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CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Analysis of Senate Bill 961: Cancer Treatment

A Report to the 2009-2010 California Legislature
April 17, 2010

CHBRP 10-05



The California Health Benefits Review Program (CHBRP) responds to requests from the State Legislature to provide independent analyses of the medical, financial, and public health impacts of proposed health insurance benefit mandates and proposed repeals of health insurance benefit mandates. CHBRP was established in 2002 by statute (California Health and Safety Code, Section 127660, et seq). The program was reauthorized in 2006 and again in 2009. CHBRP's authorizing statute defines legislation proposing to mandate or proposing to repeal an existing health insurance benefit as a proposal that would mandate or repeal a requirement that a health care service plan or health insurer (1) permit covered individuals to obtain health care treatment or services from a particular type of health care provider; (2) offer or provide coverage for the screening, diagnosis, or treatment of a particular disease or condition; or (3) offer or provide coverage of a particular type of health care treatment or service, or of medical equipment, medical supplies, or drugs used in connection with a health care treatment or service.

A small analytic staff in the University of California's Office of the President supports a task force of faculty and staff from several campuses of the University of California, as well as Loma Linda University, the University of Southern California, and Stanford University, to complete each analysis within a 60-day period, usually before the Legislature begins formal consideration of a mandate or repeal bill. A certified, independent actuary helps estimate the financial impacts, and a strict conflict-of-interest policy ensures that the analyses are undertaken without financial or other interests that could bias the results. A National Advisory Council, drawn from experts from outside the state of California and designed to provide balanced representation among groups with an interest in health insurance benefit mandates or repeals, reviews draft studies to ensure their quality before they are transmitted to the Legislature. Each report summarizes scientific evidence relevant to the proposed mandate, or proposed mandate repeal, but does not make recommendations, deferring policy decision making to the Legislature. The State funds this work through a small annual assessment on health plans and insurers in California. All CHBRP reports and information about current requests from the California Legislature are available at the CHBRP Web site, www.chbrp.org.

A Report to the 2009-2010 California State Legislature

Analysis of Senate Bill 961: Cancer Treatment

April 17, 2010

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PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Senate Bill 961 (Wright), Cancer Treatment. In response to a request from the California Senate Committee on Health on February 19, 2010, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the program's authorizing statute. Janet Coffman, MPP, PhD, Edward Yelin, PhD, Wade Aubry, MD, Miki Hong, MPH, of the University of California, San Francisco, prepared the medical effectiveness analysis Bruce Abbott, MLS, of the University of California, Davis, conducted the literature search. Helen Halpin, PhD, ScM, and Sara McMenemy, PhD, MPH, both of the University of California, Berkeley, with Alexis Muñoz, MPH, of the University of California, San Diego, prepared the public health impact analysis. Ying-Ying Meng, DrPH, and Lori Uyeno, MD, both of the University of California, Los Angeles, prepared the cost impact analysis. Jay Ripps, FSA, MAAA, of Milliman, provided actuarial analysis. Deborah Schrag, MD, MPH, of the Dana-Farber Cancer Institute and Center and Debbie Stern, RPh, of Rxperts provided technical assistance with the literature review and expert input on the analytic approach. John Lewis, MPA, and Susan Philip, MPP, both of CHBRP staff prepared the background section and synthesized the individual sections into a single report. Cherie Wilkerson provided editing services. A subcommittee of CHBRP's National Advisory Council (see final pages of this report) and a member of the CHBRP Faculty Task Force, Kathleen Johnson, PharmD, MPH, PhD, of the University of Southern California, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

CHBRP gratefully acknowledges all of these contributions but assumes full responsibility for all of the report and its contents. Please direct any questions concerning this report to:

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Susan Philip, MPP
Director

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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Senate Bill 961

The California Senate Committee on Health requested on February 19, 2010, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Senate Bill (SB) 961, a bill which would impose a health benefit mandate limiting flat dollar copays for oral anticancer medications to 200% of the lowest copy charged for a brand name medication by a health care service plan or health insurer subject to regulation by the California Department of Managed Health Care or the California Department of Insurance, unless the coverage is purchased by the California Public Employees' Retirement System .

On March 23, 2010, the federal government enacted the federal “Patient Protection and Affordable Care Act” (P.L.111-148), which was amended by the “Health Care and Education Reconciliation Act” (H.R.4872) that the President signed into law on March 30, 2010. These laws (referred to as P.L. 111-148) came into effect after CHBRP received a request for analysis for SB 961. There are provisions in P.L.111-148 that go into effect by 2014, and beyond, that would dramatically affect the California health insurance market and its regulatory environment. For example, the law would establish state-based health insurance exchanges, with minimum benefit standards, for the small group and individual markets. How these provisions are implemented in California would largely depend on regulations to be promulgated by federal agencies, and statutory and regulatory actions to be undertaken by the California state government.

There are also provisions in P.L.111-148 that go into effect within the short term or within 6 months of enactment that would expand the number of Californians obtaining health insurance and their sources of health insurance. For example, one provision would allow children to enroll onto their parent’s health plan or policy until they turn 26 years of age (effective 6 months following enactment). This may decrease the number of uninsured and/or potentially shift those enrolled with individually purchased insurance to group purchased insurance. These and other short term provisions would affect CHBRP’s *baseline* estimates of the number and source of health insurance for Californians in 2010. Given the uncertainty surrounding implementation of these provisions and given that P.L.111-148 was only recently enacted, the potential effects of these short-term provisions are not taken into account in the baseline estimates presented in this report. It is important to note that CHBRP’s analysis of specific mandate bills typically addresses the *marginal* effects of the mandate bill—specifically how the state mandate would impact coverage, utilization, costs, and the public health, holding all other factors constant. CHBRP’s estimates of these marginal effects continue to be relevant for the 12 months that would follow implementation of the mandate.

Approximately 19.5 million Californians (51%) have health insurance that may be subject to a health benefit mandate law passed at the state level (CHBRP, 2010). Of the rest of the population, a portion is uninsured, and therefore not affected by health insurance benefit mandate laws. Others have health insurance not subject to health insurance benefit mandate laws. Uniquely, California has a bifurcated system of regulation for health insurance subject to state

law. The California Department of Managed Health Care (DMHC)¹ regulates health care service plans, which offer coverage for benefits to their enrollees through health plan contracts. The California Department of Insurance (CDI) regulates health insurers², which offer coverage for benefits to their enrollees through health insurance policies. SB 961 would place requirements on DMHC-regulated health plan contracts and CDI-regulated policies—unless purchased by the California Public Employees' Retirement System (CalPERS). Therefore, approximately 18.7 million Californians (49%) have health insurance that would be subject to SB 961.

SB 961 would require that plans and policies that provide “coverage for orally administered cancer medications used to kill or slow the growth of cancerous cells...not charge a co-payment for these drugs in excess of 200% of the lowest co-payment required by the plan [/policy] for brand name medications in the plans' [/policies'] formulary.” Therefore, the bill would (on a policy-by-policy and plan contract-by-plan contract basis) limit flat dollar copays for oral anticancer medications.

This analysis assumes that the bill would affect flat dollar copays and not other forms of cost sharing. Copayments (copays) are generally defined by health plans, health insurers, DMHC, and CDI as flat dollar amounts an enrollee pays, out-of-pocket, at the time of receiving a health care service or when paying for a prescription (after any applicable deductible).

Although this analysis assumes the mandate would affect only flat dollar copays and no other form of cost sharing, the term *co-payment* is not defined in SB 961 and could, potentially, be interpreted as encompassing other forms of cost sharing.

For the purposes of this analysis, CHBRP also assumes that the cost sharing provisions current in plan contracts and policies would remain constant, so that the percentage of enrollees with coverage for oral anticancer medications subject to flat dollar copays would remain stable. However, it is possible that plans and policies could respond by increasing the percentage of enrollees whose benefit coverage is subject to coinsurance (and so not affected by the mandate).

Prescription medications may be covered through an enrollee's medical benefits or through an outpatient pharmacy benefit, if the enrollee's plan contract or policy includes an outpatient pharmacy benefit. Medications consumed during an inpatient hospital stay are generally covered by an enrollee's medical benefit. Similarly, medications consumed during a visit to a provider's office, as are many injected and intravenous anticancer medications, may be covered by an enrollee's medical benefit. However, because oral anticancer medications are typically covered through an outpatient pharmacy benefit and not through a medical benefit, this analysis focuses on oral anticancer medications covered through outpatient pharmacy benefits.

It is important to note that cost sharing arrangements found in health insurance in California differ from what is present in other states or available nationally. These differences may alter the

¹ DMHC was established in 2000 to enforce the provisions of the Knox-Keene Health Care Service Plan of 1975, see Health and Safety Code, Section 1340.

² CDI licenses “disability insurers.” Disability insurers may offer forms of insurance that are not health insurance. This report considers only the impact of the benefit mandate on health insurance policies, as defined in Insurance Code, Section 106(b) or subdivision (a) of Section 10198.6.

impact SB 961 could have in California, as opposed to the impact similar legislation could have elsewhere. For Californians with employer-based health insurance, flat dollar copays are more common, and four-tier structures for pharmaceutical benefit cost sharing (where cost sharing for fourth tier “specialty drugs” may be significantly higher) are less common (CHCF, 2009). For these reasons, many Californians may not be exposed to the high levels of cost sharing for oral anticancer medications (either through coinsurance or through fourth tier copays) that have been reported in other states. Furthermore, approximately 87% of enrollees who have health insurance that would be subject to SB 961 are enrolled in DMHC-regulated plans. DMHC reviews proposed cost sharing arrangements and requires that benefits not be subject to “exclusion, exception, reduction, deductible, or copayment that renders the benefit illusory.”³ For example, for outpatient prescription drug benefits, DMHC limits cost sharing to 50% of the cost of the drug to the plan, and specifies how such costs are to be calculated.⁴

No current California mandate requires coverage of prescription medications, and no mandates currently specify the terms of copays for oral anticancer medications, although DMHC, as noted above, limits cost sharing for all prescription drug benefits.

Although five other states have mandates relating to cost sharing for oral anticancer medications, none is equivalent to SB 961.

Medical Effectiveness

Analysis approach: SB 961 would apply to such a large number of oral anticancer medications for such a wide range of cancers that a systematic review of the literature on the effectiveness of all of them was not feasible for this analysis. Instead, CHBRP summarized general, descriptive information about these medications.

- All oral anticancer medications must be approved by the U.S. Food and Drug Administration (FDA) before they can be marketed or sold in the United States.
- To date, the FDA has approved 40 oral anticancer medications that are used to treat 54 different types of cancer.
- Oral anticancer medications have been available for decades, but the number of such medications has grown dramatically over the past decade, and more oral anticancer medications are being developed. Approximately 100 oral anticancer medications are currently under development.
- Only 11 of the 40 oral anticancer medications approved by the FDA have intravenously-administered or injectable substitutes.

³ Health and Safety Code Section 1367, California Code of Regulations Title 28 § 1300.67.4

⁴ California Code of Regulations Title 28 § 1300.67.24

- Only 9 of the oral anticancer medications approved by the FDA have generic equivalents. However, CHBRP estimates that one medication for which there is a generic equivalent—tamoxifen—will account for 24.1% of prescriptions for oral anticancer medications filled in California in 2010.
- Oral anticancer medications can be divided into three main types of medications: cytotoxic agents, targeted agents, and endocrine agents.
- Oral anticancer medications are used alone or in combination with other oral, intravenously administered, or injected anticancer medications, depending on the cancer they are being used to treat and the stage at which the cancer is diagnosed.
- The roles of oral anticancer medications in cancer treatment vary and include:
 - Presurgical treatment
 - Postsurgical treatment
 - Concurrent treatment with radiation
 - First-line treatment to kill or retard the growth of cancer cells
 - Second-line treatment of cancers that do not respond to first-line treatments
 - Treatment of early stage cancers
 - Treatment of advanced or metastatic cancers
 - Treatment of recurrent cancers
 - Treatment of cancers that cannot be surgically removed
 - Prevention of cancer recurrence in persons treated for early stage disease
- The outcome of cancer treatment varies with the stage at which cancer is diagnosed.
 - For early stage cancers, use of oral anticancer agents and other treatments can enable a person to live cancer free for many years.
 - For advanced and metastatic cancers, treatment often cannot reverse the disease and may only prolong life for a few months.

Utilization, Cost, and Coverage Impacts

CHBRP modeled the financial impact of the mandate as a shift in cost sharing related to enrollee copayments for brand name oral anticancer medications covered through outpatient pharmacy benefits, and not other benefits under which anticancer medications could be covered (e.g., medical benefits that could cover oral anticancer medications delivered during inpatient care or at a providers' office). For this analysis, CHBRP compared the lowest copay paid for any brand

name medication by enrollees in the plan or policy in which the patient was enrolled (the “benchmark copay”) with copays paid for brand name oral anticancer medications. CHBRP focused on brand name oral anticancer medications because generic oral anticancer medications are usually subject to copays that would not exceed the relevant benchmark. CHBRP then assumed, postmandate, that amounts exceeding 200% of the relevant benchmark copay would shift from patients to health plans and insurers. Statewide, this analysis estimated a decrease of \$29,000 in out-of-pocket expenses for those cancer patients.

Table 1 summarizes the estimated benefit coverage, utilization, and cost impacts of SB 961.

Benefit Coverage

Premandate, CHBRP estimates that 97.3% of enrollees with health insurance subject to the mandate (18,170,000 people) have coverage for outpatient pharmacy benefits (including coverage for oral anticancer medications). The details for enrollees with outpatient pharmacy benefit coverage are as follows:

- 82.1% (15,331,000 people) have benefit coverage subject to flat dollar copays. Some may also be subject to additional cost sharing requirements, such as deductibles or annual/lifetime caps.
- 10.4% have benefit coverage subject to cost sharing other than flat dollar copays, such as coinsurance. Some may also be subject to additional cost sharing requirements, such as deductibles or annual/lifetime caps.
- 2.3% have benefit coverage not subject to any cost sharing.
- 2.4% have benefit coverage for generic medications only.

CHBRP estimates that 15,331,000 enrollees with coverage for brand name and generic oral anticancer medications through an outpatient pharmacy benefit subject to flat dollar copays could be affected by this mandate. The figure is smaller than the number of enrollees with health insurance subject to the mandate for three reasons. A portion of the enrollees (10.4%) have benefit coverage subject to cost sharing other than flat dollar copays, and so would not be affected. A portion of the enrollees have benefit coverage with no cost sharing, and so would not be affected by the mandate. A portion of the enrollees have benefit coverage only for generic medications, and so the mandate could not be applied because the plan or policy does not cover brand name medications and has no “lowest co-payment required by the plan [/policy] for brand name medications in the plans’ [policy’s] formulary.” Without a lowest copay for a brand name medication, there is no benchmark that such a plan could exceed.

Utilization

- For enrollees with health insurance subject to the mandate, CHBRP estimates
 - 4.2 enrollees per 1,000 enrollees use outpatient oral anticancer medications during a year.

- 3.4 enrollees per 1,000 enrollees use brand name oral anticancer medications that are subject to copays during a year.
- CHBRP estimates no measurable increase in the number of oral anticancer medication users and no measurable increase in the number of prescriptions per user because:
 - The mandate will not change the number of enrollees with coverage for oral anticancer medications.
 - Although CHBRP estimates that the mandate will reduce patients' average copays by about \$0.20 per prescription (from \$16.78 to \$16.58) for brand name oral anticancer medications that are subject to flat dollar copays, the price elasticity of demand⁵ for anticancer medications is relatively small in comparison to the price elasticity for many other medications. Cancer is a life-threatening illness; consequently, patients will generally comply with prescribed treatment regimens.
 - Oncologists' prescribing decisions seem unlikely to change, as there is little evidence that oncologists base their decisions on the small differences in patient cost sharing requirements estimated by CHBRP for SB 961.

Cost

- The major impact of the mandate would be to shift some oral anticancer medication costs from patients to health plans and insurers. The average amount of the shift is estimated to be \$0.20 per prescription for covered brand name oral anticancer medications subject to copays. It is important, however, to be aware of two factors. First, there are covered generic as well as brand name oral anticancer medications (even though no reduction in copays for generics is projected). Second, coverage for prescriptions may be subject to additional cost sharing, such as a deductible, or may be subject to a different form of cost sharing, such as coinsurance, and SB 961 would not impact forms of cost sharing other than copays. Therefore, the average cost shift per prescription (inclusive of brand and generic medications and all forms of cost sharing) for all oral anticancer medication users would be \$0.09 per prescription.
- If the mandate were enacted, CHBRP estimates that approximately \$29,000 in out-of-pocket expenses would shift from patients to health plans and insurers due to lower enrollee copays.
- Less than 1% of enrollees with outpatient pharmacy benefit coverage for both brand name and generic oral anticancer medications that are subject to copays have copays of \$50 and above per prescription.
- Postmandate flat dollar copay amounts shifted from patients to plans and insurers would range from \$0 to \$65 per prescription.
- Statewide, total net annual health care expenditures by all enrollees (not just enrollees who have been diagnosed with cancer) subject to this mandate are estimated to increase by a very

⁵ Price elasticity of demand shows how the quantity demanded or supplied will change when the price changes.

small amount (\$3,000) The increase would be mainly due to the administrative costs associated with the implementation of SB 961.

- The mandate is estimated to increase premiums as follows:
 - Statewide, total health insurance premiums paid by private employers are estimated to increase by approximately \$24,000, or 0.0001%.
 - Statewide, enrollee contributions toward premiums for group health insurance regulated by DMHC or CDI are estimated to increase by approximately \$6,000.
 - Statewide, total premiums paid by purchasers of individual market health insurance are estimated to increase by approximately \$2,000.
- DMHC-regulated health plan contracts purchased by the California Department of Health Care Services (DHCS) for Medi-Cal health maintenance organization (HMO) enrollees and by the Managed Risk Medical Insurance Board (MRMIB) for beneficiaries of the Healthy Families program would not be expected to see any patient expenses or premium increases because current coverage provided for oral anticancer medication is in compliance with the mandate.

Public Health Impacts

- SB 961 is not expected to affect utilization of oral anticancer medications; therefore, no impacts on health outcomes are expected.
- For cancer patients enrolled in DMHC-regulated health plans or CDI-regulated policies (excluding enrollees in CalPERS HMOs), SB 961 will decrease patient out-of-pocket costs for oral anticancer medications by an average of \$0.20 per brand prescription for users with flat dollar copays. Compared to the other forms of cost sharing these cancer patients may face, including deductibles and/or annual/lifetime caps, and other financial burdens facing cancer patients, such as lost wages, these savings represent a small part of their total financial burden.
- Two-thirds of the prescriptions written for oral anticancer medications are written for medications used to treat breast cancer. In general, out-of-pocket expenditures and lost income for women with breast cancer can be significant. However, SB 961 would have little to no effect on these financial burdens.
- Although cancer is a substantial cause of premature mortality in California, SB 961 is not estimated to change the utilization of oral anticancer medications or result in a corresponding reduction in the premature death or economic loss associated with cancer.

Table 1. SB 961 Impacts on Benefit Coverage, Utilization, and Cost, 2010

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Benefit Coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	19,487,000	19,487,000	0	0%
Total enrollees with health insurance subject to SB 961	18,667,000	18,667,000	0	0%
Percentage of enrollees with coverage of outpatient pharmacy benefits for oral anticancer medications	97.3%	97.3%	0.0%	0%
Coverage for brand & generic medications with flat dollar copays (b)	82.1%	82.1%	0.0%	0%
All other coverages	15.2%	15.2%	0.0%	0%
Percentage of enrollees without coverage of outpatient pharmacy benefits for oral anticancer medications	2.7%	2.7%	0.0%	0%
Number of enrollees with coverage of outpatient pharmacy benefits for oral anticancer medications	18,170,000	18,170,000	0	0%
Coverage for brand & generic medications with flat dollar copays	15,331,000	15,331,000	0	0%
All other coverages	2,839,000	2,839,000	0	0%
Number of enrollees without coverage of outpatient pharmacy benefits for oral anticancer medications	497,000	497,000	0	0%
Utilization and Cost				
Users of outpatient pharmacy benefits for oral anticancer medications per 1,000 enrollees per year	4.2	4.2	0.0	0%
Users of outpatient pharmacy benefits for oral anticancer medications per 1,000 enrollees per year subject to flat dollar copays	3.4	3.4	0.0	0%
Outpatient pharmacy oral anticancer medication prescriptions per 1,000 oral anticancer medication users per year	5,146.6	5,146.6	0.0	0%
Outpatient pharmacy brand name oral anticancer medication prescriptions per 1,000 oral anticancer medication users per year	2,868.4	2,868.4	0.0	0%
Average cost per prescription of oral anticancer medications	\$853.13	\$853.13	\$0.00	0%
To health plans/insurers	\$830.11	\$830.20	\$0.09	0%
To oral anticancer medication users	\$23.02	\$22.93	-\$0.09	0%
Average copay per prescription for brand name oral anticancer medication, for users subject to flat dollar copays	\$16.78	\$16.58	-\$0.20	-1%

Table 1. SB 961 Impacts on Benefit Coverage, Utilization, and Cost, 2010 (Cont'd)

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Expenditures				
Premium expenditures by private employers for group insurance	\$43,519,324,000	\$43,519,348,000	\$24,000	0.0001%
Premium expenditures for individually purchased insurance	\$5,992,795,000	\$5,992,797,000	\$2,000	0.0000%
Premium expenditures by persons with group insurance, CalPERS HMOs, Healthy Families Program, AIM, or MRMIP (c)	\$12,820,614,000	\$12,820,620,000	\$6,000	0.0000%
CalPERS HMOs employer expenditures (d)	\$3,267,842,000	\$3,267,842,000	\$0	0.0000%
Medi-Cal HMOs state expenditures	\$4,015,596,000	\$4,015,596,000	\$0	0.0000%
Healthy Families state expenditures (e)	\$910,306,000	\$910,306,000	\$0	0.0000%
Enrollee out-of-pocket expenses for covered benefits (deductibles, copayments, etc.)	\$5,961,186,000	\$5,961,157,000	-\$29,000	-0.0005%
Enrollee expenses for noncovered benefits	\$5,365,000	\$5,365,000	\$0	0%
Total Annual Expenditures	\$76,493,028,000	\$76,493,031,000	\$3,000	0.0000%

Source: California Health Benefits Review Program, 2010.

Notes: (a) This population includes enrollees insured with private funds as well as enrollees with health insurance purchased with public funds (e.g., CalPERS HMOs, Medi-Cal HMOs, Healthy Families Program, AIM, MRMIP) enrolled in health plans and policies regulated by DMHC or CDI. Population includes enrollees aged 0-64 years and enrollees 65 years or older covered by employment sponsored insurance.

(b) Approximately 24,000 of these enrollees have a limited outpatient pharmacy benefit which includes oral anticancer medications, but excludes many other medications (such as pain medications) which are usually covered by an outpatient pharmacy benefit.

(c) Premium expenditures by enrollees include employee contributions to employer-sponsored health insurance and beneficiary contributions for health insurance that is purchased by a public program.

(d) Because SB 961 exempts CalPERS, the program would have no employer expenditures. Were it not exempted, about 58% would be state expenditures for CalPERS HMO enrollees who are state employees.

(e) Healthy Families Program state expenditures include expenditures for 7,000 beneficiaries enrolled in MRMIP and 7,000 beneficiaries enrolled in the AIM program.

Key: AIM=Access for Infants and Mothers; CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health Care.

INTRODUCTION

The California Senate Committee on Health requested on February 19th, 2010, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Senate Bill (SB) 961, a bill that would impose a health benefit mandate. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.

Potential Effects of Health Care Reform

On March 23, 2010, the federal government enacted the federal "Patient Protection and Affordable Care Act" (P.L.111-148), which was further amended by the "Health Care and Education Reconciliation Act" (H.R.4872) that the President signed into law on March 30, 2010. These laws (referred to as "P.L.111-148") came into effect after CHBRP received a request for analysis for SB 961.

There are provisions in P.L.111-148 that go into effect by 2014, and beyond, that would dramatically affect the California health insurance market and its regulatory environment. These major long-term provisions of P.L.111-148 would require that most U.S. citizens and qualified legal resident have health insurance and that large employers offer health insurance coverage or a tax-free credit to their employees. It would establish state-based health insurance exchanges, with minimum benefit standards, for the small group and individual markets. Subsidies for low-income individuals would be available to purchase into the exchanges. How these provisions are implemented in California would largely depend on regulations to be promulgated by federal agencies, and statutory and regulatory actions to be undertaken by the California state government.

There are also short-term provisions in P.L.111-148 that go into effect within 6 months or less of enactment that would expand the number of Californians obtaining health insurance and their sources of health insurance. For example:

- Children and young adults up to age 26 years of age would be allowed to enroll onto their parent's health plan or policy (effective 6 months following enactment). This provision may decrease the number of uninsured and/or potentially shift those enrolled with individually purchased insurance to group purchased insurance.
- A temporary high-risk pool for those with preexisting conditions would be established (effective 90 days following enactment). How California chooses to implement this provision would have implications for health insurance coverage for those high-risk individuals who are currently without health insurance and/or are on California's Major Risk Medical Insurance Plan (MRMIP).

These and other short term provisions would affect CHBRP's *baseline* estimates of the number and source of health insurance for Californians and corresponding total costs for 2010. Given the

uncertainty surrounding implementation of these provisions and given that P.L.111-148 was only recently enacted, the potential effects of these short-term provisions are not taken into account in the baseline estimates presented in this report. It is important to note that CHBRP's analysis of specific mandate bills typically address the *marginal* effects of the mandate bill—specifically, how the state mandate would impact coverage, utilization, costs, and public health, holding all other factors constant. CHBRP's estimates of these marginal effects continue to be relevant for the 12 months that would follow implementation of the mandate.

Approximately 19.5 million Californians (51%) have health insurance that may be subject to a health benefit mandate law passed at the state level (CHBRP, 2010). Of the rest of the population, a portion is uninsured, and therefore not affected by health insurance benefit mandate laws. Others have health insurance not subject to health insurance benefit mandate laws. Uniquely, California has a bifurcated system of regulation for health insurance subject to state law. The California Department of Managed Health Care (DMHC)⁶ regulates health care service plans, which offer coverage for benefits to their enrollees through health plan contracts. The California Department of Insurance (CDI) regulates health insurers⁷, which offer coverage for benefits to their enrollees through health insurance policies.

SB 961 would place requirements on DMHC-regulated health plan contracts and CDI-regulated policies—unless purchased by the California Public Employees' Retirement System (CalPERS). Therefore, approximately 18.7 million Californians (49%) have health insurance that would be subject to the mandate.

Bill Language

The full text of SB 161 can be found in Appendix A of this report.

SB 961 would require that plans and policies that provide “coverage for orally administered cancer medications used to kill or slow the growth of cancerous cells...not charge a co-payment for these drugs in excess of 200% of the lowest co-payment required by the plan [/policy] for brand name medications in the plans' [/policies'] formulary.” Therefore, the bill would (on a policy-by-policy and plan contract-by-plan contract basis) limit flat dollar copays for oral anticancer medications.

In DMHC regulations, the term *copayment* is used alongside the terms *coinsurance* and *deductible* and so can be assumed to be independent of them,⁸ which supports the assumption, described below, that the bill would affect only flat dollar copays and not other forms of cost sharing such as coinsurance. CDI's Web site also lists copayments as separate from coinsurance

⁶ DMHC was established in 2000 to enforce the provisions of the Knox-Keene Health Care Service Plan of 1975, see Health and Safety Code, Section 1340.

⁷ CDI licenses “disability insurers.” Disability insurers may offer forms of insurance that are not health insurance. This report considers only the impact of the benefit mandate on health insurance policies, as defined in Insurance Code, Section 106(b) or subdivision (a) of Section 10198.6.

⁸ Personal communication, Sherrie Lowenstein, DMHC, March 2010.

(CDI, 2010), as do the evidence of coverage (EOC) documents provided to enrollees by many plans and insurers.

Although this analysis assumes the mandate would affect only flat dollar copays and no other form of cost sharing, the term *co-payment* is not defined in SB 961 and could, potentially, be interpreted as encompassing other forms of cost sharing.

Cost sharing is a requirement by health plans or health insurers that enrollees pay some portion of health care expenses. Cost sharing may take many forms, such as copayments, coinsurance, deductibles, and caps. Copayments (copays) are flat dollar amounts an enrollee pays, out-of-pocket, at the time of receiving a health care service or when paying for a prescription (after any applicable deductible). In such cases, a person may pay \$10, \$40, or whatever amount his or her plan contract or policy requires, per prescription. Coinsurance is the percentage of covered health care costs for which an enrollee may be responsible. In such cases, a person may pay 15%, 20%, or whatever amount his or her plan contract or policy specifies, per prescription. A deductible is the fixed dollar amount an enrollee is required to pay out-of-pocket within a given time period (usually a year) before reimbursement begins for eligible health care services. Caps are fixed dollar limits within a given time period (usually a year or a lifetime) beyond which the enrollee is responsible for further expenses. A single enrollee may be subject to any, all, or none of these cost-sharing requirements, depending upon the terms of the plan contract or policy in which he or she is enrolled. There are a variety of cost-sharing provisions currently used in California, so cancer patients are subject to a variety of cost-sharing requirements for oral anticancer medications.

It is important to note that cost-sharing arrangements found in health insurance in California differ from what is present in other states or available nationally. These differences may alter the impact SB 961 could have in California, as opposed to the impact similar legislation could have elsewhere. For Californians with employer-based health insurance, flat dollar copays are more common, and four-tier structures for outpatient pharmacy benefit cost-sharing are less common (CHCF, 2009). For costly medications, flat dollar copays frequently result in less patient out-of-pocket expenses than do other forms of cost sharing, such as coinsurance. *Tiers* are terms used to indicate variation in copay (or other cost sharing) that is based on the drug that is being covered, the lower tiers usually being less costly to both the enrollee and to the health plan or insurer. In outpatient pharmacy benefits, a two-tier system would usually separate generic from brand name medications, and a three-tier system would further divide brand name medications into “preferred” and “not preferred,” the latter being the third tier. When a system includes a fourth tier, the fourth tier includes “specialty drugs,” which are typically very costly. In a four-tier system, many of the more expensive oral anticancer medications would be “fourth tier” and so subject to significantly higher cost sharing requirements. For costly medications, a four-tier structure for an outpatient pharmacy benefit frequently results in greater patient out-of-pocket expenses. For the reasons listed, many Californians may not be exposed to the high levels of cost sharing for oral anticancer medications that have been reported in other states. Therefore, incidents of high cost sharing for oral anticancer medications reported in the national media should be much less common in California. A recent study of national health care costs supports this conclusion, finding that Californians have the lowest percentage of insured persons with a high financial burden (Cunningham, 2010). Furthermore, approximately 87% of enrollees who

have health insurance that would be subject to SB 961 are enrolled in DMHC-regulated plans. DMHC reviews proposed cost-sharing arrangements and requires that benefits not be subject to “exclusion, exception, reduction, deductible, or copayment that renders the benefit illusory.”⁹ For example, for outpatient prescription drug benefits, DMHC limits cost sharing to 50% of the cost of the drug to the plan, and specifies how such costs are to be calculated.¹⁰

Analytic Approach and Key Assumptions

This analysis assumes the bill would limit flat dollar copays for oral anticancer medications and that the impact would vary between plan contracts and between policies.

Because the bill specifies “medications used to kill or slow the growth of cancerous cells,” this analysis assumes it would not limit copays for other medications (antipain, antinausea, etc.) that a cancer patient might use during the course of chemotherapy.

Because the bill specifies copays, this analysis assumes the bill would not limit or affect any other form of cost sharing. Therefore, this analysis assumes the bill would not affect other forms of enrollee cost sharing (e.g., coinsurance, deductibles, annual caps, or lifetime caps) which might also have an impact on an enrollee’s out-of-pocket expenses for oral anticancer medications.

Prescription medications may be covered through an enrollee’s medical benefits or through an outpatient pharmacy benefit (McDonald, 2008), if the enrollee’s plan contract or policy includes an outpatient pharmacy benefit. Medications consumed during an inpatient hospital stay are generally covered by an enrollee’s medical benefit. Similarly, medications consumed during a visit to a provider’s office, as are many injected and intravenous anticancer medications, may be covered by an enrollee’s medical benefit. However, because oral anticancer medications are typically covered through an outpatient pharmacy benefit and not through a medical benefit, this analysis focuses on oral anticancer medications covered through outpatient pharmacy benefits.

Because the bill references the “lowest co-payment required by the plan [/policy] for a brand name medication,” this analysis projects that impacts would vary for enrollees between plan contracts and between policies. Depending on the terms of an enrollee’s plan contract or policy, cost sharing might not be affected at all, or the impact might be more or less than the impact experienced by an enrollee in another plan contract or policy. For example, an enrollee with no cost sharing would see no change; an enrollee with no copay more than 200% of lowest brand name copay would see no change; an enrollee with a \$15 lowest copay for a brand name drug would see copays for oral anticancer medications be no more than \$30; an enrollee with a \$30 lowest copay for a brand name drug would see copays for oral anticancer medications limited to \$60; an enrollee with coinsurance, but no copays, would see no change; and any of these enrollees might have deductibles or caps that could affect the final share of costs that she or he might be required to pay.

⁹ Health and Safety Code Section 1367, California Code of Regulations Title 28 § 1300.67.4

¹⁰ California Code of Regulations Title 28 § 1300.67.24

For the purposes of this analysis, CHBRP also assumes that the cost sharing provisions current in plan contracts and policies would remain constant, so that the percentage of enrollees with coverage for oral anticancer medications subject to flat dollar copays would remain stable. However, it is possible that plans and policies could respond by increasing the percentage of enrollees whose benefit coverage is subject to coinsurance (and so not be affected by the mandate).

Existing California Requirements

No current California mandate requires coverage of prescription medications, and no mandates currently specify the terms of cost sharing provisions for oral anticancer medications. However, a number of mandates impact coverage of prescription medications, and DMHC reviews proposed cost-sharing arrangements and requires that benefits not be subject to “exclusion, exception, reduction, deductible, or copayment that renders the benefit illusory.”¹¹ For example, for outpatient prescription drug benefits, DMHC limits cost sharing to 50% of the cost of the drug to the plan, and specifies how such costs are to be calculated.¹² The health insurance benefit mandates that might interact with SB 961 are listed below, by Health and Safety Code (H&S), and Insurance Code (IC), where applicable.

H&S1367.21/IC10123.195 prescription drugs: off-label use

Mandate to cover “off-label” uses of FDA-approved drugs—uses other than the specific FDA-approved use—in life-threatening situations and, in cases of chronic and seriously debilitating conditions, when a set of specified provisions regarding evidence are met.

H&S 1367.22 prescription drugs: coverage of previously covered drugs; medically appropriate alternatives

Mandate to cover prescription drugs if the drug previously had been approved for coverage by the plan for a medical condition of the enrollee and the plan’s prescribing provider continues to prescribe the drug for the medical condition, provided that the drug is appropriately prescribed and is considered safe and effective for treating the enrollee’s medical condition.

H&S 1367.6/IC 10123.8 breast cancer benefits

Mandate to provide coverage for screening for, diagnosis of, and treatment for breast cancer.

H&S 1367.24 authorization for nonformulary prescription drugs

Mandate to review coverage for non-formulary drugs.

Requirements in Other States

Although five states have mandates related to cost sharing for oral anticancer medications, none is equivalent to SB 961 (BCBSA, 2009). Oregon passed the first such law in 2007, mandating

¹¹ Health and Safety Code Section 1367, California Code of Regulations Title 28 § 1300.67.4

¹² California Code of Regulations Title 28 § 1300.67.24

that plans that provide coverage for cancer chemotherapy treatment cover “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 medications.¹³ Vermont’s statutory language is similar, but specifies that coverage be no less favorable “on a financial basis.”¹⁴ Indiana law states that coverage for prescribed, orally administered chemotherapy used to kill or slow the growth of cancer “must not be subject to dollar limits, copayments, deductibles, or coinsurance provisions that are less favorable to an insured” than those that apply to coverage for intravenously injected medications.¹⁵ Iowa prohibits plans and insurers from “discriminate[ing] between coverage benefits” for prescribed, orally administered anticancer medication and covered intravenous-administered/injected medications “regardless of formulation or benefit category,” and applies the same “kill or slow” definition for oral medications.¹⁶ Hawaii requires equal coinsurance percentage or copayment amounts for medically necessary chemotherapy across both orally and intravenously administered forms, statutorily defining the two forms—both as physician-prescribed cancer treatment—and additionally delineating “oral chemotherapy” as FDA-approved.¹⁷ None of these laws is limited to copays, and none uses the lowest copay for a brand name drug as the basis of a limit.

Background of the Disease or Condition

Nearly one in two Californians born today will develop cancer at some point in their lifetime (CCR, 2009). There are an estimated 134,000 cases of cancer diagnosed each year, while approximately 1.2 million Californians alive today have a history with the disease (CCR, 2009). It is estimated that 45% of cancer cases occur in the non-elderly population—i.e., the population most relevant to SB 961 (CCR, 2009). Nearly one-quarter of deaths in California result from cancer, with approximately 55,000 deaths each year (CCR, 2009). Early diagnoses, through population-based screening, as well as advances in cancer treatment, have greatly improved survival rates of cancer patients. In California, the relative 5-year survival rate from all cancers is 64% (CCR, 2009).

The treatment options for cancer depend on the type of cancer, as well as the stage of diagnosis, and include surgical removal, radiation treatment, and medications, including chemotherapy (which may include oral anticancer medications). Medications used for patients undergoing cancer treatment include those that are used to kill or slow the growth of cancer cells (i.e., anticancer medications) as well as medications that are used to alleviate pain or reduce the side effects of chemotherapy. Traditionally, anticancer medications were delivered either through intravenous (IV) fluid or through injection in a physician’s office or hospital. Recently, oral anticancer medications have also been used in cancer treatment either as an adjunct to IV therapy, as a substitution for IV therapy, or alone. Oral anticancer medications are being prescribed more frequently for cancer treatment (DeMario and Ratain, 1998; O’Neill and Twelves, 2002.) An estimated 25% of anticancer agents currently in development are oral cancer

¹³ Oregon Revised Statutes, Volume 16, Chapter 743A.068.

¹⁴ Vermont Statutes, Title VIII, Part 3, Chapter 107, Subchapter 11, Section 4100h.

¹⁵ Indiana Code 27-8-32 and 27-13-7-20.

¹⁶ Iowa Code, Title XIII, Subtitle 1, Chapter 514C.24.

¹⁷ Hawaii Revised Statutes, Volume 9, Chapter 432:1-116.

treatments (Kuppens et al., 2005). Many of the most prevalent cancers in California, including breast cancer and colorectal cancer, can be treated using oral anticancer medications (CCR, 2009).

MEDICAL EFFECTIVENESS

As indicated in the *Introduction*, SB 961 would limit copays for orally administered medications that are used to kill or slow the growth of cancer cells, to no more than 200% of the lowest copay a health plan or health insurer charges for a brand name drug. To date, the U.S. Food and Drug Administration (FDA) has approved 40 oral anticancer medications. These medications are used to treat 54 different types of cancers and play a variety of roles in cancer treatment. This section of the report provides an overview of oral anticancer medications. SB 961 would apply to such a large number of medications that a systematic review of the literature on the effectiveness of all of them was not feasible for this analysis.

Appendix C contains two tables that list all of the oral anticancer medications approved by the FDA for marketing and sale in the United States. Table C-1 lists all oral anticancer medications in alphabetical order by brand name and also indicates the name of the agent (i.e., the generic name). Table C-2 provides additional information about each of these medications. Both the brand name and agent are indicated for each drug, as well as the year during which the FDA initially approved the drug. The cancer(s) that each medication is used to treat is listed, along with a description of the medication's role in treatment (e.g., used to treat early stage vs. advanced cancer, used alone or in combination with other medications). The table also indicates whether an intravenous/injectable alternative to the medication is available in the United States.

Literature Review Methods

A literature search was performed to retrieve literature that summarized trends in the development of oral anticancer medications and described the manner in which these medications are used. The search was limited to oral medications that are used to kill or slow the growth of cancer cells and that are prescribed to persons with a cancer diagnosis.¹⁸ Oral medications that are prescribed to persons with cancer to alleviate pain or to reduce the side effects of chemotherapy (e.g., antianemia medications¹⁹, antiemetic medications²⁰) were excluded because SB 961 would not apply to them. The literature search was limited to articles published in English from 2009 to present because the California Health Benefits Review Program (CHBRP) performed a similar search in 2009 for its report *Analysis of Senate Bill 161 Health Care Coverage: Chemotherapy Treatment* (CHBRP, 2009). The following databases that index peer-reviewed journals were searched: PubMed (MEDLINE), the Cochrane Library, Scientific Web Plus, Scopus, Web of Science, and Google Scholar. A total of 244 citations were retrieved. Ten pertinent studies were identified and reviewed. A more thorough description of the

¹⁸ Some oral medications used to treat cancer are also used to treat other diseases. CHBRP limited its analysis to persons diagnosed with cancer, because SB 961 would apply only where these medications are used to treat cancer.

¹⁹ Anemia is a condition that develops when a person's blood does not contain a sufficient number of healthy red blood cells. Persons with cancer who receive anticancer medications are at increased risk for anemia because treatment can kill healthy red blood cells as well as cancer cells. These patients are often prescribed antianemia medications to reduce the risk of developing this condition.

²⁰ Antiemetic medications are medications used to alleviate nausea and vomiting, which are common side effects of anticancer medications.

methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure is presented in Appendix B: Literature Review Methods.

Overview of Oral Anticancer Medications and Their Uses

Anticancer medications may be administered intravenously, by injection, or orally. Although oral anticancer medications have been available for many years (Bedell, 2003; Weingart et al., 2008), the number of oral anticancer medications approved by the FDA has grown dramatically over the past decade. This trend is likely to continue. According to a report issued by the National Comprehensive Cancer Network (NCCN), experts estimate that 400 anticancer medications are currently under development, and 25% of them are planned to be administered orally (Weingart et al., 2008).

Substitutability of Oral and Intravenous/Injectable Anticancer Medications

Intravenous or injected alternatives are available for only 11 of the 40 oral anticancer medications currently approved by the FDA. One of the most widely used oral anticancer medications for which an intravenous or injected alternative is available is Xeloda (generic name = capecitabine), an oral prodrug²¹ of 5-fluorouracil (5-FU), an intravenous medication that has been used for a number of years to treat metastatic breast and colon cancers (Aisner, 2007; Walko and Lindley, 2005). Other oral anticancer medications for which intravenous or injected alternatives are available include Temodar (generic name = temozolamide), Cytosan (generic name = cyclophosphamide), Vepesid (generic name = etoposide), and Hycamtin (generic name = topotecan hydrochloride).²² (See Table C-2 for a complete listing of oral anticancer medications for which intravenous or injected substitutes are available.)²³

Availability of Generic Equivalents for Oral Anticancer Medications

Most oral anticancer medications are available only as brand name medications. According to FDA's online listing of generic drugs, generic equivalents are available for only 9 of the 40 oral anticancer medications approved by the FDA (FDA, 2010b). Many oral anticancer medications are relatively new medications for which the pharmaceutical company that developed the medication (i.e., the brand name manufacturer) has exclusive marketing rights and/or for which the patent has not expired. In other cases, manufacturers do not currently market generic equivalents of brand name drugs.

Although generic equivalents are available for less than one quarter of oral anticancer medications, they account for a large percentage of prescriptions filled for these medications. CHBRP estimates that tamoxifen, a generic oral anticancer medication used to treat breast,

²¹ A prodrug is a type of anticancer medication that is administered in the inactive or a less-active form, which the body metabolizes into an active form. Prodrugs are used to optimize absorption, distribution, metabolism, or excretion of a medication or to improve a medication's ability to target cancer cells.

²² Personal conversation with Betty Chan, PharmD, February 2010.

²³ For some persons with health plans or health insurance policies to which SB 961 would apply, copays and other forms of cost sharing for intravenous or injected anticancer medications are lower than cost sharing for oral anticancer medications. In other cases, cost sharing for intravenous or injected anticancer medications is higher than cost sharing for oral anticancer medications

endometrial, ovarian, and uterine cancers, will account for 24.1% of prescriptions filled for oral anticancer medications in California in 2010.²⁴ Methotrexate sodium, a generic oral anticancer medication used to treat 10 types of cancer, is estimated to account for 10% of prescriptions filled.²⁵

Types of Oral Anticancer Medications

Oral anticancer medications may be divided into three major categories of medications:

- Cytotoxic agents
- Targeted agents
- Endocrine agents

Cytotoxic agents were the first type of anticancer medication developed.²⁶ They include some of the first oral anticancer medications, such as Myleran (generic name = busulfan), Leukeran (generic name = chlorambucil), Purinethol (generic name = mercaptopurine), and methotrexate sodium (Bedell, 2003; Weingart et al., 2008). One major limitation of both oral and intravenous cytotoxic agents is that they are associated with a high rate of side effects because they kill healthy cells, as well as cancer cells.

A number of new cytotoxic agents have been approved by the FDA over the past 15 years. One of the most widely used new cytotoxic agents is Xeloda (generic name = capecitabine). As indicated previously, Xeloda is an oral prodrug of 5-fluorouracil (5-FU), an intravenous medication. Other newer cytotoxic agents include Revlimid (generic name = lenalidomide) and Zolanza (generic name = vorinostat) (Aisner, 2007).

Targeted agents, also referred to as biological agents, are drugs that are targeted at specific cancer biologic pathways (Bedell, 2003; Weingart et al., 2008). Most new oral anticancer medications are targeted agents. Targeted agents currently approved by the FDA for use in the United States include Afinitor (generic name = everolimus), Gleevec (generic name = imatinib mesylate), Iressa (generic name = gefitinib), Nexavar (generic name = sorafenib), Sprycel (generic name = dasatinib), Sutent (generic name = sunitinib), Tarceva (generic name = erlotinib), Tassigna (generic name = nilotinib), Tykerb (generic name = lapatinib) (FDA, 2010a; NCCN, 2010; NCI, 2010; Weingart et al., 2008).

²⁴ A generic equivalent recently became available for Femara (generic name = letrozole), another oral anticancer medication used to treat breast, endometrial, ovarian, and uterine cancers. CHBRP estimates that Femara will account for 10.6% of prescriptions for oral anticancer medications filled in California in 2010.

²⁵ Methotrexate sodium is used to treat acute promyelocytic leukemia, multiple types of bladder cancer, bone cancer, breast cancer, central nervous system tumors, Desmoid tumors, gestational trophoblastic tumors, head and neck cancers, lung cancer, and multiple types of non-Hodgkins lymphoma.

²⁶ Cytotoxic agents can be divided into several major categories. Alkylating agents are a type of cytotoxic agent that interferes with the reproduction of cancer cells by breaking DNA strands. Antimetabolites are a type of cytotoxic agent that prevents the replication of cancer cells by interfering with the synthesis and repair of DNA. Other types of cytotoxic agents include antiangiogenic agents (i.e., medications that prevent the spread of cancer cells by blocking the development of new blood vessels), and natural compounds (i.e., plant alkaloids) (Bedell, 2003).

Endocrine agents are a third class of oral anticancer medications. Endocrine agents are not chemotherapeutic agents per se because they do not directly kill or slow the growth of cancer cells. Rather, these medications interfere with the activity of hormones in the body that can promote the development, growth, and spread of cancer cells, such as estrogen and androgen. Endocrine agents would be covered by SB 961 because they are used to regulate the production of hormones associated with cancer. They are used to treat cancers in which hormones play a major role, such as certain types of breast cancer, endometrial cancer, ovarian cancer, uterine cancer, and prostate cancer.

Tamoxifen, a medication that prevents tumors from using estrogen, is among the oldest and most widely used endocrine agents. This medication is used to treat advanced breast cancer, to prevent recurrence of early stage breast cancer, to reduce the risk of invasive breast cancer in women with ductal carcinoma in situ, and to reduce the risk of breast cancer in women who are at increased risk of developing this disease. It is also used to treat endometrial, ovarian, and uterine cancers. Over the past 15 years, a new class of endocrine agents for treatment of these cancers has entered the market. These medications, known collectively as aromatase inhibitors, work by reducing the amount of estrogen in the body. They are most frequently used to treat advanced breast cancer and prevent the recurrence of early stage breast cancer among postmenopausal women (Gibson et al., 2009; NCCN, 2010; NCI, 2010).

Roles of Oral Anticancer Medications in Cancer Treatment

Oral anticancer medications are used to treat frequently diagnosed cancers, such as breast, lung, prostate, and colorectal cancers. They are also used for rare cancers, such as adrenocortical cancer (cancer of the adrenal gland), dermatofibrosarcoma protuberans (a cancer of the dermis layer of skin), and retinoblastoma (an eye cancer).

The roles of oral anticancer medications in cancer treatment vary. Some oral anticancer medications, most notably tamoxifen and aromatase inhibitors, are used to reduce the likelihood of recurrence of cancer in patients with early stage cancers who were previously treated with surgery, radiation, and/or intravenous anticancer medications. Others, such as Gleevec (generic name = imatinib mesylate), are taken on an ongoing basis to prevent the growth of cancer cells. Still others, such as Xeloda (generic name = capecitabine) and Zolanza (generic name = vorinostat), are used to treat metastatic cancers, recurrent cancers, or cancers that cannot be surgically removed.

Oral anticancer medications may be used as “first-line” treatments for persons newly diagnosed with cancer or as “second-line” treatments for persons who do not respond to first-line treatments. Treatment of chronic myeloid leukemia provides an illustration. One oral anticancer medication, Gleevec (generic name = imatinib mesylate), is used as a first-line treatment for chronic myeloid leukemia. Persons with chronic myeloid leukemia who cannot tolerate Gleevec or whose cancers do not respond to it may be prescribed one of two second-line oral medications, Sprycel (generic name = dasatinib) or Tassigna (generic name = nilotinib) (NCCN, 2010).

Some oral anticancer medications are used alone, whereas others are used in combination with intravenous medications. Still others are used either alone or in combination with other anticancer medications depending on the cancer they are being used to treat or the severity or stage of the cancer. Many are used following surgery to resect a tumor. A few are used to reduce the size of a tumor prior to surgery. For example, tamoxifen and the aromatase inhibitors are given to postmenopausal women with estrogen receptor–positive breast cancer²⁷ prior to surgery if they choose to have breast-conserving surgery (i.e., lumpectomy) instead of a mastectomy. Some oral anticancer medications are used concurrently with radiation therapy. An example is Temodar (generic name = temozolomide), which is used concurrently with radiation to treat persons who are newly diagnosed with glioblastoma multiforme, a form of brain cancer (NCCN, 2010; NCI, 2010).

Effectiveness of Anticancer Medications

It is important to recognize that what constitutes an effective oral anticancer medication varies depending on the purpose for which a medication is being used. In the case of medications that are used to treat an early stage cancer or prevent recurrence of an early stage cancer, an effective medication is one that enables a person to live disease-free for multiple years. Where medications are used to treat advanced or metastatic cancers, patients are unlikely to attain long periods of disease-free survival. In the context of advanced and metastatic cancer, an effective medication is generally considered one that improves quality of life and/or prolongs survival or prevents disease progression for a period of months rather than years.

The complexity of cancer treatment makes it difficult to evaluate the effectiveness of individual oral anticancer medications. Many oral anticancer medications are prescribed as part of multidrug regimens. When patients receive more than one medication at a time, one cannot easily assess the impact of any single medication. In addition, persons with many of the cancers treated with oral anticancer medications are also treated with surgery and/or radiation. Except where all patients prescribed an anticancer medication(s) receive exactly the same surgical or radiation treatments, one cannot determine whether differences in outcomes are due to the medication or to variation in surgical or radiation treatment. Even where treatments are identical, effectiveness may vary depending on the type of cancer, cancer stage (e.g., local vs. metastatic disease), the role of hormones in producing the cancer (if any),²⁸ and other factors.

²⁷ Estrogen receptor –positive breast cancer is a form of breast cancer in which the proliferation of breast cancer cells is controlled by estrogen.

²⁸ For example, tamoxifen and aromatase inhibitors reduce the risk of recurrence of breast cancer among women with estrogen receptor –positive breast cancers, but do not benefit women with breast cancers that are not triggered by estrogen (i.e., estrogen receptor –negative breast cancer).

UTILIZATION, COST, AND BENEFIT COVERAGE IMPACTS

SB 961 would require that health plan contracts regulated by the Department of Managed Health Care (DMHC)-regulated health care service plans and California Department of Insurance (CDI)-regulated health insurers not charge copays for oral anticancer medications in excess of 200% of the lowest copayment required by the plan or policy for brand name medications. Health plans and policies offered in the group or individual markets would be subject to the mandate unless the health insurance was purchased by California Public Employees' Retirement System (CalPERS).

This section presents current, or baseline, costs, utilization, and benefit coverage related to oral anticancer medication, and then details the estimated impacts of SB 961. For further details on the underlying data sources and methods, please see Appendix D.

For this analysis, CHBRP has assumed the mandate would not impact any other forms of cost sharing (such as coinsurance, annual/lifetime benefit caps, or deductibles) for oral anticancer medications. The bill would not affect plan/insurer methods of utilization management that may impact the coverage of oral anticancer medications, such as use of formularies or prior authorization requirements.

For this analysis, CHBRP has focused on oral anticancer medications covered through outpatient pharmacy benefits. CHBRP compared the lowest copay paid for any brand name medication by enrollees in the plan or policy in which the patient was enrolled (the "benchmark copay") with the copay paid for brand name oral anticancer medications. CHBRP focused on brand name oral anticancer medications because generic oral anticancer medications are usually subject to copays that would not exceed the relevant benchmark. CHBRP calculated the amounts by which copays paid for oral anticancer medication prescriptions exceeded 200% of the relevant benchmark copay. CHBRP then assumed, postmandate, that the amounts exceeding 200% of the benchmark would shift from the patients to health plans and insurers

Present Baseline Cost and Benefit Coverage

Current Coverage of the Mandated Benefit

Although 18,667,000 persons are enrolled in DMHC-regulated plans or CDI-regulated policies that would be subject to SB 961, CHBRP estimates that the mandate would affect the coverage of only the 15,331,000 enrollees with outpatient pharmacy benefits that make brand name oral anticancer medications subject to flat dollar copays (Table 1).

CHBRP surveyed the seven largest health plans and insurers in California to estimate the current coverage of oral anticancer medications (which was found to be included in outpatient pharmacy benefits). Responses represent 82.4% of enrollees with privately funded, CDI-regulated policies and 92.0% of enrollees with privately funded, DMHC-regulated health plan contracts. Combined, responses to this survey represent 90.5% of enrollees with privately funded health

insurance subject to this mandate. Based on the responses, CHBRP estimates that 97.3% of enrollees (18,170,000 persons) in privately funded group or individual insurance plan contracts or policies subject to the mandate have outpatient pharmacy benefits that include oral anticancer medications. This figure includes the 2.4% of enrollees who have generic-only outpatient pharmacy benefits and so have coverage only for generic oral anticancer medications (Table 2). CHBRP estimates that 2.7% of enrollees (497,000 persons) with health insurance subject to the mandate have no outpatient pharmacy benefits and so do not have outpatient pharmacy benefit coverage for oral anticancer medications (Table 2). Enrollees without outpatient pharmacy benefits are enrolled in group plans/policies regulated by either DMHC and CDI or are enrolled in CDI-regulated individual market policies (Table 2). This mandate is not expected to affect enrollees without an outpatient pharmacy benefit because flat dollar copays are a form of cost sharing generally applicable to oral anticancer medications when covered through an outpatient pharmacy benefit. This mandate is not expected to affect enrollees with an outpatient pharmacy benefit that covers only generic medications. A plan or policy that does not cover brand name medications has no “lowest co-payment required by the plan [/policy] for brand name medications in the plans’ [policy’s] formulary.” Without a lowest copay for a brand name medication, there is no benchmark that such a plan could exceed.

Table 2. Current Coverage of Outpatient Pharmacy Benefits by Market Segment, California, 2010

	No Outpatient Pharmacy Benefit	Outpatient Pharmacy Benefit for Brand and Generic Medications (a)	Outpatient Pharmacy Benefit for Only Generic Medications
DMHC-regulated plans, privately funded (b)			
Large group	3.7%	96.3%	0.0%
Small group	0.0%	100.0%	0.0%
Individual	0.0%	100.0%	0.0%
All	2.8%	97.2%	0.0%
CDI-regulated policies (b)			
Large group	1.8%	98.2%	0.0%
Small group	0.2%	89.2%	10.6%
Individual	11.8%	58.2%	30.0%
All	6.0%	75.4%	18.6%
DMHC-regulated plans, Publicly funded			
CalPERS HMOs (c)	N/A	N/A	N/A
Medi-Cal HMOs	0.0%	100.0%	0.0%
Healthy Families/MRMIP/AIM	0.0%	100.0%	0.0%
Total	2.7%	94.9%	2.4%

Source: California Health Benefits Review Program, 2010

Note: (a) Approximately 24,000 of these enrollees have a limited outpatient pharmacy benefit which includes oral anticancer medications, but excludes many other medications (such as pain medications) which are usually covered by an outpatient pharmacy benefit. (b) The population includes employees and dependents covered by employer-sponsored insurance (c) SB 961 exempts CalPERS. Key: AIM=Access for Infants and Mothers; CalPERS=California Public Employees’ Retirement System; CDI=California Department of Insurance; DMHC=Department of Managed Health Care; MRMIP=Major Risk Medical Insurance Program; N/A=not applicable.

Premandate, based on plan and insurer responses to CHBRP's survey (Table 3), an estimated 97.3% of enrollees with health insurance subject to the mandate (18,170,000 people) have an outpatient pharmacy benefit that includes coverage for oral anticancer medications. The details for enrollees subject to the mandate with benefit coverage are as follows:

- 82.1% (15,331,000 people) have benefit coverage subject to flat dollar copays. Some may also be subject to additional cost sharing requirements, such as deductibles or annual/lifetime caps.
- 10.4% have benefit coverage subject to cost sharing other than flat dollar copays, such as coinsurance. Some may also be subject to additional cost sharing requirements, such as deductibles or annual/lifetime caps.
- 2.3% have benefit coverage not subject to any cost sharing.
- 2.4% have benefit coverage for generic medications only.

CHBRP estimates that 15,331,000 enrollees with coverage for brand name oral anticancer medications through an outpatient pharmacy benefit subject to flat dollar copays could be affected by this mandate. The figure is smaller than the number of enrollees with health insurance subject to the mandate for three reasons. A portion of the enrollees have benefit coverage subject to cost sharing other than flat dollar copays, and so would not be affected. A portion of the enrollees have benefit coverage with no cost sharing, and so would not be affected by the mandate. A portion of the enrollees have benefit coverage only for generic medications, and so the mandate could not be applied because the plan or policy does not cover brand name medications and so has no "lowest co-payment required by the plan [/policy] for brand name medications in the plans' [/policy's] formulary." Without a lowest copay for a brand name medication, there is no benchmark that such a plan could exceed.

Cost sharing provisions for oral anticancer medications covered through outpatient pharmacy benefits vary by the provisions of an enrollee's plan contract or policy. Outpatient pharmacy benefit copays are heavily concentrated (81.5%) in the \$1-\$49 range (Table 3).

It should be noted that oral anticancer medication cost sharing provisions for some enrollees (10.4%) subject to SB 961 are in a form other than flat dollar copays, such as coinsurance. The average cost sharing for patients enrolled in plans or policies with such provisions is estimated to be \$144.68 per prescription, with a range from \$0 to \$4,414.30. However, CHBRP has assumed that SB 961 would not affect cost sharing for these patients, because the mandate would affect only flat dollar copays.

Table 3. Outpatient Pharmacy Benefit Design by Market Segment, California, 2010

	Number of Enrollees in Plans/Policies Subject to SB 961	No Outpatient Pharmacy Benefit	Generic-Only Outpatient Pharmacy Benefit	Outpatient Pharmacy Benefit Covering Brand & Generic Oral Anticancer Medications (b)				
				No Cost Share	Cost Share			
					Other Than Flat Dollar Copays	Flat Dollar Copays \$1-\$49	Flat Dollar Copays \$50-\$99	Flat Dollar Copays \$100+ (c)
DMHC-Regulated Plans, Privately Funded								
Large group	9,445,000	3.7%	0.0%	0.4%	0.4%	94.8%	0.7%	0.0%
Small group	2,394,000	0.0%	0.0%	7.4%	24.2%	67.9%	0.5%	0.0%
Individual	785,000	0.0%	0.0%	1.4%	45.3%	53.3%	0.0%	0.0%
All	12,624,000	2.8%	0.0%	1.8%	7.7%	87.2%	0.6%	0.0%
CDI-Regulated Policies								
Large group	324,000	1.8%	0.0%	0.2%	17.8%	71.1%	9.1%	0.0%
Small group	935,000	0.2%	10.6%	15.7%	54.0%	19.4%	0.0%	0.0%
Individual	1,179,000	11.8%	30.0%	5.2%	35.7%	17.3%	0.0%	0.0%
All	2,438,000	6.0%	18.6%	8.6%	40.3%	25.3%	1.2%	0.0%
DMHC-regulated plans, publicly funded								
CalPERS HMOs (a)	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Medi-Cal HMOs	2,791,000	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%
Healthy Families/MRMIP/AIM	814,000	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%
Total	18,667,000	2.7%	2.4%	2.3%	10.4%	81.5%	0.6%	0.0%

Source: California Health Benefits Review Program, 2010

Note: The population includes employees and dependents covered by employer-sponsored insurance (excluding CalPERS).

(a) SB 961 exempts health insurance purchased by CalPERS.

(b) Approximately 24,000 of these enrollees have a limited outpatient pharmacy benefit which includes oral anticancer medications, but excludes many other medications (such as pain medications) which are usually covered by an outpatient pharmacy benefit.

(c) CHBRP's review of claim data indicated rare instances of copays greater than \$100. The maximum copay was \$125.

Key: AIM=Access for Infants and Mothers; CalPERS=California Public Employees' Retirement System; CDI=California Department of Insurance; DMHC=Department of Managed Health Care; MRMIP=Major Risk Medical Insurance Program; N/A=not applicable.

CHBRP also considered the possible impacts of SB 961 on enrollees with DMHC-regulated health insurance purchased with public funds. SB 961 exempts health insurance purchased by the California Public Employees' Retirement System (CalPERS), and so would have no impact on CalPERS HMO enrollees. CalPERS preferred provider organization (PPO) plans are not regulated by DMHC or CDI and so not subject to state level mandates. CHBRP reviewed the impact the mandate could have on Medi-Cal HMO enrollees (many of whom have health insurance that would be subject to SB 961), the Healthy Families Program (HFP), the Major Risk Medical Insurance Program (MRMIP), and the Access for Infants and Mother (AIM) program beneficiaries. All DMHC-regulated health insurance purchased with public funds for these programs provide coverage for oral anticancer medication at no charge or with minimal copay requirements (see Table 3). Therefore, the plans are already in compliance with SB 961, and there would be no impact on the enrollees.

Current Utilization Levels and Costs of the Mandated Benefit

CHBRP estimates that 4.2 per 1,000 enrollees with health insurance subject to the mandate use outpatient oral anticancer medications in a year. CHBRP estimates that 3.4 per 1,000 enrollees use brand name oral anti cancer medications in a year and have benefit coverage subject to flat dollar copays. CHBRP estimates that each patient uses approximately 5.1 oral anticancer prescriptions per year, of which approximately 2.9 are brand name anticancer medication prescriptions.

For each oral anticancer medication, the percentage of total prescriptions and the percentage of total cost of the oral anticancer medications used in California, as well as the average cost (health plan cost plus enrollee cost sharing) per prescription in 2010 are presented in Table 4. The estimated 2010 average costs per prescription were calculated using the 2008 actual costs increased at an annual trend rate of 10%. The top three most frequently prescribed oral anticancer medications in California in 2010 were tamoxifen citrate—24.1% of prescriptions; Arimidex—22.2% of prescriptions; and Femara—10.6% of prescriptions. The three oral anticancer medications with the largest share of total costs were Gleevec—16.0% of total costs; Arimidex—14.8% of total costs; and Revlimid—13.8% of total costs. The most expensive oral anticancer medications on average were Revlimid—\$8,580.96 per prescription; Sutent—\$7,024.46 per prescription; and Nexavar—\$5,432.67 per prescription.

Table 4. Outpatient Oral Anticancer Medication Prescriptions, 2010

Name	Percentage of Prescriptions	Percentage of Total Cost (a)	Average Cost Per Prescription (a)
Tamoxifen citrate	24.1%	1.2%	\$43.09
Arimidex	22.2%	14.8%	\$569.11
Femara	10.6%	7.3%	\$588.49
Methotrexate sodium	10.0%	0.3%	\$29.64
Aromasin	5.6%	3.5%	\$533.96
Xeloda	4.8%	10.0%	\$1,772.16
Mercaptopurine	3.5%	0.6%	\$152.47
Megestrol acetate	2.9%	0.3%	\$86.65
Gleevec	2.5%	16.0%	\$5,354.16
Temodar	2.4%	8.4%	\$3,008.78
Hydroxyurea	2.3%	0.2%	\$59.09
Casodex	1.7%	1.5%	\$769.23
Tarceva	1.4%	6.7%	\$4,066.16
Revlimid	1.4%	13.8%	\$8,580.96
Sutent	0.6%	4.8%	\$7,024.46
Tykerb	0.5%	2.4%	\$3,857.77
Nexavar	0.4%	2.4%	\$5,432.67
Leuprolide acetate	0.4%	0.1%	\$262.17
Cyclophosphamide	0.3%	0.1%	\$165.89
Sprycel	0.3%	2.0%	\$4,821.01
Flutamide	0.3%	0.1%	\$218.17
Other	1.8%	3.6%	\$1,720.62
Total/Average	100.0%	100.0%	\$853.13

Source: California Health Benefits Review Program, 2010

Note: (a) "Cost" here represents the total of amounts paid by the health plan/insurer plus amounts paid by the patient, out-of-pocket, due to cost sharing provisions of his/her plan contract or policy (cost sharing may take the form of copays or coinsurance and either may have applicable deductibles or annual/lifetime caps).

The estimated average cost per oral anticancer medication prescription for 2010 is \$853.13. On average, \$830.11 is paid by the health plan or insurer, and the remaining \$23.02 is paid by the users through cost sharing provisions, such as deductibles, annual/lifetime benefit caps, copays, or coinsurance. Among users with benefit coverage subject to flat dollar copays, the average flat dollar copay amount per prescription for brand name oral anticancer medication is \$16.78.

The Extent to Which Costs Resulting From Lack of Benefit Coverage Are Shifted to Other Payers, Including Both Public and Private Entities

CHBRP estimates that 2.7% of enrollees with health insurance subject to the mandate have no outpatient pharmacy benefits (Table 2). In addition, 2.4% of enrollees with an outpatient pharmacy benefit whose health insurance is subject to the mandate have coverage only for generic medications (Table 2). CHBRP estimates that these two groups incur expenses of \$5.37 million per year for oral anticancer medications for which the enrollees' health insurance does not provide coverage. CHBRP refers to these expenses as enrollee expenses for noncovered

benefits (Table 1). CHBRP recognizes that some portion of these expenses may be shifted from these enrollees to public programs or to charitable programs, but CHBRP is not able to quantify the amount of the shift.

Public Demand for Coverage

As a way to determine whether public demand exists for the proposed mandate (based on criteria specified under CHBRP's authorizing statute), CHBRP reports on the extent to which collective bargaining entities negotiate for, and the extent to which self-insured plans (which are not regulated by DMHC or CDI and so not subject to state-level mandates) currently have, coverage for the benefits specified under the proposed mandate.

Currently, the largest public self-insured plans are the PPO plans offered by CalPERS. These plans provide coverage and benefits similar to those offered in the group health insurance market subject to the mandate.

To further investigate public demand, CHBRP also utilized the mandate-specific health plan and insurer survey to ask carriers administering plans or policies for other (non-CalPERS) self-insured group health insurance programs whether the relevant coverage and benefits differed from what is offered in the commercial markets. The responding carriers indicated that there were no substantive differences, again suggesting that the market is meeting public demand.

On the basis of conversations with the largest collective bargaining agents in California, CHBRP concluded that unions currently do not include cost sharing arrangements for oral anticancer medications in their health insurance policy negotiations. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.²⁹

Given the lack of specificity in labor-negotiated benefits and the general match between health insurance subject to the mandate and self-insured health insurance (not subject to state level mandates), CHBRP concludes that public demand for coverage is essentially satisfied by the current state of the market.

Impacts of Mandated Coverage

How Would Changes in Coverage Related to the Mandate Affect the Benefit of the Newly Covered Service and the Per-Unit Cost?

Impact on supply and on the health benefit

CHBRP estimates no measurable impact on the supply or health benefit of the mandate given the demand for the brand name oral anticancer medications would face no measurable increase due to the mandate.

²⁹ Personal communication with the California Labor Federation and member organizations, January 2009.

Impact on per-unit cost

CHBRP estimates no measurable effect on the benefits or per-unit costs of oral anticancer medications, primarily because no measurable changes in utilization of oral anticancer medications are projected due to the mandate.

Postmandate benefit coverage

SB 961 would apply to the health insurance of enrollees with coverage oral anticancer medications through outpatient pharmacy benefits that are subject to flat dollar copays. The mandate would apply to health plans and policies sold in the group and individual markets (unless purchased by CalPERS). CHBRP estimates that copays for approximately 64,000 patients would be reduced.

For this analysis, CHBRP assumes that SB 961 would not affect cost sharing for the approximately 497,000 enrollees who do not have outpatient pharmacy benefits. CHBRP also assumes that SB 961 would not affect cost sharing for the 2,839,000 enrollees who have outpatient pharmacy benefits subject to forms of cost sharing other than flat dollar copays or who have benefit coverage subject to no cost sharing.

How Would Utilization Change as a Result of the Mandate?

Oral anticancer medication utilization rates are not expected to have a measurable change as a result of the mandate. In the year following implementation of the mandate, CHBRP estimates no measureable increase in the number of users and estimates no increase in the units of oral anticancer medication used by current users of anticancer medications. CHBRP's estimates are supported by the following evidence:

- 97.3% of persons with health insurance subject to the mandate have coverage for oral anticancer medications through an outpatient pharmacy benefit, and the mandate will not change the percentage of enrollees with coverage.
- The mandate is expected to reduce average copays (by about \$0.20, from \$16.78 to \$16.58) per prescription for brand name oral anticancer medications for patients with outpatient pharmacy benefits subject to flat dollar copays (Table 1), the amount of the reduction is small.
- Price elasticity³⁰ of demand for anticancer medications is relatively small compared to price elasticity for other medications. Cancer is a life-threatening illness, and patients will do whatever they can to comply with prescribed treatments. A recently conducted analysis of price elasticity of demand for two oral anticancer drugs (imatinib mesylate and erlotinib) found that a 25% reduction in out-of-pocket cost could lead to a 2.7% increase in the use of these drugs (Goldman et al., 2009). The estimated reduction in out-of-pocket costs caused by SB 961 is approximately 0.0005%, implying no likely measurable increase in utilization.

³⁰ Price elasticity of demand shows how the quantity demanded or supplied will change when the price changes.

Supporting the analysis' finding of price insensitivity among cancer patients, many oncologists report that patients are unlikely to interrupt primary therapy if at all possible and may seek other funding, such as incurring credit card debt or even obtaining second mortgages on their homes in order to pay for treatment (Weingart et al., 2008).

- Physician prescribing practices are unlikely to change, because a majority of surveyed oncologists report that cost of treatment does not affect their clinical practice (Nadler et al., 2006). Besides costs, oncologists may also have concerns regarding patients' compliance with complicated dosing regimens for oral anticancer medications, concerns that they weigh against patients' preference for the convenience of these self-administered medications (Weingart et al., 2008).

Although relatively few (11 out of 40) oral anticancer medications have an intravenous or injected substitute (see Appendix C), some do exist. No measurable increase in the number of users of anticancer medications is expected among the limited number of patients whose type and stage of cancer would allow substitution of an oral anticancer medication for an intravenous or injected anticancer medication. Postmandate, such persons might switch to an oral anticancer medication if the copay requirement is reduced. However, CHBRP could not quantify this possible change and notes that the changes in copays expected from SB 961 are modest (an average reduction of \$0.20 per prescription).

To What Extent Would the Mandate Affect Administrative and Other Expenses?

Health care plans and policies include a component for administration and profit in their premiums. In estimating the impact of this mandate on premiums, actuarial analysis assumes that health plans and insurers will apply their existing administration and profit loads to the increase in health care costs produced by the mandate. Therefore, although there may be administrative costs associated with the mandate, administrative costs as a portion of premiums would not change. In addition, SB 961 would require that plans and insurers notify enrollees and applicants of their oral chemotherapy coverage changes. These administrative costs were reflected in the standard administrative cost load associated with premiums.

Impact of the Mandate on Total Health Care Costs

Changes in total expenditures

CHBRP estimates that total net expenditures (including total premiums and out-of-pocket expenditures) for oral anticancer medications would increase by \$3,000 as a result of SB 961, mainly due to the administrative costs associated with the implementation of SB 961 (Table 1). Though SB 961 is expected to increase the premiums paid by both employers and employees, it would cause a decrease in the out-of-pocket costs paid by enrollees using brand name oral anticancer medications incurred through cost sharing provisions. Statewide, total premiums paid by private employers are estimated to increase by \$24,000, or 0.0001%. Statewide, enrollee contributions toward premiums for group health insurance subject to regulation by DMHC or CDI are estimated to increase by \$6,000. Statewide, total premiums for those with individually purchased health insurance are estimated to increase by \$2,000. The average portion of the premium paid by the employer would increase between \$0.0000 and \$0.0002 per member per month (PMPM), and the average portion of the premium paid by employees would increase

between \$0.0000 and \$0.0002 PMPM (Table 5). However, the cost of oral anticancer medications paid by enrollees due to cost sharing provisions would decrease between \$0.0000 and \$0.0002 PMPM. Premiums paid by purchasers of individual CDI-regulated products are estimated to increase \$0.0001 PMPM. Thus, total premiums, statewide, would increase by about \$33,000, but costs paid, statewide, by patients in out-of-pocket expenses for oral anticancer medications would decrease by \$29,000.

The major impact of the bill would be to shift some oral anticancer medication costs from patients to health plans and policies, ranging from \$0 to \$65 per prescription for those who have outpatient pharmacy benefits coverage premandate. On average, the amount of the shift is estimated to be \$0.20 per prescription for brand name oral anticancer medications for users with benefit coverage subject to flat dollar copays. The variations in copay amounts are related to the prices of particular oral anticancer medications, as well as the cost sharing provisions of a patient's particular health plan contract or policy. Among enrollees with outpatient pharmacy benefit coverage for both brand name and generic oral anticancer medications, less than 1% of the enrollees have flat dollar copays \$50 and above per prescription, prior to the mandate. It is important, however, to be aware of two factors. First, there are covered generic as well as brand name oral anticancer medications (even though no reduction in copays for generics is projected). Second, coverage for prescriptions may be subject to additional cost sharing, such as a deductible, or may be subject to a different form of cost sharing, such as coinsurance, and SB 961 would not impact forms of cost sharing other than copays. Therefore, the average cost shift per prescriptions (inclusive of brand and generic medications and all forms of cost sharing) for all oral anticancer medication users would be \$0.09 per prescription.

Impact on long-term costs

Longer-term impacts on health care costs as a result of the mandate are unknown but are likely to increase over time. According to a recent pharmaceutical report on cancer medication development, almost 400 new anticancer medications are in clinical development. It is estimated that one-quarter of these anticancer medications in the pipeline are planned as oral medications (Weingart et al., 2008). Many of the new medications will be expensive. As a result, costs for covering oncology medications, especially the more targeted and long-term oral anticancer medications, will continue to grow over the next several years. There are also several other factors that may be influential. For example, there is an increase in the number of patients receiving long-term treatment with more targeted oral anticancer medications (NCCN, 2010). In addition, continued growth in the use of combination treatment for various types of cancers is likely, and there is a trend of expanding indications or off-label use of existing drugs for the treatment of various cancers (NCCN, 2010).

Impacts for Each Category of Payer Resulting From the Benefit Mandate

Changes in expenditures and PMPM amounts by payer category

The impact is similar for CDI-regulated policies and for DMHC-regulated plan contracts, in the large group, small group, and individual markets, as shown in Table 5. The increases in premiums vary by market segment:

- \$0.0002 PMPM in the large group DMHC-regulated plan contracts;

- \$0.0002 PMPM in the large group CDI-regulated policies;
- \$0.0002 PMPM in the small group DMHC-regulated plan contracts;
- \$0.0001 PMPM in the small group CDI-regulated policies;
- \$0.0002 PMPM in the individual DMHC-regulated plan contracts; and
- \$0.0001 PMPM in the individual CDI-regulated policies.

Changes in the number of uninsured persons as a result of premium increases

CHBRP projects no measurable impact on the number of persons who are uninsured due to SB 961. The premiums increase estimated for the mandate is much less than the 1% threshold at which CHBRP would estimate a change in the number of persons with health insurance. Therefore, CHBRP does not anticipate a reduction in health insurance coverage, changes in availability of the benefit beyond those subject to the mandate, changes in offer rates of insurance, changes in employer contribution rates, changes in uptake of insurance by employees, or changes in purchase of individual policies as a result of SB 961 due to the size of the increase in premiums due to the mandate.

Impact on public programs

SB 961 would have no impact on Medi-Cal, the Healthy Families Program, or CalPERS and no measurable impact on other public programs. Enrollees in Medi-Cal HMOs and beneficiaries of the Healthy Families Program, AIM program, and MRMIP are provided full coverage for oral anticancer medication, with very limited patient cost sharing and no annual limits. Therefore, their coverage is compliant with SB 961. CalPERS is exempt from the mandate, so enrollees in CalPERS HMOs would not be affected.

Impact on Access and Health Service Availability

In the short term, CHBRP expects that there will be no measurable impacts on the access to and availability of oral anticancer medication as a result of SB 961. In the long run, to the extent that copays remain restricted, access to expensive oral medications could increase for some portion of the small number of enrollees who seek oral anticancer medications. For instance, there could be a significant cumulative reduction in out-of-pocket cost for a patient who needs to take a medication, such as Arimidex, over time. Such a reduction could improve access to the medication for any patient for whom the cost was a burden. However, CHBRP is unable to estimate these effects quantitatively.

Table 5. Baseline (Premandate) Per Member Per Month Premium and Total Expenditures by Market Segment, California, 2010

	DMHC-Regulated							CDI-Regulated			Total Amount
	Privately Funded			CalPERS (b) HMO	Medi-Cal HMOs (c)		Healthy Families Program HMOs (d)	Privately Funded			
	Large Group	Small Group	Indi- vidual		65 and Over	Under 65		Large Group	Small Group	Indi- vidual	
Total enrollees in plans/policies subject to state mandates (a)	9,445,000	2,394,000	785,000	820,000	175,000	2,616,000	814,000	324,000	935,000	1,179,000	19,487,000
Total enrollees in plans/policies subject to SB 961	9,445,000	2,394,000	785,000	0	175,000	2,616,000	814,000	324,000	935,000	1,179,000	18,667,000
Average portion of premium paid by employer	\$290.96	\$223.84	\$0.00	\$332.10	\$223.00	\$113.00	\$93.19	\$346.40	\$246.40	\$0.00	\$51,713,067,000
Average portion of premium paid by employee	\$72.11	\$92.31	\$364.68	\$58.61	\$0.00	\$0.00	\$11.78	\$105.37	\$79.68	\$180.77	\$18,813,408,000
Total Premium	\$363.07	\$316.14	\$364.68	\$390.70	\$223.00	\$113.00	\$104.97	\$451.77	\$326.08	\$180.77	\$70,526,476,000
Enrollee expenses for covered benefits (deductibles, copays, etc.)	\$19.77	\$25.74	\$64.43	\$20.15	\$0.00	\$0.00	\$1.52	\$58.78	\$116.51	\$44.19	\$5,961,186,000
Enrollee expenses for benefits not covered	\$0.04	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.02	\$0.00	\$0.03	\$5,365,000
Total Expenditures	\$382.89	\$341.88	\$429.11	\$410.85	\$223.00	\$113.00	\$106.50	\$510.57	\$442.59	\$224.98	\$76,493,027,000

Source: California Health Benefits Review Program, 2010.

Note: (a) This population includes persons insured with private funds (group and individual) and insured with public funds (e.g., CalPERS HMOs, Medi-Cal HMOs, Healthy Families Program, AIM, MRMIP) enrolled in health plans or policies regulated by DMHC or CDI. Population includes enrollees aged 0-64 years and enrollees 65 years or older covered by employment sponsored insurance.

(b) Of these CalPERS HMO members, about 58%, or 475,600, are state employees.

(c) Medi-Cal state expenditures for members over 65 years of age include those who also have Medicare coverage.

(d) Healthy Families Program state expenditures include expenditures for the Major Risk Medical Insurance Program (MRMIP) and the Access for Infants and Mothers (AIM) program.

Table 6. Impacts of the Mandate on Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2010

	DMHC-Regulated							CDI-Regulated			Total Amount
	Privately Funded			CalPERS (b) HMO	Medi-Cal HMOs (c)		Healthy Families Program HMOs (d)	Privately Funded			
	Large Group	Small Group	Indi- vidual		65 and Over	Under 65		Large Group	Small Group	Indi- vidual	
Total enrollees in plans/policies subject to state mandates (a)	9,445,000	2,394,000	785,000	820,000	175,000	2,616,000	814,000	324,000	935,000	1,179,000	19,487,000
Total enrollees in plans/policies subject to SB 961	9,445,000	2,394,000	785,000	0	175,000	2,616,000	814,000	324,000	935,000	1,179,000	18,667,000
Average portion of premium paid by employer	\$0.0002	\$0.0001	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0002	\$0.0000	\$0.0000	\$24,000
Average portion of premium paid by employee	\$0.0000	\$0.0000	\$0.0002	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0001	\$9,000
Total Premium	\$0.0002	\$0.0002	\$0.0002	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0002	\$0.0001	\$0.0001	\$33,000
Enrollee expenses for covered benefits (deductibles, copays, etc.)	-\$0.0002	-\$0.0001	-\$0.0001	\$0.0000	\$0.0000	\$0.0000	\$0.0000	-\$0.0002	\$0.0000	\$0.0000	-\$28,000
Enrollee expenses for benefits not covered	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0
Total Expenditures	\$0.0000	\$0.0000	\$0.0001	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$5,000
Percentage Impact of Mandate											
Insured premiums	0.0001%	0.0001%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%
Total expenditures	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%

Source: California Health Benefits Review Program, 2010.

Note: (a) This population includes persons insured with private funds (group and individual) and insured with public funds (e.g., CalPERS HMOs, Medi-Cal HMOs, Healthy Families Program, AIM, MRMIP) enrolled in health plans or policies regulated by DMHC or CDI. Population includes enrollees aged 0-64 years and enrollees 65 years or older covered by employment sponsored insurance.

(b) Of these CalPERS HMO members, about 58% or 475,600 are state employees.

(c) Medi-Cal state expenditures for members over 65 years of age include those who also have Medicare coverage.

(d) Healthy Families Program state expenditures include expenditures for the Major Risk Medical Insurance Program (MRMIP) and the Access for Infants and Mothers (AIM) program.

Key: AIM=Access for Infants and Mothers; CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health Care.

PUBLIC HEALTH IMPACTS

A total of 134,000 new cancer cases and 55,000 deaths from cancer are projected to occur in California in 2010 (CCR, 2009). It is estimated that 45% of new cancer cases will occur in the non-elderly population—i.e., the population most relevant to SB 961, which does not impact Medicare coverage (CCR, 2009). SB 961 would require California Department of Managed Health Care (DMHC)-regulated health plans and California Department of Insurance (CDI)-regulated policies (exempting California Public Employees' Retirement System [CalPERS] health maintenance organizations [HMOs]) that provide coverage for orally administered anticancer medications to charge a copayment for these drugs not in excess of 200% of the lowest copayment required by brand name medications in the plan's or policy's formulary. This section presents the overall public health impact of passage of SB 961, followed by an analysis examining the potential for reduction in gender and racial/ethnic disparities in health outcomes, and the potential for the mandate to reduce premature death and societal economic losses as a result of cancer.

Impact of the Proposed Mandate on the Public's Health

As presented in the *Medical Effectiveness* section, the Federal Drug Administration (FDA) has approved 40 oral anticancer medications to treat 54 different types of cancer. The roles of oral anticancer medications in cancer treatment vary and include reducing the likelihood of recurrence in persons who have been treated for early stage disease, first-line treatment to prevent growth of cancer cells, treatment of advanced or metastatic cancers, treatment of recurrent cancers, and treatment of cancers that cannot be surgically removed. As presented in the *Utilization, Cost, and Benefit Coverage Impacts* section, 97.3% of enrollees in health plans and policies subject to SB 961 currently have coverage for oral anticancer medications. It is expected that coverage for and utilization of oral anticancer medications will not change as a result of this mandate. SB 961 is not expected to affect utilization of oral anticancer medications, therefore no measurable impacts on health outcomes are expected.

Outside of health outcomes, other measures of public health, such as financial burdens facing cancer patients and their families, were examined. Cancer patients face a substantial financial burden (Bennett et al., 1998; Covinsky et al., 1996; Emanuel et al., 2000). Although health insurance typically covers the cost of medical treatments, patients still face out-of-pocket expenditures not covered by insurance such as lost wages, transportation costs, deductibles, coinsurance, and copayments. This can lead to spending a significant portion of household income on cancer treatment, taking out a loan or mortgage, or obtaining an additional job (Bennett et al., 1998; Covinsky et al., 1996; Emanuel et al., 2000). CHBRP estimates that 99.4% of enrollees in plans and policies subject to SB 961 have copays of less than \$50 for oral anticancer medications. Thus copayments for enrollees in DMHC-regulated plans and CDI-regulated policies may represent a much smaller financial burden on cancer patients than other forms of cost sharing, such as coinsurance. In addition, copayments for oral anticancer medications average \$17 per brand name prescription and represent a small percentage of the overall cost of oral anticancer medications—which can cost as much as \$8,600 per prescription. As a result of SB 961, copayments for oral anticancer medications will decrease an average of

\$0.20 per brand name prescription for enrollees with flat dollar copays. However, it should be noted that the impact of this mandate on each patient could differ depending on the provisions of his/her plan or policy. Though less than 1% of enrollees have copays of \$50 to \$99 per prescription, the cumulative reduction in out-of-pocket expenses for these enrollees over an extended period of time could be significant and could improve access to and compliance with a cancer treatment regimen for an individual (Avalere, 2010). Overall, the \$0.20 reduction in average copays for brand name oral anticancer medications (for enrollees with an outpatient pharmacy benefit that covers brand name medications) as a result of SB 961 is not expected to significantly impact financial burdens facing cancer patients.

Impact on the Health of the Community Where Gender and Racial Disparities Exist

Several competing definitions of “health disparities” exist. CHBRP relies on the following definition by Braveman (2006): *A health disparity/inequality is a particular type of difference in health or in the most important influences of health that could potentially be shaped by policies; it is a difference in which disadvantaged social groups (such as the poor, racial/ethnic minorities, women, or other groups that have persistently experienced social disadvantage or discrimination) systematically experience worse health or greater health risks than more advantaged groups.*

CHBRP investigated the effects that SB 961 would have on health disparities by gender, race, and ethnicity. Evaluating the impact on racial and ethnic disparities is particularly important because racial and ethnic minorities report having poorer health status and poorer relative risk indicators and survival rates (KFF, 2007). One important contributor to racial and ethnic health disparities is differential insurance rates, where minorities are more likely than whites to be uninsured; however, disparities still exist within the insured population (Kirby et al., 2006; Lillie-Blanton and Hoffman, 2005). Since SB 961 would only affect a portion of the insured population, a literature review was conducted to determine whether there are gender, racial, or ethnic disparities associated with the prevalence of cancer and the use of oral anticancer medications, beyond the disparities observed in health insurance coverage.

Impact on Gender Disparities

Among women, breast cancer is the most prevalent cancer in California, making up 42% of existing female cancer patients (CCR, 2009). In California, the lifetime risk of breast cancer is one in nine—translating into an incidence of approximately 22,500 new diagnoses a year, for a total prevalence of 284,000 women alive today who have had a breast cancer diagnosis (CCR, 2009). It is estimated that 55% of the cases of breast cancer occur in women less than 65 years old—i.e., the population most relevant to SB 961 (CCR, 2005). Although appropriate treatment may vary by stage of diagnosis and other factors, as shown in Table 4, nearly two-thirds of the prescriptions for oral anticancer agents are for one of four drugs (Arimidex, Aromasin, Femara, and Tamoxifen) all of which are used in the treatment breast cancer. These four drugs represent 27% of the cost of all oral anticancer agents (Table 4). Women with cancer are particularly likely to suffer from financial hardship. Out-of-pocket expenditures and lost income for women with breast cancer vary widely but average \$1,455 per month, and women with breast cancer face a financial burden of care ranging from 26%-98% of their monthly income, depending on income

levels (Arozullah et al., 2004). SB 961 would have little to no effects on these financial burdens, since it affects only copayments for oral anticancer medications, which are a small part of the total financial burdens.

Impact on Racial/Ethnic Disparities

There is a differential burden of cancer in racial/ethnic minorities in California (CCR, 2008). The reasons for these differences are not well understood, but are thought to result from a combination of socioeconomic factors such as poverty, education and inadequate health insurance (Brawley, 2009; Ward et al., 2004). Numerous studies have documented that individuals from lower socioeconomic groups and specific racial and ethnic minorities have greater cancer risk and poorer cancer-related outcomes. This differential burden results in lower overall survival rates, a generally more advanced stage of cancer at time of diagnosis, and a higher eventual risk of death (Albain, 2009; Sloane, 2009). Compared with whites, blacks have poorer survival once cancer is diagnosed. Five-year relative survival is lower in blacks than in whites within every stratum of stage of diagnosis for nearly every cancer site (Ward et al., 2004; Jemal et al., 2009). As cancer treatments become more sophisticated, the disparity between whites and non-whites is likely to widen (Meropol and Shulman, 2007). This is likely because disparities in socioeconomic status lead to disparities in access to new medical advances. Therefore, medical advances (such as oral anticancer medications) can exacerbate the disparities in relative racial/ethnic cancer survival rates (Tehranifar et al., 2009).

In California, non-Hispanic black men have the highest rates of cancer compared to all other racial or ethnic groups (CCR, 2008). This higher prevalence may lead to non-Hispanic black men having higher out-of-pocket medical costs for cancer compared to people of other race/ethnicities. Blacks are more likely to have lower incomes compared to whites, so out-of-pocket costs for oral chemotherapy could comprise a higher percentage of annual household income (Arozullah et al., 2004). SB 961 would have little to no effects on these disparities, since it is not expected to impact utilization of oral anticancer medications and would reduce per prescription flat dollar copays for oral anticancer medications by only \$0.20, on average.

The Extent to Which the Proposed Service Reduces Premature Death and the Economic Loss Associated With Disease

Both premature death and economic loss associated with disease are two measures used by economists and public health experts to assess the impact of a condition or disease. Premature death, often defined as death before the age of 75 (Cox, 2006), can be measured in years of potential life lost (YPLL) (Cox, 2006; Gardner and Sanborn, 1990). Economic loss associated with disease is generally an estimation of the value of the YPLL in dollar amounts (i.e., valuation of years of work life lost from premature death or lost productivity due to a disease or condition).

Premature Death

Cancer represents the greatest contributor to premature death in California, with 21.1% of all YPLL attributable to cancer (CDPH, 2009). It is estimated that in California in 2007, the YPLL per 100,000 due to cancer was 1,209, translating into nearly 200,000 YPLL each year (CDPH, 2009). Although cancer is a substantial cause of premature mortality in California, SB 961 is not estimated to change the utilization of oral anticancer medications or result in a corresponding reduction in premature death.

Economic Loss

The National Institutes of Health have estimated that the overall cost of cancer in 2005 was \$209.9 billion (USCSWG, 2005). Of this, it was estimated that \$74 billion (35%) was for direct medical costs, including health expenditures; while the remaining 65% was attributable to lost productivity due to illness (\$17.5 billion) and premature death (\$118.4 billion) (USCSWG, 2005). Although cancer in California is a substantial cause of lost productivity due to illness and premature death, SB 961 is not estimated to change the utilization of oral anticancer medications or result in a corresponding reduction in lost productivity.

APPENDICES

Appendix A: Text of Bill Analyzed

On February 19, 2010, the Senate Committee on Health requested CHBRP to analyze the following submitted text for SB 961. Below is the bill as introduced. Following is the text of the bill as will be amended as indicated by the Bill Author.

SENATE BILL No. 961

Introduced by Senator Wright
(Coauthors: Senators Cox, Negrete McLeod, and Strickland)
(Coauthor: Assembly Member Hall)

February 5, 2010

An act to add Section 1367.655 to the Health and Safety Code, and to add Section 10123.205 to the Insurance Code, relating to health care coverage.

SB 961, as introduced, Wright. Health care coverage: cancer treatment.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Existing law requires health care service plan contracts and health insurance policies to provide coverage for all generally medically accepted cancer screening tests and requires those plans and policies to also provide coverage for the treatment of breast cancer. Existing law imposes various requirements on contracts and policies that cover prescription drug benefits.

This bill would prohibit health care service plan contracts and health insurance policies that provide coverage for cancer chemotherapy treatment that is taken orally from charging or otherwise requiring a copayment or other charge for each of those dispensed prescriptions in excess of a certain unspecified amount.

Because a willful violation of the bill's requirements relative to health care service plans would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement. This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

- (a) There are 10 million Americans currently living with cancer.
- (b) Approximately 1.5 million new cases of cancer will be diagnosed in the United States in 2010.
- (c) In California, 27, 725 men and 26, 735 women are expected to die from cancer this year.
- (d) Nearly one out of every two Californians born today will develop cancer at some point in their lives.
- (e) It is likely that one in five Californians will die of cancer.
- (f) It is the intent of the Legislature that a health plan or insurer that includes on its formulary, or authorizes on the basis of medical necessity, oral medications used to treat cancer shall not require copayments or other charges for those medications at a level that effectively makes the medication inaccessible to a patient.

SEC. 2. Section 1367.655 is added to the Health and Safety Code, to read:

1367.655. A health care service plan contract issued, amended, or renewed on or after January 1, 2011, that provides coverage for chemotherapy treatment that is taken orally shall not charge or otherwise require a copayment or other charge for each of those dispensed prescriptions in excess of ____ dollars.

SEC. 3. Section 10123.205 is added to the Insurance Code, to read:

10123.205. A health insurance policy issued, amended, or renewed on or after January 1, 2011, that provides coverage for chemotherapy treatment that is taken orally shall not charge or otherwise require a copayment or other charge for each of those dispensed prescriptions in excess of ____ dollars.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

SB 961 – Amended Text, submitted to CHBRP on February 19, 2010.

SECTION 1. The Legislature finds and declares all of the following:

- (a) There are 10 million Americans currently living with cancer.
- (b) Approximately 1.5 million new cases of cancer will be diagnosed in the United States in 2010.
- (c) In California, 27, 725 men and 26, 735 women are expected to die from cancer this year.
- (d) Nearly one out of every two Californians born today will develop cancer at some point in their lives.
- (e) It is likely that one in five Californians will die of cancer.
- (f) It is the intent of the Legislature that a health plan or insurer that includes on its formulary, or authorizes on the basis of medical necessity, oral medications used to treat cancer shall not require copayments or other charges for those medications at a level that

effectively makes the medication inaccessible to a patient.

SEC. 2.

Section 1367.655 is added to the Health and Safety Code, to read:

1367.655. A health care service plan contract issued, amended, or renewed on or after January 1, 2011, that provides coverage for ~~chemotherapy treatment that is taken orally shall not charge or otherwise require a copayment or other charge for each of those dispensed prescriptions in excess of _____ dollars.~~

orally administered cancer medication used to kill or slow the growth of cancerous cells shall not charge a co-payment for these drugs in excess of 200% of the lowest co-payment required by the policy for brand name medications in the plans' formulary.

(b) Nothing in this section shall prohibit a health care service plan from requiring prior approval or authorization for the use of any medication subject to subdivision (a) of this section. However, if the plan authorizes the dispensing of such medication for any reason, the co-payment provision of subdivisions (a) shall apply.

(c) Nothing in this section shall be construed to require a health insurance policy to provide coverage for any addition medication not otherwise required by existing law.

(d) This section shall not apply to a health care benefit plan or contract entered into with the Board of Administration of the Public Employees' retirement system pursuant to the Public Employees' Medical and Hospital Care Act (Part 5 (commencing with Section 22750 of Division 5 of Title 2 of the Government Code)).

SEC. 3. Section 10123.205 is added to the Insurance Code, to read:

10123.205. A health insurance policy issued, amended, or renewed on or after January 1, 2011, that provides coverage for ~~chemotherapy treatment that is taken orally shall not charge or otherwise require a copayment or other charge for each of those dispensed prescriptions in excess of _____ dollars.~~

orally administered cancer medication used to kill or slow the growth of cancerous cells shall not charge a co-payment for these drugs in excess of 200% of the lowest co-payment required by the policy for brand name medications in the plans' formulary.

(b) Nothing in this section shall prohibit a health care service plan from requiring prior approval or authorization for the use of any medication subject to subdivision (a) of this section. However, if the plan authorizes the dispensing of such medication for any reason, the co-payment provision of subdivisions (a) shall apply.

(c) Nothing in this section shall be construed to require a health insurance policy to provide coverage for any addition medication not otherwise required by existing law.

(d) This section shall not apply to a health care benefit plan or contract entered into with the Board of Administration of the Public Employees' retirement system pursuant to the Public Employees' Medical and Hospital Care Act (Part 5 (commencing with Section 22750 of Division 5 of Title 2 of the Government Code)).

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or

infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Appendix B: Literature Review Methods

Appendix B describes methods used in the medical effectiveness literature review for SB 961, a bill that require health plans and health insurance carriers that provide “coverage for orally administered cancer medications used to kill or slow the growth of cancerous cells...not charge a co-payment for these drugs in excess of 200% of the lowest co-payment required by the plan[/policy] for brand name medications in the plans’[/policies’] formulary.”

A literature search was performed to retrieve literature that summarized trends in the development of oral anticancer medications and described the manner in which these medications are used. The search was limited to literature on oral medications that are used to kill or slow the growth of cancer cells and that are prescribed to persons with a cancer diagnosis.³¹ Oral medications that are prescribed to persons with cancer to alleviate pain or to reduce the side effects of chemotherapy (e.g., antianemia drugs³², antiemetic drugs³³) were excluded because SB 961 would not apply to them. The literature search was restricted to articles published in English from 2000 to present. The following databases that index peer-reviewed journals were searched: the Cochrane Library,³⁴ the Cumulative Index to Nursing and Allied Health Literature, Google Scholar, International Pharmaceutical Abstracts, MEDLINE, MicroMedex, and Web of Science. Web sites maintained by the following organizations were also searched: the Food and Drug Administration, Healthcare Standards (ECRI), the National Guideline Clearinghouse, the National Institutes of Health (ClinicalTrials.gov), the New York Academy of Medicine’s Index of Grey Literature, Scirus, and UptoDate. A total of 244 citations were retrieved. Ten pertinent articles were identified and reviewed.

In addition, web sites maintained by the following organizations were searched to obtain additional information about individual oral anticancer medications: FDA Approved Drug Products and Patient Information Sheets, Medline Plus: Drugs, Supplements, and Herbal Information, National Cancer Institute Drug Information Summaries, and the National Comprehensive Cancer Network. Appendix C contains a list of these medications along with descriptions of the cancers they are used to treat and their roles in cancer treatment. The table also indicates whether a generic equivalent of a medication is available and whether there is an intravenously-administered or injectable equivalent.

³¹ Some oral medications used to treat cancer are also used to treat other diseases. CHBRP limited its analysis to persons diagnosed with cancer, because SB 961 would apply only where these medications are used to treat cancer.

³² Anemia is a condition that develops when a person’s blood does not contain a sufficient number of healthy red blood cells. Persons with cancer who receive anticancer medications are at increased risk for anemia because treatment can kill healthy red blood cells as well as cancer cells. These patients are often prescribed antianemia medications to reduce the risk of developing this condition.

³³ Antiemetic medications are medications used to alleviate nausea and vomiting, which are common side effects of anticancer medications.

³⁴ The Cochrane Library includes the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effects, Health Technology Assessment, and the United Kingdom National Health Service Economic Evaluation Database.

The search terms used to locate studies relevant to the SB 961 were as follows:

Major Subject Heading (MeSH) Terms—MEDLINE and the Cochrane Library

Antibodies, monoclonal
Antineoplastic agents* AND administration, oral
Antineoplastic combined chemotherapy protocols
Benzenesulfonates
Deoxycytidine
Drug costs
Fluorouracil
Health benefit plans, employee
Indoles
Insurance, pharmaceutical services
Lenalidomide OR revlimid
Neoplasms/drug therapy
Piperazines
Prescription Fees
Pyrimidines
Pyrroles
Quinazolines
Thalidomide
Thiazoles

Keywords—all databases and websites

biologics
coinsurance
copayment
cost
cost sharing
economics
Gleevec
Lenalidomide OR Revlimid
oral chemother*
pharmaceutical benefits
specialty drugs
Tarceva
targeted therapy

Appendix C: Summary Findings on Medical Effectiveness

Table C-1 lists all oral anticancer medications that the U.S. Food and Drug Administration (FDA) has approved for marketing and sale in the United States in alphabetical order by brand name. Table C-2 provides information about each of these medications. Both the brand name and agent are indicated for each medication, along with the year during which the FDA initially approved the medication. The cancer(s) that each medication is used to treat is listed, along with a description of the medication's role in cancer treatment (e.g., treatment of early stage versus metastatic cancers, used alone or in combination with other medications). The table also indicates whether an intravenous/injectable alternative to the medication is available in the United States.

Table C-1. FDA-Approved Oral Anticancer Agents, Alpha-Ordered by Brand Name

Brand Name	Agent (Generic Name)
Afinitor	Everolimus
Alkeran	Melphalan
Arimidex	Anastrozole
Aromasin	Exemestane
Casodex	Bicalutamide
CeeNU	Lomustine
Cytosan	Cyclophosphamide
Droxia, Hydrea	Hydroxyurea
Emcyt	Estramustine
Eulexin	Flutamide
Fareston	Toremifene
Femara	Letrozole
Gleevec	Imatinib mesylate
Hexalen	Altretamine
Hycamtin	Topotecan hydrochloride
Iressa	Gefitinib
Leukeran	Chlorambucil
Matulane	Procarbazine
Megace	Megestrol acetate
Mitotane	Lysodren
Myleran	Busulfan
Nexavar	Sorafenib tosylate
Nilandron	Nilutamide

C-1. FDA-Approved Oral Anticancer Agents, Alpha-Ordered by Brand Name (cont'd)

Brand Name	Agent (Generic Name)
Nolvadex	Tamoxifen citrate
Purinethol	Mercaptopurine
Revlimid	Lenalidomide
Rheumatrex, Trexall	Methotrexate sodium
Sprycel	Dasatinib
Sutent	Sunitinib malate
Tabloid	Thioguanine
Tarceva	Erlotinib hydrochloride
Targretin	Bexarotene
Tasigna	Nilotinib hydrochloride monohydrate
Temodar	Temozolomide
Thalomid	Thalidomide
Tykerb	Lapatinib
Vepesid	Etoposide
Vesanoid	Tretinoin
Xeloda	Capecitabine
Zolinza	Vorinostat

Table C-2. FDA-Approved Oral Anticancer Agents and Their Indications

Brand Name	Agent (Generic Name)	Class	Generic Equivalent Available	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative Available
Afinitor	Everolimus	Targeted agents	No	2009	Kidney cancer	Used to treat patients with advanced, inoperable, or recurrent kidney cancer who have not responded to treatment with Nexavar or Sutent	Yes; similar to an IV-administered drug (Torisel)
Alkeran	Melphalan	Cytotoxic agents	No	1964	Epithelial ovarian cancer, Hodgkins lymphoma, melanoma, multiple myeloma, multiple types of non-Hodgkins lymphoma, solitary plasmacytoma	Used alone or in combination with other anticancer medications as first- and second-line treatment of, metastatic, inoperable, progressive, and recurrent cancers; sometimes used in combination with other anticancer medications	Yes; IV formulation of same drug

Table C-2. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd)

Brand Name	Agent (Generic Name)	Class	Generic Equivalent Available	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative Available
Arimidex**	Anastrozole	Endocrine agents	No	1995	Breast cancer, endometrial cancer, ovarian cancer, uterine sarcoma	Preoperative and postoperative treatment of postmenopausal women with early stage or locally advanced estrogen-receptor-positive breast cancers; treatment for postmenopausal women with advanced or metastatic breast cancers that have progressed despite treatment with tamoxifen; treatment of premenopausal women with breast cancer whose ovaries have been removed; also used to treat recurrent ovarian cancer, recurrent or metastatic endometrial cancer, and advanced, metastatic, inoperable, and recurrent uterine sarcoma	No

** Indicates that one or more applications to produce a generic equivalent of the drug have been filed with the FDA.

Table C-2. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd)

Brand Name	Agent (Generic Name)	Class	Generic Equivalent Available	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative Available
Aromasin**	Exemestane	Endocrine agents	No	1999	Breast cancer, endometrial cancer, uterine sarcoma	Preoperative and postoperative treatment of postmenopausal women with early stage or locally advanced estrogen-receptor-positive cancers; treatment for postmenopausal women with advanced, estrogen-receptor positive cancers that have not progressed despite treatment with tamoxifen; treatment of premenopausal women with recurrent or metastatic breast cancer whose ovaries have been removed; also used to treat recurrent or metastatic endometrial cancer and advanced, metastatic, inoperable, and recurrent uterine sarcoma	No

** Indicates that one or more applications to produce a generic equivalent of the drug have been filed with the FDA.

Table C-2. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd)

Brand Name	Agent (Generic Name)	Class	Generic Equivalent Available	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative Available
Casodex	Bicalutamide	Endocrine agents	Yes	1995	Prostate cancer	Used alone to treat localized cancer or as a second-line therapy following recurrence; used in combination with androgen deprivation therapy (ADT) to treat metastatic cancers, cancers that do not respond to ADT, and to enhance the effectiveness of radiation	No
CeeNU	Lomustine	Cytotoxic agents	No	1976	Brain tumors, Hodgkins lymphoma	Second-line treatment for inoperable, progressive, and recurrent brain tumors following radiation or surgery; second-line treatment for progressive or recurrent Hodgkins lymphoma	No

Table C-2. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd)

Brand Name	Agent (Generic Name)	Class	Generic Equivalent Available	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative Available
Cytosan	Cyclophosphamide	Cytotoxic agents	No	1999	Bone cancer, breast cancer, Hodgkin lymphoma, Merkel cell carcinoma, multiple myeloma, multiple types of leukemia, multiple types of non-Hodgkin lymphoma, neuroblastoma, ovarian cancer, paraganglioma, pheochromocytoma, retinoblastoma, small cell lung cancer, solitary plasmacytoma, thymic malignancies	Used alone or in combination with other anticancer medications for preoperative treatment, postoperative treatment, first-line treatment of early stage, locally advanced, and metastatic cancers, second-line treatment for early stage, advanced, residual, progressive, and recurrent cancers (specific uses vary by cancer); for some cancers, used in combination with radiation or growth factor; single-agent treatment for brain metastases if active against primary tumor	Yes – IV formulation of same drug

Table C-2. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd)

Brand Name	Agent (Generic Name)	Class	Generic Equivalent Available	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative Available
Droxia, Hydrea	Hydroxyurea	Cytotoxic agents	Yes – only 500 mg strength	1967	Acute myeloid, leukemia, chronic myeloid leukemia, head and neck cancers, melanoma, ovarian cancer	Used alone as low-intensity treatment for acute myeloid leukemia; used in combination with another anticancer medication and radiation to treat head and neck cancers; used to treat inoperable, metastatic, and recurrent ovarian cancer	No
Emcyt	Estramustine	Agents with both cytotoxic and endocrine properties	No	1981	Prostate cancer	Used in combination with another anticancer drug to treat metastatic or progressive cancers	No
Eulexin	Flutamide	Endocrine agents	Yes	1989	Prostate cancer	Used alone to treat localized cancer or as a second-line therapy following recurrence; used in combination with androgen deprivation therapy (ADT) to treat metastatic cancers, cancers that do not respond to ADT, and to enhance the effectiveness of radiation	No

Table C-2. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd)

Brand Name	Agent (Generic Name)	Class	Generic Equivalent Available	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative Available
Fareston	Toremifene	Endocrine agents	No	1997	Breast cancer, Desmoid tumors	First-line or second-line treatment for women with recurrent or metastatic breast cancer; treatment for residual and inoperable Desmoid tumors	No
Femara	Letrozole	Endocrine agents	Yes	1997	Breast cancer, endometrial cancer, ovarian cancer, uterine sarcoma	Preoperative and postoperative treatment of postmenopausal women with early stage or locally advanced or metastatic estrogen-receptor positive breast cancers; treatment of postmenopausal women whose breast cancers have progressed despite hormone therapy; treatment of premenopausal women with recurrent or metastatic breast cancer whose ovaries have been removed; also used to treat recurrent ovarian cancer, recurrent or metastatic endometrial cancer, and advanced, metastatic, inoperable, and recurrent uterine sarcoma	No

Table C-2. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd)

Brand Name	Agent (Generic Name)	Class	Generic Equivalent Available	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative Available
Gleevec	Imatinib mesylate	Targeted agents	No	2003	Acute lymphoblastic leukemia, chronic eosinophilic leukemia, chronic myeloid leukemia, dermatofibrosarcoma protuberans, desmoids tumors, gastrointestinal stromal tumors, myelodysplastic/ myeloproliferative diseases, systemic mastocytosis	Used alone or in combination with other anticancer medications for first-line treatment, follow-up to first-line treatment, postoperative treatment, post-transplant treatment, and treatment of metastatic, residual, inoperable, progressive, and recurrent disease (specific uses vary across cancers)	No
Hexalen	Altretamine	Cytotoxic agents	No	1990	Ovarian cancer	Used alone to treat persons with persistent, or recurrent cancers	No
Hycamtin	Topotecan hydrochloride	Cytotoxic agents	No	2007	Central nervous system tumors, cervical cancer, Merkel cell carcinoma, ovarian cancer, small cell lung cancer	Used alone or in combination with other cancer medications or radiation; first-line treatment for early stage, advanced, persistent, progressive, metastatic, inoperable, and recurrent cancers; second-line treatment for advanced, metastatic, progressive, and recurrent cancers	Yes – IV formulation of same drug

Table C-2. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd)

Brand Name	Agent (Generic Name)	Class	Generic Equivalent Available	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative Available
Iressa	Gefitinib*	Targeted agents	No	2003	Non-small-cell lung cancer	Used to treat locally advanced or metastatic cancer that has not responded to other cancer medications	No
Leukeran	Chlorambucil	Cytotoxic agents	No	1957	Chronic lymphoblastic leukemia, multiple types of lymphoma	First-line treatment for advanced cancers; second-line treatment for early stage, advanced, and progressive cancers.	No
Matulane	Procarbazine	Cytotoxic agents	No	1969	Brain tumors, Hodgkin lymphoma, multiple types of non-Hodgkin lymphoma	Used in combination with other anticancer medications for second-line therapeutic or palliative treatment of progressive and recurrent brain tumors; lymphomas a second-line treatment for advanced Hodgkin lymphoma or for progressive and recurrent Hodgkin lymphoma in persons initially treated with radiation alone; second-line treatment for progressive and recurrent cancers in persons with multiple types of non-Hodgkin lymphoma	No

* Indicates that the drug is only available through a special program under which both health professionals and patients must register with the manufacturer.

Table C-2. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd)

Brand Name	Agent (Generic Name)	Class	Generic Equivalent Available	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative Available
Megace	Megestrol acetate	Agents with both cytotoxic and endocrine properties	Yes	1971	Breast cancer, endometrial cancer, ovarian cancer, uterine sarcoma	Used to treat metastatic, inoperable, and recurrent breast cancer, endometrial cancer, and uterine sarcoma; also used to treat persistent, progressive, or recurrent ovarian cancer	No
Mitotane	Lysodren	Cytotoxic agents	No	2003	Adrenocortical cancer	Used to treat inoperable adrenal cortical carcinoma	No
Myleran	Busulfan	Cytotoxic agents	No	1954	Chronic myeloid leukemia	Combined with cyclophosphamide to prepare patients for hematopoietic progenitor cell transplantation	Yes – IV formulation of same drug
Nexavar	Sorafenib tosylate	Targeted agents	No	2005	Angiosarcoma, gastrointestinal stromal tumors, hepatocellular cancer, kidney cancer, thyroid cancer	Used alone as first line treatment for advanced, metastatic, inoperable, progressive, and recurrent cancers; second line treatment for persons who no longer benefit from Gleevec or Sutent; also used to treat persons with potentially operable hepatocellular cancers who decline surgery	Yes - similar to an IV-administered drug (Torisel)

Table C-2. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd)

Brand Name	Agent (Generic Name)	Class	Generic Equivalent Available	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative Available
Nilandron	Nilutamide	Endocrine agents	No	1996	Prostate cancer	Used alone as postoperative treatment for metastatic cancers and as a second-line treatment for recurrent cancers; used in combination with androgen deprivation therapy (ADT) to treat metastatic cancers, cancers that do not respond to ADT, and to enhance the effectiveness of radiation	No

Table C-2. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd)

Brand Name	Agent (Generic Name)	Class	Generic Equivalent Available	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative Available
Nolvadex	Tamoxifen citrate	Endocrine agents	Yes	1977	Breast cancer, Desmoid tumors, endometrial cancer, ovarian cancer, uterine sarcoma	Preoperative treatment of women with hormone receptor positive cancers who fulfill all criteria for breast conserving surgery except tumor size; postoperative treatment of postmenopausal women with early stage or locally advanced breast cancer; treatment of women with recurrent or metastatic breast cancer; used as an alternative to radiation or removal of the ovaries for premenopausal women with metastatic breast cancer; used to reduce the risk of invasive breast cancer in women with ductal carcinoma in situ; used to reduce the risk of breast cancer in women at high risk for developing the disease; also used to treat recurrent or residual ovarian cancer, recurrent or metastatic endometrial cancer, advanced, inoperable, recurrent, and metastatic uterine sarcoma, residual or inoperable Desmoid tumors	No

Table C-2. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd)

Brand Name	Agent (Generic Name)	Class	Generic Equivalent Available	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative Available
Purinethol	Mercaptopurine	Cytotoxic agents	Yes	1953	Acute lymphatic leukemia, acute promyelocytic leukemia	Used in combination with other anticancer medications to prevent recurrence of cancer	No
Revlimid	Lenalidomide*	Cytotoxic agents	No	2005	Mantle cell lymphoma, multiple myeloma, myelodysplastic syndromes, solitary plasmacytoma	Second-line treatment for relapsed or progressive mantle cell lymphoma; first-line treatment or palliative treatment for multiple myeloma; used to treat lower risk patients with myelodysplastic syndromes who have symptomatic anemia; used to treat progressive solitary plasmacytoma or smoldering myeloma that has progressed beyond stage II or active myeloma	No

* Indicates that the drug is only available through a special program under which both health professionals and patients must register with the manufacturer.

Table C-2. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd)

Brand Name	Agent (Generic Name)	Class	Generic Equivalent Available	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative Available
Rheumatrex, Trexall	Methotrexate sodium	Cytotoxic agents	Yes – for some strengths	1953	Acute promyelocytic leukemia, multiple types of bladder cancer, bone cancer, breast cancer, central nervous system tumors; Desmoid tumors, gestational trophoblastic tumors, head and neck cancers, lung cancer, multiple types of non-Hodgkins lymphoma	Used alone or in combination with other cancer medications, radiation, and/or growth factor; preoperative treatment of advanced cancers; postoperative treatment for early stage, advanced, and residual cancers; first-line treatment for early stage, advanced, metastatic, inoperable, progressive, and recurrent cancers; second-line treatment for advanced, metastatic, progressive, and recurrent cancers; used to prevent recurrence of cancer	Yes – IV formulation of the same drug

Table C-2. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd)

Brand Name	Agent (Generic Name)	Class	Generic Equivalent Available	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative Available
Sprycel	Dasatinib	Targeted agents	No	2006	Acute lymphoblastic leukemia, chronic myeloid leukemia	Used alone or in combination with other anticancer medications to treat persons with both types of leukemia who cannot tolerate the first-line anticancer medication for these cancers (i.e., Gleevec) or whose cancers do not respond to that medication; also used to treat persons with chronic myeloid leukemia whose cancers have relapsed following bone marrow transplantation	No

Table C-2. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd)

Brand Name	Agent (Generic Name)	Class	Generic Equivalent Available	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative Available
Sutent	Sunitinib malate	Targeted agents	No	2006	Angiosarcoma, gastrointestinal stromal tumor, kidney cancer, thyroid cancer	Used alone or in combination with other anticancer medications to treat persons with gastrointestinal stromal tumors who cannot tolerate the first-line anticancer medication for these cancers (i.e., Gleevec), whose cancers do not respond to that medication; also used to treat angiosarcoma, recurrent or inoperable kidney cancer, and progressive or symptomatic metastatic thyroid cancer	Yes - similar to an IV-administered drug (Torisel)
Tabloid	Thioguanine	Cytotoxic agents	No	1966	Acute nonlymphocytic leukemia	First-line treatment or treatment to prevent recurrence of cancer	No

Table C-2. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd)

Brand Name	Agent (Generic Name)	Class	Generic Equivalent Available	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative Available
Tarceva	Erlotinib hydrochloride	Targeted agents	No	2004	Non-small-cell lung cancer, pancreatic cancer	First-line treatment either alone or in combination with other anticancer medications for person with non-small-cell lung cancer who never smoked and who have a known active EGFR mutation or gene amplification; second-line treatment for persons with locally advanced or metastatic non-small cell lung cancer that has not responded to initial chemotherapy treatment; used in combination with gemcitabine as first-line or second-line treatment for locally advanced, metastatic, and inoperable pancreatic cancers	No

Table C-2. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd)

Brand Name	Agent (Generic Name)	Class	Generic Equivalent Available	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative Available
Targretin	Bexarotene	Cytotoxic agents	No	1999	Cutaneous T-cell lymphoma, mycosis fungoides, and Sezary syndrome	Used alone or in combination with other anticancer medications, radiation, interferons, phototherapy, photopheresis, or skin-directed therapies as first-line treatment for early stage, advanced, refractory or progressive cancers	No
Tasigna	Nilotinib hydrochloride monohydrate	Targeted agents	No	2007	Chronic myeloid leukemia, gastrointestinal stromal tumors	Used alone or in combination with other anticancer medications to treat persons who cannot tolerate the first-line anticancer medication for these cancers (i.e., Gleevec) or whose cancers do not respond to that medication; also used to treat persons whose cancers relapse following bone marrow transplantation	No

Table C-2. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd)

Brand Name	Agent (Generic Name)	Class	Generic Equivalent Available	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative Available
Temodar	Temozolomide	Cytotoxic agents	No	1999	Carcinoid tumors, central nervous system cancers, islet cell tumors, melanoma, mycosis fungoides, Sezary syndrome	Used concurrently with radiation treatment and as post-radiation treatment, postoperative treatment, treatment for early stage, advanced, metastatic, progressive, or recurrent cancers	Yes – IV formulation of same drug
Thalomid	Thalidomide	Cytotoxic agents	No	1998	Mantle-cell lymphoma, multiple myeloma	Used alone or in combination with other anticancer medications as a first-line treatment for newly diagnosed persons and as a second-line treatment for progressive and recurrent cancers	No
Tykerb	Lapatinib	Targeted agents	No	2007	Breast cancer	Used in combination with Xeloda to treat persons with advanced, metastatic, or recurrent breast cancers that are human epidermal growth factor receptor 2 (HER2) positive and hormone receptor negative and who have received prior therapy including an anthracycline, a taxane, and trastuzumab	No

Table C-2. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd)

Brand Name	Agent (Generic Name)	Class	Generic Equivalent Available	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative Available
Vepesid	Etoposide	Cytotoxic agents	No	2001	Bone cancer, breast cancer, central nervous system cancers, Hodgkins lymphoma, Merkel cell carcinoma, multiple myeloma, neuro-endocrine tumors, multiple types of non-Hodgkins lymphoma, non-small cell lung cancer, occult primary malignancy, ovarian cancer, prostate cancer, small cell lung cancer, solitary plasmacytoma, testicular cancer, thymic malignancies	Used alone or in combination with other anticancer medications, radiation, and/or growth factor as preoperative, postoperative, post-radiation, first-line, and post-local control treatment for early stage, advanced, metastatic, and inoperable cancers; also used as second-line treatment for residual, advanced, metastatic, progressive, and recurrent cancers (specific uses vary across cancers)	Yes – IV formulation of same drug
Vesanoid	Tretinoin	Cytotoxic agents	Yes	2004	Acute promyelocytic leukemia	Treatment of persons whose cancers have not responded to anthracycline-based cytotoxic chemotherapeutic regimens or who cannot tolerate these drugs.	No

Table C-2. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd)

Brand Name	Agent (Generic Name)	Class	Generic Equivalent Available	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative Available
Xeloda	Capecitabine	Cytotoxic agents	No	1998	Brain tumors, breast cancer, carcinoid tumors, colon cancer, esophageal cancer, gastric cancer, hepatobiliary cancers islet cell tumors, kidney cancer, ovarian cancer, pancreatic adenocarcinoma, rectal cancer	Used alone or in combination with other anticancer medications and/or radiation as preoperative therapy or postoperative therapy; used to treat residual, locally advanced, advanced, metastatic, inoperable, progressive, and/or recurrent cancers	Yes – similar to an IV-administered drug (fluorouracil)
Zolinza	Vorinostat	Cytotoxic agents	No	2006	Cutaneous T-cell lymphoma, mycosis fungoides, Sezary syndrome	Used to treat persons with persistent, progressive, and recurrent cutaneous T-cell lymphoma; used alone or in combination with other anticancer medications and/or skin-directed therapies as first-line treatment for localized or advanced mycosis fungoides and Sezary syndrome	No

Sources: Betty Chan, PharmD, Department of Clinical Pharmacy, University of Southern California; Medline Plus: Drugs, Supplements, and Herbal Information; National Cancer Institute Drug Information Summaries; National Comprehensive Cancer Network, Drugs and Biologicals Compendium; U.S. Food and Drug Administration Approved Drug Products and Patient Information Sheets and Orange book: Approved drug products with therapeutic equivalence evaluations.

Appendix D: Cost Impact Analysis: Data Sources, Caveats, and Assumptions

This appendix describes data sources, as well as general and mandate-specific caveats and assumptions used in conducting the cost impact analysis. For additional information on the cost model and underlying methodology, please refer to the CHBRP Web site at www.chbrp.org/costimpact.html.

The cost analysis in this report was prepared by the Cost Team, which consists of CHBRP task force members and staff, specifically from the University of California, Los Angeles, and Milliman Inc. (Milliman). Milliman is an actuarial firm that provides data and analyses per the provisions of CHBRP's authorizing legislation.

Data Sources

In preparing cost estimates, the Cost Team relies on a variety of data sources as described below.

Health Insurance

1. The latest (2007) California Health Interview Survey (CHIS), which is used to estimate health insurance for California's population and distribution by payer (i.e., employment-based, individually purchased, or publicly financed). The biannual CHIS is the largest state health survey conducted in the United States, collecting information from over approximately 53,000 households. More information on CHIS is available at www.chis.ucla.edu. The population estimates for both adults and children from 2007 were adjusted to reflect the following trends as of 2009 from the data sources listed: (1) the increase in the total non-institutionalized population in California, from the California Department of Finance; (2) the decrease in private market coverage (both group- and individual-level), from the CHBRP Annual Premium and Enrollment Survey, and (3) the increase in all types of public coverage, from enrollment data available from the Centers for Medicare & Medicaid Services, the California Medical Statistics Section, and the Managed Risk Medical Insurance Board. The residual population after accounting for these trends was assumed to be uninsured.
2. The latest (2009) California Employer Health Benefits Survey is used to estimate:
 - Size of firm,
 - Percentage of firms that are purchased/underwritten (versus self-insured),
 - Premiums for health care service plans regulated by the Department of Managed Health Care (DMHC) (primarily health maintenance organizations [HMOs] and Point of Service Plans [POS]),
 - Premiums for health insurance policies regulated by the California Department of Insurance (CDI) (primarily preferred provider organizations [PPOs] and fee-for-service plans [FFS]), and
 - Premiums for high deductible health plans (HDHPs) for the California population with employment-based health insurance.

This annual survey is currently released by the California Health Care Foundation/National Opinion Research Center (CHCF/NORC) and is similar to the national employer survey released annually by the Kaiser Family Foundation and the Health Research and Educational Trust. Information on the CHCF/NORC data is available at: <http://www.chcf.org/topics/healthinsurance/index.cfm?itemID=133543>.

3. Milliman data sources are relied on to estimate the premium impact of mandates. Milliman's projections derive from the Milliman Health Cost Guidelines (HCGs). The HCGs are a health care pricing tool used by many of the major health plans in the United States. See www.milliman.com/expertise/healthcare/products-tools/milliman-care-guidelines/index.php. Most of the data sources underlying the HCGs are claims databases from commercial health insurance plans. The data are supplied by health insurance companies, Blues plans, HMOs, self-funded employers, and private data vendors. The data are mostly from loosely managed healthcare plans, generally those characterized as preferred provider plans or PPOs. The HCGs currently include claims drawn from plans covering 4.6 million members. In addition to the Milliman HCGs, CHBRP's utilization and cost estimates draw on other data, including the following:
 - The MarketScan Database, which includes demographic information and claim detail data for approximately 13 million members of self-insured and insured group health plans.
 - An annual survey of HMO and PPO pricing and claim experience. The most recent survey (2008 Group Health Insurance Survey) contains data from seven major California health plans regarding their 2007 experience.
 - Ingenix MDR Charge Payment System, which includes information about professional fees paid for healthcare services, based upon approximately 800 million claims from commercial insurance companies, HMOs, and self-insured health plans.

These data are reviewed for applicability by an extended group of experts within Milliman but are not audited externally.

4. An annual survey by CHBRP of the seven largest providers of health insurance in California (Aetna, Anthem Blue Cross of California, Blue Shield of California, CIGNA, Health Net, Kaiser Foundation Health Plan, and PacifiCare) to obtain estimates of baseline enrollment by purchaser (i.e., large and small group and individual), type of plan (i.e., DMHC or CDI-regulated), cost-sharing arrangements with enrollees, and average premiums. Enrollment in plans or policies offered by these seven firms represents 95.9% of the persons with privately funded health insurance subject to state mandates. This figure represents 98.0% of enrollees in full service (non-specialty), privately funded DMHC-regulated health plan contracts and 85.3% of enrollees in full service (non-specialty), privately funded CDI-regulated policies.

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5. Premiums and enrollment in DMHC-regulated health plans and CDI-regulated policies by self-insured status and firm size are obtained annually from CalPERS for active state and local government public employees and their dependents who receive their benefits through CalPERS. Enrollment information is provided for DMHC-regulated health care service plans covering non-Medicare beneficiaries—about 74% of CalPERS total enrollment. CalPERS self-funded plans—approximately 26% of enrollment—are not subject to state mandates. In addition, CHBRP obtains information on current scope of benefits from evidence of coverage (EOCs) documents publicly available at www.calpers.ca.gov.
6. Enrollment in Medi-Cal Managed Care (DMHC-regulated health plans) is estimated based on CHIS and data maintained by the Department of Health Care Services (DHCS). DHCS supplies CHBRP with the statewide average premiums negotiated for the Two-Plan Model, as well as generic contracts that summarize the current scope of benefits. CHBRP assesses enrollment information online at <http://www.dhcs.ca.gov/dataandstats/statistics/Pages/BeneficiaryDataFiles.aspx>.
7. Enrollment data for other public programs—Healthy Families Program (HFP), Access for Infants and Mothers (AIM), and the Major Risk Medical Insurance Program (MRMIP)—are estimated based on CHIS and data maintained by the Managed Risk Medical Insurance Board (MRMIB). The basic minimum scope of benefits offered by participating health plans under these programs must comply with all requirements for DMHC-regulated health plans, and thus these plans are affected by state-level benefit mandates. CHBRP does not include enrollment in the Post-MRMIP Guaranteed-Issue Coverage Products as these persons are already included in the enrollment for individual market health insurance offered by DMHC-regulated plans or CDI-regulated insurers. Enrollment figures for AIM and MRMIP are included with enrollment for Medi-Cal in presentation of premium impacts. Enrollment information is obtained online at www.mrmib.ca.gov/. Average statewide premium information is provided to CHBRP by MRMIB staff.

General Caveats and Assumptions

The projected cost estimates are estimates of the costs that would result if a certain set of assumptions were exactly realized. Actual costs will differ from these estimates for a wide variety of reasons, including:

- Prevalence of mandated benefits before and after the mandate may be different from CHBRP assumptions.
- Utilization of mandated benefits (and, therefore, the services covered by the benefit) before and after the mandate may be different from CHBRP assumptions.
- Random fluctuations in the utilization and cost of health care services may occur.

Additional assumptions that underlie the cost estimates presented in this report are:

- Cost impacts are shown only for plans and policies subject to state benefit mandate laws.
- Cost impacts are only for the first year after enactment of the proposed mandate
- Employers and employees will share proportionately (on a percentage basis) in premium rate increases resulting from the mandate. In other words, the distribution of premium paid by the subscriber (or employee) and the employer will be unaffected by the mandate.
- For state-sponsored programs for the uninsured, the state share will continue to be equal to the absolute dollar amount of funds dedicated to the program.
- When cost savings are estimated, they reflect savings realized for one year. Potential long-term cost savings or impacts are estimated if existing data and literature sources are available and provide adequate detail for estimating long-term impacts. For more information on CHBRP's criteria for estimating long-term impacts please see: http://chbrp.org/documents/longterm_impacts08.pdf.
- Several recent studies have examined the effect of private insurance premium increases on the number of uninsured (Chernew, et al., 2005; Glied and Jack 2003; Hadley, 2006). Chernew et al. estimate that a 10% increase in private premiums results in a 0.74 to 0.92 percentage point decrease in the number of insured, while Hadley (2006) and Glied and Jack (2003) estimate that a 10% increase in private premiums produces a 0.88 and 0.84 percentage point decrease in the number of insured, respectively. The price elasticity of demand for insurance can be calculated from these studies in the following way. First, take the average percentage point decrease in the number of insured reported in these studies in response to a 1-percent increase in premiums (about -0.088), divided by the average percentage of insured persons (about 80%), multiplied by 100%, i.e., $(\{-0.088/80\} \times 100) = -0.11$. This elasticity converts the *percentage point* decrease in the number of insured into a *percentage* decrease in the number of insured persons for every 1% increase in premiums. Because each of these studies reported results for the large-group, small-group, and individual insurance markets combined, CHBRP employs the simplifying assumption that the elasticity is the same across different types of markets. For more information on CHBRP's criteria for estimating impacts on the uninsured please see: http://chbrp.org/documents/uninsured_010109.pdf.

There are other variables that may affect costs, but which CHBRP did not consider in the cost projections presented in this report. Such variables include, but are not limited to:

- Population shifts by type of health insurance: If a mandate increases health insurance costs, some employer groups and individuals may elect to drop their health insurance. Employers may also switch to self-funding to avoid having to comply with the mandate.
- Changes in benefit plans: To help offset the premium increase resulting from a mandate, subscribers/policyholders may elect to increase their overall plan deductibles or copayments. Such changes would have a direct impact on the distribution of costs between the health plan and policies and enrollees, and may also result in utilization reductions (i.e., high levels of patient cost sharing result in lower utilization of health care

services). CHBRP did not include the effects of such potential benefit changes in its analysis.

- Adverse selection: Theoretically, individuals or employer groups who had previously foregone health insurance may now elect to enroll in a health plan or policy, postmandate, because they perceive that it is to their economic benefit to do so.
- Medical management: Health plans and insurers may react to the mandate by tightening medical management of the mandated benefit. This would tend to dampen the CHBRP cost estimates. The dampening would be more pronounced on the plan types that previously had the least effective medical management (i.e., PPO plans).
- Geographic and delivery systems variation: Variation in existing utilization and costs, and in the impact of the mandate, by geographic area and delivery system models: Even within the health insurance types CHBRP modeled (HMO—including HMO and point of service (POS) plans—and non-HMO—including PPO and fee for service (FFS) policies), there are likely variations in utilization and costs by type. Utilization also differs within California due to differences in the health status of the local population, provider practice patterns, and the level of managed care available in each community. The average cost per service would also vary due to different underlying cost levels experienced by providers throughout California and the market dynamic in negotiations between providers and health plans or insurers. Both the baseline costs prior to the mandate and the estimated cost impact of the mandate could vary within the state due to geographic and delivery system differences. For purposes of this analysis, however, CHBRP has estimated the impact on a statewide level.
- Compliance with the mandate: For estimating the postmandate coverage levels, CHBRP typically assumes that plans and policies subject to the mandate will be in compliance with the coverage requirements of the bill. Therefore, the typical postmandate coverage rates for populations subject to the mandate are assumed to be 100%.

Bill Analysis-Specific Caveats and Assumptions

In most instances, oral anticancer medications are subject to outpatient pharmacy benefit cost-sharing provisions, often in the form of flat-dollar copay per prescription, coupled in some instances with a calendar year deductible or annual/lifetime caps.

The following is a brief description of methodology and assumptions used to develop the estimates of cost impacts of SB 961.

1. We used 2008 MedStat claims data for commercial members under age 65 to develop baseline cost and utilization information for oral anti-cancer medications. We used claims data for members who resided in California with cancer diagnoses (i.e., ICD-9-DX 239xx).
2. For the above cancer patients, we identified all outpatient pharmacy claims in the dataset. Outpatient pharmacy claims consisted of one record for each processed prescription. Each record had the following information:
 - a. NDC
 - b. Generic/brand name status

- c. Dispensing quantity
 - d. Total allowed cost
 - e. Member cost sharing amounts—separately for deductible, coinsurance, copay.
3. Among the prescription drug claims identified in Step 2, we identified claims for oral anticancer medications (i.e., Therapeutic Class 21 Antineoplastic Agents).
 4. For each group in which each cancer patient is enrolled, we identified the lowest copay paid per prescription for any brand name medication, other than oral anticancer medications. In identifying the lowest copayment paid per prescription, we did not adjust the copay for differences in dispensing quantity. We multiplied the lowest copay paid per brand name medication prescription by 200%. This was set as the benchmark copay for the patient.
 5. For each cancer patient, we calculated the amounts exceeding 200% of the relevant benchmark copay over the copay paid per oral anticancer medication prescription. We aggregated the excess amounts for all oral anticancer medication prescriptions for the cancer patient.
 6. We aggregated for all patients identified in Step 1 the excess of the benchmark copays over the copays paid per oral anticancer medication prescription calculated in Step 5.
 7. We calculated average changes in copays per oral anticancer medication prescription attributable to SB 961, separately for consumer driven health plans, and for other plans regulated by DMHC and by CDI.
 8. We assumed no changes in utilization of oral cancer medications due to the introduction of SB 961—only a shift of cost sharing from patients to health plans.
 9. We assumed no changes in formularies, pre-authorization requirements, or coverage provisions other than patient cost-sharing.

Appendix E: Information Submitted by Outside Parties

In accordance with CHBRP policy to analyze information submitted by outside parties during the first 2 weeks of the CHBRP review, the Office of Senator Roderick Wright chose to submit information in the form of the following publications.

Avalere Health. *Oral Oncolytics: Addressing the Barriers to Access and Identifying Areas for Engagement*, February 2010. Washington, DC: Avalere Health.

McCoy R, Grants and Education Program Manager, Maryland Affiliate of Susan G. Komen for the Cure. *Cancer Chemotherapy—Cost Sharing Equity*. Statement at the February 17, 2010 hearing of the Senate Finance Committee, U.S. Senate.

National Patient Advocate Foundation. *2009 Principles and Priorities: Statement of Principles on Access to Oral Chemotherapy Drugs*. 2009.

For information on the processes for submitting information to CHBRP for review and consideration please visit: <http://www.chbrp.org/requests.html>.

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A group of faculty and staff undertakes most of the analysis that informs reports by the California Health Benefits Review Program (CHBRP). The CHBRP **Faculty Task Force** comprises rotating representatives from six University of California (UC) campuses and three private universities in California. In addition to these representatives, there are other ongoing contributors to CHBRP from UC. This larger group provides advice to the CHBRP staff on the overall administration of the program and conducts much of the analysis. The **CHBRP staff** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and coordinates all external communications, including those with the California Legislature. The level of involvement of members of the CHBRP Faculty Task Force and staff varies on each report, with individual participants more closely involved in the preparation of some reports and less involved in others. As required by CHBRP's authorizing legislation, UC contracts with a certified actuary, Milliman Inc., to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit. Milliman also helped with the initial development of CHBRP methods for assessing that impact.

The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance and thoughtful critiques provided by the members of the National Advisory Council. However, the Council does not necessarily approve or disapprove of or endorse this report. CHBRP assumes full responsibility for the report and the accuracy of its contents.

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