CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

EXECUTIVE SUMMARY
Analysis of Senate Bill 961: Cancer Treatment

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

CHBRP 10-05

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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 Senate 961

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

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

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

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

Uniquely, California has a bifurcated system of regulation for health insurance subject to state law. The California Department of Managed Health Care (DMHC)[1] regulates health care service plans, which offer coverage for benefits to their enrollees through health plan contracts. The California Department of Insurance (CDI) regulates health insurers[2], which offer coverage for benefits to their enrollees through health insurance policies. SB 961 would place requirements on DMHC-regulated health plan contracts and CDI-regulated policies—unless purchased by the California Public Employees' Retirement System (CalPERS). Therefore, approximately 18.7 million Californians (49%) have health insurance that would be subject to SB 961.

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

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

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

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

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

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

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

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

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

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

Medical Effectiveness

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

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

- To date, the FDA has approved 40 oral anticancer medications that are used to treat 54 different types of cancer.

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

- Only 11 of the 40 oral anticancer medications approved by the FDA have intravenously-administered or injectable substitutes.

[3] Health and Safety Code Section 1367, California Code of Regulations Title 28 § 1300.67.4
[4] California Code of Regulations Title 28 § 1300.67.24

- Only 9 of the oral anticancer medications approved by the FDA have generic equivalents. However, CHBRP estimates that one medication for which there is a generic equivalent—tamoxifen—will account for 24.1% of prescriptions for oral anticancer medications filled in California in 2010.

- Oral anticancer medications can be divided into three main types of medications: cytotoxic agents, targeted agents, and endocrine agents.

- Oral anticancer medications are used alone or in combination with other oral, intravenously administered, or injected anticancer medications, depending on the cancer they are being used treat and the stage at which the cancer is diagnosed.

- The roles of oral anticancer medications in cancer treatment vary and include:

  - Presurgical treatment
  - Postsurgical treatment
  - Concurrent treatment with radiation
  - First-line treatment to kill or retard the growth of cancer cells
  - Second-line treatment of cancers that do not respond to first-line treatments
  - Treatment of early stage cancers
  - Treatment of advanced or metastatic cancers
  - Treatment of recurrent cancers
  - Treatment of cancers that cannot be surgically removed
  - Prevention of cancer recurrence in persons treated for early stage disease

- The outcome of cancer treatment varies with the stage at which cancer is diagnosed.

  - For early stage cancers, use of oral anticancer agents and other treatments can enable a person to live cancer free for many years.
  - For advanced and metastatic cancers, treatment often cannot reverse the disease and may only prolong life for a few months.

Utilization, Cost, and Coverage Impacts

CHBRP modeled the financial impact of the mandate as a shift in cost sharing related to enrollee copayments for brand name oral anticancer medications covered through outpatient pharmacy benefits, and not other benefits under which anticancer medications could be covered (e.g., medical benefits that could cover oral anticancer medications delivered during inpatient care or

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

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

Benefit Coverage

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

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

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

Utilization

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

- 3.4 enrollees per 1,000 enrollees use brand name oral anticancer medications that are subject to copays during a year.

- CHBRP estimates no measurable increase in the number of oral anticancer medication users and no measurable increase in the number of prescriptions per user because:

  - The mandate will not change the number of enrollees with coverage for oral anticancer medications.
  - Although CHBRP estimates that the mandate will reduce patients' average copays by about $0.20 per prescription (from $16.78 to $16.58) for brand name oral anticancer medications that are subject to flat dollar copays, the price elasticity of demand[5] for anticancer medications is relatively small in comparison to the price elasticity for many other medications. Cancer is a life-threatening illness; consequently, patients will generally comply with prescribed treatment regimens.
  - Oncologists' prescribing decisions seem unlikely to change, as there is little evidence that oncologists base their decisions on the small differences in patient cost sharing requirements estimated by CHBRP for SB 961.

Cost

- The major impact of the mandate would be to shift some oral anticancer medication costs from patients to health plans and insurers. The average amount of the shift is estimated to be $0.20 per prescription for covered brand name oral anticancer medications subject to copays. It is important, however, to be aware of two factors. First, there are covered generic as well as brand name oral anticancer medications (even though no reduction in copays for generics is projected). Second, coverage for prescriptions may be subject to additional cost sharing, such as a deductible, or may be subject to a different form of cost sharing, such as coinsurance, and SB 961 would not impact forms of cost sharing other than copays. Therefore, the average cost shift per prescription (inclusive of brand and generic medications and all forms of cost sharing) for all oral anticancer medication users would be $0.09 per prescription.

- If the mandate were enacted, CHBRP estimates that approximately $29,000 in out-of-pocket expenses would shift from patients to health plans and insurers due to lower enrollee copays.

- Less than 1% of enrollees with outpatient pharmacy benefit coverage for both brand name and generic oral anticancer medications that are subject to copays have copays of $50 and above per prescription.

- Postmandate flat dollar copay amounts shifted from patients to plans and insurers would range from $0 to $65 per prescription.

- Statewide, total net annual health care expenditures by all enrollees (not just enrollees who have been diagnosed with cancer) subject to this mandate are estimated to increase by a very

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

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

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

Public Health Impacts

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

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

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

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

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

Source: California Health Benefits Review Program, 2010.
Notes: (a) This population includes enrollees insured with private funds as well as enrollees with health insurance purchased with public funds (e.g., CalPERS HMOs, Medi-Cal HMOs, Healthy Families Program, AIM, MRMIP) enrolled in health plans and policies regulated by DMHC or CDI. Population includes enrollees aged 0-64 years and enrollees 65 years or older covered by employment sponsored insurance.
(b) Approximately 24,000 of these enrollees have a limited outpatient pharmacy benefit which includes oral anticancer medications, but excludes many other medications (such as pain medications) which are usually covered by an outpatient pharmacy benefit.
(c) Premium expenditures by enrollees include employee contributions to employer-sponsored health insurance and beneficiary contributions for health insurance that is purchased by a public program.
(d) Because SB 961 exempts CalPERS, the program would have no employer expenditures. Were it not exempted, about 58% would be state expenditures for CalPERS HMO enrollees who are state employees.
(e) Healthy Families Program state expenditures include expenditures for 7,000 beneficiaries enrolled in MRMIP and 7,000 beneficiaries enrolled in the AIM program.
Key: AIM=Access for Infants and Mothers; CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health Care.

Acknowledgements

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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
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

Helen Halpin, ScM, PhD, *Vice Chair for Public Health*, University of California, Berkeley
Robert Kaplan, PhD, *Vice Chair for Cost*, University of California, Los Angeles
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
Kathleen Johnson, PharmD, MPH, PhD, University of Southern California
Thomas MaCurdy, PhD, Stanford University
Joy Melnikow, MD, MPH, University of California, Davis

Task Force Contributors

Wade Aubry, MD, University of California, San Francisco
Yair Babad, PhD, University of California, Los Angeles
Nicole Bellows, PhD, University of California, Berkeley
Tanya G. K. Bentley, PhD, University of California, Los Angeles
Dasha Cherepanov, PhD, University of California, Los Angeles
Janet Coffman, MPP, PhD, University of California, San Francisco
Mi-Kyung Hong, MPH, University of California, San Francisco
Shana Lavarreda, PhD, MPP, University of California, Los Angeles
Stephen McCurdy, MD, MPH, University of California, Davis
Sara McMenamin, PhD, University of California, Berkeley
Ying-Ying Meng, DrPH, University of California, Los Angeles
Alexis Muñoz, MPH, University of California
Dominique Ritley, MPH, University of California, Davis
Chris Tonner, MPH, University of California, San Francisco
Lori Uyeno, MD, University of California, Los Angeles

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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
Karen Pollitz, MPP, Project Director, Georgetown University Health Policy Institute, 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

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**

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