

**CENTER FOR HEALTH
INFORMATION AND ANALYSIS**

**MANDATED BENEFIT REVIEW OF H.B. 986: AN ACT
RELATIVE TO HIV-ASSOCIATED LIPODYSTROPHY TREATMENT**

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Benefit Mandate Overview: H.B. 986: HIV-Associated Lipodystrophy

HISTORY OF THE BILL

The Joint Committee on Financial Services referred House Bill (H.B.) 986, “An Act relative to HIV-associated lipodystrophy treatment,” sponsored by Rep. Sciortino of Medford, to the Center for Health Information and Analysis (CHIA) for review. Massachusetts General Laws, chapter 3, section 38C requires CHIA to review and evaluate the potential fiscal impact of each mandated benefit bill referred to the agency by a legislative committee.

WHAT DOES THE BILL PROPOSE?

H.B. 986 requires that health insurance plans defined in the bill provide “coverage for medical or drug treatments to correct or repair disturbances of body composition caused by lipodystrophy syndrome, including but not limited to reconstructive surgery, such as suction-assisted lipectomy, other restorative procedures, and dermal injections or fillers for reversal of facial lipoatrophy syndrome.”

MEDICAL EFFICACY OF HIV-ASSOCIATED LIPODYSTROPHY TREATMENT

Lipodystrophy is defined as changes in body fat composition and metabolism;ⁱ acquired HIV-associated lipodystrophy (LDHIV) is the most common type.ⁱⁱ A recent survey of Massachusetts clinicians treating people with HIV estimated the prevalence of moderate to severe LDHIV cases at between 10 to 25% of the HIV/AIDS population; of these, approximately 10% were anticipated to seek medical treatment for LDHIV.ⁱⁱⁱ

No cure for LDHIV exists, but treatments for body changes caused by the condition do. Surgical interventions have been successfully used to restore fat loss or remove excess fat, and have been shown effective at improving cosmetic appearance and patient satisfaction, although they often require repeat procedures. Other fillers, implants, and fat transfers have also been used.

CURRENT COVERAGE

Most health insurers do not cover treatments to correct or repair disturbances to body composition caused by LDHIV, as most carriers consider the treatments to be cosmetic in nature. Some treatments are covered, however, in cases of abnormalities that affect a patient’s functioning, and a few small insurance carriers indicate they cover treatments for facial lipodystrophy.

i U.S. Department of Health & Human Services (US-DHHS), AIDSInfo: Side Effects of HIV Medicines, HIV and Lipodystrophy. Updated 30 September 2013; accessed 13 February 2014: <http://aidsinfo.nih.gov/education-materials/fact-sheets/22/61/hiv-and-lipodystrophy>.

ii Garg A. Acquired and inherited lipodystrophies. *N Engl J Med.* 2004 Mar 18;350(12):1220-34. Accessed 14 February 2014: <http://www.nejm.org/doi/full/10.1056/NEJMra025261>.

iii Cranston K., Fukuda H.D. Letter to Honorable Carl M. Sciortino, Jr., State Representative. 26 February 2014. Commonwealth of Massachusetts, Executive Office of Health and Human Services, Department of Public Health.

COST OF IMPLEMENTING THE BILL

Requiring coverage for this benefit by fully-insured health plans would result in an average annual increase, over five years, to the typical member's monthly health insurance premiums of between \$0.01 (0.00%) and \$0.10 (0.02%) per year.

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 Massachusetts General Laws, as well as the Group Insurance Commission (GIC) covering public employees and their dependents, would be subject to this mandate. The proposed benefit mandate 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.

The proposed mandate also affects Medicaid, which provides coverage to a large portion of the population with HIV/AIDS. CHIA's analysis does not estimate the effect of the mandate on Medicaid expenditures.

PLANS NOT AFFECTED BY THE PROPOSED BENEFIT MANDATE

Self-insured plans (i.e., where the employer policyholder retains the risk for medical expenses and uses an insurer to provide administrative functions) are subject to federal law and not to state-level health insurance benefit mandates.

State health benefit mandates do not apply to Medicare and Medicare Advantage plans whose benefits are qualified by Medicare. Consequently this analysis excludes 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 personnel and dependents), Veterans Administration, and the Federal Employee's Health Benefit Plan.

PRELIMINARY ESTIMATE OF POTENTIAL MASSACHUSETTS LIABILITY UNDER THE ACA

Analysis of the cost associated with proposed state benefit mandates is important in light of new requirements introduced by the Affordable Care Act (ACA). In accordance with the ACA, all states must set an Essential Health Benefits (EHB) benchmark that all qualified health plans (QHPs), and those plans sold in the individual and small-group markets, must cover, at a minimum. Section 1311(d)(3)(B) of the ACA, as codified in 45 C.F.R. § 155.170, explicitly permits a state to require QHPs to offer benefits in addition to EHB, provided that the state is liable to defray the cost of additional mandated benefits by making payments to or on behalf of individuals enrolled in QHPs. The state is not financially responsible for the costs of state-required benefits that are considered part of the EHB benchmark plan. State-required benefits enacted on or before December 31, 2011 (even if effective after that date) are not considered "in addition" to EHB and therefore will not be the financial obligation of the state. The policy regarding state-required benefits is effective as of January 1, 2014 and is intended to apply for at least plan years 2014 and 2015.

To provide additional information about the potential state liability under the ACA associated with mandating this benefit, CHIA generated a preliminary estimate of the incremental annual premium costs to QHPs associated with this benefit mandate; incremental premium costs exclude the cost of services already provided absent the mandate or already required by other federal or state laws. CHIA's review of the proposed health benefit mandate is not intended to determine whether or not this mandate is subject to state liability under the ACA. CHIA generated this estimate to provide neutral, reliable information to stakeholders who make decisions that impact health care access and costs in the Commonwealth.

CHIA applied the mid-range PMPM (per-member per-month) actuarial projection for 2015 cost (\$0.05) to an estimated 800,000 potential QHP members.^{iv} This results in an estimated potential incremental premium increase to QHPs of approximately \$37,000 per month or \$448,000 per year. If fewer (or more) enrollees join QHPs in the merged market than expected, the potential incremental premium cost may be less (or more) than this estimate. A final determination of the Commonwealth's liability will require a detailed analysis by the appropriate state agencies.

iv Estimated QHP membership provided by the Massachusetts Division of Insurance.

H.B. 986 Medical Efficacy Assessment: HIV-associated lipodystrophy treatment

Massachusetts H.B. 986 requires health insurance plans to provide “coverage for medical or drug treatments to correct or repair disturbances of body composition caused by lipodystrophy syndrome, including but not limited to reconstructive surgery, such as suction-assisted lipectomy, other restorative procedures, and dermal injections or fillers for reversal of facial lipoatrophy syndrome.”¹ Massachusetts General Laws (M.G.L.) c. 3 § 38C charges the Massachusetts Center for Health Information and Analysis (CHIA) with reviewing the medical efficacy of proposed mandated health insurance benefits. Medical efficacy reviews summarize current literature on the effectiveness and use of the mandated treatment or service, often compared to alternative treatments, and describe the potential impact of a mandated benefit on the quality of patient care and the health status of the population.

LIPODYSTROPHY

Lipodystrophy is defined as changes in body fat composition and metabolism.^{2,3} There is currently no clear consensus definition or specific diagnostic criteria for lipodystrophy, in part due to the variety of conditions covered by the term “lipodystrophy.”⁴

Acquired HIV-associated lipodystrophy is the most prevalent type of lipodystrophy;⁵ other acquired and congenital forms of the condition have low prevalence and are most often associated with complex metabolic disorders.^{6,7,8,9,10} This analysis will address only HIV-associated lipodystrophy (LDHIV).^v There are two specific types of LDHIV, and patients, both adults and children,¹¹ can be diagnosed with one or both:¹²

- ***Lipoatrophy:*** Fat loss that occurs in the face, arms, legs, and buttocks. This condition is more common in men, and is often the most prominent clinical sign of LDHIV.¹³
- ***Lipohypertrophy:*** Fat buildup that occurs in the abdomen, breasts (in both women and men), back of the neck and shoulders (so-called “buffalo hump”), and front of the neck and under the chin (“horse collar”), and can cause fatty growths elsewhere in the body (*lipomas*). The condition is more common in women, and is otherwise known as *lipoaccumulation* or *hyperadiposity*.

LDHIV can also result in high levels of fat (*hyperlipidemia*) and/or sugar in the blood, increasing the risk of cardiovascular disease and diabetes.¹⁴

CAUSES OF LDHIV

While the biological mechanisms behind LDHIV symptoms have not been precisely identified, it has been hypothesized that the condition may be due in part to the HIV infection itself, which may interfere with the body’s metabolism of fat. However, the prevailing theory is that LDHIV results from the use of antiretroviral combination medications used to prevent HIV from developing into AIDS;¹⁵ these include highly-active antiretroviral treatment regimens (HAART), especially those including the protease inhibitor (PI) class of drugs.¹⁶ Lipoatrophy and lipohypertrophy have each been associated with different classes of antiretroviral drugs.¹⁷ Results vary by individual, but “almost all antiretroviral drug combinations can be associated with fat redistribution.”¹⁸

^v Further references to “lipodystrophy” in this analysis will be specific to HIV-associated lipodystrophy or LDHIV.

Current HIV medicines “are less likely to cause [LDHIV] than medicines developed in the past. Many people with HIV never develop lipodystrophy”. However, even newer medicines are associated with some risk of developing LDHIV.¹⁹ Other risk factors for developing lipodystrophy include age, gender, treatment duration, and HIV infection level and duration.²⁰

PREVALENCE OF LDHIV

According to the Massachusetts Department of Public Health Office of HIV/AIDS, approximately 21,000 people in the state of Massachusetts were living with HIV/AIDS as of December 2012; 71 percent of these patients were male.²¹ This number continues to rise as people with HIV live longer – HIV has become a chronic, manageable condition²² – with fewer new cases of HIV diagnosed each year.²³

Estimates of the prevalence of LDHIV vary widely, with one recent study citing a prevalence range of 11 to 83% of patients using anti-retroviral therapies.²⁴ An older summary of twenty-two separate studies reported that for patients whose HAART regimen included the PI class of drugs, LDHIV was observed in 8 to 84% of patients, with prevalence generally higher in patients with longer-term therapy.²⁵ The wide span in prevalence estimates is due in part to varying definitions of the condition used in each study, as well as the subjective measures used to diagnose the condition. In a recent survey of Massachusetts clinicians treating people with HIV/AIDS, physicians estimated the prevalence of moderate to severe LDHIV cases in their clinics at between 10 to 25% of the HIV/AIDS population whom they treat; the physicians anticipated that approximately 10% of these patients would seek medical treatment for LDHIV.²⁶

EFFECTS OF LDHIV

Lipohypertrophy can be painful, as fat accumulates in the breasts, neck, back, and chin, and may result in headaches, sleeping and breathing difficulties, and poor posture. Hyperlipidemia and abdominal lipohypertrophy can increase the risk of cardiovascular diseases and diabetes. Moreover, the disfiguring effects of both lipoatrophy and lipohypertrophy have been associated with lower quality-of-life,^{27,28} leading to depression, isolation, and poor social functioning. In response to these body changes, some patients may switch medications; others may discontinue use of HIV medication, thereby putting themselves at risk of developing opportunistic infections and altering the course of their HIV disease.^{29,30,31,32} In fact, in one study, 30% of patients who reported lipodystrophy symptoms failed to adhere to their HAART regimen, with those having more symptoms increasingly likely to stop their treatment.³³

DIAGNOSIS AND TREATMENTS FOR LDHIV

One challenge in understanding LDHIV is a lack of a consensus case definition. Current diagnosis relies on patient self-report of fat loss or accumulation, as well as physician clinical interpretation of often heterogeneous symptoms, sometimes requiring a differential diagnosis procedure to eliminate alternative diagnoses.^{34,35} Imaging methods are sometimes used, including DEXA, CT, MRI and ultrasound scans,³⁶ but are not routinely recommended.³⁷ Several authors have concluded that “the sensitivity and specificity of subjective criteria currently used for LDHIV are poor.”³⁸

Currently, no cure exists for LDHIV. Early intervention and prevention are recommended as the best approaches to the condition, including modifying anti-retroviral therapy regimens in cases where the change does not increase the risks associated with long-term HIV management.³⁹

Treatments are available to mitigate the body changes caused by the condition, as well as to reduce associated cardiac and diabetic risks. Surgical interventions have been successfully used to restore fat losses or remove excess fat associated with lipoatrophy and lipohypertrophy.^{40,41,42} These treatments have been shown to be effective at improving cosmetic appearance and patient satisfaction, although they often require repeated procedures.^{43,44} Other fillers, implants, and fat transfers have also been used to treat LDHIV. Overall, temporary fillers are recommended over permanent fillers (none of which have been FDA-approved for dermal augmentation), as LDHIV may change over time in a patient due to the dynamic nature of the condition, the progression of the HIV infection, and changes in treatment regimens.⁴⁵ For lipohypertrophy, liposuction and breast reductions have been successfully used as treatment; again, however, fat often re-accumulates in these patients.⁴⁶

In addition to surgical interventions, Egrifta is the first FDA-approved medication for the treatment of LDHIV, specifically intended “to induce and maintain a reduction of excess visceral abdominal fat in HIV-infected patients with lipodystrophy” where surgical intervention may pose a risk to surrounding organs.^{47,48} Diet and exercise are recommended to treat hyperlipidemia and prevent progression to cardiac diseases and diabetes, and exercise may help somewhat to improve changes to body composition caused by LDHIV, although lipoatrophy is more resistant to these types of treatment regimens.^{49,50}

Endnotes

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**CENTER FOR HEALTH
INFORMATION AND ANALYSIS**

APPENDIX

**Actuarial Assessment of House Bill 986:
“An Act relative to
HIV-associated lipodystrophy treatment”**

Prepared for
Commonwealth of Massachusetts
Center for Health Information and Analysis

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Prepared by
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**Actuarial Assessment of House Bill 986:
“An Act relative to HIV-associated lipodystrophy treatment”**

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Actuarial Assessment of House Bill 986: “An Act relative to HIV-associated lipodystrophy treatment”

Executive Summary

Massachusetts House Bill 986 (H.B. 986) requires health insurance plans to provide “coverage for medical or drug treatments to correct or repair disturbances of body composition caused by lipodystrophy syndrome, including but not limited to reconstructive surgery, such as suction-assisted lipectomy, other restorative procedures, and dermal injections or fillers for reversal of facial lipoatrophy syndrome.”¹ Massachusetts General Laws (M.G.L.) c. 3 § 38C charges the Massachusetts Center for Health Information and Analysis (CHIA) with reviewing the potential impact of proposed mandated health care insurance benefits on the premiums paid by businesses and consumers. CHIA has engaged Compass Health Analytics, Inc. to provide an actuarial estimate of the effect enactment of the bill would have on the cost of health care insurance in Massachusetts.

Background

H.B. 986 requires health insurance plans to provide coverage for medical or drug treatments for lipodystrophy syndrome, and was interpreted to apply specifically to HIV-associated lipodystrophy (LDHIV). Lipodystrophy is defined as changes in body fat composition and metabolism.^{2,3} Acquired HIV-associated lipodystrophy is the most common type of lipodystrophy.⁴

According to the Massachusetts Department of Public Health Office of HIV/AIDS (MA-DPH), approximately 21,000 people in the state of Massachusetts were living with HIV/AIDS as of December 2012.⁵ Of these, an estimated 26% were under age 65 and covered by fully-insured plans subject to the proposed mandate.

Prevalence estimates for LDHIV vary widely, and are influenced by gender, age, length of HIV infection, and type and length of treatment. One evaluation of 22 studies summarized their LDHIV prevalence findings at between 8 to 84% of HIV/AIDS patients.⁶ However, a recent survey of Massachusetts clinicians treating people with HIV estimated the prevalence of moderate to severe LDHIV cases at between 10 to 25% of the HIV/AIDS population.⁷ This approximation results in an estimated 550 to 1350 cases of moderate to severe LDHIV in the under-65 fully-insured population in the state. Of these, approximately 10%, or 55 to 135 people, were anticipated to seek medical treatment for LDHIV.⁸

There is no cure for LDHIV, but therapies can be used to treat the body changes caused by the condition. Surgical interventions have been successfully used to restore fat losses or remove excess fat in lipoatrophy and lipohypertrophy.^{9,10,11} These treatments have been shown to be effective at improving cosmetic appearance and patient satisfaction, although they often require repeated procedures.^{12,13} Other fillers, implants, and fat transfers have also been used to treat LDHIV.

Most health insurers do not cover treatments to correct or repair disturbances to body composition caused by LDHIV, as most carriers consider the treatments to be cosmetic in nature. Some

treatments are covered, however, in cases of functional abnormalities. Likewise, a few small carriers did indicate that they do cover treatments for facial lipodystrophy.

Analysis

Compass estimated the impact of H.B. 986 by performing the following steps:

- Estimate the number of cases of HIV/AIDS in Massachusetts, projected for the coming five years
- Estimate the proportion of cases in the under-65 fully-insured population
- Estimate the prevalence of moderate-to-severe LDHIV and the number of patients who would seek treatment under this mandate
- Delineate projected cases by specific LDHIV type (lipohypertrophy and lipoatrophy)
- Estimate the average per-patient cost of delineated LDHIV treatments as defined by this mandate, projected for the coming five years
- Calculate the proposed mandate's incremental effect on carrier medical expense
- Estimate the impact of insurers' retention (administrative costs and profit) on premiums

Factors affecting the analysis include:

- Estimates of the prevalence of the condition, as well as the number of people who would seek treatment for it, are imprecise
- Controlled studies designed to determine the best treatment for LDHIV, useful in estimating the portion of people diagnosed with LDHIV which would use various treatments, are rare or nonexistent
- Insurance claims related to LDHIV body composition repair and correction, which would be useful in estimating the cost of treatment, are rare, adding variability to the estimates

Summary results

For each year in the five-year analysis period, Table ES-1 displays the projected net impact of the proposed mandate on medical expense and premiums using a projection of Massachusetts fully-insured membership. This analysis estimates that the mandate, if enacted, would increase fully-insured premiums by as much as 0.02% on average over the next five years; a more likely increase is in the range of 0.01%.

The degree of precision achievable in this analysis is limited by several uncertainties, including the number of people who would seek treatment and the average costs of those treatments. To account for the uncertainty in the percentage of individuals seeking treatment and the course of treatment they would seek, the high scenarios allow for a combination of more expensive assumptions, resulting in a disproportionately high impact relative to the other two scenarios.

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 and on how the benefits will change under the proposed mandate.

**Table ES-1:
Summary Results**

	2015	2016	2017	2018	2019	Average	5 Yr Total
Members (000s)	2,144	2,121	2,096	2,071	2,045		
Medical Expense Low (\$000s)	\$148	\$135	\$141	\$147	\$153	\$145	\$724
Medical Expense Mid (\$000s)	\$1,064	\$841	\$861	\$879	\$895	\$908	\$4,539
Medical Expense High (\$000s)	\$3,247	\$2,113	\$2,097	\$2,070	\$2,031	\$2,312	\$11,559
Premium Low (\$000s)	\$167	\$153	\$159	\$166	\$173	\$164	\$819
Premium Mid (\$000s)	\$1,202	\$951	\$972	\$993	\$1,011	\$1,026	\$5,129
Premium High (\$000s)	\$3,669	\$2,388	\$2,369	\$2,339	\$2,295	\$2,612	\$13,061
PMPM Low	\$0.01	\$0.01	\$0.01	\$0.01	\$0.01	\$0.01	\$0.01
PMPM Mid	\$0.05	\$0.04	\$0.04	\$0.04	\$0.04	\$0.04	\$0.04
PMPM High	\$0.14	\$0.09	\$0.09	\$0.09	\$0.09	\$0.10	\$0.10
Estimated Monthly Premium	\$512	\$537	\$564	\$592	\$622	\$566	\$566
Premium % Rise Low	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Premium % Rise Mid	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%
Premium % Rise High	0.03%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%

Actuarial Assessment of House Bill 986: An Act relative to HIV-associated lipodystrophy treatment

1. Introduction

Massachusetts House Bill 986 requires health insurance plans to provide “coverage for medical or drug treatments to correct or repair disturbances of body composition caused by lipodystrophy syndrome, including but not limited to reconstructive surgery, such as suction-assisted lipectomy, other restorative procedures, and dermal injections or fillers for reversal of facial lipoatrophy syndrome.”¹⁴ The bill was interpreted to address only HIV-associated lipodystrophy (LDHIV).¹⁵ Massachusetts General Laws (M.G.L.) c. 3 § 38C charges the Massachusetts Center for Health Information and Analysis (CHIA) with, among other duties, reviewing the potential impact of proposed mandated health care insurance benefits on the premiums paid by businesses and consumers. CHIA has engaged Compass Health Analytics, Inc. to provide an actuarial estimate of the effect enactment of the bill would have on the cost of health 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. Finally, Section 5 describes the calculation of the estimate.

2. Interpretation of H.B. 986

The following subsections describe the provisions of H.B. 986, as drafted 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. The following five sections, each addressing statutes dealing with a particular type of health insurance policy, are relevant to this analysis:

- Section 1: Insurance for persons in service of the Commonwealth (creating M.G.L. c. 32A, § 23)
- Section 2: Accident and sickness insurance policies (creating M.G.L. c. 175, § 47AA)

- Section 3: Contracts with nonprofit hospital service corporations (creating M.G.L. c. 176A, § 8EE)
- Section 4: Certificates under medical service agreements (creating M.G.L. c. 176B, § 4EE)
- Section 5: Health maintenance contracts (creating M.G.L. c. 176G, § 4W)

Section 6 of the bill (creating M.G.L. c. 118E, § 10G) directs the Division of Medical Assistance to cover LDHIV treatments. While the bill might affect Medicaid spending, depending on current coverage under MassHealth and related programs, CHIA has instructed Compass not to include that potential spending in this analysis.

All sections of the proposed bill 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.

Self-insured plans¹⁶ are subject to federal law and not to state-level health insurance benefit mandates. Nor do state mandates apply to Medicare, and this analysis assumes this proposed mandate does not affect Medicare extension/supplement plans even to the extent they are regulated by state law.

2.2. Mandated services

H.B. 986 requires each of the targeted types of health insurance plans to provide “coverage and benefits for medical or drug treatments to correct or repair disturbances of body composition caused by lipodystrophy syndrome, including but not limited to reconstructive surgery, such as suction assisted lipectomy, other restorative procedures, and dermal injections or fillers for reversal of facial lipoatrophy syndrome.”

Lipodystrophy is defined as changes in body fat composition and metabolism.^{17,18} There is currently no clear consensus definition or specific diagnostic criteria for lipodystrophy, in part due to the variety of conditions covered by the general term “lipodystrophy”.¹⁹

Acquired HIV-associated lipodystrophy (LDHIV) is by far the most prevalent type of lipodystrophy;²⁰ however, prevalence estimates for LDHIV vary widely, and are influenced by gender, age, length of HIV infection, and type and length of treatment. Other acquired and congenital forms of the condition have very low prevalence and are most often associated with complex metabolic disorders.²¹ There are two specific types of the condition that are HIV-associated,* and patients, both adults and children,²² can have one or both:²³

- *Lipoatrophy*: Fat loss that occurs in the face, arms, legs, and buttocks. This condition is more common in men, and is often the most prominent clinical sign of LDHIV.²⁴

* Further references to “lipodystrophy” in this analysis will be specific to HIV-associated lipodystrophy, or LDHIV.

- *Lipohypertrophy*: Fat buildup that occurs in the abdomen, breasts (in both women and men), back of the neck and shoulders (so-called “buffalo hump”), and front of the neck and under the chin (“horse collar”), and can cause fatty growths elsewhere in the body (*lipomas*). The condition is more common in women, and is otherwise known as *lipoaccumulation* or *hyperadiposity*.

There is no cure for LDHIV, but therapies can be used to treat the body changes caused by the condition. Surgical interventions have been successfully used to restore fat losses or remove excess fat in lipoatrophy and lipohypertrophy.^{25,26,27} These treatments have been shown to be effective at improving cosmetic appearance and patient satisfaction, although they often require repeated procedures.^{28,29} Other fillers, implants, and fat transfers have also been used to treat LDHIV.

2.3. Current coverage and medical necessity

In a survey of the eight largest insurance carriers in Massachusetts, only two plans stated that they offered coverage for LDHIV; of these two, treatments were covered for facial lipoatrophy syndrome. However, the number of fully-insured lives covered by these two carriers in Massachusetts, as well as the prevalence of this particular type of LDHIV in their populations, is not significant enough to influence the estimate of the impact of this proposed mandate on overall health insurance premiums.

In most cases, coverage for body composition treatments for LDHIV has been denied on the grounds that the treatment is not medically necessary, but is considered cosmetic in nature.³⁰ As noted, two carriers do provide insurance coverage for treatment of facial lipoatrophy syndrome; however, most only cover LDHIV for patients with functional impairment as determined by each plan’s policies and procedures for review of medical necessity.

This analysis assumes the bill makes no changes to general insurance policy requirements such as cost-sharing.

2.4. Existing laws affecting the cost of H.B. 986

No existing federal or state mandates related to the specific subject matter of this bill have been identified.³¹

3. Methodology

3.1. Steps in the analysis

Compass estimated the impact of H.B. 986 by performing the following steps:

- Estimate the number of cases of HIV/AIDS in Massachusetts, projected for the coming five years
- Estimate the proportion of cases in the under-65 fully-insured population

- Estimate the prevalence of moderate-to-severe LDHIV and the number of patients who would seek treatment under this mandate
- Delineate projected cases by specific LDHIV type (lipohypertrophy and lipoatrophy)
- Estimate the average per-patient cost of delineated LDHIV treatments as defined by this mandate, projected for the coming five years
- Calculate the proposed mandate's incremental effect on carrier medical expense
- Estimate the impact of insurers' retention (administrative costs and profit) on premiums

3.2. Data sources

The primary data sources used in the analysis were:

- Interviews with legislative staff regarding legislative intent
- Information from clinical experts
- A survey of the largest private health insurance carriers in Massachusetts
- Academic literature, including population data
- Massachusetts insurer claim data from CHIA's Massachusetts All-Payer Claim Database (APCD) for calendar years 2009 to 2012, for plans covering the overwhelming majority of the under-65 fully-insured population subject to the proposed mandate³²

The following step-by-step description of the analysis addresses limitations in some of these sources and the uncertainties they contribute to the cost estimate.

4. Factors Affecting the Cost Analysis

Several issues arise in translating the provisions of H.B. 986 into an analysis of incremental cost.

4.1. Number of HIV/AIDS cases

There were 21,074 confirmed cases of patients with HIV/AIDS living in Massachusetts as of December 2012, for a prevalence rate of 317.1 per 100,000.³³ This prevalence rate has not remained fixed in the general population over time. In fact, even as fewer cases of HIV/AIDS are diagnosed in the population, the prevalence has risen due to a decrease in the death rate, in part because of more and better treatments which have made HIV/AIDS a chronic manageable condition, resulting in people living longer.³⁴ Between 2000 and 2012, the population of Massachusetts rose 4.7%, while the number of HIV/AIDS cases in the population rose 52.4%. Given this dynamic, this analysis does not rely on a fixed HIV/AIDS prevalence rate applied to the general population to project the number of cases over the coming five-years, but instead relies on a more complicated model using cases reported to the CDC between 2000 and 2012, as well as an estimate of the number of additional cases of patients living in Massachusetts but diagnosed elsewhere.

4.2. Estimating the under-65 fully-insured HIV/AIDS cases

To narrow the number of overall HIV/AIDS cases to those in people under-65 and fully-insured, the first step was to determine the portion of cases of HIV/AIDS found in people under age 65; recent national figures estimate this number to be approximately 95.7%.³⁵

The second step was to determine the portion of cases of HIV/AIDS found in people in the fully-insured population. HIV/AIDS patients are disproportionately insured by Medicaid. In Massachusetts, while 20.3% of residents are currently enrolled in MassHealth³⁶, 45.1% of patients under 65 years old with HIV/AIDS are enrolled in MassHealth, according to the most recently available calculations.³⁷ These are removed from the count of patients used in this analysis.

After eliminating cases covered by Medicare or Medicaid, the remaining cases are assumed to be privately insured. To this number, an estimate of the portion of cases that are fully-insured (versus self-insured) is applied. This figure is calculated to be 50.1% in 2012, and is projected to fall to 45.5% over the five year period of this analysis.³⁸

4.3. Prevalence of LDHIV and the treatment population

One evaluation of 22 LDHIV studies summarized their prevalence findings at between 8% and 84% of HIV/AIDS patients.³⁹ Imprecision in the definition of lipodystrophy in general, and the varying course of LDHIV no doubt contribute to the size of this range. In another prevalence study of LDHIV, researchers further delineated the condition by gender and type, reporting prevalences in men of 38.2% for lipoatrophy, 40.1% for lipohypertrophy, and 14.4% for both conditions. For women, the study found 25.7% prevalence for lipoatrophy, 53.1% for lipohypertrophy, and 13.2% for both.⁴⁰

A recent survey of Massachusetts clinicians treating people with HIV estimated the prevalence of moderate-to-severe LDHIV cases (the subset most likely to be treated) at between 10% and 25% of the HIV/AIDS population.⁴¹ According to the Massachusetts Department of Public Health Office of HIV/AIDS (MA-DPH), approximately 21,000 people in the state of Massachusetts were living with HIV/AIDS as of December 2012,⁴² which implies an estimated 2,100 to 5,300 cases of moderate-to-severe LDHIV.

Estimating the number who will seek treatment for LDHIV under the mandate is problematic. Historical data is limited – information from the mandate sponsor as well as carriers confirms that body composition treatments for LDHIV are rarely covered by health insurance; therefore, patients who seek treatment almost never submit claims for these medical and surgical services and claim data cannot be used for estimating the number of people who seek treatment for LDHIV. Instead, this analysis again relies on information from the MA-DPH survey to estimate the number of people who will seek treatment; according to these clinicians, approximately 10% of people with moderate-to-severe LDHIV, approximately 210 to 530 people, seek treatment for their condition.⁴³

This estimate could reflect the heterogeneity of the condition's effect on various patients, meaning that many individuals' cases have not manifested in such a way as to necessitate treatment. On the other hand, because treatments are not currently covered by most insurers, it is reasonable to

assume that many patients do not seek treatment regardless of the impact of the condition. Therefore, in estimating the net impact of the proposed mandate, an increase must be included for patients who would seek treatment when coverage becomes available.

Given limited information on what portion of LDHIV patients would seek treatment, this analysis uses as its low estimate the figure provided by MA-DPH, or 10% of patients with moderate-to-severe LDHIV. To account for an increase in the number of patients who would seek treatment in response to the availability of insurance coverage for the treatments, the model increases this estimate to 25%.

Finally, as noted in the medical efficacy review for LDHIV treatment, while newer HIV medications are significantly less likely to cause lipodystrophy symptoms than older treatments, new cases still arise and patients require re-treatment over time. It is possible the higher (25%) treatment rate could taper off, but a conservative approach for the high-end scenario suggests leaving it in place for at least the five-year timeframe of this analysis.

4.4. Distribution of LDHIV by case type

Treatment for cases of LDHIV is very different, depending on the type the patient experiences. As previously explained, lipoatrophy is the loss of fat, and is most often treated with dermal injections, fillers and, less often, implants. Almost all cases will need to be retreated, often with periodic treatments each year. These cases are usually less expensive on a per-treatment basis, but the current population seeking treatment will remain constant over time as patients receive ongoing care even as fewer new cases present for treatment.

On the other hand, lipohypertrophy, the build up of fat, is most often treated surgically. These surgical treatments tend to be more expensive on a per-case basis. And while some patients may require follow-up or multiple surgeries, treatment for lipohypertrophy is most often successful through a single episode of care. This means that current patients who present for treatment of lipohypertrophy are not likely to need retreatment for this condition in the future.

The different treatment needs (injections versus surgery) and routines (ongoing versus episodic) make the estimate of the portion of LDHIV cases that are lipoatrophy, lipohypertrophy or both important to the analysis. As with overall prevalence, published estimates of the split between case types fluctuate widely and change based on the definitions used in each particular study. For this analysis, three scenarios were developed to estimate this distribution using published studies and input from clinical experts throughout the state. The prevalence results in Table 1, cited in section 4.3, were used as the baseline for development of the high-end scenario, as the number of lipohypertrophy (or both) cases was higher than described by in-state clinicians.

In-state providers reported that they were more likely to treat cases of lipoatrophy in their practices because of the nature of the condition and its amenability to treatment. Their anecdotal information was used to develop the low- and mid-level scenario estimates of case distribution.

**Table 1:
Estimated Prevalence of Lipodystrophy
in HIV-Infected Population⁴⁴**

	<u>Lipoatrophy</u>	<u>Lipohypertrophy</u>	<u>Both</u>
Men	38.2%	40.1%	14.4%
Women	25.7%	53.1%	13.2%

Moreover, as previously mentioned, antiretroviral therapies have improved over time and new cases of LDHIV are less likely to occur, meaning that lipohypertrophy cases treated surgically should diminish over time as current episodes are successfully treated and fewer new cases present for treatment in the future. To account for the nature of treatment for lipohypertrophy, a variable was introduced to the analysis to reduce the number of cases treated per year over the course of the projection period 2015 to 2019. This variable adjusts for two effects: lipohypertrophy cases do not typically need ongoing treatment over time, and fewer new cases of lipohypertrophy will present for treatment as more patients have been using newer antiretroviral therapies less likely to cause LDHIV. The variable was not applied to cases of lipoatrophy, as patients with this condition most often seek ongoing treatment.

4.5. Per-patient cost of LDHIV treatment

Treatment for LDHIV varies by the specific manifestation of the condition. For patients with lipoatrophy (loss of fat), the most common treatments include the use of fillers, implants, and fat transfers to restore fat losses. For lipohypertrophy, suction-assisted lipectomy, or liposuction, and breast reductions are the most likely treatments. Some patients may need multiple therapies to correct the symptoms, while others may have both lipoatrophy and lipohypertrophy at the same time in different parts of the body. Therefore, the variability of presentations directly impacts a calculation of average treatment cost.

For this analysis, the number of cases of moderate-to-severe LDHIV who will seek treatment was further divided into cases of lipohypertrophy, cases of lipoatrophy, and cases in which the patient experiences both. This distribution was based upon the study of the estimated prevalence of lipodystrophy in the HIV-infected population previously outlined and illustrated in Table 1.⁴⁵

Average costs per treatment type were based on a review of claim data for the entire population with and without an HIV/AIDS diagnosis. While most of these types of procedures are not paid by insurance carriers, sufficient claims were submitted to allow for the use of this information to calculate average costs for treatments based on allowable charges. However, use of this data as a basis for the calculations also introduces another degree of variability into the results.

This analysis projects the costs of the mandate five years into the future, using 4.5% annual medical inflation, based upon historical figures provided by the U.S. Bureau of Labor Statistics.⁴⁶ Finally, the analysis does not expect member cost-sharing to reduce significantly the impact of the mandate.

5. Cost Analysis

To estimate the overall impact of the proposed legislation, the following calculations were made. The analysis includes development of a best estimate mid-level scenario, as well as a low-level scenario using assumptions that produced a lower estimated impact, and a high-level scenario using more conservative assumptions that produced a higher estimated impact.

5.1. Projected cases of HIV/AIDS in Massachusetts

Table 2 shows the number of cases of HIV/AIDS in Massachusetts projected for the next five years. This number is based on the number of cases reported in the state to the CDC from 2000 to 2012, including an estimate of the number of cases of patients living in Massachusetts but diagnosed elsewhere; these historical numbers were projected forward through the coming five years.⁴⁷

Table 2:
Projected number of HIV/AIDS cases in Massachusetts

<u>Year</u>	<u>Projected Cases</u>
2015	22,722
2016	23,272
2017	23,822
2018	24,372
2019	24,922

The numbers projected in Table 2 include all cases, regardless of age or insurance coverage. To narrow this to the under-65 fully-insured population only, several factors were applied.

- Total projected HIV/AIDS cases
 - Over-65 population covered by Medicare (4.3%)
 - Population covered by Medicaid (45.1% of balance)
 - Self-insured population (52.5% to 54.5% of balance)
- = Fully-insured under-65 HIV/AIDS cases

These calculations resulted in the projected case numbers reflected in Table 3.

**Table 3:
Projected number of fully-insured under-65
HIV/AIDS cases in Massachusetts**

<u>Year</u>	<u>Projected Cases</u>
2015	5,666
2016	5,744
2017	5,819
2018	5,891
2019	5,961

5.2. Prevalence of moderate-to-severe LDHIV

As noted previously, this model assumes the prevalence of moderate-to-severe cases of LDHIV as a percentage of the number of HIV/AIDS cases in the population. Table 4 displays the values used in this analysis.

**Table 4:
Prevalence of Moderate-to-Severe LDHIV**

Low Scenario	10.0%
Mid Scenario	17.5%
High Scenario	25.0%

5.3. Number of patients seeking treatment

Again, HIV/AIDS clinicians in the state currently estimate that 10% of patients with moderate-to-severe LDHIV will seek treatment. This analysis uses this figure as a baseline, and includes an estimated increase resulting from implementation of this mandate. Table 5 displays the values used in this analysis.

**Table 5:
Patients Seeking Treatment for LDHIV**

Low Scenario	10.0%
Mid Scenario	17.5%
High Scenario	25.0%

5.4. Number of cases of lipohypertrophy and lipodystrophy

The type of LDHIV generally determines the type of treatment used, as well as if and how often treatment must be repeated. Based on a study of LDHIV prevalence by type and gender⁴⁸ as well as input from Massachusetts providers, three scenarios of distribution by case type were developed; these are displayed in Table 6.

**Table 6:
Proportion of LDHIV Cases by Type**

	<u>Lipoatrophy</u>	<u>Lipohypertrophy</u>	<u>Both</u>
Low	74.7%	23.7%	1.6%
Mid	56.0%	35.6%	8.4%
High	37.4%	47.5%	15.2%

5.5. Percent of lipohypertrophy cases treated over study period

To account for fewer new cases of LDHIV presenting over time, and for the nature of treatment for lipohypertrophy, a diminishing case assumption was applied to the number of cases of lipohypertrophy (or both) that are treated each year. The results are displayed in Table 7; note that the total does not equal 100% as a few new cases will likely present in the population annually.

**Table 7:
Percent of lipohypertrophy (or both) cases
treated per year**

<u>Year</u>	<u>% cases treated</u>
2015	70%
2016	20%
2017	15%
2018	10%
2019	5%

5.6. Average cost per case of lipohypertrophy and lipoatrophy

Claim data suggests that the average cost of treatment for LDHIV varies widely between cases of lipohypertrophy (requiring fat removal) and lipoatrophy (requiring fat augmentation), as presented in Table 8. Costs of cases in which a patient needed both types of treatments were estimated to be 80% of the sum of lipoatrophy and lipodystrophy costs in each scenario.

**Table 8:
Average Cost per Case of LDHIV by Type**

	<u>Lipoatrophy</u>	<u>Lipohypertrophy</u>	<u>Both</u>
Low Scenario	\$2,416	\$2,152	\$3,654
Mid Scenario	\$3,758	\$7,258	\$8,813
High Scenario	\$5,101	\$12,365	\$13,972

5.7. Net increase in carrier medical expense

To calculate the net increase in carrier medical expense, first the number of fully-insured under-65 HIV/AIDS cases is multiplied by the prevalence of LDHIV in those with HIV/AIDS; this number is

then multiplied by the percent of that population who would seek treatment using the assumptions outlined in section 5.3. This number is then distributed across the types of LDHIV cases outlined in section 5.4, and the appropriate average cost per case is then applied in each scenario to yield marginal total medical expenses attributable to the proposed mandate. This total is divided by projected fully-insured member months in the under-65 population, developed as described in Appendix A, yielding the medical expense per member per month (PMPM) displayed in Table 9.

**Table 9:
Estimate of Average Increase
in Carrier Medical Expense PMPM**

Low Scenario	\$0.01
Mid Scenario	\$0.04
High Scenario	\$0.09

5.8. Net increase in premium

Assuming an average retention rate of 11.5 percent, based on the CHIA’s analysis of administrative costs and profit in Massachusetts,⁴⁹ the increase in medical expense was adjusted upward to approximate the total impact on premiums. Table 9 shows the result.

**Table 9:
Total Average Net Marginal Increase
to Premiums**

Low Scenario	\$0.01
Mid Scenario	\$0.04
High Scenario	\$0.10

5.9. Five-year estimated impact

For each year in the five-year analysis period, Table 10 displays the projected net impact of the proposed mandate on medical expense and premiums using a projection of Massachusetts fully-insured membership. This analysis estimates that the mandate, if enacted, would increase fully-insured premiums by as much as 0.02% on average over the next five years; a more likely increase is in the range of 0.01%.

The degree of precision achievable in this analysis is hindered by the issues outlined in section 4; to account for the uncertainty in the percentage of individuals seeking treatment and the course of treatment they would seek, the high scenarios allow for a combination of more expensive assumptions. This results in a disproportionately larger high-end scenario cost.

This analysis assumes a small “bubble” in treatment in the first year or two if the proposed mandate were to go into effect. This reflects several factors, including decreasing prevalence of new cases due to the use of improved antiretrovirals, the episodic surgical treatments used for cases of

lipohypertrophy, and the ongoing, repeated treatments needed for lipoatrophy. Symptoms and treatment choices that drive a patient’s decision to seek treatment are relatively fluid and complex, and little data was available about timing. Ultimately, however, even as quantified, these timing adjustments have little effect on the five-year totals.

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 and on how the benefits will change under the proposed mandate.

**Table 10:
Summary Results**

	2015	2016	2017	2018	2019	Average	5 Yr Total
Members (000s)	2,144	2,121	2,096	2,071	2,045		
Medical Expense Low (\$000s)	\$148	\$135	\$141	\$147	\$153	\$145	\$724
Medical Expense Mid (\$000s)	\$1,064	\$841	\$861	\$879	\$895	\$908	\$4,539
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Premium Low (\$000s)	\$167	\$153	\$159	\$166	\$173	\$164	\$819
Premium Mid (\$000s)	\$1,202	\$951	\$972	\$993	\$1,011	\$1,026	\$5,129
Premium High (\$000s)	\$3,669	\$2,388	\$2,369	\$2,339	\$2,295	\$2,612	\$13,061
PMPM Low	\$0.01	\$0.01	\$0.01	\$0.01	\$0.01	\$0.01	\$0.01
PMPM Mid	\$0.05	\$0.04	\$0.04	\$0.04	\$0.04	\$0.04	\$0.04
PMPM High	\$0.14	\$0.09	\$0.09	\$0.09	\$0.09	\$0.10	\$0.10
Estimated Monthly Premium	\$512	\$537	\$564	\$592	\$622	\$566	\$566
Premium % Rise Low	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Premium % Rise Mid	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%
Premium % Rise High	0.03%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%

5.10. Impact on the GIC

Because the benefit offerings of GIC plans are similar to most other commercial plans in Massachusetts and do not cover the treatments proposed in the mandate for HIV-associated lipodystrophy, the estimated effect of the proposed mandate on GIC coverage is not expected to differ from that calculated for the other fully-insured plans in Massachusetts. Note that the total medical expense and premium numbers displayed in Table 10 include the GIC fully-insured membership. To calculate the medical expense separately for the self-insured portion of the GIC, the medical expense per member per month was applied to the GIC self-insured membership; the results are displayed in Table 11.

**Table 11:
GIC Self-Insured Summary Results**

	2015	2016	2017	2018	2019	Average	5 Yr Total
Members (000s)	259	259	259	258	258		
Medical Expense Low (\$000s)	\$1	\$1	\$1	\$2	\$2	\$1	\$7
Medical Expense Mid (\$000s)	\$11	\$9	\$9	\$9	\$9	\$9	\$47
Medical Expense High (\$000s)	\$33	\$22	\$22	\$22	\$21	\$24	\$119

Appendix A: Membership Affected by the Proposed Mandate

Membership potentially affected by a proposed mandate may include Massachusetts residents with fully-insured employer-sponsored health insurance (including through the GIC), non-residents with fully-insured employer-sponsored insurance issued in Massachusetts, Massachusetts residents with individual (direct) health insurance coverage, and, in some cases, lives covered by GIC self-insured coverage. Membership projections for 2015 – 2019 are derived from the following sources.

Total Massachusetts population estimates for 2012 and 2013 from U. S. Census Bureau data⁵⁰ form the base for the projections. Distributions by gender and age, also from the Census Bureau,⁵¹ were applied to these totals. Projected growth rates for each gender/age category were calculated from Census Bureau population projections to 2030.⁵² The resulting growth rates were then applied to the base amounts to project the total Massachusetts population for 2015 to 2019.

The number of Massachusetts residents with employer-sponsored or individual health insurance coverage was estimated using Census Bureau data on health insurance coverage status and type of coverage⁵³ applied to the population projections.

To estimate the number of Massachusetts residents with fully-insured employer-sponsored coverage, projected estimates of the percentage of employer-based coverage that is fully-insured were developed using historical data from the Medical Expenditure Panel Survey Insurance Component Tables.⁵⁴

To estimate the number of non-residents covered by a Massachusetts policy – typically cases in which a non-resident works for a Massachusetts employer offering employer-sponsored coverage – the number of lives with fully-insured employer-sponsored coverage was increased by the ratio of the total number of individual tax returns filed in Massachusetts by residents⁵⁵ and non-residents⁵⁶ to the total number of individual tax returns filed in Massachusetts by residents.

The number of residents with individual coverage was adjusted further to remove the estimated number of people currently covered by Commonwealth Care who will shift into MassHealth due to expanded Medicaid eligibility under the Affordable Care Act beginning in 2014.⁵⁷

Projections for the GIC self-insured lives were developed using GIC base data for 2012⁵⁸ and 2013⁵⁹ and the same projected growth rates from the Census Bureau that were used for the Massachusetts population. Breakdowns of the GIC self-insured lives by gender and age were based on the Census Bureau distributions.

Endnotes

¹ The 188th General Court of the Commonwealth of Massachusetts. Bill H. 986: An Act relative to HIV-associated lipodystrophy treatment. Accessed 13 February 2014: <https://malegislature.gov/Bills/188/House/H986>.

² U.S. Department of Health & Human Services (US-DHHS), AIDSInfo: Side Effects of HIV Medicines, HIV and Lipodystrophy. Updated 30 September 2013; accessed 13 February 2014: <http://aidsinfo.nih.gov/education-materials/fact-sheets/22/61/hiv-and-lipodystrophy>.

³ World Health Organization (WHO): HIV-associated lipodystrophy syndrome review. WHO Drug Information Vol. 16, No. 2, 2002. Accessed 14 February 2014: <http://apps.who.int/medicinedocs/en/d/Js4950e/4.4.html#Js4950e.4.4>.

⁴ Garg A. Acquired and inherited lipodystrophies. N Engl J Med. 2004 Mar 18;350(12):1220-34. Accessed 14 February 2014: <http://www.nejm.org/doi/full/10.1056/NEJMra025261>.

⁵ NOTE: “Effective January 1, 2011, the Massachusetts Department of Public Health (MDPH), Bureau of Infectious Diseases, HIV/AIDS fact sheets, epidemiologic reports and other HIV data presentations have been updated to remove all HIV/AIDS cases who were first diagnosed in another state before being reported in Massachusetts. As of January 1, 2012, this resulted in the removal of 3,529 HIV/AIDS cases, of which 914 have died and 2,615 were living. These persons living with HIV/AIDS may still continue to reside and receive care in the Commonwealth.”

As this mandate applies to HIV/AIDS cases regardless of state/place of diagnosis, calculations used in this analysis will include the additional cases of additional patients living in the Commonwealth with HIV/AIDS who were diagnosed elsewhere based on the 2012 estimate.

Massachusetts Department of Public Health Office of HIV/AIDS. The Massachusetts HIV/AIDS Epidemic at a Glance – Detailed Data Tables and Technical Notes. Accessed 25 February 2014: <http://www.mass.gov/eohhs/docs/dph/aids/2013-profiles/epidemic-glance-data.pdf>.

⁶ Chen D, Misra A, Garg A. Clinical Review 153: Lipodystrophy in human immunodeficiency virus-infected patients. Journal of Clinical Endocrinology and Metabolism. 2002 87(11):4845–4856. 25 February 2014: <http://press.endocrine.org/doi/pdf/10.1210/jc.2002-020794>.

⁷ Cranston K., Fukuda H.D. Letter to Honorable Carl M. Sciortino, Jr., State Representative. 26 February 2014. Commonwealth of Massachusetts, Executive Office of Health and Human Services, Department of Public Health.

⁸ *ibid.*

⁹ Hultman CS, McPhail LE, Donaldson JH, et. al. Surgical management of HIV-associated lipodystrophy: role of ultrasonic-assisted liposuction and suction-assisted lipectomy in the treatment of lipohypertrophy. Ann Plast Surg. 2007 Mar;58(3):255-63. Accessed 14 February 2014: http://journals.lww.com/annalsplasticsurgery/Abstract/2007/03000/Surgical_Management_of_HIV_Associated.5.aspx.

¹⁰ US-DHHS, Food & Drug Administration (FDA): HIV/AIDS Historical Time Line 2000 – 2010. Accessed 14 February 2014: <http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/hivandaidsactivities/ucm151081.htm>. Specifically, poly-L-lactic acid (Sculptra, New-Fill) is FDA-approved for facial lipoatrophy treatment.

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- ¹¹ FDA: Radiesse 1.3cc and 0.3cc (P050037) - P050037 Approval Order. Accessed 14 February 2014: http://www.accessdata.fda.gov/cdrh_docs/pdf5/P050037a.pdf. Calcium hydroxylapatite (Radiesse) is FDA-approved facial lipoatrophy treatment.
- ¹² *Op. cit.* HRSA HIV/AIDS Programs: Abnormalities of Body-Fat Distribution.
- ¹³ *Op. cit.* Behrens G., Reinhold E.S. "Lipodystrophy Syndrome".
- ¹⁴ The 188th General Court of the Commonwealth of Massachusetts. Bill H. 986: An Act relative to HIV-associated lipodystrophy treatment. Accessed 13 February 2014: <https://malegislature.gov/Bills/188/House/H986>.
- ¹⁵ Meeting to review legislative intent with sponsors and legislative and CHIA staff. December 9, 2013.
- ¹⁶ The employer policyholder retains the risk for medical expenditures and uses the carrier to provide administrative functions only.
- ¹⁷ U.S. Department of Health & Human Services (US-DHHS), AIDSInfo: Side Effects of HIV Medicines, HIV and Lipodystrophy. Updated 30 September 2013; accessed 13 February 2014: <http://aidsinfo.nih.gov/education-materials/fact-sheets/22/61/hiv-and-lipodystrophy>.
- ¹⁸ World Health Organization (WHO): HIV-associated lipodystrophy syndrome review. WHO Drug Information Vol. 16, No. 2, 2002. Accessed 14 February 2014: <http://apps.who.int/medicinedocs/en/d/Js4950e/4.4.html#Js4950e.4.4>.
- ¹⁹ Behrens G., Reinhold E.S. "Lipodystrophy Syndrome." *HIV Medicine 2007*. C. Hoffmann, J. K. Rockstroh, B. S. Kamps, editors. Pages 293-305. Accessed 14 February 2014: <http://www.hivmedicine.com/hivmedicine2007.pdf>.
- ²⁰ Garg A. Acquired and inherited lipodystrophies. *N Engl J Med*. 2004 Mar 18;350(12):1220-34. Accessed 14 February 2014: <http://www.nejm.org/doi/full/10.1056/NEJMra025261>.
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- ²³ WebMD HIV & AIDS Health Center: Lipodystrophy and HIV. Accessed 13 February 2014: http://www.webmd.com/hiv-aids/guide/lipodystrophy_and_hiv.
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- ²⁵ Hultman CS, McPhail LE, Donaldson JH, et. al. Surgical management of HIV-associated lipodystrophy: role of ultrasonic-assisted liposuction and suction-assisted lipectomy in the treatment of lipohypertrophy. *Ann Plast Surg*. 2007 Mar;58(3):255-63. Accessed 14 February 2014: http://journals.lww.com/annalsplasticsurgery/Abstract/2007/03000/Surgical_Management_of_HIV_Associated.5.aspx.
- ²⁶ US-DHHS, Food & Drug Administration (FDA): HIV/AIDS Historical Time Line 2000 – 2010. Accessed 14 February 2014: <http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/hivandaidsactivities/ucm151081.htm>. Specifically, poly-L-lactic acid (Sculptra, New-Fill) is FDA-approved for facial lipoatrophy treatment.
- ²⁷ FDA: Radiesse 1.3cc and 0.3cc (P050037) - P050037 Approval Order. Accessed 14 February 2014: http://www.accessdata.fda.gov/cdrh_docs/pdf5/P050037a.pdf. Calcium hydroxylapatite (Radiesse) is FDA-approved facial lipoatrophy treatment.

²⁸ *Op. cit.* HRSA HIV/AIDS Programs: Abnormalities of Body-Fat Distribution.

²⁹ *Op. cit.* Behrens G., Reinhold E.S. “Lipodystrophy Syndrome”.

³⁰ Compass/CHIA survey of Massachusetts insurance carriers.

³¹ Massachusetts has statutes (for example, M.G.L. c. 175 §47P) that require insurers to cover off-label use of prescription drugs for HIV/AIDS treatment. While the FDA has approved specific treatments for injectable use to correct contour deficiencies for LDHIV facial lipoatrophy, the agency regulates these products as medical devices and not as prescription drugs.

³² More information can be found at <http://www.mass.gov/chia/researcher/hcf-data-resources/apcd/>.

³³ This figure includes patients living in the state for whom HIV/AIDS was diagnosed elsewhere.

³⁴ *Op. cit.* Cranston K., Fukuda H.D. Letter to Honorable Carl M. Sciortino, Jr., State Representative.

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⁴⁰ Jacobson DL, Knox T, Spiegelman D, et. al. Prevalence of, evolution of, and risk factors for fat atrophy and fat deposition in a cohort of HIV-infected men and women. *Clin Infect Dis.* 2005 Jun 15;40(12):1837-45. Epub 6 May 2005. Accessed 25 February 2014: <http://cid.oxfordjournals.org/content/40/12/1837.full>.

⁴¹ Cranston K., Fukuda H.D. Letter to Honorable Carl M. Sciortino, Jr., State Representative. 26 February 2014. Commonwealth of Massachusetts, Executive Office of Health and Human Services, Department of Public Health.

⁴² NOTE: “Effective January 1, 2011, the Massachusetts Department of Public Health (MDPH), Bureau of Infectious Diseases, HIV/AIDS fact sheets, epidemiologic reports and other HIV data presentations have been updated to remove all HIV/AIDS cases who were first diagnosed in another state before being reported in Massachusetts. As of January 1, 2012, this resulted in the removal of 3,529 HIV/AIDS cases, of which 914 have died and 2,615 were living. These persons living with HIV/AIDS may still continue to reside and receive care in the Commonwealth.”

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⁴³ *Ibid.*

⁴⁴ *Op. cit.* Jacobson DL, Knox T, Spiegelman D, et. al. Prevalence of, evolution of, and risk factors for fat atrophy and fat deposition in a cohort of HIV-infected men and women.

⁴⁵ *Ibid.*

⁴⁶ U.S. Bureau of Labor Statistics: Consumer Price Index, CPI Databases. Accessed 5 March 2014:
<http://www.bls.gov/cpi/data.htm>.

⁴⁷ *Op. cit.* Massachusetts Department of Public Health Office of HIV/AIDS. The Massachusetts HIV/AIDS Epidemic at a Glance – Detailed Data Tables and Technical Notes.

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