

Information Summary and Recommendations

Oral Chemotherapy Drug Coverage Mandated Benefit Sunrise Review

December 2010



For more information or additional
copies of this report contact:

Office of the Assistant Secretary
P.O. Box 47850
Olympia, Washington 98504-7850

Phone: 360-236-4612
Fax: 360-236-4626

Mary C. Selecky
Secretary

Page**Contents**

1	The Sunrise Review Process
3	Executive Summary
5	Summary of Information
18	Assessment of Sunrise Criteria
24	Findings
24	Detailed Recommendations
26	Rebuttals to Draft Report
29	Appendix A: Applicant Report
61	Appendix B: Draft Bill
67	Appendix C: Follow Up to Applicant Report
71	Appendix D: Written Comments
91	Appendix E: Summary of Public Hearing
107	Appendix F: Rebuttals to Draft Report

THE SUNRISE REVIEW PROCESS

In 1997, the legislature passed House Bill 1191. This bill amended the statute on mandated health insurance benefits. The statute now requires proponents of such mandates to provide specific information to the legislature. If the legislature requests a review, the Department of Health makes recommendations on the proposal using statutory criteria. This review is done only at the request of the chairs of legislative committees, usually the House Health Care and Wellness Committee or Senate Health and Long-Term Care Committee.

The criteria for these “sunrise reviews” are contained in RCW 48.47.030. The legislature’s intent is that all mandated benefits show a favorable cost-benefit ratio and do not unreasonably affect the cost and availability of health insurance. RCW 48.47.005 states, “...the cost ramifications of expanding health coverage is of continuing concern and that the merits of a particular mandated benefit must be balanced against a variety of consequences which may go far beyond the immediate impact upon the cost of insurance coverage.”

EXECUTIVE SUMMARY

Proposal

In 2009, the legislature requested the Department of Health review a draft bill, Senate Bill 5512, under the mandated benefit law, chapter 48.47 RCW. The agency received the full proposal and began review in February 2010. The request from the legislature stated that higher patient out-of-pocket costs for oral therapies covered under pharmacy benefits compared to intravenous (IV) therapies covered under medical benefits create a major barrier to cancer care. The proposal would require health care plans to cover “orally administered anti-cancer medication used to kill or slow the growth of cancer cells on a basis not less favorable than intravenously administered or injected cancer medication, including co-pays.” The proposal would apply to state-purchased health care plans, state-regulated individual and group health care plans, disability plans, and the Basic Health Plan.

Background

The American Cancer Society estimates that one-quarter of all deaths in the United States are due to cancer. With about one million people diagnosed with cancer each year, paying for cancer treatment is very important. The actuary report submitted with the proposal estimated that about 1.5 percent of a commercially insured population has medical claims for cancer in a year.

Intravenous (IV) and injected treatments were once the primary methods of cancer treatment. However, oral treatments have become more prevalent and are the standard care for many types of cancer. The coverage structure has not kept up with this trend. Many of these drugs are effective in cancer treatment, and often don't have IV or injected alternatives. There are 40 oral anti-cancer medications that are Food and Drug Administration (FDA)-approved, only nine of which have less expensive generic equivalents.

Oral anti-cancer medications are very expensive. These drugs can run as high as \$10,000 per month. Though intravenous and injected medications can be as expensive or even more expensive, higher cost-sharing required of patients for oral medications makes them much less affordable. When an oral treatment is determined most effective, patients are sometimes forced to make their treatment choice based on cost, rather than efficacy. This can be a large financial burden on patients. The American Cancer Society estimates that one in five cancer patients use up all or most of their savings paying for treatment.

Health care plans use different cost-sharing strategies to help control their costs, such as deductibles, co-insurance, and limits on coverage. Cost-sharing is intended to sensitize patients to the financial consequences of their choices and encourage patients and physicians to choose less expensive and generic drugs. However, the strategy of using cost-sharing to help patients make good, cost-effective choices doesn't work as intended when dealing with anti-cancer medications, where options are limited. Choice should be based on what is considered the most effective treatment in these cases, not just what is the most affordable.

We identified the following problems with Washington health plans' coverage of oral anti-cancer medications: high co-pays or co-insurance, unlimited or very high patient out-of-pocket maximums on benefits, and low annual or lifetime benefit limits. Co-insurance can be as high as

50 percent on higher tier prescriptions, where many cancer medications are placed. High patient out-of-pocket maximums can mean patients must pay thousands of dollars before the plan fully covers treatment. In addition, prescription plans often limit coverage to only a few thousand dollars per year, which a cancer patient can often use up in their first month of treatment.

Recommendation

The department concludes the proposal is in the best interest of the public and the benefits outweigh the costs of parity legislation for oral anti-cancer treatments. However, we believe there are some challenges to implementation of the proposal as currently drafted. Challenges include concerns there may be unintended consequences, such as less favorable IV and injected benefits and exclusion of biologic agents that treat cancer but don't directly "kill or slow the growth of cancer cells." The other challenge identified was confusion for providers on whether the bill intends to change the way they make coverage decisions or extend drug coverage beyond what they currently cover.

The agency believes the draft language gives plans flexibility in how they implement the mandate. However, language should be added to ensure cost-sharing isn't raised in order to comply. We also believe the intent should be clarified so health care plans can be certain of whether this mandate is meant to change the way they manage their formularies or to extend drug coverage for those without prescription coverage. In addition, the definition of anti-cancer medications may need to be clarified in the bill to ensure all appropriate treatments are included.

SUMMARY OF INFORMATION

Proposal

In 2009, the legislature requested the Department of Health review a draft bill, Senate Bill 5512, under the mandated benefit law, chapter 48.47 RCW. The proposal would apply to state-purchased health plans, state-regulated individual and group health plans, disability plans, and the Basic Health Plan. The request from the legislature stated that higher patient out-of-pocket costs for oral therapies covered under pharmacy benefits compared to intravenous (IV) therapies covered under medical benefits create a major barrier to oral cancer care. The proposal would require health care plans to cover “orally administered anti-cancer medication used to kill or slow the growth of cancer cells on a basis not less favorable than intravenously administered or injected cancer medication, including co-pays.”

The proponents of this proposal, Heather Stauffer Kirk and Vicki Jones, submitted a partial proposal in 2009, and the remainder of the proposal which included financial information in February 2010. (See Appendices A and B for proposal.)

Public Participation

The department shared the proposal with interested parties and began accepting comments May 11, 2010. We received nine comments in writing. We also received input from Health Care Authority on how the proposal would impact state-purchased health care. Here is a summary of the comments received (see Appendix D for full comments):

- Five of those who commented were in support of the proposal because: (1) oral anti-cancer medications are the standard of care in many cancer types; (2) oral medications are better-tolerated and less-invasive; and (3) treatment decisions should be based on the most effective, rather than the most cost-effective treatment. The five comments in support were from cancer organizations, a neuro-oncology registered nurse, a patient, and a pharmaceutical company.
- Regence BlueShield agrees with the concept of the proposal but has serious concerns. It states this is a more complex issue than what was presented in the applicant report. Regence feels this issue requires an in-depth review, and stated it's already exploring new benefit designs to address the problem. They pointed out that this proposal was funded by a pharmaceutical company who stands to benefit from it. They also stated this proposal will cost \$3 million for Regence, as well as for the state in a time with a large budget gap.
- The Association of Washington Health Plans also has serious concerns with the proposal. It states it will significantly increase costs and utilization without an accompanying assurance of safety or effectiveness. The association feels the proposal requires coverage of all chemotherapy drugs, removes health plans' ability to use evidence-based guidelines in coverage decisions, and extends pharmacy benefits to those who currently don't have prescription coverage.

- The Washington State Medical Oncology Society has concerns that the proposal doesn't address potential "pitfalls" and could do the opposite of what is intended. The society has already seen this happen with a Washington health plan, and feels specific language needs to be added to the proposed bill to ensure patient out-of-pocket costs aren't increased. It cited Colorado's recently enacted bill as an example of language to add. The society also wants to make sure the bill addresses biologic agents that act primarily on the immune system and only indirectly on cancer cells. It states the proposed language may not include these drugs, even though they treat cancer.
- Novartis Oncology supports language that improves patient access to oral anti-cancer medications, but feels parity may result in unintended consequences. It states that their oral cancer drug, Glivec, is already adequately covered under most pharmacy benefits and that parity would result in a large increase in out-of-pocket costs for many patients. Novartis recommends specific protective language be added to the bill to prohibit movement from the pharmacy to the medical benefit.

A public hearing was held June 28, 2010, in Tumwater, Washington. Three presenters spoke on behalf of the applicant group: Heather Stauffer Kirk presented the proposal; Vicki Jones told her story of challenges in coverage for oral chemotherapy; and Ben Steinmetz from GlaxoSmithKline presented cost information. Members of the public were invited to give testimony. (See Appendix E for hearing summary.) All six people who signed in supported the proposal. Two cancer patients testified about their challenges paying for cancer treatment; one had very high out-of-pocket costs for oral treatment, and the other had high out-of-pocket costs for IV treatment.

Following the public hearing, there was a 10-day comment period and another period for rebuttals following release of the draft report. The rebuttal comments are included on pages 26-27.

Background

Cancer is a group of diseases where abnormal cells grow and spread out of control, usually forming a lump or mass called a tumor. The tumor invades and destroys healthy tissue, and cells can break off and travel to other parts of the body. The spreading is called metastasis.¹ There are both external factors, such as tobacco and radiation, and internal factors, such as hormones and inherited mutations, that cause cancer. These factors act together or in sequence to initiate or promote carcinogenesis, which can take 10 or more years between exposure and detection of cancer.²

According to the American Cancer Society, the risk of developing or dying from cancer in the United States is about one in two men and one in three women.³ An estimated 562,340 people died of cancer last year in the United States, including 11,210 in Washington. Over one million

¹ American Cancer Society Web site, http://www.cancer.org/docroot/GRY/GRY_0.asp?dictionary=&pagKey=C, accessed on May 20, 2010.

² "Cancer Facts and Figures," American Cancer Society, 2009, p. 1.

³ American Cancer Society Web Site, Detailed Guide: Cancer (General Information) Who Gets Cancer," http://ww2.cancer.org/docroot/CRI/CRI_2_3x.asp?dt=72, accessed on May 25, 2010.

people are diagnosed with cancer every year. Cancer accounts for nearly one-quarter of all deaths in the U.S. each year.⁴

Treatments for cancer include surgery, radiation, chemotherapy, hormone therapy, biological therapy, and targeted therapies. These may be performed alone or in combinations. Anti-cancer medications are delivered by IV, injection, intra-arterial, intra-peritoneal, topically, or orally. Senate Bill 5512 specifically identifies orally administered anti-cancer medication used to kill or slow the growth of cancerous cells. Anti-cancer therapies can be given to cure cancer, control it, or ease cancer symptoms.

The term chemotherapy is often used to generally identify all anti-cancer treatments. However, chemotherapy is a specific type of cancer treatment that uses drugs to kill cancer cells. It works by stopping or slowing the growth of cancer cells, which divide quickly (also called cytotoxic chemotherapy). Unfortunately, fast-growing healthy cells are often destroyed in the process, such as those that cause hair to grow.

In the past, chemotherapy was primarily delivered by the parenteral route (IV or injection) for a number of reasons, including the need to deliver a high dose of chemotherapy in a single episode. The parenteral route works best for this episodic treatment. Oral drugs are becoming more common treatment for some types of cancer. These drugs are typically given daily due to a need for tumor cells to be continually exposed.⁵

Many new oral drugs are targeted, which means they focus on molecular and cellular changes particular to cancer. They actually block the growth and spread of cancer by interfering with the specific molecules involved in tumor growth. These agents identify and attack cancer cells without harming normal cells. Some examples of targeted therapies are those that block specific enzymes and growth factor receptors involved in cancer cell development, or those that block the growth of blood vessels to tumors to stop the tumor from growing.⁶

Other common categories of oral drugs are biologic agents and hormones. Biologic agents use the body's immune system to fight cancer or lessen the side effects that may be caused by some cancer treatments. It's sometimes called immunotherapy, biotherapy, or biological response modifier therapy. These therapies are designed to repair, stimulate, or enhance the immune system responses in the body so they can fight the cancer cells. Hormone therapies add, block, or remove hormones to slow or stop the growth of certain cancers, such as prostate and breast cancer.⁷

All drugs marketed in the United States must be approved as safe and effective by the Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER). CDER evaluates brand-name and generic drugs to make sure they work correctly and that their health

⁴ "Cancer Facts and Figures," American Cancer Society, 2009, p. 6.

⁵ Weingart MD, et al., "NCCN Task Force Report: Oral Chemotherapy," *Journal of the National Comprehensive Cancer Network*, Vol. 6, Supplement 3, March 2008, p. S-1 – S-2.

⁶ National Cancer Institute Web site at <http://www.cancer.gov> and National Comprehensive Cancer Network Web site at <http://www.nccn.com>, accessed on May 18, 2010.

⁷ Ibid

benefits outweigh their known risks. Drug companies must test the drugs and provide evidence of their safety and efficacy. A team of CDER physicians, statisticians, chemists, pharmacologists, and other scientists reviews the company's data and proposed labeling. If the drug's health benefits outweigh its known risks, the drug is approved for sale.⁸

FDA approval includes a drug label, which is a report about the medical condition the drug is approved to treat, as well as its approved dosage. Cancer drugs are often used for different conditions than those for which they're FDA-approved. These new uses have evidence to support their efficacy, but drug manufacturers haven't gone through the intensive FDA approval for the new use.⁹ This is called off-label use.

When drug manufacturers are developing a new drug, they apply for patents and market exclusivity. Patents and market exclusivity prevent competing manufacturers from marketing, using, or selling a generic version for a fixed period of time. The intent is to create incentives for inventors to commit the considerable investment required to develop new drugs. It allows drug manufacturers to recover their investment and make a profit before allowing competitors to develop and market generic versions of their drugs. However, it also makes access to generic equivalents a lengthy process. There are 40 FDA-approved oral anti-cancer drugs already available and many more under development.¹⁰ Of these, only nine have generic alternatives.¹¹

Oral drugs have become the standard of care in cancer treatment of many tumor types. The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium is used by the Centers for Medicare and Medicaid Services (CMS), as well as many private health plans, to develop its oncology coverage policies. The compendium includes many oral anti-cancer treatments. For instance, an oral therapy is listed as the preferred therapy for breast cancer for invasive, metastatic, HER-2 positive patients who have failed on prior IV therapies. An oral therapy is also listed as the primary treatment in the chronic myelogenous leukemia guidelines.¹² Oral temozolomide is the current standard of care for first-line management of glioblastoma multiforme, a primary malignant brain tumor.¹³

Insurance coverage has lagged behind the rapid growth in oral anti-cancer medications. As oral cancer treatments have become more readily available and the standard of care in many cases, the coverage structure has not adapted to address these changes. "The operational and financial infrastructure of oncology practice has been based on the parenteral administration of chemotherapy. Oncology office visits and the configuration of the office space have been centered on chemotherapy infusion, and oncologists derive a substantial portion of their income from supplying and administering parenteral chemotherapy."¹⁴

⁸ www.fda.gov/drugs/developmentapprovalprocess, accessed 7/26/2010.

⁹ <http://www.cancer.org/Treatment/TreatmentsandSideEffects/TreatmentTypes/Chemotherapy/off-label-drug-use>, accessed 7/26/2010.

¹⁰ "Analysis of Senate Bill 961: Cancer Treatment," California Health Benefits Review Program, April 17, 2010, p. 21.

¹¹ "Analysis of Senate Bill 961: Cancer Treatment," California Health Benefits Review Program, April 17, 2010, p. 22.

¹² Applicant Report Submitted for Sunrise Review, p. 6.

¹³ According to Barbara Otto's written testimony. Ms. Otto is a neuro-oncology/oncology RN.

¹⁴ Weingart MD, et al., "NCCN Task Force Report: Oral Chemotherapy," *Journal of the National Comprehensive Cancer Network*, Vol. 6, Supplement 3, March 2008, p. S-2.

Structure of Prescription Coverage

IV and injected treatments are typically covered under the patient's medical benefit, while drugs the patient self-administers, such as oral and self-injected drugs, are covered under the pharmacy benefit. A recent study of 11 oral anti-cancer medications showed that all 11 were covered under the pharmacy benefits of the private payers studied.¹⁵

To control prescription use and costs, employers and health plans use strategies such as formularies, patient cost-sharing, prior authorizations, and step therapy. These strategies are intended to sensitize patients to the financial consequences of their choices. They encourage patients and physicians to choose less expensive and generic drugs. Types of patient cost-sharing include deductibles, co-payments, co-insurance, and annual and lifetime limits on benefits.

Many prescription benefits cover medications according to formularies. Some include preferred drug lists. These lists are developed by a pharmacy and therapeutics committee, which usually includes pharmacists and other specialists who choose preferred drugs based on their safety, efficacy, and clinical outcomes. These drugs will have more favorable insurance coverage than non-preferred drugs, or may be substituted by a pharmacy in place of non-preferred drugs. Plans typically cover medications at different levels based on their tiers.

Medications are placed on tiers, typically from one to five tiers. Patient cost-sharing is based on which tier a medication is placed. Typically, generic, low-cost and preferred brand-name drugs are included on the first and second tiers, and expensive brand-name and specialty drugs are on the higher tiers. Some plans will include an ancillary charge on the higher tiers if a generic or preferred alternative is available and the patient or provider chooses the non-preferred or brand drug. The plan pays only the generic amount and the patient must pay the rest of the drug's cost.

Another tier that is sometimes included is a specialty tier. Specialty drugs may appear on the plan's highest tier, or on their own tier. Specialty drugs as those used to treat complex or rare conditions, which are typically self-injected and require extra help for the patient to learn how to take and manage. These drugs typically require specialty pharmacies to fill the prescriptions because of special handling and patient counseling requirements for these products. In addition to their capability for special handling and storage, specialty pharmacies often leverage costs by purchasing at volume discounts. Regular retail pharmacies may not have the high demand for these types of medications and may not be able to purchase in bulk.

Typically, plans require deductibles be met before they begin paying for services. There is usually an individual and family deductible, and often separate deductibles for prescriptions and other medical care. The patient pays the full price of their health care until they meet the deductible amounts. Once the prescription deductibles are met, the health plan pays all or a portion of the cost of medications based on the tier.

The portion of treatment the consumer is responsible for typically comes in the form of either a co-pay or co-insurance. A co-pay is a flat dollar amount. Co-insurance is a percentage of the

¹⁵ Barnes, Lauren et al., "Oral Oncolytics/Addressing the Barriers to access and Identifying Areas for Engagement," Avalere Health and the Community Oncology Alliance (COA), Washington DC, February 2010, pp. 6-9.

cost, usually from 10 to 50 percent. Co-insurance is much more prevalent than co-pays in Washington health plans. Oral anti-cancer drugs often have up to a 50 percent co-insurance.

Plans often include patient out-of-pocket maximums on prescription benefits, either monthly or annually. Once a consumer reaches this maximum, they're no longer required to pay the co-pay or co-insurance and the plan pays 100 percent for prescriptions. In addition, many plans have a separate annual and/or lifetime limit on what they'll pay for prescriptions. Once they meet the limit, consumers are responsible for 100 percent of their prescription costs.

Prior authorizations require the provider to obtain approval for coverage of a medication prior to prescribing it. These are usually medications with safety concerns or a high potential for misuse. The health plan will have certain criteria that must be met for it to cover the drug. The health plan typically has lower-priced clinical alternatives. Sometimes step therapy is part of a pre-authorization. In step therapy the health care plan approves a patient to start on the most cost-effective, safest drug and progresses to more costly or risky therapies if necessary. Prior authorizations are used in many health plans in Washington.

Medicare's pharmacy benefit (Part D) includes almost all oral cancer medications on the formulary. The Centers for Medicare and Medicaid Services (CMS) has stated that a choice of therapies is more important in cancer treatment than other illnesses. Unfortunately, Medicare has a complicated coverage structure that includes a gap in coverage, a "donut hole." After the plan's initial coverage of \$2,000, the patient must cover \$2,850 before the plan begins covering 95 percent of the remainder of the costs.¹⁶ However, the 2010 federal health care reform bill has a plan to reduce and ultimately eliminate this coverage gap.¹⁷

Washington State Regulations

Plans Regulated by the Office of the Insurance Commissioner:

Health care plans are regulated by the Office of the Insurance Commissioner (OIC) and are licensed to sell health plans for individual and group plan coverage. Health care plans are required to submit rates and contracts for OIC regulatory review to ensure benefits required by law are contained in the contract and that rates are reasonable in relation to the benefits provided. Contracts and rates may be disapproved for these reasons. In addition, they may be disapproved if they place unreasonable restrictions on the treatment of patients; contain or incorporate by reference any inconsistent, ambiguous or misleading clauses; or include exceptions and conditions which unreasonably or deceptively affect the risk assumed in the general coverage of the contract. Self-insured group plans are regulated by the federal Employee Retirement Income Security Act (ERISA) and would not be impacted by the proposal.

Health care plans are not required to offer pharmacy benefits, although most do. A health care plan is required to disclose certain information to members. This information includes a listing of covered benefits; a copy of the current formulary if one is used; a definition of terms such as generic versus brand name; policies regarding coverage of drugs, such as how they become

¹⁶Weingart, p. S-10.

¹⁷ http://www.naic.org/index_health_reform_section.htm#seniors.

approved or are removed from the formulary; and how consumers may be involved in decisions about benefits.

Plans may not exclude coverage for off-label use of drugs that are recognized as effective in one of the standard reference compendia, relevant peer-reviewed medical literature, or the federal Secretary of Health and Human Services when medically necessary. Off-label means “the prescribed use of a drug which is other than that stated in its FDA approved labeling.”¹⁸ The health plans make the decision on what tier they place the medications.

Plans Under the Washington State Health Care Authority

Health Care Authority (HCA) contracts with health plans to provide benefits for the Public Employees Benefits Board (PEBB) plans, the Basic Health Plan, and the newly enacted Washington Health Program. This includes negotiating appropriate cost-sharing. Formularies and coverage limits vary by health plan. The PEBB plans are offered to state and higher education employees and retirees.

Public Employees Benefits Board prescription plans include a preferred drug list (PDL) that is used in the Therapeutic Interchange Program. Under this program, pharmacies automatically replace non-preferred medications with a less-expensive, preferred medication from the preferred drug list when the prescription is written by a participating prescribing provider. The Washington State Pharmacy and Therapeutics Committee develops the preferred drug list using an evidence-based review process. This group is made up of health professionals appointed by the heads of the Health Care Authority, Department of Social and Health Services, and Labor and Industries. At this time, the list does not include any anti-cancer drugs, oral or otherwise administered.

The Basic Health Plan provides subsidized plans for low-income families. In general, applicants must be Washington residents to qualify and premiums are based on age, family size, gross family income, and health plan chosen. These plans include annual deductibles and patient-of-pocket maximums. The prescription benefit includes a two-tiered pharmacy benefit. The first tier includes generic drugs and the second tier includes all brand name drugs, including many anti-cancer medications.

The Washington Health Program is a new non-subsidized version of the Basic Health Plan that began enrolling applicants for health coverage on July 1, 2010. In general, applicants must be Washington residents to qualify for this plan. Premiums are based on age, geographic location, tobacco use, and health plan option chosen. There are two options, one that provides up to \$75,000 annually in coverage, and one that provides up to \$100,000 annually. Members maintain low deductibles and, at times, no-cost coverage for basic health services. There are individual and family annual deductibles from \$500 per person and up to \$1,500 per family. The individual and family annual out-of-pocket maximum is \$3,000 per person and up to \$9,000 per family, depending on where services are accessed. This plan includes a two-tiered pharmacy benefit with the first tier (generics) deductible at \$10 to \$20, and the second tier (brand name and non-formulary drugs) requiring a 50 percent co-insurance.¹⁹

¹⁸ WAC 248-30-450(3)(b)and(4)(a).

¹⁹ <http://www.washingtonhealth.hca.wa.gov/understanding.html>, accessed July 14, 2010.

Financial Burden of Cancer

Inadequate insurance, which includes plans with high cost-sharing, is a barrier to patients having access to lifesaving cancer treatment. One in five insured cancer patients use all or most of their savings paying for cancer treatment. In 2009, nearly 29 percent of people with cancer spent more than 10 percent of their family income on their medical care.²⁰

The applicant provided detailed information on her father's treatment for a malignant brain tumor as an example of the high costs of oral anti-cancer drugs. Her father's physician prescribed an oral anti-cancer treatment as the best option, which her father chose to do. His out-of-pocket costs were \$30,598 for one year. If he had chosen an IV alternative, his insurance plan would have covered 100 percent of the treatment after his \$4,500 deductible.

For many cancer patients, financial barriers delay or limit access to needed treatment. Some decide on treatments other than those recommended by their physicians because of high out-of-pocket expenses associated with treatments such as oral chemotherapy drugs.

With IV chemotherapy, the financial burden for patients doesn't stop with direct medical costs. Patients lose work time to go to chemotherapy treatment. Usually, a friend or family member must also lose work time to transport the patient to treatment. Indirect costs also include loss of time and economic productivity resulting from cancer-related illness and death. The National Institutes of Health estimated lost productivity due to premature cancer deaths in the United States in 2005 at \$134.8 billion (estimating about 600,000 cancer deaths that year).²¹

Defining the Problem in Washington State

There has been a blanket statement in the proposal and in some comments that IV chemotherapy typically requires a small co-pay for an office/clinic/hospital visit. However, our research has found this to not be the case in Washington. Health plans have been moving away from standard co-pays as the costs of health care have risen. Washington plans impacted by this proposal typically require from 15 to 20 percent co-insurance for IV chemotherapy. What often makes the medical benefit more favorable than the prescription benefit is the lower patient out-of-pocket maximums. Many plans in Washington have patient maximums of \$2,000 to \$6,000 per year, or \$200 per day/\$600 per year for other medical care.

A scan of Washington health plans revealed many vastly different coverage structures. Below is a summary of the major issues we identified with coverage of oral anti-cancer medications:

High co-pays or co-insurance:

The Basic Health Plan has high co-insurance for many anti-cancer medications. The pharmacy benefit only has two-tiers. It includes a mere \$10 co-pay for generics, but has a 50 percent co-insurance for brand-name drugs with no patient out-of-pocket maximum. The medical benefit includes a 20 percent co-insurance for outpatient hospital or physician office visit, which would

²⁰ "Cancer Facts and Figures," American Cancer Society, 2008, p. 38.

²¹ "Cancer Trends Progress Report – 2009/2010 Update," National Cancer Institute, NIH, DHHS, Bethesda, MD, April 2010, <http://progressreport.cancer.gov>, accessed August 4, 2010.

include IV chemotherapy, but has a \$1,500 patient out-of-pocket maximum. There are also many private health plans in Washington that charge up to 50 percent co-insurance on brand-name drugs, some without patient out-of-pocket maximums. Some prescription plans even have generic-only coverage options where they don't cover any brand-name drugs.

Unlimited or very high patient out-of-pocket maximums on benefits:

Most of the Public Employees Benefits Board (PEBB) plans have low deductibles for medical and pharmacy benefits of \$100 to \$200 for individuals and \$300 to \$600 for families. However, the out-of-pocket maximums on the third tier don't typically apply. There can be up to 50 percent co-insurance for drugs on the third tier, where many oral anti-cancer drugs appear.

Many private prescription plans in Washington have unlimited or very high patient out-of-pocket maximums for their prescription benefit. Plans are more likely to have lower out-of-pocket patient maximums on their medical benefit than on their prescription benefit.

Annual and lifetime benefit limits:

In addition, many plans include annual and lifetime benefit limits on how much they'll pay. Once the limit is reached, the patient is responsible for 100 percent of the costs. Some lifetime limits are as low as \$100,000. Prescription benefits often have very low annual limits, some only \$2,000 to \$3,000 per year. Patients with cancer often use up their prescription benefit early in the year for expensive oral cancer treatments.

The Federal Patient Protection and Affordable Care Act may solve much of this problem by eliminating lifetime limits on essential benefits, which looks to include prescription benefits. In addition, the use of annual dollar limits for essential benefits will be eliminated by 2014.²²

At a public hearing we held June 28, 2010, we heard stories from some state residents that demonstrate the issues described above (see Appendix E for their testimony).

Vicki was diagnosed with multiple myeloma, a cancer of the plasma cells in the bone marrow. She was covered under an individual health plan. This disease is incurable, but treatable by a number of drugs and treatments that are given in various stages of the disease. At one point, her physician prescribed an oral drug called Revlimid, which has had tremendous success in extending the lives of myeloma patients. She then learned that this drug would cost about \$7,000 per month for treatment. She also learned that her insurance policy had a limit on prescription coverage of only \$5,000 per year. This meant she would reach her limit with the first month's dose of the drug and have to pay the full \$7,000 per month out-of-pocket for the remainder of the year.

Fortunately for Vicki, there was an IV alternative called Velcade that her policy would cover under her medical benefit. Velcade has worked for her, but she has had to go to the clinic weekly for two to four hours of treatment in the chemo room, rather than taking a pill at home. Vicki feels she should've been allowed to take the best drug for her situation, rather than the drug her insurance company decided to reimburse. In addition,

²² 2009 Federal Patient Protection and Affordable Care Act, Section 2711.

the Velcade treatment cost the insurance company more than the oral medication would've cost them. If the "no less favorable" mandate in the proposal were in effect, it may have actually saved her insurer money.²³

Judith was diagnosed with glioblastoma multiforme brain cancer. She was covered under an individual health plan. Her physician prescribed an oral anti-cancer drug called Temadar, which she'll be on for 12 months, taking five days of pills every 28 days. These pills cost about \$3,100 per month. She reached her annual prescription coverage limit of \$3,000 during her first dose in January. That means that she is paying \$3,100 out of her pocket every month.

Please note, however, that there are also plans that include high-cost-sharing for medical benefits, some with up to 50 percent co-insurance. The co-insurance rate often depends on which plan is chosen and whether the chemotherapy is given in a hospital, infusion clinic, or physician's office. Patient out-of-pocket maximums run anywhere from \$1,500 to \$10,000 or more, again depending on which plan is chosen.

Challenges Specific to Oral Anti-cancer Medications

Oral anti-cancer medications often fall under the highest tier or a specialty tier of a pharmacy benefit, usually with a high co-insurance. The treatment plans for cancer patients must be so personalized that there are often no alternative treatments. A high-cost oral medication is often the only option to save or prolong a patient's life. The strategy of using cost-sharing to help patients make cost-effective choices doesn't work as intended when dealing with life and death health conditions with limited, or often only one, option.

There are increased administrative burdens placed on providers when prescribing oral treatments. Oral agents typically require more prior authorization when compared to IV therapies. Providers are often required to provide letters of medical necessity, medical records, and lab results when requesting prior authorizations.²⁴ Step therapy is often included in health plan contracts, requiring consumers to try low-cost medications before more costly alternatives are covered.²⁵

It's difficult to substitute anti-cancer drugs for one another. Some drugs have oral and injectable counterparts, while others are available or effective in only one form or another. Of the 40 FDA-approved oral cancer medications, only 11 have IV or injected alternatives.²⁶ Oral treatments are often given in conjunction with IV or injected drugs. Whether an anti-cancer drug is developed in oral or IV form often depends on the molecular properties of the agent, rather than on a choice made by the drug developer.²⁷ Unlike non-cancer therapeutic drugs, there are not typically two or more similar anti-cancer drugs. New brand drugs typically have patents for up to 20 years,

²³ The IV Velcade treatments were billed to Vicki's insurance carrier at \$17,168 per month. The eligible contract price paid ended up being \$7,600 per month.

²⁴ "Leveling the Paying Field," *Oncology Issues*, Association of Community Cancer Centers (ACCC), May/June 2009, p. 8.

²⁵ Malkin, Jesse et al., "The Changing Face of Pharmacy Benefit Design," *Health Affairs*, Vol. 23, No. 1, January/February 2004, p. 1.

²⁶ "Analysis of Senate Bill 961: Cancer Treatment," California Health Benefits Review Program, April 17, 2010, p. 22.

²⁷ Testimony of Ben Steinmetz at public hearing.

delaying the opportunity for generic alternatives to be developed.²⁸ Cancer treatments are unique to each patient, and depend on factors like the type and location of the cancer and at what stage it is diagnosed.

According to a study of 15 pharmacy benefit manager experts, the trend toward more multi-tier pharmacy designs using co-payments to steer patients toward low-cost drugs will continue. The effects of this trend on health outcomes will depend on the drugs being targeted. The danger comes when patients are discouraged from using expensive drugs when there are no adequate substitutes. According to discussions in this study, pharmacy benefit manager (PBM) designers need to make patients more sensitive to differences in costs between treatments where there are options without encouraging them to forgo cost-effective care.²⁹ This is a danger in the case of cancer treatment, when patients may be steered toward less-effective treatment because of costs.

Health Care Authority has specifically identified challenges with the bill as drafted for its health plans based on how they implement it. If it moves anti-cancer medications from the prescription benefit to the medical benefit, it won't be able to collect the federal Retiree Drug Subsidy dollars for PEBB Medicare Part D eligible enrollees (an estimated cost of \$1.2 million annually). Implementation may be more complex than just moving the benefit. They may need to develop a specific benefit design for all anti-cancer medications.

Another challenge is that there are separate billing code systems used to identify pharmaceuticals and medical claims. Pharmacy claims are billed under unique 10-digit National Drug Codes (NDC). Medical claims are billed under J codes, which are a subset of the Healthcare Common Procedure Coding System (HCPCS). J codes don't show payers details like the diagnosis code, the biotech agent administered, dosage, or drug price.³⁰ This makes it difficult to determine how much is attributed to the actual chemotherapy drug, as compared to the IV administration, provider time, or other services. In addition, health plans often have pharmacy benefit managers run their pharmacy benefit separately from their medical benefit. PBMs leverage their buying power through their pharmacy networks, which is important with oral anti-cancer drugs, many of which are only used by a small percentage of the population.

Besides the high cost of oral anti-cancer agents, there are also non-financial challenges that have been brought to our attention. These issues will not be addressed in the proposal, but merit mention. Oncologists face challenges in ensuring patients adhere to the prescribed regimen and obtain necessary refills. There is associated lab work, office visits, and serious side-effects that must be identified at home often on weekends when the oncologist may not be available. Often the dosage instructions are complicated.

Federal and Other State Parity Laws

Oregon was the first state to pass a law to require parity for chemotherapy treatments. Senate Bill 8 passed in 2007 with very similar language to the proposal under review. Eight states and the

²⁸ Hunt, Michie Ph.D. et al., "Prescription Drugs and Intellectual Property Protection: Finding the Right Balance Between Access and Innovation," *Issue Brief*, August 200.

²⁹ Malkin, p. 5.

³⁰ Carlson, Bob, "How Four Health Plans Manage Biotech Drugs," *Biotechnology Healthcare*, May 2004, p. 33.

District of Columbia have recently followed suit by passing parity laws. Oregon's law has been enacted the longest, and they have the most experience from which to learn.

According to the Administrator of the Oregon Insurance Division of the Department of Consumer and Business Services, this law has caused positive and negative changes to policies. Whether a consumer was harmed by or benefited from the new law depended on the type of plan and how the insurer chose to implement the bill. The administrator stated that the bill was implemented in the following ways:

- Many of the largest insurers were able to maintain their original benefit structures because they already covered the two chemotherapies equally.
- Some plans created a new chemotherapy benefit that included oral, IV, and injection treatments.
- Some plans moved oral chemotherapy from the pharmacy to the medical benefit.

If a consumer had no prescription drug coverage or a high prescription out-of-pocket maximum with a reasonable medical benefit deductible prior to passage of SB 8, moving oral medications to the medical benefit had the potential for significant savings to the consumer. Creation of a new benefit for all chemotherapy treatments also had the potential for significant savings if the new benefit included a reasonable deductible.

Moving oral medications to the medical benefit hasn't worked for consumers with low co-pays on prescription drug coverage. In that case, patients are now required to meet annual deductibles before coverage begins and face potentially higher co-pays after coverage is triggered. They shared a few examples of this in complaints submitted:

- A patient with a plan that covered Armidex, an oral anti-cancer medication, at 50 percent, paid \$141 out-of-pocket for a 30-day prescription. Once SB 8 passed, her insurance plan moved Armidex under the medical benefit. She was then required to pay her \$2,500 medical deductible before her plan would cover her prescription.
- Two patients taking the oral anti-cancer medication, Femara, complained of large increases in their out-of-pocket expenses. They were paying \$25 and \$35 per month prior to SB 8. After SB 8, they were required to pay the entire \$300 per month for the drug until their medical deductibles of \$2,000 and \$500 were met. They then had to pay a 20 percent co-insurance after meeting their deductibles, which was twice what they paid before SB 8 passed.

The proposal in Washington is almost identical to Oregon's bill.

Kansas, Colorado, Hawaii, Indiana, Vermont, Iowa, Minnesota, Connecticut, and Washington D.C. have recently passed parity laws, while New Mexico and New Hampshire have passed laws requiring further study of the issue. There is similar language in all of these bills, but some have added clarifying language to address confusion or potential unintended consequences.

Some examples of language that may add clarification are:

- Colorado's enacted bill uses the language "shall be provided at a cost to the covered person not to exceed the coinsurance percentage or the copayment amount as is applied to an intravenously administered or injected cancer medication prescribed for the same

purpose.” The bill also specifies that it must be medically necessary and that the bill “Does not require the use of orally administered medications as a replacement for other cancer medications.” It further states, “A carrier shall not achieve compliance... by imposing an increase in patient out-of-pocket costs...”³¹

- Hawaii’s enacted law states, “...all chemotherapy that is considered medically necessary..., including orally administered chemotherapy, at the same copayment percentage or relative coinsurance amount as is applied to intravenously administered chemotherapy....”³²
- Massachusetts has introduced legislation that states, “An increase in patient cost sharing for anticancer medications is not allowed to achieve compliance with this provision.”³³
- Minnesota has passed legislation that states, “A health plan company must not achieve compliance with this section by imposing an increase in co-payment, deductible, or coinsurance amount for an intravenously administered or injected cancer chemotherapy agent covered under the health plan.”³⁴

Representative Brian Higgins (D-NY) introduced federal legislation in 2009 very similar to this proposal called the “Cancer Drug Coverage Parity Act.” HR 2366 proposes changes to the Employee Retirement Income Security Act (ERISA), the Public Health Service Act, and the Internal Revenue Code that are very similar to the proposal in this sunrise review. The bill has not passed Congress at this time.

The 2010 Federal Patient Protection and Affordable Care Act makes many changes to health care coverage in the United States. Many of these changes will have an impact on the problems this proposal is trying to correct. These changes include eliminating lifetime dollar limits on essential benefits immediately, and eliminating annual dollar limits on essential benefits by 2014.³⁵ However, it’s still unclear what will be included under essential benefits.³⁵

³¹ General Assembly of the State of Colorado, House Bill 10-1202, signed by the Governor 4/15/2010.

³² Hawaii Revised Statutes, Senate Bill 166, signed by Governor 7/2/2009.

³³ Commonwealth of Massachusetts, Senate Bill 2271, introduced in 2009 but has not passed.

³⁴ Minnesota State Legislature, SF 1761, signed by Governor 5/14/2010.

³⁵ Federal Patient Protection and Affordable Care Act, Section 2711.

ASSESSMENT OF THE SUNRISE CRITERIA

Social Impact

To what extent is the benefit generally utilized by a significant portion of the population?

An estimated 562,340 people died of cancer last year in the United States, including 11,210 in Washington. Over one million people are diagnosed with cancer every year.³⁶

Milliman, Inc., provided actuarial information for the applicant, estimating that about 1.5 percent of a commercially insured population has medical claims for cancer in a year. Of that number, 25 percent receive some sort of chemotherapy, while the remaining 75 percent receive treatments such as surgery, radiation, or monitoring. Currently, about half of the patients receiving chemotherapy use oral products only.³⁷

To what extent is the benefit already generally available?

Most FDA-approved oral anti-cancer medications are available to patients with prescription drug coverage. However, high co-insurance and low coverage limits make them generally unavailable.

If the benefit is not generally available, to what extent has its unavailability resulted in people not receiving needed services?

The fact that most of these drugs are unaffordable under the current benefit structures means patients often choose a more affordable treatment which may be less effective. Some patients may delay, or even stop treatments based on financial considerations. Providers often know the patient's financial situation, which influences treatment choices.

One study found that one in six cancer patients with high out-of-pocket costs are not filling their prescriptions. The study showed that over 28 percent of patients with an out-of-pocket expense of \$500 or more for a prescription abandoned their cancer medication.³⁸

The experience of Vicki Jones (page 13-14) demonstrates a patient in Washington State who was forced to choose an IV alternative over an oral treatment prescribed by her physician because her insurance policy covered the IV alternative much more favorably.

If the benefit is not generally available, to what extent has its unavailability resulted in unreasonable financial hardship?

The imbalance between what some insurers pay for IV treatment versus what they pay for oral and self-injected medications can be vast. Cancer treatment can cost \$50,000 or more per year. Cost-sharing under a pharmacy benefit can often reach 50 percent with no patient out-of-pocket maximum.

³⁶ "Cancer Facts and Figures," American Cancer Society, 2009, p. 6.

³⁷ Milliman Client Report submitted with proposal, Appendix A, p. 5.

³⁸ Gleason PP, et al., "Oral Oncology Prescription Abandonment Association with High Out-of-Pocket Member Expense," *Journal of Managed Care Pharmacy*, 2010;16:161-162, cited by "New Study Finds One in Six Cancer Patients with High Out-of-Pocket Costs Not Filling Prescriptions," Prime Therapeutics, April 9, 2010.

One in five insured cancer patients uses all or most of their savings paying for cancer treatment. In 2009, nearly 29 percent of people with cancer exceeded 10 percent of their family income for their medical costs.³⁹ We heard stories of families being forced to choose between bankrupting their families and receiving less-effective treatments.

What is the level of public demand for the benefit?

Oral anti-cancer treatments will make up nearly 25 percent of the oncology market in the next decade. There are currently 40 oral medications available and the National Comprehensive Cancer Network (NCCN) has reported that more than 100 are under development. Survey results provided by the applicant showed 92 out of 102 patients surveyed preferred oral over IV cancer medications because of fewer office visits, reduced burden on family members, and less time spent away from work and home. In addition, oral agents are increasingly becoming the standard of care for treatment of many cancer types, as incorporated in the cancer network's Clinical Practice Guidelines for Oncology.⁴⁰

Nine states and Washington D.C. have passed oral chemotherapy parity laws. Many states and the federal government have laws pending to create parity on this issue.

What is the level of interest of collective bargaining agents in negotiating privately for inclusion of this benefit in group contracts?

The applicant did not have information about this question.

Financial Impact

To what extent will the benefit increase or decrease the cost of treatment or service?

For consumers, this proposal may decrease out-of-pocket responsibilities under some plans, while potentially increasing it for others. Oregon's experience with Senate Bill 8 in 2007, which is very similar to the proposal under review, was that it depended on what type of health plan was involved and how the health plan implemented the bill. Oregon believes Senate Bill 8 resulted in the following outcomes based on how plans implemented the legislation:

Some plans moved oral anti-cancer medications from the pharmacy to the medical benefit, resulting in:

- Consumers with no prescription drug coverage or coverage with high prescription maximums along with reasonable medical benefit deductibles most likely resulted in significant savings.
- Consumers with low co-pays or co-insurance on their prescription coverage most likely were harmed because they had to meet annual medical deductibles before their plan would provide coverage, and sometimes the co-pays or co-insurance would be high once coverage was triggered.

Novartis Oncology, a pharmaceutical company, gave a specific example where moving oral drugs into the medical benefit would have a negative impact on coverage. It stated

³⁹ "Cancer Facts and Figures," American Cancer Society, 2008, p. 38.

⁴⁰ See applicant report, page 5.

that 98 percent of commercial plans in Washington include the oral anti-cancer drug, Glivec, on tier two of their formulary, with an average patient out-of-pocket cost of \$65.95 per month. Moving this drug under the medical benefit, they feel it could result in an increase in patient cost-sharing to \$900 or more per month.

Some plans created a new benefit for all chemotherapy, resulting in:

- Consumers with coverage with high prescription out-of-pocket limits likely realized significant savings if the new benefit contained reasonable deductibles.
- Consumers with low co-pays on their prescription coverage were most likely harmed if there was an annual deductible because they would have to pay full price for the prescriptions before coverage kicked in. In addition, they may have had to pay higher co-pays once coverage began.⁴¹

For health care plans, this proposal will probably increase the costs they pay for treatment in some instances, while saving costs in others. It's difficult to calculate and compare costs between oral and IV/injected therapies in general because there are so many variables in treatments and costs.

The applicant provided one example where oral treatments are less expensive than their IV alternative. The example compared IV Bevacizumab to oral Sunitinib and Sorafenib for the treatment of renal cell carcinoma. They calculated inpatient, outpatient, and pharmacy costs on a per-patient, per-month basis over the treatment period. They concluded that patients treated with IV Bevacizumab incurred an additional \$58,826 to \$60,546 in medical costs per patient, per year than those treated with oral Sunitinib or Sorafenib.⁴²

In addition, the applicant provided a comparison of prices of 18 IV and 13 oral agents. The comparison revealed that 11 of the 18 IV agents were more expensive than the highest cost oral agents. The mean monthly WAC (median wholesale acquisition cost) of the IV agents was \$12,830 compared to \$5,699 for the oral agents. The IV costs were for just the drug, not IV administration and other associated charges. This seems to indicate that health plans may actually save money by covering oral treatments.

In instances where enrollees don't have current prescription coverage, this may increase costs for health care plans. Where there are IV and oral options, there could be a potential cost savings if a less expensive oral treatment were used over the IV treatment that was already covered. However, if an oral treatment is the only option, it would be a new service to cover.

To what extent will the coverage increase the appropriate use of the benefit?

The Milliman Client Report provided by the applicant suggests parity will increase oral drug use. If the proposal works as intended, patients and their physicians will be able to choose treatment based on what the physician considers most effective, rather than what the patient can afford, whether IV or oral.

⁴¹ According to testimony before the Oregon legislature September 9, 2008, by Scott Kipper, Administrator of the Insurance Division of the Department of Consumer and Business Services.

⁴² Fournier AA et al., "Cost Implications of Intravenous Bevacizumab Treatment in Patients with Renal Cell Carcinoma," Presentation from 2009 annual meeting, American Society of Clinical Oncology.

One study found that one in six cancer patients with high out-of-pocket costs are not filling their prescriptions. The study showed that over 28 percent of patients with an out-of-pocket expense of \$500 or more for a prescription abandoned their anti-cancer medication. This has an adverse impact on patient health and may adversely impact the total cost of health care. How much this proposal increases the appropriate use of oral cancer medications will vary by health care plan. However, making these drugs more comparable to IV treatments will allow providers and patients to base their choice of treatment on what the physician recommends, rather than what the patient can afford.⁴³

To what extent will the benefit be a substitute for a more expensive benefit?

According to the Milliman Client Report, care rendered in settings such as at home, are less expensive than in facilities or physician offices. They feel there may be cost reduction when oral chemotherapy can be substituted for infused products. Facilities and physician office sites often involve services and costs beyond the drug itself.

Milliman provided an example of a study comparing the costs of oral and IV/injected therapies where there were oral and IV/injected options. They examined a case of non-small lung cancer where NCCN guidelines recommend a treatment of either infused Taxotere or Alimta or oral Tarceva. Their research showed that although the average acquisition cost of infused Taxotere/Alimta is lower than oral Tarceva, the infusion costs make the total average costs higher than patients on Tarceva.⁴⁴

The applicant also provided a comparison of drug wholesale acquisition costs for 18 IV and 13 oral medications that have been approved by the FDA over the past 10 years. The chart shows the IV agents, on average, to be 56 percent more expensive. This represents drugs costs only, not IV administration, monitoring, etc.

The example provided by Vicki Jones (page 13-14) showed that the IV Velcade treatment she underwent cost substantially more than the preferred oral treatment of Revlimid her physician recommended. Even with a much lower contracted price, the insurer paid \$600 more per month than they would have paid for Revlimid.

To what extent will the benefit increase or decrease the administrative expenses of health carriers and the premium and administrative expenses of policyholders?

The Milliman Client Report assumes parity will not affect utilization management strategies such as prior authorization, quantity limits, and formularies. Health Care Authority has stated this change would increase administrative costs for health plans by creating a specific exception to the prescription drug benefit.

What will be the impact of this benefit on the total cost of health care services and on premiums for health coverage?

According to the Milliman Client Report, the cost for most benefit plans will be under \$.50 per member, per month, which compares to a typical plan cost of over \$300 per member, per month for all benefits. However, the Milliman Client Report recognized there are thousands of variations of benefit design, which will affect parity costs.

⁴³ Gleason PP, et al., p. 1.

⁴⁴ Milliman Client Report submitted with proposal, Appendix A, page 10.

What will be the impact of this benefit on costs for state-purchased health care?

According to Health Care Authority, the average plan cost increase per member, per month would be \$.44 for the PEBB non-Medicare population and \$.69 for the PEBB Medicare population for calendar year 2010. It estimates the increase for the Basic Health population to be \$.28 per member, per month for calendar year 2010 (using average enrollment of 107,000 members per fiscal year).

However, the Health Care Authority stated it's re-evaluating the assumptions they made on the 2009 fiscal note, and feel it needs to explore other options for implementation. These estimates may change based on new assumptions once they determine how best to implement the legislation.

What will be the impact of this benefit on affordability and access to coverage?

The bill language has the potential to make oral anti-cancer agents more affordable for some and less affordable for others. Access to coverage is currently limited primarily by cost, so making these medications more affordable will likely increase access.

According to the Association of Washington Health Plans, this proposal will significantly increase costs and utilization of oral anti-cancer medications without any assurance of an increase in health care safety or effectiveness. They read the bill to remove health care plan ability to manage utilization in accordance with evidence-based guidelines and require coverage of all oral chemotherapy drugs, regardless of clinical indication or off-label use.

Efficacy

If a mandatory benefit of a specific service is sought, to what extent has there been conducted professionally accepted controlled trials demonstrating the health consequences of that service compared to no service or an alternative service?

It's impossible to generalize the efficacy of all oral anti-cancer drugs or all IV. There are vast numbers of anti-cancer drugs and so many variables regarding which drug or treatment is appropriate. Sometimes there are equivalent options of both an oral and an IV drug, but often times, they're not interchangeable. There will be instances where an oral treatment is preferred over an IV treatment and vice versa. In addition, the recommended treatment often involves a combination of oral and IV or injected therapies.

Forty oral anti-cancer drugs have been approved by the FDA. The FDA requires drug companies conduct clinical studies of efficacy before they can be approved. However, there are few studies comparing oral to IV/injected treatments. Here are two examples where an oral anti-cancer treatment was found to be more effective than an IV or injected one. Please note that these studies haven't been reviewed by an evidence-based practice center to grade reliability of the results.

- A large phase III study comparing oral capecitabine to intravenous fluorouracil plus leucovorin in patients with metastatic colorectal cancer. The results demonstrated that oral capecitabine has "at least equivalent efficacy compared with IV 5-FU/LV.

Capecitabine demonstrated clinically meaningful safety advantages and the convenience of an oral agent.”⁴⁵

- 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.

In addition, 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.⁴⁶ Evidence of efficacy, including results of clinical trials, is used in developing these guidelines.

If a mandated benefit of a category of health care provider is sought, to what extent has there been conducted professionally accepted controlled trials demonstrating the health consequences achieved by the mandated benefit of this category of health care provider?

N/A. This proposal doesn’t seek a mandated benefit of a category of health care providers.

To what extent will the mandated benefit enhance the general health status of Washington residents?

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. This will enhance the general health status of state residents by saving and improving the lives of many citizens afflicted with cancer. In addition, encouraging patients to receive the most effective care for cancer, rather than the most affordable, should decrease future treatments and hospitalizations.

⁴⁵Eric Van Cutsem et al., “Oral Capecitabine Compared with Intravenous Fluorouracil Plus Leucovorin in Patients with Metastatic Colorectal Cancer: Results of a Large Phase III Study,” *Journal of Clinical Oncology*, Vol. 19, No. 21, November 2001, pp. 4097-4106.

⁴⁶National Comprehensive Cancer Network Web site at <http://www.nccn.com>, accessed on May 18, 2010.

FINDINGS

- Cancer impacts a large population, with more than one million new cases diagnosed every year and nearly one-quarter of all deaths caused by cancer each year.⁴⁷
- There are many FDA-approved oral anti-cancer treatments.
- Oral therapies are the standard of care for many cancer types.
- Many oral anti-cancer medications do not have IV or injected alternatives.
- Many oral anti-cancer medications are only brand-name with no generic versions available.
- Many health care plans in Washington have less favorable prescription benefits than medical benefits.
- Some prescription benefits in Washington have as high as 50 percent co-insurance on brand-name drugs with no patient out-of-pocket maximum.
- Many plans require from 15 to 20 percent co-insurance for their medical plans, but with patient out-of-pocket maximums as low as \$1,500.
- Some plans have annual patient out-of-pocket maximums for the medical benefit but none for the pharmacy benefit.
- There are examples where oral anti-cancer drugs are less expensive to the insurer than their IV or injected alternatives.
- Financial barriers often delay or limit access to needed cancer treatment.
- The high cost of cancer treatment causes severe financial hardships for families. This is more prevalent in oral treatments, which typically require high patient cost-sharing.

DETAILED RECOMMENDATIONS TO THE LEGISLATURE

The Department of Health concludes the proposal is in the best interest of the public and that the benefits outweigh the costs of parity legislation for oral anti-cancer treatments. However, there are some challenges to implementation of the proposal as currently drafted.

Rationale:

Social Impact

Though the benefit is generally available, the high cost-sharing required under most insurance plans makes it inaccessible for consumers. Patients are making crucial treatment choices based on what they can afford, rather than what is in their best interest. One study found that one in six cancer patients with high out-of-pocket costs is not filling their prescriptions.

Financial Impact

It is unclear how much this proposal will increase or decrease costs for treatments. If implemented as intended, it will decrease consumer out-of-pocket costs substantially.

There are examples of oral medications that are less-costly than IV medications. This could result in potential cost savings to health care plans. However, there are too many variables in how this legislation could be implemented to determine how costs to health care plans will be impacted.

⁴⁷ “Cancer Facts and Figures,” American Cancer Society, 2009, p. 6.

Milliman has estimated the cost for most benefit plans to be under \$.50 per member, per month which compares to a typical plan cost of over \$300 per member, per month for all benefits. However, its report recognized there are thousands of variations of benefit design, which will affect parity costs.

This legislation will increase administrative costs for Health Care Authority, but since it's re-evaluating how it would implement the proposal, it is unclear by how much. Health Care Authority has estimated the average plan cost increase per member, per month would be \$.44 for the PEBC non-Medicare population and \$.69 for the PEBC Medicare population for calendar year 2010. It estimates the increase for the Basic Health population to be \$.28 for calendar year 2010 (using average enrollment of 107,000 members per fiscal year).

Affordability is a major barrier to consumers for accessing oral anti-cancer treatments. If implemented as intended, this legislation should make oral treatments more affordable for a large number of Washington residents. If oral medications are equally as affordable as IV and injected ones, the choice can be about what the physician recommends for the patient, rather than which treatment is more affordable.

Evidence of health care service efficacy

There are times when an oral treatment is preferred over an IV treatment and vice versa. In some instances, treatment involves a combination of oral and IV or injected therapies.

There are 40 oral anti-cancer medications approved by the FDA to treat certain cancer types. In addition, many oral anti-cancer medications are considered the standard of care for many cancer types. They've been incorporated into oncology treatment guidelines, including the NCCN Clinical Practice Guidelines in Oncology. The NCCN guidelines are evidence-based recommendations and treatment guidelines developed by an alliance of 21 of the world's leading cancer centers.

There are many professionally accepted controlled trials demonstrating the efficacy of specific oral medications, however very few comparing oral to IV treatments. We described two such trials earlier in the document that show an oral medication to be more effective than an IV and injected treatment for certain types of cancer.

Challenges to Implementation as Drafted

The Department of Health received comments that the proposal as drafted may have unintended consequences, such as:

- Less favorable IV and injected benefits to create parity with the benefit for oral treatments.
- The Washington State Medical Oncology Society had concerns that biologic agents may not be included in the mandate as drafted. Biologic agents strengthen the body's immune system to fight cancer, but don't directly kill cancer. The society feels these agents should be included in the mandate because they treat cancer.

- In addition, there is confusion by health care plans and the Association of Washington Health Plans on intent of the bill, including that the bill:
 - Removes plans' control over and ability to manage utilization through their existing evidence-based processes for formulary management.
 - Requires coverage of all oral chemotherapy drugs, regardless of clinical indication or off-label use.
 - Extends drug coverage to those without pharmacy benefits (many feel the bill would require oral chemo drugs to be moved under the medical benefit).

The Department of Health feels the draft language gives health care plans flexibility in how they implement the mandate. However, we believe language should be added to ensure cost-sharing isn't raised in order to comply. The department also feels the intent should be clarified so health care plans can be certain of whether this mandate is meant to change the way they manage their formularies or to extend drug coverage for those without prescription coverage. In addition, the definition of anti-cancer medications may need to be clarified in the bill to ensure all appropriate treatments are included.

REBUTTALS TO DRAFT REPORT

The department shared draft recommendations with interested parties and invited comments before finalizing the report. We received two letters of comment, which are summarized below. We revised the report where appropriate, and if we did not make a requested change, we have explained our rationale below.

International Myeloma Foundation

International Myeloma Foundation (IMF) was essentially supportive of the draft recommendations. The foundation reiterated the need for decisions in cancer treatment to be based on what is best for the patient, which is often difficult with the disparity in coverage. The only change it requested was the addition of language to ensure IV medications aren't moved under the pharmacy benefit to comply with the proposed law.

Department Response

The Department of Health feels the recommendations in the report leave flexibility for health plans to decide how best to comply with the mandate. We feel the recommendation to add language that health plans may not increase cost-sharing for IV and injected anti-cancer medications in order to comply with the mandate will address these types of concerns.

Donna Sullivan, pharmacy administrator, Washington State Health Care Authority

Dr. Sullivan has four main concerns:

- (1) The draft report seems to imply heavily that oral chemotherapy is more effective than IV chemotherapy.
- (2) Defining most effective is difficult because there are few trials comparing oral to IV chemotherapy, and the trials quoted in the department's draft report have not been reviewed by an evidence-based practice center to grade reliability of results. She states that this may be misleading to the legislature.

- (3) Some drugs are marginally more effective, such as increasing survival for 30 days, but at a much higher cost. Plans must be allowed to use evidence-based criteria to develop formularies and coverage criteria based on what is the most cost-effective therapy.
- (4) Changes in cost-sharing need to occur, and plans should be allowed to implement the legislation with cost-sharing options that would result in a “premium-neutral” benefit. If the plans’ costs go up, premiums will be raised for everyone covered, not just the patients with cancer.

Department Response

- (1) The Department of Health didn’t intend to imply that oral chemotherapy is more effective than IV chemotherapy. The intent was to show there are times when oral chemotherapy is considered the most effective treatment, and that oral chemotherapy is considered the standard of care for many cancer types. To address this concern, the department qualified statements about the effectiveness of oral treatments to show that they’re recommended or prescribed by a physician, or are considered to be the standard of care for certain types of cancer.
- (2) The department’s citations of controlled trials were included to demonstrate evidence of oral chemotherapy being more effective than IV or injected chemotherapy in some instances. Part of the sunrise criteria is to show efficacy of the health care service being reviewed. To address the concern that the legislature may be misled by these trials, the department has added the following language, “Please note that these examples haven’t been reviewed by an evidence-based practice center to grade reliability of the results.”
- (3) The department doesn’t feel the draft bill removes the ability for health plans to use evidence-based criteria to develop formularies or coverage criteria, and we do not feel the report implies this to be the case.
- (4) The department feels the recommendation to allow plans to raise cost-sharing for cancer patients to result in a “premium-neutral” benefit is counter to the intent of the proposal, which is to create more equality in co-pay and co-insurance costs between oral and IV/injected anti-cancer treatments. We didn’t amend anything in the report to address this concern.

Appendix A

Applicant Report

APPLICANT REPORT: ORAL CHEMOTHERAPY COVERAGE PARITY

Washington State Mandated Benefits Sunrise Reviews, Statutory Review Criteria (From RCW 48.47.030)

Applicants

This Sunrise Review Application is submitted by **Heather Stauffer Kirk** of St. Paul, Oregon and **Vicki Jones and the Spokane Multiple Myeloma Support Network**.

Heather Kirk is the proponent of Oregon SB 8 and Washington HB 5512, which require health insurers to cover oral chemotherapy drugs on a basis no less favorable than IV chemotherapy treatments. Reimbursement parity became a personal quest for Ms. Kirk when her father, Chuck Stauffer, was diagnosed with brain cancer and faced over \$40,000 in co-pays for his oral chemotherapy drug. Oregon SB 8 was signed into law in 2007, and has provided financial relief for many cancer patients who would otherwise have faced prohibitive co-pays for their oral chemotherapy drugs.

Ms. Kirk's passion for creating equality in cancer treatment options is receiving national attention, including a NY Times front page story featuring her father's insurance disparity situation, and most recently, the introduction of a similar cancer care parity bill in Congress. Ms. Kirk has testified on oral chemotherapy bills in other states and has appeared on behalf of patients on advocacy panels. Fortunately, her father continues to be in good health following his oral chemotherapy protocol. Heather remains dedicated to ensuring that other cancer patients are afforded the opportunity to use the most effective means necessary to reach similar positive outcomes.

Vicki Jones is a cancer fighter from Spokane Washington who co-founded the Spokane Multiple Myeloma Support Network. Multiple Myeloma is an incurable but treatable cancer of the bone marrow. Until recently, 49% of patients diagnosed with Myeloma died within five years. In the past few years, however, new cancer drugs have extended this life span. Obtaining the right treatments at the right time is a matter of life and death to myeloma patients.

The Spokane Multiple Myeloma Support Network is a group of patients who meet monthly and also stay in touch by telephone and e-mail. It provides information to the newly diagnosed, compares treatment strategies and successes, and provides a forum for discussion of issues such as dealing with side effects, what to expect from new treatments and many others. It also enables members to get together with others who are dealing with Myeloma to enjoy each others company and share the good fortune of being alive.

Assistance in the preparation and documentation of this application has also been provided by GlaxoSmithKline Pharmaceuticals.

Based on the availability of relevant information, the following criteria shall be used to assess the impact of proposed mandated benefits:

1. The Social Impact:

(i) To what extent is the benefit generally utilized by a significant portion of the population?

Patient cost-sharing responsibilities for oral anticancer agents covered under a plan's pharmacy benefit can be significantly higher than cost-sharing responsibilities for comparable IV therapies under the medical benefit due to current differences in benefit designs. This disparity in benefit design currently impedes adoption of oral agents as mainstay therapy.

According to the American Cancer Society, cancer affects close to 401 of every 100,000 people. In the state of Washington, this rate is 392 per 100,000.¹ Early treatment options for patients mostly included physician-administered chemotherapies but the advent of FDA-approved, orally administered anticancer medication has significantly increased the treatment options. According to a review of similar legislation in California conducted by the California Health Benefits Review Program (CHBRP), "to date, the FDA has approved 38 oral anticancer medications that are used to treat 52 different types of cancer."² Oral anticancer agents currently make up about 10 percent of the existing oncology market but this percentage is expected to increase to 25 in the next decade.³

(ii) To what extent is the benefit already generally available?

Most oral anticancer agents approved by the Food and Drug Administration (FDA) are typically available to all beneficiaries who purchase prescription drug coverage. While oral anticancer agents are fundamentally made available to patients, high out-of-pocket responsibilities currently impede adoption of oral agents as mainstay therapy.

In an effort to equalize this disparity, the proposed legislation (SB 5512) states:

"Every health plan issued or renewed by a member beginning January 1, 2010, that provides coverage for cancer chemotherapy treatment must cover orally administered anticancer medication used to kill or slow the growth of cancerous cells on a basis not less favorable than intravenously administered or injected cancer medications, including copayments."

The proposed legislation, therefore, is not mandating health plans to cover any new benefits, but merely requiring them to equalize patient out-of-pocket responsibilities for oral and IV therapies regardless of the benefit.

¹ Cancer Facts and Figures, 2008. American Cancer Society.

² California Health Benefits Review Program (CHBRP). (2009). *Analysis of Senate Bill 161: Health Care Coverage: Chemotherapy Treatment*. Report to California State Legislature. Oakland, CA: CHBRP. 09-07.

³ Weingart MD, et al. NCCN Task Force Report: Oral Chemotherapy. *J NCCN*. 2008;6(3):S1-S14

(iii) If the benefit is not generally available, to what extent has its unavailability resulted in persons not receiving needed services?

A patients' ability to afford their cost-sharing responsibilities is considered by providers in making treatment selections. Providers may possess knowledge of a patient's ability to afford a specific treatment regimen and may choose an IV over an oral therapy, even if it is not the ideal treatment option, because of the less significant patient out-of-pocket responsibility. According to an October 2008 National Analysts survey, "oncologists report that their presentation of therapy options is frequently influenced by patients' ability to pay. Currently, they estimate that the conversation is shaped by finances as often as 39% of the time, and they project that this figure will reach 55% over the next five years (five years ago this number was 20%)."⁴

Increasing concerns over the high out-of-pocket costs of oral anticancer agents may also cause many patients to carefully examine treatment options and medications. In many cases, a patient may refuse a recommended drug treatment, stop taking their medications, reduce their medications or switch to lower-cost alternatives due to financial reasons. The impact of high patient out-of-pocket responsibilities on medication nonadherence is well documented:

- In a recent Thomson Reuters survey, among 569 respondents with late-stage cancer, 12.3 percent said they have passed up recommended treatment because it was too expensive. This figure varies dramatically by patient income level. Twenty-five percent of late-stage cancer patients who earn less than \$40,000 a year said they have chosen not to undergo a recommended treatment due to cost — compared with 11.2 percent of those earning between \$40,000 and \$80,000 per year and 4.8 percent of those earning more than \$80,000 annually.⁵
- In a September 2008 survey of oncology nurses, over half of office based and 45 percent of outpatient hospital based nurse respondents indicated that they observe their patients making choices of treatment based on financial concerns. Half of office based and 35 percent of hospital based respondents also indicated awareness of patients refusing part of recommended drug treatment or supportive care for financial reason. The survey respondents indicated that one of the patient concerns voiced most frequently in hospital based settings were reported to be inability to afford co-pays/coinsurance.⁶

(iv) If the benefit is not generally available, to what extent has its unavailability resulted in unreasonable financial hardship?

While oral anticancer agents are fundamentally made available to patients, high out of pocket responsibilities currently impede adoption of oral agents as mainstay therapy. Therefore, for

⁴ "Oncologists Look at Oncology: The Prognosis for US Cancer Care." National Analysts Worldwide. October 2008.

⁵ "The Cost of Cancer." Research Brief. Thomson Reuters. September 2008.

⁶ Feldman, et. al. Nurses' Perceptions of Oncology Practice in Outpatient Settings in 2008: Survey of Oncology Nursing Society Members. Global Access Project & The Moran Company. September 2008.

those patients whose physician recommends an oral therapy over an IV, there is an unreasonable financial hardship due to how health benefits are designed. Patient cost-sharing responsibilities for oral anticancer agents covered under a plan's pharmacy benefit can be significantly higher than cost-sharing responsibilities for comparable IV therapies under the medical benefit due to current differences in benefit designs.

- Intravenously administered anticancer medications are typically covered under a plan's medical benefit, where most patients are only responsible for an office copayment for each episode of care and are not required to pay a separate fee for the IV drug.
- Orally administered anticancer medications, on the other hand, are typically covered under a plan's pharmacy benefit, where many of these agents are placed on a 4th or "specialty" tier of a prescription plan's formulary. For specialty medications such as 4th tier oral oncology therapies, patients are generally responsible for high out-of-pocket coinsurance. According to the Kaiser Family Foundation, the average coinsurance rate for 4th tier drugs is 28 percent.⁷ For a \$3,000 per month oral anticancer medication, this could mean close to \$900 in out-of-pocket spending per month by a patient.

The consequences of cost-related medication nonadherence are far reaching. Studies have documented considerable evidence that cost-related adherence problems jeopardize patient's health. In one study, increased cost-sharing among elderly and indigent patients led to significant increases in acute care use, long-term care admissions and deaths. In a survey of older Americans, patients who reported underusing their prescriptions drugs due to cost were almost twice as likely as other patients to experience a significant decline in their health status (32% versus 21%).⁸

Therefore, the financial barriers to access to oral anticancer agents may also create an unreasonable financial hardship for the health care system as a whole. Failure to take medications correctly has been estimated to cost the U.S. economy \$100 billion per year. Of this, \$30 billion is in direct medical costs — \$25 billion due to hospital admissions, \$5 billion because of unnecessary nursing home placement — while lower productivity and premature death add \$70 billion.⁹

(v) What is the level of public demand for the benefit?

As mentioned previously, oral anticancer agents will make up close to 25% of the oncology market in the next decade. As more oral treatment options become available, patients will express more demand for access to these preferred therapies.

In a questionnaire addressing patient preferences for oral versus intravenous treatment, 92 of the 102 patients surveyed preferred oral over intravenous therapy.¹⁰ According to the

⁷ Kaiser Family Foundation, 2008 Employer-Sponsored Health Benefits Report.

⁸ Piette, et al. A conceptually based approach to understanding chronically ill patients' responses to medication cost pressures. *Social Science & Medicine*. 62 (2006) p. 846-857.

⁹ Dezii CM. Medication noncompliance: what is the problem? *Manag Care*. 2000;9:7-12.

¹⁰ Liu G, Franssen E, Fitch MI, Warner E. Patient preferences for oral versus intravenous palliative chemotherapy. *J Clin Oncol* 1997; 15:110-115.

Association of Community Cancer Centers (ACCC), “when given a choice, patients often prefer oral over IV therapy because of such benefits as fewer office visits, reduced burden on family members, and less time spent away from work and home.”¹¹ According to an April 15, 2009 New York Times article, the Patient Advocate Foundation (PAF), which assists patients with high copays and coinsurance, “says oral medicines accounted for 56 percent of the cases in which it helped Medicare patients last year, even though far more cancer patients were on intravenous drugs.”

Several patients and their families affected by the issue of higher out-of-pocket responsibilities for oral anticancer agents have testified on behalf of similar legislation in other states. Below is an excerpt from testimony describing the benefits received by a particular patient who was treated with an oral anticancer agent:

“Lloyd couldn’t even *start* chemotherapy until his immune system was strong enough that he could risk sitting in a waiting room full of people who were coughing and sneezing. Any of their ordinary germs could have killed him.

A drug like [oral anticancer agent] would have let him take his chemo safely at home.

There were times when Lloyd was incredibly weak and barely consumed enough calories to sustain a 50-pound child. But to get chemo, he had to burn precious calories going to and from the clinic, and shivering in the doctor’s waiting room, sometimes for an hour before even going into chemo.

If he were taking chemo at home, he could have rested under a heating blanket and saved his energy for healing and fighting the disease.

Then there are the indignities of going outside the home for treatment. Lloyd still had to sit in that waiting room full of people, even when he wore a bag of green-and-yellow fluids from his liver, even when he had to carry a bucket to throw up in.

Studies suggest that [oral anticancer agent] may have reduced his nausea and improved his immune system. And even if it didn’t, taking chemo at home would have given him privacy and dignity during his worst days.”¹²

Furthermore, oral agents are increasingly becoming standards of care for many tumor types. Many oral anticancer treatments are incorporated into oncology treatment guidelines including the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines for Oncology.¹³ For breast cancer, an oral therapy is listed as the preferred therapy for

¹¹ “Leveling the Paying Field.” *Oncology Issues*. Association of Community Cancer Centers (ACCC). May/June 2009.

¹² Testimony before the Texas Senate Committee on State Affairs in support of SB1345. Pat O’Connell Red Oak, Texas.

¹³ “Covering 97 percent of all patients with cancer and updated on a continual basis, the NCCN Guidelines are developed through an explicit review of the evidence integrated with expert medical judgment by multidisciplinary panels from NCCN Member Institutions. Treatment recommendations are specific and are implemented through

invasive, metastatic, HER-2 positive patients who have failed on prior IV therapies on the NCCN Breast Cancer Guidelines.¹⁴ Further, oral therapies are also listed on the NCCN Kidney Cancer Guidelines.¹⁵ For chronic myelogenous leukemia, an oral agent is listed as primary treatment in the NCCN Guidelines.¹⁶ According to patient testimony in favor of similar legislation in Oregon, some oral anticancer agents are believed to be better tolerated than some IV therapies:

“My Dad was prescribed oral chemotherapy: a pill form, which he can take at home. It is generally much more well-tolerated than intravenous or injectable forms. We were thrilled that he would not have to go in for IV treatments, may not lose his hair, and could sleep through the brunt of the chemo effects as it’s administered before bedtime...” *A copy of the testimony submitted by Heather Kirk to the Oregon Legislature is included as Appendix I to this report and included by reference.*

Public demand has increased as witnessed in the recent New York Times article on the subject titled, “Insurance Lags as Cancer Care Comes in a Pill.”

This article raised national awareness of the issue and led to introduction of this legislation at the federal level. On May 12, 2009, Representative Brian Higgins (D-NY) introduced the “Cancer Drug Coverage Parity Act” (HR 2366). The bill proposes: “To amend the Employee Retirement Income Security Act of 1974, the Public Health Service Act, and the Internal Revenue Code of 1986 to require group and individual health insurance coverage and group health plans to provide for coverage of oral cancer drugs on terms no less favorable than the coverage provided for intravenously administered anticancer medications.”

(vi) What is the level of interest of collective bargaining agents in negotiating privately for inclusion of this benefit in group contracts?

Not applicable.

2. The financial impact:

In 2009, GlaxoSmithKline commissioned Milliman, Inc., an independent actuarial business consulting firm with 60 years experience in the healthcare arena, to analyze disparities in health plan benefit design and evaluate how much state parity legislation would cost state-regulated health plans to implement. Some answers provided below will reference Milliman’s final report which is included as Appendix II.

(i) To what extent will the benefit increase or decrease the cost of treatment of service?

performance measurement. NCCN Guidelines Panels address cancer detection, prevention and risk reduction, workup and diagnosis, treatment and supportive care.” – www.nccn.org

¹⁴ NCCN Clinical Practice Guidelines in Oncology. Breast Cancer. V.1.2009. *National Comprehensive Cancer Network.*

¹⁵ NCCN Clinical Practice Guidelines in Oncology. Kidney Cancer. V.2.2009. *National Comprehensive Cancer Network.*

¹⁶ NCCN Clinical Practice Guidelines in Oncology. Chronic Myelogenous Leukemia. V.1.2010. *National Comprehensive Cancer Network.*

The cost to treat with oral anti-cancer therapies is often less than the alternative IV therapy. It can be very difficult to make generalizations about comparing the cost of oral therapies to IV therapies because the total cost of treatment varies for different types of cancer. The following is evidence that oral therapies can be less expensive alternatives to IV therapies in many settings:

- Breast cancer: Excluding drug costs, the costs associated with administration of IV therapies constitute 10-11% of total costs while other visit-related services constitute 25-30% of total costs for early and late stage breast cancer patients. The costs for infusion-related services and supplies are a significant part of the total costs of intravenous therapies for early stage breast cancer with non-drug costs accounting for 36.4% of total costs associated with a visit to receive IV therapy.¹⁷
- In small cell lung cancer patients, 50.2% of average total costs are attributable to IV chemotherapy drugs while 11.8% is attributable to IV chemotherapy administration and 38% to other drugs and services.¹⁸
- Renal cell carcinoma patients treated with bevacizumab incur an additional \$78,598 - \$88,830 total medical cost per patient per year compared to those treated with oral agents (sunitinib or sorafenib).¹⁹

From Milliman actuarial analysis of legislation:

“Decreased cost sharing will increase the cost [to health plans] of oral chemotherapy in several ways. We list these with the estimated most expensive listed first:

- The plan will pay for the difference in cost sharing for people who would have paid the original cost sharing.
- The plan will pay for the new utilization (induced utilization) that members would have avoided because of the original cost sharing. We divide this into two pieces:
 - The new services at the old price assuming cost sharing
 - The reduced cost sharing for the new services

In addition, there may be reduced recoveries through coordination of benefits (COB). Reduced cost sharing may encourage some employed spouses or dependents to obtain coverage from the plan with lower cost sharing. We did not attempt to quantify these two factors as they vary greatly with each employer’s particular situation.”²⁰

(ii) To what extent will the coverage increase the appropriate use of the benefit?

¹⁷ Kruse GB, et al. Costs of administration of intravenous (IV) therapies in early versus late stage breast cancer in a US population JCO, 2007;25(18S): 6588.

¹⁸ Duh MS, et al. Costs associated with intravenous chemotherapy administration in patients with small cell lung cancer: A retrospective claims database analysis. Curr Med Res Opin. 2008;24(4): 967-74.

¹⁹ Fournier AA et al. Cost implications of intravenous bevacizumab treatment in patients with renal cell carcinoma. Poster presented at: 13th Annual International Meeting of the International Society of Pharmacoeconomics and Outcomes Research (ISPOR); May 3- 7, 2008; Toronto, Canada. Abstract 18265.

²⁰ Fitch, Kathryn, Kosuke Iwasaki, and Bruce Pyenson. “Parity for Oral and Intravenous/Injected Drugs.” Milliman, Inc. 2009.

See page 6-7 of Milliman report (Appendix II), section titled, “How Benefit Cost Sharing Impacts Cancer Drug Use: Elasticity.”

(iii) To what extent will the benefit be a substitute for a more expensive benefit?

Establishing parity between IV and oral chemotherapies will not induce a provider to substitute a more expensive benefit for a less expensive one. Establishing cost-sharing parity will merely reduce the financial barriers that currently impede the adoption of orally administered treatment as mainstay cancer therapy.

(iv) To what extent will the benefit increase or decrease the administrative expenses of health carriers and the premium and administrative expenses of policyholders?

From Milliman actuarial analysis of legislation:

“In our analysis, we do not address administrative costs and assume parity does not affect utilization management strategies such as prior authorization, quantity limits and restricted formularies.”²¹

(v) What will be the impact of this benefit on the total cost of health care services and on premiums for health coverage?

The following are Milliman’s key findings regarding the financial impact on premiums for health coverage as a result of this legislation:

- For most benefit plans, parity will cost under \$0.50 Per Member Per Month (PMPM), which compares to a typical plan cost of over \$300 PMPM for all benefits.
- However, there are literally thousands of variations of benefit design, and some of the plan design features can affect parity costs.

(vi) What will be the impact of this benefit on costs for state-purchased health care?

State-purchased health care was not specifically analyzed in the Milliman study. For a complete listing and description of Milliman’s key data sources and their application, please see Appendix A of the final Milliman report (Appendix II of this application).

(vii) What will be the impact of this benefit on affordability and access to coverage?

From Milliman actuarial analysis of legislation:

“Technology continues to change the nature of medical treatment, and a number of new, innovative, and often costlier treatments have emerged for serious diseases such as cancer. However, these new treatments may be viewed skeptically by those who ultimately shoulder the costs, payers and employers, who need to control healthcare costs. Payers use a variety

²¹ Ibid.

of techniques to control costs including utilization management and increased member cost sharing. Employers have increased patient out of pocket responsibilities or required higher employee contributions; the former has the member pay more for care received, while the latter reduces net wages.

In certain instances, technology has outpaced payer and employer management of healthcare benefits. This issue has become evident with the emergence of orally-administered anticancer agents. Because of how benefit designs have evolved, intravenous/injected chemotherapy drugs are typically covered through medical benefits, while oral chemotherapy drugs are most often covered through pharmacy benefits. Medical benefits often bring relatively low cost burdens to patients for chemotherapy because they may require only an office visit copay or have a cap on out-of-pocket expenditures. In contrast, pharmacy benefits can be more burdensome for patients as some designs require unlimited cost sharing, for example, 25% of the drug price with no cap on out of pocket expenses. Such pharmacy benefit structures can make high cost oral anticancer medications unaffordable.”²²

By adopting cost-sharing parity between IV and oral chemotherapy, oral chemotherapy may become more affordable to patients and will therefore increase their access to coverage of these therapies.

3. Evidence of health care service efficacy:

(i) If a mandatory benefit of a specific service is sought, to what extent has there been conducted professionally accepted controlled trials demonstrating the health consequences of that service compared to no service or an alternative service?

FDA approval of all prescription medications must occur before they are marketed and sold in the United States. According to the FDA:

“Drug companies seeking approval to sell a drug in the United States must test it. First, the drug company or sponsor performs laboratory and animal tests to discover how the drug works and whether it's likely to be safe and work well in humans. Next, a series of tests in humans is begun to determine whether the drug is safe when used to treat a disease and whether it provides a real health benefit. The company then sends FDA's Center for Drug Evaluation and Research (CDER) the data from these tests to prove the drug is safe and effective for its intended use. A team of CDER physicians, statisticians, chemists, pharmacologists, and other scientists reviews the company's data and proposed labeling. If this review establishes that a drug's health benefits outweigh its known risks, the drug is approved for sale.”²³

²² Ibid.

²³ Approved Drugs: Questions and Answers. U.S. Food and Drug Administration (FDA). <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm054420.htm>

(ii) If a mandated benefit of a category of health care provider is sought, to what extent has there been conducted professionally accepted controlled trials demonstrating the health consequences achieved by the mandated benefit of this category of health care provider?

Not applicable.

(iii) To what extent will the mandated benefit enhance the general health status of the state residents?

Not applicable.

The department may supplement these criteria to reflect new relevant information or additional significant issues.



Parity for Oral and Intravenous/Injected Cancer Drugs

Prepared by
Milliman, Inc., NY

Kathryn Fitch, RN, MEd
Principal and Healthcare Management Consultant

Kosuke Iwasaki, FIAJ, MAAA, MBA
Consulting Actuary

Bruce Pyenson, FSA, MAAA
Principal and Consulting Actuary

Commissioned by GlaxoSmithKline
January 25, 2010

TABLE OF CONTENTS

EXECUTIVE SUMMARY	1
BASICS OF CANCER DRUGS FROM THE STANDPOINT OF BENEFIT DESIGN	3
Primer on Cancer Chemotherapy	3
Overview of Cancer Drug Coverage and Benefit Designs	3
THE COST AND UTILIZATION IMPACT OF PARITY FOR ORAL CANCER DRUGS	4
Defining Parity	4
Cancer Patients and Utilization of Chemotherapy	5
How Benefit Cost Sharing Impacts Cancer Drug Use: Elasticity	6
Cost Impact of Parity for Oral Cancer Drugs for Various Benefit Designs	7
IMPLICATIONS FOR PAYERS AND EMPLOYERS	12
Oral/Infused Parity Legislation	12
Impact on Large Employers	12
Conclusion	12
APPENDIX A: DESCRIPTION OF KEY DATA SOURCES AND THEIR APPLICATION	14
APPENDIX B: METHODOLOGY	15
REFERENCES	17

EXECUTIVE SUMMARY

Technology continues to change the nature of medical treatment, and a number of new, innovative, and often costlier treatments have emerged for serious diseases such as cancer. However, these new treatments may be viewed skeptically by those who ultimately shoulder the costs, payers and employers, who need to control healthcare costs. Payers use a variety of techniques to control costs including utilization management and increased member cost sharing. Employers have increased patient out of pocket responsibilities or required higher employee contributions; the former has the member pay more for care received, while the latter reduces net wages.

In certain instances, technology has outpaced payer and employer management of healthcare benefits. This issue has become evident with the emergence of orally-administered anticancer agents. Because of how benefit designs have evolved, intravenous/injected chemotherapy drugs are typically covered through medical benefits, while oral chemotherapy drugs are most often covered through pharmacy benefits. Medical benefits often bring relatively low cost burdens to patients for chemotherapy because they may require only an office visit copay or have a cap on out-of-pocket expenditures. In contrast, pharmacy benefits can be more burdensome for patients as some designs require unlimited cost sharing, for example, 25% of the drug price with no cap on out of pocket expenses. Such pharmacy benefit structures can make high cost oral anticancer medications unaffordable.

This research report examines the concept of "parity" between oral and infused drugs – in particular, equalizing patient cost-sharing for all chemotherapy drugs regardless of formulation. Treatment choice is, of course, complex. In addition to medical effectiveness and safety, financial considerations figure prominently for the provider, payer and patient. The cost sharing inequity in some plan designs for intravenous/injected and oral chemotherapy products is becoming more apparent as high-cost oral products come to market with many more under development. The benefit design issue we address here will likely continue to grow in importance.

Several state legislatures have passed or are considering "parity" legislation that would require state-regulated payers to cover oral chemotherapy drugs with the same cost sharing as intravenous/injected chemotherapy drugs. This paper addresses a particular benefits issue – how much parity legislation might cost a payer.

As described in the body of the text, for most benefit plans, parity will cost under \$0.50 Per Member Per Month (PMPM), which compares to a typical commercial plan cost of over \$300 PMPM for all benefits. However, there are literally thousands of benefit design variations, and plan design features can affect parity costs. Parity for some plan designs with very high cost sharing for oral specialty drugs and low cost sharing for medical benefits could cost about \$1.00 PMPM, or, in unusual circumstances, more. Parity for other plan designs that have low overall cost sharing could cost as little as \$0.05 to \$0.10 PMPM.

In addition to our parity cost estimates, significant new findings presented here include estimates of elasticity for oral chemotherapy drugs – how increasing cost sharing reduces the consumption of higher cost oral chemotherapy drugs. This elasticity for chemotherapy drugs is a finding that hasn't previously been published.

This paper presents models and assumptions that a payer can consider to estimate the impact of parity for oral and intravenous/injected chemotherapy. We do not address administrative costs associated with parity. Development of insurance rates is, of course, the domain of actuaries, and actuaries with appropriate expertise should be involved in any rate calculation.

We note that our assumptions and analysis are general and do not presume any particular therapy. Similarly, we do not address the efficacy or safety of different therapies. In authoring this paper, the authors and Milliman are making no endorsement of any product or policy.

GlaxoSmithKline, a pharmaceutical company that manufactures, markets, and is developing intravenous/injected and oral chemotherapy drugs, commissioned Milliman to develop and author this paper. GlaxoSmithKline provided oncology disease state and treatment expertise, background information on iv/oral chemotherapy treatment paradigms, information on the current status of oral/iv parity legislation, and the general editing of these sections.

BASICS OF CANCER DRUGS FROM THE STANDPOINT OF BENEFIT DESIGN

Primer on Cancer Chemotherapy

Anticancer drug therapy is one of the three pillars of cancer treatment along with surgical treatment and radiation therapy. Anticancer drug therapy is generally categorized into three types; cytotoxic agents, biologic agents and hormonal agents. These categories include both oral and intravenous/injectable products. Treatment recommendations depend on the type and stage of cancer, along with patient characteristics.

Cytotoxic agents are the traditional therapies that damage cancer cells by interfering with cellular division but have the drawback of killing healthy cells along with cancer cells. Major types of cytotoxic agents include alkylating agents, antimetabolites, and plant alkaloids. Biologic agents, also called targeted agents, target specific cancer biologic pathways. Hormonal therapy interferes with hormone dependent pathways that promote the development or growth of cancer cells and plays an important role in treating breast and prostate cancers.

Historically, intravenous therapies have been the predominant route for administering anticancer drug therapy. Although oral cytotoxic and hormone products have been available for decades, the past 10 years has seen accelerated development of oral anticancer drugs, particularly biologics. Experts estimate that more than one quarter of the 400 chemotherapy drugs now in the development pipeline are planned as oral drugs.¹

Evidence based treatment guidelines, including those issued by the National Comprehensive Cancer Network (NCCN)², recommend various combinations of chemotherapy depending on the particular cancer and stage. These recommendations are made without regard to the route of administration. Protocols may recommend a single oral or single infused treatment protocol, a combination of infused products only, and oral and infused product combinations. For a few treatment protocols, NCCN guidelines indicate an oral product or an infused product as being potentially substitutable.

Cytotoxic products, which are predominantly given by intravenous infusion, are generally administered episodically to deliver the maximum tolerated dose to optimize cell kill in a single episode. The interval between doses allows for recovery from potential side effects. Biologic products are optimally effective when taken chronically, often daily, to continuously expose the tumor cells and tumor microenvironment to the drug therapy. This goal of chronic administration is consistent with the convenience of oral administration when available. There are pros and cons to each option, cytotoxic or biologic, intravenous or oral, which need to be weighed by patients and healthcare providers.^{3 4}

Overview of Cancer Drug Coverage and Benefit Designs

Infused and oral medications typically have different dispensing sites, and the dispensing site often defines which portion of a health benefit applies. Intravenous medication, most often administered in a physician's office or hospital outpatient infusion center, is generally covered as a physician service or hospital outpatient service and defined as medical benefits. Oral anticancer medication is typically dispensed by a pharmacy and covered under a pharmacy benefit. Injectable anticancer medication may be self administered and covered under a pharmacy benefit or administered in a physician's office or outpatient hospital setting and covered under a medical benefit. On average, as a percent of all covered medical benefits, average patient cost sharing for a typical medical benefit is lower, and cost sharing for the prescription benefit as a percent of covered prescription benefits is higher.

THE COST AND UTILIZATION IMPACT OF PARITY FOR ORAL CANCER DRUGS

Defining Parity

The term "parity" for health benefits has most prominently referred to requiring coverage for mental health and substance abuse services on the same basis as medical benefits. Traditional benefit designs covered mental health and substance abuse services with higher cost sharing (for example, 50% coinsurance) and "inside" limits (for example, 20 visit annual maximum) that meant less coverage than for other services.⁵ Parity legislation passed in the 1990s applied only to benefit maximums, and full parity was signed into law in October 2008.^{6,7}

State parity legislation for oral chemotherapy drug coverage typically requires that insurance coverage for orally administered chemotherapy medications shall be provided on a basis no less favorable than coverage for injected or intravenously administered chemotherapy medications. For the purpose of this report, we define oral/intravenous/injected chemotherapy parity to mean that the percent patient cost sharing for an oral chemotherapy drug will be no more than that of an intravenous/injected chemotherapy drug. We apply the following algorithm:

Definition of Oral/Intravenous/Injected Chemotherapy Parity

For an individual who receives both oral and intravenous/injected chemotherapy drugs, the percent cost sharing for the oral chemotherapy drugs will be no more than the percent cost sharing for their intravenous/injected chemotherapy drugs.

For an individual who receives only oral chemotherapy drugs, the percent cost sharing for the oral chemotherapy drugs will be no more than the average percent cost sharing for the intravenous/injected drugs as administered by their benefit plan.

Traditional prescription drug designs, with fixed copays, such as \$25 or \$40 per script, do not impose large cost sharing for expensive drugs. However, some plan designs with unlimited coinsurance, for example 25% or 33% or higher, can impose a significant cost sharing burden when the prescription costs thousands of dollars, which is not an unusual cost for a chemotherapy product whether it is intravenous/injected or oral.

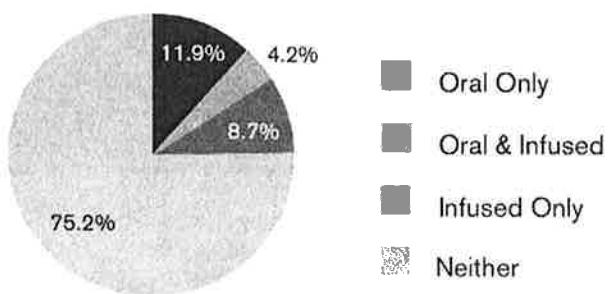
Many medical benefit designs offer some form of cap on member out-of-pocket costs. The trend toward prescription drug benefits with unlimited coinsurance, together with the introduction of often expensive oral agents, has made intravenous/injected-oral parity an issue.

In our analysis, we do not address administrative costs and assume parity does not affect utilization management strategies such as prior authorization, quantity limits and restricted formularies.

Cancer Patients and Utilization of Chemotherapy

Using the approach described in the Methodology section, we estimate approximately 1.5% of a commercially insured population has medical claims for cancer in a one year period. Although chemotherapy is a significant treatment option for cancer patients, most patients with a cancer diagnosis do not receive chemotherapy in a year. Figure 1 provides the distribution of cancer patients by chemotherapy treatment showing about 25% of cancer patients receive chemotherapy during a year. The remaining three-quarters of patients may be treated using a variety of other non-chemotherapeutic treatment modalities, such as surgery, radiation therapy or monitoring.

Figure 1: Distribution of Cancer Patients by Chemotherapy Treatment

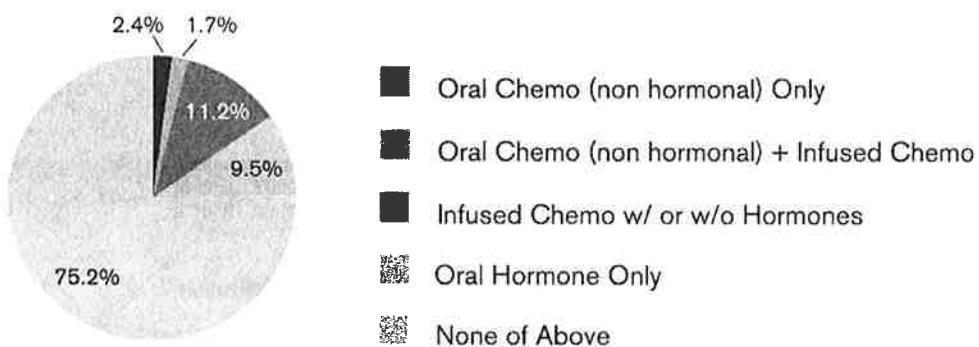


N = 172,547 cancer patients. Excludes basal cell skin cancer

Source: Milliman's work on MedStat Commercial 2007

Figure 2 shows the distribution of patients by the kinds of cancer drugs (hormonal, non-hormonal, oral, infused) they take in one year. Almost half of patients receiving chemotherapy use oral products only, and most of that usage is hormonal agents which are generally low cost. Of those cancer patients receiving chemotherapy treatment, only 17% (2.4% plus 1.7% out of 24.8%) receive chemotherapy that does not include hormonal treatment.

Figure 2: Distribution of Cancer Patients by Type of Chemotherapy



N = 172,547 cancer patients. Excludes basal cell skin cancer

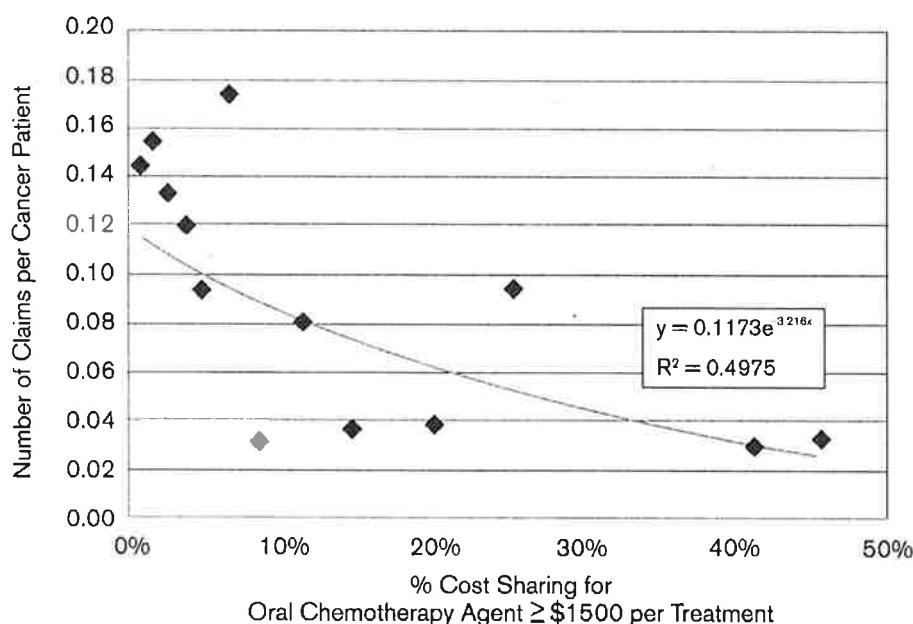
Source: Milliman's work on MedStat Commercial 2007

How Benefit Cost Sharing Impacts Cancer Drug Use: Elasticity

Higher out-of-pocket costs discourage the use of medical services and products, and this has been shown for high-cost pharmaceuticals.⁸ In particular, we demonstrate that higher cost sharing for oral chemotherapy agents is associated with lower utilization of these drugs. This is shown in Figure 3 below, which is based on examination of the medical claims of thousands of cancer patients. Our finding contrasts with other studies, which have assumed no price elasticity.⁹

The diamonds in Figure 3 correspond to different plan designs, each diamond representing a distinct percent cost share for oral chemotherapy drugs. The chart shows an inverse relationship between the percent cost sharing, and number of claims per patient. In other words, higher percent cost sharing leads to fewer claims per patient for oral chemotherapy. The formula in the chart shows the elasticity function fitted to the data points, along with the corresponding R² value. The data sources and approach we used is described in the Methodology section.

Figure 3: Relationship Between % Cost Share or Oral Cytotoxic Rx and Number of Oral Cytotoxic Claims Per Cancer Patient Age 20-69



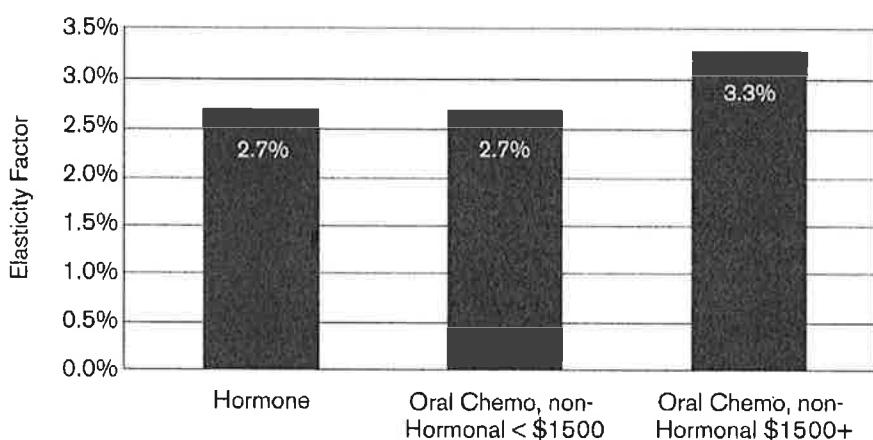
N = 24,474 cancer patients spread among 13 cost-sharing categories. Source: Milliman's analysis of MedStat Commercial 2007, 2008Q1-3 and Milliman proprietary data from 2007. Oral chemotherapy category does not include hormonal therapies. The box shows the best fit of a typical elasticity curve.

These data suggest that oral/intravenous/injected chemotherapy parity will increase drug utilization, which will increase cost.

In economics, elasticity measures the sensitivity of one variable to another, which is the percentage change that will occur in one variable in response to a 1-percent increase in another variable¹⁰. Actuaries have long recognized that higher cost sharing reduces utilization, and typical actuarial practice recognizes this phenomenon in setting premium rates for health insurance products.

In Figure 4, we show the elasticity factors of three types of oral chemotherapy drugs: hormonal agents, less expensive non-hormonal agents (under \$1500 per claim), and more expensive non-hormonal agents (\$1500 or more per claim).

Figure 4: Elasticity: % Utilization Caused by 1 Percentage Decrease in % Cost Share for Oral Cancer Drugs



Source: Milliman analysis of MedStat Commercial 2007, 2008Q1-3
Milliman Health Cost Guideline 2009

In Figure 4, elasticity means the percent increase in utilization caused by a 1 percentage point decrease in cost sharing. For example, the elasticity factor of 3.3% applies to oral chemotherapy, non hormonal drugs costing \$1500 or more. The 3.3% elasticity factor shown means if the percent cost sharing for the drug goes down from 20% to 19%, the utilization of these drugs will increase by 3.3%. The 3.3% elasticity factor is consistent with Figure 3 and further described in the Methodology section. For the hormones and lower cost oral chemotherapy drugs, we used standard actuarial elasticity factors.

Cost Impact of Parity for Oral Cancer Drugs for Various Benefit Designs

We applied the elasticity relationships described above to estimate the additional drug cost of parity. It is impossible to define one cost for parity that will apply to all benefit designs, because variations in plan design have a significant impact. Plans vary in the amount of cost sharing for medical and pharmacy benefits, and they vary in how that cost sharing is arranged – copays, coinsurance, deductibles, out-of-pocket maximums, etc. Therefore, to show the additional costs of oral/intravenous/injected parity, we developed ranges and characterizations of health benefit designs.

To put plan cost sharing into perspective, we offer the following:

- A typical PPO benefit design has average cost sharing of 17% across all benefits¹¹
- A typical, 3-tier drug benefit, \$10/\$25/\$40 has average cost sharing of 25% across all drugs¹²

Oral/intravenous/injected parity costs depend on both the oral chemotherapy drug cost sharing and the intravenous/injected drug cost sharing, because parity reduces the oral cost sharing to the level

of the intravenous/injected cost sharing. In general, the cost of parity follows the relationships below:

Pre-Parity Benefits	Cost of Introducing Parity
Low cost sharing for oral chemotherapy drugs	Lower Cost to Plan
High cost sharing for oral drugs and Low cost sharing for intravenous/injected chemotherapy drugs	Higher Cost to Plan

If cost sharing for oral chemotherapy drugs is already low, as is the case with traditional prescription drug benefit designs with copays, parity will have only a small cost impact. However, for plans with unlimited coinsurance for expensive drugs, parity can add modest amounts to plan costs.

To present concrete examples of the impact of parity, the authors simulated the impact of oral/intravenous/injected parity for a variety of benefit designs using the definition of oral/Intravenous/Injected chemotherapy parity stated at the beginning of this section. The simulation was done for each patient taking oral chemotherapy, including hormonal agents. We simulated parity for over 60 benefit designs which comprised over 32 million member months and 43,000 cancer patients. We segmented the benefit designs into three categories, with the medium category typical of traditional PPO designs¹³ and the high category including Consumer Driver Health Plans.¹⁴ We show sample medical and prescription drug benefits for the ranges of cost sharing in the tables below:

Sample Medical Benefit by Cost-Sharing Level

Cost Sharing Level	Effective Average Coinsurance	Sample Medical Benefit
Low	Under 12%	\$100 deductible, 15% coinsurance, \$1,500 out-of-pocket maximum
Medium	12% to 17%*	\$200 deductible, 20% coinsurance, \$1,500 out-of-pocket maximum
High	Above 17%	\$400 deductible, 20% coinsurance, \$2,000 out-of-pocket maximum

*Close to a typical PPO benefit design.

Sample Prescription Drug Benefit by Cost-Sharing Level

Cost Sharing Level	Effective Coinsurance for Expensive Oral Drugs	Sample Drug Benefit
Low	Under 5%	\$10 Generic/\$25 Preferred Brand/\$40 Non-Preferred Brand (including Specialty)
Medium	5% to 10%	\$10 Generic/\$25 Preferred Brand/\$40 Non-Preferred Brand/10% coinsurance Specialty
High	Above 10%**	\$10 Generic/\$25 Preferred Brand/\$40 Non-Preferred Brand/25% Coinsurance Specialty

**Typical for benefits with coinsurance in a 3rd or 4th tier or specialty tier

We used the average cost sharing for medical benefits as an indicator of intravenous/injected drug cost sharing, because the deductible and coinsurance and out-of-pocket limits typically apply to intravenous/injected drugs.

The extra plan costs for parity are relatively small, as shown in the following table. The extra costs are shown Per Member Per Month (PMPM):

Extra Plan Cost of Parity Benefits in \$PMPM (Costs Trended to 2009)

Medical Benefit Cost Sharing Percentage	Oral Chemotherapy Cost Sharing Percentage		
	Low	Medium	High
Low			\$0.50 to \$1.30
Medium	\$0.05 to \$0.10	\$0.15 to \$0.20	\$0.25 to \$0.35
High			\$0.20 to \$0.30

These figures do not include plan administrative costs. These figures compare to a PMPM claim cost of \$319 for a typical commercially insured individual based on Milliman's 2008 Group Health Insurance Survey, trended to 2009 dollars.

Decreased cost sharing will increase the cost of oral chemotherapy in several ways. We list these with the estimated most expensive listed first:

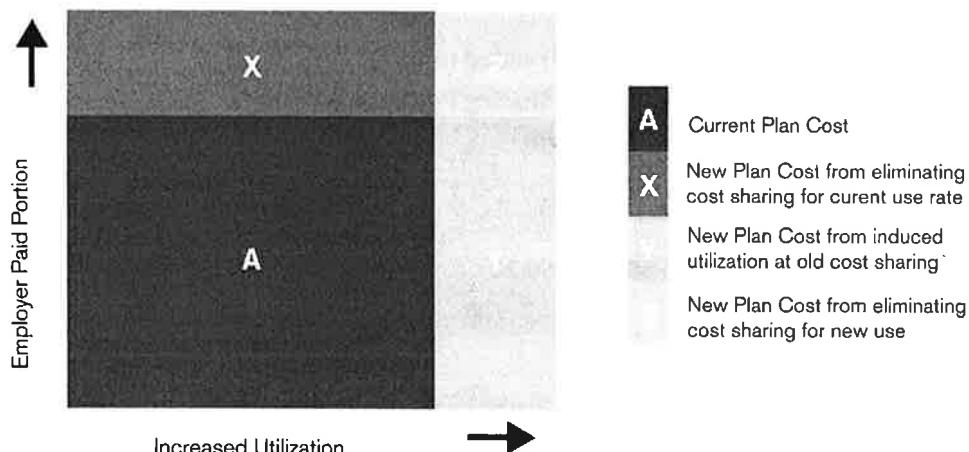
- The plan will pay for the difference in cost sharing for people who would have paid the original cost sharing.
- The plan will pay for the new utilization (induced utilization) that members would have avoided because of the original cost sharing. We divide this into two pieces:
 - The new services at the old price assuming cost sharing
 - The reduced cost sharing for the new services

In addition, there may be reduced recoveries through coordination of benefits (COB). Reduced cost sharing may encourage some employed spouses or dependents to obtain coverage from the plan with lower cost sharing. We did not attempt to quantify these two factors as they vary greatly with each employer's particular situation.

We also made no adjustment for changes in the utilization of intravenous/injected chemotherapy, as our analysis did not indicate an impact on intravenous/injected chemotherapy associated with increased utilization of oral chemotherapy.

Figure 5 shows the elements of increased costs (other than COB).

Figure 5: How Reducing Cost Sharing Increases Payer Cost (Elasticity)



The relative contribution of each component will vary with benefit design details.

Case Study Cost Comparison: Injectable versus Oral Chemotherapy

In general, care rendered in less intensive settings (such as home) is less expensive than care rendered in facilities or physician offices, which has led to widespread promotion of outpatient services as an alternative to inpatient services.¹⁵ The possibility that some chemotherapy can be administered orally instead of intravenous/injected raises the potential for cost reduction in cases where oral or infused products are therapeutically similar. For many services, facility or physician office sites can involve services and costs beyond the particular drug, its acquisition cost, or the principle services being rendered.

Although both oral and infused treatment options require close monitoring and follow up, infused therapies incur costs associated with IV administration. Several studies report costs associated with infused chemotherapy, although the reported costs vary. A study of the costs of IV administration in a metastatic breast cancer population identified chemotherapy per visit costs of \$2,477, with IV administration accounting for approximately 10% (\$252); the study drug accounting for 59% (\$1,463); and other drugs and services accounting for 31% (\$763).¹⁶ Another study of chemotherapy cost for small cell lung cancer patients reported a cost per chemotherapy visit of \$787, with 50% of the cost for the IV chemotherapy drug (\$395); 12% of the cost for IV chemotherapy administration procedures (\$93); and 38% for other visit related drugs and services (\$300).¹⁷

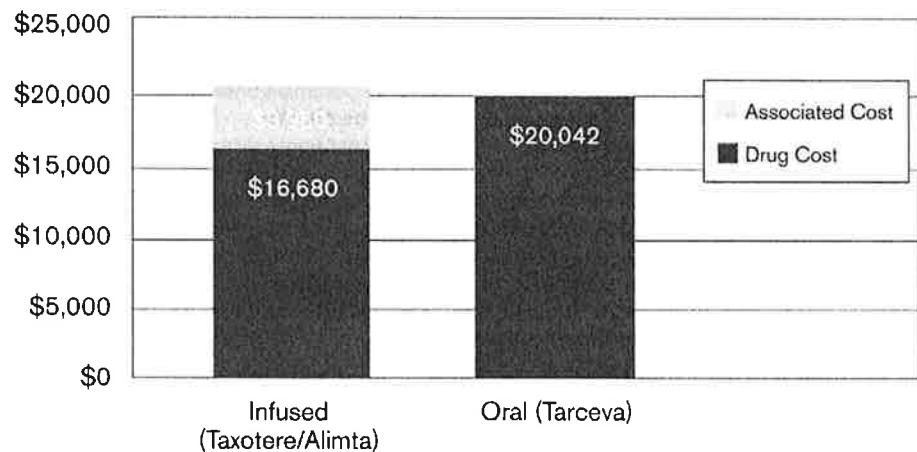
Currently, there are only a handful of cancer treatments with oral or infused chemotherapy options, although a number of oral chemotherapy drugs are in development. To compare the costs of oral and intravenous/injectable administration in a case where there are oral or intravenous/injectable options, we examine the case of non small cell lung cancer where NCCN guidelines recommend treatment with one of infused Taxotere or infused Alimta or oral Tarceva.¹⁸

Using Medstat 2007 and Q1-Q3 2008, we identified members coded with lung cancer and having one or more claims for Taxotere, Alimta or Tarceva. We identified the average number of treatment claims per patient and the average drug cost per treatment to calculate a course of therapy drug cost. The average number of claims was 4.8/patient for Taxotere and Alimta and 4.9/patient for Tarceva. The intravenous/injected drugs accounted for 63% of the claims while the oral accounted

for 37% of the claims. We identified the associated infusion costs incurred on the day of infusion administration by performing a claim line examination and determined costs that would go away if the infusion did not occur.

Although the average acquisition cost of Taxotere/Alimta is lower than Tarceva, the associated infusion costs move the total average costs somewhat higher than for patients on the oral product Tarceva (see Figure 6). We did not factor in nonpayer costs that may be incurred with oral administration including additional education on drug administration, compliance and side effects. In this case, the costs of infused and oral therapy appear to be very close. Because oral chemotherapy is sometimes combined with infused agents, and because oral and infused agents are not often directly substitutable, we believe the hypothesis of cost reduction by avoiding infusion-related costs is unproved through this example. We did not attempt to compare clinical outcomes for this case. Figure 6 summarizes our findings.

**Figure 6: Allowed Cost Comparison Per Course of Therapy
(Total cost paid by payer and member)
(Average Number of Claims/Patient)**



N= 270 patients; Infused Taxotere and Alimta
N =154 patients; Oral Tarceva
Source: Milliman's work on MedStat 2007, 2008Q1-3
Costs trended to 2009
Lung cancer patients identified with one IP, one ER or 1 physician claim coded with ICD-9 162.xx

IMPLICATIONS FOR PAYERS AND EMPLOYERS

Oral/Infused Parity Legislation

In 2007, Oregon was the first state to pass oral/intravenous/injectable chemotherapy parity legislation - Senate Bill 8 (SB 8). This legislation requires that:

"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."

Several advocacy organizations, including the National Patient Advocate Foundation¹⁹ and the American Cancer Society²⁰, have taken an active role in supporting similar legislation in other states. Since the beginning of 2009, oral/infused chemotherapy parity legislation has passed in five states (Indiana, Hawaii, Vermont, Iowa, and the District of Columbia) and has been introduced in 20 other states.

State insurance legislation typically amends insurance laws. The state Insurance Commissioner is usually required to convert the intent of an Act into rules and regulations that can be put into practice by insurers and used by the regulators to test insurers for compliance. Seemingly simple parity language like, "no less favorable to an insured," can be interpreted by regulators in different ways. For example, if a patient receives both infused and oral drugs, parity could mean the insured should pay the same percent cost sharing or the same dollar cost sharing. Suppose the infused drug cost \$1000 with 5% cost sharing (\$50), and the oral drug cost \$2000. Parity could mean the same 5% cost sharing or \$100 for the oral drug (the same percent), or it could mean \$50 cost sharing (the same dollar amount). As with other features of state insurance regulation, mandates for oral/infused parity are likely to be implemented in ways that vary by state.

Federal legislation to amend the Employee Retirement Income Security Act (ERISA) and other acts has been introduced by Representative Brian Higgins (NY) in May 2009.²¹ HR 2366 would require "group and individual health insurance coverage and group health plans to provide for coverage of oral cancer drugs on terms no less favorable than the coverage provided for intravenously administered anticancer medications." ERISA, not states, governs self-insured health benefit plans, which is why this proposal and other federal mandates are structured as amending ERISA.

Impact on Large Employers

Most benefit designs will have low parity costs, especially for programs sponsored by large employers. The member cost burden challenge with oral/infused cost sharing is most pronounced when specialty or high-cost drugs are subject to coinsurance. A 25% coinsurance for a \$100 drug is \$25, which is a typical cost sharing amount for a brand prescription. However, 25% for a drug that costs \$10,000 is \$2,500, and such cost sharing can quickly become unaffordable for many people. Such high cost-sharing for expensive prescription drugs is today relatively uncommon among large employer-sponsored programs. According to a recent survey, only 14% of large employers have drug programs with coinsurance.²² For large employers this information may be most relevant to those considering shifting to a specialty tier design.

Conclusion

The expected continued growth of specialty pharmaceutical products, some of which are very expensive, has prompted an array of benefit design and benefit management techniques.²³ Some insurers and employers are responding to this increasing cost pressure by increasing member cost share through benefit designs with unlimited coinsurance for expensive products, sometimes called

a specialty tier.²⁴ While such benefit designs may be lower cost to the payer, they can impose a significant cost burden on members and may limit the physician and patient choice of treatment. Oral/infused parity will increase costs the most for payers with benefit designs that include such a specialty tier.

The costs and methodology shown in this paper should be used as guides for employers or insurers who want to calculate parity costs for their own programs. Under reasonable scenarios, the additional costs of oral/infused parity are minimal -- an increase estimated at well below \$1.00 PMPM for typical benefit plans that cost over \$300 PMPM (claims costs only). Actual costs will, of course, fluctuate from year to year and employer to employer depending on the therapies individuals receive and the treatments that become available.

If oral/infused parity legislation follows the same pattern as mental health parity, medical management and contract management will continue²⁵ which is our assumption in estimating costs. Typically, for specialty pharmacy, this includes prior authorization, concurrent review, and medical appropriateness reviews as well as encouraging use of preferred providers or contracted specialty pharmacies.²⁶ Such techniques may become more important because of parity legislation. Managing oncology treatment overall is the subject of increasing payer attention.

APPENDIX A: DESCRIPTION OF KEY DATA SOURCES AND THEIR APPLICATION

Thompson Reuters Medstat database. This dataset contains all paid claims generated by over 20 million commercially insured lives. Member identification codes are consistent from year-to-year and allow for multi-year longitudinal studies. Information includes diagnosis codes, procedure codes and DRG codes, NDC codes along with site of service information, and the amounts paid by commercial insurers. For this study, we used Medstat 2007 through 3rd Quarter 2008.

Milliman's 2009 Health Cost Guidelines. The Guidelines provide a flexible but consistent basis for the determination of health claim costs and premium rates for a wide variety of health plans. The Guidelines are developed as a result of Milliman's continuing research on health care costs. First developed in 1954, the Guidelines have been updated and expanded annually since that time. The Guidelines are continually monitored as they are used in measuring the experience or evaluating the rates of health plans, and as they are compared to other data sources. The Standard Demographics in the Guidelines were developed to be representative of the age and sex distribution for a typical large insured group. The Standard Demographics were developed using data from large insurers combined with Department of Labor Sources. We use the Guidelines to demographically adjust our target population to a typical working age population.

Milliman Medical Index (MMI). The MMI examines key components of medical spending and the changes in these components over time. The MMI incorporates proprietary Milliman studies to determine representative provider-reimbursement levels over time, as well as other reliable sources, including the Kaiser Family Foundation/Health Research and Educational Trust 2007, *Annual Employer Health Benefit Survey* (Kaiser/HRET), to assess changes in health plan benefit level by year. The MMI includes the cost of services paid under an employer health-benefit program, as well as costs paid by employees in the form of deductibles, coinsurance, and copayments. The MMI represents the total cost of payments to healthcare providers, the most significant component of health insurance program costs, and excludes the non-medical administrative component of health plan premiums. The MMI includes detail by provider type (e.g., hospitals, physicians, and pharmacies), for utilization, negotiated charges, and per capita costs, as well as how much of these costs are absorbed by employees in the form of cost sharing. We used the annual MMI cost trends to trend the MedStat cost data to 2008 dollars.

Milliman Group Insurance Survey™ (GIS). The GIS measures premiums and experience of HMOs and PPOs based on a uniform population and benefit design. The Survey provides statistics on fully insured HMOs and PPOs that serve the commercial large or midgroup market. Companies use the Survey to benchmark their financials to the competition. HMO and PPO results are presented separately by metropolitan statistical area (MSA), state, region, and nationwide. The results are based on questions answered by at least three companies. Company identities are kept strictly confidential.

APPENDIX B: METHODOLOGY

Cancer Identification

We identified an individual as having cancer if they had one inpatient, one ER or 2 or more physician claims on separate days coded with the following ICD-9 codes in any position of the claim:

140.xx through 172.xx
174.xx through 208.9x

Of people identified with cancer claims, we identified patients receiving one or more oral and/or intravenous/infused chemotherapy drug using NDC and J codes. The complete list of chemotherapy drugs is available upon request to the authors.

Methodology for Elasticity Calculation

Data Sources

The following data sources were used in this research:

- Milliman *Health Cost Guideline* 2009 for Hormonal drugs and Oral Chemo drugs costing less than \$1500 per claim
- MedStat Commercial 2007 and 2008Q1-3 for Oral Chemo drugs more than \$1500 per claim

Hormonal drugs and Oral Chemo drugs costing less than \$1500 per claim

We used standard actuarial coefficients and the average allowed and cost share for both Hormonal drugs and Oral Chemotherapy drugs with allowed amounts less than \$1500 per claim. These factors, which are not specific to hormonal drugs or oral chemotherapy drugs show that a 1 percentage point reduction in cost sharing produces a 2.7% increase in utilization. The following table shows the average allowed amounts for these two categories.

	Hormone	Oral Cytotoxic <\$1500
Average Allowed Amount per Claim	\$307	\$400

The average allowed are from our analysis of MedStat for 2007 and 1Q-3Q 2008.

Oral Chemotherapy drugs costing more than \$1500 per claim

We developed the elasticity factor for oral chemotherapy drugs costing more than \$1500 per claim using MedStat Commercial 2007, 2008Q1-3 and Milliman's proprietary database with 2007 data. For purposes of calculating elasticity, we selected benefit designs with relatively low intravenous/injected drug cost sharing (greater than 2.5% and less than 5.5%) and grouped benefit designs based on similar ranges of oral chemotherapy cost sharing. We then used regression analysis to develop a best fit elasticity curve between,

y : Number of oral non-hormonal chemo claims per cancer patient

x : % Cost Share of oral non-hormonal chemo claims

We found

$$y = 0.01173e^{-3.216x}, \text{ with } R^2 = .4975$$

Based on the formula above, the elasticity, which is % utilization increase caused by 1 percentage point decrease in % cost share, is calculated as,

$$\frac{0.01173e^{-3.216(x-1\%)}}{0.01173e^{-3.216x}} - 1 = e^{3.216 \times 1\%} - 1 = 3.3\%$$

REFERENCES

- ¹ Weingart SN, Bach PB, Johnson SA et al. NCCN task force report: oral chemotherapy. Journal of the National Comprehensive Cancer Network. 2008;6:S1-S17.
- ² NCCN guidelines available at http://www.nccn.org/professionals/physician_gls/f_guidelines.asp
- ³ Weingart SN, Bach PB, Johnson SA et al. NCCN task force report: oral chemotherapy. Journal of the National Comprehensive Cancer Network. 2008;6:S1-S17.
- ⁴ Goodin S. Advancing the safe and appropriate use of oral chemotherapy agents supplement. American Journal of Health System Pharmacy. 2007;64:S1-S35.
- ⁵ Mechanic D, McAlpine DD, Mission Unfulfilled: Potholes On The Road To Mental Health Parity, Health Affairs. 1999;18:7-21.
- ⁶ Health Insurance Reform for Consumers. http://www.cms.hhs.gov/healthinsreformforconsumers/04_thementalhealthparityact.asp
- ⁷ Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008. <http://www.govtrack.us/congress/bill.xpd?bill=h110-6983>.
- ⁸ Gleason PP, Starner, CI Gunderson BW, et al. Association of Prescription Abandonment with Cost Share for High-Cost Specialty Pharmacy Medications. J Manag Care Pharm. 2009;15:648-658.
- ⁹ Analysis of Senate Bill 161 Health Care Coverage: Chemotherapy Treatment. California Health Benefits Review Program, Apr 17, 2009. http://www.chbrp.org/documents/sb_161final.pdf
- ¹⁰ Robert S. Pindyck, Daniel L. Rubinfeld, Microeconomics (6th Edition), Princeton Hall, 2004.
- ¹¹ Milliman Medical Index, <http://www.milliman.com/expertise/healthcare/products-tools/mmi/pdfs/milliman-medical-index-2009.pdf>. For 2009, the MMI average benefits are an in-network deductible of \$473, various copays (e.g., \$75 for ER visits, \$19 for physician OV, 14% coinsurance for non-copay services, etc.).
- ¹² Milliman 2009 Health Cost Guidelines Rating Structures. Private Communication.
- ¹³ Milliman Medical Index 2009, op cit.
- ¹⁴ Burke J, Pipich R, Consumer Driven Impact Study. Milliman Research Report. Apr 2008. Available at, <http://www.milliman.com/expertise/healthcare/publications/rr/pdfs/consumer-driven-impact-studyRR-04-01-08.pdf>
- ¹⁵ Pyenson B, Zenner P, Chye P, Silver bullets for outpatient cost increases? The Actuary, Nov 2002. <http://www.soa.org/library/newsletters/the-actuary/2000-09/2002/november/act0211.pdf>
- ¹⁶ Kruse GB, Amonker MM, Smith G et al. Analysis of costs associated with administration of intravenous single-drug therapies in metastatic breast cancer in a U.S. population. J Manag Care Pharm. 2008;14:1-14.
- ¹⁷ Duh MS, Weiner JR, Lefebvre P et al. Costs associated with intravenous chemotherapy administration in patients with small cell lung cancer. A retrospective claims database analysis. Curr Med Res Opin. 2008;24:967-64.
- ¹⁸ NCCN guidelines available at http://www.nccn.org/professionals/physician_gls/f_guidelines.asp
- ¹⁹ National Patient Advocacy Foundation, Statement of Principles on Access to Oral Chemotherapy Drugs. Available at, <http://www.npaf.org/state/2007-principles-priorities.html#oral%20chemo>

²⁰ Staff Analysis of 161, Alaska Senate, Hearing date: Apr 29, 2009. Available at, http://info.sen.ca.gov/pub/09-10/bill/sen/sb_0151-0200/sb_161_cfa_20090428_105319_sen_comm.html

²¹ Cancer Drug Coverage Parity Act of 2009, HR 2366. <http://thomas.loc.gov/cgi-bin/query/z?c111:H.R.2366.IH>:

²² Prescription Drug Benefit Cost and Plan Design Report, 2008–09 edition, The Pharmacy Benefit Management Institute, http://www.pbsmi.com/2008_report/index.html

²³ Sullivan SD, The Promise of Specialty Pharmaceuticals: Are They Worth the Price? J Manag Care Pharm. 2008;14:S3-S6. Available at http://www.amcp.org/data/amcp/JMCPSupp_May08.pdf

²⁴ Gleason PP, Starner, CI Gunderson BW, et al. Association of Prescription Abandonment with Cost Share for High-Cost Specialty Pharmacy Medications. J Manag Care Pharm. 2009;15:648-658.

²⁵ Melek SP, Pyenson BS, Fitch, KF. An actuarial analysis of the impact of HR 1424 "The Paul Wellstone Mental Health and Addiction Equity Act of 2007." Milliman, Inc. <http://edlabor.house.gov/testimony/071007SteveMelekTestimony.pdf>

²⁶ Stern D, Benefit Design Innovations to Manage Specialty Pharmaceuticals. J Manag Care Pharm. 2008;14:S12-S16. Available at http://www.amcp.org/data/amcp/JMCPSupp_May08.pdf

Appendix B

Draft Bill

SENATE BILL 5512

State of Washington**61st Legislature****2009 Regular Session****By** Senators Marr, Parlette, Pflug, and Murray

Read first time 01/26/09. Referred to Committee on Health & Long-Term Care.

1 AN ACT Relating to chemotherapy treatment costs; adding a new
2 section to chapter 41.05 RCW; adding a new section to chapter 48.20
3 RCW; adding a new section to chapter 48.21 RCW; adding a new section to
4 chapter 48.41 RCW; adding a new section to chapter 48.42 RCW; adding a
5 new section to chapter 48.43 RCW; adding a new section to chapter 48.44
6 RCW; adding a new section to chapter 48.46 RCW; and adding a new
7 section to chapter 70.47 RCW.

8 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

9 NEW SECTION. **Sec. 1.** A new section is added to chapter 41.05 RCW
10 to read as follows:

11 Every health plan offered to public employees and their covered
12 dependents under this chapter that (1) provides coverage for cancer
13 chemotherapy treatment, (2) is not subject to Title 48 RCW, and (3) is
14 established or renewed beginning January 1, 2010, must cover orally
15 administered anticancer medication used to kill or slow the growth of
16 cancerous cells on a basis not less favorable than intravenously
17 administered or injected cancer medications, including copayments.

1 **NEW SECTION.** **Sec. 2.** A new section is added to chapter 48.20 RCW
2 to read as follows:

3 Every disability insurance policy issued or renewed beginning
4 January 1, 2010, that provides coverage for cancer chemotherapy
5 treatment must cover orally administered anticancer medication used to
6 kill or slow the growth of cancerous cells on a basis not less
7 favorable than intravenously administered or injected cancer
8 medications, including copayments.

9 **NEW SECTION.** **Sec. 3.** A new section is added to chapter 48.21 RCW
10 to read as follows:

11 Every group disability insurance policy issued or renewed beginning
12 January 1, 2010, that provides coverage for cancer chemotherapy
13 treatment must cover orally administered anticancer medication used to
14 kill or slow the growth of cancerous cells on a basis not less
15 favorable than intravenously administered or injected cancer
16 medications, including copayments.

17 **NEW SECTION.** **Sec. 4.** A new section is added to chapter 48.41 RCW
18 to read as follows:

19 Every health plan issued or renewed by a member beginning January
20 1, 2010, that provides coverage for cancer chemotherapy treatment must
21 cover orally administered anticancer medication used to kill or slow
22 the growth of cancerous cells on a basis not less favorable than
23 intravenously administered or injected cancer medications, including
24 copayments.

25 **NEW SECTION.** **Sec. 5.** A new section is added to chapter 48.42 RCW
26 to read as follows:

27 Beginning January 1, 2010, every person or entity regulated under
28 RCW 48.42.010 that provides coverage for cancer chemotherapy treatment
29 must cover orally administered anticancer medication used to kill or
30 slow the growth of cancerous cells on a basis not less favorable than
31 intravenously administered or injected cancer medications, including
32 copayments.

33 **NEW SECTION.** **Sec. 6.** A new section is added to chapter 48.43 RCW
34 to read as follows:

1 Every health plan issued or renewed beginning January 1, 2010, that
2 provides coverage for cancer chemotherapy treatment must cover orally
3 administered anticancer medication used to kill or slow the growth of
4 cancerous cells on a basis not less favorable than intravenously
5 administered or injected cancer medications, including copayments.

6 NEW SECTION. **Sec. 7.** A new section is added to chapter 48.44 RCW
7 to read as follows:

8 Every health care service contract issued or renewed beginning
9 January 1, 2010, that provides coverage for cancer chemotherapy
10 treatment must cover orally administered anticancer medication used to
11 kill or slow the growth of cancerous cells on a basis not less
12 favorable than intravenously administered or injected cancer
13 medications, including copayments.

14 NEW SECTION. **Sec. 8.** A new section is added to chapter 48.46 RCW
15 to read as follows:

16 Every health maintenance agreement issued or renewed beginning
17 January 1, 2010, that provides coverage for cancer chemotherapy
18 treatment must cover orally administered anticancer medication used to
19 kill or slow the growth of cancerous cells on a basis not less
20 favorable than intravenously administered or injected cancer
21 medications, including copayments.

22 NEW SECTION. **Sec. 9.** A new section is added to chapter 70.47 RCW
23 to read as follows:

24 Every schedule of benefits established or renewed beginning January
25 1, 2010, that provides coverage for cancer chemotherapy treatment must
26 cover orally administered anticancer medication used to kill or slow
27 the growth of cancerous cells on a basis not less favorable than
28 intravenously administered or injected cancer medications, including
29 copayments.

--- END ---

Appendix C

Follow Up to Applicant Report

Oral Chemotherapy Mandated Benefit Sunrise Follow Up Questions

1. Question 3(i) requests information on professionally accepted controlled trials demonstrating health consequences of one service compared to alternative services or no services. In this case, the trials should compare the outcomes of IV versus oral chemotherapy.

Do you have any specific examples of professionally accepted trials where an oral treatment is shown to be more effective than an IV/injected treatment?

Response from Applicant

Applicant provided an article from the online magazine, Medical News Today, Bowel Cancer Patients Live Longer Taking Xeloda – Analysis Confirms that Oral Xeloda is Superior to IV 5-FU.¹

2. Question 2(iii) asks whether the proposed benefit may be a substitute for a more expensive benefit.

Can you provide examples of cases where an oral treatment may save a health carrier money over an IV/injected option? You have one example in your response to 2(i) regarding renal cell carcinoma treatment where the IV treatment ends up costing more than the oral options. Could you elaborate on this example and provide some other examples where an oral treatment would be a less expensive substitute for an IV/injected one?

Response from Applicant

Applicant provided two articles in response to this question:

The first is an article from the Journal of Managed Care Pharmacy, Analysis of Costs Associated with Administration of Intravenous Single-Drug Therapies in Metastatic Breast Cancer in a U.S. Population, Gregory B. Kruse, MPH, MSc; Mayur M. Amonkar, PhD; Gregory Smith, BA; Dean C. Skonieczny, MBA, BSE; and Spyros Stavrakas, PhD.²

The second is an abstract from the American Society of Clinical Oncology, Cost Implications of Intravenous Bevacizumab Treatment in Patients with Renal Cell Carcinoma (RCC): A Retrospective Claims Database Analysis.³

3. The proposal states anecdotally that oral anticancer medications are very expensive. Can you provide specific, detailed examples of high-cost chemotherapy drug treatments and what they are used to treat?

Response from Applicant

The applicant did not provide a direct response to this request, but included an example in the hearing testimony of how much her father's oral treatment cost. It is attached at the end of Appendix E.

¹ "Bowel Cancer Patients Live Longer Taking Xeloda – Analysis Confirms that Oral Xeloda is Superior to IV 5-FU," *Medical News Today*, June 30, 2008, www.medicalnewstoday.com.

² Gregory B. Kruse, et al., "Analysis of Costs Associated with Administration of Intravenous Single-Drug Therapies in Metastatic Breast Cancer in a U.S. Population," *Journal of Managed Care Pharmacy*, 2008;14(9):844-57.

³ "Cost Implications of Intravenous Bevacizumab Treatment in Patients with Renal Cell Carcinoma (RCC): A Retrospective Claims Database Analysis," E. Dial, et al., *Journal of Clinical Oncology*, 2009, cited by American Society of Clinical Oncology abstract, 2009.

Appendix D

Written Comments

Oral Chemotherapy Drug Coverage
Written Comments Received
June 28, 2010

On behalf of Genentech, thank you allowing us to comment on this issue. We greatly appreciate your engaging in a thorough review of the serious barriers all too many insured cancer patients face when prescribed oral anti-cancer medications. On May 17, Genentech submitted by email a series of studies and resources on this topic that have been relied upon in other states assessing action on this issue. We encourage you to consider these documents during the Sunrise Review process.

Considered the founder of the biotechnology industry, Genentech has been delivering on the promise of biotechnology for more than 30 years, using human genetic information to discover, develop, manufacture and commercialize medicines to treat patients with serious or life-threatening medical conditions. Today, Genentech is among the world's leading biotechnology companies, with multiple product on the market and a promising development pipeline.

Genentech supports legislation that reduces barriers to accessing treatment for cancer patients, especially when complicated insurance benefit formulas all too often result in a number of patients foregoing vital treatment. We support legislation that helps ensure access to treatment for all cancer patients while not negatively impacting patients on intravenous therapies.

Intravenous therapies are most often covered under a medical benefit, and patients pay a reasonable office co-payment to have their medicine administered. Oral medications, however, usually fall under a pharmacy benefit that often requires patients to pay a percentage of the drug cost, which can be very high. The result is that even though the medications may be priced similarly, an oral anti-cancer medication often will cost the patient a great deal more. The Community Oncology Alliance recently identified health insurance benefit design as a barrier to providing the best treatment for cancer patients. At the same time, the potential costs to cover oral anti-cancer medicines was found to be quite manageable when spread out over the insured on a per member per month (PMPM) basis in a report by Milliman, Inc..

Oncologists have new tools in oral cancer therapies that did not exist until recently. According to an April 2010 study by the California Health Benefits Review Program (CHBRP), which is operated by the University of California to advise the California Legislature on health insurance mandates, only 11 of 40 oral anti-cancer medications have an intravenous or injectable alternative. The National Comprehensive Cancer Network has reported that 100 oral anti-cancer medications are currently under development, which represents 25% of the pipeline of important potentially new cancer treatment options.

As more and more innovative oral anti-cancer treatments are approved, the unfortunate barriers caused by health insurance benefit formulas that require disproportionate out-of-pocket costs for oral versus intravenous medications will surely lead the doctors of insured patients – and the patients themselves – to make difficult decisions about whether to pursue the most promising treatment, or to try something less than optimal due to out-pocket-cost. When faced with this decision, many patients forgo treatment. In fact, a recent study by pharmacy benefit manager Prime Therapeutics shows that high out-of-pocket costs alone deter at least 1-in-6 cancer patients from obtaining their oral medications. Certainly, if a co-pay is so high that a patient cannot afford it, the result is a *de facto* denial of coverage.

Steve Hansen, Northwest Regional Manager
Genentech, State Government Affairs

As an experienced neuro-oncology/oncology RN, I've had the opportunity to see first-hand the impact of advances in cancer care over the past 34 years. The new oral chemotherapy and targeted therapy drugs have been among the most important. The cost of cancer care is more than just the cost of the drugs. Oral therapies that can be administered at home can reduce direct and indirect costs - both in time and money - of invasive procedures for intravenous access (and the potential for infection), transportation to treatment facilities, and outpatient clinic visits for drug infusion.

While there are cases when conventional parenteral chemotherapies are of added benefit, there are times when oral agents are standard of care. In the case of glioblastoma multiforme, a primary malignant brain tumor, oral temozolomide is the ***current standard of care for first-line management*** at diagnosis. The initial treatment regimen is for temozolomide daily, concurrent with radiation therapy for 6 weeks, followed by temozolomide for five days every twenty-eight days. For patients who do not have prescription coverage, the out of pocket cost for this is roughly \$8500 for the 6-week course, and \$3000 per month thereafter. A parenteral formulation that is covered under infusional chemotherapy benefits has become available, but it is more costly, and is not practical for daily administration. In other words, the current standard of care for glioblastoma multiforme is more cost effective in the oral form, but is often only "covered" in the most expensive and less efficient parenteral form.

As an oncology professional, a patient advocate, and a family member/caregiver for cancer survivors, I ask your support in approving the proposed bill for oral chemotherapy coverage parity under consideration.

Barbara Otto MSN, RN, CNRN, OCN

The Washington Affiliates of Susan G. Komen for the Cure strongly supports legislation in Washington State which would address the disparity of insurance coverage between intravenous chemotherapy drugs and oral chemotherapy drugs. Other states are leading the way. Already, Oregon, Indiana, Iowa and Vermont passed oral chemotherapy parity legislation, and legislation is pending in a number of other states.

Susan G. Komen for the Cure believes that health decisions should be made between a patient and her doctor and should not have to be based on financial factors. In addition, persons with cancer should be protected from high out-of-pocket medical costs that could lead to financial hardship and even bankruptcy.

As you may know, breast cancer is a national and state epidemic. In 2009 alone, almost 200,000 people in the United States were diagnosed with the disease and more than 40,000 died. Washington has one of the highest incidence rates of breast cancer in the nation, and we expect more than 4,500 women to be diagnosed breast cancer this year and 720 will lose their battle with the disease.

Oral chemotherapy is quickly emerging as an attractive option for breast cancer patients who, with support from their doctors, will comply with the prescribed oral regimens and self-monitor for potential complications. While oral chemotherapy drugs have been around for decades, they have been developing at an increasing rate in recent years. In fact, more than a quarter of the 400 anti-cancer agents in the pipeline today are intended as oral drugs. Unfortunately, there is often a significant difference in the amount cancer patients in our country must pay out of pocket for an oral drug and how much they pay for an intravenous product. Intravenous therapies are traditionally covered under a medical benefit, under which most patients are only responsible for an office co-payment for each visit and are not required to pay a separate fee for the intravenous drug. By contrast, oral chemotherapy is generally covered under a prescription drug benefit, which tends to have higher co-payments. And because oral chemotherapy drugs can be extremely expensive, patients may be exposed to very high out-of-pocket costs — up to a third or more of the cost of some drugs. The end result is that some patients pay hundreds or even thousands of dollars a month for their cancer care.

The Puget Sound Affiliate of Susan G. Komen for the Cure represents thousands of men, women and families affected by breast cancer in Washington State. Everyday we hear from families—including families with health insurance—that they need financial help while in treatment. **A change must occur**

so that individual health insurance and group health plans provide coverage of oral cancer drugs on terms no less favorable than the coverage provided for intravenously-administered chemotherapy. At the same time, we must ensure that in adopting this policy, health insurers are not allowed to reduce coverage for intravenous therapies.

Cheryl Shaw, Executive Director
Komen Puget Sound Affiliate

Stephanie Bast, Board President Komen
Komen Eastern Washington Affiliate

Christine McDonald, Executive Director
Komen Oregon and Southwest Washington Affiliate

Thank you for the opportunity to provide comments to the Sunrise Review for insurance coverage parity of oral chemotherapy medications as envisioned in 2009 Senate Bill 5512. Regence BlueShield feels this is a timely topic and important discussion given the increased focus on health care cost in the newly reformed system. In that light, we respectfully submit the following comments for your consideration.

First and most importantly, Regence agrees with the proponents of this legislation that no patient should be deprived of the most clinically efficacious treatment option available because of financial burden; especially in the case of life-threatening illnesses such as cancer. We recognize that in the area of oral chemotherapy medications, despite our best efforts, traditional health plan benefit design has not always been able to keep pace with the creativity and ingenuity of the pharmaceutical industry. However, just as the pharmaceutical industry is free to develop new medications at a pace that makes financial sense, Regence strongly believes the health insurance industry should be allowed the time to address benefit design inequities in a manner that protects the financial interests of their members. Addressing coverage inefficiencies in such a manner is not as simple as requiring a certain type or level of coverage, but instead involves in-depth examination over a period of time, much the same as the clinical trial process for new medications.

This is not to say that Regence is asking for unlimited time in order to forever forestall government intervention. In fact, our argument that this legislation addresses an issue that is not yet ripe is for quite the opposite reason. Regence is exploring new benefit designs that would address the inequity between oral and intravenous chemotherapy reimbursement and standardize coverage for the entire universe of treatments and drugs that exist in the ever-expanding gray area between medical and pharmacy benefits. However, this type of ingenuity comes with the risk of being incredibly costly for certain types of members – such as those on individual and small group products – if it is mandated for all Regence customers. In essence, forcing Regence and other health plans to inefficiently address this specific issue could endanger our ability to address the larger universe in which it resides.

We have some experience with the potential pitfalls of premature government intervention on this issue. Similar laws have been enacted recently in other states. Health plans in those states have experienced difficulty in creating “parity” between benefits that are akin to apples and oranges. Some plans have even considered reducing coverage levels for IV treatment in order to create this “parity.” While Regence feels this sort of solution is not in the best interest of consumers, it is understandable given the fiduciary responsibility health plans have to *all* of their members.

Additional factors to consider as it relates to the timeliness of this proposed mandate: Given the changes coming within federal reform – particularly the definition of essential benefits – it may make more sense to wait until at least 2014 to make this kind of change. This window would give commercial health plans time needed to develop benefits that are appropriate and make sense for all members. It should also be pointed out that any benefits not in the essential benefit package have to be paid for by the state for subsidized health plans purchased through the exchange.

While Regence does acknowledge room for debate as to the ultimate timing for resolution of this issue, we feel it necessary to point to flaws contained in the applicant proposal submitted by the proponents of this legislation, the most important of which is that the report fundamentally misunderstands the fact that there are many different benefit configurations across group and individual plans. For example, most individual and group plans have moved away from basic up-front co-pay designs for office visits, due to insurance premium costs. Additionally, there may be some group plans that offer unlimited co-pay amounts for pharmacy. Unfortunately, the benefit designs are not as black and white as is alluded to in the applicant report. This will come into issue when carriers and regulators are deciphering "parity" between the two forms of chemotherapy drug coverage. An unintended consequence due to the differing plan designs is that a member may currently have a "better" drug benefit for oral chemotherapy coverage vs. intravenous coverage, but after adjustments for "parity" have been made, the "better" drug benefit may be pared down. This type of situation, as mentioned above, could lead to the entire issue of pharmacy vs. medical benefit parity being set back as health plans struggle to keep premiums in check.

Regence also feels we would be remiss if it was not noted for the record that both the applicant report and accompanying actuarial analysis were compiled and funded by a pharmaceutical company that stands to benefit financially from passage of this legislation. GlaxoSmithKline – the world's second largest pharmaceutical manufacturer – markets oral chemotherapy medications.

Finally, we would like to conclude our comments by putting in real terms what \$.50 per member per month – the probable cost to insurance premiums of this legislation as indicated by Milliman in its actuarial report – actually means. For Regence, that would translate to more than \$3 million in additional cost every year that we would have no choice as a non-profit but to seek from our members in additional premiums. Our largest competitors in the domestic fully-insured market – also non-profits – would likely see similar annual costs. The fiscal note attached to this bill listed the cost to the state – which is likely facing yet another multi-billion dollar budget gap for the 2011-2013 biennium, even after two years of painful cuts and revenue enhancements – at more than \$3 million per biennium.

So, instead of allowing the private health insurance sector to develop a potentially less-costly solution to a larger problem over time – which again, we are already working to achieve at Regence – this legislation would immediately increase the profits of the second most profitable industry in the nation with money from the depleted coffers of Washington state and the stressed checkbooks of millions of its citizens. We think ours is the more reasonable path forward and we offer to work with all interested parties to ensure its timely success.

Regence BlueShield thanks you for the opportunity to submit comments to the Sunrise Review. We hope that this information is given careful consideration. Please don't hesitate to contact us with further questions.

Chris Bandoli, Regulatory and Legislative Analyst
Regence BlueShield

On behalf of Novartis Oncology, I appreciate this opportunity to provide comments prior to the June 28 meeting of the Sunrise Review for Oral Chemotherapy Drug Coverage. Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG which provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, preventive vaccines, diagnostic tools, cost-saving generic pharmaceuticals and consumer health products. Novartis Oncology, a business unit within the Novartis group company, strives to become the world's premier oncology business by consistently discovering, developing and making broadly available novel therapies that may improve and extend the lives of people

living with cancer. The Novartis Oncology business is headquartered in the United States in Florham Park, New Jersey.

We strongly believe that patients should be able to access the most appropriate therapy for their cancer diagnosis. Novartis is committed to developing treatments for people with cancer and encourages using efficient ways to evaluate each patient's specific disease and clinical factors to determine the most appropriate therapy. The promise of personalized medicine lies in the identification of the right drug for the right patient, and ensuring the patient has access to the drug. Scientific advances in understanding the molecular targets involved in cancer have the potential to dramatically improve the care of patients by identifying those patients most likely to respond, reducing side effects, and avoiding unnecessary treatment, thus reducing unnecessary treatment costs. Since the introduction of Glivec® and other targeted therapies, our industry has increasingly filled its pipelines with new targeted agents.

Oral oncolytics offer patients ease of administration and facilitate treatment at home, yet health insurance benefit design differences can make it difficult to determine coverage levels and limits for these drugs. Oral oncolytics, when covered, are covered within the outpatient drug benefit and are assigned a set co-pay based on the formulary tier. Conversely, traditional injectable chemotherapy is covered under the insured's medical benefit. The accompanying patient co-insurance for each chemotherapy administration varies with the plan. Intravenous infusions and injected oncolytics usually require a co-insurance of 20% of the amount the insurer reimburses the oncologist or administering provider for the cost of the drug, the administration, and the fees of the administration site or physician's office, but can be higher.

Legislative efforts to ensure patients' access to oral agents should avoid the concept of "parity", since parity could result in oral oncolytics being placed in the same cost structure as injectables, rather than in the outpatient drug benefit, where oral oncolytics are currently being covered. Most insured patients already enjoy coverage for some oral oncolytics through their insurance or health plan via the outpatient drug benefit. In Washington, for example, 98% of commercial plans include Glivec on Tier 2 of the formulary or preferred drug list. The average patient outpatient drug co-pay for Washington residents enrolled in a commercial plan – the average amount paid by the patient for a month of therapy – is \$65.95. Ninety-four percent of Washington residents with commercial insurance pay less than \$100 a month for Glivec. Washington Medicare beneficiaries enrolled in Part D also enjoy good access to Glivec within their selected Part D plans. Twenty percent of Medicare plans offer Glivec in Tier 2 or 3, and 80 percent offer it in Tier 4. The average monthly out of pocket for the period of time until Part D catastrophic coverage takes effect, which would usually be after two months of Glivec therapy, is \$313. Legislation that requires, permits, or encourages movement of oral oncolytics from the outpatient drug benefit to the medical benefit in an attempt at "parity" could result in a patient's cost sharing increasing from \$100 or less to \$900 or more per month, and insurers' and plans' costs decreasing.

With 25 percent of the oncology drug pipeline in oral form, an ever-increasing number of patients stand to benefit from access to oral agents. In many cases, these oral agents, with their targeted affinity for tumors and decreased side effect profile, have the potential to allow patients to tolerate long term therapy. This will result in certain cancers eventually being classified as chronic diseases, as long as a patient is adherent to their oncolytic therapy.

Compliance with oral oncolytic therapy is a key to successful treatment. Legislation that ensures coverage for oral agents should also ensure that supportive care is accessible. As with all oral agents, it is difficult to ensure patients' adherence and compliance with oral oncolytics. Reasons behind this possible lack of compliance include side effects, costs of therapy, variable insurance coverage, and lack of care coordination. Recent studies on oral oncolytic coverage show decreased adherence to life saving therapies when there are higher patient costs.

Novartis Oncology supports language that improves patients' access to appropriate chemotherapy care. Lack of specificity and poor drafting in bills designed to increase patients' access to oral agents can result in some patients paying more for the oral oncolytics than they currently pay. It is necessary to ensure

that legislation intended to benefit patients by increasing access is not drafted in a way that mandates “parity” in a way that would result in an increase in patients’ costs for safe, cost-effective oral chemotherapy agents. Language in the previous SB 5512 does this, by recognizing that insurance coverage is necessary, and should be provided with oral costs “no less favorable”, without specifically identifying a parity requirement. In addition, we recommend that protective language be included to prohibit insurers and health plans from shifting coverage for oral agents from the outpatient drug benefit to the medical benefit, which would be in compliance with the drafted “no less favorable language”, and which would decrease insurers’ costs and increase patients’ shares of the costs, thus impeding access.

Thank you again for this opportunity to comment as part of the Sunrise Review. We will have someone in attendance at the hearing on June 28, but do not plan to make public comments unless the direction of the discussion changes in a way that would impede patients’ access by creating the possibility of drastically increased co-pays.

**Tracy L. Baroni Allmon, R.Ph., J.D.
Executive Director, Health Policy**

On behalf of the American Cancer Society Cancer Action Network and those we serve, I write to ask you to support legislation to require health insurance plans to provide the same coverage for orally administered chemotherapy treatments, as is extended for intravenously dispensed, or injected, chemotherapy.

Researchers are continually identifying new, more effective and less invasive therapies for cancers. These include an emerging number of anti-cancer medications that can be taken by mouth as a liquid, tablet, or capsule. For many patients, these oral chemotherapy medications are a significant improvement over intravenously dispensed or injected (IV) chemotherapy medicines that require a trip to a physician’s office or medical facility. The American Cancer Society has identified a number of barriers to IV chemotherapy treatments including travel distance, the associated costs of travel and medical costs of treatment, and the time required for multiple treatments over long stretches of time. To help ease this burden for patients and their families, the Society provides a “Road to Recovery” program where we arrange for volunteer drivers to transport patients to and from treatments. Demand for this program is high, and unfortunately at times we have had to turn patients away. Increasing access to oral forms of chemotherapy that can be taken outside of a medical facility will help reduce this demand by minimizing the number of visits to the doctor a patient will need.

Oral therapies benefit patients in a number of ways. Oral anti-cancer drugs are less invasive and more comfortable because no needle is involved; they offer convenience to patients and save time; and they are much easier to administer than injections. These aspects of oral chemotherapy medicines address an important element of patient and family quality of life because these medicines can be taken at home, thereby reducing substantially the number of visits a patient must make to the hospital or cancer clinic during active treatment.

No person whose health and ability to function is already compromised by their cancer should have to choose between saving their life or their life-savings. Without addressing the high out-of-pocket costs of oral chemotherapies to make them on par with out-of-pocket costs for comparable forms of intravenous injection chemotherapies, this will be the terrible choice many cancer patients will face.

Thank you for your consideration. I respectfully ask that you support legislation to address the disparity in insurance coverage between oral and intravenous chemotherapies.

**Erin Dziedzic, Director of Government Relations, Washington State
American Cancer Society Cancer Action Network**

The Washington State Medical Oncology Society, representing over 130 Oncologists across our state, thanks the Department of Health for an opportunity to comment on HB and SB 5512 requiring that “Every health plan … that provides coverage for cancer chemotherapy treatment must cover orally administered anticancer medication used to kill or slow the growth of cancerous cells on a basis not less favorable than intravenously administered or injected cancer medications, including copayments.”

We are conceptually in favor of achieving parity for oral and parenterally administered chemotherapy drugs. Most health plans pay for oral drugs through a pharmacy benefit that includes deductibles and tiered copays that incentivize the use of generic and less expensive medications. Oral anti-cancer drugs are largely brand name and often outrageously expensive. Many plans put these drugs into 4th tier copayments that on average require patients to pay more than 25% of the cost of the medication. Some of these drugs cost as much as \$5000 a month. Cancer patients, many of whom are disabled by their disease and living off savings and fixed incomes, cannot afford this. The alternative is IV chemotherapy. Typically these drugs are covered by a health plans medical benefit. Medical benefits, as compared to pharmacy benefits, also have deductibles, and an increasing number have copays for drugs though most do not and those that do, have an out of pocket cap that limits costs to a much lower level than equivalent oral therapies.

It only seems fair that this discrepancy should be rectified, allowing patients greater access to therapies that may be more convenient, better tolerated, and that may actually be less expensive than IV treatments with similar efficacy. However, oncologists live in the trenches of the war on cancer and at the intersection of cancer care and cancer economics. We are concerned that the proposed legislation does not address potential pitfalls that could lead to the exact opposite of what many of its proponent’s desire.

We have seen one health plan in our state develop and begin to market a health plan that would meet the demands of the Oregon law on drug parity, a statute that is nearly identical to HB and SB 5512, by moving all drugs given in a physician’s office, largely IV chemotherapeutics, from the medical benefit to the pharmacy benefit. Achieving parity in this manner may level the playing field for drug companies with oral chemotherapeutics, but circumvents the intention to improve patient access to needed therapies. Quite the opposite, it will inhibit or prohibit patients from accessing oral and IV chemotherapies alike. Further, it would represent a billing nightmare for oncology clinics as they attempted to establish and collect individual drug copayments for each and every drug at each and every treatment. This loophole has been addressed by Colorado’s oral chemotherapy parity law, but has been neglected by the Oregon statute. The Washington State Medical Oncology Society cannot support legislation in our state that fails to close this loophole.

We have one other comment that addresses the wording of the statute that defines chemotherapy, “anticancer medication used to kill or slow the growth of cancerous cells.” Many of our newest anti-cancer drugs have modes of action quite different from classic chemotherapy. A new drug soon to be released to treat Malignant Melanoma, for example, acts primarily upon the immune system and only indirectly on cancer cells. It may be semantics, but we would suggest that trying to define anticancer medication may prove limiting.

Thank you for affording us the opportunity to comment on this important issue. We urge that you make changes to the proposed language of this statute that will both provide parity for oral chemotherapy drugs and provide and protect access to them for our patients.

Jeffery Ward, MD
President, Washington State Medical Oncology Society

I am writing in support of the proposal to provide comparable benefits for cancer medication.

I was diagnosed with lymphoma in 2005 and underwent eight cycles of CHOP chemotherapy in 2006 as an insured member of Group Health Cooperative. During the course of treatment, my white cell count dropped to dangerous levels, and my oncologist said I needed Neupogen to bring it back to normal or the treatment would be discontinued.

Taking Neupogen was a hardship for two reasons:

1) Although friends in my cancer support group were receiving a newer long-lasting version of Neupogen called Neulasta once a week, Group Health would not prescribe it because it was somewhat more expensive than getting the older Neulasta seven times a week. This meant I had to have daily injections instead of weekly injections. I had to drive to the hospital every day despite feeling weak and nauseated, a total of 50 roundtrips or so.

2) Despite the fact that my insurance was supposed to cover drugs given in a hospital, Group Health sent me bills for the Neupogen injections. They claimed that I could theoretically inject the Neupogen at home myself, so they considered it a "prescription" drug, which my plan didn't cover. I had to call Group Health over and over and write them many letters over three months time before they finally agreed to pay for it, and then they told me it was being paid out of their "charity" fund, which was humiliating.

Group Health never paid for my oral chemotherapy drugs (such as prednisone) or the ancillary drugs that they prescribed for the nausea caused by chemotherapy (such as lorazepam and metoclopramide).

I don't believe cancer patients should be denied standard care, nor should they have to plead with their health care providers to pay for medication because it is considered "prescription" or "oral." I was only 46 at the time, and if I were older might not have had the stamina and determination to insist that my health care provider cover the cost of treatment. I ask that you please do the right thing for cancer patients by providing comparable benefits.

I would be glad to provide further information on request.

Steven Brown, Olympia, Washington

On behalf of our member healthcare plans, thank you for the opportunity to provide input regarding the Department of Health's (DOH) review of a proposal that would mandate coverage of oral chemotherapy drugs on a basis "not less favorable" than intravenously administered or injected ones.

As part of the Sunrise Review, we think the following questions should be addressed.

- What is the anticipated financial impact of mandating coverage of oral chemotherapy drugs?
- How will these additional costs affect healthcare coverage purchasers, including individuals, families, and state and private health care programs?
- How will the proposed changes help promote cost-effective, evidence-based services that improve quality of care?

In addition, we offer the following comments for your consideration. Mandating coverage of oral chemotherapy drugs on a basis no less favorable than injected drugs will significantly increase costs and utilization --- without any assurance that health care safety or effectiveness will increase. It will also have unintended consequences for many members who will see this change as benefit "take-away".

Increased Costs and Utilization

Based on our member healthcare plans' extensive expertise and experience, we have determined that utilization will expand in an uncontrolled, relatively high-cost manner. Those millions of dollars in increased costs would necessarily be passed onto employers, individuals and families in our state who are already struggling to continue to afford coverage.

Primary cost-drivers associated with the proposed mandate include that it would increase utilization of high-cost drugs, require extension of drug benefits to those who currently do not have that benefit, lower patient cost-sharing for these drugs to zero in some cases, remove healthcare plans' ability to manage utilization in accordance with evidence-based guidelines, and require coverage of all oral chemotherapy drugs, regardless of clinical indication or off-label use. Additional administrative costs would be incurred as a result of required system changes to track pharmacy benefits and diagnoses at the point of sale.

In effect, this proposal would mandate coverage of oral chemotherapy drugs, which will result in greater overall utilization of those drugs. Earlier use of therapies, more widespread clinical application, and increased marketing on the part of oral chemotherapy manufacturers will further add to increased utilization.

We understand the analysis report posted on the DOH web-site was funded by a major oral chemotherapy manufacturer. We are concerned that the analysis fails to recognize the predictable shift that would occur towards greater utilization of those higher-cost drugs if healthcare plans were prevented from employing evidence-based guidelines. For example, evidence-based guidelines indicate that certain medications, such as intravenous chemotherapy medications, should be attempted first.

Patient Safety

We have not seen convincing data that show improved treatment results associated with oral chemotherapy. Neither have we seen data on the impact of this requirement on patient safety; we are concerned that oral chemotherapies are inherently less controlled than IV therapies. Prescription errors are more common than are medication errors in IV-infusion centers. We also would like to point out that IV-infusion can be administered in the home, using a home-care agency and a home-IV-infusion supplier. These services would be covered as medical benefits.

In the Applicant Report Proposal Assessing Sunrise Criteria, on the DOH Web Site, the question about improved health status of state residents has been dismissed as "not applicable." However, the health status of state residents is absolutely fundamental to DOH activities. We submit that responsible answers to this question are needed before implementing new requirements.

Unintended Consequences

The proposed mandate would affect enrollees differently depending on their coverage plan. It should be noted that some would actually experience the mandate as a benefit "take-away". For example, an enrollee covered under a traditional plan, with a medical deductible and coinsurance and a typical multi-tier pharmacy benefit including co-pays, would now need to pay for the whole cost of the drug until his or her deductible is met, rather than just paying a flat co-payment per prescription.

Ultimately, under federal healthcare reform, the essential benefit package in 2014 will likely have a significant impact on what happens with oral chemotherapy drug coverage. If such drugs are not included in the essential benefit package, but are mandated in Washington, it appears the State would be obligated to pay the cost of providing this benefit for subsidized individuals purchasing coverage through the exchange.

Coverage and Processes Today

Most healthcare plans already have a benefit review process in place that allows them to provide coverage for oral chemotherapy when patient safety and clinical indications support that option. The proposed mandate, however, would seem to require coverage of high-cost oral chemotherapy drugs without taking into consideration evidence-based guidelines, patient safety, or cost-effectiveness of alternatives. It also would have the effect of requiring pharmacy benefit coverage for those who currently do not have that benefit.

We appreciate the difficult cost impact of some oral chemotherapy medications for certain individuals, especially for those who lack a pharmacy benefit. We do not think, however, that a select group of members should be penalized for the benefit of another. Instead, we believe it is in the best interest of Washington residents to preserve carriers' flexibility to design healthcare coverage plans that provide appropriate access to effective treatments.

Thank you again for the opportunity to provide input. We look forward to offering additional input and comments as the Sunrise Review process progresses. In the interim, please do not hesitate to give me a call at 425-396-5375 if you have any questions or would like to discuss.

**Sydney Smith Zvara, Executive Director
The Association of Washington Health Plans (AWHP)**

Thank you for the opportunity to provide comments on the Sunrise Review of Senate Bill 5512 regarding insurance coverage parity for oral cancer chemotherapy medications.

In developing the analysis for the Sunrise Review, the Washington State Health Care Authority (HCA) has begun to re-evaluate our assumptions regarding how we would implement this legislation. Given the complexity of implementing this proposal, HCA would explore development of a specific benefit design for cancer chemotherapy medications to be implemented by the Public Employees Benefits Board (PEBB) and Basic Health programs. Based on the outcome of this evaluation, it is expected that the fiscal note HCA submitted on this legislative proposal in 2009 will change. A copy of the 2009 fiscal note is attached.

Even if the HCA analysis and assumptions were to remain unchanged, there is an additional cost to HCA not reflected in the fiscal note. In the fiscal note analysis, HCA assumed that the PEBB and Basic Health programs would change the cost sharing method for orally administered cancer chemotherapy medications from a prescription drug benefit to the medical benefit for injected and intravenously administered medications. Based on this assumption, HCA would not be able to collect the federal Retiree Drug Subsidy dollars associated with the oral anticancer drugs utilized by PEBB Medicare Part D eligible enrollees – an additional estimated cost of \$1.2 million annually.

Comments on the Applicant Report and Actuarial Information

There is currently a disparity related to the share of the cost of a cancer chemotherapy medication borne by a patient depending on whether the medication is administered intravenously or injected versus orally administered medications. The applicant proposes removing this disparity that results in a patient paying a smaller portion of the cost of an intravenous medication than for an orally administered medication. Given that many of the newer cancer protocols with oral medications have better outcomes and remission rates and that patient compliance with these protocols is essential for achieving these goals, it is a timely subject for review and discussion.

The actuarial analysis provided by Milliman, Inc. is consistent with the Health Care Authority fiscal note on SB 5512 submitted to the Office of Financial Management in February 2009. Milliman, Inc., as HCA's contracted actuary, provided estimates of the impact of the legislation on the average per member per month costs for the PEBB and Basic Health programs.

Comments on the Legislative Proposal - SB 5512

The legislation directs health care coverage that provides for cancer chemotherapy treatment “must cover orally administered anticancer medication used to kill or slow the growth of cancerous cells on a basis not less favorable than intravenously administered or injected cancer medications, including copayments.” The proposal applies to all PEBC health plans and to Basic Health coverage.

While HCA assumes the intent of this legislation is to make oral anticancer drugs more affordable for cancer patients, the bill does not mandate that health plans cover oral anticancer drugs in either the medical or the pharmacy benefit; rather it mandates that all cancer chemotherapy be covered at the same benefit level to the patient. The legislation requires parity and provides discretion on the part of insurers and employer groups to redesign the benefits to achieve the goal of parity.

HCA now believes that implementation of the parity requirement is more complex than simply determining whether to pay for all cancer chemotherapy medications under the current medical benefit or the current pharmacy benefit. Implementation may require the development of a specific benefit design for all cancer chemotherapy medications. Depending on how the legislation is implemented, potential complexities include:

The cost impact to our PEBC and BH members.

- How the medications will be dispensed – whether through pharmacies or other health care providers - and the capacity for providers to dispense and bill for dispensing the medications.
- The cost of the medications paid by our health plans based on the type of provider dispensing a medication.
- The ability of our health plans to implement the benefit design.
- The cost impacts to providers for administration of the medications.
- The potential administrative burden on health plans, providers, and members based on the benefit design.
- Cost impacts to PEBC as an employer.

Conclusion

The Health Care Authority will explore the development of separate benefit designs for all cancer chemotherapy medications in order to balance the impacts and complexities of the parity requirement. The agency will need to evaluate this issue from the perspective of our various stakeholders – our health plans, health care providers, as well as the PEBC and Basic Health members.

Dennis Martin

Washington State Health Care Authority

(Fiscal note attached)

Individual State Agency Fiscal Note

Bill Number: 5512 SB	Title: Chemotherapy treatment costs	Agency: 107-Wash State Health Care Authority
-----------------------------	--	---

Part I: Estimates

No Fiscal Impact

Estimated Cash Receipts to:

FUND	FY 2010	FY 2011	2009-11	2011-13	2013-15
Basic Health Plan Trust Account-Non-Appropriated 172-6	23,369	44,685	68,054	85,264	85,264
Public Employees' and Retirees Insurance Account-Non-Appropriated 721-6	614,507	1,274,582	1,889,089	2,738,200	2,738,200
Basic Health Plan Subscription Acct-Non-Appropriated 761-6	144	297	441	612	612
Total \$	638,020	1,319,564	1,957,584	2,824,076	2,824,076

Estimated Expenditures from:

Fund	FY 2010	FY 2011	2009-11	2011-13	2013-15
General Fund-State 001-1	158,600	328,961	487,561	706,714	706,714
General Fund-Federal 001-2	23,075	47,861	70,936	102,820	102,820
General Fund-Private/Local -7 001	1,625	3,371	4,996	7,240	7,240
Basic Health Plan Trust Account-Non-Appropriated 172 -6	23,369	44,685	68,054	85,264	85,264
Public Employees' and Retirees Insurance Account-Non-Appropriated 721-6	431,207	894,389	1,325,596	1,921,426	1,921,426
Health Services Account-State -1 760	179,760	373,541	553,301	775,126	775,126
Basic Health Plan Subscription Acct-Non-Appropriated 761-6	144	297	441	612	612
Total \$	817,780	1,693,105	2,510,885	3,599,202	3,599,202

The cash receipts and expenditure estimates on this page represent the most likely fiscal impact. Factors impacting the precision of these estimates, and alternate ranges (if appropriate), are explained in Part II.

Check applicable boxes and follow corresponding instructions:

- If fiscal impact is greater than \$50,000 per fiscal year in the current biennium or in subsequent biennia, complete entire fiscal note form Parts I-V.
- If fiscal impact is less than \$50,000 per fiscal year in the current biennium or in subsequent biennia, complete this page only (Part I).
- Capital budget impact, complete Part IV.
- Requires new rule making, complete Part V.

Legislative Contact:	Michl Needham	Phone: (360) 786-7442	Date: 01/31/2009
Agency Preparation:	Christy Vaughn	Phone: 3602523378	Date: 02/09/2009
Agency Approval:	Dennis Martin	Phone: (360) 923-2831	Date: 02/09/2009
OFM Review:	Nick Lutes Oral Chemotherapy Coverage Sunrise	Phone: 360-902-0570	Date: 02/10/2009 Page 85 of 110

Part II: Narrative Explanation

II. A - Brief Description Of What The Measure Does That Has Fiscal Impact

Briefly describe by section number, the significant provisions of the bill, and any related workload or policy assumptions, that have revenue or expenditure impact on the responding agency.

See attached narrative.

II. B - Cash receipts Impact

Briefly describe and quantify the cash receipts impact of the legislation on the responding agency, identifying the cash receipts provisions by section number and when appropriate the detail of the revenue sources. Briefly describe the factual basis of the assumptions and the method by which the cash receipts impact is derived. Explain how workload assumptions translate into estimates. Distinguish between one time and ongoing functions.

See attached narrative.

II. C - Expenditures

Briefly describe the agency expenditures necessary to implement this legislation (or savings resulting from this legislation), identifying by section number the provisions of the legislation that result in the expenditures (or savings). Briefly describe the factual basis of the assumptions and the method by which the expenditure impact is derived. Explain how workload assumptions translate into cost estimates. Distinguish between one time and ongoing functions.

See attached narrative.

Part III: Expenditure Detail

III. A - Expenditures by Object Or Purpose

	FY 2010	FY 2011	2009-11	2011-13	2013-15
FTE Staff Years					
N-Grants, Benefits & Client Services	817,780	1,693,105	2,510,885	3,599,202	3,599,202
Total:	\$817,780	\$1,693,105	\$2,510,885	\$3,599,202	\$3,599,202

III. C - Expenditures By Program (optional)

Program	FY 2010	FY 2011	2009-11	2011-13	2013-15
BH Benefits (070)	203,129	418,226	621,355	860,390	860,390
WSHIP, HCTC (080)	144	297	441	612	612
PEBB Benefits Fund (850)	614,507	1,274,582	1,889,089	2,738,200	2,738,200
Total \$	817,780	1,693,105	2,510,885	3,599,202	3,599,202

Part IV: Capital Budget Impact

None.

Part V: New Rule Making Required

Identify provisions of the measure that require the agency to adopt new administrative rules or repeal/revise existing rules.

None.

HCA Fiscal Note

Bill Number: SB 5512

Chemotherapy Treatment Costs

HCA Request #: 09-20-02

Part II: Narrative Explanation

II. A - Brief Description Of What The Measure Does That Has Fiscal Impact

Section 1 of this bill adds a section to chapter 41.05 RCW which requires the health plans offered by the Public Employees Benefits Board (PEBB) that provide coverage for cancer chemotherapy costs to cover orally administered anticancer medication on a basis not less favorable than medications that are administered intravenously or injected cancer medications effective January 1, 2010.

Section 9 of this bill adds a section to chapter 70.47 RCW which requires the Basic Health (BH) schedule of benefits that provides coverage for cancer chemotherapy treatment to cover orally administered anticancer medication on a basis not less favorable than medications that are administered intravenously or injected cancer medications effective January 1, 2010.

Currently all PEBB and BH health plans provide coverage for cancer chemotherapy treatment. Medications that are administered intravenously or injected are typically considered medical services. The cost sharing method that is applied to claims for these medications is more favorable than the cost sharing method for oral medications that are currently administered under the prescription drug benefit for BH health plans and some PEBB plans.

Fiscal Impact:

The Health Care Authority (HCA) has made several assumptions about this bill. Changes in the assumptions could have significant impacts on the expenditure estimates. HCA has made assumptions as to how the proposed legislation would be implemented. This fiscal analysis was made based upon those assumptions and the costs associated with any different interpretation of the bill are not estimated within this analysis.

HCA assumes that the intent of the legislation is to change the cost sharing method that is currently used for orally administered chemotherapy medications by moving the benefit for these medications from the prescription drug benefit to the more favorable medical benefit that is used for injected and intravenously administered chemotherapy medications. This change will increase the total cost of the PEBB and BH benefits effective January 1, 2010.

HCA assumes that the reference to "orally administered anticancer medication" does not intend to expand the health plans' prescription drug formulary to include anticancer medications that are currently excluded from coverage such as vitamin supplements, medical foods, and medications available without a prescription.

Benefits Impacts

The benefit changes required by this bill would increase the administrative costs for the health plans due to the specific exception that it creates to the prescription drug benefit. In addition to the administrative costs, the health plans would see increased benefit costs due to the differences in how medical claims and pharmacy claims are reimbursed in addition to the change in the cost sharing method for the orally administered medications from the less favorable prescription drug benefit category¹⁰ to the more favorable medical benefit category¹⁰.

HCA Fiscal Note

Bill Number: SB 5512

Chemotherapy Treatment Costs

HCA Request #: 09-20-02

HCA's contracted actuary, Milliman Inc., estimates that the average plan cost increase per subscriber per month for the PEBB non-Medicare population would be \$0.44 for CY2010. They estimate that the average cost increase per subscriber per month for the PEBB Medicare population would be \$0.69 for CY2010. The average cost increase per member per month for the BH population is estimated to be \$0.28 for CY2010. For the basis of calculating the BH cost impact, the average enrollment of 107,000 members (requested Maintenance Level) was used for each fiscal year.

Operational Impacts

HCA would need to make updates to both PEBB and BH publications and member materials as a result of this benefit change. The changes would be made in conjunction with the annual Open Enrollment material updates and would therefore not result in additional administrative costs to HCA.

II. B – Cash Receipts Impact

HCA estimates the following cash receipts based on the increased costs:

Cash Receipts	FY10	FY11	FY12	FY13	FY14	FY15
721 PEBB Insurance Account	614,507	1,274,582	1,369,100	1,369,100	1,369,100	1,369,100
172 Basic Health Trust	23,369	44,685	42,632	42,632	42,632	42,632
761 Basic Health Subscription	144	297	306	306	306	306
Total	638,020	1,319,564	1,412,038	1,412,038	1,412,038	1,412,038
Biennial total		1,957,584		2,824,076		2,824,076

II. C - Expenditures

The estimated total expenditures are detailed below:

Expenditures	FY10	FY11	FY12	FY13	FY14	FY15
721 PEBB Insurance Account	431,207	894,389	960,713	960,713	960,713	960,713
001 General Fund State	158,600	328,961	353,357	353,357	353,357	353,357
001 General Fund Federal	23,075	47,861	51,410	51,410	51,410	51,410
001 GF-Local	1,625	3,371	3,620	3,620	3,620	3,620
760 Health Services Account	179,760	373,541	387,563	387,563	387,563	387,563
172 Basic Health Trust	23,369	44,685	42,632	42,632	42,632	42,632
761 Basic Health Subscription	144	297	306	306	306	306
Total	817,780	1,693,105	1,799,601	1,799,601	1,799,601	1,799,601
Biennial total		2,510,885		3,599,202		3,599,202

Please see the "PEBB-UMP" attachment for additional detail on the PEBB benefits impacts.

Part IV: Capital Budget Impact

None.

Part V: New Rule Making Required

Oral Chemotherapy Coverage Sunrise
None.

HCA Fiscal Note

Bill #: SB 5512

PEBB-UMP Impact

HCA Request: 09-20-01

	FY 10	FY 11	FY 12	FY 13	FY 14	FY 15
--	-------	-------	-------	-------	-------	-------

Expenditure change

721 Benefits	614,507	1,274,582	1,369,100	1,369,100	1,369,100	1,369,100
Total	614,507	1,274,582	1,369,100	1,369,100	1,369,100	1,369,100

Revenue change

State Share	\$ 325,000	\$ 674,101	\$ 724,090	\$ 724,090	\$ 724,090	\$ 724,090
Employee Share (1)	\$ 44,318	\$ 91,923	\$ 98,739	\$ 98,739	\$ 98,739	\$ 98,739
Other Enrollment	\$ 47,932	\$ 99,417	\$ 106,790	\$ 106,790	\$ 106,790	\$ 106,790
Non Medicare Retirees	\$ 30,111	\$ 62,455	\$ 67,086	\$ 67,086	\$ 67,086	\$ 67,086
Medicare Retirees	\$ 167,146	\$ 346,686	\$ 372,395	\$ 372,395	\$ 372,395	\$ 372,395
Total	\$ 614,507	\$ 1,274,582	\$ 1,369,100	\$ 1,369,100	\$ 1,369,100	\$ 1,369,100

State Share Source

48.8% GF-State	158,600	328,961	353,357	353,357	353,357	353,357
7.1% GF-Federal	23,075	47,861	51,410	51,410	51,410	51,410
0.5% GF-Local	1,625	3,371	3,620	3,620	3,620	3,620
19.7% Other Appropriated	64,025	132,798	142,646	142,646	142,646	142,646
23.9% Non Appropriated	77,675	161,110	173,057	173,057	173,057	173,057
100.0% Total Active revenue	325,000	674,101	724,090	724,090	724,090	724,090

Cover Sheet Fund 721 Expenditures(2)	431,207	894,389	960,713	960,713	960,713	960,713
--------------------------------------	---------	---------	---------	---------	---------	---------

Employer Funding rate impact

	Enrollment					
MCO		41,589				
Self-Insure		69,890				
Waivers		5,973				
	117,452	\$ 0.23	\$ 0.48	\$ 0.51	\$ 0.51	\$ 0.51

Notes:

- 1) This fiscal note assumes that state employees pay an average of 12% of the cost of medical premiums in CY 10 and following years.
- 2) Since the Cover Sheet Fund 721 does not include the GF-S, GF-F, and GF-L as revenue, but does include them as expenditures, the bolded funds above, (less Funds 418, 438, and 439) equal the Cover Sheet Fund 721 expenditure line.

Appendix E

Public Hearing Summary

**Oral Chemotherapy Drug Coverage Sunrise
Public Hearing Summary
June 28, 2010**

Kristi Weeks opened the hearing. Ms. Weeks is the Director of Policy and Legislation at the Department of Health in the Health Systems Quality Assurance Division. She introduced Sherry Thomas, sunrise review coordinator. Kristi explained that we have a couple of participants by phone. She then introduced the panel members:

- Panel members are Katie Golub and Peter Beaton from the Department of Health. Katie is the program manager for the Cancer Registry and Peter is an economist for our rules development office.
- Lauren Kiolet is our public member. She is a retired school teacher who has had a lot of personal experience dealing with cancer.

Ms. Weeks explained how the hearing will work and asked participants to focus on the statutory criteria when presenting or testifying. She stated we expect our draft report, which will include staff recommendations and will be based in part on this hearing, to go to the Secretary of Health in October. She explained the hearing is intended for the proponents to make their presentation and for opponents and other interested parties to comment on the proposal. Panel members and department staff will ask questions. The panel's role is to make sure we have all the information we need to make a good recommendation. She asked that those testifying stay after their presentations if possible in case there are follow up questions. Ms. Weeks explained that the sign-in sheet used for testimony is also used to create our contact list for updating participants on the process.

There will be a 10-day comment period following the hearing to address topics brought up at the hearing, clarify things said, etc, and for those who could not attend the hearing to send additional information to us.

Ms. Weeks reminded participants that there are statutory criteria for this process and asked them to stick to the criteria as much as possible during testimony. This is not a legislative hearing and political arguments or other factors not included in the statute will neither help nor harm the proposal under review. It is the legislature's job to take those into account and they have asked the department to look at specific criteria. Ms. Weeks stated she will keep the hearing on time and within the constraints of the review. She reminded participants that the focus should be on the applicant's report.

Ms. Weeks then introduced the applicant group. She explained Heather Kirk will present first, followed by Vicki Jones, who is a patient and the co-applicant, who will present by phone from Spokane. Third will be Ben Steinmetz, from GlaxoSmithKline, who will present by phone from Philadelphia.

Applicant Presentation

Heather Stauffer Kirk

Heather Stauffer Kirk presented the proposal. Ms. Kirk told participants why this proposal is important to her and her family. She explained that her father Chuck Stauffer, is a fourth generation Oregon hop and filbert farmer and the heart of her family. In December 2005, two days after his grandson's second birthday and the morning after his wife's 57th birthday, he was diagnosed with a malignant brain tumor. Nine days before Christmas, he underwent brain surgery. They removed the bulk of the tumor as the first step in treatment. They then developed a plan of attack.

Chemotherapy and radiation were recommended simultaneously for 42 continuous days. The most effective treatment for her dad's type of tumor was one of oral chemotherapy, which they were unfamiliar with at the time. They were so pleased to learn that oral chemotherapy, in the form of a pill that can be taken at home, is generally better tolerated and less invasive than IV or injected forms. Patients can often sleep through the chemotherapy and it can be self-administered at home rather than in a doctor's office. Also, she stated there is less hair loss and fewer side-effects than traditional forms.

They quickly learned that her dad's type of chemotherapy was not covered by his health insurance equal to the IV or injectable forms. His out-of-pocket copay was over \$5,500 for his first round of chemo. This was after meeting his deductible and out-of-pocket maximum. His chemotherapy treatment was to continue monthly for at least two years, and possibly indefinitely. After his first round, his prescription benefit was exhausted. He was left to pay 100% of his prescription medications, in addition to his chemotherapy, with no prescription out-of-pocket maximum.

Ms. Kirk stated that health care plans cover oral chemotherapy differently. Most categorize it as a prescription drug benefit. Individuals with a percentage copay are at a great disadvantage regarding chemotherapy prescriptions. These treatments are incredibly costly. In spite of these high costs, comparisons show oral chemotherapy drugs are often less expensive than IV drugs. In order for her dad's health insurance to pay for his treatment at 100% after meeting his deductible or an out-of-pocket maximum, he would have had to choose a less effective form of treatment. This was against his doctor's recommendation. Though more expensive for the insurance company, IV treatment would have been covered 100%. Ms. Kirk stated that IV treatment can be more costly due to harsh side effects, higher hospitalization rates, and required outpatient administration of the drug. It would have been less effective for her dad, as there is no chemical equivalent in alternate forms.

Ms. Kirk stated that nearly all standard chemotherapy drugs have no chemical equivalent available in an IV or injectable form. Patients are sometimes forced to choose a less effective form of treatment, which ends up costing insurance companies more. Instead, Ms. Kirk's dad was paying \$1,715 every 28 days for an indefinite amount of time. Ms. Kirk provided a chart (Attachment A) that details his copays. The middle column show his out-of-pocket costs for one year, \$30,598. If it would have been an injected or IV treatment, it would have been \$4,500.

Ms. Kirk assembled a workgroup consisting of herself, a good friend with a legislative background, Senator Courtney's legislative assistant, a lobbyist from her dad's insurance company, and lobbyists from the American Cancer Society. Together they drafted language stating health insurance companies should treat orally administered chemotherapies no less favorably than IV or injectable forms. Through this process, they realized some insurance companies had very favorable prescription benefits. They did not want to adversely impact them so they were very careful in drafting the language. Ms. Kirk spent a great deal of time at the capitol building in Salem, Oregon meeting personally with key legislators. Many of them chose to co-sponsor the bill. In these conversations she learned some legislators were hesitant to develop a health care mandate. Oregon's own legislative council determined SB 8 was not a health care mandate under Oregon law. It did not require insurance companies to cover anything new. Ms. Kirk stated the proposed legislation in Washington is also not considered a mandate as it only changes the way an existing benefit is covered.

She carefully researched and prepared her testimony to present before the Senate and House health care committees. Ms. Kirk was fortunate that the lobbyist for her dad's insurance company, Regence Blue Cross Blue Shield of Oregon, was empathetic, wise, and experienced. He offered testimony in support of their bill and worked with Regence to determine what changes were feasible for them to implement. Senate Bill 8 passed through both committees unanimously.

Just before the bill reached committee, Regence issued full reimbursement to her dad for his chemotherapy out-of-pocket expenses. Along with other unsuspecting Oregon cancer patients in the same insured category, he received a check for thousands of dollars. Although their relief and gratitude were overwhelming, Ms. Kirk stated their goal remained to eliminate the potential for this to happen for any other cancer patient in the future.

After her exhaustive and emotional testimony before the Senate and House committees and meetings with many legislators, Senate Bill 8 was put on the agenda and passed the Oregon House unanimously and passed the Senate unanimously except for one vote. On June 25, 2007, Senate Bill 8 was signed by Oregon Governor Ted Kulongoski. Insurance companies were left to determine the best way to cover all forms of chemotherapy beginning January 1, 2008. Ms. Kirk was contacted shortly after by others interested in implementing similar legislation in other states.

Ms. Kirk stated that following implementation, a handful of complaints reached the Oregon legislature by patients with existing insurance benefits that were adversely affected. These complaints were isolated to one small insurance company and the way they chose to implement the law. Some existing cancer patients who had prescription coverage were left to meet their deductible before the coverage kicked in. This transition only existed for the first year, for patients undergoing treatment as their plan changed. Compared to the inequality that existed prior to Senate Bill 8, these changes were relatively insignificant. The bill accomplished Ms. Kirk's objective, and has made oral chemotherapy more accessible to Oregon patients and treated fairly by insurance companies.

Her family has been able to enjoy the last few years with their dad in good health. His chemotherapy treatment was complete after 24 months. He's been able to enjoy the knowledge that their efforts alleviated for many others the problem that hit their family so hard at their hardest time.

Similar legislation has passed in several states, including Hawaii, Indiana, Iowa, Vermont, Colorado, Connecticut, Kansas, Minnesota, and D.C. Her father's story was featured on the cover of the New York Times in April 2009. House Resolution 2366, the Cancer Drug Coverage Parity Act, was introduced in Congress by New York Congressman Brian Higgins in May 2009. A light was shed on orally administered chemotherapy with the unfortunate diagnosis of Senator Ted Kennedy. Senator Kennedy's course of treatment was identical to her dad's. Orally administered chemotherapy is clearly the wave of the future for many types of cancer. It is inevitable that insurance coverage will have to catch up with technology.

It is Ms. Kirk's hope that insurance companies take it upon themselves to provide adequate coverage to all cancer patients. And if not, she hopes we will ensure all forms of chemotherapy are treated equally in Washington State. She is so pleased that they were able to turn this devastating family illness into an opportunity to bring fairness, health, and ultimately hope to cancer patients across the country. She thanks everyone for their time. Following her presentation is Vicki Jones, who is a first-hand survivor with experience in your own state of Washington, followed by Ben Steinmetz, from GlaxoSmithKline, who will present clinical and financial data. Thank you very much.

Vicki Jones

Vicki introduced herself as a 57 year old accountant working full-time as a Controller for a company based on the east coast. Because she works over the internet from Spokane, she has had to maintain her own health coverage. Ms. Jones believes it was in 2001 that she became a policy holder with Lifewise of Washington. Her research showed it to be a reliable company, offering good standard coverage with premiums that were fairly affordable. She stated she has been, for the most part, very happy with them.

In 2004 Ms. Jones was diagnosed with Multiple Myeloma, a cancer of the plasma cells in the bone marrow. It is an incurable but treatable disease. Patients live an average of 5-7 years with treatment. She stated she was so glad she had good health coverage. There are various drugs available to treat Myeloma. Patients have a small arsenal of drugs. When one stops working another is used until the arsenal is depleted or new drugs become available. Stem cell transplantation is also included in that arsenal.

In 2008, after four years in which various treatments and stem cell transplant had brought several short remissions, her cancer was again relapsed and raging and had to be treated. Her doctor prescribed a drug called Revlimid. Revlimid is one of two novel myeloma drugs that have come on the market within the past few years. The other is Velcade. Both have had tremendous success in extending the lives of myeloma patients.

By this time Ms. Jones had learned that, although her health coverage was good, it had a flaw she never expected. The amount her insurance will pay for prescriptions is limited to \$5,000 a year.

On the face of it, she stated she would have thought that was enough. But Revlimid and Velcade both cost well over that limit. The Revlimid her doctor prescribed was to cost approximately \$7,000 per month. She stated she could go on Revlimid and leave her family bankrupt or find an alternative. Fortunately for her, the other drug, Velcade, is administered intravenously. Her insurance would cover it as a medical benefit, not a pharmacy benefit. Her doctor agreed reluctantly to change her treatment based on what her insurance would cover.

Velcade is very costly too, and her treatment requires going to the clinic weekly and being treated for two to four hours in the chemo room. Though passing the CPA exam was easier than interpreting her medical bills, Ms. Jones stated she can tell you with certainty that her treatment with Velcade costs more than the \$7,000 the Revlimid oral drug would have cost. Right now, thankfully, the Velcade is working. But she cannot tell you how disheartening it was to find out she could not take the drug her doctor prescribed because of an outdated division in insurance reimbursement that had nothing to do with either cost or medical care. Ms. Jones stated she should have the best drug for her situation, not the drug her insurance company decides to reimburse based only on whether it is oral or IV. When you buy insurance, you think you're doing the right thing. You think you're covered. Finding out that is not the case is devastating. Fighting cancer is exhausting and painful. Having to fight without every weapon available is just wrong.

To look at Ms. Jones today, she states you would not know she has cancer. Thanks to the care she's received, she still works full time and remains very active. But if cancer has touched your life you will understand this: Not one day since her diagnosis has been free of this battle. Four years ago, she and her husband started a Multiple Myeloma Support Group in Spokane. Through this group and through an on-line list supported by the International Myeloma Foundation, they have encountered many people affected by this same oral versus IV coverage disparity. She is trying to speak for all of them. The astronomical prices of the drugs that mean life itself to them are at issue, certainly. But that is a fight to be won by bigger guns than them. Ms. Jones stated that they just have to concentrate on their own cancer battles. And they must not allow limits on health coverage we have diligently paid for, month after month, in health long before in sickness, even as premiums have skyrocketed, to limit the coverage they have! Insurance companies must be required to cover oral and IV drugs equally. Thank you.

Ben Steinmetz

Mr. Steinmetz introduced himself as Vice President of Patient Access and Reimbursement for GlaxoSmithKline's oncology area. He's been involved in oncology research, development, and commercialization for close to 25 years. In disclosure, GlaxoSmithKline is a pharmaceutical company that manufactures, markets, and is developing both intravenous and oral anticancer agents. Mr. Steinmetz stated he wanted to speak with you today about three topics; a brief overview of cancer treatment and the new types of advances that are taking place in targeted therapies, contrast medical versus pharmacy coverage, and share some financial considerations in IV and oral cancer agents. To review the central objectives here with parity, there are two components. One, there could be parity for where there is a molecule that is available both as an IV and as an oral agent. However, the reality is that there are very few molecules that have both available. Equally important is when there is an oral medication that is really the best medication, in some cases far and away the best for a patient, that they have the opportunity to

receive that and not an alternate, maybe much less effective, therapy because of the out-of-pocket cost of the chemotherapy.

Mr. Steinmetz explained that historically, cytotoxic chemotherapy has been of what many oncologists would call a demonstration of poison that indiscriminately targets both normal cells and cancer cells in the body with the hope that the cytotoxic kills more of the rapidly dividing cancer cells than the bone cells. These drugs are given in doses that do cause significantly toxicities, sometimes life-threatening toxicities, such as nerve damage, heart damage, and mucositis. Following administration of these agents, the patient might need one to three weeks to recover before they can receive another treatment. Because of the relatively infrequent or episodic administration, these drugs are applied by intravenous administration. Scientific advances cancer researchers are now working on are these so called targeted agents that try to find a mutation or something aberrant like a cancer cell and preferentially target those cells in contrast to normal cells. Many of these types of approaches require continuous exposure for the patient. Continuous exposure could be through intravenous administration or it could be through oral administration on a daily basis to have a continuous suppression of the cancer and easy for the patient to take.

Mr. Steinmetz pointed out that often a pharmaceutical developer has little choice in whether an agent is made into intravenous or oral. It depends on the properties of the molecule itself. As Ms. Kirk and Ms. Jones pointed out, there is a disparity in the way IV and oral agents are reimbursed by insurance companies. Intravenous agents are typically covered under a medical benefit, which could be a flat copay for the visit, or sometimes a coinsurance, often with no cap. Pharmacy benefits, typically for oral medications, can have in some cases coinsurance where you pay the dispenser of the drug with no cap at all. He stated that Ms. Kirk and Ms. Jones did a very nice job describing this.

He stated that this type of legislation has passed in a number of states. The question is in reality, what is the cost of parity. There are a number of considerations when calculating the cost of parity; including shifting of the out-of-pocket costs from the patient to the insurance plan and the potential for increased utilization of oral medications. If the out-of-pocket goes down, there will be more utilization. There is potential for less utilization of IV treatments if more oral therapies are used. There are costs associated with implementing these changes at the plan level.

Mr. Steinmetz discussed that GlaxoSmithKline commissioned Milliman, Inc. to author a white paper to help quantify the costs of parity in a commercial population. GSK provided the oncology and disease background information and Milliman designed the analysis, math and calculations by themselves. The findings from Milliman were that the costs of parity in general across the U.S. would be in the order of \$.50 per member per month for a typical commercial insurance plan. That is on the basis of over \$300 per member per month, so \$.50 divided by 300. But they also recognize that there are literally thousands of types of benefit plans that exist in the U.S. so they simulated a variety of plans, based on some with good coverage or oral or bad coverage, good coverage for IV, or bad coverage for IV, etc. What they found was for plans that already have good coverage for orals, the cost for parity would be relatively low, \$.05 to \$.10 per member per month. For the plans with poor coverage for oral, the cost would be closer to \$1.00 per member per month. These figures do not include administrative costs. These figures include elasticity, meaning as the cost to the patient goes down, they projected, included in these figures,

a higher utilization of oral agents. What was not included in these figures was, would there be less use of IV, and would there be savings.

Mr. Steinmetz stated that the final question is, what is the relative cost of IV and all anticancer drugs and the presenters before me did a nice job of laying that out. He went back and reviewed every anticancer drug that was approved by the Food and Drug Administration for the last ten years, from January 2000 to January 2010. There were 41 new molecules approved by the FDA for cancer for their first indications. Excluding medications given by other methods of administration and those removed from the market or that have gone generic, there were 31 agents left; 18 IV and 13 oral. He stated it is very difficult to compare the cost of an IV versus an oral because they are for different types of patients, different tumors, and different stages of disease. He looked at the average monthly cost of the 18 IV agents and those 13 oral agents and, with the caveat that it is very difficult with different indications, the bottom line is that the 18 IV agents' average monthly cost was more than \$12,000 per month, whereas the average monthly cost of the oral agents was \$5,700 per month. Mr. Steinmetz stated he hopes he has left participants with an appreciation of some of the advances in the treatment of cancer, moving to these targeted agents, and that he's shed a little bit of light on the cost of the therapies of both IV and oral as well as the analysis that was done by Milliman. He thanked the participants.

Questions from Panel

Question from Peter Beaton

Congratulations on getting that through the Oregon Legislature. Since the bill passed in 2008, is there any data on how the insurance companies have been impacted by the change?

Response from Heather Kirk

She stated she does not have any data on how they've been impacted. She knows how most of them have implemented it and that is by creating a new tier for these drugs rather than covering it under the major medical benefit or the prescription benefit. It's kind of its own entity, but apart from that, she doesn't know.

Question from Peter Beaton

Was the language the same as this bill?

Response from Heather Kirk

The language was very similar.

Question from Peter Beaton

Rather than making a change to put it under the medical benefit, they've created a new charging mechanism for these oral drugs?

Response from Heather Kirk

Yes, or a new tier.

Question from Peter Beaton

Do you know what the costs are that are associated with those? Is it a higher copay, a percentage?

Response from Heather Kirk

She stated she doesn't know, but she knows it creates the equality they were going for. One of the reasons why the insurance companies chose to handle it that way was because, the way they drafted the language to state no less favorable... for those with good prescription benefits to move oral chemo to the major medical benefit would have been detrimental for them. They are keeping it fair for everyone.

Question from Lauren Kiolet

Was there ever any concern raised that there might be other illnesses or diseases that would have similar situations and this might be opening up pandora's box? Did that question ever arise.

Response from Heather Kirk

It did a little bit. There might be others that fit, but she stated for them, there was such disparity between chemotherapy treatments, and they wanted to take one step at a time. For Ms. Kirk, when her family was hit with cancer, she stated she wanted to make sure chemotherapy coverage was handled fairly. That was the objective. She stated she has no doubt that at some point those things will probably have to be addressed too, but that was her priority to start with.

Question from Lauren Kiolet

You mentioned your personal experience with Regence, but were there other insurance companies that were less enthusiastic to look at this or was there any opposition?

Response from Heather Kirk

Not in Oregon. No one spoke out against it. She stated she doesn't know if that's because Oregon was the first state to do it, or whether it was just the right thing to do.

Question from Katie Golub

What is the status of the federal legislation?

Response from Heather Kirk

She didn't know. She hasn't checked lately. Occasionally she says she foes online to check it and it hasn't really moved. She hopes to get involved with that and contact the Congressman who initiated that but hasn't yet.

Question from Peter Beaton

On the federal level, do you know how people on social security or Medicaid or Medicare handle this issue with oral versus IV, this charge issue?

Response from Heather Kirk

Ms. Kirk did not know but asked if Ben could address that.

This legislation is really for the non self-insured, the ERISA population. Medicaid/Medicare is a really different reimbursement bailiwick. There are dramatic discounts provided in many cases to Medicaid. Medicare has Part A and Part B. It's rare to find an identical molecule in both IV and oral. They cover oral as if it's an IV in reality. It's very difficult to draw parallels.

Heather Kirk

Ms. Kirk stated she has copies of the bills that passed in other states if the panel would like to see the language.

Public Testimony

Lori Bielinski

Ms. Bielinski introduced herself as a 48 year old woman living in Tacoma who was diagnosed with breast cancer at age 39. Five months following her breast cancer diagnosis, she was given a diagnosis of cervical cancer, early stage. Six months after that, she was diagnosed with atypical hyperplasia for ovarian cancer. She stated she was a young cancer patient with a unique set of circumstances where even today, at age 48, she still has all of her female organs or at least parts of them. She stated that is pretty lucky considering she is still pre-menopausal.

Treating cancers involves the consideration of hormone receptors, depending if your cancer is hormone receptor positive or negative. In Ms. Bielinski's case they were all hormone receptor positive so the maintenance treatments were unique. There was careful consideration of the two mathematical equations for lowering the number for recurrence or raising your number for non-recurrence. She stated she feels very blessed with very good providers. They were considerate of all the circumstances she was facing and her desire to have the least effect of reaction or side-effects on her body to make her even sicker from the treatment than she was from the condition she was dealing with.

She stated when you are a patient with cancer, it's the worst thing you can hear. When you are trying to decide what's going to happen to you, you don't look at the categories of health insurance benefits, whether it's the percentage of the cost of the treatment you're going to pay, a copay, or a hospital percentage that is even higher than a regular coinsurance percentage. She stated she is a former insurance commissioner employee. She has worked in health policy, so she was cued to look particularly for investigational because at her age her oncologist wanted to use a prostate cancer drug on a breast cancer maintenance because the Tamoxifen wasn't doing its job. Ms. Bielinski said she told her doctor to stop and wait a month because she needed to find out if this was an investigational drug. If so, she didn't know if she could afford it. She was a single woman with a home who needed to make sure she could work and pay for her home and those things too. She stated she did her work with her insurer, Regence Blue Shield in Washington State and learned it was not an investigational drug and that it would be covered. She went about making appointments.

Once committed to the treatment, it would be a monthly injection for three years. It was the replacement of Tamoxifen for Ms. Bielinski. She stated she asked multiple times how much it would cost her and they thought it was around \$600 or \$700. To her, that meant an office copay visit, what she was told by her oncology office. The first day of my injections they walked her from the treatment room where she had her exam into a larger room and then into a private room where she received her injection, which took about four and a half minutes. She stated it was surprisingly quick and hurt like you-know-what.

She went back a month later, got her second injection, and asked again about cost. She still hadn't received a bill or explanation of benefits. The day after she received her second injection,

she received an explanation of benefits showing the drug was being bill at \$3,092 per injection and that it was a hospital visit, so she had to pay a hospital percentage instead of her copay. She stated she was certain there was an error on behalf of her clinic and called. After transferring her to three different people, they explained that it went through what's called "revenue enhancement," which she reacted dramatically to. No department should ever have anything called "revenue enhancement" and if you do, don't tell the patient. Ms. Bielinski finally got a call back from the manager of the oncology clinic who said since it is a chemotherapy drug, they have to bill it that way. She then called Regence Blue Shield and asked why it was being handled this way. She said she told them she had done her homework and was told it wasn't investigational. Now they were telling her it's chemotherapy so she's being billed a hospital visit, when she received the chemotherapy in her doctor's clinic.

This went on the two and a half of the three years she was on the drug. It was resolved after she refinanced her house twice to pay for treatment. The cost of the drug to the drug company, which was AstraZeneca, told her it was a \$90 drug. The average wholesale price of that drug is \$458. What Multicare was billing her insurance company was \$3,092. She said she did enough research to learn that the average wholesale cost of the drug is a reasonable expectation for her to have been billed. She hired a lawyer to try to negotiate with her insurer, who said they have to pay the \$3,092 because it's in their contract with the facility.

Ms. Bielinski stated that the reason she told this story is not that the injection was oral chemotherapy or injectable chemotherapy. She said the bottom line is she has a benefit handbook approved by the Office of the Insurance Commissioner. That is a law in this state. When she read her benefit handbook, she said she was alerted enough to ask about investigational drugs more than the average consumer would have. She just thought she had done her homework. She stated she would never have thought for a minute that going to the same clinic she had been going to for all her treatments would have resulted in \$300 per month out-of-pocket for her for three years to maintain her non-recurrence and to make sure her non-recurrence would be kept at a low percentage.

The perceived deception on behalf of a consumer when they are reading their handbook is that if you have cancer, it's covered. If you have to endure chemotherapy, you don't have to know if it's a pill or an injection or a soak. It's not your job to know that. It's your job to show up and fight the disease. If you pay an insurance premium, it's not your job to know how they're going to administer it. She stated it's her job to know she paid her premium on time and that it's a covered condition in her policy.

Ms. Bielinski stated she works in state government in the health care industry, not with cancer. She said she finds it interesting that the words mandate and cost per member per month are infected with the idea that it's going to cost everybody more money. Isn't it going to cost everybody more money if she's not covered? Isn't it going to cost everybody more money if she's not a productive consumer, when she was a minute ago, but because of application of a benefit plan she paid a lot of money for and thought would take care of her isn't doing its job? What happens to her as a productive consumer? She might not be working. She may now be out of work. She may lose her home. She stated there are all kinds of things that fall into that category. But in her case, Regence Blue Shield knew, and in the process renegotiated a new

contract and didn't fix the problem. They had two chances to fix it and they didn't fix it in her three years of treatment. They said it was acceptable practice. She stated she still thinks it's unacceptable practice. If insurance is not for catastrophic conditions, what is it for? In working in politics, in health care, Ms. Bielinski stated she was told every day that insurance would never, not cover cancer. That they would never, not cover chemotherapy. What difference does it make if it's a pill or an IV, except that if she takes a pill, it's less invasive to her, the one trying to survive? Is the greater out-of-pocket, the greater cost, really supposed to be to the person paying the premium? Or is it supposed to be to the entity accepting your premiums, whose job it is to manage the risk of the purchasers in the plan? She stated she doesn't think the risk is her job. Her job is to make sure she's not in a smoky room, eating healthy and exercising, and doing her medical regimen so that she can live. Her job is to make sure she's not costing them more money by making bad choices. When they mention costs and mandates and parity, she would suggest that having cancer is not fair. There is no parity in cancer. You shouldn't have to fight for the ability to be covered in a health plan that you've spent \$6,000 or \$8,000 per year on. From the day you are diagnosed with cancer ,every negotiation for a health policy benefit for her and her employees (she's a small business manager) costs more than the person who doesn't have cancer. That's not parity. She stated her risk means that her whole group, all four of her employees, pay more because she has cancer. She stated if she looks at a benefit handbook and sees that her chemotherapy is supposed to be covered and her cancer is supposed to be covered, she should expect that it is whether it's an injection or a soak or a pill.

Judith Lorbeir

Ms. Lorbeir stated she is a patient right now on chemotherapy and she had a dose this morning. She asked that we forgive her if she reads because she gets tired in the afternoon. This is testimony for oral chemotherapy drug parity, Senate Bill 5512. Ms. Lorbeir stated she retired from the City of Tacoma in January 2005 where she was the environmental coordinator and environmental lobbyist with the City of Tacoma. She retired early, and while the city employees have a fabulous insurance policy with Regence Blue Shield, she felt she could not afford to stay with the city's plan and so chose to enroll in an individual insurance plan with Regence Blue Shield. She pays \$422 per month for coverage.

In November 209, she was diagnosed with glioblastoma multiforme brain cancer. She had surgery to remove the tumor and began chemotherapy and radiation immediately. She was still with Regence Blue Shield on an individual plan, which covers most of her ongoing medical expenses, but no longer covers her prescriptions. The annual prescription coverage on her insurance plan has a \$3,000 deductible per year. Ms. Lorbeir stated she blew through that in the first two weeks of January. Additionally, she will pay \$8,000 in stop-gap insurance coverage and other miscellaneous medical charges which are not covered by her Regence plan.

The chemotherapy drug she's taking is called Temadair. She takes five days of pills every twenty-eight days. She will be on this drug for twelve months. In her case, the pills cost approximately \$3,100 every twenty-eight days out of her pocket, cash. She stated that oral chemotherapy is the standard of care for the first line of treatment for patients with brain cancer and other similar cancers. There is no other choice. Oral chemotherapy poses a tremendous financial burden on patients in the state of Washington because the insurance companies have chosen to cover certain forms as a prescription drug, not as chemotherapy treatment. In her case,

it is \$3,100 out of her pocket for the Temadar prescription every twenty-eight days. She will be taking this drug for a year in addition to the other medications and insurance expenses she has. These expenses were not part of her long-term retirement plan. She did not expect to have to spend her life savings to save my life.

There is a measure in Congress titled, Cancer Drug Coverage Parity Act. This Act aims to do what a few proactive states have already done and that is to level the playing field regarding parity for oral chemotherapy treatment. The State of Oregon, and congratulations to you because you did a really good job, was the first in the nation to pass a bill in 2007 which addresses the issue of parity in chemotherapy drugs. Washingtonians, however, are still being prescribed oral chemotherapy which their insurance companies treat as prescription drugs, not as treatment. The inequity of this practice and cost associated with it makes no sense.

Ms. Lorbeir stated she strongly recommends the State of Washington join Oregon and other states in making treatment more affordable, allowing patients like her to focus less on the fight to pay for treatment and more on the fight of this disease. Last week she stated she submitted some additional language for Senate Bill 5512 for consideration. She feels it clarifies and expands the language in the 2009 version of SB 5512. Here are her recommended changes:

Orally administered anticancer medications shall be considered medical benefits under all insurance policies and such policies shall cover orally-administered anticancer medications on the same basis as intravenously administered or injected anticancer medications that are covered as medical benefits.

No such policy shall reclassify such anticancer medications, whether orally administered, intravenously administered or injected, as other than medical benefits nor should the policy increase the coinsurance, copayment, deductible or other out-of-pocket expense imposed under such policies for such medications, to achieve compliance with the referenced RCW sections.

Wrap up

Kristi Weeks invited anyone else who wanted to speak to come forward. Nobody did so she wrapped up the hearing.

Next steps: There will be an additional ten-day written comment period, so if you think of anything when you get back to the office or back home that you forgot or would like to add, we will take those comments until 5:00 PM July 9.

Between July 9 and early September, we will be writing the draft report based on the proposal we received, comments we have received, and what we've heard today at the hearing. Once the draft report is written, we will send it out to everyone on our interested parties list. It will be truly draft form, so we will have another comment period.

Then we will submit the report to the Secretary of the Department of Health for approval in about October. Once the Secretary has approved the report, it is submitted to the Office of Financial Management for approval to be released to the Legislature. OFM provides policy and fiscal support to the Governor, Legislature, and state agencies. Once it has gotten everyone's

approval, it will be released to the Legislature. It is due to them by December 1. We have a pretty decent track record lately of getting them in on time and I am sure this one will be too. As soon as the final report is released to the Legislature, we will post it to our Web site and that will be the final form. That's all we have today. We look forward to hearing from you. Thank you again for your participation.

Signed in at Hearing in Support of Proposal (nobody signed in opposed)

Heather Kirk, applicant

Lori Bielinski

J. Fischer, representing GSK

J. Lorbeir

Jonathan Eames, representing Genentech

Erin Dziedzic, representing American Cancer Society

Carrie Glover, representing American Cancer Society

Attachment A – submitted by Heather Kirk for her presentation

**Out-of-Pocket Costs for 1 Year
Comparing Oral vs. Injection/Intravenous Chemotherapy**

	Type of Chemo	
	Oral ¹	Injection/Intravenous
Initial Diagnosis, Surgery & Radiation ²	\$4500	\$4500
Initial Round of Chemotherapy	\$5518	\$0
Chemo Jan 06	\$1715	\$0
Chemo Feb 06	\$1715	\$0
Chemo Mar 06	\$1715	\$0
Chemo Apr 06	\$1715	\$0
Chemo May 06	\$1715	\$0
Chemo June 06	\$1715	\$0
Chemo July 06	\$1715	\$0
Chemo Aug 06	\$1715	\$0
Chemo Sept 06	\$1715	\$0
Chemo Oct 06	\$1715	\$0
Chemo Nov 06	\$1715	\$0
Chemo Dec 06	\$1715	\$0
Total Out-of-Pocket Cost to Patient	\$30,598	\$4500

¹ Based on a prescription plan of 50% co-pay

² Based on a \$500 deductible and \$4000 out-of-pocket max requirement

Appendix F

Rebuttals to Draft Report

Rebuttals to Draft Report

My concerns with the report and the DOH recommendations:

1. The report seems to imply heavily that oral chemotherapy is more effective than IV chemo. It states several times that the choice of drug should be based on the “most effective treatment and not cost”. Defining most effective is difficult because there are very few head to head trials to compare the oral and chemo drugs. The head to head trials that are out there (and quoted by DOH) have not been reviewed by an evidence based practice center to grade the reliability of the results and can be very misleading to the legislature. This is also a slippery slope because some drugs may be marginally more effective (increase survival on average of 30 days) but cost 10 times more. Plans need to be able to use evidence based criteria to develop formularies and coverage criteria based on what the evidence says is the most **cost-effective therapy**.
2. DOH recommends that “...language should be added to ensure cost-sharing is not raised in order to comply [with the legislation]”. Regardless of how this legislation is implemented some changes in the cost-share structure is going to occur at some level. Also changes to the cost-sharing needs to be allowed to change over time as costs go up (i.e. annual plan design changes). I recommend that the plans be allowed to implement this legislation with cost-sharing options that would result in a “premium-neutral” benefit. Meaning that the overall premium would not change but the individuals cost-sharing for either IV or oral medications may change. After that annual changes would be allowed and the IV and oral drugs would need to be treated alike. Basically you cannot ensure that patients cost-sharing will not go up. If the plans costs go up then the premiums will be raised for all covered lives, not just the patients with cancer.

Donna L. Sullivan, Pharm.D., M.S.
Pharmacy Administrator
Washington State Health Care Authority &
Medicaid Purchasing Administration

On behalf of the International Myeloma Foundation (IMF), the oldest and largest myeloma foundation dedicated to improving the quality of life of myeloma patients while working toward prevention and a cure, I am writing to submit comments on the Oral Chemotherapy Drug Coverage Mandated Benefit Sunrise Review.

Myeloma is a cancer in the bone marrow affecting production of red cells, white cells, and stem cells. It is also called “multiple myeloma” because multiple areas of bone marrow may be involved. Myeloma is the second most common blood cancer after lymphomas. Each year, approximately 20,000 Americans are diagnosed with myeloma and 10,000 lose their battle with this disease. At any one time there are over 100,000 myeloma patients undergoing treatment for their disease in the U.S. Although incidence of many of cancers are decreasing, myeloma cases are increasing in incidence. Once a disease of the elderly, it is now being found in increasing

numbers in people under 65 and it is not uncommon to find patients in their thirties. Even while they live with the disease, myeloma patients can suffer debilitating fractures and other bone disorders, severe side effects of their treatment, and other problems that profoundly affect their quality of life, and significantly impact the cost of their health care.

In the last few years we have seen dramatic and important advances in treatments for multiple myeloma. However, the needless disparity in coverage between oral and intravenous chemotherapy drugs is a critical issue for many of our patients. The IMF believes patients and their doctors should be able to take advantage of the treatment that is best for the patient, and not have to select their treatment based on insurance coverage. IMF supports Senate Bill 5512 to eliminate these outdated cost inequities between oral and IV chemotherapy drugs that threaten patient care and quality of life. As you know from your analysis of the issue, affordability is a major barrier for myeloma patients when it comes to access for oral treatments and, as a result of this barrier, many patients may have to forego the optimal treatment as recommended by their physicians. We are encouraged that the Washington State Department of Health is now taking the necessary steps to correct this inequity in access to treatment for all cancer patients and we stand ready and willing to work with you to do so.

IMF agrees with the Department of Health that language should be added to the legislation to ensure cost-sharing is not raised in order for insurance companies to be in compliance. However, we are concerned that compliance with this legislation could lead to efforts to move cancer medications given intravenously from the medical benefit of the health plan to the pharmacy benefit. Many cancer medications in the pharmacy benefit are classified under the highest tier or under a specialty tier with high patient co-pays and many of these medications do not have generic equivalents. IMF is concerned that patients with high pharmacy co-pays or no access to a pharmacy benefit would not be able to afford their medication regardless of the delivery method. Therefore, IMF urges the Department to include language to ensure that this practice is not allowed in order to be in compliance with the legislation.

We also agree with the Department's assessment as well as with the Washington State Medical Oncology Society that the definition of anti-cancer medicines should be modified to ensure that biologic agents are also covered under the legislation. Biologic agents strengthen the patient's immune system to fight cancer and should be included in the definition as they also treat cancer.

We applaud your efforts and thank you for the opportunity to provide comments. Please do not hesitate to contact us should you have any questions or need more information.

David Girard, Executive Director
International Myeloma Foundation (IMF)