

Issue Brief:

Mammography Mandates, Benchmark Plan Choices, and Essential Health Benefits

CHBRP Issue Brief:

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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

The Affordable Care Act of 2010 (ACA) includes provisions that require coverage for new federal benefit mandates as well as a provision that requires coverage of "essential health benefits" (EHBs) for most health insurance products sold in the individual and small-group markets, including the qualified health plans (QHPs) that will be sold through state health benefit exchanges. Lists of state-level and federal benefit mandates have been compiled by the California Health Benefits Review Program (CHBRP), but EHBs have yet to be defined in California. However, when coverage for EHBs is required in 2014, some current state-level benefits mandates may exceed them. Such a possibility is of particular interest because the ACA will require the state to defray the costs of requiring QHPs to provide coverage that exceeds EHBs.²

CHBRP offers this issue brief to show how state benefit mandates may exceed EHBs and how evidence-based analysis of the impacts of such mandates may inform discussions of whether to keep or repeal them.

Because state-level benefit mandates and EHBs are often written broadly, it is necessary to look at each state mandate and the tests, treatments, and services the mandate addresses in order to determine whether it may exceed EHBs. CHBRP recommends then assessing the medical effectiveness, cost, and public health impacts of each mandate that seems to exceed EHBs in order to determine the effects of the required "excess" benefit coverage. This issue brief follows that recommendation, focusing on California state benefit mandates that require coverage for screening mammography, addressing how they could exceed EHBs, and providing an evidence-based analysis of the impacts that currently result from what could become "excess" coverage in 2014.

In the sections that follow, this brief provides:

- A general discussion of state benefit mandates, federal benefit mandates, and EHBs;
- A policy analysis of how California's state-level mammography mandates could exceed EHBs by requiring screening mammography coverage for women younger than 40 years;
- Background information on breast cancer incidence and mortality rates; and
- An analysis of the evidence on medical effectiveness and the 2012 cost, utilization, and public
 health impacts associated with a screening mammography benefit provided to women younger
 than 40 years for whom required benefit coverage of screening mammography as of 2014 may
 exceed EHBs.

Short summaries of each of this brief's sections follow.

¹ Available at: www.chbrp.org/publications.html.

² ACA Section 1311(d)(3)(B).

Policy Analysis: Mammography Coverage Requirements

Uniquely, California has a bifurcated system of regulation for health insurance subject to state 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. Because of this bifurcated system of regulation, California has two sets of state-level benefit mandates; each benefit mandate applies to DMHC-regulated plans or to CDI-regulated policies, but not to both.

In California, there are six state-level benefit mandates that require coverage for screening mammography, two of them⁵ requiring screening mammography coverage for women younger than 40 years. All six are presented in Appendix A. The two benefit mandates requiring screening mammography for women younger than 40 years could exceed EHBs, depending on the selection of a "benchmark plan," as recommended by U.S. Department of Health and Human Services (CCIIO, 2012).

- Selection of a benchmark plan subject only to federal regulation would mean that EHBs would require screening mammography coverage for women aged 40 years or older. DMHC-regulated plans are now required to cover screening mammography upon provider referral, regardless of enrollee age. CDI-regulated policies are currently required to cover a baseline screening mammogram for women aged 35 to 39 years. Therefore, both DMHC-regulated plans and CDI-regulated policies would be required to exceed EHBs by covering screening mammography for women younger than 40 years were EHBs to be defined by a plan or policy subject only to federal regulation.
- Selection of a CDI-regulated policy as the benchmark plan would have a similar though lesser impact. CDI-regulated policies would not exceed EHBs. However, DMHC-regulated plans, which account for a greater number of enrollees, would exceed EHBs because of the requirement to cover screening mammograms for women younger than 35 years and more than one mammogram for women aged 35 to 39 years.
- Selection of a DMHC-regulated policy as the benchmark plan would define EHBs as requiring screening mammography upon provider referral. In such a circumstance, neither DMHC-regulated plans nor CDI-regulated policies would be required to exceed EHBs.

This issue brief focuses on the first scenario—a benchmark plan subject to only federal regulation.

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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 but benefit mandates generally impact only health insurance policies, as defined in Insurance Code, Section 106(b) or subdivision (a) of Section 10198.6.

⁵ California Health and Safety Code 1367.65 and California Insurance Code 10123.81.

Background on Breast Cancer among Women Younger than 40 Years

The incidence of breast cancer among women younger than 40 years is low in comparison to the incidence among women aged 40 years or older. For California women aged 35 to 39 years, the incidence rate per 100,000 is 55.2 compared to 118.7 per 100,000 for California women aged 40 to 45 years (see Figure 1). Rates for women younger than 35 years are still lower, and rates for women aged 45 years or older are considerably higher. Breast cancer mortality rates for women younger than 40 years follow the same pattern, the mortality rate for older women being 2 to 15 times greater than that for younger women (see Figure 1).

Medical Effectiveness

- Current clinical practice guidelines (see Appendix C) do not recommend routine mammography screening of asymptomatic women younger than 40 years at average risk for breast cancer.
- There is *insufficient evidence* to determine whether routine screening mammography among women younger than 40 years reduces mortality due to breast cancer.
- There is *insufficient evidence* to evaluate if the practice of baseline screening using mammography in women aged 35 to 39 years reduces mortality due to breast cancer.
- There is a *preponderance of evidence* that breast cancer screening in women younger than 40 years will result in false positives and unnecessary follow-up procedures.

Benefit Coverage, Utilization, and Cost

Were EHBs to be defined by a benchmark plan subject only to federal regulation (requiring screening mammography coverage only for women aged 40 years or older), the following would be true:

- Small group and individual market DMHC-regulated plans and CDI-regulated policies would be required to exceed EHBs by covering screening mammograms for women younger than 40 years.
- Of an estimated 2 million Californian women aged 20 to 39 years, approximately 497,000 (25%) are enrolled in small group or individual market plans or policies regulated by DMHC or CDI. For this group, CHBRP estimates that 32,240 screening mammograms will be performed in 2012. Required coverage for these screening mammograms may exceed EHBs.

• Required coverage for these 32,240 screening mammograms would cost an estimated \$4,236,000, approximately 0.0054% of total expenditures. This figure represents a likely upper bound of related costs that the state could be asked to defray because only a portion of these mammograms would be performed for enrollees in QHPs purchased through the Exchange.

Public Health Impacts

Because there is insufficient evidence to determine the medical effectiveness of screening mammography for women aged 20 to 39 years, CHBRP is unable to associate any reduction in mortality with the 32,240 mammograms associated with required benefit coverage that could exceed EHBs.

Conclusion

As California moves toward selecting its benchmark plan and defining EHBs for the state, CHBRP recommends using evidenced-based analysis, similar to what is provided in this issue brief, to help inform discussions of whether to keep or repeal state benefit mandates that could exceed EHBs. Evidenced-based analysis can provide decision-makers with a more comprehensive understanding of the impacts of state benefit mandates that exceed EHBs—not only potential costs, but also reviews of the medical effectiveness evidence and estimates of the mandate's public health impacts for Californians.

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⁶ For this analysis, CHBRP defines expenditures as the cost of health insurance (premiums) plus enrollee expenses for mammography as a covered benefit.

INTRODUCTION

In March 2010, the federal government passed the Patient Protection and Affordable Care Act (P.L.111-148) and the Health Care and Education Reconciliation Act (P.L. 111-152). These laws, together referred to as the Affordable Care Act (ACA), include a number of provisions that would directly and indirectly prompt changes in health care delivery, finance, and coverage, and that would affect benefits covered by California health insurance products. Specifically, the ACA includes provisions that require coverage for new federal benefit mandates. One of these mandates requires coverage of "essential health benefits" (EHBs) for most health insurance products sold in the individual and small-group markets, including the qualified health plans (QHPs) that will be sold through state health insurance exchanges.

The California Health Benefits Review Program (CHBRP), a program established in 2002, responds to requests from the California State Legislature for independent evidence-based analysis of the medical, financial, and public health impacts of proposed health insurance benefit mandates and repeals. CHBRP makes no recommendations regarding bills, but, instead, aims to support discussion among stakeholders by providing evidence-based analyses.

While EHBs have yet to be defined in California, in 2014, when coverage for EHBs will be required, some state-level benefit mandates may exceed EHBs. The ACA requires the state to defray the costs of requiring QHPs to provide coverage that exceeds EHBs. As a result, there is significant interest in whether any such requirements are present in California. CHBRP offers this issue brief to show how state benefit mandates may exceed EHBs and how evidence-based analysis may inform discussions of whether to keep or repeal state benefit mandates that exceed EHBs.

Because state-level benefit mandates and EHBs are written broadly and so affect coverage for complex sets of benefits, it is necessary to look at each state benefit mandate and the tests, treatments, and services it addresses in order to determine whether its coverage requirements may exceed EHBs. CHBRP recommends then assessing the medical effectiveness, cost, and public health impacts of each mandate that seems to exceed EHBs in order to determine the impacts of the "excess" benefit coverage.

Between 2009 and 2011, CHBRP analyzed four bills that required coverage for screening mammography. Building on work done for those reports, this issue brief focuses on two of the six California state benefit mandates that require coverage for screening mammography, first addressing how the two could exceed EHBs and then providing an evidence-based analysis of these two mandates' impacts.

Specifically, this brief provides:

⁷ Additional information about the program is available on CHBRP's website: www.chbrp.org.

⁸ ACA Section 1311(d)(3)(B).

⁹ CHBRP's reports on Assembly Bill 137 (2011) and Senate Bill 173 (2011), as well as Assembly Bill 113 (2010) and Assembly Bill 56 (2009), are available at: www.chbrp.org/docs/index.php?action=view.

- A general discussion of state benefit mandates, federal benefit mandates, and EHBs;
- A policy analysis of how California's state-level mammography mandates could exceed EHBs by requiring screening mammography coverage for women younger than 40 years;
- Background information on breast cancer incidence and mortality rates; and
- An analysis of the evidence on medical effectiveness and the 2012 cost, utilization, and public health impacts associated with a screening mammography benefit provided to women younger than 40 years for whom required benefit coverage of screening mammography as of 2014 may exceed EHBs.

State Benefit Mandates, Federal Benefit Mandates, and Essential Health Benefits

As defined by CHBRP's authorizing statute, ¹⁰ a health insurance benefit mandate law can require health insurance products to provide coverage or offer to cover ¹¹ any of the following: (1) coverage for screening, diagnosis, or treatment of a specific disease or condition; (2) coverage for specific types of health care treatments or services; (3) coverage for services by specific types of health care providers. A mandate can also specify that benefit coverage be provided with specified terms that may affect cost sharing, prior authorization requirements, or other aspects of benefit coverage.

State Benefit Mandates

Uniquely, California has a bifurcated system of regulation for health insurance subject to state benefit mandates. The California Department of Managed Health Care (DMHC)¹² regulates health care service plans, which offer benefit coverage to their enrollees through health plan contracts. The California Department of Insurance (CDI) regulates health insurers, ¹³ which offer benefit coverage to their enrollees through health insurance policies. California state benefit mandates only apply to health insurance regulated at the state level by either DMHC or CDI. Because of this bifurcated system of regulation, California has two sets of state-level benefit mandates. CHBRP is currently aware of 48 benefit mandate laws enforced by DMHC and 46 enforced by CDI. The sets of mandates enforced by DMHC and CDI are similar but not identical. To see a list of benefit mandates current in California, see CHBRP's document, *Current Mandates: Health Insurance Benefit Mandates in California State Law.*¹⁴

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¹⁰ Available at: www.chbrp.org/documents/authorizing statute.pdf.

¹¹ The majority of health insurance benefit mandates in California are "mandates to cover" particular service(s), treatment(s), health condition(s) or provider type(s) in all products, but there are also a number of "mandates to offer." CHBRP's list of California state benefit mandates includes information on which mandates are "mandates to cover" and which are "mandates to offer," available at: www.chbrp.org/publications.html.

¹² DMHC was established in 2000 to enforce the Knox-Keene Health Care Service Plan of 1975; see Health and Safety Code, Section 1340.

¹³ CDI licenses "disability insurers." Disability insurers may offer forms of insurance that are not health insurance but benefit mandates generally impact only health insurance policies, as defined in Insurance Code, Section 106(b) or subdivision (a) of Section 10198.6.

¹⁴ Available at: <u>www.chbrp.org/publications.html</u>.

Federal Benefit Mandates

Federal benefit mandates can be similar to state-level benefit mandates in the tests, treatments, and services for which they require coverage and in the plans and policies subject to the mandate. However, federal benefit mandates can apply more broadly than state benefit mandates. For example, federal benefit mandates may apply to Medicare or to self-insured plans, which are not subject to state-level benefit mandates. There were federal benefit mandates in place prior to the passage of the ACA, and the ACA added federal benefit mandates that apply to most DMHC-regulated plans and CDI-regulated policies in the individual and group markets in California.

CHBRP is aware of ten federal benefit mandates, six of which were enacted by the ACA. ¹⁵ One of the federal benefit mandate requirements in the ACA requires coverage of specified preventive health services, ¹⁶ including coverage of screening mammography. The federal preventive services benefit mandate will be a focus of this issue brief.

Essential Health Benefits

Starting in 2014, the ACA will require health insurance products sold through a state's exchange and many outside a state's exchange to cover EHBs. The ACA will require nongrandfathered small-group and individual market plans and policies—including but not limited to QHPs sold through an exchange—to cover EHBs. Most QHPs in California (like the rest of California's small-group and individual market plans and policies) will be regulated by DMHC or CDI. Therefore, each QHP will be subject either to the set of state-level benefit mandates enforced by DMHC or to the set enforced by CDI. In 2014, QHPs subject to both state-level and federal benefit mandates must meet the most demanding benefit coverage requirement. If the state-level mandate exceeds EHBs, the ACA will require the state to defray the costs of requiring QHPs to provide this "excess" coverage. The U.S. Department of Health and Human Services (HHS) has not yet offered guidance on how such cost calculations would be made.

The ACA offers a list of ten categories that broadly define EHBs.²⁰ To further define EHBs for 2014-2015, HHS has proposed that each state select a benchmark plan (CCIIO, 2012). HHS has

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¹⁵ A CHBRP document, *Health Insurance Benefit Mandates in California State Law*, lists the federal benefit mandates currently known to CHBRP and is available at: www.chbrp.org/publications.html.

¹⁶ ACA Section 1001 modifying Section 2713(a) of the PHSA

¹⁷ A grandfathered health plan is defined as "A group health plan that was created—or an individual health insurance policy that was purchased—on or before March 23, 2010. Grandfathered plans are exempted from many changes required under the Affordable Care Act. Plans or policies may lose their 'grandfathered' status if they make certain significant changes that reduce benefits or increase costs to consumers" (www.healthcare.gov/glossary/g/grandfathered-health.html).

¹⁸ ACA, Section 1311(d)(3)(B).

¹⁹ CHBRP reviews proposed benefit mandates, and this brief is focused on current benefit mandate laws. It is important to note, however, that the state may place additional requirements on plans and policies in California outside of mandated benefit laws. For example, through a combination of law and regulation, DMHC-regulated plans are required to cover a set of "minimum benefits" or "basic health care services." This set of requirements is broad enough to interact with many benefit mandate laws.

²⁰ The list of 10 categories as defined in Section 1302(b) of the ACA includes: (1) Ambulatory patient services; (2) Emergency services; (3) Hospitalization; (4) Maternity and newborn care; (5) Mental health and substance use disorder services, including behavioral health treatment; (6) Prescription drugs; (7) Rehabilitative and habilitative services and devices; (8) Laboratory services; (9) Preventive and wellness services and chronic disease management; and (10) Pediatric services, including oral and vision care.

suggested that a benchmark plan subject to state-level benefit mandates would, in effect, make the state-level benefit mandates fall "within" and so not exceed EHBs. Based on the options provided by HHS, the chosen benchmark plan may be *subject to* or *not subject to* state-level and/or federal benefit mandates. HHS guidance offers four sets of choices for defining EHBs:

- The largest plan by enrollment in any of the three largest *small-group insurance products* in the state's small group market, which would be subject to either DMHC-enforced benefit mandates or CDI-enforced benefit mandates;
- Any of the largest three *state employee health benefit plans* by enrollment, which could be a DMHC-regulated California Public Employees' Retirement System (CalPERS) Health Maintenance Organization (HMO) plan subject to DMHC-enforced benefit mandates or a CalPERS Preferred Provider Plan (PPO) subject only to federal benefit mandates;
- Any of the largest three national *Federal Employee Health Benefits Plan (FEHBP)* options by enrollment, most of which are subject only to federal benefit mandates; or
- The *largest insured commercial non-Medicaid HMO* operating in the state, which is likely a DMHC-regulated plan subject to DMHC-enforced benefit mandates.

If a state chooses a benchmark plan *not subject* to state-level benefit mandates, state-level benefit mandates could require QHPs (and other small-group and individual market plans) to exceed EHBs. If a state chooses a benchmark plan *subject* to most of the state's benefit mandates, benefit mandate laws may address only some markets (e.g., the individual market but not the small-group market), so that some plans might still be subject to state-level mandates that exceed EHBs. Therefore, a chosen benchmark plan could include some but not all of a state's benefit mandates in EHBs.

California's situation is even more complex because the state has two sets of similar (but not identical) state-level benefit mandates. Since a chosen benchmark plan may be subject to either DMHC or CDI, *but not to both*, only one set of California's state-level benefit mandates can be included in EHBs through choice of a benchmark plan.

Because no benchmark plan has yet been selected in California, this analysis will consider three possible definitions for EHBs as they are likely to be defined by state-level and federal benefit mandates. This analysis further assumes the selected benchmark option will not be a grandfathered²² plan or policy. Table 1 identifies California's options and highlights what benefit mandates would be included in each option.

²¹ All states have benchmark plan options that include plans *subject to* and plans *not subject to* the state's benefit mandates. Health insurance plans *not subject* to a state's state-level benefit mandates include all self-insured plans and policies, which are subject only to federal law.

²² Some plans and policies are grandfathered (USDL, 2010) and not required to comply with all federal benefit

²² Some plans and policies are grandfathered (USDL, 2010) and not required to comply with all federal benefit mandates.

Table 1. California's Benchmark Plan Options and Essential Health Benefits in 2014-2015

| Benchmark Plan Options | Benchmark Plan Option Impact on Essential Health Benefits (EHB) Requirements | | | |
|---|--|--|--|--|
| Plan or policy (a) subject only to federal regulation: • State employee health benefits plan (CalPERS PPO) • FEHBP | Includes Benefit coverage required by federal benefit mandates | | | |
| DMHC-regulated plan (a) options: Small-group insurance product State employee health benefits plan (CalPERS HMO) Largest insured commercial non-Medicaid HMO | Includes Benefit coverage required by federal benefit mandates, and DMHC-enforced benefit mandates (b) | | | |
| CDI-regulated policy (a) options: • Small-group insurance product | Includes Benefit coverage required by federal benefit mandates, and CDI-enforced benefit mandates (c) | | | |

Source: California Health Benefits Review Program, 2012.

Notes: (a) Assumes a nongrandfathered plan or policy (UDSL, 2010). (b) DMHC-enforced benefit mandates are in the California Health and Safety Code (H&SC). (c) CDI-enforced benefit mandates are in the California Insurance Code (IC).

Key: CalPERS=California Public Employees' Retirement System; CDI=California Department of Insurance; DMHC=Department of Managed Health Care; EHBs=Essential Health Benefits; FEHBP=Federal Employee Health Benefits Plan; HMO=Health Maintenance Organization; and PPO=Preferred Provider Organization.

Interaction of State Benefit Mandates, Federal Benefit Mandates, and Essential Health Benefits

In California, the state's bifurcated system of health insurance regulation increases the complexity of possible benchmark plan options. As can be seen from Table 1, the all nongrandfathered benchmark plan options in California will all be subject to federal benefit mandates. The benchmark plan may also be subject to either DMHC-enforced benefit mandates or CDI-enforced benefit mandates, which, as stated earlier, are similar but not identical. Therefore, California's benchmark plan options may be subject to the set of state-level benefit mandates enforced by DMHC, to the set of benefit mandates enforced by CDI, or to neither. For a more detailed discussion of the possible interactions of benchmark plan options, EHBs, and state-level benefit mandates, see CHBRP's document CHBRP ISSUE BRIEF: Interaction between California's State Benefit Mandates and the Affordable Care Act's "Essential Health Benefits." 23

For this brief, the important determination is whether the chosen benchmark plan would or would not be subject to either of California's state benefit mandates that require coverage of screening mammography. Depending on the choice of benchmark plan, one or both mandates could exceed the EHB screening mammography requirements by requiring coverage for screening mammography for women younger than 40 years.

²³ Available at: <u>www.chbrp.org/publications.html</u>.

POLICY ANALYSIS: MAMMOGRAPHY COVERAGE REQUIREMENTS

State and federal benefit mandates, as previously stated, include numerous test, treatments, and services. Benefit mandates are further complicated by terms and conditions of coverage, including which markets are subject to the benefit mandate and which are excluded, what cost sharing requirements are allowed or not allowed for the benefit mandate, what age range is subject to the benefit mandate, and in what timeframe is coverage of the benefit mandate required (e.g., immediately or after an interval). While state-level benefit mandates may exceed EHBs in the tests, treatments, and services they require, this issue brief focuses on state benefit mandates that may exceed EHBs not in the tests, treatments, or services required, but in the further details of the required terms and conditions of coverage.

Screening and Diagnostic Mammography

Mammography is used as both a screening test and a diagnostic test. Diagnostic mammography is a test that may be used when a person has symptoms that suggest the presence of breast cancer, such as a lump in the breast. As a diagnostic test, the test may also be used to confirm the results of other tests or may be used to determine the most appropriate course of treatment. CHBRP is unaware of any state-level mandate that might exceed EHBs in terms of requirements for mammography as a diagnostic test. The focus of this brief is on *required coverage for mammography as a screening test*, which denotes testing of asymptomatic individuals in order to identify new breast cancer cases before symptoms are evident.

Mandated Screening Mammography Coverage

Mandated screening mammography coverage may exceed EHBs, depending on the chosen benchmark plan. Following is a description of the screening mammography mandates, federal and state-level, that will influence EHBs, depending on whether the benchmark plan is subject only to federal regulation, to DMHC regulation, or to CDI regulation.

For all nongrandfathered²⁴ health insurance (including both DMHC-regulated plans and CDI-regulated policies), a federal benefit mandate requires coverage of screening mammography. The ACA's preventive services benefit mandate²⁵ requires coverage of screening mammography based on the 2002 United States Preventive Services Task Force (USPSTF) breast cancer screening recommendations, ²⁶ which recommend screening mammography for women aged 40 years or older (USPSTF, 2010).

EHBs are likely to be defined by a nongrandfathered benchmark plan. Therefore, the definition of EHBs is likely to include the federal preventive services benefit mandate's screening mammography coverage requirement for women aged 40 years or older.

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²⁴ Some plans and policies are grandfathered (USDL, 2010) and not required to comply with all federal benefit mandates.

²⁵ ACA Section 1001 modifying Section 2713(a) of the PHSA.

²⁶ The USPSTF has issued newer recommendations on screening mammography but the ACA specifies use of the 2002 recommendations for its preventive services benefit mandate.

Both DMHC and CDI enforce sets of state-level benefit mandates that require coverage of screening mammography. However, their requirements are not identical to each other or to the federal benefit mandate requirement.

For DMHC-regulated plans, three benefit mandates in the Health and Safety Code (H&SC) require coverage of screening mammography. All three H&SC mammography-relevant benefit mandates are presented in Appendix A. One of these benefit mandates, H&SC 1367.65, requires screening mammography coverage upon provider referral, regardless of the enrollee's age.²⁷

For CDI-regulated policies, three benefit mandates in the California Insurance Code (IC) require coverage of screening mammography. All three IC mammography-relevant benefit mandates are also presented in Appendix A. One of these benefit mandates, IC 10123.81, requires coverage of a baseline screening mammogram for women aged 35 to 39 years.²⁸

State-level screening mammography mandates could exceed EHBs by requiring screening mammography coverage for younger enrollees. The federal benefit mandate requires coverage of screening mammography for women aged 40 years or older. As illustrated in Table 2, two state benefit mandates could exceed EHBs by requiring screening mammography for younger women.

- If the chosen benchmark plan is subject only to federal regulation,
 - o DMHC-regulated plans would exceed EHBs by requiring screening mammography coverage for women younger than 40 years
 - o CDI-regulated policies would exceed EHBs by requiring coverage for a baseline screening mammogram for women aged 35 to 39 years.
- If the chosen benchmark plan is a CDI-regulated policy,
 - o DMHC-regulated plans would exceed EHBs by requiring screening mammography coverage for women younger than 35 years and by requiring coverage for more than one mammogram for women aged 35 to 39 years.
 - o CDI-regulated plans would not exceed EHBs in terms of screening mammography coverage requirements.
- If the chosen benchmark plan is a DMHC-regulated plan,
 - o DMHC-regulated plans would not exceed EHBs in terms of screening mammography coverage requirements.
 - o CDI-regulated plans would not exceed EHBs in terms of screening mammography coverage requirements.

This issue brief focuses on the first scenario—a benchmark plan subject to only federal regulation.

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²⁷ The other two require only coverage for "generally medically acceptable" screening mammography. For this analysis, CHBRP assumes that the phrase "generally medically acceptable" would align the second two benefit mandates with national clinical guidelines listed in Appendix C (none of which recommend routine screening mammography for women younger than 40 years).

²⁸ The other two require only coverage for "generally medically acceptable" screening mammography. For this analysis, CHBRP assumes that the phrase "generally medically acceptable" would align the second two benefit mandates with national clinical guidelines listed in Appendix C (none of which recommend routine screening mammography for women younger than 40 years).

Table 2. Screening Mammography - California's State-Level Benefit Mandates May Exceed Essential Health Benefits in 2014-2015

| Benchmark Plan Option | Benchmark Plan Option Impact on Essential | Interaction with Essential Health Benefits | | |
|--|---|--|--|--|
| | Health Benefits (EHB) Requirements | California H&SC 1367.65 Requirements: DMHC-regulated plans must cover screening mammography at provider referral, regardless of enrollee age. | California IC 10123.81 Requirements: CDI-regulated polices must cover, a baseline screening mammogram for women aged 35 to 39 years. | |
| Plan or policy (a) subject only to federally-regulation: • State employee health benefits plan (CalPERS PPO) • FEHBP | Benefit coverage required by federal benefit mandates: screening mammography for women aged 40 years or older | Exceeds EHBs – for women younger than 40 years | Exceeds EHBs – for women aged 35 to 39 years | |
| DMHC- regulated plan (a): Small-group insurance product State employee health benefits plan (CalPERS HMO) Largest insured commercial non-Medicaid HMO | Includes Benefit coverage required by federal benefit mandates: screening mammography for women aged 40 years or older; <i>and</i> DMHC-enforced, state-level benefit mandate: coverage of screening mammography upon provider referral, regardless of the enrollee's age (b) | Within EHBs | Within EHBs | |
| CDI- regulated policy (a): • Small-group insurance product | Includes Benefit coverage required by federal benefit mandates: screening mammography for women aged 40 years or older; and CDI-enforced, state-level benefit mandates: coverage of a baseline mammogram for women aged 35 to39 years (c) | Exceeds EHBs—for women younger than 34 years <i>and</i> for women aged 35 to 39 years who have more than one screening mammogram | Within EHBs | |

Source: California Health Benefits Review Program, 2012.

Notes: (a) Assumes a nongrandfathered plan or policy (USDL, 2010). (b) DMHC-enforced benefit mandates are in the California Health and Safety Code (H&SC). (c) CDI-enforced benefit mandates are in the California Insurance Code (IC).

Key: = CalPERS=California Public Employees' Retirement System; CDI=California Department of Insurance; DMHC=Department of Managed Health Care; EHBs=Essential Health Benefits; FEHBP=Federal Employee Health Benefits Plan; H&SC=California Health & Safety Code; HMO=Health Maintenance Organization; IC=California Insurance Code; and PPO=Preferred Provider Organization.

BACKGROUND ON BREAST CANCER

This section provides an overview of breast cancer incidence, mortality, and racial/ethnic disparities among women younger than 40 years. Although breast cancer is the cancer most commonly diagnosed in California women, with approximately 23,280 (excluding in situ²⁹ cancers) new cases diagnosed annually (ACS, 2011), the incidence of breast cancer among women younger than 40 years is comparatively low. According to the California Cancer Registry (CCR), breast cancer mortality rates for younger and older women follow the same pattern as incidence rates, with older women experiencing a 2 to 15 times greater mortality rate than younger women (Figure 1). Among insured California women aged 20 to 39 years, 0.2% reported ever being diagnosed with breast cancer in 2005 (CHIS, 2005).

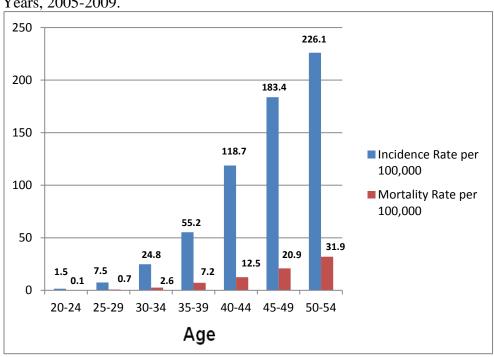


Figure 1. Breast Cancer Incidence and Mortality Rates for California Women Aged 20 to 54 Years, 2005-2009.

Source: California Health Benefits Review Program, adapted from the California Cancer Registry (CCR, 2011) and California Department of Public Health (CDPH) Center for Health Statistics Death Master Files.

Notes: Data reflect all breast cancer incidence excluding in situ cancers. Rates are per 100,000 women in California from 2005-2009.

Screening mammography in women younger than 40 years is less common than among women aged 40 or older. No national guidelines recommend screening mammography for women

²⁹ In situ cancer refers to cancer cells that are confined to the ducts or lobules of the breast and have not invaded deeper tissues in the breast or spread to other organs. *In situ* breast cancer is sometimes referred to as non-invasive or pre-invasive breast cancer (ACS, 2011).

younger than 40 years (Smith et al., 2011; Lee et al., 2010; ACOG, 2003; Qaseem et al., 2007), due to the very low cancer prevalence among women younger than 40 years (Yankaskas et al., 2010). Women younger than 40 years are generally diagnosed with breast cancer after presenting with symptoms or as a result of an abnormal finding on an examination, and not because of a screening mammogram. This may reflect diagnosis of more advanced breast cancer (Gajdos et al., 2000). Younger, premenopausal women are also found to have higher mammographic breast density (Wolfe, 1976), and higher breast density has been shown to increase the likelihood that cancer may be missed by a screening mammogram (Foxcroft et al., 2004; Boyd et al., 2007; Nelson et al., 2012). In women younger than 36 years, rates of distant metastases are higher and survival rates are lower compared to older women (Kollias et al., 1997; Kim et al., 1998; Fowble et al., 1994; De La Rochefordiere et al., 1993; Guenther et al., 1996).

BRCA Mutation Carriers

Although cancer rates in young women are low and national guidelines do not recommend screening for women younger than 40 years with average risk, it has been suggested that women at high risk from *BRCA* mutations may benefit from screening mammography before age 40 years. The estimated prevalence of *BRCA* mutation carriers in non-Hispanic white women without Ashkenazi heritage in the United States is 0.24%. A California-specific estimate of *BRCA* mutation carrier prevalence was not available. Among women with invasive breast cancer, the estimated prevalence of the *BRCA* mutation is 7.6% in non-Hispanic white women younger than 35 years in the San Francisco Bay Area (Whittemore et al., 2004).

A consensus guideline for *BRCA* mutation carriers recommends starting screening mammography between the ages of 25 and 30 years because of increased familial risk associated with *BRCA* mutation and the diagnosis of breast cancer at an early age (Daly et al., 2010). The limited evidence about the effectiveness of screening in this high-risk group of women is discussed in the *Medical Effectiveness* section.

Breast Cancer Incidence and Mortality Rates by Race/Ethnicity

Racial and ethnic disparities in the incidence, treatment, and outcomes for breast cancer and screening mammography exist in California for women younger than 40 years. As presented in Table 3, the incidence of breast cancer (excluding *in situ* cancers) in California varies by race/ethnicity, with Blacks aged 30 to 34 years having the highest incidence rates of breast cancer followed by non-Hispanic whites, Asian/Pacific Islanders, and Hispanic/Latinas. Black women aged 20 to 39 years also have the highest breast cancer mortality rates compared to all other races/ethnicities in this age group (CCR, 2011). Research studies suggest that prevalence of mutations in the *BRCA1* gene, which are associated with a significant increase in the rates of breast cancer, also vary by race/ethnicity. The highest rates were found among Ashkenazi Jewish women, and the lowest were found among Asian American women (John et al., 2007).

Table 3. Breast Cancer Incidence rates and Mortality Rates for California Women Aged 30 to 39 Years by Race/Ethnicity.

| | Incidenc | e Rate per 10 | 0,000 (a) | Mortality Rate per 100,000 (a) | | |
|-----------------|-------------|---------------|-------------|--------------------------------|-------------|-------------|
| Population | 25-29 years | 30-34 years | 35-39 years | 20-29 years | 30-34 years | 35-39 years |
| Hispanic/Latina | 7.0 | 20.6 | 46.1 | 0.7 | 2.9 | 7.1 |
| | | | | | | |
| White | 7.4 | 27.7 | 61.6 | 0.7 | 1.9 | 7.1 |
| (non-Hispanic) | | | | | | |
| Black | 8.4 | 31.9 | 61.2 | 1.6 | 6.7 | 13.1 |
| (non-Hispanic) | | | | | | |
| Asian/Pacific | 8.0 | 25.2 | 55.7 | 0.5 | 1.7 | 5.1 |
| Islander | | | | | | |

Source: California Health Benefits Review Program, adapted from the California Cancer Registry (CCR, 2011) and California Department of Public Health (CDPH) Center for Health Statistics Death Master Files.

Notes: (a) Data reflect all breast cancer incidence excluding in situ cancers. Rates are per 100,000 women in California from 2005-2009.

Rates of breast cancer by ethnicity in California differ somewhat from reports based on U.S. rates. Although overall in the United States white women are more likely to be diagnosed with breast cancer, African American women younger than 35 years have more than twice the incidence of invasive breast cancer and three times the incidence of all types of breast cancer compared to young white women (Althius and Brogan, 2003; Donovan et al., 2007; Shavers et al., 2003), and African American women are more likely than white women to die from breast cancer (U.S. Cancer Statistics Working Group, 2006). Among younger women, the age-specific invasive breast cancer mortality rate for African American women aged 30 to 34 years is 7.2 per 100,000 compared to 3.2 per 100,000 for white women. For African American women aged 35 to 39 years, the age-specific invasive breast cancer mortality rate is 15.5 per 100,000 compared to 7.8 per 100,000 for white women (Yankaskas, 2005).

MEDICAL EFFECTIVENESS

This medical effectiveness analysis addresses three questions pertinent to mandated mammography coverage that could exceed EHBs:

- Does mammography screening (i.e., providing screening mammograms to asymptomatic women) reduce mortality due to breast cancer for women younger than 40 years?
- Does the practice of establishing a baseline screening using mammography for women aged 35 to 39 years reduce mortality due to breast cancer?
- What are the harms of mammography screening in a population of women younger than 40 years?

To provide some context for this review of the literature, we first provide a summary of mammography screening guidelines in the United States, followed by a description of the approach taken to answer these questions and a discussion of the findings. The research approach and methods used to conduct this literature review are presented in Appendix B: Literature Review Methods.

Mammography Screening Guidelines

The current USPSTF clinical practice guidelines on mammography screening issued in 2009 recommend biennial screening mammography for women aged 50 to 74 years (USPSTF, 2009). In addition, these guidelines indicate that the decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take patient context into account, including the patient's values regarding specific benefits and harms (USPSTF, 2009). These replaced previous recommendations issued in 2002 that recommended biennial screening starting at age 40 years (USPSTF, 2002).

A summary of the mammography screening guidelines in the United States is presented in Appendix Table C-1. Guidelines issued by the American Cancer Society (ACS), American College of Physicians, the American College of Obstetrician and Gynecologists (ACOG), and the American College of Radiologists (ACR) all recommend that regular mammography screening should begin at age 40 (Smith et al., 2011; Lee et al., 2010, ACOG, 2003; Qaseem et al., 2007).

No national guidelines recommend routine mammography screening of women younger than 40 years. The only guidelines pertaining to women in this age group are for women who have an increased risk of breast cancer. Both the American Cancer Society (ACS) and the American College of Radiology (ACR) recommend that screening for high-risk women begin at age 30 years (Lee et al. 2010, Smith et al., 2011).

Study Findings

Routine mammography screening of asymptomatic women younger than 40 years at average risk for breast cancer has never been recommended by any clinical practice guideline, and there are no randomized controlled trials that assess the effectiveness of such screening. This review of the literature found no studies that directly addressed the mortality impact of breast cancer screening in women younger than 40 years. The studies identified only addressed mammogram performance measures, such as sensitivity, specificity, positive predictive value, recall rate, and false positives.

Evidence on Breast Cancer Mammography Screening for Women Younger than 40 Years

Breast density (i.e., the composition of breast tissue) is an important risk factor for the development of breast cancer (Lee et al., 2010; Boyd et al., 2009). In addition, mammography screening performance measures are worse for women with dense breast tissue (Lee et al., 2010; Boyd et al., 2009). The proportion of mammographically dense breast tissue declines with age, with younger women being more likely to have dense breast tissue (Boyd et al., 2009). Therefore, mammography screening does not perform as well in younger women.

To document mammography performance measures in younger women, Yankaskas and colleagues conducted an analysis of Breast Cancer Surveillance Consortium data (Yankaskas, 2010). Their analysis was limited to screening mammography among women aged 18 to 39 years and included data on 117,738 women who were followed for 1 year after their initial mammogram. As shown in Table 4, compared to women aged 40 to 49 years, mammography performance measures of women younger than 40 years were inferior (Yankaskas et al., 2010). In addition, none of the performance measures for mammography in women younger than 40 years met national target rates set forth by the Agency for Healthcare Research and Quality (formerly known as the Agency for Health Care Policy and Research) and adopted by the American College of Radiology (ACR, 2003). The authors conclude that mammography performance measures in women younger than 40 years were poor and were inferior to mammography performance measures in women aged 40 to 49 years, and they speculate that it is most likely attributable to the low cancer prevalence in this group of younger women (Yankaskas et al., 2010).

In a different study, Rosenberg et al. (1998) found that mammographic sensitivity (the rate at which breast cancer is correctly identified by mammography) varied by age, with sensitivity rates at 54% for women younger than 40 years, 77% in women aged 40 to 49 years, and 78% in women aged 50 to 64 years. In addition, Johnstone et al. (2001) found that, owing to the low prevalence of breast cancer in women younger than 30 years, routine screening with mammography in this population is not supported.

There is insufficient evidence to determine whether routine screening mammography among women younger than 40 years prevents mortality due to breast cancer.

Table 4. Summary of Mammography Performance Measures.

| | Sensitivity (b) | Specificity (c) | Recall Rate (d) | Cancer Detection Rate (e) |
|-----------------------------------|-----------------|-----------------|--------------------|---------------------------------|
| AHCPR Target Rate (a) | > 85% | > 90% | <10% | 2-10 |
| Women <40 (f) | 76.5% | 87.1% | 13.0% | 1.7% |
| Women 35-39 (f) | 76.1% | 87.5% | 12.7% | 1.6% |
| Women <40 with family history (f) | 78.7% | 85.1% | 15.0% | 1.4% |
| Women 40-44 (f) | 82.4% | n/a | n/a | 2.3% |
| Women 45-49 (f) | 87.3% | n/a | n/a | 4.3% |

Source: California Health Benefits Review Program, adapted from Basset (Bassett et al., 1994) and Yankaskas (Yankaskas et al., 2010).

Note: (a) Bassett et al., 1994. (b) Sensitivity is the proportion of breast cancers detected when breast cancer is present. (c) Specificity is the proportion of negative test results when cancer is absent. (d) Recall Rate is the percentage of mammograms that led to further testing such as a biopsy or additional imaging due to inconclusive or suspicious test results (higher sensitivity leads to higher recall rates). (e) Cancer Detection Rate is the number of cancers found per 1000 women screened. (f) Yankaskas et al., 2010.

Key: AHPCR= Agency for Health Care Policy and Research (now known as Agency for Healthcare Research and Quality); n/a = not available.

Breast Cancer Screening among High-Risk Women

There are many different ways to define being at high risk for breast cancer. The most common four definitions of high risk are: (1) women who are carriers of or are first-degree relatives of a carrier of the BRCA gene mutation; (2) lifetime risk of breast cancer of 20% or more; (3) personal history of breast cancer; and (4) a history of chest radiation received between the ages of 10 and 30 years (Lee et al., 2010). No randomized controlled trials of the mortality impact of mammography screening among high-risk women have been conducted (Lee et al., 2010). This review found two articles summarizing the evidence on screening mammography in women at increased risk for breast cancer, but none of these studies were limited to women younger than 40 years (Brekelmans et al., 2001; Lehman et al. 2007). The three studies that did report data for high-risk women younger than 40 years had mixed results. One study found that the rate of cancer detection using screening mammography for women aged 30 to 39 years at high risk of breast cancer was similar to that of women aged 40 to 49 years overall (Sickles, 2010). The author concluded that it could be extrapolated that the mortality impact of screening women aged 40 to 49 years and high-risk women aged 30 to 39 years were similar (Sickles, 2010). Berrington de Gonzalez et al. (2009) found that there would be no net benefit of annual screening of BRCA carriers until age 35 years, at which point there would be a small benefit. While Yankaskas et al. (2010) found that mammography performance characteristics were similar in women younger than 40 years with a family history of breast cancer and in women in this same age group

without a family history, the authors do not recommend routine screening of young women with a family history of breast cancer.

Baseline Screening Mammograms for Women Aged 35 to 39 Years

In 1980, the American Cancer Society issued recommendations that women aged 35 to 40 years should have a baseline screening mammogram (Dodd, 1992). The rationale was to provide a comparison for mammograms taken when regular screening begins at age 40 years. Follow-up recommendations issued by the American Cancer Society in 1992 dropped the recommendation for a baseline screening mammogram (Dodd, 1992). It is estimated that approximately 29% of asymptomatic women aged 30 to 39 years have had a mammogram for screening purposes (Kapp et al., 2009). No literature was identified that examined the impact of a baseline screening mammogram for women aged 35 to 39 years on breast cancer mortality.

There is insufficient evidence to evaluate if the practice of establishing a baseline screening using mammography for women aged 35 to 39 years reduces mortality due to breast cancer.

Potential Harms

Potential harms as a result of breast cancer screening using mammography include radiation exposure, pain during procedures, patient anxiety, unnecessary medical procedures due to false-positive results, and overdiagnosis (Nelson et al., 2009).

The evidence on the impact of radiation exposure from mammography screening starting at younger ages is mixed. Brenner et al. (2002) report that the radiation risk from mammography screening outweighs the benefits of mammography screening for women younger than 50 years. Other researchers estimated that the radiation dose from one mammogram is so small that it induces less than one case of breast cancer for every million screened (Brodersen et al., 2010). Studies of *BRCA* carriers who underwent screening mammography found that these women did not have higher breast cancer risk compared to *BRCA* carriers who did not undergo mammography screening (Narod, 2011; Goldfrank et al., 2006). Age of first mammography screening and number of mammograms received were also not associated with risk of breast cancer (Narod, 2011; Goldfrank et al., 2006).

For every 625 women aged 35 to 39 years who undergo mammography, 79 will need to complete additional imaging tests, and 78 will receive false-positive results for every case of invasive breast cancer detected (Yankaskas et al., 2010). There is evidence that among women aged 40 to 64 years, women who receive false-positive results are more likely to use more health care services in the future -- both breast and non-breast related -- compared to women who did not receive false-positive results (Barton et al., 2001).

Overdiagnosis is the detection of breast cancer that would not have been diagnosed in a women's lifetime in the absence of screening (Biesheuvel et al., 2007). Research studies estimating the overdiagnosis rate for women younger than 40 years were not found. A review of the estimates of overdiagnosis in women aged 40 years or older found that the range of overdiagnosis among women aged 40 to 49 years was -4%- to 7.1% (Biesheuvel et al., 2007).

There is insufficient evidence to determine whether routine screening mammography among women younger than 40 years results in harms from radiation exposure and significant overdiagnosis of breast cancer. There is a preponderance of evidence to conclude that breast cancer screening in women younger than 40 years will result in false positives and unnecessary follow-up procedures.

BENEFIT COVERAGE, UTILIZATION, AND COST

In this section, CHBRP estimates the 2012 benefit coverage, utilization, and costs of screening and diagnostic mammograms performed for women aged 20 to 39 years with privately purchased health insurance that is regulated by DMHC or CDI.

As previously discussed in the *Policy Analysis* section, as of 2014, state-required coverage of screening mammograms by privately purchased small-group and individual market health insurance for this age group could exceed EHBs. Such a situation is likely to occur if EHBs are defined by a benchmark plan subject only to federal regulation. Although no benchmark plan has been chosen, CHBRP's intent is to provide estimates of utilization and costs in 2012 related to coverage of state-level mammography mandates that may exceed EHBs in 2014.

For further details on the underlying data sources and methods, please see Appendix D.

The findings presented below are also presented at the end of this section in Table 5.

Current Benefit Coverage, Utilization, and Cost

In 2012, approximately 16.4 million Californians have privately purchased health insurance that is regulated by DMHC or CDI and so subject to state-level benefit mandates.

Current Benefit Coverage

As previously described, state-level benefit mandates require coverage for screening mammograms for women younger than 40 years (see *Policy Analysis* section). Therefore CHBRP has assumed:

- 100% of enrollees in DMHC-regulated plans have coverage for screening mammograms for women younger than 40 years; and
- 100% of enrollees in CDI-regulated policies have coverage for a baseline screening mammogram for women aged 35 to 39 years.

<u>Current Utilization</u>

In 2012, nearly 2 million women aged 20 to 39 years are estimated to have privately purchased health insurance that is regulated by DMHC or CDI, and therefore subject to state-level benefit mandates.

CHBRP estimates that a total of 96,610 screening mammograms will be performed in 2012 for women aged 20 to 39 years. Approximately, 85,370 (87%) of these screening mammograms will be performed for women aged 35 to 39 years.

CHBRP estimates that the total number of 2012 diagnostic mammograms to be performed for this group will be slightly higher, with 112,430 performed for women aged 20 to 39 years. Approximately 57,830 (51%) of these diagnostic mammograms will be performed for women aged 35 to 39 years.

Current Unit Cost

The average per-unit cost of diagnostic and screening mammograms combined is \$135. The average per-unit cost of a diagnostic mammogram is \$160, and the average per-unit cost of a screening mammogram is \$106. Unit cost would be unchanged, regardless of whether benefit coverage exceeds EHBs.

Exceeding Essential Health Benefits

Of the estimated 16.4 million Californians who have privately purchased health insurance that is subject to state-level benefit mandates, approximately 5.5 million (33%) are enrolled in small-group or individual market plans or policies. Small-group and individual market plans and policies will be required to cover EHBs, so state-level mandates could exceed EHBs for these two markets.

Required Benefit Coverage Exceeding Essential Health Benefits

As described in the *Policy Analysis* section, a benchmark plan subject only to federal regulation would define EHBs as requiring coverage for screening mammography for women aged 40 years or older. Both DMHC-regulated plans and CDI-regulated policies would then be required to exceed EHBs by providing screening mammography coverage to younger women.

Required coverage for diagnostic mammograms would not exceed EHB requirements.

Utilization Related to Required Benefit Coverage Exceeding Essential Health Benefits

Of the estimated 2 million California women aged 20 to 39 years who have privately purchased health insurance that is subject to state-level benefit mandates, approximately 497,000 (25%) are enrolled in the small-group or individual market.

Of the screening mammograms to be performed in 2012, CHBRP estimates that 32,240 will be for women aged 20 to 39 years who are enrolled in the small-group or individual market health insurance regulated by DMHC or CDI. Approximately 28,150 (87%) of these screening mammograms will be performed for women aged 35 to 39 years. These are the utilization figures that relate to state-level mammography mandates requiring coverage that could exceed EHBs.

Expenditures Related to Required Benefit Coverage Exceeding Essential Health Benefits

For each analysis, CHBRP estimates total expenditures as being the cost of health insurance (premiums) plus enrollee expenses (copays, coinsurance, deductibles, etc) for the test, treatment, or service being analyzed.

For this issue brief, CHBRP estimates that 2012's total statewide expenditures (premiums plus enrollee expenses related to mammograms) includes approximately \$4,236,000 (0.0054% of total expenditures) related to utilization of screening mammograms by women aged 20 to 39 who

are enrolled in small group or individual market plans or policies. This is the expenditure figure that relates to state-level mammography mandates requiring coverage that could exceed EHBs.

This estimate is likely upper bounds in terms of what costs the state might be asked to defray because, in 2014, the small-group and individual markets will be divided, with some portion sold inside the Exchange and some portion sold outside the Exchange. Although plans and policies outside the Exchange will be required to cover EHBs, the state will only be responsible for defraying the cost of requiring QHPs sold through the Exchange to provide coverage that exceeds EHBs.

Table 5. Mammography Issue Brief: Privately Purchased Health Insurance, Benefit Coverage, Utilization, and Cost, 2012

| | Large-Group, Small-Group, and Individual Markets (a) | Small-Group and Individual Markets (b) | Utilization and Expenditures Related to Required Benefit Coverage Exceeding EHBs (c) |
|--|---|---|--|
| Benefit Coverage | | | |
| Total enrollees with privately purchased health insurance | 16,400,000 | 5,473,000 | |
| Total enrollees with privately purchased health insurance subject to state-level required mammography coverage requirements | 16,400,000 | 5,473,000 | |
| Percentage of enrollees with state-level required mammography coverage for women aged 20 to 39 years | 100.0% | 100.0% | |
| Utilization | | | |
| Number of women receiving screening mammograms | | | |
| Women aged 20 to 29 years | 2,270 | 760 | 33% |
| Women aged 30 to 34 years | 9,9740 | 3,330 | 33% |
| Women aged 35 to 39 years | 84,370 | 28,150 | 33% |
| Total number of women aged 20 to 39 years receiving screening mammograms | 96,610 | 32,240 | 33% |
| Number of women receiving diagnostic | | | |
| mammograms | 24070 | | |
| Women aged 20 to 29 years | 24,950 | 8,330 | |
| Women aged 30 to 34 years | 29,640 | 9,890 | |
| Women aged 35 to 39 years | 57,830 | 19,300 | |
| Total number of women aged 20 to 39 years receiving diagnostic mammograms | 112,430 | 37,520 | |
| Cost | h105 (5) | φ10 <i>c</i> () | Т |
| Unit cost per mammogram | \$135 (d) | \$106 (e) | |
| Total Expenditures (f) | \$76,063,407,000 | \$4,236,000 | 0.0054% |

Source: California Health Benefits Review Program, 2012.

Notes: (a) Excludes enrollees with publicly purchased health insurance (DMHC-regulated plans purchased by CalPERS, MRMIB, or California Department of Health Care Services (DHCS). (b) Excludes all large-group market insurance, both privately and publicly purchased. (c) Assumes the chosen benchmark plan is subject only to federal regulation; this column expresses the second column of figures as a percentage of the first when the second column would exceed EHBs. (d) Diagnostic and screening mammograms. (e) Screening mammograms only. (f) Total Expenditures is calculated as health insurance premiums and mammography-related expenses paid by enrollees for covered benefits (copays, coinsurance, deductibles, etc).

Key: EHBs = Essential Health Benefits; PMPM = Per Member per Month.

PUBLIC HEALTH IMPACTS

The public health analysis addresses two questions related to mandated screening mammography coverage that could exceed the EHBs.

- Is there a public health impact for mammography screening among women younger than 40 years overall or for high-risk *BRCA* mutation carriers younger than 40 years?
- Are there racial/ethnic disparities related to breast cancer and mammography screening in women younger than 40 years?

Public Health Impacts

Is there a public health impact for mammography screening among women younger than 40 years overall or for high-risk *BRCA* mutation carriers younger than 40 years?

Due to insufficient evidence (as presented in the *Medical Effectiveness* section) for mammography screening in women aged 20 to 39 years, CHBRP cannot project a public health impact for the utilization of screening mammography that the *Benefit Coverage*, *Utilization*, *and Cost* section indicates could be related to state-level mandates requiring benefit coverage that may exceed the EHBs.

The public health impact of screening mammography related to state-level mandates requiring benefit coverage that may exceed EHBs is unknown for *BRCA* mutation carriers because of the limited evidence of the effectiveness of screening mammography for this population, the long-term effects of radiation exposure from annual screening mammography for women younger than 40 years, and lack of evidence that screening mammography reduces mortality for *BRCA* mutation carriers.

Harms

As noted in the *Medical Effectiveness* section, there is evidence to suggest that the use of screening mammography has potential harms, such as discomfort and pain during the procedure, consequences of false-positive and false-negative tests, overdiagnosis, and radiation exposure. CHBRP is not able to make a quantitative estimate of the harms of screening mammography for women younger than 40 years given the limited data available and the small number of screening mammograms performed in this age group.

Impact on Racial/Ethnic Disparities

Are there racial/ethnic disparities related to breast cancer and mammography screening in women younger than 40 years?

Kapp et al. (2010) reports that the false-positive rate among women younger than 40 years who received their first screening mammogram was highest among African American women

(14.1%), followed by Hispanic women (13.9%), non-Hispanic White women (13.3%), and Asian women (10.4%)

Racial and ethnic disparities exist for screening mammography, breast cancer incidence, and breast cancer mortality for African American women as compared to other racial/ethnic groups. CHBRP cannot estimate the impact on racial/ethnic disparities for screening mammography for women younger than 40 years because there is insufficient evidence of the effectiveness of screening mammography in this age group. Therefore, CHBRP cannot project a public health impact related to state-level mandates requiring benefit coverage for women younger than 40 years that may exceed the EHBs for racial and ethnic disparities.

CONCLUSION

California has not yet selected a benchmark plan that will help define EHBs for the state in 2014 and 2015. Depending on under whose regulation the selected benchmark plan falls—federal regulation, DMHC regulation, or CDI regulation—a differing set of benefit mandates will be included in the EHBs. This issue brief focused on the scenario of a benchmark plan being subject only to federal regulation, thus including only federal benefit mandates and no state benefit mandates, and showed how state benefit mandates could exceed EHBs. However, while DMHC-enforced benefit mandates and CDI-enforced benefit mandates are similar, they are not identical. If California selects a DMHC-regulated plan or a CDI-regulated policy, there may still be state benefit mandates enforced by the other regulator (including screening mammography coverage requirements) that would exceed EHBs and for which the state would be required to defray the costs.

As California moves toward selecting its benchmark plan and defining EHBs for the state, CHBRP recommends using evidenced-based analysis, similar to what is provided in this issue brief, to help inform discussions of whether to keep or repeal state benefit mandates that could exceed EHBs. Evidenced-based analysis can provide decision-makers with a more comprehensive understanding of the impacts of state benefit mandates that exceed EHBs—not only potential costs, but also reviews of the medical effectiveness evidence and estimates of the mandate's public health impacts for Californians.

APPENDICES

Appendix A: State-Level, Mammography-Relevant Benefit Mandates

All six state-level benefit mandates that require coverage for screening mammography follow.

Immediately below are the two state-level health insurance benefit mandates that may require mammography coverage that exceed EHBs because they require benefit coverage for women younger than 40 years.

California Health and Safety Code 1367.65³⁰

- (a) On or after January 1, 2000, every health care service plan contract, except a specialized health care service plan contract, that is issued, amended, delivered, or renewed shall be deemed to provide coverage for mammography for screening or diagnostic purposes upon referral by a participating nurse practitioner, participating certified nurse midwife, or participating physician, providing care to the patient and operating within the scope of practice provided under existing law.
- (b) Nothing in this section shall be construed to prevent application of copayment or deductible provisions in a plan, nor shall this section be construed to require that a plan be extended to cover any other procedures under an individual or a group health care service plan contract. Nothing in this section shall be construed to authorize a plan enrollee to receive the services required to be covered by this section if those services are furnished by a nonparticipating provider, unless the plan enrollee is referred to that provider by a participating physician, nurse practitioner, or certified nurse midwife providing care.

California Insurance Code 10123.81³¹

On or after January 1, 2000, every individual or group policy of disability **insurance** or self-insured employee welfare benefit plan that is issued, amended, or renewed, shall be deemed to provide coverage for at least the following, upon the referral of a nurse practitioner, certified nurse midwife, or physician, providing care to the patient and operating within the scope of practice provided under existing law for breast cancer screening or diagnostic purposes:

- (a) A baseline mammogram for women age 35 to 39, inclusive.
- (b) A mammogram for women age 40 to 49, inclusive, every two years or more frequently based on the women's physician's recommendation.
 - (c) A mammogram every year for women age 50 and over.

Nothing in this section shall be construed to require an individual or group policy to cover the surgical procedure known as mastectomy or to prevent application of deductible or copayment provisions contained in the policy or plan, nor shall this section be construed to require that coverage under an individual or group policy be extended to any other procedures.

Nothing in this section shall be construed to authorize an insured or plan member to receive the coverage required by this section if that coverage is furnished by a nonparticipating provider,

June 7, 2012

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³⁰ As of January 31, 2012.

³¹ As of February 3, 2012.

unless the insured or plan member is referred to that provider by a participating physician, nurse practitioner, or certified nurse midwife providing care.

Immediately below are four mammography-relevant, state-level benefit mandates that seem unlikely to exceed EHBs. All four require "generally medically acceptable" mammography coverage to be provided. However, as noted in Appenidix C, national clinical guidelines do not recommend screening mammography for asymptomatic women younger than 40 years. Therefore, it seems unlikely that these benefit mandates would exceed the federal benefit mandates, which require coverage for screening mammography beginning at age 40 years.

California Health and Safety Code 1367.665³²

Every individual or group health care service plan contract, except for a specialized health care service plan contract, that is issued, amended, delivered, or renewed on or after July 1, 2000, shall be deemed to provide coverage for all generally medically accepted cancer screening tests, subject to all terms and conditions that would otherwise apply.

California Health and Safety Code 1367.6³³

- (a) Every health care service plan contract, except a specialized health care service plan contract, that is issued, amended, delivered, or renewed on or after January 1, 2000, shall provide coverage for screening for, diagnosis of, and treatment for, breast cancer.
- (b) No health care service plan contract shall deny enrollment or coverage to an individual solely due to a family history of breast cancer, or who has had one or more diagnostic procedures for breast disease but has not developed or been diagnosed with breast cancer.
- (c) Every health care service plan contract shall cover screening and diagnosis of breast cancer, consistent with generally accepted medical practice and scientific evidence, upon the referral of the enrollee's participating physician.
- (d) Treatment for breast cancer under this section shall include coverage for prosthetic devices or reconstructive surgery to restore and achieve symmetry for the patient incident to a mastectomy. Coverage for prosthetic devices and reconstructive surgery shall be subject to the copayment, or deductible and coinsurance conditions, that are applicable to the mastectomy and all other terms and conditions applicable to other benefits.
- (e) As used in this section, "mastectomy" means the removal of all or part of the breast for medically necessary reasons, as determined by a licensed physician and surgeon.
- (f) As used in this section, "prosthetic devices" means the provision of initial and subsequent devices pursuant to an order of the patient's physician and surgeon.

California Insurance Code 10123.20³⁴

(a) Every individual or group disability insurance policy that covers hospital, medical, or surgical expenses that is issued, amended, delivered, or renewed on or after July 1, 2000, shall be deemed to provide coverage for all generally medically accepted cancer screening tests, subject to all other terms and conditions that would otherwise apply.

As of January 31, 2012.
 As of January 31, 2012.

³⁴ As of February 3, 2012.

(b) This section shall not apply to vision-only, dental-only, accident-only, specified disease, hospital indemnity, Medicare supplement, long-term care, or disability income insurance, except that for accident-only, specified disease, or hospital indemnity insurance, coverage for benefits under this section shall apply to the extent that the benefits are covered under the general terms and conditions that apply to all other benefits under the policy or contract. Nothing in this section shall be construed as imposing a new benefit mandate on accident-only, specified disease, or hospital indemnity insurance.

California Insurance Code 10123.28³⁵

- (a) Every policy of disability insurance that provides coverage for hospital, medical, or surgical expenses, that is issued, amended, delivered, or renewed on or after January 1, 2000, shall provide coverage for screening for, diagnosis of, and treatment for, breast cancer.
- (b) No policy of disability insurance that provides coverage for hospital, medical, or surgical expenses shall deny enrollment or coverage to an individual solely due to a family history of breast cancer, or who has had one or more diagnostic procedures for breast disease but has not developed or been diagnosed with breast cancer.
- (c) Every policy of disability insurance shall cover screening and diagnosis of breast cancer, consistent with generally accepted medical practice and scientific evidence, upon the referral of the insured's participating physician.
- (d) Treatment for breast cancer under this section shall include coverage for prosthetic devices or reconstructive surgery to restore and achieve symmetry for the patient incident to a mastectomy. Coverage for prosthetic devices and reconstructive surgery shall be subject to the deductible and coinsurance conditions applied to the mastectomy and all other terms and conditions applicable to other benefits.
- (e) As used in this section, "mastectomy" means the removal of all or part of the breast for medically necessary reasons, as determined by a licensed physician and surgeon.
- (f) As used in this section, "prosthetic devices" means the provision of initial and subsequent devices pursuant to an order of the patient's physician and surgeon.
- (g) For purposes of this section, disability insurance does not include accident only, credit, disability income, specified disease and hospital confinement indemnity, coverage of Medicare services pursuant to contracts with the United States government, Medicare supplement, long-term care insurance, dental, vision, coverage issued as a supplement to liability insurance, insurance arising out of a workers' compensation or similar law, automobile medical payment insurance, or insurance under which benefits are payable with or without regard to fault and that is statutorily required to be contained in any liability insurance policy or equivalent self-insurance.

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³⁵ As of January 31, 2012.

Appendix B: Literature Review Methods

Studies of mammography screening in women younger than 40 years were identified through searches of PubMed, the Cochrane Library, Web of Science, EconLit, and Business Source Complete, and the Cumulative Index of Nursing and Allied Health Literature. The search was limited to abstracts of studies published in English from 2000 to present. Of the 423 articles found in the literature review, 61 were reviewed for potential inclusion in this issue brief on the effectiveness of mammography screening on women younger than 40 years, and a total of 23 studies were included in the medical effectiveness review for this brief. The other articles were eliminated because they did not focus on women younger than 40 years, did not break out results by age, or did not focus on the benefits or harms of mammography screening.

CHBRP classifies research by levels I-V. Level I research includes well-implemented randomized controlled trials (RCTs) and cluster RCTs. Level II research includes RCTs and cluster RCTs with major weaknesses. Level III research consists of nonrandomized studies that include an intervention group and one or more comparison group, time series analyses, and cross-sectional surveys. Level IV research consists of case series and case reports. Level V represents clinical/practical guidelines based on consensus or opinion. Using these standards, most of the research related to the medical effectiveness of mammography in women younger than 40 years would be classified as Level III, IV, and Level V.

Appendix C: Summary of Published Clinical Guidelines for Mammography Screening

Table C-1 summarizes the recommendations of five U.S. organizations issuing clinical guidelines for mammography screening.

Table C-1. Summary of U.S. Clinical Guidelines for Mammography Screening

| # | Guideline Developer | Evidence or Consensus Based | Issue Year | Screening Age Range for Average-Risk Population | Screening Interval for Average-Risk Population | Comments |
|---|--|-----------------------------------|---------------|--|--|---|
| 1 | U.S. Preventive Services Task Force: Screening for Breast Cancer: Recommendations and Rationale (USPSTF, 2009) | Evidence based | 2009 | 50 to 74 years | Every 2 years | The decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take patient context into account, including the patient's values regarding specific benefits and harms There is insufficient evidence to assess the benefits and harms of screening mammography for women aged 75 years or older |
| 2 | American Cancer Society: Guidelines for Breast Cancer Screening Update 2003 (Smith et al., 2011) (a) | Evidence based | 2003 | 40 years and older, continuing as long as woman is in good health | Annually | Women should be educated about the benefits, limitations, and harms of screening. Women at high risk might benefit from other strategies, such as earlier screening initiation, shorter screening intervals, or addition of other modalities such as ultrasound or magnetic resonance imaging. |
| 3 | American College of Physicians: Screening Mammography for Women 40–49 Years of Age: A Clinical Practice Guideline (Qaseem et al., 2007 ⁽⁾ (b) | Evidence based | 2007 | 40 to49 years (see Comments) | Clinician should base screening mammography decisions on benefits and harms of screening, a woman's preferences, and her breast cancer risk profile. | Guideline focuses only on mammography in women aged 40 to 49 years. Clinician should inform patients about potential benefits and harms of screening mammography. Screening mammography every 1 to 2 years is reasonable for those women reluctant to discuss screening. |

| # | Guideline Developer | Evidence or Consensus Based | Issue Year | Screening Age Range for Average-Risk Population | Screening Interval for Average-Risk Population | Comments |
|---|---|-----------------------------------|---------------|--|--|--|
| 4 | American College of Obstetrician and Gynecologists: Breast Cancer Screening (ACOG, 2003) | Evidence based | 2003 | 40 to 49 years 50 years and older | Every 1 to 2 years Annually | In 2009, the American College of Obstetricians and Gynecologists (ACOG) maintained its current advice that women aged 40 to 49 years continue mammography screening every 1 to 2 years and women aged 50 years or older continue annual screening. |
| 5 | American College of Radiology: Guidelines for Breast Cancer Screening (Lee et al., 2010) | Evidence based | 2010 | 40 years and older | Annually | Mammographic screening before the age of 40 years may benefit those women at high risk for breast cancer. |

Notes: (a) American Medical Association and American College of Radiology concur with American Cancer Society guidelines. (b) American College of Preventive Medicine and American Academy of Family Physicians concur with the American College of Physicians.

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 website at www.chbrp.org/costimpact.html.

The cost information in this issue brief was prepared by the members of cost team, which consists of CHBRP task force members and contributors from the University of California, San Diego, and the University of California, Los Angeles, as well as the contracted actuarial firm, Milliman, Inc. (Milliman, 2010). Milliman provides data and analyses per the provisions of CHBRP's authorizing legislation.

Data Sources

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

Health insurance

- 1. The latest (2009) California Health Interview Survey (CHIS), which is used to estimate health insurance for California's population and distribution by payer (i.e., employment-based, individually purchased, or publicly financed). The biennial CHIS is the largest state health survey conducted in the United States, collecting information from approximately 50,000 households. More information on CHIS is available at www.chis.ucla.edu.
- 2. The latest (2011) California Employer Health Benefits Survey is used to estimate:
 - size of firm,
 - percentage of firms that are purchased/underwritten (versus self-insured),
 - premiums for health care service plans regulated by the Department of Managed Health Care (DMHC) (primarily health maintenance organizations [HMOs] and Point of Service Plans [POS]),
 - premiums for health insurance policies regulated by the California Department of Insurance (CDI) (primarily preferred provider organizations [PPOs] and fee-for-service plans [FFS]), and
 - premiums for high deductible health plans (HDHPs) for the California population with employment-based health insurance.
 - This annual survey is currently released by the California Health Care Foundation/National
 Opinion Research Center (CHCF/NORC) and is similar to the national employer survey
 released annually by the Kaiser Family Foundation and the Health Research and Educational
 Trust. Information on the CHCF/NORC data is available at:
 https://www.chcf.org/publications/2010/12/california-employer-health-benefits-survey.
- 3. Milliman data sources are relied on to estimate the premium impact of mandates. Milliman's projections derive from the Milliman Health Cost Guidelines (HCGs). The HCGs are a health care pricing tool used by many of the major health plans in the United States. See 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 (2010 Group Health Insurance Survey) contains data from seven major California health plans regarding their 2010 experience.
- Ingenix MDR Charge Payment System, which includes information about professional fees paid for healthcare services, based upon approximately 800 million claims from commercial insurance companies, HMOs, and self-insured health plans.
- These data are reviewed for applicability by an extended group of experts within Milliman but are not audited externally.

Issue Brief Specific Caveats and Assumptions

To determine utilization rates among persons in California with privately purchased health insurance regulated by DMHC or CDI, the rates of mammography per 1,000 enrollees are assumed to be the same for all market segments, and were determined using the Milliman health outcomes data. The rates differentiated between screening and diagnostic mammography, and by age group, as follows:

Screening Mammography per 1,000 Enrollees

Ages 20-29 = 0.14

Ages 30-34 = 0.61

Ages 35-39 = 5.14

Diagnostic Mammography per 1,000 Enrollees

Ages 20-29 = 1.52

Ages 30-34 = 1.81

Ages 35-39 = 3.53

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CHBRP gratefully acknowledges all of these contributions but assumes full responsibility for all of the issue brief and its contents. Please direct any questions concerning this brief 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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Garen Corbett, MS 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

Catherine Acquah, MHA, University of California, Los Angeles Wade Aubry, MD, University of California, San Francisco Diana Cassady, PhD, University of California, Davis Janet Coffman, MPP, PhD, University of California, San Francisco Gina Evans-Young, University of California, San Francisco Margaret Fix, MPH, University of California, San Francisco Erik Groessl, PhD, University of California, San Diego Julia Huerta, MPH, University of California, Davis Shana Lavarreda, PhD, MPP, University of California, Los Angeles Jennifer Kempster, MS, University of California, San Diego Stephen McCurdy, MD, MPH, University of California, Davis Sara McMenamin, PhD, University of California, San Diego 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

Deborah Chollet, PhD, Senior Fellow, Mathematica Policy Research, Washington, DC **Michael Connelly, JD,** President and CEO, Catholic Healthcare Partners, Cincinnati, OH **Joseph P. Ditré Esq,** Executive Director, Consumers for Affordable Health Care, Augusta, ME

Allen D. Feezor, Deputy Secretary for Health Services, North Carolina Department of Health and Human Services, Raleigh, NC

Charles "Chip" Kahn, MPH, President and CEO, Federation of American Hospitals, Washington, DC **Jeffrey Lerner, PhD,** President and CEO, ECRI Institute Headquarters, Plymouth Meeting, PA

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

Garen Corbett, MS, Director
John Lewis, MPA, Associate Director
Laura Grossmann, MPH, Principal Policy Analyst
Tory Levine-Hall, Health Policy Intern
Stephanie McLeod, MPP, Graduate Health Policy Intern
Hanh Kim Quach, 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 chbrp.org www.chbrp.org

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