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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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