adhere to drug regimens used in treating HIV).

For the purpose of this analysis, we assume the variability in diagnosis rate and the relatively high rate of prescription for diagnosed cases combine to produce an estimate of 50 to 90 percent for the proportion of the affected population who receive treatment.

4.2. Per-patient monthly cost of mito-cocktail

As with diagnostic information, calculation of the costs of treating mitochondrial disease with the mito-cocktail through analysis of claim data does not yield complete or accurate information. This is due in part to the diagnostic issues, as well as to the previously noted “infinite number” of ingredient combinations that could make up a mito-cocktail, making identification of the treatment complex and likely incomplete in available pharmacy claim data. In fact, in a survey of the state’s largest insurance carriers, none is able to identify treatments specific to mitochondrial disease in their claim data.

Therefore, this analysis will use information obtained through interviews with two compounding pharmacists in Massachusetts, both of whom specialize in the preparation of the mito-cocktail. According to the pharmacists, the average monthly cost of the mito-cocktail ranges from

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39 Amy Goldstein, MD, Division of Child Neurology, Childrens Hospital of Pittsburgh, interview. (December 12, 2012). Katherine B. Sims, MD, Massachusetts General Hospital Director Neurogenetics Clinic, interview. (January 29, 2013). Mark S. Korson, MD, Associate Professor of Pediatrics, Genetics/Metabolism, Tufts Floating Hospital for Children, interview. (January 29, 2013).
approximately $300 to $600, depending on the specific ingredients and dosages prescribed by the treating physician. Both pharmacists identified outliers to these averages, but noted that most patients fall into this approximate range.

This analysis must project the cost of the mito-cocktail for five years; the model assumes the cost of these treatments will rise at a rate approximating the average medical inflation rate over the past decade, which was 3.8 percent between 2003 and 2012. To be conservative, the model will apply an annual increase of four percent over the years since 2012, and will continue to use four percent through 2018.

4.3. Existing coverage for mitochondrial disease and the mito-cocktail

Current insurance coverage for the mito-cocktail in treating mitochondrial disease is unclear. According to a survey of insurance carriers in Massachusetts, most say that the mito-cocktail is not a covered benefit as most ingredients (vitamins and nutritional supplements) are available over-the-counter and are not FDA-approved, and that such treatments have not been scientifically proven as safe or effective. Only one carrier reported coverage for CoQ10 as a pharmacy benefit subject to prior authorization; this insurer identified 46 members in the past two years with the diagnosis of disorders of mitochondrial metabolism, and had approved six requests for vitamin or nutritional supplements. This same carrier stated that vitamins are not a covered benefit, highlighting how actual coverage for the mito-cocktail and its composite elements can vary.

According to the compounding pharmacies, some insurers have sometimes covered the mito-cocktail as an exception to general policy benefits, always requiring significant documentation and communication with the carrier. For some insurers, this exception had been made only for patients who are children. More recently, even these exceptional allowances have become more restricted, in part in response to additional oversight put in place by the carriers’ pharmacy benefit managers.

Given this complexity and inconsistency, this analysis assumes that the mito-cocktail is not currently a covered benefit as defined in the proposed mandate. If this assumption is incorrect for some insurance carriers or products, then the impact of the proposed mandate on insurance premiums would diminish in proportion to the currently existing coverage.

Mitochondrial disease can be severely debilitating. People diagnosed with many forms of the disease may be disproportionately likely to be declared disabled or medically-needy for insurance program eligibility, and may therefore be underrepresented in employer-sponsored plans, except as dependents. And while estimating this is not possible based on available information, to the extent sufferers are not in the commercially-insured population because they meet the requirements for disability status under MassHealth or Medicare, the impact of the mandate on commercial insurers would be reduced.

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5. Analysis

The following sections describe the series of calculations used to estimate the overall impact of the proposed legislation. The results provide a best estimate "mid-level" scenario; by varying assumptions in the model, low-level and high-level scenarios were produced as well, resulting in a range of estimates for the impact of the mandate.

5.1. Insured membership affected by the mandate

Table 1 shows the number of members in plans potentially affected by the mandate. As noted, people over the age of 64 are excluded. Further, no attempt has been made to adjust the projection for possible future effects of the federal Affordable Care Act on the number of people enrolling in fully-insured plans.

<table>
<thead>
<tr>
<th>Year</th>
<th>Projected Members</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>2,218,814</td>
</tr>
<tr>
<td>2015</td>
<td>2,194,845</td>
</tr>
<tr>
<td>2016</td>
<td>2,170,890</td>
</tr>
<tr>
<td>2017</td>
<td>2,146,143</td>
</tr>
<tr>
<td>2018</td>
<td>2,120,524</td>
</tr>
</tbody>
</table>

The resulting population numbers for each year were used in conjunction with projected prevalence and treatment rates, and unit costs to produce yearly cost estimates. As discussed in the following sections, these numbers were developed based on academic research and interviews with clinical experts and compounding pharmacists.

5.2. Prevalence and treatment rates

As noted previously, the analysis assumes a range of 11.8 to 20 patients per 100,000 with a midpoint of 15.9 per 100,000 for the prevalence rate of mitochondrial disease in the covered population, shown in Table 2. Of these patients, we assume 50 to 90 percent would be treated with the mito-cocktail, with the mid-point for this assumption set at 70 percent of patients, shown in Table 3.

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Prevalence per 100,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Scenario</td>
<td>11.8</td>
</tr>
<tr>
<td>Mid Scenario</td>
<td>15.9</td>
</tr>
<tr>
<td>High Scenario</td>
<td>20.0</td>
</tr>
</tbody>
</table>
Table 3:
Treatment Rate

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Scenarios</td>
<td>50%</td>
</tr>
<tr>
<td>Mid Scenarios</td>
<td>70%</td>
</tr>
<tr>
<td>High Scenarios</td>
<td>90%</td>
</tr>
</tbody>
</table>

5.3. Per patient cost of mito-cocktail

As noted in Section 4.2, estimates of the monthly cost of the mito-cocktail per patient range on average between $300 and $600; an inflation rate of four percent is applied to these 2012 estimates. Table 4 displays the resulting monthly costs for 2013.

Table 4:
Estimate of 2013 Monthly Cost of Mito-Cocktail Treatment per Patient

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Cost (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Scenarios</td>
<td>$324</td>
</tr>
<tr>
<td>Mid Scenarios</td>
<td>$487</td>
</tr>
<tr>
<td>High Scenarios</td>
<td>$649</td>
</tr>
</tbody>
</table>

5.4. Net increase in carrier medical expense

To calculate the net impact of the mandate, as expressed in the medical expense (i.e., the amount carriers pay out for services, whether under medical or pharmacy benefits) per member per month (PMPM), we first multiply the prevalence rate by the treatment rate to yield the treated population. This number is then multiplied by the monthly cost of the mito-cocktail per patient, and the entire product is divided by the relevant covered population; the results are displayed in Table 5.

Table 5:
Estimate of Increase in Carrier Medical Expense (PMPM)

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Increase (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Scenarios</td>
<td>$0.02</td>
</tr>
<tr>
<td>Mid Scenarios</td>
<td>$0.05</td>
</tr>
<tr>
<td>High Scenarios</td>
<td>$0.12</td>
</tr>
</tbody>
</table>

5.5. Net increase in premium

Assuming an average retention rate of 10.2 percent, based on CHIA’s analysis of administrative costs and profit in Massachusetts, the medical expense is adjusted upward to approximate the impact on premiums, as displayed in Table 6.

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Table 6:  
Estimate of Increase in Premium (PMPM)

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Estimate (PMPM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>$0.02</td>
</tr>
<tr>
<td>Mid</td>
<td>$0.06</td>
</tr>
<tr>
<td>High</td>
<td>$0.13</td>
</tr>
</tbody>
</table>

5.6. Five-year estimated impact

For each year in the five-year analysis period, Table 7 displays the projected net impact of the proposed mandate on medical expense and premiums using a projection of the Massachusetts fully-insured membership. The analysis finds that H.B. 977 will increase premiums by as much as 0.03 percent on average over the next five years, though the more likely range is closer to 0.01 percent.

The degree of precision achievable in this analysis is limited by the lack of empirical data about a rare condition and a highly heterogeneous treatment. But while the results have some variation measured by the ratio between low- and high-level scenarios, even the high-level estimate represents a small increase in overall premiums.

The impact of H.B. 977 on premiums rises steadily throughout the analysis period because of the underlying assumptions about continuing increases in the average cost of the mito-cocktail treatment. Finally, the impact of the bill 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, on how the benefits will change under the proposed mandate, and upon the disease prevalence in a specific population.

Table 7
Summary Results

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>Average</th>
<th>5 Yr Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Members (000's)</td>
<td>2,219</td>
<td>2,195</td>
<td>2,171</td>
<td>2,146</td>
<td>2,121</td>
<td>2,170</td>
<td></td>
</tr>
<tr>
<td>Medical Expense Low ($000's)</td>
<td>$508</td>
<td>$523</td>
<td>$538</td>
<td>$553</td>
<td>$568</td>
<td>$538</td>
<td>$2,690</td>
</tr>
<tr>
<td>Medical Expense Mid ($000's)</td>
<td>1,441</td>
<td>1,482</td>
<td>1,525</td>
<td>1,568</td>
<td>1,611</td>
<td>1,525</td>
<td>7,626</td>
</tr>
<tr>
<td>Medical Expense High ($000's)</td>
<td>3,110</td>
<td>3,200</td>
<td>3,291</td>
<td>3,384</td>
<td>3,477</td>
<td>3,293</td>
<td>16,463</td>
</tr>
<tr>
<td>Premium Low ($000's)</td>
<td>$566</td>
<td>$582</td>
<td>$599</td>
<td>$616</td>
<td>$633</td>
<td>$599</td>
<td>$2,996</td>
</tr>
<tr>
<td>Premium Mid ($000's)</td>
<td>1,604</td>
<td>1,651</td>
<td>1,698</td>
<td>1,746</td>
<td>1,794</td>
<td>1,698</td>
<td>8,492</td>
</tr>
<tr>
<td>Premium High ($000's)</td>
<td>3,464</td>
<td>3,563</td>
<td>3,665</td>
<td>3,768</td>
<td>3,872</td>
<td>3,667</td>
<td>18,333</td>
</tr>
<tr>
<td>Change in PMPM Low</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
</tr>
<tr>
<td>Change in PMPM Mid</td>
<td>0.06</td>
<td>0.06</td>
<td>0.07</td>
<td>0.07</td>
<td>0.07</td>
<td>0.07</td>
<td>0.07</td>
</tr>
<tr>
<td>Change in PMPM High</td>
<td>0.13</td>
<td>0.14</td>
<td>0.14</td>
<td>0.15</td>
<td>0.15</td>
<td>0.14</td>
<td>0.14</td>
</tr>
<tr>
<td>Estimated Monthly Premium</td>
<td>$487</td>
<td>$512</td>
<td>$537</td>
<td>$564</td>
<td>$592</td>
<td>$538</td>
<td>$538</td>
</tr>
<tr>
<td>Premium % Change Low</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
</tr>
<tr>
<td>Premium % Change Mid</td>
<td>0.01%</td>
<td>0.01%</td>
<td>0.01%</td>
<td>0.01%</td>
<td>0.01%</td>
<td>0.01%</td>
<td>0.01%</td>
</tr>
<tr>
<td>Premium % Change High</td>
<td>0.03%</td>
<td>0.03%</td>
<td>0.03%</td>
<td>0.03%</td>
<td>0.03%</td>
<td>0.03%</td>
<td>0.03%</td>
</tr>
</tbody>
</table>