



CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Executive Summary
Analysis of Assembly Bill 1000:
Cancer Treatment

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

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**California Health Benefits Review Program
1111 Franklin Street, 11th Floor
Oakland, CA 94607
Tel: 510-287-3876
Fax: 510-763-4253
www.chbrp.org**

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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Assembly Bill 1000

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

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

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

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

Analysis of AB 1000

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

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

Because the bill specifies "medication[s] used to kill or slow the growth of cancerous cells," (referred to as *anticancer medications* in this report), this analysis assumes it would not affect

¹ CHBRP's authorizing statute is available at: http://www.chbrp.org/documents/authorizing_statute.pdf.

² CHBRP's estimates are available at http://www.chbrp.org/other_publications/index.php.

³ DMHC was established in 2000 to enforce the Knox-Keene Health Care Service Plan of 1975; see Health and Safety Code, Section 1340.

⁴ CDI licenses "disability insurers." Disability insurers may offer forms of insurance that are not health insurance. This report considers only the impact of the benefit mandate on health insurance policies, as defined in Insurance Code, Section 106(b) or subdivision (a) of Section 10198.6.

cost sharing for other medications (antipain, antinausea, etc.) that a cancer patient might use during the course of chemotherapy.

The bill would also require that these plans and policies:

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

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

The bill specifies limits, including that AB 1000 shall:

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

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

AB 1000 would also require that plans and policies:

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

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

Lastly, the bill would:

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

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

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

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

Medical Effectiveness

AB 1000 would apply to such a large number of oral anticancer medications for such a wide range of cancers that a systematic review of the literature on the effectiveness of all of them was not feasible during the 60 days within which CHBRP must complete its reports. Instead, CHBRP summarized general, descriptive information about these medications.

- All oral anticancer medications must be approved by the U.S. Food and Drug Administration (FDA) before they can be marketed or sold in the United States.
- To date, the FDA has approved 42 oral anticancer medications that are used to treat 57 different types of cancer. Ten of these have generic equivalents.
- Oral anticancer medications have been available for decades, but the number of such medications has grown dramatically over the past decade, and more oral anticancer medications are being developed. Approximately 100 oral anticancer medications are currently under development.
- For many oral anticancer medications, there are no intravenous or injected substitutes (and vice versa). However, there are some important exceptions such as Xeloda (capecitabine), Temodar (temozolamide), and methotrexate sodium.
- Oral anticancer medications can be divided into three main types of medications: cytotoxic agents, targeted agents, and endocrine agents.

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

⁶ California Code of Regulations Title 28 § 1300.67.24.

- Oral anticancer medications are used alone or in combination with other oral, intravenously administered, or injected anticancer medications, depending on the cancer they are being used to treat and the stage at which the cancer is diagnosed.
- The roles of oral anticancer medications in cancer treatment vary and include:
 - Presurgical treatment;
 - Postsurgical treatment;
 - Concurrent treatment with radiation;
 - First-line treatment to kill or retard the growth of cancer cells;
 - Second-line treatment of cancers that do not respond to first-line treatments;
 - Treatment of early stage cancers;
 - Treatment of advanced or metastatic cancers;
 - Treatment of recurrent cancers;
 - Treatment of cancers that cannot be surgically removed;
 - Prevention of cancer recurrence in persons treated for early stage disease.
- The outcome of cancer treatment varies with the stage at which cancer is diagnosed.
 - For early stage cancers, use of oral anticancer agents and other treatments can enable a person to live cancer free for many years.
 - For advanced and metastatic cancers, treatment often cannot reverse the disease and may only prolong life for a few months.
- When compared to intravenous and injectable anticancer medications, oral anticancer medications have both advantages and disadvantages. Advantages are that oral anticancer medications may allow administration of the medication on a daily basis, may be more convenient for patients, and may reduce the risk of infection or other infiltration complications. Disadvantages include less certainty in patient adherence to treatment regimens and a reduction in interaction between patients and their health care providers to manage complications of treatment.

Benefit Coverage, Utilization, and Cost Impacts

To perform the analysis, CHBRP compared current cost sharing (as a percentage of the cost of the medication) for nongeneric (brand name) oral anticancer medications to current cost sharing for nongeneric injectable/intravenous anticancer medications. CHBRP modeled compliance with

the mandate as resulting in the lower of the two cost-sharing percentages being applied to nongeneric oral anticancer medications.

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

Benefit Coverage Impacts

- Although AB 1000 is not expected to expand benefit coverage, CHBRP estimates that almost all enrollees with health insurance subject to the mandate have at least some coverage for anticancer medications.
- AB 1000 would affect the health insurance of the 20.1 million enrollees with health insurance not purchased by CalPERS whose insurance provides an outpatient prescription drug benefit.
 - 100% of these enrollees are estimated to have coverage for intravenous and injected anticancer medications.
 - 97.4% of these enrollees are estimated to have coverage for *nongeneric* oral anticancer medications.
 - Approximately 2.6% of these enrollees have no coverage for outpatient oral *nongeneric* anticancer medications, because they have generic-only coverage.

Utilization Impacts

- CHBRP estimates that 0.3% of enrollees with health insurance subject to the mandate will use nongeneric oral anticancer medications during the year following implementation.
 - Of those enrollees using nongeneric anticancer medications, CHBRP estimates that 62.9% use oral only, 29.2% use injected or intravenous only, and 8.0% use a combination of oral and injected/intravenous anticancer medications.
- CHBRP does not estimate a measurable increase in the number of oral anticancer medications users nor a measurable increase in the number of prescriptions per user because:
 - The bill does not extend benefit coverage for nongeneric oral anticancer medications to enrollees currently without coverage. It only affects cost sharing for those enrollees already with benefit coverage for nongeneric anticancer medications.
 - The price elasticity of demand⁷ for anticancer medications is relatively small in comparison to the price elasticity for many other medications. Cancer is a life-threatening illness; consequently, patients will generally comply with prescribed treatment regimens.
 - Few oral anticancer medications have injected or intravenously administered substitutes, and clinical indications may differ between administration forms. A limited number of enrollees have a type and stage of cancer that would allow substitution of an oral anticancer medication for an intravenous or injected anticancer medication. Some portion

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

of these may opt for intravenous or injected medications premandate due to cost considerations. This dynamic cannot be quantified due to the complex clinical factors that are involved when considering potential substitutions.

Cost Impacts

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

AB 1000. However, because the population enrolled in MRMIP is very small (8,000) and high risk, it is difficult to estimate this impact with accuracy.

- The estimated premium increases would not have a measurable impact on number of persons who are uninsured.

Public Health Impacts

- CHBRP does not project a measurable increase in utilization of oral anticancer medications as a result of AB 1000. Therefore, the only potential public health impact as a result of AB 1000 is a reduction in out-of-pocket costs for oral anticancer medications. This could reduce the financial burden and related health consequences faced by cancer patients.
- Breast cancer is the most prevalent cancer in California, almost exclusively affecting women. Approximately 70% of the prescriptions and 31% of the total cost for nongeneric oral anticancer medications are for drugs used to treat breast cancer. Therefore, to the extent that AB 1000 reduces out-of-pocket costs for patients, there is a potential to reduce the financial burden faced by women undergoing treatment for breast cancer.
- After breast cancer, the next three most common cancers in California are colorectal, prostate, and lung cancer. Non-Hispanic blacks in California have higher rates of diagnoses of these three cancers compared to all other racial and ethnic groups. These three cancers may all be treated using nongeneric oral anticancer medications; therefore, to the extent that AB 1000 reduces out-of-pocket costs for nongeneric oral anticancer medications, non-Hispanic black cancer patients could face a reduced financial burden.
- The utilization of nongeneric oral anticancer medications is not projected to change measurably as a result of AB 1000. Therefore, there is no expected reduction in premature death or economic loss as a result of the passage of this mandate.

Potential Effects of the Federal Affordable Care Act

The federal “Patient Protection and Affordable Care Act” (P.L.111-148) and the “Health Care and Education Reconciliation Act” (H.R.4872) were enacted in March 2010. These laws (together referred to as the “Affordable Care Act [ACA]”) are expected to dramatically affect the California health insurance market and its regulatory environment, with most changes becoming effective in 2014. How these provisions are implemented in California will largely depend on pending legal actions, funding decisions, regulations to be promulgated by federal agencies, and statutory and regulatory actions to be taken by California state government. The provisions that go into effect during these transitional years would affect the baseline, or current enrollment, expenditures, and premiums. It is important to note that CHBRP’s analysis of specific mandate bills typically address the marginal effects of the mandate bill—specifically, how the proposed

mandate would impact benefit coverage, utilization, costs, and public health, holding all other factors constant. CHBRP's estimates of these marginal effects are presented in this report.

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

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

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

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

⁸ Affordable Care Act, 1311(d)(3)(B).

⁹ Affordable Care Act, Section 1302(b)(1)(F).

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

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

Source: California Health Benefits Review Program, 2011

Notes: (a) This population includes persons with privately funded and publicly funded (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans, Healthy Families Program, AIM, MRMIP) health insurance products regulated by DMHC or CDI. Population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employment-sponsored insurance.

(b) This excludes enrollees in CalPERS HMOs and enrollees without an outpatient prescription drug benefit.

(c) Premium expenditures by enrollees include employee contributions to employer-sponsored health insurance and enrollee contributions for publicly purchased insurance.

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

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

Key: AIM=Access for Infants and Mothers; CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health; MRMIB=Managed Risk Medical Insurance Board; MRMIP=Major Risk Medical Insurance Program.

ACKNOWLEDGMENTS

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

Janet Coffman, MPP, PhD, of the University of California, San Francisco, prepared the medical effectiveness analysis. Sara McMenamin, PhD, of the University of California, San Diego, prepared the public health impact analysis. Ying-Ying Meng, DrPH, of the University of California, Los Angeles, prepared the cost impact analysis. Susan Pantely, FSA, MAAA, of Milliman, provided actuarial analysis. David Guarino and John Lewis, MPA, of CHBRP staff, prepared the introduction and synthesized the individual sections into a single report. A member of the CHBRP Faculty Task Force, Kathleen Johnson, PharmD, MPH, PhD, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

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

California Health Benefits Review Program
1111 Franklin Street, 11th Floor
Oakland, CA 94607
Tel: 510-287-3876
Fax: 510-763-4253
<http://www.chbrp.org>

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Susan Philip, MPP
Director

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 CHBRP's authorizing legislation, UC contracts with a certified actuary, Milliman Inc., to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit. Milliman also helped with the initial development of CHBRP methods for assessing that impact. The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance and thoughtful critiques provided by the members of the National Advisory Council. However, the Council does not necessarily approve or disapprove of or endorse this report. CHBRP assumes full responsibility for the report and the accuracy of its contents.

Faculty Task Force

Todd Gilmer, PhD, *Vice Chair for Cost*, University of California, San Diego
Joy Melnikow, MD, MPH, *Vice Chair for Public Health*, University of California, Davis
Ed Yelin, PhD, *Vice Chair for Medical Effectiveness*, University of California, San Francisco
Wayne S. Dysinger, MD, MPH, Loma Linda University Medical Center
Susan L. Ettner, PhD, University of California, Los Angeles
Theodore Ganiats, MD, University of California, San Diego
Sheldon Greenfield, MD, University of California, Irvine
Sylvia Guendelman, PhD, LCSW, University of California, Berkeley
Kathleen Johnson, PharmD, MPH, PhD, University of Southern California
Thomas MaCurdy, PhD, Stanford University

Task Force Contributors

Wade Aubry, MD, University of California, San Francisco
Diana Cassidy, PhD, University of California, Davis
Janet Coffman, MPP, PhD, University of California, San Francisco
Margaret Fix, MPH, University of California, San Francisco
Eric Groessl, PhD, University of California, San Diego
Heather J. Hether, PhD, University of California, Davis
Mi-Kyung Hong, MPH, University of California, San Francisco
Matt hew Ingram, MPH, MPP, University of California, Berkeley
Shana Lavarreda, PhD, MPP, University of California, Los Angeles
Jennifer Lewsey, MS, University of California, San Diego
Stephen McCurdy, MD, MPH, University of California, Davis
Sara McMenamin, PhD, University of California, San Diego
Ying-Ying Meng, DrPH, University of California, Los Angeles
Ninez Ponce, PhD, University of California, Los Angeles
Dominique Ritley, MPH, University of California, Davis
Meghan Soulsby, MPH, University of California, Davis
Chris Tonner, MPH, University of California, San Francisco
Arturo Vargas Bustamante, PhD, MA, MPP, University of California, Los Angeles

National Advisory Council

Lauren LeRoy, PhD, President and CEO, Grantmakers In Health, Washington, DC, *Chair*

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Trudy Lieberman, Director, Health and Medicine Reporting Program, Graduate School of Journalism, City University of New York, New York City, NY

Marilyn Moon, PhD, Vice President and Director, Health Program, American Institutes for Research, Silver Spring, MD

Carolyn Pare, CEO, Buyers Health Care Action Group, Bloomington, MN

Michael Pollard, JD, MPH, Senior Fellow, Institute for Health Policy Solutions, Washington, DC

Christopher Queram, President and CEO, Wisconsin Collaborative for Healthcare Quality, Madison, WI

Richard Roberts, MD, JD, Professor of Family Medicine, University of Wisconsin-Madison, Madison, WI

Frank Samuel, LLB, Former Science and Technology Advisor, Governor’s Office, State of Ohio, Columbus, OH

Patricia Smith, President and CEO, Alliance of Community Health Plans, Washington, DC

Prentiss Taylor, MD, Regional Center Medical Director, Advocate Health Centers, Advocate Health Care, Chicago, IL

J. Russell Teagarden, Vice President, Clinical Practices and Therapeutics, Medco Health Solutions, Inc, Brookfield, CT

Alan Weil, JD, MPP, Executive Director, National Academy for State Health Policy, Washington, DC

CHBRP Staff

Susan Philip, MPP, Director

Garen Corbett, MS, Principal Policy Analyst

David Guarino, Policy Analyst

John Lewis, MPA, Principal Policy Analyst

Karla Wood, Program Specialist

California Health Benefits Review Program

University of California

Office of the President

1111 Franklin Street, 11th Floor

Oakland, CA 94607

Tel: 510-287-3876 Fax: 510-763-4253

chbrpinfo@chbrp.org

www.chbrp.org

The California Health Benefits Review Program is administered by the Division of Health Sciences and Services at the University of California, Office of the President. The Division is led by John D. Stobo, M.D., Senior Vice President.