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Analysis of Assembly Bill 1000: Cancer Treatment

A Report to the 2011-2012 California Legislature
April 21, 2011

CHBRP 11-15

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 2011-2012 California State Legislature

Analysis of Assembly Bill 1000: Cancer Treatment

April 21, 2011

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Additional free copies of this and other CHBRP bill analyses and publications may be obtained by visiting the CHBRP Web site at http://www.chbrp.org.

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PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill 1000. In response to a request from the California Assembly Committee on Health on February 18, 2011, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the program's authorizing statute.

Janet Coffman, MPP, PhD, of the University of California, San Francisco, prepared the medical effectiveness analysis. Sara McMenamin, PhD, of the University of California, San Diego, prepared the public health impact analysis. Ying-Ying Meng, DrPH, of the University of California, Los Angeles, prepared the cost impact analysis. Susan Pantely, FSA, MAAA, of Milliman, provided actuarial analysis. David Guarino and John Lewis, MPA, of CHBRP staff, prepared the introduction and synthesized the individual sections into a single report. A member of the CHBRP Faculty Task Force, Kathleen Johnson, PharmD, MPH, PhD, 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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All CHBRP bill analyses and other publications are available on the CHBRP Web site, http://www.chbrp.org.

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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Assembly Bill 1000

The California Assembly Committee on Health requested on February 18, 2011, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 1000, a bill that would impose a health benefit mandate related to cost-sharing for oral cancer medications. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.[1]

Approximately 21.9 million Californians (59%) have health insurance that may be subject to a health benefit mandate law passed at the state level.[2] Of the rest of the state's population, a portion is uninsured (and so has no health insurance subject to any benefit mandate), and another portion has health insurance subject to other state laws or only to federal laws.

Uniquely, California has a bifurcated system of regulation for health insurance subject to state-level benefit mandates. The California Department of Managed Health Care (DMHC)[3] regulates health care service plans, which offer benefit coverage to their enrollees through health plan contracts. The California Department of Insurance (CDI) regulates health insurers,[4] which offer benefit coverage to their enrollees through health insurance policies.

DMHC-regulated plans and CDI-regulated policies with prescription drug benefits, except those purchased by the California Public Employees' Retirement System (CalPERS), would be subject to AB 1000. Therefore, the mandate would affect the health insurance of approximately 20.1 Californians (54%).

Analysis of AB 1000

AB 1000 would mandate that plans and policies which provide coverage for cancer chemotherapy treatment be required to:

- Review the percentage cost share for *oral* nongeneric (brand name) anitcancer medications and *injected/intravenous* nongeneric anticancer medications and *apply the lower of the two* as the cost-sharing provision for *oral* nongeneric anticancer medications.

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[1] CHBRP's authorizing statute is available at: http://www.chbrp.org/documents/authorizing_statute.pdf.
[2] CHBRP's estimates are available at http://www.chbrp.org/documents/insur_source_est_2011.pdf.
[3] DMHC was established in 2000 to enforce the Knox-Keene Health Care Service Plan of 1975; see Health and Safety Code, Section 1340.
[4] 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.

Because the bill specifies "medication[s] used to kill or slow the growth of cancerous cells," (referred to as *anticancer medications* in this report), this analysis assumes it would not affect cost sharing for other medications (antipain, antinausea, etc.) that a cancer patient might use during the course of chemotherapy.

The bill would also require that these plans and policies:

- Provide coverage for a prescribed, orally administered, nongeneric cancer medication used to kill or slow the growth of cancerous cells.

However, limits in the bill language (see the following text) make clear that it would not expand coverage.

The bill specifies limits, including that AB 1000 shall:

- Not apply to plans/policies that do not provide coverage for prescription drugs;
- Not require a plan/policy to provide coverage for any additional medication;
- Not prohibit a plan/insurer from removing a prescription drug from its formulary of covered prescription drugs;
- Not apply to plans purchased by CalPERS.

All plans and policies subject to AB 1000—even those without an *outpatient* prescription drug benefit—cover prescription drugs under benefits covering hospitalization or outpatient visits or procedures. However, AB 1000 explicitly does not require plans/policies to provide coverage for prescription drugs or to add any drugs to their formularies. Therefore, CHBRP assumes the bill would not affect plans/policies that provide no outpatient prescription drug coverage and would not require plans/policies that provide generic-only outpatient prescription drug coverage to begin covering nongeneric oral anticamcer medications.

AB 1000 would also require that plans and policies:

- Not provide for an increase in enrollee cost sharing for nongeneric cancer medications to any greater extent than the contract provides for an increase in enrollee cost sharing for other nongeneric covered medication.

This provision is broad, and may have the effect of limiting plans' and insurers' ability to alter benefit designs for renewing contracts (e.g., increasing copayments) for its outpatient prescription drug benefit. Given the myriad of benefit design options that plans/insurers may develop and purchasers may choose in response to this provision, this report holds current benefit designs constant and does not address potential impacts of this provision.

Lastly, the bill would:

- Sunset on January 1, 2016, unless otherwise legislated.

This analysis does not directly address the potential impacts of this provision.

No current California mandate requires coverage of prescription medications, and no mandates currently specify the terms of cost-sharing provisions for nongeneric oral anticancer medications. DMHC does review proposed cost-sharing arrangements and requires that benefits not be subject to "exclusion, exception, reduction, deductible, or copayment that renders the benefit illusory."[5] For outpatient prescription drug benefits, existing regulations by DMHC limit cost sharing to 50% of the cost of the drug to the plan, and specifies how such costs are to be calculated.[6] These regulations also require for *coinsurance* on drugs that it either: (1) have a per prescription out-of-pocket maximum; (2) apply toward the plan's total annual out-of-pocket maximum; or (3) apply toward a prescription drug-specific annual out-of-pocket maximum. CDI-regulated policies are not subject to these limits.

CHBRP is aware of nine states that have mandates related to cost sharing for oral anticancer medications, though none is precisely equivalent to AB 1000.

Medical Effectiveness

AB 1000 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 during the 60 days within which CHBRP must complete its reports. 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 42 oral anticancer medications that are used to treat 57 different types of cancer. Ten of these have generic equivalents.
- 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.
- For many oral anticancer medications, there are no intravenous or injected substitutes (and vice versa). However, there are some important exceptions such as Xeloda (capecitabine), Temodar (temozolamide), and methotrexate sodium.
- 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 treat and the stage at which the cancer is diagnosed.

[5] Health and Safety Code Section 1367, California Code of Regulations Title 28 § 1300.67.4.
[6] California Code of Regulations Title 28 § 1300.67.24.

- 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.

- When compared to intravenous and injectable anticancer medications, oral anticancer medications have both advantages and disadvantages. Advantages are that oral anticancer medications may allow administration of the medication on a daily basis, may be more convenient for patients, and may reduce the risk of infection or other infiltration complications. Disadvantages include less certainty in patient adherence to treatment regimens and a reduction in interaction between patients and their health care providers to manage complications of treatment.

Benefit Coverage, Utilization, and Cost Impacts

To perform the analysis, CHBRP compared current cost sharing (as a percentage of the cost of the medication) for nongeneric (brand name) oral anticancer medications to current cost sharing for nongeneric injectable/intravenous anticancer medications. CHBRP modeled compliance with the mandate as resulting in the lower of the two cost-sharing percentages being applied to nongeneric oral anticancer medications.

Table 1 summarizes the estimated utilization, cost, and benefit coverage impacts of AB 1000.

Benefit Coverage Impacts

- Although AB 1000 is not expected to expand benefit coverage, CHBRP estimates that almost all enrollees with health insurance subject to the mandate have at least some coverage for anticancer medications.

- AB 1000 would affect the health insurance of the 20.1 million enrollees with health insurance not purchased by CalPERS whose insurance provides an outpatient prescription drug benefit.

  - 100% of these enrollees are estimated to have coverage for intravenous and injected anticancer medications.

  - 97.4% of these enrollees are estimated to have coverage for *nongeneric* oral anticancer medications.

  - Approximately 2.6% of these enrollees have no coverage for outpatient oral *nongeneric* anticancer medications, because they have generic-only coverage.

Utilization Impacts

- CHBRP estimates that 0.3% of enrollees with health insurance subject to the mandate will use nongeneric oral anticancer medications during the year following implementation.

  - Of those enrollees using nongeneric anticancer medications, CHBRP estimates that 62.9% use oral only, 29.2% use injected or intravenous only, and 8.0% use a combination of oral and injected/intravenous anticancer medications.

- CHBRP does not estimate a measurable increase in the number of oral anticancer medications users nor a measurable increase in the number of prescriptions per user because:

  - The bill does not extend benefit coverage for nongeneric oral anticancer medications to enrollees currently without coverage. It only affects cost sharing for those enrollees already with benefit coverage for nongeneric anticancer medications.
  - The price elasticity of demand[7] 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.
  - Few oral anticancer medications have injected or intravenously administered substitutes, and clinical indications may differ between administration forms. A limited number of enrollees have a type and stage of cancer that would allow substitution of an oral anticancer medication for an intravenous or injected anticancer medication. Some portion of these may opt for intravenous or injected medications premandate due to cost considerations. This dynamic cannot be quantified due to the complex clinical factors that are involved when considering potential substitutions.

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

Cost Impacts

- AB 1000 would shift some nongeneric oral anticancer medication costs from users to health plans and insurers through reduced cost sharing. In total, users would see a reduction in out-of-pocket costs of an estimated $2,650,000 due to lesser cost-sharing requirements.
    - On average, the amount of the shift is estimated to be $100.28 per user per year.
    - Postmandate amounts shifted from users to plan/insurer would range from $0 to $18,262 per user per year. The wide variation is related to the price of particular nongeneric oral anticancer medications, the utilization of a particular user, and the cost-sharing provisions of any one user's contract or policy.
- Total net annual expenditures are estimated to increase by $487,000, or 0.0005%, mainly due to the administrative costs associated with the implementation of AB 1000.
- The mandate is estimated to increase premiums by about $3,137,000 (0.0036%). The distribution of the impact on premiums is as follows:
    - Total premiums for private employers are estimated to increase by $2,030,000, or 0.0039%.
    - Enrollee contributions toward premiums for group insurance are estimated to increase by $541,000, or 0.0036%.
    - Total premiums for those with individually purchased insurance are estimated to increase by $565,000, or 0.0084%.
    - Increases in insurance premiums vary by privately purchased market segment, ranging from approximately 0.0030% (DMHC-regulated large-group plans) to 0.0139% (CDI-regulated individual policies). Increases as measured by per member per month (PMPM) payments are estimated to range from approximately $0.0120 (DMHC-regulated large-group plans) to $0.0383 (CDI-regulated small-group policies).
- AB 1000 exempts health insurance purchased by CalPERS.
- AB 1000 would apply Medi-Cal Managed Care, Healthy Families Program (HFP), and Access for Infants and Mothers (AIM). However, the California Department of Health Care Services (DHCS), which administers Medi-Cal, and the Managed Risk Medical Insurance Board (MRMIB), which administers HFP and AIM, would not be expected to face measurable expenditure or premium increases as these plans currently cover oral anticancer medication benefits with minimal or no cost-sharing requirements. Major Risk Medical Insurance Program (MRMIP) plans have cost-sharing provisions similar to those included in privately purchased plans; therefore, MRMIP plans would face some impacts as a result of AB 1000. However, because the population enrolled in MRMIP is very small (8,000) and high risk, it is difficult to estimate this impact with accuracy.
- The estimated premium increases would not have a measurable impact on number of persons who are uninsured.

Public Health Impacts

- CHBRP does not project a measurable increase in utilization of oral anticancer medications as a result of AB 1000. Therefore, the only potential public health impact as a result of AB 1000 is a reduction in out-of-pocket costs for oral anticancer medications. This could reduce the financial burden and related health consequences faced by cancer patients.

- Breast cancer is the most prevalent cancer in California, almost exclusively affecting women. Approximately 70% of the prescriptions and 31% of the total cost for nongeneric oral anticancer medications are for drugs used to treat breast cancer. Therefore, to the extent that AB 1000 reduces out-of-pocket costs for patients, there is a potential to reduce the financial burden faced by women undergoing treatment for breast cancer.

- After breast cancer, the next three most common cancers in California are colorectal, prostate, and lung cancer. Non-Hispanic blacks in California have higher rates of diagnoses of these three cancers compared to all other racial and ethnic groups. These three cancers may all be treated using nongeneric oral anticancer medications; therefore, to the extent that AB 1000 reduces out-of-pocket costs for nongeneric oral anticancer medications, non-Hispanic black cancer patients could face a reduced financial burden.

- The utilization of nongeneric oral anticancer medications is not projected to change measurably as a result of AB 1000. Therefore, there is no expected reduction in premature death or economic loss as a result of the passage of this mandate.

Potential Effects of the Federal Affordable Care Act

The federal "Patient Protection and Affordable Care Act" (P.L.111-148) and the "Health Care and Education Reconciliation Act" (H.R.4872) were enacted in March 2010. These laws (together referred to as the "Affordable Care Act [ACA]") are expected to dramatically affect the California health insurance market and its regulatory environment, with most changes becoming effective in 2014. How these provisions are implemented in California will largely depend on pending legal actions, funding decisions, regulations to be promulgated by federal agencies, and statutory and regulatory actions to be taken by California state government. The provisions that go into effect during these transitional years would affect the baseline, or current enrollment, expenditures, and premiums. 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 proposed mandate would impact benefit coverage, utilization, costs, and public health, holding all other factors constant. CHBRP's estimates of these marginal effects are presented in this report.

Essential health benefits offered by qualified health plans in the Exchange and potential interactions with AB 1000

The ACA requires beginning 2014 that states "make payments…to defray the cost of any additional benefits" required of qualified health plans (QHPs) sold in the Exchange beyond the essential health benefits (EHBs) outlined in the ACA.[8]

EHBs explicitly include "prescription drugs."[9] In order to determine whether any additional state fiscal liability as it relates to the Exchange would be incurred under AB 1000, the following factors would need to be examined:

- A determination of whether AB 1000 actually constitutes a requirement of "additional benefits," given provisions (c), (d), and (e), which state that it does not require the coverage of additional medications, does not prohibit plans/insurers from removing drugs from formulary, and does not apply to plans which do not provide coverage for prescription drugs;
- The scope of "prescription drug" benefits in the final EHB package;
- A determination of whether the cost-sharing requirement under AB 1000 is consistent with the cost-sharing structures of the QHPs to be offered in the California Exchange;
- The number of enrollees in QHPs; and,
- The methods used to define and calculate the cost of additional benefits.

[8] Affordable Care Act, 1311(d)(3)(B).
[9] Affordable Care Act, Section 1302(b)(1)(F).

Table 1. AB 1000 Impacts on Benefit Coverage, Utilization, and Cost, 2011

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Benefit coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	21,902,000	21,902,000	0	0%
Total enrollees with health insurance subject to AB 1000 (b)	20,103,000	20,103,000	0	0%
Percentage of enrollees subject to AB 1000 with coverage for:				
Nongeneric oral anticancer medications	97.4%	97.4%	0.0%	0%
Injected/intravenous anticancer medications	100.0%	100.0%	0.0%	0%
Number of enrollees subject to AB 1000 with coverage for:				
Nongeneric oral anticancer medications	19,575,775	19,575,775	0	0%
Injected/intravenous anticancer medications	20,103,000	20,103,000	0	0%
Utilization and cost				
Annual number of scripts per 1,000 enrollees who have coverage for prescription drugs				
Nongeneric oral anticancer medications	11.05	11.05	0.00	0%
Average cost per script, paid by plans/insurers and enrollees				
Nongeneric oral anticancer medications	$1,480.65	$1,480.65	$0.00	0%
Total annual cost of nongeneric oral anticancer medications				
Costs paid by plans/insurers	$301,020,000	$303,670,000	$2,650,000	1%
Costs paid by enrollees	$13,587,000	$10,937,000	–$2,650,000	–20%
Costs paid by plans/insurers and enrollees	$314,607,000	$314,607,000	$0	0%
Expenditures				
Premium expenditures by private employers for group insurance	$52,713,266,000	$52,715,296,000	$2,030,000	0.0039%
Premium expenditures for individually purchased insurance	$6,724,851,000	$6,725,416,000	$565,000	0.0084%
Premium expenditures by persons with group insurance, CalPERS HMOs, Healthy Families Program, AIM or MRMIP (c)	$15,173,472,000	$15,174,013,000	$541,000	0.0036%
CalPERS HMO employer expenditures	$3,465,785,000	$3,465,785,000	$0	0.0000%
Medi-Cal Managed Care Plan expenditures	$8,657,688,000	$8,657,688,000	$0	0.0000%
MRMIB Plan expenditures (d)	$1,050,631,000	$1,050,632,000	$1,000	0.0001%
Enrollee out-of-pocket expenses for covered benefits (deductibles, copayments, etc.)	$7,548,415,000	$7,545,765,000	–$2,650,000	–0.0351%
Enrollee expenses for noncovered benefits (e)	$8,624,000	$8,624,000	$0	0%
Total Expenditures	$95,342,732,000	$95,343,219,000	$487,000	0.0005%

Source: California Health Benefits Review Program, 2011

Notes: (a) This population includes persons with privately funded and publicly funded (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans, Healthy Families Program, AIM, MRMIP) health insurance products regulated by DMHC

or CDI. Population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employment-sponsored insurance.
(b) This excludes enrollees in CalPERS HMOs and enrollees without an outpatient prescription drug benefit.
(c) Premium expenditures by enrollees include employee contributions to employer-sponsored health insurance and enrollee contributions for publicly purchased insurance.
(d) MRMIB Plan expenditures include expenditures for 874,000 enrollees of the Healthy Families Program, 8,000 enrollees of MRMIP, and 7,000 enrollees of the AIM program.
(e) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.
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; MRMIB=Managed Risk Medical Insurance Board; MRMIP=Major Risk Medical Insurance Program.

INTRODUCTION

The California Assembly Committee on Health requested on February 18, 2011, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 1000, a bill that would impose a health benefit mandate related to cost-sharing for oral anticancer medications. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.[10]

Approximately 21.9 million Californians (59%) have health insurance that may be subject to a health benefit mandate law passed at the state level.[11] Of the rest of the state's population, a portion is uninsured (and so has no health insurance subject to any benefit mandate) and another portion has health insurance subject to other state law or only to federal laws.

Uniquely, California has a bifurcated system of regulation for health insurance subject to state-level benefit mandates. The California Department of Managed Health Care (DMHC)[12] regulates health care service plans, which offer benefit coverage to their enrollees through health plan contracts. The California Department of Insurance (CDI) regulates health insurers,[13] which offer benefit coverage to their enrollees through health insurance policies.

AB 1000 would not directly affect coverage for persons enrolled in programs or health insurance products not subject to California benefit mandates. Examples would include those enrolled in Medicare Advantage plans or those who have coverage through self-insured employer plans, such as the California Public Employees' Retirement System (CalPERS) preferred provider organizations (PPOs). These forms of coverage are exempted from state insurance regulation by federal laws. AB 1000 would not directly affect uninsured persons who have no coverage.

DMHC-regulated plans and CDI-regulated policies, except plans purchased by CalPERS and those without an outpatient prescription drug benefit, would be subject to AB 1000. Therefore, the mandate would affect the health insurance of approximately 20.1 Californians (54%).

Analysis of AB 1000

The full text of AB 1000 can be found in Appendix A.

AB 1000 mandates that plans and policies which provide coverage for cancer chemotherapy treatment be required to:

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[10] CHBRP's authorizing statute is available at: http://www.chbrp.org/documents/authorizing_statute.pdf.
[11] CHBRP's estimates are available at: http://www.chbrp.org/documents/insur_source_est_2011.pdf.
[12] DMHC was established in 2000 to enforce the Knox-Keene Health Care Service Plan of 1975; see Health and Safety Code, Section 1340.
[13] 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.

(1) Review the percentage cost share for *oral* nongeneric (brand name) cancer medications and *intravenous or injected* nongeneric cancer medications and *apply the lower of the two* as the cost-sharing provision for *oral* nongeneric cancer medications;
(2) Not provide for an increase in enrollee cost sharing for nongeneric cancer medications to any greater extent than the contract provides for an increase in enrollee cost sharing for other nongeneric covered medications.

The bill also requires that these plans:

(3) Provide coverage for a prescribed, orally administered, nongeneric cancer medication used to kill or slow the growth of cancerous cells.

But bill language specifies limitations, including that AB 1000 shall:

(4) Not apply to plans/policies that do not provide coverage for prescription drugs;
(5) Not require a plan/insurer to provide coverage for any additional medication;
(6) Not prohibit a plan/insurer from removing a prescription drug from its formulary of covered prescription drugs;
(7) Not apply to plans purchased by CalPERS.

The bill would also sunset on January 1, 2016, unless otherwise legislated.

Analytic approach and key assumptions

This analysis relies on a number of analytical assumptions.

- Because the bill specifies "medication[s] used to kill or slow the growth of cancerous cells," this analysis assumes it would not affect cost sharing for other medications (antipain, antinausea, etc.) that a cancer patient might use during the course of chemotherapy.

- Through coverage of hospital and physician/provider services as part of a medical benefit, all plans and policies—even those without an *outpatient* prescription drug/pharmacy benefit—do cover prescription drugs. But the specified limitations make clear that the bill does not require plans/policies that do not already provide coverage for nongeneric prescription drugs on an outpatient basis (i.e., no outpatient prescription drug benefit, or a generic-only benefit) to begin covering them. Therefore CHBRP assumes the bill would not affect these plans/policies, despite this ambiguity.

- The proposed mandate states that a contract/policy "shall not provide for an increase in enrollee cost sharing for nongeneric cancer medications to any greater extent than the contract [or policy] provides for an increase in enrollee [an insured's] cost sharing for other nongeneric covered medications." This language is broad, and may have the effect of limiting plans' and insurers' ability to alter benefit designs for renewing contracts (e.g., increasing copayments) for its outpatient prescription drug benefit. Given the myriad of benefit design options that plans/insurers may develop and purchasers may

choose in response to this provision, this report holds current benefit designs constant and does not address potential impacts of this provision.

- The bill establishes a sunset date of January 1, 2016. This analysis does not explicitly address this provision, in following with CHBRP's approach of analyzing the impact of mandates for the 12 months following implementation.

Chemotherapy treatment

The word *chemotherapy* can indicate the use of any medication (such as aspirin or penicillin) to treat any disease. However, the term commonly refers to medications used for cancer treatment. As specified in the language of the bill, this analysis interprets the term to refer to anticancer medications, specifically medicines that kill or slow the growth of cancerous cells. Other medications that might be prescribed to a person undergoing chemotherapy, such as antinausea, antipain, or antidiarrhea medications, have been excluded from the analysis because the bill language excludes them.

Which anticancer medications are recommended to a person with cancer is highly dependent on the nature of the diagnosed cancer and the stage of disease at the time of diagnosis. Not all cancers are treated with the same anticancer medications; there may be none, several, or only one appropriate medication. Furthermore, the recommended anticancer medications may differ for persons with the same type of cancer, depending on whether treatment is intended for an early or later stage of the disease, as well as patient-specific characteristics (e.g., kidney or liver function).

Orally administered, injected, intravenously administered

Anticancer medications can be administered in many ways:

- Oral—taken by mouth (usually as pills);
- Intravenous—infused through a vein;
- Injected—injected into a muscle or under the skin.

Other, less common means of administration also exist. Some medications can be applied topically (as a lotion) or infused directly into another portion of the body (e.g., artery, chest cavity, bladder, cerebrospinal fluid). Some can be injected directly into a tumor.

The manner in which anticancer medications are administered depends upon the specific medicine. Traditionally, the intravenous route has been most common. Medications that can be injected or orally administered are increasingly available and are expected to become even more present in coming years (Stern, 2008). However, although a few medications are available in more than one dosage form, most cancer drugs are administered by only one route.

Cost sharing for prescription Drugs

AB 1000 defines "cost sharing" explicitly for the purposes of the section as "copayment, coinsurance, or deductible provisions applicable to coverage for oral, intravenous, or injected nongeneric cancer medications." Cost sharing, in general, is a requirement by health plans or health insurers that enrollees pay some portion of health care expenses. 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. 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 AB 1000 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 than coinsurance (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 may be used to differentiate cost-sharing levels for subcategories of drugs covered under the outpatient pharmacy benefit. "Tiers" refer to variation in copayments (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. A two-tier system would usually separate generic from nongeneric (brand name) medications, and a three-tier system would further divide nongeneric 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. Four-tier structures for outpatient pharmacy benefit cost sharing are less common in California than nationally (CHCF, 2010).

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 would 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 affected by AB 1000 are enrolled in DMHC-regulated plans, which currently have limits on outpatient prescription drug cost sharing (see the following text).

Existing California requirements

No current California mandate requires coverage of prescription medications, and no mandates currently specify the terms of cost-sharing provisions specifically for oral anticancer medications. However, a number of requirements impact coverage of prescription medications.

For DMHC-regulated plans, the Department requires that benefits not be subject to "exclusion, exception, reduction, deductible, or copayment that renders the benefit illusory."[14] DMHC-regulated plans are also subject to specific limitations regarding prescription drug cost sharing.[15] Cost-sharing (copayments, coinsurance, and deductibles) rules require the following:

1. A copayment cannot exceed than the retail price of the drug.
2. A copayment or percentage coinsurance shall not exceed 50% of the "cost to the plan."
3. If a plan uses coinsurance, it must either:
    a. Have a maximum dollar amount cap on the percentage coinsurance that will be charged for an individual prescription;
    b. Apply toward an annual out-of-pocket maximum for the product; or
    c. Apply toward an annual out-of-pocket maximum for the prescription drug benefit.

CDI-regulated policies are not subject to these requirements.

Other requirements that might interact with AB 1000 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.

[14] California Code of Regulations Section 1300.67.4.
[15] California Code of Regulations, Section 1300.67.24.

H&S 1367.6/IC 10123.8 breast cancer benefits

Mandate to provide coverage for screening for, diagnosis of, and treatment for breast cancer.[16]

H&S 1367.24 authorization for nonformulary prescription drugs

Mandate to review coverage for nonformulary drugs.

Requirements in other states

CHBRP is aware of nine states that have mandates related to cost sharing for oral cancer drugs, though none is precisely equivalent to AB 1000. These are: Oregon, Vermont, Indiana, Iowa, Hawaii, Colorado, Connecticut, Kansas, and Minnesota (BCBSA, 2010). Oregon passed the first such law in 2007, mandating 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.[17] Vermont's statutory language is similar, but specifies that coverage be no less favorable "on a financial basis."[18] 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.[19] 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.[20] Hawaii requires equal coinsurance percentage or copayment amounts for medically necessary chemotherapy across both orally and intravenously administrated forms, statutorily defining the two forms—both as physician-prescribed cancer treatment—and additionally delineating "oral chemotherapy" as FDA-approved.[21] In 2010, Colorado, Connecticut, Kansas, and Minnesota also enacted legislation related to oral cancer drugs (BCBSA, 2010).

Background of the disease or condition

Nearly one in two Californians born today will develop cancer at some point in his or her lifetime (CCR, 2010). There are an estimated 144,000 cases of cancer diagnosed each year, whereas approximately 1.3 million Californians alive today have a history with the disease (CCR, 2010). It is estimated that 45% of cancer cases occur in the non-elderly population—i.e., the population most relevant to SB 961 (CHBRP, 2010; CCR, 2010). Nearly one-quarter of deaths in California result from cancer, with approximately 55,000 deaths each year (CCR,

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[16] Due to this existing mandate, persons enrolled in policies without pharmacy benefits may still have coverage for prescriptions related to breast cancer treatment, including oral anticancer medications. However, responses to CHBRP's Bill-Specific Survey indicating no coverage for oral anticancer medications did not specify breast cancer treatment as an exception. Therefore, CHBRP assumes in this analysis that no exception would be made for persons with a breast cancer diagnosis.

[17] Oregon Revised Statutes, Volume 16, Chapter 743A.068.

[18] Vermont Statutes, Title VIII, Part 3, Chapter 107, Subchapter 11, Section 4100h.

[19] Indiana Code 27-8-32 and 27-13-7-20.

[20] Iowa Code, Title XIII, Subtitle 1, Chapter 514C.24.

[21] Hawaii Revised Statutes, Volume 9, Chapter 432:1-116.

2010). 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 63% (CCR, 2010).

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 (not affected by AB 1000). 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 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, 2010).

Potential Effects of Federal Affordable Care Act

The federal "Patient Protection and Affordable Care Act" (P.L.111-148) and the "Health Care and Education Reconciliation Act" (H.R.4872) were enacted in March 2010. These laws (together referred to as the "Affordable Care Act [ACA]") are expected to dramatically affect the California health insurance market and its regulatory environment, with most changes becoming effective in 2014. How these provisions are implemented in California will largely depend on pending legal actions, funding decisions, regulations to be promulgated by federal agencies, and statutory and regulatory actions to be taken by California state government.

The provisions that go into effect during the transitional years (2011-2013) would affect the baseline, or current enrollment, expenditures, and premiums. 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 proposed mandate would impact benefit coverage, utilization, costs, and public health, holding all other factors constant. CHBRP's estimates of these marginal effects are presented in this report. Each of the provisions that have gone into effect by January 2011 has been considered to determine whether they may affect CHBRP's 2011 Cost and Coverage Model. There are still a number of provisions that have gone into effect for which data are not yet available. Where data allow, CHBRP has made adjustments to the Cost and Coverage Model to reflect changes in enrollment and/or baseline premiums. These adjustments are discussed in further detail in Appendix D.

A number of ACA provisions will need regulations and further clarity. One example is the ACA's requirement for certain health insurance to cover "essential health benefits." Effective 2014, Section 1302(b) will require small-group and individual health insurance, including "qualified health plans" that will be sold in the California Exchange, to cover specified

categories of benefits. These essential health benefits (EHBs) are defined as ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care. The Secretary of Health and Human Services is charged with defining these categories through regulation, ensuring that the EHB floor "is equal to the scope of benefits provided under a typical employer plan." In addition, the ACA would allow a state to "require that a qualified health plan offered in [the Exchange] offer benefits in addition to the essential health benefits." If the state does so, the state must make payments to defray the cost of those additionally mandated benefits, either by paying the individual directly, or by paying the qualified health plan. This ACA requirement could interact with existing and proposed California benefit mandates, especially if California decided to require qualified health plans to cover California-specific mandates, and those mandates were determined to go beyond the EHB floor. Federal regulations regarding which benefits are to be covered under these broad EHB categories and other details, such as how the subsidies for purchasers of qualified health plans are structured, are forthcoming.[22]

Essential health benefits offered by qualified health plans in the Exchange and potential interactions with AB 1000

The ACA requires beginning 2014 that states "make payments…to defray the cost of any additional benefits" required of QHPs sold in the Exchange beyond the essential health benefits (EHBs) outlined in the ACA.[23]

EHBs explicitly include "prescription drugs."[24] In order to determine whether any additional state fiscal liability as it relates to the Exchange would be incurred under AB 1000, the following factors would need to be examined:

- A determination of whether AB 1000 actually constitutes a requirement of "additional benefits", given provisions (c), (d), and (e), which state that it does not require the coverage of additional medications, does not prohibit plans/insurers from removing drugs from formulary, and does not apply to plans that do not provide coverage for prescription drugs;
- The scope of "prescription drug" benefits in the final EHB package;
- A determination of whether the cost-sharing requirement under AB 1000 is consistent with the cost-sharing structures of the QHPs to be offered in the California Exchange;
- The number of enrollees in QHPs; and
- The methods used to define and calculate the cost of additional benefits.

[22] For further discussion on EHBs and potential interaction with state mandates, please see, *California's State Benefit Mandates and the Affordable Care Act's "Essential Health Benefits"* available at: http://www.chbrp.org/documents/ACA-EHB-Issue-Brief-011211.pdf.
[23] Affordable Care Act, 1311(d)(3)(B).
[24] Affordable Care Act, Section 1302(b)(1)(F).

MEDICAL EFFECTIVENESS

As indicated in the *Introduction*, AB 1000 would require health plans and health insurance carriers that provide coverage for chemotherapy treatment for cancer to provide coverage for orally administered medications that are used to kill or slow the growth of cancer cells, on the same basis as anticancer medications that are intravenously administered or injected. To date, the U.S. Food and Drug Administration (FDA) has approved 42 oral anticancer medications. These medications are used to treat 57 different of types of cancers and play a variety of roles in cancer treatment. This section of the report provides an overview of oral anticancer medications. AB 1000 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 and whether a generic version is available.

Literature Review Methods

The medical effectiveness analysis draws heavily on research conducted for CHBRP's analysis of SB 961 (CHBRP, 2010). Descriptive information on oral anticancer medications has been updated, but the literature search and effectiveness analysis are adapted from the 2010 analysis. The conclusions of that analysis remain relevant to this analysis of AB 1000, for which the medical effectiveness questions remain the same.

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.[25] Oral medications that are prescribed to persons with cancer to alleviate pain or to reduce the side effects of chemotherapy (e.g., antianemia medications [26], antiemetic medications [27]) were

[25] Some oral medications used to treat cancer are also used to treat other diseases. CHBRP limited its analysis to persons diagnosed with cancer, because AB 1000 would apply only where these medications are used to treat cancer.

[26] 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.

excluded because AB 1000 would not apply to them. The literature search was limited to articles published in English from 2009 to early 2010 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 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 approximately 25% of them are planned to be administered orally (Weingart et al., 2008).

Substitutability of Oral and Intravenous/Injectable Anticancer Medications

For many oral anticancer medications, there are no intravenous or injected substitutes (and vice versa). However, there are some important exceptions. 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 prodrug[28] 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), Cytoxan (generic name = cyclophosphamide), Vepesid (generic name = etoposide), and Hycamtin (generic name = topotecan hydrochloride).[29] (See Table C-2 for a complete listing of oral anticancer medications for which intravenous or injected substitutes are available.)[30]

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

[28] 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.

[29] Personal conversation with Betty Chan, PharmD, February 2010.

[30] For some persons with health plans or health insurance policies to which AB 1000 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

Availability of Generic Equivalents for Oral Anticancer Medications

The provisions of AB 1000 would only apply to cost sharing for *nongeneric* oral anticancer medications. Most oral anticancer medications are available only as brand-name (i.e., nongeneric) medications. Generic equivalents are available for only 10 of the 42 oral anticancer medications approved by the FDA (see Table C-2). 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. In 2010, CHBRP estimated that tamoxifen, a generic oral anticancer medication used to treat breast, endometrial, ovarian, and uterine cancers, would account for 24.1% of prescriptions filled for oral anticancer medications in California (CHBRP, 2010). A generic equivalent recently became available for Arimidex (generic name = anastrozole), another oral anticancer medication used to treat breast, endometrial, ovarian, and uterine cancers. CHBRP estimates that Arimidex accounted for 39.3% of prescriptions for nongeneric oral anticancer medications filled in California in 2009. Methotrexate sodium, a generic oral anticancer medication used to treat 10 types of cancer, was estimated to account for 10% of prescriptions filled.[31] Cost sharing for generic medications would not be directly affected by the provisions of AB 1000.

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.[32] They include some of the first oral anticancer medications, such as Myleran (generic name = busulfan), Leukeran

[31] 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-Hodgkin lymphoma.

[32] 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).

(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 Zolinza (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), Tasigna (generic name = nilotinib), Tykerb (generic name = lapatinib) (FDA, 2010a; NCCN, 2010; NCI, 2010; Weingart et al., 2008).

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 AB 1000 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. Endocrine agents include tamoxifen, a medication that prevents tumors from using estrogen, that is used primarily to treat or prevent breast cancer. Over the past 15 years, a new class of endocrine agents for treatment of cancers associated with estrogen have been developed. These medications, known collectively as aromatase inhibitors, 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 Zolinza (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 Tasigna (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 (remove all or part of) a tumor. A few are used to reduce the size of a tumor prior to surgery. For example, tamoxifen and the aromatase inhibitors may be given to postmenopausal women with estrogen receptor–positive breast cancer[33] 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).

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

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),[34] and other factors.

[34] 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).

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

AB 1000 would require all health plans and policies that provide coverage for cancer chemotherapy treatment to review the percentage cost share for oral nongeneric (brand name) anticancer medications and injected/intravenous nongeneric anticancer medications, applying the lower of the two as the cost-sharing provision for oral nongeneric anticancer medications. DMHC-regulated health care service plans and CDI-regulated health insurance policies with coverage for outpatient prescription drugs would be affected by AB 1000, excluding plans purchased by the California Public Employees' Retirement System (CalPERS).

This section presents current, or baseline, costs and coverage related to nongeneric oral cancer medication, and then details the estimated utilization, cost, and coverage impacts of AB 1000. For further details on the underlying data sources and methods, please see Appendix D at the end of this document.

In order to conduct its analysis within the required 60-day timeframe, CHBRP compared current cost sharing for nongeneric oral anticancer medications to current cost sharing for nongeneric injectable/intravenous anticancer medications. CHBRP then assumed that postmandate compliance would result in the lower of the two cost-sharing percentages being applied to oral anticancer medications. This analysis draws on the approach used to analyze SB 161 (CHBRP, 2009), a bill that would have had benefit coverage, utilization, and cost impacts similar to AB 1000. The updated analysis takes into account differences in bill language, but relies on some previous data.

Present Baseline Cost and Coverage

Current Coverage of Mandated Benefit

AB 1000 would affect the coverage of approximately 20.1 million enrollees in DMHC-regulated health care service plans and CDI-regulated health insurance policies in California with outpatient prescription drug coverage (Table 3). This excludes the estimated 968,000 enrollees who do not have outpatient prescription drug coverage, and the 831,000 enrollees in plans purchased by CalPERS, which are exempt from the mandate.

As discussed in the *Introduction*, all plans and policies subject to AB 1000—even those without an *outpatient* prescription drug/pharmacy benefit—cover some form of prescription drugs under benefits covering hospitalization or outpatient visits or procedures. But the bill explicitly does not require plans/policies that do not provide coverage for nongeneric prescription drugs as part of their prescription drug benefit to begin covering nongenerics. For example, a policy that only includes coverage for generic drugs as part of their outpatient prescription drug benefit would not be required to cover brand-name (nongeneric) drugs under AB 1000.

Based on CHBRP's 2010 Bill-Specific Coverage Survey, and CHBRP's 2011 Annual Premiums and Coverage Survey, CHBRP estimates that 527,000 enrollees subject to the mandate with an outpatient prescription drug benefit (2.6%) have no coverage for outpatient nongeneric oral anticancer medications, because they have a generic-only benefit. [35,36]

Cost-sharing provisions for anticancer medications provided on an outpatient basis vary widely by contract/policy. Enrollees who have coverage for oral anticancer medications generally access the coverage as an outpatient prescription drug benefit. Copayments for these benefits generally range from $0 to $50 per prescription. However, medication cost sharing provisions for some enrollees are in the form of coinsurance, which can range from 0% to 40% after any applicable deductible has been met. The deductible amount also varies by contract/policy.

In terms of publically purchased coverage, Medi-Cal Managed Care and Managed Risk Medical Insurance Board (MRMIB) plans (including plans for the Healthy Families Program [HFP], Access for Infants and Mothers [AIM], and Major Risk Medical Insurance Program [MRMIP]) all provide coverage for nongeneric oral anticancer medications.

Current Utilization Levels and Costs of the Mandated Benefit

Based on Milliman's analysis of 2009 California claims data, CHBRP estimates that enrollees with coverage of oral anticancer medications receive 11.05 prescriptions of nongeneric oral anticancer medication per year per 1,000 enrollees (Table 1) and that 0.3% of enrollees with coverage subject to the mandate will use nongeneric oral anticancer medications in a year. Of the enrollees using all forms of nongeneric anticancer medications, CHBRP estimates that 62.9% use oral only, 29.2% use injected or intravenous only, and 8.0% use a combination of oral and injected/intravenous anticancer medications.

The estimated average annual cost per nongeneric oral anticancer medication prescription for 2011 is $1,480.65. The percentage distribution of prescriptions, the average cost (health plan cost plus enrollee cost sharing), and the distributions of total cost are presented in Table 2.

[35] Six of the seven largest health plans and insurers in California that were surveyed responded to the SB 161 (2009) survey. Responses to the survey represented 76.5% of the CDI-regulated market and 90.5% of DMHC-regulated market. Combined, responses to this survey represented 88.4% of the privately insured market.

[36] This relies on data from CHBRP's 2010 Bill-Specific Survey of specifying the percentage of enrollees with brand-name drug coverage. This proportion was then applied by market segment to data on outpatient prescription drug coverage from CHBRP's 2011 Annual Enrollment and Premium Survey to produce these estimates.

Table 2. Outpatient Nongeneric Oral Anticancer Medication Prescriptions, 2011

Name	Percentage of Prescriptions	Average Cost Per Prescription (a)	Percentage of Total Cost (a)
Arimidex (b)	40.5%	$677.23	18.5%
Femara	20.9%	$701.26	9.9%
Aromasin	10.4%	$619.49	4.4%
Xeloda	8.7%	$2,096.07	12.4%
Gleevec	5.8%	$6,118.76	23.9%
Temodar	4.6%	$3,127.41	9.7%
Tarceva	2.5%	$4,672.25	8.0%
Casodex	1.6%	$825.44	0.9%
Tykerb	1.0%	$3,882.59	2.6%
Sprycel	0.7%	$6,794.43	3.1%
Nexavar	0.7%	$6,835.49	3.0%
Megace ES	0.5%	$727.97	0.2%
Purinethol	0.3%	$467.21	0.1%
Fareston	0.2%	$770.41	0.1%
Alkeran	0.2%	$159.71	0.0%
Leukeran	0.2%	$350.07	0.1%
Trexall	0.2%	$230.20	0.0%
Zolinza	0.2%	$9,558.40	1.1%
CeeNU	0.2%	$88.38	0.0%
Matulane	0.1%	$1,260.16	0.1%
Tasigna	0.1%	$9,997.56	0.8%
Afinitor	0.1%	$7,663.14	0.6%
Vesanoid	0.1%	$6,124.31	0.5%
Other	0.3%	$899.55	0.2%
TOTAL/AVERAGE	**100.0%**	**$1,480.65**	**100.0%**

Source: California Health Benefits Review Program, 2011
Notes: (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).
(b) Generic equivalents recently became available for Arimidex (generic name = anastrozole), which is used to treat breast, endometrial, ovarian, and uterine cancers. Therefore, the figures present in this table for Arimidex would be expected to change as use of the generics increases.

Table 2 notes which are the three most frequently prescribed nongeneric oral anticancer medications:

- Arimidex—40.5% of prescriptions;
- Femara—20.9% of prescriptions;
- Aromasin—10.4% of prescriptions.

Table 2 also notes that the three most expensive nongeneric oral anticancer medications on an average cost per prescription basis are:

- Tasigna—$9,997.56 per prescription;
- Zolinza—$9,558.40 per prescription;

- Nexavar—$6,835.49 per prescription.

As a percent of total costs, these are:

- Gleevec—22.4% of total costs
- Arimidex—18.4% of total costs
- Xeloda—11.6% of total costs

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

Because AB 1000 would not expand coverage for nongeneric oral anticancer medications, the costs potentially being shifted to other payers premandate that may change postmandate would be those for *covered* benefits. CHBRP recognizes that some portion of out-of-pocket expenses for covered benefits by enrollees utilizing nongeneric oral anticancer medications may be shifted to public programs, or to drug-assistance or charitable programs, but the extent of such a potential shift is unknown.

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 therefore 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 to the survey indicated that there were no substantive differences (CHBRP, 2009).

In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.[37] It is possible that such negotiations can impact the cost-sharing arrangements for anticancer medications; however, whether they do is unclear.

[37] Personal communication with the California Labor Federation and member organizations, January 2009.

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 per-unit cost

CHBRP estimates that the mandate would have no measurable short-term effect on the per-unit costs of nongeneric oral anticancer medications or the per-unit cost of other anticancer medications, primarily because CHBRP does not project a measurable change in utilization of nongeneric oral anticancer medications due to the mandate.

Postmandate coverage

AB 1000 would not require coverage for nongeneric oral anticancer medications for enrollees currently without it. Therefore, CHBRP estimates that the percentage of affected enrollees with coverage for nongeneric medications would remain 97.4% postmandate.

Changes in coverage as a result of premium increases

CHBRP projects no measurable impact on the number of persons who are uninsured because the estimated premiums increase is estimated to be approximately 0.0036%—which is less than the 1% threshold at which CHBRP would estimate a change in the number of persons covered by insurance.

How Would Utilization Change as a Result of the Mandate?

Overall utilization rates (expenses) are not projected to change as a result of the mandate. Among enrollees who had coverage prior to the mandate, CHBRP estimates a reduction of $2,650,000 for the insured population subject to the mandate in out-of-pocket expenses due to the mandate's required changes in enrollee cost-sharing provisions. CHBRP modeled the shift of cost sharing by comparing the cost-sharing percentage of outpatient nongeneric oral anticancer medications and cost-sharing percentage of nongeneric injectable/intravenous anticancer medications, and then assuming, postmandate, that the lower of the two cost-sharing percentages would be applied to the nongeneric oral anticancer medications (see Appendix D for details).

CHBRP assumes no increase in the number of users and no increase in the units of nongeneric oral anticancer medication or utilization of nongeneric oral anticancer medications among existing users of anticancer medications. As with other health benefits, CHBRP recognizes that a decrease in out-of-pocket expenditures may make it easier for some enrollees to use more drugs or more-expensive drugs, regardless of their medical effectiveness, or may encourage some patients to use nongeneric oral anticancer medications when they would otherwise have forgone them, delayed their use, or used generic versions. Additionally, CHBRP recognizes there may be pharmaceutical company–induced demand. However, CHBRP concluded that such potential increases would not measurably affect utilization. CHBRP's assumptions are supported by the following evidence:

- AB 1000 would not extend benefit coverage for nongeneric oral anticancer medications to enrollees currently without coverage. It would only affect cost sharing for nongeneric oral anticancer medications for those enrollees already with benefit coverage for these medications.

- Price elasticity[38] of demand for anticancer medications is low. Cancer is a life-threatening illness, and patients will tend to do whatever they can to comply with prescribed treatments. Price elasticity of demand for anticancer drugs has been estimated to be as low as −0.01, which is much lower than the price elasticity of demand for traditional pharmaceuticals, which is usually estimated around −0.3 to −0.5 (Goldman et al., 2006). Based on a National Comprehensive Cancer Network Task Force report, many oncologists report that patients are unlikely to interrupt primary therapy if at all possible and may seek other funding, such as second mortgages on their homes to pay for treatment (Weingart et al., 2008).

- Although there are exceptions (see Appendix C), many nongeneric oral anticancer medications have no intravenous or injected substitute, and clinical considerations further limit substitutability.

Although no increase in the number of users of anticancer medications is projected among enrollees with cancer, there is some possibility of substitution of oral in place of intravenous/injected anticancer medications. Although relatively few nongeneric oral anticancer medications have an intravenous or injected substitute (Appendix C), some do exist. Therefore, enrollees without outpatient oral anticancer medication coverage who were diagnosed with cancer, who were undergoing chemotherapy, and who were prescribed a nongeneric oral anticancer medication for which an intravenous substitute was available and clinically appropriate for the type and stage of cancer, may have been influenced by coverage and cost considerations to use the intravenous option. Postmandate, such persons may switch to a nongeneric oral anticancer medication. This dynamic cannot be quantified due to the complex clinical factors that are involved when considering potential substitutions. It is also possible that some enrollees, facing reduced cost sharing for a nongeneric oral drug for which a *generic* version is available, may choose the brand-name (nongeneric) version postmandate, leading to increased nongeneric (decreased generic) utilization. However this impact cannot be quantified because it would be contingent upon many factors, particularly the difference in cost sharing for nongeneric and generic anticancer drugs postmandate for that specific contract or policy.

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 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,

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

compliance with AB 1000 would require that plans and insurers notify members and applicants of their oral chemotherapy coverage changes. Health plans and insurers may also need to increase staff specialized in utilization management. These administrative changes were reflected in the standard administrative cost load associated with premiums.

Impact of the Mandate on Total Health Care Costs

CHBRP estimates that total net expenditures (including total premiums and out-of-pocket expenditures) for nongeneric oral anticancer medications and services would increase by $487,000, or 0.0005%, as a result of AB 1000 (Table 1). Though AB 1000 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 members using nongeneric oral anticancer medications incurred through the cost sharing provisions of a policy or contract.

Total premiums for private employers are estimated to increase by $2,030,000, or 0.0039%. Enrollee contributions toward premiums for group insurance are estimated to increase by $541,000, or 0.0036%. Total premiums for those with individually purchased insurance are estimated to increase by $565,000, or 0.0084%. The reduction in enrollee expenses for nongeneric oral anticancer medications due to cost sharing provisions would range from $0.0106 to $0.0314 PMPM in privately purchased health insurance, depending on market segment.

The major impact of the bill would be to shift some nongeneric oral anticancer medication costs from patients to health plans and policies, ranging from $0 to $18,262 per user per year. On average, the amount of the shift is estimated to be $100.28 per user per year. The wide variations in cost sharing are related to the price of a particular oral medication, as well as the benefit structure of a particular health plan or policy, that a patient has.

Therefore, total premiums are estimated to increase by $3,137,000, but there is also a reduction in out-of-pocket expenses for enrollees using covered nongeneric oral anticancer medications. This reduction in enrollee expenses for covered medications is $2,650,000.

Costs or Savings for Each Category of Payor Resulting From the Benefit Mandate

Premium impacts for privately purchased market segments are estimated (see Table 4) to be:

- 0.0030% for the large-group DMHC-regulated plans;
- 0.0074% for the large-group CDI-regulated policies;
- 0.0039% for the small-group DMHC-regulated plans;
- 0.0115% for the small-group CDI-regulated policies;

- 0.0033% for the individual DMHC-regulated plans; and
- 0.0139% for the individual CDI-regulated policies.

In terms of per member per month (PMPM) premiums, impacts are estimated to be:

- $0.0120 PMPM for the large-group DMHC-regulated plans;
- $0.0370 PMPM for the large-group CDI-regulated policies;
- $0.0138 PMPM for the small-group DMHC-regulated plans;
- $0.0383 PMPM for the small-group CDI-regulated policies;
- $0.0133 PMPM for the individual DMHC-regulated plans; and
- $0.0278 PMPM for the individual CDI-regulated policies.

AB 1000 would apply to Medi-Cal Managed Care, Healthy Families Program (HFP), and Access for Infants and Mothers (AIM). However, the California Department of Health Care Services (DHCS), which administers Medi-Cal, and the Managed Risk Medical Insurance Board (MRMIB), which administers HFP and AIM, would not be expected to face measurable expenditure or premium increases as those plans currently cover oral anticancer medication benefits with minimal or no cost-sharing requirements.

MRMIP (Major Risk Medical Insurance Program) plans have cost-sharing provisions similar to those included in privately purchased plans. They are therefore expected to face some impact. However, this impact is difficult to estimate with accuracy because:

- There are small number of enrollees (8,000);
- This is a high-risk population, and their utilization rates would vary from other market segments;
- MRMIP enrollees face an annual benefit limit of $75,000, and therefore, enrollee out-of-pocket costs may differ from other market segments.

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. It is estimated that a quarter of antineoplastic agents in the pipeline are planned as oral medications (Weingart et al., 2008). According to a recent pharmaceutical report on cancer medication development, almost 650 new medications and new indications for existing

anticancer medications are in clinical development. Many of the new medications will be expensive. As a result, health plans' and insurers' costs for 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. In addition, a 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. In a recent study, the majority of oncologists believe that patients should have access to effective therapies regardless of cost. The implied cost-effectiveness standard among this group of oncologists was $300,000/quality-adjusted life-year (QALY)[39], much higher than the generally accepted threshold for health interventions of $50,000-$100,000 per QALY. Some studies in Europe have demonstrated cost savings from replacing intravenous cancer therapy with oral therapy (Findlay et al., 2008).

Impact on Access and Health Service Availability

CHBRP expects that there will be impacts on the access to and availability of oral anticancer medication as a result of AB 1000 in the long run. To the extent that cost sharing will be reduced and limits will be removed, access to expensive oral medications would be expected to increase for the small number of enrollees who seek oral anticancer medications. Nonetheless, possible implementation of prior authorization requirements and formularies are expected to mediate the response by the health plans and insurers to this increase in demand. CHBRP is unable to estimate these effects quantitatively.

[39] The QALY is based on the number of years of life that would be added by the intervention. Each year in perfect health is assigned the value of 1.0, down to a value of 0.0 for death. If the extra years would not be lived in full health, for example if the patient would lose a limb, or be blind, or be confined to a wheelchair, then the extra life-years are given a value between 0 and 1 to account for this.

Table 3. Baseline (Premandate) Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2011

	DMHC- Regulated							CDI-Regulated			Total
	Privately Funded Plans (by Market)			CalPERS	Medi-Cal Managed Care Plans			Privately Funded Policies (by Market)			
	Large Group	Small Group	Individual	HMO (b)	65 and Over (c)	Under 65	MRMIB Plans (d)	Large Group	Small Group	Individual	
Total enrollees in plans/policies subject to state mandates (a)	10,526,000	2,241,000	733,000	831,000	285,000	3,539,000	889,000	397,000	1,118,000	1,343,000	21,902,000
Total enrollees in plans/policies subject to AB 1000	9,885,008	2,212,386	694,452	0	285,000	3,539,000	889,000	337,143	1,037,527	1,223,170	20,102,686
Average portion of premium paid by employer	$317.59	$267.09	$0.00	$347.55	$346.00	$176.00	$98.48	$375.44	$270.30	$0.00	$65,887,370,000
Average portion of premium paid by employee	$82.91	$83.47	$399.69	$86.89	$0.00	$0.00	$13.79	$122.08	$64.15	$199.13	$21,898,323,000
Total Premium	$400.51	$350.57	$399.69	$434.44	$346.00	$176.00	$112.27	$497.52	$334.45	$199.13	$87,785,693,000
Enrollee expenses for covered benefits (deductibles, copays, etc.)	$21.82	$32.63	$84.77	$22.41	$0.00	$0.00	$4.68	$63.15	$123.11	$58.53	$7,548,415,000
Enrollee expenses for benefits not covered (e)	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.13	$0.42	$8,624,000
Total Expenditures	$422.32	$383.20	$484.46	$456.84	$346.00	$176.00	$116.95	$560.67	$457.69	$258.08	$95,342,732,000

Source: California Health Benefits Review Program, 2011

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

(b) Of these CalPERS HMO members, about 58%, or 482,000, are state employees or their dependents.

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

(d) MRMIB Plan expenditures include expenditures for 874,000 enrollees of the Healthy Families Program, 8,000 enrollees of MRMIP, and 7,000 enrollees of the AIM program.

(e) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Table 4. Impacts of AB 1000 on Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2011

	DMHC- Regulated							CDI-Regulated			Total
	Privately Funded Plans (by Market)			CalPERS	Medi-Cal Managed Care Plans			Privately Funded Policies (by Market)			
	Large Group	Small Group	Individual	HMO (b)	65 and Over (c)	Under 65	MRMIB Plans (d)	Large Group	Small Group	Individual	
Total enrollees in plans/policies subject to state mandates (a)	10,526,000	2,241,000	733,000	831,000	285,000	3,539,000	889,000	397,000	1,118,000	1,343,000	21,902,000
Total enrollees in plans/policies subject to AB 1000	9,885,008	2,212,386	694,452	0	285,000	3,539,000	889,000	337,143	1,037,527	1,223,170	20,102,686
Average portion of premium paid by employer	$0.0095	$0.0105	$0.0000	$0.0000	$0.0000	$0.0000	$0.0001	$0.0279	$0.0310	$0.0000	$2,032,000
Average portion of premium paid by employee	$0.0025	$0.0032	$0.0133	$0.0000	$0.0000	$0.0000	$0.0000	$0.0091	$0.0073	$0.0278	$1,106,000
Total Premium	$0.0120	$0.0138	$0.0133	$0.0000	$0.0000	$0.0000	$0.0001	$0.0370	$0.0383	$0.0278	$3,137,000
Enrollee expenses for covered benefits (deductibles, copays, etc.)	–$0.0106	–$0.0111	–$0.0107	$0.0000	$0.0000	$0.0000	–$0.0001	–$0.0314	–$0.0307	–$0.0222	–$2,650,000
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	$0.0014	$0.0026	$0.0027	$0.0000	$0.0000	$0.0000	$0.0000	$0.0055	$0.0077	$0.0056	$487,000
Percentage Impact of Mandate											
Insured Premiums	0.0030%	0.0039%	0.0033%	0.0000%	0.0000%	0.0000%	0.0001%	0.0074%	0.0115%	0.0139%	0.0036%
Total Expenditures	0.0003%	0.0007%	0.0006%	0.0000%	0.0000%	0.0000%	0.0000%	0.0010%	0.0017%	0.0022%	0.0005%

Source: California Health Benefits Review Program, 2011

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

(b) Of these CalPERS members, about 58%, or 482,000, are state employees or their dependents.

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

(d) MRMIB Plan expenditures include expenditures for 874,000 enrollees of the Healthy Families Program, 8,000 enrollees of MRMIP, and 7,000 enrollees of the AIM program.
(e) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

PUBLIC HEALTH IMPACTS

A total of 144,000 new cancer cases and 55,000 deaths from cancer were projected to occur in California in 2011 (CCR, 2010). It was estimated that 45% of new cancer cases would occur in the non-elderly population—i.e., the population most relevant to AB 1000, which does not impact Medicare coverage (CCR, 2010). AB 1000 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 review the percentage cost share for oral nongeneric anticancer medications and intravenous or injected nongeneric anticancer medications and apply the lower of the two as the cost-sharing provision for oral nongeneric anticancer medications. This section presents the overall public health impact of passage of AB 1000, 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. This section also draws heavily on research conducted for CHBRP's previous analyses of SB 961 (CHBRP, 2010) and SB 161 (CHBRP, 2009). The conclusions of those analyses remain relevant to AB 1000.

Impact of the Proposed Mandate on the Public's Health

As presented in the *Medical Effectiveness* section, the federal Food and Drug Administration (FDA) has approved 42 oral anticancer medications to treat 57 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 *Benefit Coverage, Utilization, and Cost Impacts* section, 97.4% of enrollees in health plans and policies subject to AB 1000 with coverage for outpatient prescription drugs currently have coverage for *nongeneric* oral anticancer medications affected by AB 1000. CHBRP does not project a change in utilization of oral anticancer medications as a result of this mandate. Therefore no measurable impacts on health outcomes are projected.

CHBRP estimates that 0.3% of people with coverage subject to the mandate will use outpatient oral anticancer medications during the year following implementation. Of the people using nongeneric anticancer medications, CHBRP estimates that 62.9% use oral only, 29.2% use injected or intravenous only, and 8.0% use a combination of oral and injected/intravenous anticancer medications.

As presented in the *Medical Effectiveness* section, relatively few oral anticancer medications have an injected or intravenous substitute. AB 1000 is not projected to increase utilization of oral anticancer medications. Therefore, the only public health impact of AB 1000 is that it could lead to a decrease of $2.65 million in out-of-pocket expenditures paid by cancer patients. Research

shows that the financial burden faced by cancer patients can be substantial. One study found that 45% of cancer patients with substantial care needs report a sense of financial burden (Emanuel et al., 2000). Cancer treatment can also have significant long-term economic consequences; one study found that one-third of families lose all or most of their savings after a cancer diagnosis (Covinsky et al., 1996). Nonmedical costs due to cancer treatment, such as transportation costs and lost wages, can also result in a substantial burden for cancer patients and their families (Bennett et al., 1998).

To the extent that AB 1000 results in a reduction in out-of-pocket costs, it has the potential to reduce the financial burden faced by 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 AB 1000 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 AB 1000 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' diagnoses (CCR, 2010). In California, the lifetime risk of breast cancer is one in eight—translating into an incidence of approximately 23,800 new diagnoses a year, for a total prevalence of 291,000 women alive today who have had a breast cancer diagnosis (CCR, 2010). 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 AB 1000 (CCR, 2005). Although appropriate treatment may vary by stage of diagnosis and other factors, as shown in Table 2, approximately 70% of nongeneric oral anticancer agents are for one of three drugs (Arimidex, Femara, and Aromasin) all of which are used in the treatment of breast cancer. These three drugs represent approximately 31% of the cost of all nongeneric oral anticancer agents (Table 3).

Women with cancer are particularly likely to suffer from financial hardship. The above three drugs may be prescribed for years to reduce the risk of breast cancer recurrence, and therefore have the potential for a high overall cost burden. 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). To the extent to which AB 1000 reduces out-of-pocket costs for patients, there is a potential to reduce the financial burden faced by women undergoing treatment for breast cancer.

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 et al., 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 (Jemal et al., 2009; Ward et al., 2004). As cancer treatments become more sophisticated, the disparity between whites and non-whites is likely to widen (Meropol and Schulman, 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, 2010). This higher prevalence may result in 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). To the extent that AB 1000 reduces their out-of-pocket costs for nongeneric oral anticancer agents, non-Hispanic blacks could face a reduced financial burden as well.

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, AB 1000 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, whereas 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 and premature death, AB 1000 is not projected 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 18, 2011, the Assembly Committee on Health requested that CHBRP analyze AB 1000.

BILL NUMBER: AB 1000 INTRODUCED
BILL TEXT

INTRODUCED BY Assembly Member Perea

FEBRUARY 18, 2011

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

LEGISLATIVE COUNSEL'S DIGEST

AB 1000, as introduced, Perea. 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, until January 1, 2016, would require health care service plan contracts and health insurance policies that provide coverage for cancer chemotherapy treatment to provide coverage for a prescribed, orally administered, nongeneric cancer medication, as specified. The bill would require a health care service plan or health insurer to review the percentage cost share, as defined, for oral nongeneric cancer medications and intravenous or injected nongeneric cancer medications and to apply the lower of the 2 as the cost-sharing provision for oral nongeneric cancer medications. The bill would limit increases in cost sharing for nongeneric cancer

medications, as specified. The bill would specify that its provisions do not apply to health care service plan contracts or health insurance policies that do not provide coverage for prescription drugs. The bill would specify that its provisions do not apply to a health care benefit plan, contract, or health insurance policy with the Board of Administration of the Public Employees' Retirement System.

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

1367.655. (a) A health care service plan contract issued, amended, or renewed on or after January 1, 2012, that provides coverage for cancer chemotherapy treatment shall provide coverage for a prescribed, orally administered, nongeneric cancer medication used to kill or slow the growth of cancerous cells and shall review the percentage cost share for oral nongeneric cancer medications and intravenous or injected nongeneric cancer medications and apply the lower of the two as the cost-sharing provision for oral nongeneric cancer medications. A health care service plan contract shall not provide for an increase in enrollee cost sharing for nongeneric cancer medications to any greater extent than the contract provides for an increase in enrollee cost sharing for other nongeneric covered medications.

(b) For purposes of this section, "cost share" means copayment, coinsurance, or deductible provisions applicable to coverage for oral, intravenous, or injected nongeneric cancer medications.

(c) Nothing in this section shall be construed to require a health care service plan contract to provide coverage for any additional medication not otherwise required by law.

(d) Nothing in this section shall prohibit a health care service plan from removing a prescription drug from its formulary of covered prescription drugs.

(e) This section shall not apply to a health care service plan contract that does not provide coverage for prescription drugs.

(f) 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).

(g) This section shall remain in effect only until January 1, 2016, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2016, deletes or extends that date.

SEC. 2. Section 10123.205 is added to the Insurance Code, to read:

10123.205. (a) A health insurance policy issued, amended, or renewed on or after January 1, 2012, that provides coverage for cancer chemotherapy treatment shall provide coverage for a prescribed, orally administered, nongeneric cancer medication used to kill or slow the growth of cancerous cells and shall review the percentage cost share for oral nongeneric cancer medications and intravenous or injected nongeneric cancer medications and apply the lower of the two as the cost-sharing provision for oral nongeneric cancer medications. A health insurance policy shall not provide for an increase in insured cost sharing for nongeneric cancer medications to any greater extent than the policy provides for an increase in an insured's cost sharing for other nongeneric covered medications.

(b) For purposes of this section, "cost share" means copayment, coinsurance, or deductible provisions applicable to coverage for oral, intravenous, or injected nongeneric cancer medications.

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

(d) Nothing in this section shall prohibit a health insurer from removing a prescription drug from its formulary of covered prescription drugs.

(e) This section shall not apply to a health insurance policy that does not provide coverage for prescription drugs.

(f) This section shall not apply to a policy of health insurance purchased by 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).

(g) This section shall remain in effect only until January 1, 2016, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2016, deletes or extends that date.

SEC. 3. 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

The below describes the literature review methods used in the analysis of SB 961 (2010), upon which the Medical Effectiveness *section of this report is based.*

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.[40] Oral medications that are prescribed to persons with cancer to alleviate pain or to reduce the side effects of chemotherapy (e.g., antianemia drugs[41], antiemetic drugs[42]) were excluded because SB 961 would not apply to them (CHBRP, 2010). The literature search was restricted to articles published in English from 2000 to February 2010. The following databases that index peer-reviewed journals were searched: the Cochrane Library,[43] 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.

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[40] 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 961would apply only where these medications are used to treat cancer.

[41] 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.

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

[43] 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 Web sites

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
Cytoxan	Cyclophosphamide
Droxia, Hydrea	Hydroxyurea
Emcyt	Estramustine
Eulexin	Flutamide
Fareston	Toremifene
Femara	Letrozole
Gleevec	Imatinib mesylate
Hexalen	Altretamine
Hycamtin	Topotecan hydrochloride
Iressa	Gefitinib
Leukeran	Chlorambucil
Lysodren	Mitotane
Matulane	Procarbazine
Megace	Megestrol acetate
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
Oforta	Fludarabine
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
Votrient	Pazopanib
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	Astrocytoma (nerve tissue tumor), islet cell tumors, kidney cancer, Waldenström's macroglobulinemia/ lymphoplasmacytic lymphoma	Used to treat patients with advanced, inoperable, or recurrent kidney cancer who have not responded to treatment with Nexavar or Sutent; used for treatment of nerve tissue tumor , acute myeloid leukemia, and lymphoma	Yes—similar to an IV-administered drug (Torisel): for Kidney cancer only (not FDA approved for astrocytoma)
Alkeran	Melphalan	Cytotoxic agents	No	1964	Epithelial ovarian cancer, melanoma, multiple myeloma, multiple types of Hodgkin lymphoma, plasmacytoma	Used in advanced, inoperable ovarian cancer; used as palliative treatment for multiple myeloma	Yes—IV formulation of same drug[44]

[44] The IV formulation of Alkeran (melphalan) is used to treat Hodgkin lymphoma, melanoma, multiple myeloma, ovarian cancer, plasmacytoma.

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	Yes	1995	Breast cancer, endometrial cancer, ovarian cancer, uterine sarcoma	Postoperative treatment of postmenopausal women with hormone receptor–positive breast cancer; treatment of postmenopausal women with advanced or metastastic breast cancer that has progressed despite treatment with tamoxifen; treatment of premenopausal women with breast cancer whose ovaries have been removed	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
Aromasin**	Exemestane	Endocrine agents	No	1999	Breast cancer, endometrial cancer, uterine sarcoma	Postoperative treatment of postmenopausal women with hormone-receptor positive breast cancer following 2 to 3 years of tamoxifen; treatment of postmenopausal women with advanced or metastastic breast cancer that has progressed despite treatment with tamoxifen	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, Hodgkin lymphoma	Second-line treatment for inoperable, progressive, and recurrent brain tumors following radiation or surgery; second-line treatment for progressive or recurrent Hodgkin 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
Cytoxan	Cyclophosphamide	Cytotoxic agents	Yes	1999	Basal cell and squamous cell skin cancers, bone cancer, breast cancer, glioblastoma, glioma, Merkel cell carcinoma, multiple myeloma, multiple types of leukemia, multiple types of lymphoma, neuroblastoma, mycosis fungoides/ Sézary syndrome, 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, meningioma, ovarian cancer	Used in treatment of resistant chronic 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; used alone as low-intensity treatment for acute myeloid leukemia	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 prostate 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	Used in treatment for postmenopausal women with recurrent or metastatic hormone-receptor positive breast cancer; treatment for residual and inoperable desmoid tumors	No
Femara	Letrozole	Endocrine agents	No	1997	Breast cancer, endometrial cancer, ovarian cancer, uterine sarcoma	Postoperative treatment of postmenopausal women with early stage or locally advanced or metastatic hormone receptor–positive breast cancers; treatment of postmenopausal women whose breast cancers have progressed despite hormone therapy with antiestrogen; extended treatment for postmenopausal women with early stage breast cancer following 5 years treatment with tamoxifen; treatment for ovarian 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
Gleevec	Imatinib mesylate	Targeted agents	No	2003	Chordoma, chronic myeloid leukemia, dermatofibrosarcoma protuberans, desmoid tumors, gastrointestinal stromal tumors, lymphoblastic lymphoma	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	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[45]

[45] The IV formulation of Hycamtin (topotecan hydrochloride) is used to treat bone cancer, central nervous system lymphoma, cervical cancer, Merkel cell carcinoma, ovarian cancer, as well as small-cell lung cancer.

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 agemts	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 lymphoid leukemia; multiple types of lymphoma	Treatment for early stage, advanced, and progressive cancers	No
Lysodren	Mitotane	Cytotoxic agents	No	2003	Adrenocortical cancer	Used to treat inoperable adrenal cortical carcinoma	No
Matulane	Procarbazine	Cytotoxic agents	No	1969	Brain tumors, Hodgkin's lymphoma, multiple types of non-Hodgkin's lymphoma	Use as second-line treatment for advanced Hodgkin lymphoma or for progressive and recurrent Hodgkin lymphoma in persons initially treated with radiation alone; used in combination with other anticancer medications for second-line therapeutic or palliative treatment of progressive and recurrent brain tumors; 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; treatment for metastatic, inoperable, and recurrent uterine sarcoma; also used to treat persistent, progressive, or recurrent ovarian cancer	No
Myleran	Busulfan	Cytotoxic agents	No	1954	Chronic myeloid leukemia	Palliative for initial and maintenance treatment for chronic myeloid leukemia	Yes—IV formulation of same drug
Nexavar	Sorafenib tosylate	Targeted agents	No	2005	Angiosarcoma, gastrointestinal stromal tumors; hepatocellular (liver) cancer, kidney cancer, thyroid cancer	Used alone as first-line treatment for advanced, metastatic, inoperable, progressive, and recurrent kidney and liver cancers; also used to treat persons with potentially operable hepatocellular cancers who decline surgery; second-line treatment for persons who no longer benefit from Gleevec or Sutent	No***

*** Drug has similarity to Torisel, but only in indication for renal cancer, both drugs have different mechanisms of actions and indications.

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; 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
Oforta	Fludarabine	Cytotoxic agents	No	2008	Refractory B-cell chronic lymphocytic leukemia	Used in treatment of relapsed or refractory B-cell chronic lymphocytic leukemia whose disease has not responded to, or has progressed during or after treatment with at least one standard alkylating agent–containing regimen	Yes—IV formulation of same drug
Purinethol	Mercaptopurine	Cytotoxic agents	Yes	1953	Acute lymphatic leukemia, acute promyelocytic leukemia, lymphoblastic lymphoma	Used in combination with other anticancer medications to prevent recurrence of cancer	No
Revlimid	Lenalidomide*	Cytotoxic agents	No	2005	Multiple myeloma, multiple types of non-Hodgkin lymphoma, myelodysplastic syndromes, solitary plasmacytoma	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 smoldering myeloma that has progressed beyond stage II or active myeloma; second-line treatment for relapsed or progressive mantle cell lymphoma, and diffuse large B-cell 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
Rheumatrex, Trexall	Methotrexate sodium	Cytotoxic agents	Yes—for some strengths	1953	Acute promyelocytic leukemia, breast cancer, desmoid tumors, head and neck cancers, lung cancer, multiple types of non-Hodgkin lymphoma, trophoblastic cancers	Used alone or in combination with other cancer medications or radiation in early-stage, advanced, residual, and metastatic cancers (uses vary across cancers type)	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 (Ph+) lymphoblastic leukemia; chronic myeloid leukemia (in chronic, accelerated or blast phase, resistant or intolerant to prior therapy, including newly diagnosed chronic myeloid leukemia (Ph+) in chronic phase), post-allogeneic stem cell transplantation treatment for chronic myeloid leukemia, gastrointestinal stromal tumor	Used as first line or second line, 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; 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	Gastrointestinal stromal tumor(GIST), islet cell tumors, kidney cancer, non-GIST soft tissue sarcoma,	Used alone or in combination with other anticancer medications to treat persons with advanced kidney cancer or 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; used to treat advanced, refractory thyroid cancer; treatment of pancreatic neuroendocine tumors; treatment of non-GIST soft tissue sarcoma	No***
Tabloid	Thioguanine	Cytotoxic agents	No	1966	Acute myeloid leukemia, lymphoblastic lymphoma	Used in combination with other anticancer medications as 1st line treatment to prevent recurrence of cancers	No

*** Drug has similarity to Torisel, but only in indication for renal cancer, both drugs have different mechanisms of actions and indications.

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	Chordoma, non–small-cell lung cancer, pancreatic cancer	First-line treatment either alone or in combination with other anticancer medications for locally advanced, metastatic non–small-cell lung cancer; 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 (i.e., mycosis fungoides, and Sézary syndrome) refractory to prior systemic treatment	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	Accelerated or chronic phase chronic myeloid leukemia refractory to prior therapy, first-line treatment chronic-phase PH+ 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 as first-line treatment for chronic-phase PH+ chronic myeloid leukemia; treatment of progressive disease when patient no longer benefits from other anticancer medications (i.e., Gleevec or Sutent)	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	Advanced melanoma, bone cancer, brain tumors (anaplastic astrocytoma, glioblastoma, glioma), central nervous system lymphoma, mycosis fungoides/ Sézary syndrome, neuroendocrine tumors, refractory soft tissue sarcoma	Used alone or concurrently with radiation treatment and as post-radiation treatment, postoperative treatment, treatment for early stage, advanced, metastatic, progressive, refractory, or recurrent cancers	Yes—IV formulation of same drug
Thalomid	Thalidomide	Cytotoxic agents	No	1998	Multiple myeloma, solitary plasmacytoma, Waldenström's macroglobulinemia/ lymphoplasmacytic lymphoma	Used alone or in combination with other anticancer medications as a first-line treatment for newly diagnosed, 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 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	Small-cell lung cancer	Used alone or in combination with other anticancer medications, radiation 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[46]
Vesanoid	Tretinoin	Cytotoxic agents	Yes	2004	Acute promyelocytic leukemia, gastrointestinal stromal tumors	Used alone or in combination with other anticancer medications for cancers that have not responded to anthracycline-based cytotoxic chemotherapeutic regimens or who cannot tolerate these drugs	No
Votrient	Pazopanib	Targeted agents	No	2009	Advanced renal cell cancer, kidney cancer, thyroid cancer	Used in treatment of advanced cancers	No

[46] IV indications are: bone cancer, breast cancer, central nervous system cancers, Hodgkin lymphoma, Merkel cell carcinoma, multiple myeloma, neuro-endocrine tumors, multiple types of non-Hodgkin lymphoma, non–small-cell lung cancer, occult primary malignancy, ovarian cancer, prostate cancer, small cell lung cancer, solitary plasmacytoma, testicular cancer, thymic malignancies.

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	Advanced or metastatic breast cancer; advanced or metastatic colorectal cancer; adjuvant (postoperative) treatment of Dukes Stage C (advanced) colon cancer, brain tumors, carcinoid tumors, 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 (i.e., mycosis fungoides, Sézary syndrome)	Used to treat 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 Sézary syndrome	No

Sources: Betty Chan, PharmD, Department of Clinical Pharmacy, University of Southern California; National Cancer Institute Drug Information Summaries; National Comprehensive Cancer Network, Drugs and Biologics Compendium; PubMed Health Drugs and Supplements; U.S. Food and Drug Administration Approved Drug Products and Patient Information Sheets and *Orange Book: Approved Drug Products With Therapeutic Equivalence Evaluations* (FDA, 2010b).

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 http://www.chbrp.org/costimpact.html.

The cost analysis in this report was prepared by the members of cost team, which consists of CHBRP task force members and contributors from the University of California, San Diego, and the University of California, Los Angeles, as well as the contracted actuarial firm, Milliman, Inc. (Milliman). Milliman 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 in the following text.

Health insurance

1. The latest (2009) California Health Interview Survey (CHIS, 2009), which is used to estimate health insurance for California's population and distribution by payor (i.e., employment-based, individually purchased, or publicly financed). The biennial CHIS is the largest state health survey conducted in the United States, collecting information from approximately 50,000 households. More information on CHIS is available at http://www.chis.ucla.edu.

2. The latest (2010) 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/publications/2010/12/california-employer-health-benefits-survey.

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 http://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 (2010 Group Health Insurance Survey) contains data from seven major California health plans regarding their 2010 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 an estimated 93.7% of the persons with health insurance subject to state mandates. This figure represents an estimated 94.4% of enrollees in full service (nonspecialty) DMHC-regulated health plans and an estimated 90.1% of enrollees in full service (non-specialty) CDI-regulated policies.[47]

[47] CHBRP analysis of the share of enrollees included in CHBRP's Bill-Specific Coverage Survey of the major carriers in the state is based on "CDI Licenses with HMSR Covered Lives Greater Than 100,000" as part of the Accident and Health Covered Lives Data Call, December 31, 2009, by the California Department of Insurance, Statistical Analysis Division, data retrieved from The Department of Managed Health Care's interactive Web site "Health Plan Financial Summary Report," July-September 2010," and CHBRP's Annual Enrollment and Premium Survey.

Publicly funded insurance subject to state benefit mandates

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 http://www.calpers.ca.gov.

6. Enrollment in Medi-Cal Managed Care (beneficiaries enrolled in Two-Plan Model, Geographic Managed Care, and County Operated Health System 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/RASS_General_Medi_Cal_Enrollment.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 http://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 1 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. (2005) 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% increase in premiums (about –0.088), divided by the average percentage of insured persons (about 80%), multiplied by 100%, i.e., ({[–0.088/80] × 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%.

Potential Effects of the Federal Affordable Care Act

As discussed in the *Introduction*, there are a number of the ACA provisions that have already gone into or will go into effect over the next 3 years. Some of these provisions affect the baseline or current enrollment, expenditures, and premiums. This subsection discusses adjustments made to the 2011 Cost and Coverage Model to account for the potential impacts of the ACA that have gone into effect by January 2011. It is important to emphasize that CHBRP's analysis of specific mandate bills typically address the marginal effects of the mandate bill—specifically, how the proposed mandate would impact benefit coverage, utilization, costs, and public health, holding all other factors constant. CHBRP's estimates of these marginal effects are presented in the *Benefit Coverage, Utilization, and Cost Impacts* section of this report.

CHBRP reviewed the ACA provisions and determined whether and how these provisions might affect:

1. The number of covered lives in California, and specifically the makeup of the population with health insurance subject to state mandates
2. Baseline premiums and expenditures for health insurance subject to state mandates, and
3. Benefits required to be covered in various health insurance plans subject to state mandates

There are still a number of provisions that have gone into effect for which data are not yet available. Where data allow, CHBRP has made adjustments to the 2011 Cost and Coverage Model to reflect changes in enrollment and/or baseline premiums and these are discussed here.

Coverage for adult children

PPACA Section 2714, modified by HR 4872, Section 2301, requires coverage for adult children up to age 26 as dependants to primary subscribers on all individual and group policies, effective September 23, 2010. California's recently enacted law, SB 1088 (2010) implements this provision. This could potentially affect both premiums and enrollment in 2011. According to the California Health Interview Survey (CHIS, 2009) approximately 22% of Californians aged 19-25 (1,063,000) were estimated to be uninsured at some point in 2009. As a result of the ACA, many of these young adults will likely gain access to health insurance through a parent. This dynamic may diminish the number of uninsured and may also shift some young adults from the individually-purchased health insurance market into the group market. The Departments of Treasury, Labor, and Health and Human Services estimate, for 2011, the number of young adults newly covered by his/her parent's plan would be about 0.78 to 2.12 million (using high and low take-up rate assumptions respectively). Of these young adults, about 0.2 to 1.64 million would have previously been uninsured. The corresponding incremental cost impact to group insurance policies is estimated to be a premium increase of 0.5% to 1.2%. Based on the responses to the Annual Enrollment and Premium survey, there has been an increase of 1% to 1.5% in enrollment for the 19-25 year olds and the increase varies depending on whether the parents were enrolled in the large group, small group or individual markets. Based on analysis of the estimates from the Departments of the Treasury, Labor, and Health and Human Services as well as CHIS 2009 data, approximately 25% of the increase in enrollment represents a shift from the individual market and approximately 75% were previously uninsured. CHBRP took these estimates into account and adjusted underlying population data since source data did not reflect the effects of this provision, because shift in populations were expected to be significant, and to account for potential lags in enrollment (e.g., due to awareness).

Minimum medical loss ratio requirement

PPACA Section 2718 requires health plans offering health insurance in group and individual markets to report to the Secretary of Health and Human Services the amount of premium revenue spent on clinical services, activities to improve quality, and other non-claim costs. Beginning in 2011, large-group plans that spend less than 85% of premium revenue and small-group/individual market plans that spend less than 80% of premium revenue on clinical services and quality must provide rebates to enrollees. According to the Interim Final Rule, (45 CFR Part 158) "Issuers will provide rebates to enrollees when their spending for the benefit of policyholders on reimbursement for clinical services and quality improvement activities, in relation to the premiums charged, is less than the MLR standards established pursuant to the

statute."[48] The requirement to report medical loss ratio is effective for the 2010 plan year, whereas the requirement to provide rebates is effective January 1, 2011. The MLR requirement, along with the rebate payment requirement, will affect premiums for 2011, but the effects are unknown and data are not yet available. There is potential for substantial impact on markets with higher administrative costs, including the small and individual group markets. Responses to CHBRP's Annual Enrollment and Premiums Survey indicate that carriers intend to be in compliance with these requirements. For those that may not be in compliance, the requirement to pay rebates is intended to align the MLR retrospectively. Therefore for modeling purposes, CHBRP has adjusted administrative and profit loads to reflect MLRs that would be in compliance with this provision.

Pre-Existing Condition Insurance Plan (PCIP)

PPACA Section 1101 establishes a temporary high-risk pool for individuals with pre-existing medical conditions, effective 90 days following enactment until January 1, 2014. In 2010, California enacted AB 1887 and SB 227, providing for the establishment of the California Pre-Existing Conditions Insurance Plan (PCIP) to be administered by the Managed Risk Medical Insurance Board (MRMIB) and federally funded per Section 1101. MRMIB has projected average enrollment of 23,100 until the end of 2013, when the program will expire. As of December 2010, there were approximately 1,100 subscribers.[49] The California PCIP is not subject to state benefit mandates,[50] and therefore this change does not directly affect CHBRP's Cost and Coverage Model. CHBRP has revised its annual update of *Estimates of the Sources of Health Insurance in California.*[51] to reflect that a slight increase in the number of those who are insured under other public programs that are not subject to state level mandates.

Prohibition of pre-existing condition exclusion for children

PPACA Sections 1201& 10103(e): Prohibits pre-existing condition exclusions for children. This provision was effective upon enactment). California's recently enacted law, AB 2244 (2010) implements this provision. AB 2244 also prohibits carriers that sell individual plans or policies from refusing to sell or renew policies to children with pre-existing conditions. Carriers that do not offer new plans for children are prohibited from offering for sale new individual plans in California for five years.[52] This provision could have had significant premium effects, especially for the DMHC- and CDI-regulated individual markets. The premium information is included in the responses to CHBRP's Annual Enrollment and Premium Survey. Thus the underlying data used in CHBRP annual model updates captured the effects of this provision.

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[48] Department of Health and Human Services, *Interim Final Rule: Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act.* 45 CFR Part 158. December 1, 2010.

[49] Enrollment report presented at the Managed Risk Medical Insurance Board Meeting, January 19, 2010. Available at: http://www.mrmib.ca.gov/MRMIB/Agenda_Minutes_011911/Agenda_Item_9.a_PCIP_Board_Report_for_Dec_2010_FINAL.pdf.

[50] Correspondence with John Symkowick, Legislative Coordinator, MRMIB, October 19, 2010.

[51] See: http://www.chbrp.org/documents/insur_source_est_2010.pdf.

[52] See enacted language at: http://www.leginfo.ca.gov/pub/09-10/bill/asm/ab_2201-2250/ab_2244_bill_20100930_chaptered.pdf.

Prohibition of lifetime limits and annual benefit limit changes

PPACA Section 2711 prohibits individual and group health plans from placing lifetime limits on the dollar value of coverage, effective September 23, 2010. Plans may only impose annual limits on coverage and these annual limits may be no less than $750,000 for "essential health benefits." The minimum annual limit will increase to $1.25 million on September 23, 2011, and to $2 million September 23, 2012. Earlier in 2010, CHBRP conducted an analysis of SB 890 which sought to prohibit lifetime and annual limits for "basic health care services" covered by CDI-regulated policies. CHBRP's indicated that DMHC-regulated plans were generally prohibited from having annual or lifetime limits. The analysis also indicated that less than 1% of CDI-regulated policies in the state had annual benefit limits and of those, the average annual benefit limit was approximately $70,000 for the group market and $100,000 for the individual market. Almost all CDI-regulated policies had lifetime limits in place and the average lifetime limits was $5 million. After the effective date of the PPACA Section 2711, removal of these limits may have had an effect on premiums. As mentioned, premium information is included in the responses to CHBRP's Annual Enrollment and Premium Survey. Thus the underlying data used in CHBRP annual model updates captured the effects of this provision to remove lifetime limits and to increase annual limits for those limited number of policies that had annual limits that fell below $750,000.

Medi-Cal Managed Care Enrollment: Seniors and persons with disabilities

While the PPACA allows states the option to expand coverage to those not currently eligible for Medicaid (Medi-Cal in California), large-scale expansions are not expected to be seen during 2011. However, as a result of the 2010-2011 California Budget Agreement, there are expected to be shifts in coverage for seniors and persons with disabilities. Specifically, "Seniors and persons with disabilities who reside in certain counties which have managed care plans, and who are not also eligible to enroll in Medicare, will be required to enroll in a managed care plan under a phased-in process."[53] The Medi-Cal Managed Care enrollment in CHBRP's 2011 Cost and Coverage Model has been adjusted to reflect this change. Baseline premium rates have also been adjusted to reflect an increase in the number of seniors and persons with disabilities in Medi-Cal Managed Care. Information from DHCS indicate these changes will go into effect July 1, 2011 and would affect approximately 427,000 Medi-Cal beneficiaries.[54] CHBRP used data from DHCS to adjust enrollment in Medi-Cal Managed Care, and to adjust premiums to account for the change in acuity in the underlying populations.[55]

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[53] Taylor, M. Legislative Analyst, *The Budget Package 2010-11 California Spending Plan*. LAO: November, 2010. Available at: http://www.lao.ca.gov/reports/2010/bud/spend_plan/spend_plan_110510.pdf.

[54] Data from the Department of Health Care Services, Medi-Cal Managed Care Division. Received January 14, 2011.

[55] See the study conducted for DHCS by Mercer on this topic: Mercer, *Medi-Cal Acuity Study: Seniors and Persons with Disabilities*. September 28, 2010. Available at: http://www.dhcs.ca.gov/provgovpart/Documents/Waiver%20Renewal/SPD_Study_092810.pdf

Bill Analysis-Specific Caveats and Assumptions

In most instances, orally administered anticancer medications are subject to the plans or policies' outpatient pharmacy benefits' cost sharing provisions, often in the form of flat-dollar copayments per prescription, coupled in some instances with a calendar-year deductible. Intravenously administered and injectable anticancer medications are generally covered as part of a physician office visit when the drug is administered outside of a hospital environment, and are subject to cost sharing requirements associated with a physician's office visit. The differences in forms of cost sharing between outpatient prescription drug benefit coverage and physician's office visit complicate the quantification of the impacts of AB 1000 on costs borne by the enrollee and the plan/insurer.

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

- 2009 MedStat claim data for commercial members under age 65 was used to develop baseline cost and utilization information for nongeneric oral anticancer medications and nongeneric intravenously administered and injectable anticancer medications. Claims data for enrollees who reside in California, had a diagnosis of cancer, and received nongeneric anticancer medications on an outpatient basis was used. Baseline cost of nongeneric oral anticancer medications was trended from 2009 to 2011, at a 10% annual rate of increase in cost per prescription. Because observed utilization rates were stable from 2006 to 2009, no utilization trending rates were applied to adjust to 2011.
- No changes in utilization of oral cancer medications due to the introduction of AB 1000 was assumed, only a shift of cost sharing from patients to health plans/insurers based on the evidences summarized in the *Benefit Coverage, Utilization, and Cost Impacts* section.
- Formularies, preauthorization requirements, and other coverage provisions (other than patient cost sharing) were assumed to be unchanging.
- For patients who received both nongeneric oral and nongeneric intravenous/injectable anticancer medications, the shift of cost sharing was modeled by comparing the cost sharing percentage of nongeneric oral cancer medications and cost-sharing percentage of nongeneric injectable/intravenous cancer medications, then assuming that the lower cost-sharing percentage would be applied to nongeneric oral anticancer medications postmandate (see detailed calculations in example 1 and 2).
- For patients who received only nongeneric oral anticancer medications, the patient's nongeneric oral cancer drug cost-sharing percentage was compared to the weighted average cost-sharing percentage for nongeneric injectable/intravenous cancer medications for all patients. An assumption was then made that the lower cost-sharing percentage would be applied postmandate (see detailed calculations in example 3). The weighted average cost-sharing percentage for nongeneric injectable/intravenous cancer drugs was calculated separately for all patients enrolled in DMHC-regulated health plans and CDI-regulated health policies. This is a rough approximation of the effect of AB 1000,

because it uses the average cost-sharing percentage for nongeneric injectable/intravenous cancer medications rather than the cost-sharing percentage applicable by the benefit provision's of the patient's particular health plan, which is unknown.

Example 1

Member 1 incurred the following claims on oral cancer medications and injectable cancer medications:

1. Oral cancer medications—Nine scripts with a total cost of $14,017, including $13,821 paid by health plan cost and $196 paid by the member.

2. Injectable cancer medications—20 services with a total cost of $13,890, including $13,890 paid by health plan, and $0 paid the member.

For Member 1, her cost-sharing amount as a percentage of cost for oral cancer medications is 1.4% (= 1 − 13,821/14,017). Her cost-sharing amount for injectable cancer medications is 0.0% (= 1 − 13,890/13,890). The impact of SB 161 under our assumption is that Member 1 will pay $0 (= 14,017 × 0.0%, the lesser of 1.4% and 0.0%) copay on her oral cancer medications (CHBRP, 2009).

Example 2

Member 2 incurred the following claims on oral cancer medications and injectable cancer medications:

1. Oral cancer medications—Four scripts with a total cost of $5,582, including $5,358 paid by health plan and $224 paid by the member

2. Injectable cancer medications—Six services with a total cost of $2,963, including $2,391 paid by health plan and $571 paid the member

For Member 2, her cost-sharing amount as a percentage of cost for oral cancer medications is 4.0% (= 1 − 5,358/5,582). Her cost-sharing amount for injectable cancer medications is 19.3% (= 1 − 2,391/2,963). The impact of SB 161 under our assumption is that Member 2 will pay $224 (= 5,582 × 4.0%, lesser of 4.0% and 19.3%) copay on her oral cancer medications (CHBRP, 2009) .

Example 3

Member 3 incurred the following claims on oral cancer medications and injectable cancer medications:

1. Oral cancer medications—Nine scripts with a total cost of $5,794, including $4,635 paid by health plan and $1,159 paid by the member.

2. Injectable cancer medications—Zero services with $0.

For Member 3, her cost-sharing amount as a percentage of cost for oral cancer drugs is 20.0% (= 1 − 4,635/5,794). Since she had no injectable cancer drug claims, we use the weighted average cost-sharing percentage for injectable/intravenous cancer drugs for all patients (3.8% in this example) as her cost-sharing amount for injectable cancer medications. The impact of SB 161 under our assumption is that Member 3 will pay $223 (= 5,793 × 3.8%, the lesser of 20.0% and 3.8%) (CHBRP, 2009).

Appendix E: Information Submitted by Outside Parties

The legislative request for analysis of AB 1000 was received on February 18, 2011 and in accordance with CHBRP policy, the program analyzes information submitted by outside parties during the first two weeks of the CHBRP review period.

The following documents were submitted by the Office of Assemblymember Henry Perea on April 6, 2011:

Camacho FT, Wu J, Wei W, Kimmick G, Anderson RT, Balkrishnan R. Cost impact of oral capecitabine compared to intravenous taxane-based chemotherapy in first-line metastatic breast cancer. *Journal of Medical Economics*. 2009;12(3):238-45.

Leukemia & Lymphoma Society. *Oral Chemotherapy: Cost Effectiveness*. Fact Sheet.

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Shiroiwa T, Fukuda T, and Tsutani K. Cost-effectiveness analysis of XELOX for metastatic colorectal cancer based on the NO16966 and NO16967 trials. *British Journal of Cancer*. 2009;101:12-18.

The following documents were submitted by the Office of Assemblymember Henry Perea on April 14, 2011:

New Mexico Legislative Finance Committee (LFR). *Fiscal Impact Report: CS/Senate Bill 385/aSCORC*. Santa Fe, NM; March 8, 2011.

Washington State Department of Health. Information Summary and Recommendations: Oral Chemotherapy Drug Coverage Mandated Benefit Review. December 2010. Publication No. 631-014.

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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