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Mandated Benefit Review of SB 1070: An Act to Relative to Oral Cancer Therapy



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Introduction

On October 7, 2011, the Joint Committee on Health Care Financing referred *Senate Bill 1070: An Act relative to oral cancer therapy* (S1070) to the Division of Health Care Finance and Policy (the Division) for review. S1070, before the 2011-2012 Session of the Massachusetts Legislature, mandates oral and intravenous chemotherapies be covered equitably under medical benefit plans.

The Division, pursuant to the provisions of M.G.L. c. 3 § 38C which requires it to evaluate the impact of mandated benefit bills referred by legislative committees for review, commissioned a study by Compass Health Analytics (Compass)¹ of the actuarial estimate of the effect that the bill would have on the cost of health care insurance. The full report was prepared by Compass' James Highland, Heather Clemens, Lars Loren, and Joshua Roberts, and is available as an addendum to this Mandated Benefit review.

This review is thus broken into three sections: (1) an overview of the mandate, (2) a summary of Compass' actuarial analysis, and finally (3) a literature review examining the medical efficacy of the bill's mandate.

¹ Compass Health Analytics, Inc. "Actuarial Assessment of Senate Bill 1070: An Act relative to oral cancer therapy." 2012.

S1070 in Context

Insurance benefit plans are structured such that the policy holder receives their benefits through two modes: medical benefits and pharmacy benefits. Because of differences in co-pays and out-of-pocket expense caps with regard to those two different benefit modalities, chemotherapy received intravenously in a hospital setting (and therefore as a medical benefit) may often cost a patient less than oral chemotherapy received via their pharmacy benefits. S1070 was drafted with the intent to abolish the financial discrepancy for patients between oral and intravenous chemotherapies.

S1070 reads as follows:

SECTION 1. Notwithstanding the provisions of any general law, rule, or regulation to the contrary, a health benefit plan that provides coverage for cancer chemotherapy treatment must provide coverage for a prescribed, orally administered anticancer medication used to kill or slow the growth of cancerous cells on a basis no less favorable than intravenously administered or injected cancer medications that are covered as medical benefits. An increase in patient cost sharing for anticancer medications is not allowed to achieve compliance with this provision.²

Although similar legislation tends to reference some or all of the following sections of the Massachusetts General Laws that govern different types of health plans, S1070 does not specify the types of health plans to which the mandate is intended to apply. For the purposes of the actuarial analysis, the Division and representatives from Compass met with the bill's authors on December 20, 2011 to discuss the legislative intent. As was determined at the meeting, the actuarial analysis assumes that S1070 shall apply to "commercial fully-insured plans and plans administered by the Group Insurance Commission"³ (GIC). It is upon this understanding of the bill's legislative intent that the actuarial analysis was developed.

² <http://www.malegislature.gov/Bills/187/Senate/S01070>. Accessed 6/18/12.

³ Compass: p.i.

Financial Impact

Methodology

In order to capture the marginal effect of the proposed legislation on health insurance premiums, Compass looked at two possible effects specifically: enactment of the legislation may result in (1) an increase in consumption of oral chemotherapies resulting from a lower financial burden on the patient, and (2) “some portion of the cost-sharing for orally-administered drugs will shift from patients to insurers.”⁴ The report summary further explains their methodology.

To estimate the overall impact of the proposed legislation, we considered the impact on three patient populations:

- Members who currently use oral chemotherapy treatments
- Members who refuse oral treatment and substitute IV treatment due to cost
- Members who forgo treatment due to cost

For each population, we estimated, using an all-payer claim database, per member per month (PMPM) medical costs and member cost-sharing as a base for projecting the impact of the proposed bill, and estimated the effect of the bill on that PMPM base. We then adjusted the resulting PMPM costs for projected health care inflation, specifically for oral chemotherapy, for the five-year period required for the analysis (2013-2017), and adjusted further for insurer retention for administrative costs and profit. Finally, we applied the result to the fully-insured membership, projected for the five-year period. A best estimate “mid-level” scenario was developed, as well as low- and high-level scenarios.

4 Ibid.

Findings

As indicated in the table below, the five-year total estimated impact on insurance premiums ranges from 0.008 to 0.044 percent of annual premium (0.023 percent of annual premium in the mid-level scenario), with an average marginal cost ranging from 0.04 to 0.23 dollars per-member per-month (or 0.12 dollars per-member per-month in the mid-level scenario).

Compass' 5-Year Cost Projection Scenarios⁵

	2013	2014	2015	2016	2017	Average	5 Yr Total
Members	1,986,462	1,965,622	1,944,347	1,923,077	1,901,099		
Medical Expense Low (\$000's)	\$620	\$711	\$816	\$936	\$1,074	\$831	\$4,157
Medical Expense Mid (\$000's)	1,733	2,081	2,498	2,998	3,596	2,581	12,906
Medical Expense High (\$000's)	2,932	3,675	4,604	5,768	7,223	4,840	24,202
Premium Low (\$000's)	\$682	\$782	\$898	\$1,030	\$1,181	\$914	\$4,572
Premium Mid (\$000's)	1,907	2,289	2,748	3,297	3,955	2,839	14,196
Premium High (\$000's)	3,225	4,042	5,065	6,345	7,945	5,324	26,622
PMPM Low	\$0.03	\$0.03	\$0.04	\$0.04	\$0.05	\$0.04	\$0.04
PMPM Mid	\$0.08	\$0.10	\$0.12	\$0.14	\$0.17	\$0.12	\$0.12
PMPM High	\$0.14	\$0.17	\$0.22	\$0.27	\$0.35	\$0.23	\$0.23
Estimated Monthly Premium	\$464	\$487	\$512	\$537	\$564	\$513	\$513
Premium % Rise Low	0.006%	0.007%	0.008%	0.008%	0.009%	0.008%	0.008%
Premium % Rise Mid	0.017%	0.020%	0.023%	0.027%	0.031%	0.023%	0.023%
Premium % Rise High	0.029%	0.035%	0.042%	0.051%	0.062%	0.044%	0.044%

Regarding the steady rate of premium inflation over the five-year projection, Compass notes, “Current drug development trends suggest an increasingly large portion of cancer treatment drugs will be orally administered and increasingly-targeted drugs developed for smaller patient bases and will be increasingly expensive.”⁶

With this mind, and considering chemotherapy drugs are already generally quite expensive, Compass determines that the overall increase in premiums that would result from enactment of S1070 is still a relatively small one. This is due to the fact that “the vast majority of plans in the market require copayments but not [uncapped] coinsurance for pharmacy benefits, limiting the patient’s cost-sharing exposure for expensive drugs.”⁷ They further note, “[GIC] plans are among those that would be minimally affected,”⁸ and that “most of the increase in premiums will fall on the membership of those plans that do rely on member cost-sharing employing coinsurance.”⁹

5 Compass: p.iii.

6 Compass: p.ii.

7 Ibid.

8 Ibid.

9 Ibid.

Medical Efficacy and Patient Preference: A Literature Review

Clinical Background and Patient Preference

The American Society of Clinical Oncology (ASCO) defines chemotherapy as any anti-neoplastic agent used to treat cancer, given through oral and parenteral routes.¹⁰ In setting standards for the administration of chemotherapy, the ASCO stipulates that the same standards for chemotherapy administration safety should apply in all settings in which a patient might receive cancer treatment - be it as an inpatient or outpatient in a hospital, or at home as a consumer of chemotherapies distributed by a local pharmacy.¹¹ Setting standards was intended to assist oncology practices in creating the safest possible processes for chemotherapy administration. Over the last decade, advances in the delivery of chemotherapy coupled with the ability to better manage toxicities have resulted in a shift of oncology care from the inpatient to the outpatient setting.

Chemotherapy has traditionally been administered mainly through parenteral routes including intravenous and intramuscular injections. However, with the increase in the availability of new oral agents, oral drugs have become common in the treatment of some types of cancer. These drugs are often administered daily due to a need for tumor cells to be continually exposed to the drug.^{12,13} Many newer oral chemotherapy drugs target the molecular and cellular changes associated with cancer and therefore block the growth and spread of the cancer by interfering with the specific molecules involved in tumor growth. Thus, these drugs are designed to identify and attack cancer cells without harming normal cells.^{14,15}

10 ASCO-ONS Standards for Safe Chemotherapy Administration. (20!!) www.asco.org/ASCOv2/Practice

11 Jaconson, JO, et al: Revisions to the 2009 American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards: Expanding the Scope to Include Inpatient Settings. *J Oncology Practice* December 13, 2011

12 Weingart MD, et al. "NCCN Task Force Report: Oral Chemotherapy," *Journal of the National Comprehensive Cancer Network*, Vol. 6, Supplement 3, March 2008, pages S-1 to S-2.

13 Aisner, Joseph. "Overview of the changing paradigm in cancer treatment: Oral chemotherapy." *American Journal of Health-Systems Pharmacology*. 2007; Vol 64; May 1, 2007; Supplement 5: S4-7.

14 National Cancer Institute Web site at <http://www.cancer.gov> and National Comprehensive Cancer Network Web site at <http://www.nccn.com>

15 Goodin S, Oral chemotherapeutic agents: Understanding mechanisms of action and drug interactions. *Am J Health-Syst Pharm*. 2007;64(Suppl 5):S15-24

Studies have also shown that a majority of patients prefer oral to parenteral chemotherapy because it is considered a more convenient treatment option.^{16,17,18,19} The resulting shift from hospital to home-based administration of chemotherapy (via orally administered chemotherapy drugs), has yielded a need for oncology healthcare providers to create robust support mechanisms for the safe use of oral chemotherapy.^{20,21} Concerns include the difficulty of obtaining the medications through retail pharmacies, patients' lack of preparedness for side effects, and unfamiliarity with the techniques to mitigate drug toxicity.

Medical Efficacy

Although patient preference may be something doctors consider in prescribing a course of treatment, Compass found the instances in which there exist perfectly substitutable oral and intravenous chemotherapy drugs (with regard to medical efficacy) to be rare. Rather, with the advance of medical research and biotechnology, oral chemotherapy is more often becoming the standard course of treatment in many instances.

The National Comprehensive Cancer Network (NCCN) has identified several oral chemotherapies as preferred or first-line treatment modalities for particular tumor types.²² As oral drugs became the standard treatment for many tumors, the Centers for Medicaid and Medicare Services (CMS) approved the NCCN Drugs and Biologics Compendium as one of the compendiums used as the basis for coverage and reimbursement policies.

... There are many oral anti-cancer medications included as preferred treatment for many cancer types in treatment guidelines, including the NCCN Clinical Practice Guidelines in Oncology. For example, oral temozolomide is the current standard of care for first-line management of glioblastoma multiforme, a primary malignant brain tumor. The cancer network guidelines are evidence-based recommendations and treatment guidelines developed by an alliance of 21 of the world's leading cancer centers. Evidence of efficacy, including results of clinical trials, is used in developing these guidelines.²³

16 Borner, M, et al. Answering Patients' Needs: Oral Alternatives to Intravenous Therapy. *The Oncologist* 2001;6(supp 4):12-16

17 SO J, Improving the quality of oral chemotherapy services using home care. *European Journal of Cancer Care* 2010;19:35-39

18 Liu G., et al. Patient preferences for oral versus intravenous palliative chemotherapy. *Journal of Clinical Oncology* 1997;15:110-115

19 Gornas M, Szczylik C, Oral treatment of metastatic breast cancer with capecitabine: what influences the decision-making process? *European Journal of Cancer Care* 2010;19:131-136

20 Simchowitz B, et al. Perceptions and Experiences of Patients Receiving Oral Chemotherapy. *Clinical Journal of Oncology Nursing*, August 2010;14;4:447-53

21 Oakley C, Johnson J, Ream E, Developing an intervention for cancer patients prescribed oral chemotherapy: a generic patient diary. *European Journal of Cancer Care*, 2010;19:21-28

22 Khandelwal N, et al, Impact of Clinical Oral Chemotherapy Program on Wastage and Hospitalizations. *American Journal of Managed care*, May 2011;17, Special Issue:e169-e173

23 Washington State Department of Health. "Oral chemotherapy drug coverage mandated benefit sunrise review: Information summary and recommendations." December 2010. <http://www.doh.wa.gov/hsqa/sunrise/Documents/OralChemo.pdf>

Oral chemotherapy has in fact proven effective in treating several types of cancer, including breast cancer, colon cancer, cutaneous T-cell lymphoma, chronic myeloid leukemia, gastrointestinal stromal tumor, acute lymphoblastic leukemia, non-small cell lung cancer, pancreatic cancer, multiple myeloma, myelodysplastic syndrome, advanced renal cell carcinoma, and prostate cancer.²⁴

- Studies have shown that oral chemotherapy (capecitabine, specifically) is an effective alternative to intravenous chemotherapy in the treatment of colon cancer^{25,26,27} and advanced colorectal cancer.²⁸ Treatment with oral capecitabine also showed significantly less overall toxicity than the intravenous chemotherapy in the afore-cited studies.
- A study of medical efficacy of “oral maintenance chemotherapy” treatment of high-risk neuroblastoma cancer patients²⁹ found that, indeed, the treatment had some measurable success in increasing the event-free survival rate. The oral chemotherapy (monoclonal anti-GD2-antibody (MAB) ch14.18,” or MAB ch14.18) “improved the long-term outcome compared to no additional therapy.” Moreover, the study found that “immunotherapy with MAB ch14.18 may prevent late relapses.”
- “A randomized phase III clinical trial presented March 5, 2010, at the Genitourinary Cancers Symposium in San Francisco showed the oral drug cabazitaxel improved survival of some patients with advanced prostate cancer compared with those who received the injected drug, docetaxel. Cabazitaxel received FDA approval June 17, 2010.”³⁰

24 Goodin, Susan. “Oral chemotherapeutic agents: understanding mechanisms of action and drug interactions.” American Journal of Health-Systems Pharmacology. 2007; Vol 64; May 1, 2007; Supplement 5: S15-24.

25 Peck, P. “Gentler Oral Chemotherapy Shows Efficacy in Advanced Colon Cancer”. MedPage Today, June 29, 2005. at <http://www.medpagetoday.com/tbprint.cfm>. Accessed December 16, 2011

26 Allegra A, Sargent DJ, Adjuvant Therapy for Colon Cancer – The Pace Quickens. N Engl J Med 2005;352;26:2746-48.

27 Twelves C, et al. Capecitabine as Adjuvant Treatment for Stage III Colon Cancer. N Engl J Med

28 Washington State Department of Health. “Oral chemotherapy drug coverage mandated benefit sunrise review: Information summary and recommendations.” December 2010. <http://www.doh.wa.gov/hsqa/sunrise/Documents/OralChemo.pdf>

29 Simon, Thorsten; Barbara Hero; Andreas Faldum; Rupert Handgretinger; Martin Schrappe; Thomas Klingebiel; and Frank Berthold. “Long term outcome of high-risk neuroblastoma patients after immunotherapy with antibody ch14.18 or oral metronomic chemotherapy.” BMC Cancer. 2011, 11: 21. BioMed Central Cancer Research Article, Open Access. <http://www.biomedcentral.com/1471-2407/11/21>

30 Washington State Department of Health. “Oral chemotherapy drug coverage mandated benefit sunrise review: Information summary and recommendations.” December 2010. <http://www.doh.wa.gov/hsqa/sunrise/Documents/OralChemo.pdf>

Conclusion

The Division does not take a position in support of, or in opposition to, any legislation referred for review, but we do find the financial impact of Senate Bill 1070 to be small. Even under conservative market assumptions, enactment of the bill will cause no more than a 0.044 percent increase in insurance premiums – a relatively small increase, considering the cost of the drugs for which the legislation would increase access.

Still, our actuaries caution,

The impact of S.B. 1070 on any one individual, employer-group, or carrier may vary significantly from the overall results of this analysis; the impact on specific entities will depend on the current level of benefits each receives or provides and on how the benefits will change under the enacted bill.³¹

The Washington state health department, in conducting a review of a similar mandate, noted that “Removing the financial incentive from the decision on what treatment to choose will enable patients and physicians to make choices based on what the physician feels is the most-effective treatment for their patients’ medical needs.”³² The findings of this report are intended to provide objective data to legislators relevant to the growing list of cancers treatable by oral chemotherapies and oral chemotherapies viewed by oncologists as the more efficacious medical treatment of those cancers.

³¹ Compass: p.ii.

³² Washington State Department of Health. “Oral chemotherapy drug coverage mandated benefit sunrise review: Information summary and recommendations.” December 2010.
<http://www.doh.wa.gov/hsqa/sunrise/Documents/OralChemo.pdf>



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An Act relative to oral cancer therapy**

Prepared for
Commonwealth of Massachusetts
Division of Health Care Finance and Policy

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Prepared by
Compass Health Analytics, Inc.



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An Act relative to oral cancer therapy**

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This report was prepared by James Highland, PhD, MHSA, Heather Clemens, FSA, MAAA, Lars Loren, JD, and Joshua Roberts.

Actuarial Assessment of Senate Bill 1070: An Act relative to oral cancer therapy

Executive Summary

Senate Bill 1070, before the 2011-2012 session of the Massachusetts Legislature, requires health insurance plans to cover orally-administered anti-cancer medication (chemotherapy) on a basis not less favorable than intravenously-administered or injected cancer medications covered as medical benefits. The Massachusetts Division of Health Care Finance and Policy (the Division) engaged Compass Health Analytics, Inc. to provide an actuarial estimate of the effect that enactment of the bill would have on the cost of health care insurance in Massachusetts.

Background

Orally-administered chemotherapy represents a growing portion of chemotherapy administered to cancer patients. Under most health insurance plans, orally administered (as opposed to intravenously administered or injected) drugs are typically covered under the plan's pharmacy benefit, which often has patient-cost-sharing requirements (copays, coinsurance, deductibles, etc.) that differ from cost-sharing requirements for the plan's medical benefit, under which most IV and injected medications are covered. In some cases, the cost-sharing provisions of the pharmacy benefits are open-ended; for example, a pharmacy coinsurance provision might require a patient to pay a fixed percentage of the cost of prescription drugs without the limits on out-of-pocket expenditures typically present in medical benefits.

Senate Bill 1070 requires insurers to cover orally-administered anticancer medication on a basis no less favorable than the basis under which they cover IV or injected anticancer medications. It is targeted primarily at plans with pharmacy benefits with substantial coinsurance requirements (anywhere from 20 to 50 percent) with no cap on the patient's out-of-pocket expense. Combined with a drug that might cost thousands of dollars per month, coinsurance can result in a heavy financial burden on a patient.

The bill will likely have two major effects. First, some portion of the cost-sharing for orally-administered drugs will shift from patients to insurers. Second, some patients who avoided orally administered drugs because of high cost-sharing requirements, or avoided treatment altogether, might switch to orally-administered drugs. This analysis looks at those components.

Note that S.B. 1070, in the form presented to the Division for review, does not specify the types of insurance plans to which it will apply. For purposes of this analysis Compass assumed it will apply to commercial fully-insured plans and plans administered by the Group Insurance Commission (GIC).

Analysis

To estimate the overall impact of the proposed legislation, we considered the impact on three patient populations:

- Members who currently use oral chemotherapy treatments
- Members who refuse oral treatment and substitute IV treatment due to cost
- Members who forgo treatment due to cost

For each population, we estimated, using an all-payer claim database, per member per month (PMPM) medical costs and member cost-sharing as a base for projecting the impact of the proposed bill, and estimated the effect of the bill on that PMPM base. We then adjusted the resulting PMPM costs for projected health care inflation, specifically for oral chemotherapy, for the five-year period required for the analysis (2013-2017), and adjusted further for insurer retention for administrative costs and profit. Finally, we applied the result to the fully-insured membership as projected for the five-year period. A best estimate “mid-level” scenario was developed, as well as low- and high-level scenarios.

Summary results

Table ES-1 below summarizes the effect of S.B. 1070 on premium costs for fully-insured plans, averaged over five years. We estimate the bill, if enacted, would increase fully-insured premiums by 0.008 percent to 0.044 percent on average over the next five years.

This analysis captures an average across the entire fully-insured market. The impact of S.B. 1070 on any one individual, employer-group, or carrier may vary significantly from the overall results of this analysis; the impact on specific entities will depend on the current level of benefits each receives or provides and on how these benefits will change under the enacted bill.

Only a relatively small portion of the commercial fully-insured members in Massachusetts have pharmacy benefits employing cost-sharing arrangements with the potential to produce extremely high burdens on members (i.e., arrangements relying on an uncapped coinsurance requirement). The relatively small size of the overall increase in premiums is mostly due to the correspondingly small portion of that membership within the overall market. Therefore, most of the increase will fall on the membership of those plans that do rely on member cost-sharing employing coinsurance.

A vast majority of plans in the market require copayments but not coinsurance for pharmacy benefits, limiting the patient’s cost-sharing exposure for expensive drugs. Group Insurance Commission (GIC) plans are among those that would be minimally affected by the passage of S.B. 1070.

It is also worth noting that the impact of S.B. 1070 on premiums rises steadily throughout the projected period. Current drug development trends suggest that an increasingly large portion of cancer treatment drugs will be more precisely targeted and orally administered, and that these new drugs, developed for smaller patient bases, will be increasingly expensive per user.

Table ES-1
Estimated Incremental Impact of S.B. 1070 on Premium Costs

	2013	2014	2015	2016	2017	Average	5 Yr Total
Members	1,986,462	1,965,622	1,944,347	1,923,077	1,901,099		
Medical Expense Low (\$000's)	\$ 620	\$ 711	\$ 816	\$ 936	\$ 1,074	\$ 831	\$ 4,157
Medical Expense Mid (\$000's)	1,733	2,081	2,498	2,998	3,596	2,581	12,906
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PMPM Low	\$ 0.03	\$ 0.03	\$ 0.04	\$ 0.04	\$ 0.05	\$ 0.04	\$ 0.04
PMPM Mid	0.08	0.10	0.12	0.14	0.17	0.12	0.12
PMPM High	0.14	0.17	0.22	0.27	0.35	0.23	0.23
Estimated Monthly Premium	\$ 464	\$ 487	\$ 512	\$ 537	\$ 564	\$ 512	\$ 512
Premium % Rise Low	0.006%	0.007%	0.008%	0.008%	0.009%	0.008%	0.008%
Premium % Rise Mid	0.017%	0.020%	0.023%	0.027%	0.031%	0.023%	0.023%
Premium % Rise High	0.029%	0.035%	0.042%	0.051%	0.062%	0.044%	0.044%

Actuarial Assessment of Senate Bill 1070: An Act relative to oral cancer therapy

1. Introduction

Senate Bill 1070 requires health insurance plans to cover orally-administered anti-cancer medication (chemotherapy) on a basis not less favorable than intravenously-administered or injected cancer medications covered as medical benefits. The Massachusetts Division of Health Care Finance and Policy (the Division) engaged Compass Health Analytics, Inc. to provide an actuarial estimate of the effect that enactment of the bill would have on the cost of health care insurance in Massachusetts.

Assessing the cost impact entails analyzing the incremental effect of the bill on spending for insurance plans subject to the proposed law. This in turn requires estimating spending under the provisions of the proposed law and comparing that projection 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 describes the basic methodology used for the estimate. Section 4 discusses important considerations in translating S.B. 1070's language into estimates of its incremental impact on health care costs. Section 5 describes the details of the analysis and the results.

2. Interpretation of S.B. 1070

S.B. 1070, as drafted for analysis by the Division, provides (in its entirety):

SECTION 1. Notwithstanding the provisions of any general law, rule, or regulation to the contrary, a health benefit plan that provides coverage for cancer chemotherapy treatment must provide coverage for a prescribed, orally administered anticancer medication used to kill or slow the growth of cancerous cells on a basis no less favorable than intravenously administered or injected cancer medications that are covered as medical benefits. An increase in patient cost sharing for anticancer medications is not allowed to achieve compliance with this provision.

2.1 Definition of anticancer medication

S.B. 1070 identifies anticancer medication as that which is "used to kill or slow the growth of cancerous cells." For the purpose of this analysis, we will assume that definition includes agents that directly attack cancer (and other) cells (cytotoxic agents), that interfere with biologic

processes specific to certain cancer cells (biologic agents), and that slow the growth of cancer cells by, for example, depriving them of selected chemicals (often hormonal treatments)¹.

2.2 Parity in cost-sharing

The primary intent of the mandate is to address situations in which the cost-sharing burden on the patient is much higher for oral chemotherapy agents than it is for intravenous (IV) or injected agents. The latter are typically covered under the patient's medical plan's core benefit, with cost-sharing requirements the same as those for any other medical service; the former are often covered under a pharmacy benefit, which in some cases has higher cost-sharing requirements. Indeed, many of the cases brought to the attention of the Legislature as it first considered this bill involved an oral agent costing thousands of dollars per month covered by a pharmacy benefit with a coinsurance requirement under which the patient had to pay 20 to 50 percent of the cost.

For the purpose of this analysis, we assume that parity in cost-sharing means that the cost-sharing features of the pharmacy benefit meet some basic test of actuarial equivalence with the cost-sharing features of the medical benefit. That is, the expected financial exposure arising from all cost-sharing requirements to which the patient is subject – the copayments, the coinsurance percentages, the deductible and maximum amounts – is equal for the medical and pharmacy benefits, for a given level of required expenditure on covered benefits. But we do not assume the bill requires that the cost sharing dollar amount is necessarily the same. For example, if a member has a choice between an oral and an equivalent IV agent, and the cost sharing structure (percentages, caps, etc.) for each is the same, but the oral agent is much more expensive, the member's share of the cost of the oral agent will be a larger number of dollars and, we assume, allowed under the proposed mandate.

The bill's last sentence, "An increase in patient cost sharing for anticancer medications is not allowed to achieve compliance with this provision," limits an insurer's ability to treat all anti-cancer agents equally, with respect to cost-sharing, by raising the cost-sharing on IV/injected agents.

Note the bill does not specify whether oral agents are ultimately covered under a pharmacy or medical benefit, as long as they have cost-sharing no worse than that for IV/injected agents. And in theory, the bill might address policy terms other than cost-sharing requirements, but we believe these will not significantly affect the analysis.^{2,3}

¹ Some question remains about whether covered anti-cancer drugs include those that indirectly affect cancer cells by, for example, boosting the body's immune system. We did not intentionally include these agents on our list of oral chemotherapy agents, though some may have been present in the lists of agents we obtained from secondary sources.

² For example, if a policy required a member to use a particular network (a pharmacy network) and the member had to go outside the network to get a specialized oral agent, would the insurer be required to cover the drug and might the member be subject to out-of-network cost-sharing? For purposes of the actuarial analysis, we expect this fact set to be rare, and will assume the covering insurer will bear the cost, with cost-sharing comparable to that for IV/injected agents.

³ The Massachusetts MH parity mandate (M.G.L. c. 175 § 47B; c. 176A § 8A; c. 176B § 4A; c. 176G § 4M; c. 32A § 22) already establishes some precedent for covering pharmacy services as under the medical benefit,

2.3 Plans affected by the proposed mandate

The language of S.B. 1070 differs from that of most other mandate bills reviewed by the Division in that it makes no explicit reference to existing chapters of the Massachusetts General Laws. Other mandate bills have typically inserted their provisions into the various statute chapters governing insurance companies and other health insurance carriers, including hospital and medical service corporations and HMOs (chapters 175, 176A, 176B, and 176G).

The bill contains no explicit definition of “health benefit plan.” To provide some guidance for this analysis, we might turn to the definition contained in M.G.L. c. 176O, “Health Insurance Consumer Protections.” M.G.L. c. 176O § 1 defines a “health benefit plan” as “a policy, contract, certificate or agreement entered into, offered or issued by a carrier to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services,” and defines a “carrier” as one of the health insurance entities defined under chapters 175, 176A, 176B, and 176G (as well as preferred provider arrangements under chapter 176I). This set of plans is that covered by the typical mandate.

State health benefit mandates do not apply to Medicare, and we assume this mandate likewise does not apply to Medicare extension/supplement plans even to the extent they are regulated by state law. Such plans are typically excluded from mandate legislation. Furthermore, most Medicare beneficiaries have drug coverage under Part D plans, which do not have the unlimited out-of-pocket maximums that create the most severe hardship for patients.

While no state benefit mandates apply to self-insured plans in general, some apply to the self-insured plans administered by the Group Insurance Commission for the benefit of state and local employees (under M.G.L. c. 32A and c. 32B). S.B. 1070 contains no guidance as to whether its provisions extend to GIC plans⁴; however conversations with legislative staff indicated that the mandate should apply to the GIC plans.

Initial conversations about the scope of the bill raised the possibility that it would apply to Medicaid. However, Medicaid coverage does not subject clients to large cost-sharing loads, so decisions about whether to use oral or IV therapies probably don’t depend on current cost-sharing terms. Therefore, whether or not Medicaid finds its way into the scope of the bill, we ignore it in this analysis.

With no explicit guidance in the bill, we will make assumptions, based on the language of typical mandate legislation and conversations with legislative staff and the Division⁵, that allow us to proceed with the analysis. For the purpose of this analysis, we assume S.B. 1070 applies to all commercial fully-insured plans and to the GIC. Furthermore we assume the mandate applies to

requiring “For the purposes of this section, psychopharmacological services . . . shall be treated as a medical benefit and shall be covered in a manner identical to all other medical services.”

⁴ Even if we assume the definition of plans as those listed in chapter 176O, the bill would still need an explicit provision to reach GIC self-insured plans. A few GIC plans are fully-insured, and the mandate would reach those even without explicitly addressing the GIC.

⁵ We reviewed these assumptions with members of the legislative staff on December 20, 2011.

plan members who are residents of the Commonwealth or who work for employers whose primary place of business is in the Commonwealth.

2.4 Medical necessity

While the bill does not expand the population treated for cancer, it does alter coverage for a particular therapy, and it includes no explicit provision to alter insurers' standard latitude to evaluate the medical necessity of services. Carriers, responding to a survey of benefit plans conducted for this analysis, indicated that they rarely intervene with the member's oncologist's therapy choices. Indeed, the only time the medical necessity issue arises, even hypothetically, is when both an IV/injection therapy and an oral therapy are available and the insurer decides, for reasons of cost or its own evaluation of medical efficacy, it will not pay for the oral therapy. These situations are uncommon to begin with (see the discussion of substitution below in this report), even if the insurers intend to intervene. Therefore, we assume that insurers will retain the ability to review utilization, but that they rarely exercise it.

2.5 Existing laws affecting the cost of S.B. 1070

Massachusetts mandate requiring coverage for off-label drugs in treating cancer

Massachusetts has on the books a mandate requiring insurers to cover "off-label uses of prescription drugs used in the treatment of cancer."⁶

In responses to a survey sent to support this analysis, several carriers noted the current interpretation of the off-label mandate – that if a drug is indicated as treatment for one type of cancer, insurers must cover it for all types of cancer – might increase the cost of S.B. 1070. While we do not disagree with the assertion that the off-label mandate itself expands the use of covered anti-cancer drugs, the only way the off-label mandate can interact with S.B.1070 to raise costs even further would be if lower cost-sharing burdens prompted even more off-label use than is now underway. As discussed in subsequent sections of this report, we see limited opportunities for patients to switch treatment as a result of the proposed mandate, and we assume this interaction between the off-label mandate and S.B. 1070 is not significant.

The Affordable Care Act standard for essential prescription drug coverage

The federal Affordable Care Act (ACA) includes prescription drug coverage as an essential health benefit. The December 2011 HHS Bulletin "Essential Health Benefits"⁷ states that HHS intends to propose a prescription drug standard similar to that found in Medicare Part D. If that standard incorporates the cost-sharing design of Part D then the resulting plan is not likely to include an unlimited out-of-pocket maximum, and even though Part D requires some cost-sharing, patients

⁶ M.G.L. c. 175 §§ 47K, 47L; c. 176A § 8N; c. 176B § 4N; c. 176G § 4E

⁷ Centers for Medicare and Medicaid Services, Center for Consumer Information and Insurance Oversight, "Essential Health Benefits Bulletin," December 16, 2011. http://cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf

would not be subject to the most burdensome cost-sharing for oral chemotherapy agents that might currently exist under a few commercial plans.

If such a prescription drug cost-sharing design were required, the net impact of S.B. 1070 would be less than this analysis estimates. However, because the standard is not yet in place, we exclude consideration of it from this analysis.⁸

3. Methodology

3.1 Steps in the analysis

Compass estimated the impact of S.B. 1070 by employing the following steps:

- Estimate the populations covered by the mandate.
- Estimate the amount of cost-sharing borne by patients using oral chemotherapy that will shift to the insurers if the bill is enacted:
 - Measure the cost of oral chemotherapy agents.
 - Measure the average cost-sharing percentage for oral chemotherapies.
 - Measure the average cost sharing for drugs administered to cancer patients under a medical benefit.
 - Apply the difference in cost-sharing rates to the cost of oral chemotherapies.
- Estimate (ranges for) the effect of members who either shift to oral chemotherapies they previously avoided due to the cost-sharing burden or who had previously foregone treatment and begin to use oral chemotherapy once the cost-sharing burden is removed.
- Estimate the impact on premiums by accounting for insurers' retention (administrative costs and profit).
- Estimate changes in per member cost by combining the cost estimates and population information, and project the per member cost over the next 5 years.

⁸ Note also that under the ACA the federal government will provide premium tax credits to assist eligible persons with purchasing affordable qualified health plans through the exchanges. The federal Center for Consumer Information and Insurance Oversight (CCIIO) stated its intention to clarify its December 2011 bulletin to require that any state-mandated benefits enacted after December 2011 could not be part of the set of essential health benefits for which the federal government would provide tax credits, at least for 2014 and 2015, unless the benefits were already included within the essential benefit set regardless of the mandate. Thus, to the extent that S.B.1070 has a net actuarial cost, Massachusetts would have to pay for any subsidy attributable to that cost, thereby potentially raising the cost to Massachusetts of subsidizing coverage in those years. However, because this cost to taxpayers does not directly affect commercial premium payers, it will not be a factor in this analysis. Center for Consumer Information and Insurance Oversight, "Frequently Asked Questions on Essential Health Benefits Bulletin", <http://cciio.cms.gov/resources/files/Files2/02172012/ehb-faq-508.pdf>.

3.2 Data sources

The primary data sources used in the analysis were:

- Interviews with legislative and Division staff regarding legislative intent
- Studies submitted in testimony before the Legislature
- Interviews with clinical experts
- Government reports and data and academic literature, including population data, cited as appropriate
- Massachusetts insurer claim and membership data from the Division's 2009 Health Care Quality and Cost Council (HCQCC) all-payer claim database, for plans covering the overwhelming majority of the under-65 fully insured population subject to mandates
- A survey of major carriers soliciting information on their benefit structures for oral and IV chemotherapies

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

4. Factors Affecting the Analysis

Several issues arise in translating the provisions of S.B. 1070 and existing law into an analysis of incremental cost.

4.1 Ongoing evolution of chemotherapy agents

One of the major trends in the evolution of anti-cancer medication is the development of increasingly precisely-targeted drugs. These drugs address increasingly narrow classes of cancer, but often with greater success and fewer side effects than past treatments. Development costs, fewer targeted patients over which to spread those costs, and the availability of patent protection all make these drugs relatively expensive. And with increasing frequency, these drugs are developed for oral administration.⁹ Therefore it is reasonable to expect the portion of cancer patients who are treated with oral chemotherapy to increase, and to expect the average cost of oral chemotherapy treatment to increase faster than the rate of general health care cost increases.

⁹ The National Comprehensive Cancer Network (NCCN) reported in 2008 that "more than one quarter of the 400 antineoplastic agents now in the pipeline are planned as oral drugs. Compared with the oral chemotherapy drugs available before 1996, these newer drugs, consistent with their parenteral contemporaries, are considered costly. For example, the estimated yearly cost of lenalidomide for a patient with multiple myeloma is \$74,000, and, depending on dosage, the yearly cost of imatinib for patients with chronic myelogenous leukemia (CML) ranges from \$29,000 to \$57,000. [...] The availability of these new drugs has had an immediate impact on pharmacy budgets. Spending on oral chemotherapy drugs, while still a small proportion of total pharmacy benefit costs, has more than doubled between 2002 and 2006, from 0.3% to 0.7%." Weingart, SN, Bach, PB, et. al. NCCN Task Force Report: Oral Chemotherapy, Journal of the National Comprehensive Cancer Network, 2008;6:S1-S17.
http://www.nccn.org/JNCCN/PDF/JNSU3_combined_Oral_Chemo_2008.pdf.

Indeed, the three-year average cancer drug price increase observed in the Express Scripts 2010 Drug Trend Report¹⁰ is close to 21 percent per year, and the report projected a similar rate for the subsequent three years.

It is worth noting in the claim data examined for this analysis, future trends notwithstanding, that the average total cost per patient per year (before insurance coverage) for persons in treatment with IV chemotherapy is approximately ten times the cost of patients in treatment with oral agents, because many oral agents are inexpensive, many IV agents are expensive, and IV agents have large administration costs (see Appendix C). However, average cost-sharing per person is approximately twice as high for oral chemotherapy users due to the different cost-sharing rules for pharmacy benefits.

4.2 Oral chemotherapy agents included in the analysis

Measuring the volume of oral chemotherapy utilization, and the average cost-sharing to which it is subject, required that we identify oral chemotherapy agents in claim data (pharmacy claims). To do so, we began with a list of agents included in testimony on S.B. 1070 before the legislature¹¹ and supplemented it with additional research, input from carriers, and an interview with an oncological pharmacist. The list of agents we used appears in Appendix A.

Note that while many oral chemotherapy agents are very expensive, others have existed for a long time and are relatively cheap. These include hormonal therapies that are widely prescribed. Thus some of the most commonly used drugs are inexpensive and unlikely to trigger the kind of severe cost-sharing burdens brought before the Legislature's attention.

To execute the analysis, we also needed to identify intravenous/injected chemotherapy agents and related services for use in calculating average cost-sharing for IV/injected chemotherapy. We employed a set of HCPCS¹² "J" codes (drug codes) appearing in Appendix B. Additionally, we included revenue codes for IV service (258) with a primary cancer diagnosis as IV Chemotherapy and included the series of CPT codes specifically identified as IV chemotherapy administration.

4.3 Limitations of available claim data

Measuring the current cost of oral chemotherapy drugs and estimating the portion of those costs borne by patients entails using the claim data available to the Division (i.e., that accumulated for the HCQCC). That database has some limitations:

- It includes claims from the largest carriers, covering the overwhelming majority of fully-insured members, but excludes some small plans that might have a pharmacy cost-sharing arrangement different from the Massachusetts norm. Therefore when we generalize our findings from the HCQCC data to the entire Massachusetts fully-insured

¹⁰ Express Scripts, "Complex Challenges, New Solutions: 2010 Drug Trend Report".
<http://www.expressscripts.com/research/research/dtr/archive/2010/dtrFinal.pdf>

¹¹ Milliman, "Parity for Oral and Intravenous/Injected Cancer Drugs", January 25, 2010

¹² Healthcare Common Procedure Coding System

population, we will need to acknowledge and address the effect of this missing portion of the insured market in the analysis.

- The last full year for which data were available was 2009. A noted, oral chemotherapy is evolving rapidly and is increasingly expensive, and we will account for this in our estimates of how costs increase over time.

4.4 Current coverage

Much of the impetus for S.B. 1070 comes from cases, many presented in testimony before the Legislature, of patients who were faced with very large cost-sharing requirements when they had to pay, under their pharmacy benefits, relatively large coinsurance percentages on very expensive drugs, sometimes costing thousands of dollars per month.

Fully-insured plans

In preparation for this analysis, we submitted to the Massachusetts carriers covering the overwhelming majority of fully-insured members a questionnaire about their current coverage for oral chemotherapy. Among plans responding to the questionnaire, the cost-sharing arrangements that produce the sort of extreme burden described in testimony on the bill are relatively rare. With Massachusetts standards for creditable coverage in place and requiring at least some level of pharmacy coverage, it is possible the prevalence of extremely burdensome cost-sharing is lower in Massachusetts than it is in other states in which oral chemotherapy parity legislation has been considered.

This is not to say that burdensome cost-sharing does not exist in Massachusetts, or that some plans do not employ it extensively, or that the burden on any individual requiring an oral chemotherapy agent under this type of coverage isn't large, but the market share of those plans appears to be relatively small. As noted above, because plans that extensively employ burdensome cost-sharing serve only a small portion of the market and do not appear to have a significant presence in the claim data, the amount they contribute to the cost of S.B. 1070 will be small but subject to uncertainty.

Ultimately, looking at the fully-insured market as a whole, the percentage increase in premiums is relatively small. But if any of these smaller plans employs a more burdensome cost-sharing arrangement, the medical costs of that plan will increase by a proportion significantly greater than that applying to the state-wide average premium.

GIC plans

The GIC's commercial plans currently have a pharmacy benefit with a copayment structure (depending on the drug, the mode of filing the prescription, and the number of days supplied). It does not have in place plans with large, uncapped coinsurance requirements. The medical coverage typically includes a deductible and office visit copayments.

We do not think S.B. 1070 will have a measurable effect on the GIC plans. Depending on how the GIC ultimately reconfigures its benefits to meet the requirements of S.B. 1070, at worst some portion of the copayments might be absorbed by the insurer.¹³

4.5 Cost arising from the administration of oral agents

One of the arguments for encouraging the use of oral chemotherapy agents is that the cost of administering such drugs appears to be less than the cost of administering IV agents, since taking a pill requires less equipment and manpower than delivering intravenous therapy. We can measure much of the administration cost for IV therapy in claim data, but even oral therapies have administration costs, much of which we cannot measure with data sources available to us.

For example, the very expensive oral chemotherapy agents driving much of the support for this bill, because of their cost, are often closely managed by pharmacy benefit managers who require careful monitoring on the part of prescribers and pharmacists. The cost of these measures is not always captured in claims.

5. Analysis

To estimate the overall impact of the proposed legislation, we considered the impact on three patient populations:

- Members who currently use oral chemotherapy treatments
- Members who refuse oral treatment and substitute IV treatment due to cost
- Members who forgo treatment due to cost

For each population, we estimated per-member per-month (PMPM) medical costs and member cost-sharing from the HCQCC claim database as a base for projecting the impact of the proposed bill and estimated the effect of the bill on that PMPM base. The overall impact of S.B. 1070 is the sum of the impact on each of these populations.

We then adjusted the resulting PMPM costs for projected health care inflation, particularly for oral chemotherapy, for the five-year period required for the analysis (2013-2017), and adjusted further for insurer retention for administrative costs and profit. Finally, we multiplied the result by the fully-insured membership, projected for the five-year period, to arrive at dollar estimates.

¹³ Note that a portion of the GIC population is covered by a plan with a program to encourage members to select lower-cost medication when both a more expensive brand name drug and a generic equivalent are available. Under that program, if a provider requests that the member receive a covered brand-name drug with no substitution when a generic equivalent is available, the member will pay the copayment applicable to the generic drug plus the difference between the cost of the generic drug and the cost of the brand-name drug. Furthermore, the difference between the cost of the generic drug and the cost of the brand-name drug does not apply towards a member's deductible or out-of-pocket maximum. While in theory, this might create a heavy cost-sharing burden for a patient, and therefore S.B. 1070 might shift some of that burden to the insurer (and the GIC), for purpose of this analysis we expect this situation to be rare, especially since the very expensive drugs that are the impetus for the bill are not likely to have generic equivalents.

A best estimate “mid-level” scenario was developed, as well as a low-level scenario using assumptions that produced a lower total dollar estimate, and a high-level scenario using more conservative assumptions that produced a higher total dollar estimated impact.

5.1 Insured membership affected by the mandate

Table 1 shows the number of people potentially affected by the mandate. Self-insured plans (other than those sponsored by the GIC) are not subject to the mandate. This analysis does not include individuals with Medicare coverage and federally-regulated “medigap” policies. We have excluded people over age 64. Furthermore, we have not attempted 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 1:
Commercial Fully-Insured under-65 Projected Population

<u>Year</u>	<u>Projected Members</u>
2013	1,986,462
2014	1,965,622
2015	1,944,347
2016	1,923,077
2017	1,901,099

5.2 Cost of patients currently using oral chemotherapy

Number of patients currently using oral chemotherapy

The number of patients currently using oral chemotherapy treatments was estimated as the percentage of members in the 2009 claims database with claims for oral chemotherapy prescriptions (based on the drugs listed in Appendix A). This percentage was used for the mid-level scenario. The low-level scenario uses a percentage calculated based on findings reported in a 2010 study¹⁴ presented to the Legislature in testimony on S.B. 1070: approximately 1.5% of the commercially-insured population has cancer-related claims in a given year and, of those, 16.1% use oral chemotherapy, either alone or in conjunction with infused therapy. The high-level scenario is the percentage used for the mid-level scenario plus the difference between the mid- and low-level assumptions. Table 2 provides the values used in the analysis.

¹⁴ Milliman, “Parity for Oral and Intravenous/Injected Cancer Drugs”, January 25, 2010

**Table 2:
Percentage of Members with Claims in a Year
Using Oral Chemotherapy in that Year**

Low Scenario	0.24%
Medium Scenario	0.55%
High Scenario	0.85%

Current costs of oral chemotherapy

Based on analysis of the claim data, and supported by the responses to the carrier questionnaire, most people with fully-insured commercial coverage in Massachusetts have prescription drug coverage with cost-sharing in the form of copayments only, which limits the member’s out-of-pocket cost-sharing. The claim data show that in 2009 approximately 99 percent of those with claims for oral chemotherapy prescriptions (based on drugs listed in Appendix A) had a total out-of-pocket amount for these claims of \$500 or less for the year. For the remaining one percent or less of the members, out-of-pocket amounts ranged from just over \$500 to about \$14,000. Table 3 illustrates this distribution of per-user out-of-pocket costs against the allowed charges per user.

**Table 3
Distribution of Member Annual Out-of-Pocket Costs by
Total Annual Allowed Amount for Oral Chemotherapy Agents (\$000)**

