CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Analysis of Senate Bill 161 Health Care Coverage: Chemotherapy Treatment

A Report to the 2009-2010 California Legislature
April 17, 2009
Revised June 26, 2009

CHBRP 09-07

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. In 2002, CHBRP was established to implement the provisions of Assembly Bill 1996 (California Health and Safety Code, Section 127660, et seq.) and was reauthorized by Senate Bill 1704 in 2006 (Chapter 684, Statutes of 2006). The statute defines a health insurance benefit mandate as a requirement that a health insurer or managed care health plan (1) permit covered persons 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 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 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, reviews draft studies to ensure their quality before they are transmitted to the Legislature. Each report summarizes scientific evidence relevant to the proposed mandate, or proposed mandate repeal, but does not make recommendations, deferring policy decision making to the Legislature. The State funds this work through a small annual assessment on health plans and insurers in California. All CHBRP reports and information about current requests from the California Legislature are available at the CHBRP Web site, www.chbrp.org.

A Report to the 2009-2010 California State Legislature

Analysis of Senate Bill 161
Health Care Coverage:
Chemotherapy Treatment

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Revision: a misprint was corrected. Estimates of postmandate, out-of-pocket expenditures presented on p.34 were corrected to match the accurate figures already present in Table 1.

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PREFACE

This report provides an analysis of the medical, financial, and public health impacts of SB 161, a bill to mandate that, if chemotherapy coverage is provided, coverage of oral cancer medication must be provided on a basis no less favorable than coverage of intravenous or injected cancer medications. In response to a request from the California Senate Committee on Health on February 13, 2009, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the provisions of Senate Bill 1704 (Chapter 684, Statutes of 2006) as chaptered in Section 127600, et seq. of the California Health and Safety Code.

Janet Coffman, MPP, PhD, and Wade Aubry, MD, all of the University of California, San Francisco, prepared the medical effectiveness analysis. Bruce Abbott, MLS, of the University of California, Davis, conducted the literature search. Sara McMenamin, MPH, PhD, Matthew Ingram, BA, and Helen Halpin, ScM, PhD, of the University of California, Berkeley, prepared the public health impact analysis. Ying-Ying Meng, DrPH, of the University of California, Los Angeles, prepared the cost impact analysis. Jay Ripps, FSA, MAAA, of Milliman, provided actuarial analysis. Debi L. Reissman, PharmD, of Rxperts, and Charles L. Bennett, MD, PhD, MPP, of Northwestern University, provided technical assistance with the literature review and expert input on the analytic approach. John Lewis, MPA, of CHBRP staff prepared the background section and synthesized the individual sections into a single report. Cherie Wilkerson provided editing services. A subcommittee of CHBRP's National Advisory Council (see final pages of this report) and a member of the CHBRP Faculty Task Force, Kathleen Johnson, PharmD, MPH, PhD, of the University of Southern California School of Pharmacy, 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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California Health Benefits Review Program Analysis of Senate Bill 161, Health Care Coverage: Chemotherapy Treatment

The California Senate Committee on Health requested on February 13, 2009, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Senate Bill (SB) 161. In response to this request, CHBRP undertook this analysis pursuant to the provisions of Senate Bill 1704 (Chapter 684, Statutes of 2006) as codified in Section 127600, et seq. of the California Health and Safety Code.

SB 161 places requirements on health insurance policies regulated by the California Department of Insurance (CDI) and health plans regulated by the Department of Managed Health Care (DMHC). For both plans and policies that provide coverage for chemotherapy treatments, the bill would mandate that coverage for orally administered anticancer medications be provided on a basis no less favorable than coverage provided for injected or intravenously administered anticancer medications. The bill specifically addresses "medication used to kill or slow the growth of cancerous cells." Therefore, the mandate would not impact coverage for other drugs commonly prescribed to cancer patients, such as antipain, antidiarrhea, or antinausea medications.

Health plans and insurers apply a variety of administration and utilization management strategies to covered benefits to promote appropriate utilization and to control costs. Common strategies include provisions for cost sharing with members or enrollees. Requiring prior authorization, developing clinical guidelines, or covering only medications listed in a formulary are examples of other strategies. The exact set of provisions applicable to a person's coverage depends upon the contract or policy he or she has with a plan or insurer. Adding to the complexity of the situation, there is a great deal of variation in contracts and policies, even among those issued by a single plan or insurer. The bill's phrase "no less favorable" could apply to all utilization management strategies. However, in order to complete its analysis within the specified 60-day timeframe, CHBRP has made the simplifying assumption that coverage is already "no less favorable" for all aspects of benefits administration and utilization management except cost sharing.

Cost sharing provisions require members or enrollees to pay some portion of expenses. Common cost sharing provisions include deductibles, coinsurance, and copayments, but the provisions applicable to a person's coverage depend on his or her contract or policy. Cost sharing for medications is frequently complicated by tiered pricing. A plan or insurer may assign drugs to tiers (generic drugs in the lowest, and very expensive drugs in the highest) and apply varying copayments and coinsurance rates to different tiers. As with cost sharing in general, the impact of tiers (if any) depends on the specifics of a person's contract or policy.

In most instances, oral anticancer medications are subject to pharmacy plan patient cost sharing provisions, often a flat-dollar copayment per prescription. In some instances, the copayment may be coupled with a deductible. Intravenous and injectable anticancer medications delivered

outside a hospital setting are generally covered as part of a physician office visit. Medical benefit cost sharing may involve copayments or a percentage coinsurance. In some instances, either may be coupled with a deductible.

Cost sharing provisions vary widely by contract/policy, and the mandate only requires "coverage no less favorable" within a contract or policy, but does not require all contracts or policies to meet any one standard. For the purposes of this analysis, CHBRP assumes that health plans and insurers would comply with the mandate by reviewing the percentage cost share applied to oral anticancer medications and to intravenous/injected anticancer medication, then applying the lower of the two as the cost sharing provision for oral anticancer medications. In many cases, such a practice would lower patient out-of-pocket costs for oral anticancer medications.

The bill's phrase "no less favorable than" is vague, and so plans and insurers might comply with the mandate in ways contrary to the assumptions modeled in this report. For example, a plan or insurer could issue a contract or policy in which coinsurance (after any applicable deductible has been met) is the standard form of cost sharing for all anticancer medication. Such compliance would be "no less favorable," but would, in many instances, increase patient out-of-pocket costs for oral anticancer medications (which may previously have been subject only to a fixed-dollar copay). The estimates resulting from these assumptions therefore represent an upper bound in terms of cost for carriers.

Alternative compliance on the part of plans and insurers could lead to cost, utilization, and public health impacts different from those shown in this report.

Medical Effectiveness

Analysis approach: SB 161 would apply to such a large number of 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 reviewed the literature on orally administered anticancer medications generally and described the most widely utilized and most costly oral anticancer medications prescribed to Californians.

- All oral anticancer medications must be approved by the U.S. Federal Drug Administration (FDA) before they can be marketed or sold in the United States.

- To date, the FDA has approved 38 oral anticancer medications that are used to treat 52 different types of cancer.

- Oral anticancer medications have been available for decades, but the number of such medications has grown dramatically over the past decade, and more oral anticancer medications are being developed. Experts estimate that 100 oral anticancer medications are currently under development.

- Oral anticancer medications can be divided into three main types of medications:
  - Cytotoxic agents
  - Targeted agents
  - Hormones

- The roles of oral anticancer medications in cancer treatment vary and include:
  - Prevention of cancer recurrence in persons treated for early stage disease
  - First-line treatment to prevent growth of cancer cells
  - Second-line treatment of cancers that do not respond to first-line treatments
  - Presurgical treatment
  - Postsurgical treatment
  - Treatment of early stage cancers
  - Treatment of advanced or metastatic cancers
  - Treatment of recurrent cancers
  - Treatment of cancers that cannot be surgically removed

- Oral anticancer medications are used alone or in combination with other oral, intravenous, or injected anticancer medications, depending on the cancer they are being used treat.

- For many oral anticancer medications, there are no intravenous or injected substitutes (and vice versa). However, there are some important exceptions such as Xeloda, Temodar, and methotrexate sodium.

- The most frequently prescribed oral anticancer medications in California in 2006 were three hormone drugs (Arimidex, tamoxifen citrate, and Femara) that are used to treat breast, ovarian, endometrial, and uterine cancers.

- The most expensive oral anticancer medications prescribed to Californians are Revlimid (for multiple myeloma and myelodysplastic syndromes), Sutent (for gastrointestinal stromal tumors and for kidney, renal cell, and thyroid cancers), and Nexavar (for hepatocellular, kidney, renal cell, and thyroid cancers).

- The three oral anticancer medications that account for the largest share of total costs for such medications in California are Arimidex, Gleevec (for several types of leukemia, as well as dermatofibrosarcoma protuberans, desmoid tumors, gastrointestinal stromal tumors, myelodysplastic/myeloproliferative diseases, and systemic mastocytosis), and Xeloda (for brain tumors, islet cell tumors, and for breast, colon, esophageal, gastric, ovarian, pancreatic, and rectal cancers).

Utilization, Cost, and Coverage Impacts

Analysis approach: CHBRP modeled the impact of the mandate as a shift in cost sharing provisions. To perform the analysis, CHBRP compared current cost sharing (as a percentage of the cost of the medication) for oral cancer medications to current cost sharing for injectable/intravenous cancer medications. CHBRP then assumed that postmandate compliance with the mandate would result in the lower of the two cost sharing percentages being applied to oral cancer medications.

Table 1 summarizes the estimated utilization, cost and coverage impacts of SB 161.

Coverage

- Premandate, CHBRP estimates that the almost all enrollees with coverage subject to the mandate have at least some coverage for anticancer medications.
    - 100% of enrollees are estimated to have at least some coverage for inpatient anticancer medications and outpatient intravenous and injected anticancer medications.
    - 97.8% of enrollees are estimated to have at least some coverage for outpatient oral anticancer medications.
    - Approximately 472,000 enrollees (2.2%) have no coverage for outpatient oral anticancer medication.[1] This group includes persons with coverage from small group or individual market policies regulated by CDI.

Utilization

- CHBRP estimates that 0.4% of people with coverage subject to the mandate will use oral anticancer medications during the year following implementation.
- Of the people using outpatient anticancer medications, CHBRP estimates that 69.5% use oral only, 20.2% use injected or intravenous only, and 10.3% use a combination of oral and injected/intravenous anticancer medications.
- CHBRP estimates no measurable increase in the number of oral anticancer mediation users and no increase in the number of prescriptions per user because:
    - Premandate, 97.8% of enrollees with coverage subject to this mandate have some coverage for oral anticancer medications. In addition, public/private assistance programs exist to help with access to anticancer medications.
    - Price elasticity of demand[2] for anticancer medications is low. Cancer is a life-threatening illness, and patients will do whatever they can to comply with prescribed treatments.

[1] Some portion of this population may have coverage for generic (but not brand name) oral anticancer medications, but CHBRP is unable to specify. Therefore, the analysis assumes that none have coverage for any oral anticancer medications.

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

- Oncologists' prescribing decisions seem unlikely to change materially, as there is little evidence that oncologists base their decisions on patient cost sharing requirements and because there are no intravenous or injected substitutes for many oral anticancer medications (and vice versa).

Costs

- The major impact of the bill would be to shift some oral anticancer medication costs from patients to health plans and policies. On average, the amount of the shift is estimated to be $98 per user per year.

    - Prior to the mandate, enrollees without coverage for oral anticancer medications (2.2% of enrollees with coverage subject to the mandate) are estimated to incur $8,440,000 in out-of-pocket expenses for such drugs in 2009. If the mandate were enacted, that $8,440,000 in out-of-pocket expenses would be shifted to health plans and policies. In addition, enrollees would see a further reduction of $6,227,000 due to lesser patient cost sharing requirements.

    - Approximately 1.6% of the enrollees among this population who use oral anticancer medications have out-of-pocket costs for such medications over $1,000 per year.

    - Postmandate amounts shifted from patient to plan/insurer would range from $0 to $7,800 per user per year. The wide variations is related to the price of particular oral anticancer medications and the cost sharing provisions of any one person's contract or policy.

- Total net annual expenditures are estimated to increase by $5,007,000 annually, or 0.0059%, mainly due to the administrative costs associated with the implementation of SB 161.

- The mandate is estimated to increase premiums by about $19,674,000. The distribution of the impact on premiums is as follows:

    - Total premiums for private employers are estimated to increase by $7,287,000, or 0.0144%.

    - Total employer premiums for California Public Employees' Retirement System (CalPERS) health maintenance organizations (HMOs) are estimated to increase by $282,000, or 0.0089%. Of the amount CalPERS would pay in additional total premiums, about 59%, or $166,000, would be the cost borne by the General Fund for CalPERS members who are state employees.

    - Enrollee contributions toward premiums for group insurance are estimated to increase by $1,704,000, or 0.013%.

    - Total premiums for those with individually purchased insurance are estimated to increase by $10,401,000, or 0.175%.

- In terms of per member per month (PMPM) costs, employer premiums for large groups are expected to increase by $0.0259 for DMHC-regulated plans and $0.0409 for CDI-regulated policies. Employer premiums for small groups are expected to increase by $0.0278 PMPM for DMHC-regulated plans and by $0.2401 PMPM for CDI-regulated policies.

- Although SB 161 would apply to Medi-Cal Managed Care plans and the Healthy Families program, these programs would not be expected to face any expenditure or premium increases because they currently provide oral anticancer medication benefits in accordance with the coverage mandated by the bill.

- Premiums are expected to increase by 0.025%. Increases in insurance premiums vary by market segment, ranging from approximately 0.01% to 0.470%. Increases as measured by PMPM payments are estimated to range from approximately $0.03 to $0.80. The greatest impact on premiums will be in the small group and individual markets regulated by CDI.

Public Health Impacts

- When compared to intravenous and injectable anticancer medications, oral anticancer medications have both advantages and disadvantages. Advantages include the facts 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.

- Utilization of oral anticancer medications is not expected to increase as a result of SB 161. Therefore, the only potential public health impact as a result of SB 161 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. Sixty-five percent of the prescriptions and 33% of the total cost for oral anticancer medications are for drugs used to treat breast cancer. Therefore, to the extent that SB 161 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 are all treated using oral anticancer medications; therefore, to the extent that SB 161 reduces out-of-pocket costs for oral anticancer medications, non-Hispanic black cancer patients could face a reduced financial burden.

- The utilization of oral anticancer medications is not expected to change as a result of SB 161. Therefore, there is no expected reduction in premature death or economic loss as a result of the passage of this mandate.

Table 1. Summary of Coverage, Utilization, and Cost Impacts of SB 161

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Coverage				
Total population in plans subject to state regulation (a)	21,340,000	21,340,000	0	0.000%
Total population in plans subject to SB 161	21,340,000	21,340,000	0	0.000%
Enrollees with coverage for oral anticancer medications				
Percentage	97.8%	100.0%	2.2%	2.261%
Number	20,868,000	21,340,000	472,000	2.261%
Enrollees with coverage for intravenous and injected anticancer medications				
Percentage	100%	100%	0	0.000%
Number	21,340,000	21,340,000	0	0.000%
Utilization and Cost				
Outpatient oral anticancer medication users per 1,000 member per year	85	85	0	0.000%
Oral anticancer medication prescriptions per 1,000 members with coverage per year	25.62	25.62	0	0.000%
Cost of oral anticancer medications				
Cost to health plans/insurers	$364,582,000	$379,249,000	$14,667,000	
Cost to enrollee cancer patients	$17,206,000	$2,539,000	−$14,667,000	
Expenditures				
Premium expenditures by private employers for group insurance	$50,546,207,000	$50,553,494,000	$7,287,000	0.0144%
Premium expenditures for individually purchased insurance	$5,944,229,000	$5,954,630,000	$10,401,000	0.1750%
Premium expenditures by individuals with group insurance, CalPERS, Healthy Families, AIM, or MRMIP (b)	$13,475,994,000	$13,477,698,000	$1,704,000	0.0126%
CalPERS employer expenditures (c)	$3,161,160,000	$3,161,442,000	$282,000	0.0089%
Medi-Cal state expenditures	$4,112,865,000	$4,112,865,000	$0	0.0000%
Healthy Families state expenditures	$643,247,000	$643,247,000	$0	0.0000%
Individual out-of-pocket expenditures for covered benefits (deductibles, copayments, etc.)	$6,384,077,000	$6,377,850,000	−$6,227,000	−0.0975%
Out-of-pocket expenditures for noncovered benefits	$8,440,000	$0	−$8,440,000	-100.000%
Total annual expenditures	$84,276,219,000	$84,281,226,000	$5,007,000	0.0059%

Source: California Health Benefits Review Program, 2009.
Notes: (a) This population includes privately insured (group and individual) and publicly insured (e.g., CalPERS, Medi-Cal, Healthy Families, AIM, MRMIP) individuals enrolled in health insurance products regulated by DMHC or CDI. This population includes enrollees aged 0-64 years and enrollees 65 years or older covered by employment sponsored insurance. (b) Premium expenditures by individuals include employee contributions to employer-sponsored health insurance and member contributions to public insurance. (c) Of the CalPERS employer postmandate expenditures, about 59%, or $166,000, would be state expenditures for CalPERS members who are state employees.
Key: CalPERS=California Public Employees' Retirement System

INTRODUCTION

Senate Bill (SB) 161 would mandate that coverage for orally administered anticancer medications be on a basis no less favorable than coverage for injected or intravenously administered anticancer medications. The California Health Benefits Review Program (CHBRP) undertook this analysis in response to a request from the California Assembly Committee on Health on February 13, 2009. SB 161 was introduced by Senator Roderick Wright on February 14, 2009.

As a state benefit mandate bill[3], SB 161 directly affects insurance coverage subject to California law. Therefore, were the bill to become law, Knox-Keene[4] Health Service Plans regulated by the Department of Managed Health Care (DMHC) and the health insurance policies regulated by the California Department of Insurance (CDI) would be subject to the mandate. The bill would affect plans and policies in the large group, small group, and individual insurance markets. In addition, SB 161 would affect the coverage of persons enrolled in the California Public Employees' Retirement System (CalPERS) health maintenance organizations (HMOs), Medi-Cal Managed Care, Healthy Families, and other publicly funded programs that contract with DMHC-regulated health plans. (Please see Appendix D for a detailed description of the underlying assumptions related to the *Utilization, Cost, and Coverage Impacts* section of this analysis.)

SB 161 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 CalPERS preferred provider organizations (PPOs). These forms of coverage are exempted from state insurance regulation by federal laws. SB 161 would not directly affect uninsured persons who have no coverage.

Bill Language

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

The bill references chemotherapy treatments, which it specifies as prescribed medications used to kill or slow the growth of cancerous cells. The bill also uses the phrase "on a basis no less favorable" when referring to the coverage of oral, injected, and intravenous anticancer medications.

[3] Senate Bill (SB) 1704, CHBRP's authorizing legislation defines a benefit mandate bill as "a proposed statute that requires a health care service plan or a health insurer, or both, to…offer or provide coverage of a particular type of health care treatment or service." Thus, those enrolled in health insurance products offered by health care service plans or health insurers are the portion of the population directly affected by a benefit mandate bill.

[4] Health maintenance organizations in California are licensed under the Knox-Keene Health Care Services Plan Act, which is part of the California Health and Safety Code.

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.

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 format, most cancer drugs are administered by only one route.

Coverage "on a basis no less favorable"

Coverage for anticancer medications can differ in any of a number of ways, depending on the provision of a person's contract or policy with a plan or insurer—and a single plan or insurer may issue contracts or policies with widely varying provisions.

At a very broad level, anticancer medications may be covered as pharmacy plan benefits or as medical plan benefits, and most plans and insurers depend on the dispensing site to determine which will be the form of coverage (Stern, 2008). Intravenous anticancer medication, which is usually provided in a hospital or a physician's office, is generally covered as a medical benefit. Oral anticancer medications (usually pills) dispensed by a pharmacy are usually covered as a

pharmacy benefit. Some injected anticancer medications are considered "self-injectable," and so are regularly delivered through a pharmacy and covered as a pharmacy benefit. However, other injected anticancer medications are administered only in a physician's office (or hospital) and are covered as medical benefits. In part, these variations are due to the fact that pharmacy benefits are relatively new for health plans and policies, having been added in the 1970s and 1980s, long after hospitalization and physician visits had become covered medical benefits (McDonald, 2008). Partly for this reason, medications may be covered as medical benefits when delivered in a hospital or in a physician's office, as was the case before the general introduction of pharmacy benefits. In all cases, the variation is primarily driven by the site of delivery, rather than the form of the medication.

For both medical and pharmacy benefits, payers have devised strategies to promote appropriate utilization and control of costs. A short list of these strategies includes creation of formularies, maximization of manufacturer rebates, quantity restrictions, use of prior authorization, development of clinical guidelines, and implementation of patient cost sharing (Stern, 2008).

Cost sharing requires members or enrollees to pay some portion of expenses. Common cost sharing provisions include deductibles, coinsurance, and copayments. A deductible is a fixed dollar amount the member/enrollee must pay out of pocket within a given time period (such as a year) before reimbursement begins for eligible health care services. Coinsurance is the percentage of covered health care costs, after any applicable deductible, for which the enrollee is responsible. A copayment is a form of cost sharing in which the enrollee pays a fixed dollar amount out of pocket at the time of receiving a health care service or when paying for a prescription (after any applicable deductible). Cost sharing for medications is frequently complicated by tier pricing. A plan or insurer may assign drugs to tiers (generic drugs in the lowest and very expensive drugs in the highest) and apply varying copayments and coinsurance rates to different tiers. As with cost sharing in general, the impact of tiers (if any) depends on the specifics of a person's contract or policy.

The variety of cost sharing provisions currently used in California makes it difficult to generalize about the ways in which a cancer patient may be required to pay out of pocket for any anticancer medication. Generally, the pattern of cost sharing will depend on whether the medication is covered as a medical or pharmacy benefit, but the details of a person's contract or policy determine which cost sharing provisions are applicable.

For example, fixed copayments are a common form of cost sharing for medications delivered through a pharmacy and covered as pharmacy benefits. In such cases, a person pays $10, $40, or whatever amount his or her coverage indicates for each prescription. However, some plans and polices specify coinsurance for one or more medications. Under such terms, a person pays 15%, 20%, or whatever percentage of the medications cost is specified in his/her terms of coverage. To make matters even more complicated, the terms of coverage may (or may not) include a deductible. In such an instance, the person would be responsible for the full price of the medication subject to coinsurance until he or she spends beyond whatever deductible is specified in his or her terms of coverage, up to an out-of-pocket maximum.

The coverage of medications delivered as medical benefits is equally complex. A copayment associated with a physician office visit may cover the medication as well, so that there is no extra patient cost sharing for the medication. However, coinsurance may be applicable, in which case the patient pays the coinsurance percentage of the cost of the medication. Alternatively, depending on the exact terms of coverage, the cost of the office visit and the cost of both medications may be applicable to the deductible specified in a person's terms of coverage.

Key Assumptions and Analytic Approach

SB 161 mandates coverage for oral anticancer medications be "on a basis no less favorable" than the coverage provided for injected or intravenous anticancer medications. Plans and policies utilize a variety of administration and utilization management strategies, including cost sharing with patients. For this analysis, CHPRP assumes that current administration and utilization management strategies for all anticancer medications (e.g., prior authorization requirements, formularies, etc.), except cost sharing, are already generally comparable or "no less favorable." CHBRP makes this simplifying assumption (which essentially holds all but one variable constant) in order to complete its analysis within the specified 60-day timeframe.

Cost sharing provisions vary widely by contract/policy, and the mandate only requires "coverage no less favorable" within a contract or policy, but does not require all contracts or policies to meet any one standard. For the purposes of this analysis, CHBRP assumes that health plans and insurers would comply with the mandate by reviewing the percentage cost share applied to oral anticancer medications and to intravenous/injected anticancer medication, then applying the lower of the two as the cost sharing provision for oral anticancer medications. In many cases, such a practice would lower patient out-of-pocket costs for oral anticancer medications.

The bill's phrase "no less favorable than" is vague, and so plans and insurers might comply with the mandate in ways contrary to the assumptions modeled in this report. For example, a plan or insurer could issue a contract or policy in which coinsurance (after any applicable deductible has been met) is the standard form of cost sharing for all anticancer medication. Such compliance would be "no less favorable," but would, in many instances, increase patient out-of-pocket costs for oral anticancer medications (which may previously have been subject only to a fixed-dollar copay). The estimates resulting from these assumptions therefore represent an upper bound in terms of cost for carriers.

Alternative compliance on the part of plans and insurers could lead to cost, utilization, and public health impacts different from those shown in this report and it is likely that some mix of many compliance strategies would be utilized by the plans and insurers in California.[5]

[5] Personal communication, Sherrie Lowenstein, Department of Managed Health Care, March 2009.

Existing California Requirements

No current California mandates require coverage parity among administration forms (oral, intravenous, injected) of anticancer medication or any other type of medication.

Coverage for outpatient prescription drugs are not mandated benefit, and no mandates currently specify the terms of cost sharing provisions.

However, there are a number of health insurance benefit mandates that might have some interaction with compliance to SB 161's mandate beyond this report's focus on cost sharing. Interaction would be particularly likely for the coverage to persons whose plan or policy had not previously included any outpatient prescription drug benefit. Examples of relevant mandates that may have an interaction effect are listed by Health and Safety Code (H&S), with Insurance Code (IC):

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

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

H&S 1367.6/IC 10123.8 breast cancer benefits

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

H&S 1367.22 prescription drug benefits; medically appropriate alternatives

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

H&S 1367.24 authorization for nonformulary prescription drugs

Mandate to review coverage for non-formulary drugs

Requirements in Other States—Oregon

In 2008, Oregon enacted a mandate with language nearly identical to SB 161.

"A health benefit plan that provides coverage for cancer chemotherapy treatment must provide coverage for a prescribed, orally administered anticancer medication used to kill or slow the growth of cancerous cells on a basis no less favorable than intravenously administered or injected cancer medications that are covered as medical benefits." (ORS, Volume 16, Chapter 743A.068)

Limited information is available on the means by which Oregon plans and policies have complied, and the differences in the health insurance markets between the two states make it unclear how relevant Oregon's experience would be for California.

No survey of Oregon plans[6] has established the prevalence of any means of compliance with the new mandate, although anecdotal information is available from the bill author and the Oregon Division of Insurance. Plans without any pharmacy benefits were a focus of the legislation. A primary purpose of the legislation's sponsor[7] was to mandate coverage of oral anticancer medication by such plans. Postmandate, the sponsoring legislator's office has had contact with persons who were without coverage and now have it. However, some of these contacts reported difficulty in pursuing coverage for oral anticancer medications that have multiple clinical purposes. In these cases, despite an enrollee's cancer diagnosis, a plan has designated a medication "hormone replacement therapy" instead of "chemotherapy" and denied coverage. The frequency with which coverage has been denied in this manner is unclear. In terms of plans with premandate pharmacy benefits, the situation is also unclear. The Oregon Insurance Division has received complaints (precise figures are not available) related to oral anticancer medication coverage since the mandate was enacted.[8] Some complaints related to plans that complied by covering oral anticancer medications in a fashion more similar to traditional medical benefits, thereby making the oral anticancer medications subject to coinsurance and, in some instances, deductibles. In some cases in which patients had previously been responsible only for copayments, patient out-of-pocket costs for oral anticancer medications increased. Again, the frequency with which plans complied in such a manner is unknown.

Oregon experience may be generally inapplicable to California because the two insurance markets are different. In California, the percentage of people with coverage subject to state mandates who do not have coverage of oral anticancer medications is only 2.2%, and the rate of HMO penetration in California is 42.9%. The percentage of individuals without pharmacy benefits in Oregon is unknown, but the rate of HMO penetration in that state is only 27.1%. Therefore, exclusion of coverage of oral anticancer medications appears to be less common in California. Similarly, deductibles and coinsurance, which are more prevalent in PPOs, may be less frequent in California. Finally, where California's Medi-Cal Managed Care program would be subject to the mandate through its contracts with DMHC-regulated plans, the Oregon Health Plan (Oregon's equivalent to Medi-Cal) provides little coverage for eligible persons through

[6] Personal communication, Ronald Fredrickson, Oregon Insurance Division, March 2009.
[7] Personal communication, Sasha Pollock, Office of Oregon State Sentaor Peter Courtney, March 2009.
[8] Personal communication, Sasha Pollock, office of Oregon State Senator Peter Courtney, March 2009.

plans or policies subject to the Oregon mandate. Less than 10% of the Oregon Health Plan's enrollees have such coverage.[9]

Background of the Disease or Condition

Nearly one in two Californians born today will develop cancer at some point in their lifetime (CCR, 2008). There are an estimated 140,000 cases of cancer diagnosed each year, while approximately 1.2 million Californians alive today have a history with the disease (CCR, 2008). Nearly one-quarter of mortality in California is a result of cancer, with 55,000 deaths each year (CCR, 2008). 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, 2008).

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. Medications used for patients undergoing cancer treatment include medications 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. These medications are generally used in on-going chronic treatment rather than short term, acute treatment. 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). Four of the five most prevalent cancers in California, such as breast cancer and colorectal cancer, can be treated using oral anticancer medications (Hofer et al., 2008).

Oral anticancer medications have several advantages over intravenously administered agents. First, many anticancer medications are most effective when cancer cells are continually exposed to the medication for prolonged periods of time through daily administration of the medication (Aisner, 2007; Findlay et al., 2008; Weingart et al., 2008). Daily administration of medication is more practical when the medication can be administered orally instead of intravenously. Oral anticancer medications offers the benefit of allowing for treatment in a patient's home, which can be especially welcome with patients undergoing palliative care (Aisner, 2007; O'Neill and Twelves, 2002). Patients using oral treatments also avoid the risk of developing complications from venous catheters during lengthy IV treatment regimens (O'Neill and Twelves, 2002). Intravenous therapy can place a heavy time burden on patients' lives and interfere with other activities, and oral anticancer medications can offer a respite from frequent hospital and clinic visits (Findlay et al., 2008; Yabroff et al., 2005). A majority (90%) of patients prefer oral anticancer medications to traditional IV anticancer medications primarily due to the greater convenience of oral treatment (57%), but only when oral medications are as medically effective as their IV counterparts (Aisner, 2007; Borner et al., 2002; Fallowfield, 2005; Liu et al., 1997).

[9] Personal communication, Sharon Hill, Oregon Health Plan, March 2009.

Because patients who are treated with oral anticancer medications do not need to regularly visit hospitals or clinics to receive medication, use of oral anticancer medications could result in a reduced burden on patient care services (Twelves et al., 2001). Increased patient independence could, however, hold some risks for patients who would otherwise benefit from the support and advice offered by frequent contact with an oncology team. Some research has suggested that more patient contact with caregivers could aid in the education of the patient, helping to avoid medical complications and to manage side effects (Cassidy et al., 1999). The most important problem with oral anticancer medications is lack of adherence to treatment regimens, which some studies show to be as high as 50%, and is of particular concern in pediatric and elderly patients (Palmieri and Barton, 2007). Missing doses or "catching up" for missed doses can adversely affect a drug's effectiveness as well as a patient's health. In addition, many oral anticancer medications interact with other prescription medications, nonprescription medications, and food. Although some patients may prefer to manage their own medications, others may find the process difficult, especially if they are severely ill and do not have reliable assistance from family or friends (Aisner et al., 2007; Bedell, 2003; Weingart et al., 2008).

MEDICAL EFFECTIVENESS

As indicated in the *Introduction*, SB 161 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 38 oral anticancer medications. These medications are used to treat 52 different of types of cancers and can play different roles in treatment. This section of the report provides an overview of these medications, focusing on those that are most frequently prescribed, most expensive, or result in the highest expenditures for health plans and consumers.

Literature Review Methods

SB 161 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 during the 60 days within which California Health Benefits Review Program (CHBRP) must complete its reports. All oral anticancer medications must be approved by the FDA before they can be marketed or sold in the United States. In addition, many oncologists follow evidence-based prescribing guidelines issued by the National Comprehensive Cancer Network (NCCN), which are also used by Medicare and private health plans and health insurers to set coverage policies for anticancer medications.[10]

Appendix C contains a table that lists all of the oral anticancer medications approved by the FDA and their generic and brand names. The table also contains information regarding the cancers these medications are used to treat and the roles of these medications in cancer treatment. This information was obtained from FDA labeling information for these medications as well as the NCCN guidelines that address both "on-label" and "off-label" uses for which there is evidence of effectiveness. In addition, the last column in the table indicates whether an intravenous or injected alternative to the oral medication is available.

To identify a subset of drugs to discuss in greater depth, CHBRP analyzed data on pharmaceutical claims filed in 2006 (the latest year for which data were available to CHBRP) for Californians enrolled in health plans and health insurance policies. The analysis was limited to oral medications that are used to kill or slow the growth of cancer cells and that were prescribed to persons with a cancer diagnosis.[11] Oral medications that are prescribed to persons with cancer to alleviate pain or to reduce the side effects of chemotherapy (e.g., antianemia drugs[12], antiemetic drugs[13]) were excluded because SB 161 would not apply to them.

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[10] Personal communication, Charles Bennett, MD, PhD, March 20, 2009. The NCCN's guidelines for use of anticancer medications are contained in its Drugs and Biologics Compendium, which can be accessed on the organization's Web site. www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 20, 2009.

[11] 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 161would apply only where these medications are used to treat cancer.

[12] 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

CHBRP's analysis identified the oral anticancer medications that accounted for the largest proportions of prescriptions filled by persons in California with coverage during 2006 and those estimated to have the highest average cost per prescription in 2009. "Cost," in this instance, represents the total of amounts paid by the health plan/insurer plus amounts paid by the patient through cost sharing provisions. The analysis also identified those medications estimated to account for the highest percentages of total cost in 2009, which was determined by multiplying the number of prescriptions written by the cost per prescription. The cost estimates for 2009 were developed by trending forward data on actual costs in 2006. These drugs are discussed below. The full results of the analysis are presented in Table 3 in the *Utilization, Cost, and Coverage Impacts* section of the report.

In addition, 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 literature search was limited to articles published in English from 1994 to present. 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 312 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

As indicated above, the FDA has approved 38 oral anticancer medications for marketing and sale in the United States. Evidence-based guidelines issued by NCCN recommend the use of these medications to treat 52 different types of cancer (NCCN, 2009). They are used for frequently diagnosed cancers, such as breast, lung, and colorectal cancers, as well as 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).

Oral anticancer medications have been available for decades. Some of the first oral anticancer medications developed include Myleran (generic name = busulfan), Leukeran (generic name = chlorambucil), Purinethol (generic name = mercaptopurine), and methotrexate sodium (Bedell, 2003; Weingart et al., 2008). Over the past decade, the number of oral anticancer medications approved by the FDA has grown dramatically. This trend is likely to continue. According to a report issued by NCCN, experts estimate that 400 anticancer medications are currently under development, and 25% of them are planned to be orally administered (Weingart et al., 2008).

Oral anticancer medications may be divided into three major categories of medications: cytotoxic agents, targeted agents, and hormones. Cytotoxic agents were the first type of anticancer medication developed. One major limitation of both oral and intravenous cytotoxic agents is that they kill healthy cells as well as cancer cells, and thus, are associated with a high rate of side effects. Alkylating agents are a type of cytotoxic agent that interferes with the reproduction of

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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.

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

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. Some antimetabolites used to treat cancer are prodrugs, a type of medication administered in the inactive or a less-active form that 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 (Bedell, 2003). 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).

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. Classes of oral targeted agents include camptothecins, histone deacetylase inhibitors, and tyrosine kinase inhibitors.

Hormones are a third class of oral anticancer medications. Hormones 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 or growth of cancer cells, such as estrogen and androgen. Hormones would be covered by SB 161 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, and prostate cancer.

The roles of oral anticancer medications in cancer treatment vary. Some oral anticancer medications, such as tamoxifen citrate, are used to prevent 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), Alkeran (generic name = melphalan), and Zolinza (generic name = vorinostat), are used to treat metastatic cancers, recurrent cancers, or cancers that cannot be surgically removed. 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.

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 prolongs survival or prevents disease progression for a period of months rather than years.

For many oral anticancer medications, there are no intravenous or injected substitutes. This is especially true of hormones and targeted agents. However, there are intravenous or injected alternatives to some oral anticancer medications. 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 medication that is a prodrug 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). Other widely used oral anticancer medications for which intravenous or injected alternatives are available include Temodar (generic name = temozolamide), Trexall (generic name = methotrexate sodium), cyclophosphamide, and etoposide.

Highly Utilized and High-Cost Oral Anticancer Agents

On the basis of its analysis of pharmaceutical claims filed in 2006, CHBRP estimates that 0.5% of persons enrolled in health insurance plans or policies affected by SB 161 will use anticancer medications each year. Of the people using anticancer medications, 69.5% use oral medications only, 20.2% use intravenous or injected medications only, and 10.3% use a combination of oral and injected/intravenous medications.

The most widely utilized and most expensive oral anticancer medications prescribed in California in 2006 are described below. The findings from CHBRP's analysis may not fully reflect utilization and expenditures in California in 2009 for two major reasons. First, at least three new oral anticancer medications have been approved since 2006 (Tykerb, Tasigna, and Hycamtin).[14] Some persons with cancer may be prescribed these medications instead of older oral anticancer medications, or they may be prescribed these medications in combination with older medications. In addition, on December 24, 2008, the FDA approved a generic version of Femara, one of the oral anticancer medications with the largest number of prescriptions written in 2006. Expenditures for this medication may decrease significantly if the generic drug is widely substituted for the brand name medication.

Top Oral Anticancer Medications in California by Volume of Prescriptions

In 2006, the three oral anticancer medications for which the largest numbers of prescriptions were filled in California were

1. Arimidex (generic name = anastrozole)—25.2% of prescriptions
2. Tamoxifen citrate (no brand name drug)[15]—22.1% of prescriptions
3. Femara (generic name = letrozole)—12.0% of prescriptions

Arimidex, tamoxifen citrate, and Femara account for over 50% of prescriptions for oral anticancer medications filled in California in 2006. All three are hormones used to treat women with breast cancer. They prevent the growth of breast cancer cells by depriving them of estrogen

[14] Tykerb (generic name = lapatinib) is used in combination with another oral anticancer medication (Xeloda) to treat women with advanced, metastatic, or recurrent breast cancer that are human epidermal growth factor receptor 2 (HER2) positive and hormone receptor negative and whose cancers have not responded to prior therapy including an anthracycline, a taxane, and trastuzumab. Tasigna (generic name = nilotinib) is used to treat adults with chronic myeloid leukemia who cannot tolerate Gleevec (generic name = imatinib), the first-line treatment for this cancer, whose cancers do not respond to Gleevec, or whose cancers have relapsed following bone marrow transplantation. Hycamtin (generic name = topotecan hydrochloride) is used to treat persons with small-cell lung cancer.

[15] The FDA approved the marketing and sale of multiple generic versions of tamoxifen citrate in 2003. The manufacturer of the brand name version, Nolvadex, subsequently ceased marketing it (FDA, 2009).

(FDA, 2009; NCCN, 2009; NCI, 2009). Given that breast cancer is one of the most prevalent cancers in California, it is not surprising that three oral medications used to treat breast cancer were the most widely prescribed oral anticancer medications in 2006.

These medications are prescribed to postmenopausal women with early stage breast cancers following treatment with surgery and radiation and/or anticancer medications.[16] In such women, these medications are used to prevent recurrence of breast cancer and to prevent the development of cancer in the unaffected breast. They are also used to treat women with metastatic breast cancers. In women with metastatic cancers, the medications are used to extend life and improve the quality of life but cannot cure the disease. Tamoxifen citrate is also used to reduce the risk of invasive breast cancer in women with ductal carcinoma in situ and to reduce the risk of breast cancer in women who are at increased risk of developing this disease. Arimidex and Femara are used to treat postmenopausal women with breast cancer who experienced disease progression following treatment with tamoxifen citrate (FDA, 2009; NCCN, 2009; NCI, 2009).

All three medications are also used to treat recurrent ovarian cancer, metastatic and recurrent endometrial cancer, and advanced, metastatic, inoperable, and recurrent uterine sarcoma. Tamoxifine citrate is also used to treat residual or inoperable[17] desmoid tumors (NCCN, 2009).

Top Oral Anticancer Medications in California by Average Cost Per Prescription[18]

The three oral anticancer medications that are estimated to have the highest average cost per prescription filled in California in 2009 are

1. Revlimid (generic name = lenalidomide)—$9,819.40 per prescription
2. Sutent (generic name = sunitinib malate)—$8,118.68 per prescription
3. Nexavar (generic name = sorafenib tosylate)—$6,548.64 per prescription

Revlimid is used in combination with dexamethasone, a corticosteroid medication to treat multiple myeloma, a cancer of plasma cells, which are found in bone marrow. This medication is used as a first- or second-line treatment for persons with this cancer or as palliative treatment for persons who are not candidates for bone marrow transplantation, which is a standard treatment for this cancer. Revlimid is also used to treat persons with myelodysplastic syndromes who have transfusion-dependent anemia. This medication is an analog of thalidomide, a medication known to cause life-threatening birth defects and, thus, cannot be used by women who are pregnant, planning to become pregnant, or breastfeeding. It is only available through a special program under which both health professionals and patients are required to register with the manufacturer (Aisner, 2007; FDA, 2009; NCCN, 2009).

Sutent is a tyrosine kinase inhibitor that is used to treat gastrointestinal stromal tumors and kidney, renal cell, and thyroid cancers. For gastrointestinal stromal tumors, Sutent is used if a

[16] The specific treatment for early stage breast cancer depends on the type of breast cancer, whether the cancer has spread to the lymph nodes, and patient preference.
[17] Inoperable tumors are cancers that cannot be surgically removed from the affected person's body.
[18] The dollar amounts listed are based on a combination of prescriptions for 30- to 90-day supplies of medication.

patient cannot tolerate Gleevec (the first-line medication for this cancer), if a patient's cancer progresses despite Gleevec, or if a patient has an inoperable tumor. Sutent is also used to treat recurrent or inoperable kidney cancer, advanced renal cell carcinoma, and progressive and metastatic thyroid cancers (FDA, 2009; NCCN, 2009; NCI, 2009).

Nexavar is a tyrosine kinase inhibitor that is used to treat hepatocellular, kidney, renal cell, and thyroid cancers. Depending on the cancer, Nexavar is used to treat advanced, metastatic, inoperable, progressive, and/or recurrent cancers (FDA, 2009; NCCN, 2009; NCI, 2009).

Top Oral Anticancer Medications in California by Percentage of Total Costs for All Oral Drugs

The total cost for a medication is the product of the number of prescriptions filled for a drug and the cost per prescription. The three oral anticancer medications that are estimated to account for the highest percentages of total costs for all oral anticancer medications prescribed in California in 2009 are:

1. Arimidex (generic name = anastrozole)—18.4% of total allowed costs
2. Gleevec (generic name = imatinib mesylate)—15.1% of total allowed costs
3. Xeloda (generic name = capecitabine)—9.5% of total allowed costs.

As noted above, Arimidex is a hormone used to treat breast, endometrial, and ovarian cancers.

Gleevec is a tyrosine kinase inhibitor used to treat several types of leukemia, as well as dermatofibrosarcoma protuberans, desmoid tumors, gastrointestinal stromal tumors, myelodysplastic/myeloproliferative diseases, and systemic mastocytosis. Depending on the type of cancer, Gleevec may be used to treat localized, metastatic, residual, inoperable, progressive, and/or recurrent cancers (FDA, 2009; NCCN, 2009; NCI, 2009). Gleevec is considered a major advance in treatment of chronic myeloid leukemia because it restores normal cellular function, enabling physicians and patients to manage this cancer as a chronic disease. A randomized controlled trial (RCT) found that Gleevec was superior to the traditional treatment for chronic myeloid leukemia, a combination of interferon and Depocyt (generic name = cytarabine), an intravenous anticancer medication (O'Brien et al., 2003). Gleevec is also associated with minimal side effects for persons with this type of cancer (Weingart et al., 2008).

Xeloda is an antimetabolite that is used to treat persons with brain tumors, islet cell tumors, and breast, colon, esophageal, gastric, ovarian, pancreatic, and rectal cancers (FDA, 2009; NCCN, 2009; NCI, 2009). It is an oral prodrug 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).

RCTs have compared the effectiveness of Xeloda to the combination of 5-FU and leucovorin, another intravenous medication, for treatment of metastatic colorectal cancer and have also assessed the effectiveness of Xeloda in combination with Eloxatin (generic name = oxaliplatin). RCTs that compared Xeloda to the combination of 5-FU and leucovorin reported no statistically significant differences in time to disease progression and overall survival. However, Xeloda was

associated with fewer adverse effects (Ward et al., 2006). A meta-analysis of six RCTs that compared the combination of Xeloda and Eloxatin to the combination of 5-FU and Eloxatin found no statistically significant differences in time to disease progression and overall survival (Arkenau et al., 2008).

Findings from studies of the use of Xeloda to treat metastatic breast cancer suggest that it may be more effective than intravenous medications. One RCT found that persons with metastatic breast cancer who were given Xeloda survived longer than persons treated with a standard combination of oral cyclophosphamide, oral methotrexate, and intravenous 5-FU (Findlay et al., 2008). A second RCT found that persons who received a combination of Xeloda and an intravenous medication, Taxotere (generic name = docetaxel), had a longer length of time to disease progression and longer overall survival than persons who received Taxotere alone (Jones et al., 2004). A third RCT reported that Xeloda was as effective as Taxol (generic name = paclitaxel), another intravenous medication, in persons with metastatic breast cancer previously treated with anthracycline agents (Findlay et al., 2008).

Summary

- To date, the FDA has approved 38 oral anticancer medications that are used to treat 52 different types of cancer.
- Oral anticancer medications have been available for decades, but the number of such medications has grown dramatically over the past decade, and more oral anticancer medications are under development.
- Oral anticancer medications can be divided into three main types of medications:
  - Cytotoxic agents
  - Targeted agents
  - Hormones.
- The roles of oral anticancer medications in cancer treatment vary and include:
  - Prevention of recurrence in persons who have been treated for early stage disease
  - First-line treatment to prevent growth of cancer cells
  - Second-line treatment of cancers that do not respond to first-line treatments
  - Presurgical treatment
  - Postsurgical treatment
  - Treatment of early stage cancers
  - Treatment of advanced or metastatic cancers
  - Treatment of recurrent cancers
  - Treatment of cancers that cannot be surgically removed.
- Oral anticancer medications are used alone or in combination with other oral, intravenous, or injected anticancer medications, depending on the cancer they are being used treat.

- For many oral anticancer medications, there are no intravenous or injected substitutes (and vice versa). However, there are some important exceptions such as Xeloda, Temodar, and Trexall.

- The most frequently prescribed oral anticancer medications in California in 2006 were three hormone drugs (Arimidex, tamoxifen citrate, and Femara) that are used to treat breast, ovarian, endometrial, and uterine cancers.

- The most expensive oral anticancer medications in California are Revlimid (for multiple myeloma and myelodysplastic syndromes), Sutent (for gastrointestinal stromal tumors and for kidney, renal cell, and thyroid cancers), and Nexavar (for hepatocellular, kidney, renal cell, and thyroid cancers).

- The three oral anticancer medications that account for the largest percentage of total costs for such medications were Arimidex, Gleevec (for several types of leukemia as well as dermatofibrosarcoma protuberans, desmoid tumors, gastrointestinal stromal tumors, myelodysplastic/myeloproliferative diseases, and systemic mastocytosis), and Xeloda (for brain tumors, islet cell tumors, and breast, colon, esophageal, gastric, ovarian, pancreatic, and rectal cancers).

UTILIZATION, COST, AND COVERAGE IMPACTS

SB 161 would require all health plans and policies that provide coverage for chemotherapy treatment to provide coverage for prescribed, orally administered anticancer medicationson on a basis no less favorable than the coverage provided by the relevant contract or policy for intravenously administered or injected anticancer medications. Privately insured and publicly funded health plans and policies would be subject to the mandate, including products offered in group or individual markets and regulated by the Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI).

This section presents current, or baseline, costs and coverage related to oral anticancer medication, and then details the estimated utilization, cost, and coverage impacts of SB 161. 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 assumed that all other aspects administration and utilization management were already "no less favorable" and then modeled the impact of the mandate as a shift in cost sharing provisions. To do so, CHBRP compared current cost sharing for oral anitcancer medications to current cost sharing for injectable/intravenous cancer medications. CHBRP then assumed that postmandate compliance would result in the lower of the two cost sharing percentages being applied to oral cancer medications. "Cost" here represents the total of amounts paid by the health plan/insurer plus amounts paid by the patient through cost sharing provisions, such as deductible, copayments or coinsurance.

Present Baseline Cost and Coverage

Current Coverage of Mandated Benefit

SB 161 would affect the coverage of 21,340,000 persons enrolled in group or individual insurance plans or policies in California with cancer chemotherapy coverage (Table 4). CHBRP surveyed the seven largest health plans and insurers in California regarding their coverage and benefit levels for anticancer medication. Six responded. Responses to the survey represented 76.5% of the CDI-regulated market and 90.5% of DMHC-regulated market. Combined, responses to this survey represent 88.4% of the privately insured market.

Using the responses of the six carriers, CHBRP estimates that 100% of persons with coverage subject to the mandate have some coverage for intravenous or injected anticancer medications, and that 97.8% have some coverage for oral anticancer medications. CHBRP also concluded that benefits for all anticancer medications delivered in a hospital setting are already "no less favorable" in terms of cost sharing provisions. Therefore, this analysis focuses on anticancer medications delivered outside a hospital setting.

Table 2. Current Coverage by Market Segment, California, 2009

	Oral Anticancer Medications
DMHC-regulated plans	
Large group	100%
Small group	100%
Individual	100%
All	100%
CDI-regulated policies	
Large group	100%
Small group	88%
Individual	66%
All	83%
CalPERS	100%
Medi-Cal	100%
Healthy Families	100%
MRMIP	100%
AIM	100%
Total	98%

Source: Source: California Health Benefits Review Program, 2009
Note: The population includes employees and dependents covered by employer-sponsored insurance (including CalPERS).
Key: CalPERS=California Public Employees' Retirement System; CDI=California Department of Insurance; DMHC=Department of Managed Health Care.

CHBRP estimates that 2.2% of enrollees (472,000 persons) with coverage subject to the mandate have no oral anticancer medication coverage outside a hospital setting (Table 1).[19] Persons without coverage are enrolled in small group or individual market policies regulated by CDI (Table 2).

According to CDI's interpretation[20] of the current breast cancer treatment mandate (Insurance Code 10123.8), 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 anitcancer 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.

[19] Some portion of this population may have coverage for generic (but not brand name) oral anticancer medications, but CHBRP is unable to specify. Therefore, the analysis assumes that none have coverage for any oral anticancer medications.
[20] Personal communication, B. Hinze, California Department of Insurance, April 2009

Cost sharing provisions for anticancer medications delivered outside a hospital setting vary widely by contract/policy. Enrollees who have coverage for oral anticancer medications generally access the coverage as a pharmacy benefit. Pharmacy benefit copayments 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 funded coverage, CHBRP reviewed the impact the mandate could have on the California Public Employees' Retirement System (CalPERS) health maintenance organizations (HMOs), Medi-Cal Managed Care, and the Healthy Families Program. CalPERS HMOs cover oral anticancer medication with similar cost sharing provisions as are used in privately insured DMHC-regulated plans. Therefore, the mandate would impact CalPERS HMO coverage. Medi-Cal Managed Care and Healthy Families are considered group coverage since the California Department of Health Services and Major Risk Medical Insurance Board (MRMIB) act as group purchasers for Medi-Cal and Healthy Family beneficiaries. However, both Medi-Cal and Healthy Families plans already cover oral anticancer medication at no charge. Therefore, these plans are already in compliance with SB 161.

Current Utilization Levels and Costs of the Mandated Benefit

Based on Milliman's analysis of 2006 California claims data, CHBRP estimates that enrollees with coverage of oral anticancer medications receive 25.62 prescriptions of oral anticancer medication per year per 1,000 enrollees (Table 1) and that that 0.4% of people with coverage subject to the mandate will use outpatient oral anticancer medications in a year. Of the people using all forms of anticancer medications, CHBRP estimates that 69.5% use oral only, 20.2% use injected or intravenous only, and 10.3% use a combination of oral and injected/intravenous anticancer medications.

The estimated average annual cost per oral anticancer medication prescription for 2009 is $698.31. 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 3. The estimated 2009 average costs per prescription were calculated using the 2006 actual costs increased at an annual trend rate of 10%.

The top three most frequently prescribed oral anticancer medications in California in 2006 were Arimidex—25.2% of prescriptions; tamoxifen citrate—22.1% of prescriptions; and Femara—12% of prescriptions. The most expensive oral anticancer medications were Revlimid—$9,819.40 per prescription; Sutent—$8,118.68 per prescription; and Nexavar—$6,548.64 per prescription. The three oral anticancer medications with the largest share of total costs were Arimidex—18.4% of total costs; Gleevec—15.1% of total costs; and Xeloda—9.5% of total costs.

Table 3. Outpatient Oral Anticancer Medication Prescriptions, 2009

Name	Percent of Prescriptions	Average Cost Per Prescription (a)	Percent of Total Cost (a)
Arimidex	25.2%	$511.56	18.4%
Tamoxifen citrate	22.1%	$62.78	2.0%
Femara	12.0%	$510.40	8.8%
Methotrexate sodium	9.9%	$44.02	0.6%
Aromasin	5.5%	$511.06	4.0%
Xeloda	4.2%	$1,588.45	9.5%
Megestrol acetate	3.1%	$114.43	0.5%
Mercaptopurine	2.9%	$187.36	0.8%
Temodar	2.7%	$2,404.95	9.4%
Casodex	2.0%	$871.81	2.5%
Gleevec	2.0%	$5,293.96	15.1%
Hydroxyurea	1.9%	$78.95	0.2%
Tarceva	1.5%	$4,134.21	9.2%
Revlimid	0.5%	$9,819.40	6.7%
Flutamide	0.5%	$311.64	0.2%
Nexavar	0.4%	$6,548.64	3.8%
Sutent	0.4%	$8,118.68	4.3%
Trexall	0.4%	$189.56	0.1%
Cyclophosphamide	0.3%	$236.94	0.1%
Etoposide	0.3%	$1,060.32	0.4%
Purinethol	0.2%	$378.99	0.1%
Vesanoid	0.2%	$4,790.28	1.1%
Other	1.7%	$821.94	2.0%
Total/average	**100.0%**	**$698.31**	**100.0%**

Source: California Health Benefits Review Program, 2009
Note: (a) "Cost" here represents the total of amounts paid by the health plan/insurer plus amounts paid by the patient (for example, copayments or coinsurance).

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

Two types of cost transfers to private insurance programs could arise: first, people taking up employer-based insurance for oral anticancer medication coverage instead of public insurance; and second, people who use their employer-based insurance rather than relying on charity programs in the private sector. With regard to the first, no cost shifting is expected to occur from public programs (i.e., Medi-Cal and Healthy Families) to the privately insured market because persons with publicly funded coverage are unlikely to have access to employment-based coverage. However, lack of insurance coverage may also cause people who need oral anticancer medications to qualify for Medi-Cal coverage as medically needy or in other categories. These persons may switch to private insurance after the mandate. Second, most pharmaceutical companies have programs to assist under- and uninsured patients with oral anticancer medications as part of their commitment to charitable efforts (Wilkinson, 2003). CHBRP recognizes that there may be some shift in costs from these charitable programs to carriers as a result of coverage. CHBRP was not able to quantify these effects as part of this analysis.

Public Demand for Coverage

As a way to determine whether public demand exists for the proposed mandate (based on criteria specified under Senate Bill 1704 [2007]), CHBRP reports on the extent to which collective bargaining entities negotiate for, and the extent to which self-insured plans currently have, coverage for the benefits specified under the proposed mandate.

Currently, the largest public self-insured plans are the preferred provider organization (PPO) plans offered by CalPERS. These plans provide coverage and benefits similar to those offered in the privately insured market subject to the mandate (fully described in the preceding section on premandate coverage). To further investigate public demand, CHBRP also utilized the analysis-specific health plan and insurer survey to ask carriers administering plans or policies for other (non-CalPERS) self-insured groups whether the relevant coverage and benefits differed from what is offered in the commercial markets. The responding carriers indicated that there were no substantive differences, again suggesting that the market is meeting public demand.

On the basis of conversations with the largest collective bargaining agents in California, CHBRP concluded that unions currently do not include cost sharing arrangements in their health insurance policy negotiations. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and coinsurance levels.[21]

Given the lack of specificity in labor-negotiated benefits and the general match between private insurance subject to the mandate and self-insured health insurance products, CHBRP concludes that public demand is essentially satisfied by the current state of the market.

Impacts of Mandated Coverage

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

Impact on per-unit cost

CHBRP estimates that the mandate would have no material short-term effect on the per-unit costs of oral anticancer medications or the per-unit cost of other anticancer medications, primarily because we project no material change in utilization of anticancer medications due to the mandate.

Postmandate coverage

SB 161 would apply to the coverage of 21,340,000 persons in California with cancer chemotherapy coverage in group or individual market health plans or policies; 97.8% of persons with coverage subject to the mandate already have coverage for oral anticancer medications. For

[21] Personal communication with the California Labor Federation and member organizations, January 2007

this analysis, CHBRP assumes no change in the coverage of enrollees in DMHC-regulated plans or large group CDI-regulated policies. A total of 472,000 persons in small group and individual market CDI-regulated policies (2.2% of persons with coverage subject to the mandate) currently have no coverage of oral anticancer medications and so would be newly covered, postmandate. Out of these 472,000 enrollees gaining coverage, an estimated 1,900, or 0.4%, are expected to be oral anticancer medication users, and therefore may have reduced financial burdens associated with their conditions.

Changes in coverage as a result of premium increases

It is possible that SB 161 will have the unintended consequence of causing small group employers or individuals to drop health care coverage altogether as a result of an increase in premiums. However, CHBRP projects no measurable impact on the number of persons who are uninsured because the estimated premiums increase is 0.025%—which is less than the 1% threshold at which CHBRP would estimate a change in the number of persons covered by insurance. Specifically, CHBRP does not anticipate a reduction in insurance coverage, changes in availability of the benefit beyond those subject to the mandate, changes in offer rates of insurance, changes in employer contribution rates, changes in take-up of insurance by employees, or changes in purchase of individual policies as a result of SB 161 due to the small size of the increase in premiums due to the mandate.

How Would Utilization Change as a Result of the Mandate?

Overall utilization rates (expenses) are not expected to change as a result of the mandate. Postmandate, $8,440,000 in out-of-pocket expenses incurred by enrollees who were previously without coverage would be shifted to health plans and insurers. Among enrollees who had coverage prior to the mandate, CHBRP estimates a reduction of $6,227,000 in out-of-pocket expenses due to the mandate's required alterations in member cost sharing provisions. CHBRP modeled the shift of cost sharing by comparing the cost sharing percentage of outpatient oral cancer medications and cost sharing percentage of outpatient injectable/intravenous cancer medications, and then assuming, postmandate, that the lower of the two cost sharing percentages would be applied to oral cancer medications.

CHBRP assumes no increase in the number of users and no increase in the units of oral anticancer medication or utilization of 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 patients to demand more drugs or more-expensive drugs, regardless of their medical effectiveness, or may induce some patients to use oral anticancer medications when they would otherwise have forgone it or delayed its use . Additionally, CHBRP recognizes there may be pharmaceutical company–induced demand. However, CHBRP concluded that such potential increases would be immaterial. CHBRP's assumptions are supported by the following evidence:

- 97.8% of enrollees with coverage subject to the mandate already have some coverage for oral anticancer medications, and public and private assistance programs exist. In addition, Medi-Cal coverage as medically needy or under other categories may be available for those cancer

patients who could not afford cancer treatments. Also, most pharmaceutical companies have programs to assist under- and uninsured patients with oral anticancer medications as part of their commitment to charitable efforts (Wilkinson, 2003).

- Price elasticity[22] of demand for anticancer medications is low. Cancer is a life-threatening illness, and patients will 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, 2008).

- Oncologists' prescribing behaviors are unlikely to change materially. Oncologists play a pivotal role in cancer treatment decisions. Physician prescribing practices are unlikely to change, because a majority of oncologists report that cost of treatment does not affect their clinical practice (Nadler, 2006). They may also have concerns regarding patients' compliance with complicated dosing regimens for oral anticancer medications, which they will need to weigh against patients' preference for the convenience of these self-administered medications (Weingart, 2008). Moreover, although there are exceptions (Appendix C), many oral anticancer medications have no intravenous or injected substitute.

CHBRP does estimate that SB 161 would mandate new oral anticancer medication coverage for approximately 472,000 enrollees. Although no increase in the number of users of anticancer medications is expected among this group, there is some possibility among these persons for postmandate substitutions of oral in place of intravenous/injected anticancer medications. Although relatively few oral anticancer mediations have an intravenous or injected substitute (Appendix C), some do exist. Therefore, persons without outpatient oral anticancer medication coverage who were diagnosed with cancer, who were undergoing chemotherapy, and who were prescribed an oral anticancer medication for which an intravenous substitute was available, may have been influenced by coverage and cost considerations to use the intravenous option. Postmandate, such persons might switch to an oral anticancer medication. However CHBRP could not quantify the possible change.

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

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, SB 161 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 oral anticancer medications and services would increase by $5,007,000, or 0.0059%, as a result of SB 161 (Table 1). Though SB 161 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 oral anticancer medications incurred through the cost sharing provisions of a policy or contract. Total premiums for private employers are estimated to increase by $7,287,000, or 0.0144%. Enrollee contributions toward premiums for group insurance are estimated to increase by $1,704,000, or 0.0126%. Total premiums for those with individually purchased insurance are estimated to increase by $10,401,000, or 0.175%. The average portion of the premium paid by the employer would increase between $0.03 and $0.24 per member per month (PMPM), and the average portion of the premium paid by employees would increase between $0.01 and $0.04 PMPM (Table 5). However, the cost of oral anticancer medications paid by members due to cost sharing provisions would decrease between $0.02 and $0.03 PMPM. Premiums paid by purchasers of individual CDI-regulated products are estimated to increase $0.80 PMPM, and the cost of oral anticancer medications paid by members of those plans to decrease by approximately $0.51 PMPM .Thus, total premiums would increase by about $19,673,000, but costs paid for by members out of pocket would decrease by $6,227,000 for oral anticancer medications, plus another $8,440,000 for members without coverage prior to the mandate.

The major impact of the bill would be to shift some oral anticancer medication costs from patients to health plans and policies, ranging from $0 to $7,800 per user per year who has prescription drug coverage premandate. On average, the amount of the shift is estimated to be $98 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. Among enrollees who have coverage for oral anticancer medications, around 1.6% of those who use oral anticancer medications have out-of-pocket costs for such medications over $1,000 per year, absent the mandate.

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

The impact is significantly higher for CDI-regulated policies than for DMHC-regulated plans, especially in the small group and individual markets, specifically, as shown in Table 5. SB 161 is estimated to increase cost by:

- 0.001% for the large group DMHC-regulated plans;
- 0.002% for the large group CDI-regulated policies;
- 0.002% for the small group DMHC-regulated plans;
- 0.014% for the small group CDI-regulated policies;
- 0.0035% for the individual DMHC-regulated plans; and
- 0.1255% for the individual CDI-regulated policies.

The reason that impacts are greater among the CDI-regulated policies is that to become compliant with SB 161, most CDI-regulated policies that originally do not have coverage for oral anticancer medications would need to provide such coverage. Some DMHC-regulated plans will have to reduce oral anticancer medications cost sharing to be as favorable as the cost sharing for injectable and intravenously administered anticancer medications.

For affected markets, premiums are expected to increase on average by 0.025%. The increases in premiums vary by market segment:

- $0.03 PMPM in the large group DMHC-regulated plans;
- $0.05 PMPM in the large group CDI-regulated policies;
- $0.04 PMPM in the small group DMHC-regulated plans;
- $0.28 PMPM in the small group CDI-regulated policies;
- $0.04 PMPM in the individual DMHC-regulated plans; and
- $0.80 PMPM in the individual CDI-regulated policies.

Total employer premium expenditures for CalPERS HMOs are estimated to increase by $282,000, or 0.0089%. Of the amount CalPERS would pay in additional total premium, about 59%, or $166,380, would be the cost borne by the General Fund for CalPERS members who are state employees.

Medi-Cal Managed Care and Healthy Families provide full coverage for oral anticancer medication, with no cost sharing and no annual limits, which is compliant with the mandated benefit offering required under SB 161. Therefore, Medi-Cal Manage Care and Healthy Families are expected to face no impact if SB 161 were to be enacted.

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 cancer 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)[23], much higher than the generally accepted threshold for health interventions of $50,000 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 SB 161 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.

[23] 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 4. Baseline (Premandate) Per Member Per Month Premium and Expenditures by Market Segment, California, 2009

	DMHC-Regulated							CDI-Regulated			Total Amount
					Medi-Cal (c)						
	Large Group	Small Group	Indi-vidual	CalPERS (b) HMO	Managed Care 65 and Over	Managed Care Under 65	Healthy Families Managed Care	Large Group	Small Group	Indi-vidual	
Total population in plans subject to state regulation (a)	11,100,000	2,844,000	966,000	820,000	159,000	2,366,000	715,000	400,000	932,000	1,038,000	21,340,000
Total population in plans subject to SB 161	11,100,000	2,844,000	966,000	820,000	159,000	2,366,000	715,000	400,000	932,000	1,038,000	21,340,000
Average portion of premium paid by Employer	$279.83	$246.48	$0.00	$321.26	$239.00	$128.09	$74.97	$341.25	$288.13	$0.00	$58,443,353,000
Average portion of premium paid by employee	$69.94	$71.52	$330.89	$56.69	$0.00	$0.71	$10.22	$97.61	$54.11	$169.28	$19,440,350,000
Total premium	$349.77	$318.00	$330.89	$377.95	$239.00	$128.80	$85.19	$438.86	$342.24	$169.28	$77,883,703,000
Member expenses for covered benefits (deductibles, copayments, etc.)	$18.90	$24.61	$54.10	$19.49	$0.00	$0.59	$2.32	$53.72	$124.95	$41.39	$6,384,077,000
Member expenses for benefits not covered	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.18	$0.51	$8,440,000
Total expenditures	$368.67	$342.62	$385.00	$397.44	$239.00	$129.39	$87.51	$492.58	$467.37	$211.18	$84,276,220,000

Source: California Health Benefits Review Program, 2009.

Notes: (a) The population includes privately insured (group and individual) and publicly insured (e.g., CalPERS, Medi-Cal, Healthy Families, AIM, MRMIP) individuals enrolled in health insurance products regulated by DMHC or CDI. This population includes enrollees aged 0-64 years and enrollees 65 years or older covered by employment sponsored insurance.

(b) Of these CalPERS members, about 59% or 483,800 are state employees.

(c) Medi-Cal state expenditures for members under 65 years of age include expenditures for the Major Risk Medical Insurance Program (MRMIP) and the Access for Infants and Mothers (AIM) program. Medi-Cal state expenditures for members over 65 years of age include those with Medicare coverage.

Table 5. Impacts of the Mandate on Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2009

	DMHC-Regulated							CDI-Regulated			Total Amount
					Medi-Cal (c)						
	Large Group	Small Group	Indi-vidual	CalPERS (b) HMO	Managed Care 65 and Over	Managed Care Under 65	Healthy Families Managed Care	Large Group	Small Group	Indi-vidual	
Total population in plans subject to state regulation (a)	11,100,000	2,844,000	966,000	820,000	159,000	2,366,000	715,000	400,000	932,000	1,038,000	21,340,000
Total population in plans subject to SB 161	11,100,000	2,844,000	966,000	820,000	159,000	2,366,000	715,000	400,000	932,000	1,038,000	21,340,000
Average portion of premium paid by employer	$0.0259	$0.0278	$0.0000	$0.0287	$0.0000	$0.0000	$0.0000	$0.0409	$0.2401	$0.0000	$7,569,000
Average portion of premium paid by employee	$0.0065	$0.0078	$0.0421	$0.0051	$0.0000	$0.0000	$0.0000	$0.0117	$0.0417	$0.7958	$12,104,000
Total Premium	$0.0324	$0.0356	$0.0421	$0.0338	$0.0000	$0.0000	$0.0000	$0.0527	$0.2818	$0.7958	$19,673,000
Member expenses for covered benefits (deductibles, copayments, etc.)	−$0.0287	−$0.0287	−$0.0287	−$0.0287	$0.0000	$0.0000	$0.0000	−$0.0447	−$0.0348	−$0.0166	−$6,227,000
Member expenses for benefits not covered	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	−$0.1819	−-$0.5142	−$8,440,000
Total expenditures	$0.0037	$0.0069	$0.0134	$0.0051	$0.0000	$0.0000	$0.0000	$0.0079	$0.0651	$0.2650	$5,006,000
Percentage Impact of Mandate											
Insured premiums	0.0093%	0.0112%	0.0127%	0.0089%	0.0000%	0.0000%	0.0000%	0.0120%	0.0823%	0.4701%	0.0253%
Total expenditures	0.0010%	0.0020%	0.0035%	0.0013%	0.0000%	0.0000%	0.0000%	0.0016%	0.0139%	0.1255%	0.0059%

Source: California Health Benefits Review Program, 2009.

Notes: (a) The population includes privately insured (group and individual) and publicly insured (e.g., CalPERS, Medi-Cal, Healthy Families, AIM, MRMIP) individuals enrolled in health insurance products regulated by DMHC or CDI. This population includes enrollees aged 0-64 years and enrollees 65 years or older covered by employment sponsored insurance.

(b) Of these CalPERS members, about 59%, or 483,800, are state employees.

(c) Medi-Cal state expenditures for members under 65 years of age include expenditures for the Major Risk Medical Insurance Program (MRMIP) and the Access for Infants and Mothers (AIM) program. Medi-Cal state expenditures for members over 65 years of age include those with Medicare coverage.

PUBLIC HEALTH IMPACTS

Impact of the Proposed Mandate on the Public's Health

The Impact on the Health of the Community

As presented in the *Medical Effectiveness* section, the FDA has approved 38 orally administered anticancer medications to treat 52 different types of cancer. The roles of oral anticancer medications in cancer treatment vary and include the prevention 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. CHBRP estimates that 0.4% of people with coverage subject to the mandate will use outpatient oral anticancer medications during the year following implementation. Of the people using anticancer medications, CHBRP estimates that 69.5% use oral only, 20.2% use injected or intravenously administered only, and 10.3% 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. In addition, although SB 161 would extend coverage for oral anticancer medications to 472,000 people, as presented in the *Utilization, Cost, and Coverage Impacts* section, SB 161 is not expected to increase utilization of oral anticancer medications. Therefore, the only public health impact of SB 161 is that it could lead to a decrease of $14.7 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 SB 161 results in a reduction in out-of-pocket costs, it has the potential to reduce the financial burden faced by cancer patients.

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

CHBRP investigated the effects that SB 161 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 worse indicators (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). A literature review was conducted to determine whether there are gender, racial, or ethnic disparities associated with the use of oral anticancer medications.

Gender disparities

Breast cancer is the most prevalent cancer in California, almost exclusively affecting women (CCR, 2008). As shown in Table 3, nearly two-thirds of the prescriptions for oral anticancer agents are for one of four drugs (Arimidex, Aromasin, Femara, and Tamoxifen) used to treat breast cancer. These four drugs represent 33% of the cost of all oral anticancer agents (Table 3). In California, the lifetime risk of breast cancer is one in nine—translating into 22,000 new diagnoses a year, for a total of 272,800 women alive today who have had a breast cancer diagnosis (CCR, 2008). Women with cancer are particularly likely to suffer from financial hardship. Out-of-pocket expenditures and lost income for women with breast cancer vary widely but average $1,455 per month, and women with breast cancer face a financial burden of care ranging from 26%-98% of their monthly income, depending on income levels (Arozullah et al., 2004).

Racial/ethnic disparities

There is a differential burden of cancer in racial/ethnic minorities in the United States. This differential burden shows in lower overall survival rates, a generally more advanced stage of cancer at time of diagnosis, and the higher eventual risk of death (Sloane, 2009). After breast cancer, the next three most common cancers in California are colorectal, prostate, and lung cancer—all of which can be treated with oral anticancer medications. In California, non-Hispanic blacks have the highest rates of these cancers compared to all racial or ethnic groups (CCR, 2008; Kwong et al., 2005). This suggests that non-Hispanic blacks may have higher out-of-pocket medical costs compared to people of other race/ethnicities. Blacks are more likely to have lower incomes compared to whites, where out-of-pocket costs for oral chemotherapy could comprise a higher percentage of annual household income (Arozullah et al., 2004).

Sixty-five percent of the prescriptions and 33% of the total cost for oral anticancer medications are for drugs used to treat breast cancer. Therefore, to the extent to which SB 161 reduces out-of-pocket costs for patients, there is a potential to reduce the financial burden faced by women undergoing treatment for breast cancer. Non-Hispanic blacks have higher rates of cancer compared to people in all other racial or ethnic groups; therefore, to the extent that SB 161 reduces their out-of-pocket costs for oral anticancer agents, non-Hispanic blacks could face a reduced financial burden as well.

<u>The Extent to Which the Proposed Service Reduces Premature Death and the Economic Loss Associated With Disease.</u>

As presented in the *Medical Effectiveness* section, in most cases, the evidence does not indicate that oral anticancer medications are more effective compared to intravenous or injectable anticancer medications. In addition, although there is evidence that the use of oral anticancer medications compared to IV or injectable anticancer medications results in the reduction of economic losses to patients in the form of foregone wages and travel to care (Houts et al., 1984), as presented in the *Utilization, Cost, and Coverage Impacts* section, the utilization of oral anticancer medications is not expected to change as a result of SB 161. Therefore, there is no expected reduction in premature death or economic loss as a result of the passage of this mandate.

APPENDICES

Appendix A: Text of Bill Analyzed

BILL NUMBER: SB 161 INTRODUCED
BILL TEXT

INTRODUCED BY Senator Wright

FEBRUARY 14, 2009

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

LEGISLATIVE COUNSEL'S DIGEST

SB 161, as introduced, Wright. Health care coverage: chemotherapy treatment.

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

This bill would require health care service plan contracts and health insurance policies that provide coverage for cancer chemotherapy treatment to provide coverage for prescribed, orally administered anticancer medications, as specified, on a basis no less favorable than intravenously administered or injected cancer medications covered under the contracts or policies.

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 health care service plan contract issued, amended, or renewed on or after January 1, 2010, that provides coverage for cancer chemotherapy treatment shall provide coverage for a prescribed, orally administered cancer medication used to kill or slow the growth of cancerous cells on a basis no less favorable than intravenously administered or injected cancer medications covered under the contract.

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

10123.205. A health insurance policy issued, amended, or renewed on or after January 1, 2010, that provides coverage for cancer chemotherapy treatment shall provide coverage for a prescribed, orally administered cancer medication used to kill or slow the growth of cancerous cells on a basis no less favorable than intravenously administered or injected cancer medications covered under the policy.

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

Appendix B describes methods used in the medical effectiveness literature review for SB 161, a bill that 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 medications that are intravenously administered or injected

To date, the United States Food and Drug Administration (FDA) has approved 38 oral anticancer medications that are used to treat 52 different types of cancer. SB 161 would apply to such a large number of drugs that a systematic review of the literature on the effectiveness of all of them was not feasible during the 60 days within which California Health Benefits Review Program (CHBRP) must complete its reports. All oral anticancer medications must be approved by the FDA before they can be marketed or sold in the United States. In addition, many oncologists follow evidence-based prescribing guidelines issued by National Comprehensive Cancer Network (NCCN), which are also used by Medicare and private health plans and health insurers to set coverage policies for anticancer medications.

To identify the most widely prescribed and most costly oral anticancer medications used by Californians, CHBRP analyzed data on pharmaceutical claims filed in 2006 (the latest year for which data were available to CHBRP) for members of health maintenance organizations (HMOs) and preferred provider organizations (PPOs) in California. The analysis was limited to oral anticancer medications that are used to kill or slow the growth of cancer cells. Oral anticancer medications that are prescribed to persons with cancer to alleviate pain or to reduce the side effects of chemotherapy (e.g., antianemia drugs[24], antiemetic drugs[25]) were excluded because SB 161 would not apply to them. The full results of the analysis are presented in Table 3 in the *Utilization, Cost, and Coverage Impacts* section of the report.

CHBRP also performed a literature search to retrieve literature that summarizes trends in the development of oral anticancer agents and describes the manner in which these drugs are used. The literature search was limited to articles published in English from 1994 to present. The following databases that index peer-reviewed journals were searched: PubMed (MEDLINE), the Cochrane Library, CABI, EconLit, Scientific Web Plus, Scopus, Web of Science, and Google Scholar. A total of 312 citations were retrieved. Ten pertinent studies were identified and reviewed.

[24] 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 chemotherapy 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 drugs to reduce the risk of developing this condition.

[25] Antiemetic drugs are drugs used to alleviate nausea and vomiting, which are common side effects of chemotherapy.

The search terms used to locate studies relevant to the AB 513 were as follows:

PubMed (MEDLINE), Cochrane Library, EconLit Scientific Web Plus, Scopus, Web of Science

("Anticarcinogenic Agents"[Majr] AND "Anticarcinogenic Agents "[Pharmacological Action]) OR "Antineoplastic Agents "[Pharmacological Action] AND "Antineoplastic Agents"[Majr] AND ("Administration, Oral"[Mesh]) AND ("Study Characteristics "[Publication Type] OR "Clinical Trial "[Publication Type] OR "Evaluation Studies "[Publication Type] OR "Validation Studies "[Publication Type] OR "Meta-Analysis "[Publication Type]) AND ("humans"[MeSH Terms] AND English[lang]) OR oral chemotherap*[text]

Google Scholar

Oral chemotherapy

Appendix C: Summary Findings on Medical Effectiveness

Table C-1 lists all oral anticancer agents that the U.S. Food and Drug Administration (FDA) has approved for marketing and sale in the United States. The drugs are grouped by therapeutic class. For each drug, both the generic and brand name are indicated along with the year during which the FDA initially approved the drug. The cancer(s) that each drug is used to treat is listed, along with information on the drug's role in cancer treatment (e.g., treatment of early stage versus metastatic cancers, whether the drug is used alone or in combination with other drugs). The table also indicates whether an intravenous/injectable alternative to the drug is available in the United States.

Table C-1. FDA-Approved Oral Anticancer Agents and Their Indications

Class	Agent (Generic Name)	Brand Name	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative
Alkylating Agents	Busulfan	Myleran	1954	Chronic myeloid leukemia	Combined with cyclophosphamide to prepare patients for hematopoietic progenitor cell transplantation	Yes
	Chlorambucil	Leukeran	1957	Chronic lymphoblastic leukemia, multiple types of lymphoma	First-line treatment for advanced cancers; second-line treatment for early stage, advanced, and progressive cancers.	No

Table C-1. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd.)

Class	Agent (Generic Name)	Brand Name	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative
	Cyclophosphamide	N/A—generic drug	1999	Bone cancer, breast cancer, Hodgkin lymphoma, multiple myeloma, multiple types of leukemia, multiple types of non-Hodgkin lymphoma, neuroblastoma, ovarian cancer, retinoblastoma, small cell lung cancer, solitary plasmacytoma	Used alone or in combination with other anticancer medications for preoperative treatment, first-line treatment of early stage and advanced 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	Yes
	Lomustine	CeeNU	1976	Brain tumors, Hodgkins lymphoma	Second-line treatment for inoperable, progressive, and recurrent brain tumors following radiation or surgery; second-line treatment for progressive or recurrent Hodgkins lymphoma	No

Table C-1. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd.)

Class	Agent (Generic Name)	Brand Name	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative
Alkylating Agents (cont'd.)	Melphalan	Alkeran	1964	Epithelial ovarian cancer, Hodgkins lymphoma melanoma, multiple myeloma, multiple types of lymphoma, solitary plasmacytoma	Used alone or in combination with other anticancer medications as first- and second-line treatment of metastatic, inoperable, progressive and , recurrent cancers; sometimes used in combination with other anticancer medications (specific uses vary by cancer)	Yes
	Procarbazine	Matulane	1969	Brain tumors, Hodgkin lymphoma, multiple types of non-Hodgkin lymphoma	Used in combination with other anticancer medications for second-line therapeutic or palliative treatment of progressive and recurrent brain tumors; lymphomas a second-line treatment for advances Hodgkin lymphoma or for progressive and recurrent Hodgkin lymphoma in persons initially treated with radiation alone; second-line treatment for progressive and recurrent cancers in persons with multiple types of non-Hodgkin lymphoma	No

Table C-1. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd.)

Class	Agent (Generic Name)	Brand Name	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative
Alkylating Agents (cont'd.)	Temozolamide	Temodar	1999	Central nervous system cancers, islet cell tumors, melanoma, mycosis fungoides, Sezary syndrome	Used concurrently with radiation treatment and as postradiation treatment, postoperative treatment, treatment for early stage, advanced, metastatic, progressive, or recurrent cancers (specific uses vary across cancers)	Yes
Anti-angiogenic agents	Lenalidomide*	Revlimid	2005	Multiple myeloma, myelodysplastic syndromes, solitary plasmacytoma	Used in combination with dexamethasone for persons who have received at least one prior treatment for multiple myeloma, as primary treatment for persons with advanced cancers, or as palliative treatment for persons who are not transplant candidates; used to treat persons with myelodysplastic syndromes who have transfusion-dependent anemia; first-line treatment for progressive solitary plasmacytoma	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-1. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd.)

Class	Agent (Generic Name)	Brand Name	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative
Anti-angiogenic agents (cont'd.)	Thalidomide	Thalomid	1998	Mantle-cell lymphoma, multiple myeloma	Used alone or in combination with other anticancer medications as a first-line treatment for newly diagnosed persons and as a second-line treatment for progressive and recurrent cancers	No
Anti-metabolites	Capecitabine	Xeloda	1998	Brain tumors, breast cancer, colon cancer, esophageal cancer, gastric cancer, islet cell tumors, ovarian cancer, pancreatic adenocarcinoma, rectal cancer	Used alone or in combination with other anticancer medications and/or radiation as preoperative therapy, postoperative therapy, and to treat inoperable, residual, locally advanced, advanced, metastatic, progressive, and/or recurrent cancers (specific uses vary across cancers)	Yes
	Hydroxyurea	Droxia, Hydrea	1967	Acute myeloid, leukemia, chronic myeloid leukemia, head and neck cancers, melanoma, ovarian cancer	Used alone as low-intensity treatment for acute myeloid leukemia; used in combination with another anticancer medication and radiation to treat head and neck cancers; used to treat inoperable, metastatic, and recurrent ovarian cancer	No
	Mercaptopurine	Purinethol	1953	Acute lymphatic leukemia, acute promyelocytic leukemia	Used in combination with other anticancer medications to prevent recurrence of cancer	No

Table C-1. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd.)

Class	Agent (Generic Name)	Brand Name	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative
	Methotrexate sodium	Rheumatrex, Trexall	1953	Acute promyelocytic leukemia, breast cancer, gestational trophoblastic tumors, head and neck cancers, lung cancer, multiple types of non-Hodgkins lymphoma, soft tissue sarcoma	Used alone or in combination with other cancer medications, radiation, and/or growth factor; preoperative treatment of advanced cancers; postoperative treatment for early stage, advanced, and residual cancers; first-line treatment for early stage, advanced, and inoperable cancers; second-line treatment for advanced, metastatic, progressive, and recurrent cancers; used to prevent recurrence of cancer (specific uses vary across cancers)	Yes
	Thioguanine	Thioguanine	1966	Acute nonlymphocytic leukemia	First-line treatment or treatment to prevent recurrence of cancer	No

Table C-1. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd.)

Class	Agent (Generic Name)	Brand Name	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative
Campto-thecins	Topotecan hydrochloride	Hycamtin	2007	Small cell lung cancer	Second-line treatment for progressive and recurrent cancers	No
Histone deacetylase inhibitors	Vorinostat	Zolinza	2006	Cutaneous T-cell lymphoma, mycosis fungoides, Sezary syndrome	Used to treat persons with persistent, progressive, and recurrent cutaneous T-cell lymphoma; used alone or in combination with other anticancer medications and/or skin-directed therapies as first-line treatment for localized or advanced mycosis fungoides and Sezary syndrome	No

Table C-1. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd.)

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

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

Table C-1. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd.)

Class	Agent (Generic Name)	Brand Name	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative
Hormones (cont'd.)	Exemestane	Aromasin**	1999	Breast cancer, endometrial cancer, uterine sarcoma	Preoperative and postoperative treatment of postmenopausal women with early stage or locally advanced estrogen-receptor–positive cancers; treatment for postmenopausal women with advanced, estrogen-receptor positive cancers that have not progressed despite treatment with tamoxifen; treatment of premenopausal women with recurrent or metastatic breast cancer whose ovaries have been removed; also used to treat recurrent or metastatic endometrial cancer and advanced, metastatic, inoperable, and recurrent uterine sarcoma	No
	Flutamide	Eulexin; generic version available	1989	Prostate cancer	Used alone to treat localized cancer or as a second-line therapy following recurrence; used in combination with androgen deprivation therapy (ADT) to treat metastatic cancers, cancers that do not respond to ADT, and to enhance the effectiveness of radiation	No

Table C-1. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd.)

Class	Agent (Generic Name)	Brand Name	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative
Hormones (cont'd.)	Letrozole	Femara; generic version available	1997	Breast cancer, endometrial cancer, ovarian cancer, uterine sarcoma	Preoperative and postoperative treatment of postmenopausal women with early stage or locally advanced or metastatic estrogen-receptor positive breast cancers; treatment of postmenopausal women whose breast cancers have progressed despite hormone therapy; treatment of premenopausal women with recurrent or metastatic breast cancer whose ovaries have been removed; also used to treat recurrent ovarian cancer, recurrent or metastatic endometrial cancer, and advanced, metastatic, inoperable, and recurrent uterine sarcoma	No
	Nilutamide	Nilandron	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-1. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd.)

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

Table C-1. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd.)

Class	Agent (Generic Name)	Brand Name	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative
Hormones (cont'd.)	Toremifene	Fareston	1997	Breast cancer, Desmoid tumors	First-line or second-line treatment for women with recurrent or metastatic breast cancer; treatment for residual and inoperable Desmoid tumors	No
Natural compounds	Etoposide	N/A—generic drug	2001	Bone cancer, breast cancer, central nervous system cancers, Hodgkins lymphoma, Merkel cell carcinoma, multiple myeloma, multiple types of non-Hodgkins lymphoma, non-small cell lung cancer, ovarian cancer, prostate cancer, small cell lung cancer, solitary plasmacytoma, testicular cancer	Used alone or in combination with other anticancer medications, radiation, and/or growth factor as preoperative, postoperative, postradiation, 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

Table C-1. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd.)

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

Table C-1. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd.)

Class	Agent (Generic Name)	Brand Name	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative
Tyrosine kinase inhibitors (cont'd.)	Erlotinib hydrochloride	Tarceva	2004	Non–small-cell lung cancer, pancreatic cancer	First-line treatment either alone or in combination with other anticancer medications for person with non–small-cell lung cancer who never smoked and who have a known active EGFR mutation or gene amplification; second-line treatment for persons with locally advanced or metastatic non-small cell lung cancer that has not responded to initial chemotherapy treatment; used in combination with gemcitabine as first-line or second-line treatment for locally advanced, metastatic, and inoperable pancreatic cancers	No
	Gefitinib*	Iressa	2003	Non–small-cell lung cancer	Used to treat locally advanced or metastatic cancer that has not responded to other cancer medications	No

Table C-1. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd.)

Class	Agent (Generic Name)	Brand Name	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative
	Imatinib mesylate	Gleevec	2003	Acute lymphoblastic leukemia, chronic eosinophilic leukemia, chronic myeloid leukemia, dermatofibrosarcoma protuberans, desmoids tumors, gastrointestinal stromal tumors, myelodysplastic/ myeloproliferative diseases, systemic mastocytosis	Used alone or in combination with other anticancer medications for first-line treatment, follow-up to first-line treatment, postoperative treatment, posttransplant treatment, and treatment of metastatic, residual, inoperable, progressive, and recurrent disease (specific uses vary across cancers)	No
	Lapatinib	Tykerb	2007	Breast cancer	Used in combination with Xeloda to treat persons with advanced, metastatic, or recurrent breast cancers that are human epidermal growth factor receptor 2 (HER2) positive and hormone receptor negative and who have received prior therapy including an anthracycline, a taxane, and trastuzumab	No

* 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-1. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd.)

Class	Agent (Generic Name)	Brand Name	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative
Tyrosine kinase inhibitors (cont'd.)	Nilotinib hydrochloride monhydrate	Tasigna	2007	Chronic myeloid leukemia	Used alone or in combination with other anticancer medications to treat persons who cannot tolerate the first-line anticancer medication for these cancers (imatinib mesylate = Gleevec) or whose cancers do not respond to that medication; also used to treat persons whose cancers relapse following bone marrow transplantation	No
	Sorafenib tosylate	Nexavar	2005	Hepatocellular cancer, kidney cancer, renal cell cancer, thyroid cancer	Used alone to treat persons with advanced, metastatic, inoperable, progressive, and recurrent cancers (specific uses vary across cancers); also used to treat persons with potentially operable hepatocellular cancers who decline surgery	No

Table C-1. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd.)

Class	Agent (Generic Name)	Brand Name	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative
Tyrosine kinase inhibitors (cont'd.)	Sunitinib malate	Sutent	2006	Gastrointestinal stromal tumor, kidney cancer, renal cell cancer, thyroid cancer	Used alone or in combination with other anticancer medications to treat persons with gastrointestinal stromal tumors who cannot tolerate the first-line anticancer medication for these cancers (imatinib mesylate = Gleevec), whose cancers do not respond to that medication, or who have inoperable tumors; also used to treat recurrent or inoperable kidney cancer, advanced renal cell cancer, and progressive or symptomatic metastatic thyroid cancer	No
Mis-cellaneous	Altretamine	Hexalen	1990	Ovarian cancer	Used alone to treat persons with persistent, or recurrent cancers	No
	Estramustine	Emcyt	1981	Prostate cancer	Used in combination with another anticancer drug to treat metastatic or progressive cancers	No

Table C-1. FDA-Approved Oral Anticancer Agents and Their Indications (cont'd.)

Class	Agent (Generic Name)	Brand Name	Year FDA Approved	Indication(s)	Treatment Role	IV/Injectable Alternative
Mis-cellaneous (cont'd.)	Lysodren	Mitotane	2003	Adrenocortical cancer	Used to treat inoperable adrenal cortical carcinoma	No
	Megestrol acetate	Megace	1971	Breast cancer, endometrial cancer, uterine sarcoma	Second-line treatment of metastatic, inoperable, and recurrent breast cancer; treatment for inoperable, metastatic, and recurrent endometrial cancer; postoperative treatment for women with inoperable, advanced, metastatic, and recurrent uterine sarcoma	
	Tretinoin	Vesanoid	2004	Acute promyelocytic leukemia	Treatment of persons whose cancers have not responded to anthracycline-based cytotoxic chemotherapeutic regimens or who cannot tolerate these drugs.	No

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

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/analysis_methodology/cost_impact_analysis.php.

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

Data Sources

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

Private health insurance

1. The latest (2007) California Health Interview Survey (CHIS), which is used to estimate insurance coverage for California's population and distribution by payer (i.e., employment-based, privately purchased, or publicly financed). The biannual CHIS is the largest state health survey conducted in the United States, collecting information from over approximately 53,000 households. More information on CHIS is available at www.chis.ucla.edu/

2. The latest (2008) California Employer Health Benefits Survey is used to estimate:

- size of firm,
- percentage of firms that are purchased/underwritten (versus self-insured),
- premiums for plans regulated by the Department of Managed Health Care (DMHC) (primarily health maintenance organizations [HMOs] and point of service Plans [POS]),
- premiums for 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 covered under 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: www.chcf.org/topics/healthinsurance/index.cfm?itemID=133543.

3. Milliman data sources are relied on to estimate the premium impact of mandates. Milliman's projections derive from the Milliman Health Cost Guidelines (HCGs). The HCGs are a health care pricing tool used by many of the major health plans in the United States. See www.milliman.com/expertise/healthcare/products-tools/milliman-care-guidelines/index.php. Most of the data sources underlying the HCGs are claims databases from commercial health insurance plans. The data are supplied by health insurance companies, Blues plans, HMOs, self-funded employers, and private data vendors. The data are mostly from loosely managed health care plans, generally those characterized as preferred provider plans, or PPOs. The HCGs currently include claims drawn from plans covering 4.6 million members. In addition to the Milliman HCGs, CHBRP's utilization and cost estimates draw on other data, including the following:

- The MarketScan Database, which includes demographic information and claim detail data for approximately 13 million members of self-insured and insured group health plans.
- An annual survey of HMO and PPO pricing and claim experience. The most recent survey (2008 Group Health Insurance Survey) contains data from seven major California health plans regarding their 2007 experience.
- Ingenix MDR Charge Payment System, which includes information about professional fees paid for healthcare services, based upon approximately 800 million claims from commercial insurance companies, HMOs, and self-insured health plans.

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

4. An annual survey by CHBRP of the seven largest providers of health insurance in California (Aetna, Anthem Blue Cross of California, Blue Shield of California, CIGNA, Health Net, Kaiser Foundation Health Plan, and PacifiCare) to obtain estimates of baseline enrollment by purchaser (i.e., large and small group and individual), type of plan (i.e., DMHC- or CDI-regulated), cost sharing arrangements with enrollees, and average premiums. Enrollment in these seven firms represents 96.0% of the privately insured market: 98.0% of privately insured enrollees in full-service health plans regulated by DMHC and 82% of lives privately insured health insurance products regulated by CDI.

Publicly Funded Coverage

5. Premiums and enrollment in DMHC- and CDI-regulated plans by self-insured status and firm size are obtained annually from CalPERS for active state and local government public employees and their family members who receive their benefits through CalPERS. Enrollment information is provided for fully funded, Knox-Keene licensed health care service plans covering non-Medicare beneficiaries—comprise about 75% of CalPERS total enrollment. CalPERS self-funded plans—approximately 25% of enrollment—are not subject to state mandates. In addition, CHBRP obtains information on current scope of benefits from health plans' evidence of coverage (EOCs) publicly available at www.calpers.ca.gov.

6. Enrollment in Medi-Cal Managed Care (Knox-Keene licensed plans regulated by DMHC) 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 www.dhcs.ca.gov/dataandstats/statistics/Pages/BeneficiaryDataFiles.aspx.

7. Enrollment data for other public programs—Healthy Families, 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 plans under these programs must comply with all requirements of the Knox-Keene Act, and thus these plans are affected by changes in coverage for Knox-Keene licensed plans. CHBRP does not include enrollment in the Post-MRMIP Guaranteed-Issue Coverage Products as these persons are already included in the enrollment for individual health insurance products offered by private carriers. Enrollment figures for AIM and MRMIP are included with enrollment for Medi-Cal in presentation of premium impacts. Enrollment information is obtained online at www.mrmib.ca.gov/. Average statewide premium information is provided to CHBRP by MRMIB staff.

General Caveats and Assumptions

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

- Prevalence of mandated benefits before and after the mandate may be different from CHBRP assumptions.
- Utilization of mandated services 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 products subject to state-mandated health insurance benefits.
- 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://www.chbrp.org/analysis_methodology/cost_impact_analysis.php

- Several recent studies have examined the effect of private insurance premium increases on the number of uninsured (Chernew et al., 2005; Glied and Jack, 2003; Hadley, 2006). Chernew et al. estimate that a 10% increase in private premiums results in a 0.74 to 0.92 percentage point decrease in the number of insured, whereas 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 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://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

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 coverage: If a mandate increases health insurance costs, then some employer groups and individuals may elect to drop their coverage. 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, health plan members 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 the insured person, 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 insurance may now elect to enroll in an insurance plan postmandate because they perceive that it is to their economic benefit to do so.
- Health plans may react to the mandate by tightening their 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).
- Variation in existing utilization and costs, and in the impact of the mandate, by geographic area and delivery system models: Even within the plan types CHBRP modeled (HMO—including HMO and POS plans—and non-HMO—including PPO and

FFS policies), there are likely variations in utilization and costs by these plan types. Utilization also differs within California due to differences in the health status of the local commercial 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 health plans and providers. 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.

Bill Analysis-Specific Methods and Assumptions

In most instances, orally administered anticancer medications are subject to pharmacy plan patient 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 provided outside of a hospital environment, and are subject to medical plan patient cost sharing provisions. In contrast to prescription drug coverage, there is much more variation in patient cost sharing for physician office visits; patient cost sharing may be in the form of flat-dollar copayments or percentage coinsurance, coupled in some instances with a deductible. The differences in forms of patient cost sharing between prescription drug coverage and physician office visit coverage, including in particular the range of variation in the latter, complicate the quantification of the impacts of SB 161 on patient and health plan/insurer costs.

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

- 2006 MedStat claim data for commercial members under age 65 was used to develop baseline cost and utilization information for oral anticancer medications and intravenously administered and injectable anticancer medications. Claim data for members who reside in California, had a diagnosis of cancer, and received anticancer medications outside a hospital was used. Baseline cost and utilization of oral anticancer medications were trended from 2006 to 2009, assuming a 5% annual rate of increase in number of prescriptions and a 10% annual rate of increase in cost per prescription.

- Other than normal trend, no changes in utilization of oral cancer medications due to the introduction of SB 161 was assumed, only a shift of cost sharing from patients to health plans/insurers.

- Formularies, preauthorization requirements, and other coverage provisions (other than patient cost sharing) were assumed to be unchanging.

- For patients who received both oral and intravenous/injectable anticancer medications, the shift of cost sharing was modeled by comparing the cost sharing percentage of oral cancer medications and cost sharing percentage of injectable/intravenous cancer medications,

then assuming that the lower cost sharing percentage would be applied to oral anticancer medications postmandate (see detailed calculations in example 1 and 2).

• For patients who received only oral anticancer medications, the patient's oral cancer drug cost sharing percentage was compared to the weighted average cost sharing percentage for 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 injectable/intravenous cancer drugs was calculated separately for all patients enrolled in DMHC-regulated health plans and CDI-regulated health plans. This is a rough approximation of the effect of SB 161, because it uses the average cost sharing percentage for 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.

• For patients who do not currently have prescription drug coverage prior to the mandate, the amount of the cost shift from the patient to the health plan/insurer was estimated as the difference between 100% and the weighted average cost sharing percentage for injectable/intravenous cancer medications times the estimated total costs of oral anticancer medications for those patients. For these patients, utilization of oral anticancer medications was assumed to be identical to those of patients who had prescription drug coverage,

Example 1

Member 157159601 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 157159601, 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 157159601 will pay $0 (= 14,017 × 0.0%, the lesser of 1.4% and 0.0%) copay on her oral cancer medications.

Example 2

Member 153763001 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 153763001, 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 157159601 will pay $224 (= 5,582 × 4.0%, lesser of 4.0% and 19.3%) copay on her oral cancer medications.

Example 3

Member 523845701 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 cost, including $4,635 paid by health plan and $1,159 paid by the member.

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

For Member 523845701, 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 523845701 will pay $223 (= 5,793x 3.8%, the lesser of 20.0% and 3.8%).

Appendix E: Information Submitted by Outside Parties

In accordance with CHBRP policy to analyze information submitted by outside parties during the first 2 weeks of the CHBRP review, the following parties chose to submit information.

No information was submitted directly by interested parties for this analysis.

For information on the processes for submitting information to CHBRP for review and consideration please visit: http://www.chbrp.org/recent_requests/index.php.

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California Health Benefits Review Program Committees and Staff

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 the CHBRP authorizing legislation, UC contracts with a certified actuary, Milliman Inc. (Milliman), to assist in assessing the financial impact of each benefit mandate bill. 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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