CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Analysis of Senate Bill 173: Mammograms

A Report to the 2011-2012 California Legislature
April 7, 2011

CHBRP 11-09

The California Health Benefits Review Program (CHBRP) responds to requests from the State Legislature to provide independent analyses of the medical, financial, and public health impacts of proposed health insurance benefit mandates and proposed repeals of health insurance benefit mandates. CHBRP was established in 2002 by statute (California Health and Safety Code, Section 127660, et seq). The program was reauthorized in 2006 and again in 2009. CHBRP's authorizing statute defines legislation proposing to mandate or proposing to repeal an existing health insurance benefit as a proposal that would mandate or repeal a requirement that a health care service plan or health insurer (1) permit covered individuals to obtain health care treatment or services from a particular type of health care provider; (2) offer or provide coverage for the screening, diagnosis, or treatment of a particular disease or condition; or (3) offer or provide coverage of a particular type of health care treatment or service, or of medical equipment, medical supplies, or drugs used in connection with a health care treatment or service.

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A Report to the 2011-2012 California State Legislature

Analysis of Senate Bill 173
Mammograms

April 7, 2011

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Suggested Citation:

California Health Benefits Review Program (CHBRP). (2011). *Analysis of Senate Bill 173: Mammograms.* Report to California State Legislature. Oakland, CA: CHBRP. 11-09.

PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Senate Bill 173. In response to a request from the California Senate Committee on Health on February 4, 2011, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the program's authorizing statute.

Janet Coffman, MPP, PhD, and Margaret Fix, MPH, of the University of California, San Francisco, prepared the medical effectiveness analysis. Bruce Abbott, MLS, of the University of California, Davis, conducted the literature search. Sara McMenamin, PhD, of the University of California, San Diego, prepared the public health impact analysis. Arturo Vargas Bustamante, PhD, MA, MPP, of the University of California, Los Angeles, prepared the cost impact analysis. Susan Pantely, FSA, MAAA, of Milliman, provided actuarial analysis. Diana Miglioretti, PhD, of Group Health Research Institute, and Colin Wells, MD, of the University of California, Los Angeles, provided technical assistance with the literature review and expert input on the analytic approach. John Lewis, MPA, of CHBRP staff prepared the introduction and synthesized the individual sections into a single report. A subcommittee of CHBRP's National Advisory Council (see final pages of this report) and a member of the CHBRP Faculty Task Force, Wayne Dysinger, MD, MPH, of Loma Linda University, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

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

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Director

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The California Senate Committee on Health requested on February 4, 2011, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Senate Bill (SB) 173: Mammograms, a bill that would impose a health benefit mandate. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.[1]

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

SB 173 would not directly affect "Every Woman Counts," a program operated by the California Department of Public Health that does not provide health insurance coverage but does provide screening for breast cancer to the uninsured.

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

DMHC-regulated plans and CDI-regulated policies would be subject to SB 173. Therefore, the mandate would affect the health insurance of approximately 21.9 million Californians (59%).

Current California code and regulation mandate coverage for breast cancer screening by both DMHC-regulated plans and CDI-regulated policies.[5]

CHBRP is unaware of any existing law that requires plans or insurers to provide mammography reports. Such reports are generally provided by providers and imaging centers, rather than health plans or insurers.

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[1] CHBRP's authorizing statute is available at: http://www.chbrp.org/documents/authorizing_statute.pdf.
[2] CHBRP's estimates are available at: http://www.chbrp.org/other_publications/index.php.
[3] DMHC was established in 2000 to enforce the Knox-Keene Health Care Service Plan of 1975; see Health and Safety Code, Section 1340.
[4] CDI licenses "disability insurers." Disability insurers may offer forms of insurance that are not health insurance. This report considers only the impact of the benefit mandate on health insurance policies, as defined in Insurance Code, Section 106(b) or subdivision (a) of Section 10198.6.
[5] Health & Safety Code Section 1367.6 and Insurance Code Section 10123.8; also Basic Health Care Services; California Health and Safety Code, Section 1345 and Section 1300.67 of the California Code of Regulations, Title 28; Cancer Screening; Health and Safety Code Section 1367.665 and Insurance Code Section 10123.20.

SB 173 contains two separate mandates, one requiring coverage for "comprehensive breast screening" and one related to mammography reports.

SB 173 would require DMHC-regulated plans and CDI-regulated policies to cover "comprehensive breast cancer screening" for enrollees whose mammograms indicate they have dense or heterogeneous breast tissue and for enrollees "believed to be" at increased risk for breast cancer. SB 173 does not further define "comprehensive breast cancer screening." As previously noted, current code already requires coverage for all generally medically accepted cancer screening tests. Based on review by one of the two regulators[6] and legal counsel,[7] CBHRP assumes that plans and insurers would still retain the ability to conduct utilization review and to base coverage decisions on medical necessity and that coverage would remain the same. Therefore, CHBRP assumes that SB 173 would not expand benefit coverage for breast cancer screening.

SB 173 would also require that mammography reports issued by DMHC-regulated plans or CDI-regulated policies contain information about breast density and, when applicable, a recommendation to persons with dense breasts to pursue supplementary screening tests.

Since health plans and insurers do not issue mammography reports, only radiologists and imaging centers do, health plans and insurers would be in compliance with the mammography reports as considered by SB 173.

Breast cancer is a disease that affects primarily women. It is one of the most commonly diagnosed cancers in California, but survival rates are high when it is diagnosed at an early stage.

Of the 50 states and the District of Columbia, all but one (Utah being the exception) mandate coverage for mammography screening. CHBRP is unaware of any existing law in another state that requires plans or insurers to provide mammography reports or to provide specific information in such reports.

Medical Effectiveness

- The medical effectiveness analysis addressed two questions.
    - Did the modality detect more cancers?
    - Did the modality result in fewer cancer deaths or better health outcomes?
- Three modalities are used to screen *asymptomatic women* for breast cancer: mammography, breast magnetic resonance imaging (BMRI), and ultrasound. A new modality, breast

[6] Personal communication, A. Abu-Rahma, California Department of Managed Health Care (DMHC), February 2011.
[7] Personal communication, Office of the General Counsel, University of California, Office of the President, March 2011.

tomosynthesis (also referred to as three-dimensional mammography), was recently approved by the U.S. Food and Drug Administration (FDA).

- The medical effectiveness of mammography for breast cancer screening is well established. Multiple randomized controlled trials (RCTs) have found that mammography screening reduces breast cancer mortality, especially among women aged 50 to 74 years.

- The medical effectiveness review for SB 173 focused on evidence of the effectiveness of BMRI and ultrasound. No studies of the effectiveness of breast tomosynthesis were identified, most likely because this screening modality was only recently approved by the FDA. The literature regarding the efficacy of BMRI and ultrasound encompasses primarily observational studies, including those analyzed in systematic reviews and meta-analyses.

- Studies of BMRI

    - Most studies found that the high sensitivity of BMRI may be useful to identify breast cancers in a *targeted population of high-risk women*.
    - False-positive rates for BMRI were higher than false-positive rates for mammography; a meta-analysis of eight studies estimated that the false-positive rate for BMRI was twice as high as the false-positive rate for mammography.
    - There is insufficient evidence that BMRI screening decreases breast cancer mortality or improves health outcomes.

- Studies of Breast Ultrasound

    - There is insufficient evidence that ultrasound improves the sensitivity of breast cancer screening when it is used to screen asymptomatic women with dense breast tissue or those considered at high risk for breast cancer (e.g., women ages 40–49 years).
    - False-positive rates for breast ultrasound were higher than false-positive rates for mammography; a large observational study reported that the false-positive rate for breast ultrasound was twice as high as the false-positive rate for mammography.
    - There is insufficient evidence that breast ultrasound decreases breast cancer mortality or improves health outcomes.

- Benefits and Harms of BMRI and Breast Ultrasound Screening

    - The lack of evidence of improvement in sensitivity suggests that breast ultrasound is no more effective than mammography for screening asymptomatic women.
    - The higher sensitivity of BMRI relative to mammography for detecting breast cancer among asymptomatic high-risk women must be weighed against the harms associated with higher false-positive rates.
    - Higher false-positive rates increase the numbers of unnecessary follow-up testing and biopsies, which can cause anxiety and discomfort and may result in overdiagnosis and overtreatment.

- It is unknown whether the benefits of BMRI and breast ultrasound screening outweigh the harms because no studies of their impact on survival or other health outcomes were identified.

Benefit Coverage, Utilization, and Cost Impacts

The expected benefit coverage, cost, and utilization impacts for SB 173 are as follows:

- DHMC-regulated plans and CDI-regulated policies are currently compliant with "comprehensive breast screening" as defined by SB 173. Therefore, no measurable change is expected.
- Health plans and insurers do not issue mammography reports, therefore, the report requirements SB 173 would place on plans and insurers would have no impact.
- As no measurable change in benefit coverage is expected, no measurable change in utilization is projected.
- As no measurable change in benefit coverage is expected, no measurable change in cost is expected.
- As no measurable change in benefit coverage or cost is expected, no measurable change in the number of uninsured persons is expected.
- Baseline utilization estimates are the following: 5.2 million receive mammograms, 487 thousand receive breast ultrasound, and 51 thousand receive breast MRIs.
- Average per-unit costs (including additional follow-up services to verify screening results) are the following: $190 for mammograms, $186 for breast ultrasounds, and $1,750 for breast MRIs. In contrast to mammography, baseline utilization and per-unit costs for breast ultrasound and breast MRIs cannot distinguish between screening and diagnostic utilization.

Public Health Impacts

- SB 173 is not expected to impact utilization of comprehensive breast cancer screening; therefore, no public health impact is expected.
- Gender and racial/ethnic disparities in breast cancer prevalence and screening patterns exist in California. However, utilization for comprehensive breast cancer screening is not expected to change as a result of SB 173. Therefore, SB 173 would not impact gender, racial, or ethnic disparities in breast cancer screening, early diagnosis, or mortality rates.

- There are more than 4,200 deaths in California each year due to breast cancer, but since SB 173 is not estimated to impact utilization of comprehensive breast cancer screening, no impact on premature mortality due to breast cancer is estimated.

- Although breast cancer results in over $1.5 billion in economic loss each year in California, SB 173 is not estimated to change the utilization of breast cancer screening or result in a corresponding reduction in economic loss.

Potential Effects of the Federal Affordable Care Act

The federal "Patient Protection and Affordable Care Act" (P.L.111-148) and the "Health Care and Education Reconciliation Act" (H.R.4872) were enacted in March 2010. These laws (together referred to as the "Affordable Care Act" [ACA]) are expected to dramatically affect the California health insurance market and its regulatory environment, with most changes becoming effective in 2014. How these provisions are implemented in California will largely depend on pending legal actions, funding decisions, regulations to be promulgated by federal agencies, and statutory and regulatory actions to be taken by California state government. The provisions that go into effect during these transitional years would affect the baseline, or current enrollment, expenditures, and premiums. It is important to note that CHBRP's analysis of specific mandate bills typically address the marginal effects of the mandate bill—specifically, how the proposed mandate would impact benefit coverage, utilization, costs, and public health, holding all other factors constant. CHBRP's estimates of these marginal effects are presented in this report.[8]

Essential Health Benefits Offered by Qualified Health Plans in the Exchange and Potential Interactions with SB 173

Essential health benefits (EHBs) are defined to include ambulatory patient services; laboratory services; and preventive and wellness services and chronic disease management. The ACA requires that beginning in 2014, states "make payments…to defray the cost of any additional benefits" required of QHPs sold in the Exchange. Health and Human Services (HHS) qualified health plans.[9] This potential liability would depend on three factors:

- differences in the scope of benefits in the final EHB package and the scope of mandated benefits in SB 173;

- the number of enrollees in QHPs; and

- the methods used to define and calculate the cost of additional benefits.

[8] For a discussion on essential health benefits (EHBs) and potential interaction with state mandates, please see, *California's State Benefit Mandates and the Affordable Care Act's "Essential Health Benefits"* available at: http://www.chbrp.org/other_publications/index.php.
[9] Affordable Care Act, 1311(d)(3)(B).

EHBs may all be considered to include benefits and services mandated by SB 173. In addition, HHS when promulgating regulations on EHBs is to ensure that the EHB floor "is equal to the scope of benefits provided under a typical employer plan." Virtually all employers provide coverage for services mandated under SB 173. Because mammography services as defined under SB 173 is considered standard coverage for employer-based plans, and because it is likely to be considered part of EHBs, it is unlikely that there would be any additional fiscal liability to the state for qualified health plans offered in the Exchange as a result of this mandate.

Preventive Services Required Under ACA and SB 173

"New plans" (i.e., those not covered under the ACA's "grandfather" provisions) were required to cover certain preventive services at zero cost sharing beginning September 23, 2010. The U.S. Preventive Services Task Force (USPSTF) recommends screening every 2 years for women age 50 to 74 years. For women age 40 to 49 years, the USPSTF recommends that the decision to initiate biennial screening be made by individual women on the basis of their level of risk for breast cancer and their values regarding the benefits and harms of screening. Mammography, therefore, can fall under the ACA's requirement of zero cost sharing. Based on CHBRP's analysis of current coverage rates, virtually all health plans and policies have coverage for mammography services. SB 173 does not affect the cost sharing of mammography services. Any premium impacts resulting from the ACA's requirements to cover preventive services at zero cost sharing is reflected in the baseline premiums presented in this report and does not affect the marginal impact of SB 173 (which is expected to have no marginal cost impact).

INTRODUCTION

The California Senate Committee on Health requested on February 4, 2011, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Senate Bill (SB) 173: Mammograms, a bill that would impose a health benefit mandate. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.[10]

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

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DMHC-regulated plans and/or CDI-regulated policies would be subject to SB 173. Therefore, the mandate would affect the health insurance of approximately 21.9 million Californians (59%).

Existing California requirements

Existing legislation addresses breast cancer screening for both health care service plans regulated by DMHC and insurance policies regulated by CDI. Current California code[14] mandates that both DMHC-regulated plans and CDI-regulated policies cover breast cancer screening "consistent with generally accepted medical practice and scientific evidence, upon the referral of the enrollee's participating physician." Current code[15] also requires that plans and policies cover "all generally medically accepted cancer screening tests." DMHC-regulated plans are also required to cover "basic health care services," including a range of preventive care services. Regulations further specify that health plans are to cover "preventive health services (including

[10] CHBRP's authorizing statute is available at: http://www.chbrp.org/documents/authorizing_statute.pdf.
[11] CHBRP's estimates are available at: http://www.chbrp.org/other_publications/index.php.
[12] DMHC was established in 2000 to enforce the Knox-Keene Health Care Service Plan of 1975; see Health and Safety Code, Section 1340.
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[14] Health & Safety Code Section 1367.6 and Insurance Code Section 10123.8
[15] Health & Safety Code Section 1367.665 and Insurance Code Section 10123.20.

services for the detection of asymptomatic diseases), which shall include, under a physician's supervision…(1) reasonable health appraisal examinations on a periodic basis."[16] Laws related to CDI-regulated policies do not have a similar set of broad "basic health care services" requirements.

Guidelines from national organizations are summarized in Appendix C (Table C-1) as an example of "generally medically accepted cancer screening" for breast cancer. The majority of these guidelines recommend mammography as the breast cancer screening test for all asymptomatic women.

CHBRP is unaware of any existing law that requires plans or insurers to provide mammography reports. Such reports are generally provided by providers and imaging centers, rather than health plans or insurers.

Bill language, analytic approach, and key assumptions

The full text of SB 173 can be found in Appendix A.

SB 173 contains two separate mandates, one requiring coverage for "comprehensive breast screening" and one related to mammography reports.

SB 173 would require DMHC-regulated plans and CDI-regulated policies to cover "comprehensive breast cancer screening" for enrollees whose mammograms indicate they have dense or heterogeneous breast tissue and for enrollees "believed to be:" at increased risk for breast cancer. SB 173 does not further define "comprehensive breast cancer screening." As previously noted, current code already requires coverage for all generally medically accepted cancer screening tests. Based on review by one of the two regulators[17] and legal counsel,[18] CBHRP assumes that plans and insurers would still retain the ability to conduct utilization review and to base coverage decisions on medical necessity and that coverage would remain the same. Therefore, CHBRP assumes that SB 173 would not expand benefit coverage for breast cancer screening.

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Since health plans and insurers do not issue mammography reports, only radiologists and imaging centers do, health plans and insurers would be in compliance with the mammography reports as considered by SB 173,

[16] Basic Health Care Services; California Health and Safety Code, Section 1345 and Section 1300.67 of the California Code of Regulations, Title 28.
[17] Personal communication, A. Abu-Rahma, California Department of Managed Health Care (DMHC), February 2011.
[18] Personal communication, Office of the General Counsel, University of California, Office of the President, March 2011.

Requirements in other states

Of the fifty states and the District of Columbia, all but one (Utah being the exception) mandate coverage for mammography screening (BCBSA, 2010).

CHBRP is unaware of any existing law in another state that requires plans or insurers to provide mammography reports or to provide specific information in such reports.

Potential Effects of Federal Affordable Care Act

The federal "Patient Protection and Affordable Care Act" (P.L.111-148) and the "Health Care and Education Reconciliation Act" (H.R.4872) were enacted in March 2010. These laws (together referred to as the "Affordable Care Act" [ACA]) are expected to dramatically affect the California health insurance market and its regulatory environment, with most changes becoming effective in 2014. How these provisions are implemented in California will largely depend on pending legal actions, funding decisions, regulations to be promulgated by federal agencies, and statutory and regulatory actions to be taken by California state government. The provisions that go into effect during these transitional years would affect the baseline, or current enrollment, expenditures, and premiums. It is important to note that CHBRP's analysis of specific mandate bills typically address the marginal effects of the mandate bill—specifically, how the proposed mandate would impact benefit coverage, utilization, costs, and public health, holding all other factors constant. CHBRP's estimates of these marginal effects are presented in this report.[19]

Essential Health Benefits Offered by Qualified Health Plans in the Exchange and Potential Interactions with SB 173

Essential health benefits (EHBs) are defined to include ambulatory patient services; laboratory services; and preventive and wellness services and chronic disease management. The ACA requires that beginning in 2014, that states "make payments…to defray the cost of any additional benefits" required of QHPs sold in the Exchange. Health and Human Services (HHS) qualified health plans.[20] This potential liability would depend on three factors:

- differences in the scope of benefits in the final EHB package and the scope of mandated benefits in SB 173;
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EHBs may all be considered to include benefits and services mandated by SB 173. In addition, HHS when promulgating regulations on EHBs is to ensure that the EHB floor "is equal to the

[19] For discussion on essential health benefits (EHBs) and potential interaction with state mandates, please see, *California's State Benefit Mandates and the Affordable Care Act's "Essential Health Benefits"* available here: http://www.chbrp.org/other_publications/index.php.
[20] Affordable Care Act, 1311(d)(3)(B).

scope of benefits provided under a typical employer plan." Virtually all employers provide coverage for services mandated under SB 173. Because mammography services as defined under SB 173 is considered standard coverage for employer-based plans, and because it is likely to be considered part of EHBs, it is unlikely that there would be any additional fiscal liability to the state for qualified health plans offered in the Exchange as a result of this mandate.

Preventive Services Required Under ACA and SB 173

"New plans" (i.e., those not covered under the ACA's "grandfather" provisions) were required to cover certain preventive services at zero cost sharing beginning September 23, 2010. The U.S. Preventive Services Task Force (USPSTF) recommends breast cancer screening with mammography every 2 years for women age 50 to 74 years. For women age 40 to 49 years, the USPSTF recommends that the decision to initiate biennial breast cancer screening be made by individual women on the basis of their level of risk for breast cancer and their values regarding the benefits and harms of screening. Mammography, therefore, can fall under the ACA's requirement of zero cost sharing. Based on CHBRP's analysis of current coverage rates, virtually all health plans and policies have coverage for mammography services. SB 173 does not affect the cost sharing of comprehensive breast cancer screening services. Any premium impacts resulting from the ACA's requirements to cover preventive services at zero cost sharing is reflected in the baseline premiums presented in this report and does not affect the marginal impact of SB 173 (which is expected to have no marginal cost impact).

Background on Breast Cancer

Breast cancer is an abnormal growth in cells that line the lobules (milk-producing glands) or the ducts (vessels that carry milk). Clinicians classify the cancer according to the location of its origin. Those cancers that are confined to a duct or lobule are known as *carcinoma in situ* or noninvasive cancer cells that are still encapsulated in the duct or lobule (NCI, 2011). According to the National Cancer Institute (NCI), ductal carcinoma in situ (DCIS) can progress to invasive cancer, but estimates of the likelihood vary widely. Since mammography became a standard screening tool in the late 1980s, the number of DCIS diagnoses has increased substantially. Approximately 18% of all newly diagnosed breast cancers were noninvasive breast tumors attributed to DCIS. Lobular carcinoma in situ (LCIS) is considered to be unlikely to progress to invasive cancer of its own accord, but its diagnosis does indicate a higher risk for DCIS and invasive cancers (NCI, 2011).

Incidence and Prevalence

Breast cancer is the most common cancer diagnosed in California, with nearly 24,000 new cases expected in 2011 (CCR, 2010). This translates to an annual incidence rate of 123.1 cases of invasive breast cancer, or 153.09 cases of all breast cancer incidence, per 100,000 women in California (CCR, 2011). An average newborn girl's chance of eventually being diagnosed with

invasive breast cancer in California is approximately one in eight (i.e., 12%) (CCR, 2010). There are nearly 300,000 women currently living with breast cancer in California (CCR, 2010).

Although breast cancer is the most common cancer found among women in California, when diagnosed early, survival rates are high. In California, 71% of breast cancer is diagnosed in the early stages (CCR, 2010). Among California women, the 5-year relative survival rate for breast cancer is 91% (CCR, 2010). This rate varies with the stage at diagnosis with a 99% 5-year relative survival rate for localized breast cancer (most often DCIS), 85% for regional breast cancer (IDC/ILC), and 25% for distant breast cancer (IDC/ILC) (CCR, 2010).

There are more than 4,200 deaths expected from breast cancer in California in 2011 (CCR, 2010). This is equivalent to an annual mortality rate of 21.4 per 100,000 women (CCR, 2011). Since 1988, breast cancer mortality among women in California has declined by 32% (CCR, 2010). A sustained decrease in breast cancer mortality in the United States and California during the last 20 years is attributed, in part, to the increased use of mammography screening during the 1980s, as well as improvements in treatments and reduction of hormone-replacement therapy (CCR, 2010).

Breast Cancer Screening

Although different organizations have different guidelines, age 40 has been traditionally regarded as an age at which women should be offered annual screening for breast cancer with mammography (CCR, 2010). In California, 84.6% of women aged 40-64 years with health insurance had a mammogram within the last 2 years (CHIS, 2009). Another 8.6% had a mammogram more than 2 years ago, and 6.8% reported never having had a mammogram (CHIS, 2009). Women who have not had a mammogram report that the main reason for not having had one was: laziness (23.2%), painful or embarrassing (10.6%), did not know it was needed (13.8%), financial reasons (6.7%), and other reasons (45.8%) (CHIS, 2009). Women who were categorized as “didn’t know it was needed” indicated that they did not know the mammogram was needed, the doctor did not tell them it was needed, they have not had any problems with their breasts, or that they were too young to have a mammogram. Other studies have found that insurance status and physician recommendation are significant predictors of mammography utilization (Scheuler et al., 2008).

Breast Cancer Risk

There are many factors that have been associated with an increased risk of breast cancer. Some of these factors include: a family history of breast or ovarian cancer, a personal history of breast or ovarian cancer, prior benign biopsy, personal history of atypical ductal hyperplasia, radiation exposure, high breast density, hormone therapy use, oral contraceptive use, later age of birth of first child (or no children), early age at menarche, and being overweight or obese in menopausal women (CCR, 2010; Saslow et al., 2007; Graubard et al., 2010; Barlow et al., 2006; Tice et al., 2008; Hunter et al., 2010). It is estimated that nearly all women have one or more of these risk

factors (CHIS, 2003; CHIS, 2005; Tice et al., 2008). The American Cancer Society has issued separate screening recommendations for women they categorize as high risk (Saslow et al., 2007). Women with one or more of the following factors are classified as high risk by the ACS: (1) *Genetic: BRCA1* or *BRCA2* gene mutation, Li-Fraumeni syndrome, and first-degree relatives, Cowden and Bannayan-Riley-Ruvalcaba syndromes and first-degree relatives, (2) *Family History:* First-degree relative of *BRCA* carrier, but untested, (3) *Clinical History:* Chest irradiation between age 10 and 30 years (e.g., Hodgkin's disease treatment), and (4) *High Estimated Lifetime Risk* (i.e., lifetime risk of >20% as defined by risk assessment tool). It is estimated that approximately 1% of women ages 30 and older would be classified as high risk based on having one or more of the ACS-identified factors (Graubard et al., 2010).

Breast Composition

The American College of Radiologists Breast Imaging Reporting and Data System (BI-RADS) categorizes mammographic breast composition as follows: (1) the breast is almost entirely fat (<25% glandular), (2) scattered fibroglandular densities (25%-50%), (3) heterogeneously dense breast tissue (51%-75%), and (4) extremely dense (>75% glandular) (ACR, 2003). It is estimated that 9% of women have breast tissue composed of almost entirely fat, 44% have scattered fibroglandular densities, 38% have heterogeneously dense breast tissue, and 9% have extremely dense breast tissue (Tice et al., 2008). SB 173 specifies that women with "heterogeneous or dense breast tissue" should have coverage for comprehensive breast screening. It is estimated that 47% of women have heterogeneously dense or extremely dense breast tissue (Tice et al., 2008).

Demographic Differences

Breast cancer overwhelmingly affects women, although a small number of cases are diagnosed in men, as well. In California, it is estimated that 0.7% of cases of breast cancer occur in men—about 165 cases and 30 deaths each year (CCR, 2010). Routine screening of men using mammography or other screening tests is not routinely performed.

As presented in Table 1, the incidence of breast cancer in California varies by race/ethnicity, with non-Hispanic whites having the highest rates (174.8 per 100,000 women), followed by blacks (154.9 per 100,000 women), and Asian/Pacific Islanders and Hispanics having the lowest rates (129.2 and 108.9 per 100,000 women, respectively) (CCR, 2011). Research suggests that prevalence of mutations in the *BRCA1* gene also vary by race/ethnicity, with the highest rates found among Ashkenazi Jewish women and lowest among Asian American women (John et al., 2007).

Self-reported screening rates using mammography do not vary significantly by race/ethnicity among insured women ages 40-64 years (CHIS, 2009). Among those who are screened with mammography, breast composition does vary by race/ethnicity with Asian/Pacific Islander women having higher rates of either heterogeneously dense or extremely dense breasts (Tice et al., 2008). There are also disparities by race/ethnicity in terms of the degree to which breast

cancer is diagnosed at an early stage (i.e., in situ or localized), with blacks (63%) and Hispanics (64%) having lower rates of early diagnosis compared to non-Hispanic whites (72%) or Asian/Pacific Islanders (73%) (CCR, 2010). Mortality rates from breast cancer vary by race/ethnicity, with blacks having the highest rates (31.9 per 100,000 women), followed by non-Hispanic whites (23.7 per 100,000 women), and Hispanics and Asian/Pacific Islanders having the lowest mortality rates (16.6 and 13.3 per 100,000 women, respectively) (CCR, 2011).

Table 1. Incidence, Breast Composition, Screening, and Mortality for Breast Cancer Overall and by Race/Ethnicity in California

Population	Cancer Incidence Rate (a)	Heterogeneously Dense or Extremely Dense Breast Tissue (b)	Screening Rate (c)	% Cancer Found at an Early Stage (d)	Mortality Rate (e)
Overall	153.1	47%	84.6% (83.3–85.9)	71%	21.4
Hispanic	108.9	42%	83.7% (80.2–87.1)	64%	16.6
Non-Hispanic white	174.8	44%	85.6% (84.3–86.8)	72%	23.7
Black	154.9	45%	85.1% (80.6–89.6)	63%	31.9
Asian/Pacific Islander	129.2	64%	82.5% (77.4–87.6)	73%	13.3

Sources and Notes: (a) Data from the California Cancer Registry. Data are age adjusted to the 2000 U.S. Standard Million Population and reflect all breast cancer incidence including in-situ cancers. Rates are per 100,000 women in California in 2008.
(b) Data calculated from Tice et al., 2008.
(c) Data taken from CHIS, 2009. Screening is reported as mammography within the last 2 years for women ages 40–64 years with health insurance. Rates of screening listed for Asian/Pacific Islanders are for Asians only.
(d) Data taken from CCR, 2010. Early stage is defined as cancer found in situ or localized. Data are for 2008.
(e) Data from the California Cancer Registry. Data are age adjusted to the 2000 U.S. Standard Million Population. Rates are per 100,000 women in California in 2008.

MEDICAL EFFECTIVENESS

Four modalities are used to screen *asymptomatic women* for breast cancer: clinical breast exam (CBE),[21] mammography, breast magnetic resonance imaging (BMRI), and breast ultrasound. A new modality, breast tomosynthesis (also referred to as three-dimensional mammography), was recently approved by the U.S. Food and Drug Administration.

The medical effectiveness of mammography for breast cancer screening is well established. Eight large randomized controlled trials (RCTs) have found that mammography screening reduces breast cancer mortality, especially among women aged 50 to 74 years. Further information regarding the effectiveness of mammography may be found in CHBRP's report on AB 137 (2011), a bill that addresses coverage for mammography (CHBRP, 2011).

The medical effectiveness review for SB 173 focused on evidence of the effectiveness of two newer screening modalities, BMRI and ultrasound. Breast tomosynthesis is not discussed because CHBRP did not identify any studies of the accuracy of this new screening modality or its effects on health outcomes.

National guidelines for breast cancer screening differ with regard to BMRI and breast ultrasound. Two national guidelines for breast cancer screening recommend BMRI screening for women at high risk for breast cancer (Lee et al., 2010; Smith et al., 2011), whereas another guideline concludes that there is insufficient evidence to recommend for or against screening (USPSTF, 2009), and two make no recommendation for or against use of this screening modality (ACOG, 2003; Qaseem et al., 2007). One guideline suggests ultrasound screening may be appropriate for women with dense breast tissue or who are at high risk for breast cancer and cannot be screened with BMRI (Lee et al., 2010), whereas the other four guidelines make no recommendation regarding this modality (ACOG, 2003; Qaseem et al., 2007; Smith et al., 2011; USPSTF, 2009).

Literature Review Methods

The conclusions drawn regarding the medical effectiveness of the screening modalities in this section are based on the best available evidence from peer-reviewed literature. Studies of the effectiveness of BMRI and ultrasound screening were identified through searches of 320 abstracts. The search was limited to abstracts of peer-reviewed research studies that were published in English. The search was limited to studies published from 2008 to present, because CHBRP had previously conducted a thorough literature search on these screening modalities in 2008 for its report AB 2234 (CHBRP, 2008). A total of five systematic reviews and seven

[21] CBE is considered part of a woman's periodic preventive health exam and is generally covered by insurance and health plans as a preventive service. Due to the focus of SB 173, CBE is not within the scope of the bill, as this exam is generally provided during a woman's periodic preventive health care visit to her physician. Evidence is inconclusive regarding the effectiveness of CBE and is so noted by clinical guidelines that state varying degrees of support for recommending CBE as standard practice (Smith et al., 2011; USPSTF, 2009).

individual studies[22] were included in the medical effectiveness review for SB 173. A more thorough description of the methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure is presented in Appendix B: Literature Review Methods. Appendix C includes tables describing the studies that CHBRP reviewed (Tables C-1, C-2a, and C-2b).

Screening Modalities

It should be noted that to be effective, screening tests must be able to detect disease earlier than with the absence of screening, and must be able to distinguish disease from non-disease. Furthermore, once diagnosed through screening, patients undergoing treatment should achieve better outcomes compared with patients initiating treatment following presentation of symptoms (Bermejo-Perez et al., 2008).

Screening modalities are applied only to asymptomatic persons. In this case, women who experience no symptoms related to breast cancer may be screened by one or two primary methods: mammography or clinical breast exam (CBE). Some women may be screened with BMRI and/or ultrasound/ultrasonography in addition to mammography or CBE.

Mammography

Mammography may be performed using film or digital technology. Film mammography is performed by compressing the breast between a plastic plate, and an x-ray cassette that contains x-ray film that is developed into a large film-screen. Digital mammography is similar to conventional (film-screen) mammography: both use x-ray radiation to produce an image of the breast; however, digital mammography records and stores an electronic image into a computer rather than on film. Digital mammography allows the radiologist to alter the magnification, orientation, brightness, and contrast of the image to see certain areas more clearly. According to the US Food and Drug Administration, as of February 2011, there are 21,507 mammography machines in the United States, of which 12,344 (57%) are film and 9,163 (43%) are digital (FDA, 2011).[23]

BMRI

MRI uses a magnet linked to a computer to create detailed pictures of areas inside the body without the use of radiation. Each MRI produces hundreds of images of the breast from side to side, top to bottom, and front to back to create a three-dimensional image. Typically a patient lies face down on the bed with breasts falling through openings into a breast coil. The breast coil is a signal receiver that works with the MRI to create the images (Elmore et al., 2005). Two sets of images of the breast are taken: an initial set and a second set where a contrast agent, gadolinium,

[22] Findings from one study were reported in two articles (Peters et al., 2008; Saunders et al., 2009).

[23] Some radiologists use sophisticated pattern-recognition computer software known as computer-aided detection (CAD) to assist in identifying suspicious features on digital images, with the goal of improving accuracy. Film images must be digitally scanned before CAD can be activated, whereas digital mammography images are already downloaded into the computer for CAD.

is administered to the patient by intravenous injection. The images are transferred from the MRI machine into a computer for the radiologist to study.

Ultrasound

Ultrasound screening is performed by using a transducer to direct high-frequency sound waves at the breast. These waves produce a picture called a sonogram. A breast ultrasound can record all areas of the breast, including the area closest to the chest wall, which is difficult to obtain with a mammogram. A radiologist reviews the sonogram to detect abnormalities and distinguish between solid tumors and fluid-filled cysts.

Study Findings

When reviewing studies of screening tests it is importat it is important to consider the tradeoff between sensitivity and specificity. Sensitivity refers to the proportion of breast cancers detected when breast cancer is present, or the true-positive rate. Specificity refers to the likelihood that test results will be negative when cancer is absent. For screening tests, one may want to place a higher priority on sensitivity to minimize the number of false-negative test results. On the other hand, a test with high sensitvity but low specificity could generate a large number of false-positive results, which could lead to unnecessary follow-up testing, biopsies, and treatment.

Epidemiologic Terminology

Sensitivity refers to the proportion of breast cancers detected when breast cancer is present, or the true-positive rate.

Specificity is defined as the likelihood of the test being negative when cancer is absent. If the test specificity is low, the test would have a high false-positive rate that could result in unnecessary interventions.

Positive Predictive Value is defined as the proportion of those testing positive who actually have the disease for which the test is designed to detect. Predictive values are highly dependent upon the prevalence of a disease in a population.

Recall Rate is the number of patients recalled for further testing due to inconclusive or suspicious test results. Some recalled patients have positive findings, and some have negative findings, meaning their recall was unnecessary.

Breast MRI (BMRI)

The medical effectiveness literature review revealed nine recent systematic reviews and individual studies related to the use of BMRI in breast cancer screening (Table 2). All of these studies assessed the accuracy of BMRI screening relative to other screening tests. None examined the impact of BMRI screening on health outcomes.

BMRI versus mammography
A meta-analysis by Granader et al. (2008) pooled findings from three large cohort studies[24] that compared BMRI to mammography among women at high risk for breast cancer. (This meta-analysis included one study included in Lord et al., 2007, and one study included in Bermejo-Perez et al., 2008). Findings were reported separately for women who were *BRCA 1/2* carriers and women with strong family histories of breast cancer without known *BRCA 1/2* mutation. BMRI was more sensitive than mammography for both groups of women (84% vs. 33% for *BRCA 1/2* carriers and 81% vs. 41% for strong family history without known *BRCA 1/2* mutation). The rate of false-positive results was twice as high for BMRI as for mammography among both groups of women (10% vs. 5%). The authors of one of the studies included in the meta-analysis reported that BMRI led to twice as many unneeded additional examinations compared to mammography and three times as many unneeded biopsies (Kriege et al., 2004).

Lee et al. (2009) conducted a systematic review of seven studies[25] that compared the sensitivity of BMRI and mammography for screening high risk women (including four studies included in Lord et al., 2007, three studies included in Bermejo-Perez et al., 2008, and one study included in Granader et al., 2008). Consistent with previous studies, the authors found that BMRI was more sensitive than mammography (74% to 100% vs. 33% to 59%). The variation in sensitivity across the studies included in the systematic review was due in part to differences in the criteria used to classify the results of a BMRI examination as positive (i.e., suspicious for breast cancer).

A retrospective cohort study published after the studies included in the systematic reviews described the experience of a large U.S. cancer center with BMRI screening of women with family history of breast cancer, including *BRCA 1/2* carriers (Yu et al., 2008). All patients screened at this cancer center received biannual CBE and annual mammography. BMRI screening was performed at patient and physician discretion. Among 374 women who received 976 BMRIs, nine cancers were detected, seven of which were found only on BMRI. Biopsies were performed on 15% of women based on BMRI results. The positive predictive value of BMRI for biopsy among all women screened was 9%. The authors reported that the positive predictive value of BMRI was positively associated with the strength of family history of breast cancer (i.e., higher positive predictive value for women with stronger family histories). False-positive rates ranged from 6% for women with more than two first-degree relatives or one first-degree plus one or more second-degree relatives with breast cancer to 16% for women with more than two second degree relatives but no first degree relatives with breast cancer. The authors conclude that BMRI screening should be provided only to women with the highest-risk family histories of breast cancer.

[24] These studies included a study by Kriege et al., 2004, that was included in CHBRP's report on AB 2234.
[25] These studies included a study by Hagen et al, 2007, that was included in CHBRP's report on AB 2234.

BMRI versus mammography and ultrasound

Two recent small observational studies have compared the performance of ultrasound with BMRI and mammography (Saunders et al., 2009; Trop et al., 2010). Saunders et al. (2009) enrolled women with a family history of breast cancer (including *BRCA1/2* carriers) or a previously diagnosed breast condition (e.g., atypical ductal hyperplasia, ductal carcinoma in situ). Trop et al. (2010) enrolled women who were *BRCA1/2* carriers or had a family history of *BRCA1/2* mutations and at least a 30% risk of being a *BRCA1/2* carrier, some of whom had been previously treated for breast cancer. Both studies found that BMRI was more sensitive for detecting breast cancers than mammography or ultrasound. A second article by Saunders and colleagues reported that the recall rate for BMRI detected lesions was 12.5% during the first year of their study and 7.5% in the second year (Peters et al., 2008).[26]

BMRI in addition to mammography

Lord et al. (2007) performed a systematic review of the effectiveness of BMRI in addition to mammography with or without ultrasound and CBE in women at high risk as defined in various ways. No randomized clinical trials were available for review. They reported that all five studies, which together included 2,059 women, found MRI/mammography increased sensitivity compared to mammography alone (93%-100% vs. 25%-59%). A meta-analysis of three studies including 1,545 women comparing MRI/mammography to mammography alone found MRI/mammography was more sensitive (94%, CI: 86%-98%) than mammography and the incremental sensitivity for MRI was 58% (CI: 47%-70%). Incremental sensitivity of MRI decreased as other screening modalities (ultrasound and CBE) were added. Authors noted that specificity of MRI plus conventional testing ranged from 77% to 96%. One of the studies included in the systematic review estimated that test recall rates were three to five times higher when MRI was added to mammography versus mammography alone. This indicates that an additional 71 to 74 follow-up studies were conducted with 7 to 46 additional benign biopsies performed per 1,000 screenings—this is considered a high recall rate. No significant differences in the tumor size or lymph node involvement were noted by any of the studies for women whose cancers were found by BMRI.

Bermejo-Perez et al. (2008) recently published a systematic review of eight studies on BRCA mutation carriers and cancer surveillance (two of which are included in the Lord et al., 2007, review). They concluded that although supplementing mammography screening with BMRI screening for all *BRCA1/2* carriers achieved the highest diagnostic performance (83% to 95% sensitivity), the false-positive rates (of up to 14% of one study's population) leading to unnecessary biopsies was a critical consideration. The authors caution that inherent study biases may have artificially increased the sensitivity rates, too. The authors note that it is uncertain whether the benefits of treatment at an early stage (due to MRI diagnosis) outweigh the harm of overdetection of cancers that would never have manifested clinically.

A meta-analysis by Granader et al. (2008) pooled findings from three cohort studies that assessed the effectiveness of supplementing mammography with BMRI for screening women at high risk for breast cancer (including one study included in Lord et al., 2007, and one study included in

[26] A study that included women with dense breasts or breast implants as well as women at high risk due to genetic mutation, family history, or history of breast conditions reported a recall rate for BMRI of 15% for targeted ultrasound and 13% for biopsies.

Bermejo-Perez et al., 2008). Findings were reported separately for women who were *BRCA1/2* carriers and women with strong family histories of breast cancer without known *BRCA1/2* mutation. Adding BMRI to mammography was associated with greater sensitivity among both groups of women (93% vs. 33% for *BRCA1/2* carriers and 95% vs. 41% for strong family history without known *BRCA1/2* mutation). The rate of false-positive results for BMRI was twice as high as the false-positive rate for mammography among both groups of women (10% vs. 5%) and that the false-positive rate for BMRI and mammography combined was higher still (14%)..

Lee et al. (2009) conducted a systematic review of studies that compared the sensitivity of BMRI screening plus mammography screening to mammography alone among high-risk women (including four studies included in Lord et al., 2007, three studies included Bermejo-Perez et al., 2008, and one study included in Granader et al., 2008). Consistent with previous studies, the authors found that the combination of mammography and BMRI was more sensitive than mammography alone (83% to 100% vs. 33% to 59%). The variation in sensitivity across the studies included in the systematic review was due in part to differences in the criteria used to classify the results of a BMRI examination as positive (i.e., suspicious for breast cancer). In five of the seven studies included in the systematic review, there was no correlation between findings from BMRI and mammography screening. The authors suggest that this lack of correlation may indicate that additional and different information is obtained by supplementing mammography with BMRI.

Studies of high-risk women show that BMRI detects incrementally more cancers than mammography, but no studies have been conducted to show whether BMRI reduces breast cancer mortality or otherwise improves breast cancer outcomes. The increase in detected cancers is accompanied by an increase in the need for repeat testing and an increase in false-positive biopsies. Findings from these studies suggest that false-positive rates are lowest among women with the strongest family histories of breast cancer. No studies have assessed whether BMRI screening improves survival or other health outcomes.

Table 2. Summary of Findings of Medical Effectiveness of Breast MRI Screening Studies

Citation	Research Design (a)	Sensitivity/ Specificity PPV (b)	Recall Rate/ Cancer Detection Rate	Size of Effect	Generalizability (to Population Affected by Mandate)	Conclusion
Lord et al., 2007	**Level III:** Five studies including 2,059 women (mean age range 40-47 years) at high risk for breast cancer screened by BMRI and reporting sensitivity for each study.	Range for BMRI from 5 studies: Sensitivity 93%–100% Specificity 77%-96% Pooled estimate of three studies showed sensitivities as follows: BMRI+mammogram: 94% (95% CI (c): 86%-98%) Incremental BMRI: 58% (95% CI: 47%-70%)	Recall rate for 3 studies ranged between 71 to 74 additional false positives/1,000 screenings (3-5 times higher for MRI than mammography) Five studies ranged between 10 to 24 additional cancers detected/1,000 screenings	A clinically meaningful effect was found for young women undergoing BMRI	Generalizable because the population in each study has a high lifetime breast cancer risk, and the mean age range of women enrolled in the studies was 40 to 47 years	Adding BMRI to mammography showed consistently higher sensitivity (93% to 100%) compared with mammography alone (25% to 59%) or mammography plus ultrasound ± CBE (49% to 67%) but is also associated with higher false-positive rates
Bermejo-Perez et al., 2008 (d)	**Level III:** Eight prospective and retrospective studies looking at women (mean age of 46 years or less) who were *BRCA1/2* carriers and were screened with BMRI to evaluate diagnostic performance	Range from 8 studies: Sensitivity BMRI: 77%-100% Mammography: 20%-50% Specificity BMRI: 81%-97.5% Mammography: +96% Positive predictive value 12.5%-66.7%	61 cancers detected in all 8 studies	A small clinically meaningful effect was found for women at high risk	Somewhat generalizable because the population is limited to women at high risk due to *BRCA1/2* genes	Screening BMRI had the highest sensitivity of all screening methods but low positive predictive value

Citation	Research Design (a)	Sensitivity/ Specificity PPV (b)	Recall Rate/ Cancer Detection Rate	Size of Effect	Generalizability (to Population Affected by Mandate)	Conclusion
Granader et al., 2008 (e)	**Level III:** Eight prospective and retrospective studies looking at women who were *BRCA1/2* carriers and/or had strong family history of breast cancer and were screened with BMRI, mammogram, or both to evaluate diagnostic performance.	**Sensitivities (95% CI)** BMRI: 96.6% (95% CI: 0.946–0.986) Mammography: 37.5% (95% CI: 0.298-0.45) BMRI+Mammography: 94.4% (95% CI: 0.896-0.992)	**All women at increased risk** Cancer detection rate: BMRI: 0.020 (95% CI: 0.011-0.028) Mammography: 0.007 (95% CI: 0.004-0.009) BMRI+Mammography: 0.019 (95% CI: 0.010-0.029) **Women w/increased risk who are *not BRCA1/2* carriers** **Cancer detection rates:** BMRI=0.011 (95% CI: 0.003-0.019), Mammography=0.005 (95% CI: 0.002-0.008), BMRI+Mamm=0.012 (95% CI: 0.004-0.020). False-positives: MRI=0.10 (95% CI: 0.03-0.18) Mammography=0.05 (95% CI: 0.03-0.06) BMRI+Mamm= 0.14 (95% CI: 0.04-0.24). **Women who are *BRCA1/2* carriers Cancer detection rates:** B MRI=0.027 (95% CI: 0.015-0.040) mammography=0.010 (95% CI: 0.005-0.016) Mamm+BMRI=0.031 (95%		Generalizable because the population in each study has a high lifetime breast cancer risk (*BRCA1/2* carrier or strong family history of breast cancer)	BMRI has higher sensitivity than mammography to detect breast cancer in high-risk women but also has a higher rate of false-positive results.

Citation	Research Design (a)	Sensitivity/ Specificity PPV (b)	Recall Rate/ Cancer Detection Rate	Size of Effect	Generalizability (to Population Affected by Mandate)	Conclusion
			CI: 0.018-0.045). False-positive rates BMRI: 0.10 (95% CI: 0.01-0.19) Mammography 0.05 (95% CI: 0.03-0.07), Mammography+BMRI=0.14 (95% CI: 0.04-0.24)			
Peters et al., 2008, and Saunders et al., 2009 (f)	**Level III:** Prospective comparative trial of 72 women aged 50 years or under at high risk of developing breast cancer due to family history including known genetic mutation and women at high risk		Recall rate after BMRI scans was 10.1% overall 15 lesions—all visible on MRI; 4 lesions visible on BMRI only; 1 visible on all 3 imaging modalities; 2 lesions were seen on mammogram but not ultrasound; 8 seen on ultrasound but not mammogram		Generalizable because the population in each study has a high lifetime breast cancer risk and ranged in age from 25 to 50 years	Small sample size limits ability to assess the effects of trimodal screening with mammography, BMRI, and breast ultrasound
Yu et al., 2008	**Level III**: Prospective study of comparing mammography to BMRI screening in women (mean age 49 yrs; range 21–88 yrs) with family history or genetic predisposition to breast cancer. Stratified patients by family history	PPV Overall: 9% Patients with the strongest family histories: 13% Patients with less significant family histories: 6%	BMRI: Cancer detection rate of 0.7% (7/976) for screening MRI Cancer detection rate: All patients: 29 (3%) BMRI only: 9(2%) No MRI: 20 (3%) Cancer detection rate: No BMRI: 260 biopsies		Generalizable because the population in each study has a high lifetime breast cancer risk and the patients ranged in age from 21 to 88 years with a mean age of 49 years	The positive predictive value of BMRI is low overall but highest for women with the strongest family histories of breast cancer

Citation	Research Design (a)	Sensitivity/ Specificity PPV (b)	Recall Rate/ Cancer Detection Rate	Size of Effect	Generalizability (to Population Affected by Mandate)	Conclusion
	profiles in an attempt to simplify identification of patients who would benefit most from MRI screening		Cancer detected in 20. BMRI screening: 74 biopsies Cancer detected in 7 of them			
Lee et al., 2009(g)	**Level III:** Seven studies including 2,626 women at high risk for breast cancer screened by BMRI and reporting sensitivity for each study.	Range from 7 studies: **Sensitivity** Mammography: 32.6%-58.8% BMRI: 73.9%-100% Combined: 83%-100%	Number of cancers detected ranged from 12-43 In 6 of 7 studies, there was no statistically significant correlation between BMRI and mammography results	A clinically meaningful effect was found for women at high risk	Generalizable because the population in each study has a high lifetime breast cancer risk (primarily based on genetic mutation or family history)	BMRI is more sensitive than mammography and provides additional and different information
Price and Chen, 2009	**Level III:** Prospective comparative trial		7 cancers detected=4.1% Only 1 of 7 cancers detected by BMRI was also detected by mammography		Generalizable because the population in each study has a high lifetime breast cancer risk and ranged in age from 22 to 67 year s with a mean age of 46 years	Small sample size limits ability to assess the effects of BMRI screening

Citation	Research Design (a)	Sensitivity/ Specificity PPV (b)	Recall Rate/ Cancer Detection Rate	Size of Effect	Generalizability (to Population Affected by Mandate)	Conclusion
Trop et al., 2010	**Level III:** Prospective comparative trial enrolling 184 women at high risk of breast cancer	Sensitivity: 83% Specificity: 93.6%	Cancers detected: 10/12 Recall rate (overall): 83/380 (21.8) Biopsy rate: Overall 17/83 Positive 7/17	Because of the limited number of cancers detected, differences in the sensitivities of BMRI, ultrasound, and mammography were not significantly significant	Generalizable because the population in each study has a high lifetime breast cancer risk, and ranged in age from 21 to 75 years with a mean age of 45 years	Small sample size limits ability to assess the effects of trimodal screening with mammography, BMRI, and breast ultrasound

Sources: Bermejo-Perez et al., 2008; Granader et al., 2008; Lee et al., 2009; Lord et al., 2007; Peters et al., 2008; Price and Chen, 2009; Saunders et al., 2009; Trop et al., 2010; Yu et al., 2008.

Notes:

(a) Level I=Well-implemented RCTs and cluster RCTs, Level II=RCTs and cluster RCTs with major weaknesses, Level III=Nonrandomized studies that include an intervention group and one or more comparison group, time series analyses, and cross-sectional surveys, Level IV=Case series and case reports, Level V=Clinical/practice guidelines based on consensus or opinion.

(b) PPV = positive predictive value

(c) CI = confidence interval

(d) Bermejo-Perez et al. (2008) shares three studies in common with the Lord et al. (2007) systematic review.

(e) Granader et al. (2008) shares four studies in common with Lord et al. (2007) systematic review and three studies in common with the Bermejo-Perez et al. (2008) systematic review.

(f) Peters et al., 2008, and Saunders et al., 2009, presented findings from the first and second years of the same study.

(g) Lee et al. (2009) shares three studies in common with Lord et al. (2007), four studies in common with Bermejo-Perez et al. (2008), and three studies in common with Granader et al. (2008).

Ultrasound

Six studies of breast ultrasound screening were identified. Findings are summarized in Table 3. All of these studies assessed the accuracy of breast ultrasound screening relative to other screening tests. None examined the impact of breast ultrasound screening on health outcomes.

Ultrasound screening following negative mammogram

Nothacker and colleagues (2009) conducted a systematic review of six large (n = 1,500+ women) observational studies[27] of the use of breast ultrasound following negative findings on a mammogram. The authors found that ultrasound detected some cancers not found by mammography and that most of the cancers detected were among women with heterogeneously dense or extremely dense breast tissue. Among studies included in the systematic review, the positive predictive value of ultrasound screening for biopsies ranged from 2% to 28%, which means that biopsies found no breast cancers in 72% to 98% of women whose ultrasound results suggested they might have cancer. The variation in positive predictive value across studies was due to differences in the criteria used to determine whether a lesion was likely to be cancerous. Nothacker et al. (2009) noted that most studies had not followed women for sufficient periods of time to calculate sensitivity, specificity, and negative predictive value.

Ultrasound screening regardless of mammogram findings

A large (n=2,809 women), multisite observational study completed after the studies included in the systematic review assessed the effectiveness of adding ultrasound screening to mammography screening regardless of mammography findings among women with heterogeneously dense or extremely dense breast tissue who were at high risk of breast cancer (Berg et al., 2008).[28] The authors found that supplementing mammography with ultrasound increased the number of breast cancers detected among high-risk women with dense breasts from 1.1 to 7.2 cancers per 1,000 women. Supplementing mammography with ultrasound also substantially increased the number of false-positive results. The positive predictive value of biopsy recommendations for mammography plus ultrasound (11.2%) was half that of mammography alone (22.6%). The false-positive rate was twice as high (8.1% vs. 4.4%).

Three studies have compared the performance of ultrasound with BMRI and mammography (Peters et al., 2008; Saunders et al., 2009; Trop et al., 2010; Warner et al., 2004).[29] A study by Warner et al. (2004)[30] explored use of ultrasound in women at high risk of breast cancer due to gene mutation in *BRCA1/2*. Trop et al. (2010) enrolled women who were *BRCA1/2* carriers or had a family history of *BRCA1/2* mutations and at least a 30% risk of being a *BRCA1/2* carrier, some of whom had been previously treated for breast cancer. Saunders et al. (2009) enrolled

[27] These studies included a study by Corsetti et al. (2008) discussed in CHBRP's report on AB 2234. (CHBRP, 2008).

[28] Risk factors included personal history of breast cancer, lifetime risk of breast cancer of ≥25%, 5-year risk of breast cancer of ≥2.5%, atypical ductal hyperplasia, atypical lobular hyperplasia, lobular carcinoma in situ, atypical papiloma, *BRCA1/2* mutation, history of prior chest radiation (Berg et al., 2008).

[29] Peters et al., 2008, and Saunders et al., 2009, reported findings from the first and second years of the same study.

[30] Warner et al., 2004, is not discussed separately in the section on BMRI because it was included in the systematic reviews by Lord et al. (2007), Bermejo-Perez et al. (2008), Granader et al. (2008), and Lee et al. (2009).

women with a family history of breast cancer (including *BRCA1/2* carriers) or a previously diagnosed breast condition (e.g., atypical ductal hyperplasia, ductal carcinoma in situ). All three studies found that BMRI was more sensitive for detecting breast cancers than mammography or ultrasound. Saunders et al. (2009) found that ultrasound was useful for further examination of lesions identified by BMRI, suggesting that ultrasound may be better suited to diagnostic evaluation of women with suspected breast cancer than screening of asymptomatic women.

A study of a new method for performing breast ultrasound, automated whole breast ultrasound, was identified (Kelly et al., 2010). The authors assessed the effectiveness of supplementing mammography with automated whole breast ultrasound in 4,419 women who had dense breast tissue and a personal or family history of breast cancer, and/or breast implants. The authors report a doubling in the number of cancers detected per 1,000 women and a positive predictive value for biopsies similar to that of mammography. It is unknown as to whether automated whole breast ultrasound has been used in facilities other than those that participated in this study.

CHBRP found that breast ultrasound detects additional breast cancers in asymptomatic women with dense breast tissue that are not detected by mammography. However, the rate of false-positive findings is high relative to mammography. Ultrasound is also less sensitive (i.e., has a higher rate of false negatives) than BMRI. No studies have assessed whether breast ultrasound screening improves survival or other health outcomes.

Table 3. Summary of Findings of Medical Effectiveness of Ultrasound for Breast Cancer Screening

Citation	Research Design	Sensitivity/ Specificity PPV	Recall Rate/ Cancer Detection Rate	Size of Effect	Generalizability (to Population Affected by Mandate)	Conclusion
Warner et al., 2004	**Level III:** An observational study to evaluate ultrasound screening	Sensitivity Ultrasound: 33% (compared with MRI: 77% Mammography: 36% CBE: 9.1%) Specificity Ultrasound: 96% (compared with MRI: 95.4% Mammography: 99.8% CBE: 99.3%)	7 cancers detected by ultrasound	No clinically meaningful effect was found	Somewhat generalizable since the study focused only on women aged 25 to 65years who are *BRCA1/2* mutation carrier	In *BRCA1* and *BRCA2* mutation carriers, MRI is more sensitive for detecting breast cancers than mammography, ultrasound, or CBE alone

Table 3. Summary of Findings of Medical Effectiveness of Ultrasound for Breast Cancer Screening (Cont'd)

Citation	Research Design	Sensitivity/ Specificity PPV	Recall Rate/ Cancer Detection Rate	Size of Effect	Generalizability (to Population Affected by Mandate)	Conclusion
Berg et al., 2008	**Level III:** Comparative study of performance of screening with ultrasound +mammography compared to mammography alone in 2,809 women at elevated risk of breast cancer.	PPV of biopsy recommendation after full diagnostic workup (PPV2): Mammography: 84/276 (22.6%, 95% CI: 14.2%-33%) Ultrasound 21/235 (8.9%, 95% CI: 5.6%-13.3%) Ultrasound+mammography 31/276 (11.2%, 95% CI: 7.8%-15.6%). Differences between mammography + ultrasound and mammography alone: Sensitivity: 27.5% (95% CI: 9.52-45.48) Specificity: −6.12% (95% CI: −7.24 to −5) PPV(odds ratio): 0.65 (95% CI: 0.36-1.19)	Comparison of mammography +US vs. mammography difference: Recall rate: 4.2 (95% CI: 1.1-7.2)		Somewhat generalizable since the study focused only on women at elevated risk for breast cancer, with at least heterogeneously dense breast tissue in at least one quadrant. Women ranged in age from 25 to 91 years with a median age of 55 years.	Adding a single screening ultrasound to mammography will yield an additional 1.1 to 7.2 cancers per 1,000 high-risk women, but will also substantially increase the number of false positives

Table 3. Summary of Findings of Medical Effectiveness of Ultrasound for Breast Cancer Screening (Cont'd)

Citation	Research Design	Sensitivity/ Specificity PPV	Recall Rate/ Cancer Detection Rate	Size of Effect	Generalizability (to Population Affected by Mandate)	Conclusion
Peters et al., 2008, and Saunders et al., 2009	**Level III:** Study enrolled 72 women. Surveillance involved a CBE every 6 months and trimodality imaging (mammogram, high-resolution ultrasound, and dynamic MRI) performed once a year for 2 years.		Detected 3/15 malignant lesions . 9 lesions detected via ultrasound 7/9 visible on ultrasound but not BMRI		Somewhat generalizable since the study focused only on women with a high risk due to family history, *BRCA1/2* mutation carrier, or previous breast cancer. All women <50 yrs.	Small sample size limits ability to assess the effects of trimodal screening with mammography, BMRI, and breast ultrasound
Nothacker et al., 2009	Systematic review of 6 cohort studies	PPV: ranged 2%-28%			Somewhat generalizable, examined studies in which breast ultrasound was used as supplemental examination to neg. mammography results in women with dense breasts. Asymptomatic women with negative breast exam and breast density ACR 2-4. Median age ranged from 48 to 61 years.	Supplemental breast ultrasound in the population of women with dense breasts (ACR 3 and 4) permits detection of small and otherwise undetected breast cancers, but the positive predictive value for biopsy was approximately one-third of the positive predictive value of mammography

Table 3. Summary of Findings of Medical Effectiveness of Ultrasound for Breast Cancer Screening (Cont'd)

Citation	Research Design	Sensitivity/ Specificity PPV	Recall Rate/ Cancer Detection Rate	Size of Effect	Generalizability (to Population Affected by Mandate)	Conclusion
Kelly et al., 2010	**Level I:** A randomized control trial to evaluate ultrasound screening by itself or in addition to mammography.	PPV: 38.4% Ultrasound alone Sensitivity: 67% (95% CI: 53%-79%; 38 out of 57) Specificity: 89.9% (95% CI: 89.1%-90.6%)	The number of detected invasive cancers 10 mm or less in size tripled from 7 to 21 when ultrasound findings were added to mammography: 23 (40) (27.5,54) Recall rates Mammography: 4.2% Ultrasound: 7.2% Mammography plus ultrasound: 9.6%		Generalizable because the study enrolled asymptomatic women either with a family history, dense breasts, or over 35 yrs old	Use of a new ultrasound modality increased the number of small invasive cancers detected but also increased the percentage of women recalled for further imaging
Trop et al., 2010	**Level III:** An observational study to evaluate ultrasound screening; enrolled 184 women, and 387 screening rounds were performed	Sensitivity: 42% Specificity: 93.8%	For ultrasound: 5/12 cancers detected Overall recall rate: 44/387 (11.4) Biopsy rate: Overall 21/44 (47.7) Positive findings: 6/21 (28.6)		Somewhat generalizable, studies asymptomatic women either confirmed as *BRCA1/2*carriers, or having a greater than 30% probability of being so as estimated by BRCAPRO.[31] Women ranged in age from 21 to 75 years, with a mean age of 45 years	Small sample size limits ability to assess the effects of trimodal screening with mammography, BMRI, and breast ultrasound

Source: Berg et al., 2008; Kelly et al., 2010; Nothacker et al., 2009; Saunders et al., 2009; Trop et al., 2010; Warner et al., 2004.
[a]Incremental cancer detection rate was calculated as the rate of cancers detected by ultrasound-only among mammography-negative subjects undergoing systematic ultrasound for radiologically dense breasts.
Key: CBE=clinical breast exam; CI=95% confidence interval; MRI= magnetic resonance imaging.

[31] BRCAPRO is a software program for assessing the probability that an individual carries a germline deleterious mutation of the BRCA1 and BRCA2 genes.

Harms of Screening

Conventional mammography is an effective screening tool for women aged 50 years and older, particularly those women who have less-dense breast tissue. However, for specific high-risk subpopulations, mammography (digital and conventional with or without CAD) is limited in its ability to detect breast cancer in mammographically dense breast tissue that can obscure radiologic features of breast cancer. BMRI and ultrasound are more sensitive to cancers in mammographically dense breast tissue, but result in higher false-positive tests.

Harms associated with BMRI and breast ultrasound screening are primarily related to false-positive readings that result in a higher rate of benign biopsies. A meta-analysis of findings from three studies with sound reference standards conducted by Granader et al. (2008) estimated that the false-positive rate for BMRI screening was twice the false-positive rate of mammography screening (10% vs. 5%). A large observational study by Berg et al. (2008) found that the false-positive rate of breast ultrasound was twice as high as the false-positive rate of mammography (8.1% vs. 4.4%). Higher rates of false-positive results mean that more women will undergo further testing and biopsies that are ultimately deemed to be unnecessary. Women with false-positive results may also experience unnecessary anxiety about their health. Most of the studies summarized in Tables 2 to 3 recognized the harms of false-positive tests. Specifically, the authors calculated the increase in additional follow-up studies and unnecessary biopsies that can cause anxiety and discomfort, and can be costly.

Some women who obtain BMRI or breast ultrasound screening may be overdiagnosed and overtreated, especially those who are screened and subsequently diagnosed with ductal carcinoma in situ (DCIS). A substantial percentage of women with DCIS have cancers that will not progress to invasive breast cancer. However, physicians are unable to determine which women diagnosed with DCIS are at risk for invasive breast cancer if not treated. In the absence of such information, physicians tend to treat all women with DCIS and other forms of breast cancer aggressively.

In addition, it is unknown whether the benefits of BMRI and breast ultrasound screening outweigh the harms, because no studies were identified that analyzed the effects of BMRI or breast ultrasound screening on health outcomes.

Limitations

Randomized controlled trials (RCTs) are considered the “gold standard” for study methodologies, as they allow researchers more control over possible biases that may artificially affect the study outcome. The majority of the studies summarized here are observational studies that may be subject to lead-time bias (early diagnosis that falsely appears to prolong survival), length bias (screening that overrepresents less-aggressive disease), overdiagnosis bias (diagnosing disease that will not cause symptoms or death), and healthy volunteer bias (patient selection bias) (Moses, 2008). Evidence regarding the effects of BMRI and breast ultrasound screening is weaker than evidence regarding the effectiveness of mammography screening, which as been the evaluated in multiple RCTs (CHBRP, 2011).

Summary of Results

Current clinical consensus finds that conventional mammography is the gold standard for breast cancer screening because of the evidence regarding its effectiveness based on controlled trials in large numbers of women that document a decrease in breast cancer mortality. Due to limitations in the technology associated with mammography and the higher prevalence of breast cancer in the older age groups, this screening test appears to be most effective in women older than 50 years and those with less-dense breast tissue.

Current evidence suggests that mammography, ultrasound, and BMRI complement each other by detecting cancers undetected by their counterparts. However, such screening modalities lead to higher recall rates and increased benign biopsy rates. The medical effectiveness literature provides insufficient evidence at this time to determine whether the benefits of BMRI and breast ultrasound screening outweigh the harms for women at high risk for breast cancer, because no studies have assessed whether BMRI and breast ultrasound screening improves survival or other health outcomes.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

Senate Bill (SB) 173 would require coverage for "comprehensive breast screening" and mammography reports. SB 173 would require DMHC-regulated plans and CDI-regulated policies to cover "comprehensive breast cancer screening" for enrollees known to have heterogeneously dense or extremely dense breast tissue and for enrollees at increased risk for breast cancer. The bill would also require that mammography reports issued by DMHC-regulated plans or CDI-regulated policies to contain information about breast density and, when applicable, a recommendation to persons with dense breasts to pursue supplementary screening tests.

This section presents the current, or baseline, costs and benefit coverage related to "comprehensive breast screening" and mammography reports, and the estimated utilization, cost and benefit coverage impacts if SB 173 is enacted. For further details on the underlying data sources and methods, please see Appendix D at the end of this document.

Current (Baseline) Benefit Coverage, Utilization and Cost

Current Coverage of the Mandated Benefit

Approximately 21,902,000 persons in California are enrolled in health plans or policies that would be subject to the mandate. Current coverage for SB 173 mandated benefits as determined by a survey of the seven largest providers of health insurance in California is 100%. CHBRP surveys the largest major health plans and insurers about coverage. Responses to this survey represented 29.56% of the privately funded, CDI-regulated market and 69.69% of the privately funded, DMHC-regulated market. Combined, responses to this survey represent 61.34% of the privately funded market subject to state mandates.[32]

On the basis of this survey, CHBRP estimates that 100% of male and female enrollees in DMHC-regulated plans and CDI-regulated policies have benefit coverage compliant with SB 173. Publicly funded plans such as the California Public Employees' Retirement System (CalPERS HMOs), Medi-Cal Managed Care Plans, Healthy Families Program (HFP), Access for Infants and Mothers (AIM), and Managed Risk Medical Insurance Board (MRMIB) have "comprehensive breast cancer screening" compliant with SB 173. Since health plans and insurers do not issue mammography reports, only radiologists and imaging centers do, health plans and insurers would be in compliance with the mammography reports as considered by SB 173.

SB 173 would not alter the current mandate for breast cancer screening coverage for health plans. In addition, On the basis of input from the regulator, DMHC, input from legal counsel,

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

and the existing delivery system of reports related to breast cancer screening results, CHBRP assumes that SB 173 would be unlikely to alter the behavior of health plans. CHBRP thus estimates that about 100% of enrollees currently have coverage for breast screening and reports as mandated by SB 173.

Current Utilization Levels

CHBRP's Bill-Specific Coverage Survey found that 100% of enrollees DMHC-regulated plans and CDI-regulated policies have benefit coverage for breast screening as mandated by SB 173. The latest baseline utilization rates for comprehensive breast screening tests are: 5.2 million for mammography, 487 thousand for breast ultrasound, and 51 thousand for breast MRIs. It is important to point out that in contrast to mammography, baseline utilization estimates for breast ultrasound and breast MRIs cannot distinguish between screening and diagnostic utilization.

Per-Unit Cost

The latest average per-unit costs (including additional follow-up services due to verify screening results) for comprehensive breast screening tests are the following: $190 for mammograms, $186 for breast ultrasounds, and $1,750 for breast MRIs. SB 173 is not expected to affect the per-unit cost of breast screening because an estimated 100% of enrollees have breast-screening coverage in compliance with SB 173.

Current (Baseline) Premiums and Expenditures

Per member per month (PMPM) premiums and expenditures for privately funded DMHC-regulated plans prior to the mandate are $422.32 in large-group plans, $383.20 in small-group plans, and $484.46 in individual plans. Per member per month (PMPM) premiums and expenditures for publicly funded DMHC-regulated plans prior to the mandate are $456.84 in California Public Employees' Retirement System health maintenance organization (CalPERS HMO), $346.00 in Medi-Cal Managed Care Plans (65 and Over), $176.00 in Medi-Cal Managed Care Plans (Under 65), and $116.95 in Managed Risk Medical Insurance Board (MRMIB) Plans. Per member per month (PMPM) premiums and expenditures for CDI-regulated policies prior to the mandate are $560.67 in large-group plans, $457.56 in small-group plans, and $257.66 in individual plans.

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

Comprehensive breast cancer screening is covered for an estimated 100% of enrollees in DMHC-regulated plans and CDI-regulated policies, as would be required by SB 173. Therefore, CHBRP estimates no cost shifting as a result of SB 173.

Public Demand for Coverage

Considering the criteria specified by CHBRP's authorizing statute, CHBRP reviews public demand for benefits relevant to a proposed mandate in two ways. CHBRP considers the bargaining history of organized labor and compares the benefits provided by self-insured health plans or policies (which are not regulated by the DMHC or CDI and so not subject to state-level mandates) with the benefits that are provided by plans or policies that would be subject to the mandate.

Breast cancer screening is a covered benefit for the members of at least one large union.[33]

Among publicly funded self-insured health insurance policies, the preferred provider organization (PPO) plans offered by CalPERS currently have the largest number of enrollees. The CalPERS PPOs provide benefit coverage similar to what is available through group health insurance plans and policies that would be subject to the mandate.

To further investigate public demand, CHBRP used the Bill-Specific Coverage Survey. In the survey, CHBRP asked carriers who act as third-party administrators for (non-CalPERS) self-insured group health insurance programs whether the relevant benefit coverage differed from what is offered in group market plans or policies that would be subject to the mandate. The responses indicated that there were no substantive differences.

Impacts of Mandated Benefit Coverage

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

Impact on access and health treatment/service availability

CHBRP does not estimate changes in supply of breast cancer screening due to SB 173. No supply constraints are currently associated with breast cancer screening. SB 173 is not expected to change access to breast cancer screening and among enrollees to DMHC-regulated plans and CDI-regulated policies. Likewise, no changes in access and production of mammography reports is expected since health plans are not responsible for producing the mammography reports considered by SB 173. Therefore, no new impact on breast cancer screening rates is expected as a consequence of SB 173.

[33] Personal communication, S Flocks, California Labor Federation, March 2011.

Impact on the health benefit of the newly covered treatment/service
SB 173 would not be expected to change coverage of breast cancer screening since CHBRP estimates than 100% of enrollees in DMHC-regulated plans and CDI-regulated policies already have coverage for breast cancer screening.

Impact on per-unit cost
CHBRP estimates no measurable effects on per-unit cost of breast cancer screening since no changes in coverage are anticipated as a result of this mandate. No measurable effects on the per-unit cost of mammography reports is expected since health plans and policies are not responsible for producing the mammography reports considered by SB 173.

How Would Utilization Change as a Result of the Mandate?

As no measurable change in benefit coverage would be expected, no measurable change in utilization is projected.

To What Extent Would the Mandate Affect Administrative and Other Expenses?

SB 173 is not expected to alter the share of premiums paid by employees, employers, policyholders, or public agencies that enroll their beneficiaries in DMHC-regulated plans. In addition, this mandate would not be expected to increase administrative expenses for health plans and insurers for breast cancer screening coverage since health plans and insurers that would be subject to SB 173 already cover an estimated 100% of enrollees in a compliant fashion.

Impact of the Mandate on Total Health Care Costs

SB 173 would not be expected to increase total expenditures of employees with DMHC-regulated health plans or CDI-regulated health policies. Likewise, SB 173 would not be expected to increase total expenditures of employers in the small-group, large-group, or individual markets. State plans (i.e. CalPERS HMOs, Medi-Cal Managed Care Plans, Healthy Families Program [HFP], Access for Infants and Mothers [AIM], Major Risk Medical Insurance Program [MRMIP]) would be unaffected as well.

Potential cost offsets or savings in the short term
SB 173 would not be expected to change coverage of breast cancer screening by a measurable amount because 100% of enrollees in plans subject to the mandate are already covered. Health plans and insurers subject to the mandate are not responsible for producing the mammography reports considered by SB 173. Since no changes in the coverage of breast cancer screening or mammography reports are expected no cost offsets or savings are expected in the short term.

Impacts on long-term costs
SB 173 would not change PMPM premiums or total expenditures of employers and employees with DMHC-regulated health plans or CDI-regulated health policies, or of State plans. Since no changes in the coverage of breast cancer screening or mammography reports would be expected, no cost offsets no effects on long-term costs are expected.

Impacts for Each Category of Payor Resulting from the Benefit Mandate

SB 173 would not be expected to increase total expenditures and PMPM premiums in the large-group, small-group, or individual markets for DMHC-regulated plans or CDI-regulated policies. Total expenditures and PMPM premiums in CalPERS HMOs, Medi-Cal Managed Care, AIM, and MRMIB Plans are not expected to increase.

Impacts on the Uninsured and Public Programs As a Result of the Cost Impacts of the Mandate

Since SB 173 would not be expected to lead to premium increases, CHBRP estimates no measurable loss of health insurance coverage as a result of SB 173. CHBRP's method for estimating the impact of premium increases on the number of individuals who drop their private insurance is described on CHBRP's Web site.[34]

CHBRP estimates that the mandate would produce no measurable impact on public programs.

[34] CHBRP's method for estimating the effect of premium increases on the number of individuals who drop their private insurance is described on CHBRP's Web site http://www.chbrp.org/other_publications/index.php.

PUBLIC HEALTH IMPACTS

SB 173 would require coverage for comprehensive breast screening if either (1) a mammogram demonstrates heterogeneously dense or extremely dense breast tissue, or (2) a patient is believed to be at increased risk for breast cancer due to family history, genetic testing, or other factor determined by his/her provider. SB 173 would also require that every mammography report include information about breast composition, and, when applicable, a note advising patients with dense breast tissue that supplementary testing may be warranted.

As presented in the *Medical Effectiveness* section, the use of BMRI, ultrasound, or 3D mammography as an adjunct to mammography increases the ability to detect more breast cancer, but there is insufficient evidence to determine whether BRMI, as a primary screening tool for women with heterogeneously or extremely dense breasts or for women at increased risk for breast cancer, reduces breast cancer mortality or improves health outcomes. As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, SB 173 is not expected to impact utilization of comprehensive breast screening with BMRI, ultrasound, or 3D mammography. Therefore, no public health impact is expected.

Impact on Gender and Racial Disparities

Several competing definitions of "health disparities" exist. CHBRP relies on the following definition: *A health disparity/inequality is a particular type of difference in health or in the most important influences of health that could potentially be shaped by policies; it is a difference in which disadvantaged social groups (such as the poor, racial/ethnic minorities, women or other groups that have persistently experienced social disadvantage or discrimination) systematically experience worse health or great health risks than more advantaged groups* (Braveman, 2006).

CHBRP investigated the effect that SB 173 would have on health disparities by gender, race, and ethnicity. Evaluating the impact on racial and ethnic disparities is particularly important because racial and ethnic minorities report having poorer health status and worse health indicators (KFF, 2007). One important contributor to racial and ethnic health disparities is differential rates of insurance, where minorities are more likely than whites to be uninsured; however disparities still exist within the insured population (Kirby et al, 2006; Lille-Blanton and Hoffman, 2005). Since SB 173 would only affect the insured population, a literature review was conducted to determine whether there are gender, racial, or ethnic disparities associated with the prevalence and screening for breast cancer outside of disparities attributable to differences between insured and uninsured populations.

<u>Prevalence of Increased Risk Factors for Breast Cancer by Gender and Race/Ethnicity</u>

Breast cancer overwhelmingly affects women, although a small number of cases are diagnosed in men as well. In California, it is estimated that 0.7% of cases of breast cancer occur in men—

about 165 cases and 30 deaths each year (CCR, 2010). Because of the very low incidence of breast cancer among men, routine breast cancer screening is not recommended.

As presented in Table 1, the incidence, screening, state of diagnosis, and mortality rates of breast cancer in California varies by race/ethnicity, with non-Hispanic whites having the highest rates of breast cancer incidence and Asian/Pacific Islanders and Hispanics having the lowest rates. Screening rates using mammography also vary by race/ethnicity, with black and non-Hispanic white women reporting breast cancer screening using mammography in the last 2 years at significantly higher rates compared to Hispanic women. In addition, blacks and Hispanics have lower rates of early diagnosis compared to non-Hispanic whites or Asian/Pacific Islanders. Mortality rates from breast cancer vary by race/ethnicity, with blacks having the highest rates followed by non-Hispanic whites and Hispanics and Asian/Pacific Islanders having the lowest mortality rates.

Impact on Gender Disparities

As mentioned previously, gender disparities in breast cancer prevalence exist in California—with 99.3% of the cases of breast cancer occurring among women. Since SB 173 is not expected to impact utilization of comprehensive breast cancer screening—and there is currently no routine breast cancer screening among males—this mandate is not expected to impact gender disparities in breast cancer.

Impact on Racial/Ethnic Disparities

Racial/ethnic disparities in breast cancer prevalence and screening patterns exist in California. However utilization for comprehensive breast cancer screening is not expected to change as a result of SB 173. Therefore, SB 173 would not impact racial and ethnic disparities in breast cancer screening, early diagnosis, or mortality rates.

Impacts on Premature Death and Economic Loss

Premature death is often defined as death before the age of 75 (Cox, 2006). The overall impact of premature death due to a particular disease can be measured in years of potential life lost prior to age 75 and summed for the population (generally referred to as "YPLL") (Cox, 2006; Gardner and Sanborn, 1990). In California, it is estimated that there are nearly 102,000 premature deaths each year accounting for more than 2 million YPLL (Cox, 2006). In order to measure the impact of premature mortality across the population impacted by a proposed mandate, CHBRP first collects baseline mortality rates. Next, the medical effectiveness literature is examined to determine if the proposed mandated benefit impacts mortality. In cases where a reduction in mortality is projected, a literature review is conducted to determine if the YPLL has been established for the given condition. Some diseases and conditions do not result in death and therefore a mortality outcome is not relevant.

Economic loss associated with disease is generally presented in the literature as an estimation of the value of the YPLL in dollar amount (i.e., valuation of a population's lost years of work over a lifetime). For CHBRP analyses, a literature review is conducted to determine whether lost productivity has been established in the literature. In addition, morbidity associated with the disease or condition of interest can also result in lost productivity; either by causing the worker to miss days of work due to their illness or due to their role as a caregiver for someone else who is ill.

Premature Death

There are more than 4,200 deaths in California each year due to breast cancer (CCR, 2010). Literature suggests that among those who die prematurely due to breast cancer, an average of 22.9 years of life are lost (Max, 2009). This translates to nearly 100,000 life years lost prematurely each year in California due to breast cancer. Although breast cancer is a cause of premature death in California, SB 173 is not estimated to change the utilization of breast cancer screening or result in a reduction in premature deaths.

Economic Loss

The data available on lost productivity in California associated with breast cancer suggests that for each life lost prematurely to breast cancer, there is a cost of lost productivity of $355,000 converted to 2008 dollars (Max, 2009). This translates into over 1.5 billion dollars in lost productivity each year in California as a result of breast cancer. Although breast cancer is related to economic loss, SB 173 is not estimated to change the utilization of breast cancer screening or result in a corresponding reduction in economic loss.

APPENDICES

Appendix A: Text of Bill Analyzed

On February 4, 2011 the Senate Committee on Health requested that CHBRP analyze SB 173.

Below is the proposed bill language as received by CHBRP to analyze on February 4, 2011.

Bill No.
as introduced, Simitian.
General Subject: Health care coverage: mammograms.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975 (Knox-Keene Act), provides for the licensure and regulation of health care service plans by the Department of Managed Health Care, and makes a willful violation of its provisions a crime. Existing law provides for the licensure and regulation of health insurers by the Department of Insurance. Existing law requires health care service plan contracts, except specialized health care service plan contracts, and certain health insurance policies to provide a certain level of coverage for mammograms and breast cancer screening and diagnosis, as specified.

This bill would require those health care service plan contracts and health insurance policies to include additional benefits for comprehensive ~~ultrasound~~ screening under specified circumstances. The bill would require a patient receiving treatment under those coverage provisions to also receive information on breast density, as specified.

Because a willful violation of the bill's provisions under the Knox-Keene Act is a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

An act to amend Section 1367.65 of the Health and Safety Code, and to amend Section 10123.81 of the Insurance Code, relating to health care coverage.
The people of the State of California do enact as follows:

SECTION 1. Section 1367.65 of the Health and Safety Code

is amended to read:
1367.65. (a) *(1)* 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 and surgeon, providing care to the patient and operating within the scope of practice provided under existing law.

(2) In addition to the coverage required under paragraph (1), on or after January 1, 2012, every health care service plan contract that is issued, amended, delivered, or renewed shall also provide additional benefits for comprehensive ~~ultrasound~~ screening of an entire breast or breasts if a mammogram demonstrates heterogeneous or dense breast tissue based on the Breast Imaging Reporting and Data System established by the American College of Radiology or if a patient is believed to be at increased risk for breast cancer due to family history or prior history of breast cancer, positive genetic testing, or other indications as determined by his or her nurse practitioner, nurse midwife, or physician and surgeon.

(3) On and after January 1, 2012, every mammography report provided to a patient pursuant to the coverage specified under paragraph (1) or (2) shall include information about breast density, based on the Breast Imaging Reporting and Data System established by the American College of Radiology. When applicable, the report shall also include the following notice:

"If your mammogram demonstrates that you have dense breast tissue, which could hide small abnormalities, you might benefit from supplementary screening tests, which can include a breast ultrasound screening or a breast MRI examination, or both,

depending on your individual risk factors. A report of your mammography results, which contains information about your breast density, has been sent to your physician's office and you should contact your physician if you have any questions or concerns about this report."

(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 and surgeon, nurse practitioner, or certified nurse midwife providing care.

SEC. 2. Section 10123.81 of the Insurance Code is amended to read:

10123.81. *(a)* 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 and surgeon, providing care to the patient and operating within the scope of practice provided under existing law for breast cancer screening or diagnostic purposes:
~~(a)~~
(1) A baseline mammogram for women age 35 to 39, inclusive.
~~(b)~~
(2) A mammogram for women age 40 to 49, inclusive, every two years or more frequently based on the women's physician's recommendation.
~~(c)~~
(3) A mammogram every year for women age 50 and over.

(b) In addition to the coverage required under subdivision (a), on or after January 1, 2012, every health insurance policy that is issued, amended, delivered, or renewed shall also provide additional benefits for comprehensive ~~ultrasound~~ screening of an entire breast or breasts if a mammogram demonstrates heterogeneous or dense breast tissue based on the Breast Imaging Reporting and Data System established by the American College of Radiology or if a patient is believed to be at increased risk for breast cancer due to family history or prior history of breast cancer, positive genetic testing, or other indications as determined by his or her nurse practitioner, nurse midwife, or physician and surgeon.

(c) On and after January 1, 2012, every mammography report provided to a patient pursuant to the coverage specified under subdivision (a) or (b) shall include information about breast density, based on the Breast Imaging Reporting and Data System established by the American College of Radiology. When

applicable, the report shall also include the following notice:

"If your mammogram demonstrates that you have dense breast tissue, which could hide small abnormalities, you might benefit from supplementary screening tests, which can include a breast ultrasound screening or a breast MRI examination, or both, depending on your individual risk factors. A report of your mammography results, which contains information about your breast density, has been sent to your physician's office and you should contact your physician if you have any questions or concerns about this report."

~~Nothing~~
(d) 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~~
(e) 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, unless the insured or plan member is referred to that provider by a participating physician *and surgeon*, nurse practitioner, or certified nurse midwife providing care.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Appendix B: Literature Review Methods

Appendix B describes methods used in the medical effectiveness literature review conducted for SB 173. A discussion of CHBRP's system for grading evidence, as well as lists of MeSH Terms, Publication Types, and Keywords, follows.

The literature search for SB 173 updates literature searches performed in 2008 for AB 2234. Although there are important differences between these two bills, both address coverage for breast magnetic resonance imaging (BMRI) and breast ultrasound screening. The literature search was limited to studies published in English from January 2008 to present. The following databases of peer-reviewed literature were searched: MEDLINE (PubMed), the Cochrane Database of Systematic Reviews, the Cochrane Register of Controlled Clinical Trials, the Cumulative Index of Nursing and Allied Health Literature, Global Health, Web of Science, EconLit, and Business Source Complete. In addition, Web sites maintained by the following organizations that index or publish systematic reviews and evidence-based guidelines were searched: Agency for Healthcare Research and Quality, International Network of Agencies for Health Technology Assessment, the National Cancer Institute's Physician Data Query, National Health Service Centre for Reviews and Dissemination, National Institute for Health and Clinical Excellence, and the Scottish Intercollegiate Guideline Network.

CHBRP reviewed meta-analyses and systematic reviews as well as randomized controlled trials (RCTs) and nonrandomized studies with comparison groups that were published after the studies included in the meta-analyses and systematic reviews.

Two reviewers screened the title and abstract of each citation retrieved by the literature search to determine eligibility for inclusion. The reviewers acquired the full text of articles that were deemed eligible for inclusion in the review and reapplied the initial eligibility criteria. Abstracts for 320 articles were identified. Five systematic reviews and seven individual studies[35] were included in the medical effectiveness review.[36]

Evidence Grading System

In making a "call" for each outcome measure, the medical effectiveness lead and the content expert consider the number of studies as well the strength of the evidence. To grade the evidence for each outcome measured, the team uses a grading system that has the following categories:

- research design,
- statistical significance,
- direction of effect,

[35] Findings from one study were reported in two articles (Peters et al., 2008; Saunders et al., 2009).
[36] The systematic reviews included two individual studies that were cited in CHBRP's report on AB 2234 (Kriege et al., 2004; Hagen et al., 2007).

- size of effect, and
- generalizability of findings.

The grading system also contains an overall conclusion that encompasses findings in these five domains. The conclusion is a statement that captures the strength and consistency of the evidence of an intervention's effect on an outcome. The following terms are used to characterize the body of evidence regarding an outcome:

- clear and convincing evidence,
- preponderance of evidence,
- ambiguous/conflicting evidence, and
- insufficient evidence.

The conclusion states that there is "clear and convincing" evidence that an intervention has a favorable effect on an outcome if most of the studies included in a review have strong research designs and report statistically significant and clinically meaningful findings that favor the intervention.

The conclusion characterizes the evidence as "preponderance of evidence" that an intervention has a favorable effect if most, but not all five, criteria are met. For example, for some interventions, the only evidence available is from nonrandomized studies. If most such studies that assess an outcome have statistically and clinically significant findings that are in a favorable direction and enroll populations similar to those covered by a mandate, the evidence would be classified as a "preponderance of evidence favoring the intervention." In some cases, the preponderance of evidence may indicate that an intervention has no effect or an unfavorable effect.

The evidence is presented as "ambiguous/conflicting" if their findings vary widely with regard to the direction, statistical significance, and clinical significance/size of the effect.

The category "insufficient evidence" of an intervention's effect is used when there is little if any evidence of an intervention's effect.

Search Terms

The search terms used to locate studies relevant to SB 173 were as follows:

Medical Subject Headings (MeSH) Terms—PubMed
Breast Neoplasms/diagnosis
Breast Neoplasms/prevention and control
Mammography
Mass Screening
preventive health services
primary prevention

Insurance (exploded MeSH)

Keywords—PubMed, Business Source Complete, CINAHL, Cochrane, and PDQ
Mammogr*
Breast Cancer
Screen*

* Indicates that a term was truncated to maximize the number of publications retrieved.

Publication Types
Comparative Study
Randomized Controlled Trial
Evaluation Studies
Meta-Analysis
Practice Guideline
Systematic Review

Appendix C: Clinical Practice Guidelines and Studies Regarding Breast MRI and Breast Ultrasound Screening

Appendix C describes clinical practice guidelines for breast cancer screening with breast magnetic resonance imaging (BMRI) and breast ultrasound, and the characteristics of studies of the accuracy of these screening tests. Table C-1 summarizes the clinical practice guidelines. Table C-2a describes studies of breast MRI screening. Table C-2b describes studies of breast ultrasound. Findings from these studies are summarized in Tables 2 and 3 in the Medical Effectiveness section of the report.

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

Guideline Developer	Evidence or Expert Opinion Based	Issue Year	Mammography	Breast MRI	Breast Ultrasound
U.S. Preventive Services Task Force: Screening for Breast Cancer: Recommendations and Rationale (USPSTF, 2009)[a]	Evidence based	2009	Women 40-49 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 Women aged 50-74 years: every 2 years	**The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of magnetic resonance imaging (MRI)**	No recommendation
American College of Obstetrician and Gynecologists: Breast Cancer Screening (ACOG, 2003)	Evidence based	2003	Women 40-49 years: Every 1 to 2 years Women 50 years and older: Annually	No recommendation	No recommendation
American College of Physicians: Screening Mammography for Women 40-49 Years of Age: A Clinical Practice Guideline (Qaseem et al., 2007)	Evidence based	2007	Women ages 40-49 years: every 1 to 2 years (Guideline only focuses on women in this age group)	No recommendation	No recommendation

Table C-1. Summary of U.S. Clinical Guidelines for Mammography Screening (Cont'd)

Guideline Developer	Evidence or Expert Opinion Based	Issue Year	Mammography	Breast MRI	Breast Ultrasound
American Cancer Society: Guideline for Breast Cancer Screening as an Adjunct to Mammography; Review of Current ACS Guidelines and Issues in Cancer Screening (Saslow et al., 2007; Smith et al., 2011)	Evidence based and expert opinion	2003	Women 40 years and older: annually	**In addition to mammography** Annual MRI screening (based on evidence) for • *BRCA* mutation or first-degree relative of *BRCA* carrier, but untested • Lifetime risk for breast cancer of ~20%-25% or greater, as defined by models that are largely dependent on family history Annual MRI screening (based on expert opinion) for • Radiation to chest between age 10 and 30 years • Women with Li-Fraumeni, Cowen, or Bannayan-Riley-Ruvalcaba syndrome and first-degree relatives Insufficient Evidence to Recommend for or Against MRI Screening • Lifetime risk for breast cancer of 15%-20%, as defined by BRCAPRO or other models that are largely dependent on family history • Heterogeneously or extremely dense breast on mammography • Women with a personal history of breast cancer (including ductal carcinoma in situ), Lobular carcinoma in situ, or atypical lobular hyperplasia, Recommend Against MRI Screening (Based on Expert Consensus Opinion) • Women with >15% lifetime risk of breast cancer	No recommendation

Table C-1. Summary of U.S. Clinical Guidelines for Mammography Screening (Cont'd)

Guideline Developer	Evidence or Expert Opinion Based	Issue Year	Mammography	Breast MRI	Breast Ultrasound
American College of Radiology and the Society of Breast Imaging: Breast Cancer Screening with Imaging: Recommendations from the Society of Breast Imaging and the ACR (Lee et al., 2010)	Evidence based	2010	Women 40 years and older: annually	**In addition to mammography** Recommends MRI Annually starting by age 30 • Proven carriers of a deleterious *BRCA* mutation • Untested first-degree relatives of proven *BRCA* mutation carriers • Women with >20% lifetime risk for breast cancer on the basis of family history Annually starting 8 years after the radiation therapy • Women with histories of chest irradiation (usually as treatment for Hodgkin's disease) May be considered in women with between 15% and 20% lifetime risk for breast cancer on the basis of personal history of breast or ovarian cancer or biopsy-proven lobular neoplasia or atypical ductal hyperplasia	**In addition to mammography** Ultrasound can be considered in • high-risk women for whom magnetic resonance imaging (MRI) screening may be appropriate but who cannot have MRI for any reason • women with dense breast tissue

Sources: ACOG, 2003; Lee et al., 2010; Qaseem et al., 2007; Saslow et al., 2007; Smith et al., 2011; USPSTF, 2009.
Note: [a] The American Academy of Family Physicians and the American College of Preventive Medicine concurs with the USPSTF (AAFP, 2011; ACPM, 2009).

Table C-2a. Summary of Published Studies on Effectiveness of Breast MRI in Cancer Screening

Citation	Type of Study	Intervention vs. Control Group	Population Studied	Location
Lord et al., 2007 (a)	Systematic review Meta-analysis of 5 studies	BMRI with mammography (± ultrasound and CBE) vs. mammography alone	2,059 women at high risk of breast cancer (mean age range 40-47 yrs) participated in 4,534 BMRIs	Germany, United Kingdom, United States, Italy, Canada
Bermejo-Perez et al., 2008 (b)	Systematic review of 8 studies	BMRI vs. mammography (± ultrasound and CBE)	Women carrying mutations in *BRCA1/2* genes with a mean age of 46 yrs or less	Germany, United Kingdom, United States, other
Granader et al., 2008 (c)	Systematic review Meta-analysis of 8 studies	BMRI with mammography vs. mammography alone	Women at high risk of breast cancer based on genetic mutation or strong family history	Germany, United Kingdom, United States, Italy, Canada
Peters et al., 2008, and Saunders et al., 2009 (d)	Prospective diagnostic test evaluation	CBE every 6 months and trimodality imaging (mammogram, ultrasound, and MRI) performed once a year for 2 years	72 women aged 50 years or under at high risk of developing breast cancer due to family history including known genetic mutation and women at high risk due to previously diagnosed breast conditions; 139 screening MRI scans were performed	Western Australia
Yu et al., 2008	Prospective diagnostic test evaluation	BMRI (in addition to mammography) vs. mammography	MRI screening in 374 women (age range 21-88 yrs; mean age 49 yrs) resulting in a total of 976 MRIs during the study period.	United States
Lee et al., 2009 (e)	Systematic review Meta-analysis of 5 studies	Correlation between mammography and MRI for screening high risk women	2,626 women at high risk of breast cancer based on genetic mutation or strong family history participated in 25 screening rounds	United Kingdom, Canada, Germany, Italy, Austria, and Norway
Price and Chen, 2009	Prospective diagnostic test evaluation	BMRI with mammography	171 asymptomatic patients (age range 22-67 years, mean 46 years) participated in 209 breast MRI scans	Australia

Table C-2a. Summary of Published Studies on Effectiveness of Breast MRI in Cancer Screening (Cont'd)

Citation	Type of Study	Intervention vs. Control Group	Population Studied	Location
Trop et al., 2010	Prospective diagnostic test evaluation	Yearly Mammogram and MRI and biannual ultrasound and CBE	184 women at high risk of breast cancer (age range 21-75 yrs; median age 45) participated in 387 screening rounds	Canada

Sources: Bermejo-Perez et al., 2008; Granader et al., 2008; Lee et al., 2009; Lord et al., 2007; Peters et al., 2008; Price and Chen, 2009; Saunders et al., 2009; Trop et al., 2010; Yu et al., 2008.

(a) All studies included in the Lord et al. (2007) meta-analysis are included in the literature review the American Cancer Society conducted for its MRI Screening Guideline (Saslow et al., 2007).

(b) Three studies included in the Bermejo-Perez et al. (2008) systematic review are included in the literature review the American Cancer Society conducted for its for its MRI Screening Guideline (Saslow et al., 2007). Three studies in the Bermejo-Perez et al. (2008) study are also included in the Lord et al. (2007) meta-analysis.

(c) Three studies included in the Granader et al. (2008) systematic review are included in the literature review the American Cancer Society conducted for its for its MRI Screening Guideline (Saslow et al., 2007). Three studies included in Granader et al. (2008) are also included in the Bermejo-Perez et al. (2008) and four are also included in the Lord et al. (2007) meta-analysis.

(d) Peters et al., 2008, and Saunders et al., 2009, presented findings from the first and second years of the same study.

(e) Four studies included in the Lee et al. (2009) systematic review are included in the literature review the American Cancer Society conducted for its for its MRI Screening Guideline (Saslow et al., 2007). Four studies included in Lee et al. (2009) are also included in the Bermejo-Perez et al. (2008), three are also included in the Granader et al. (2008) and three are included in the Lord et al. (2007) meta-analysis.

Table C-2b. Summary of Published Studies on Effectiveness of Ultrasound for Breast Cancer Screening

Citation	Type of Study	Intervention vs. Control Group	Population Studied	Location
Warner et al., 2004	Prospective diagnostic test evaluation study	Four methods of breast cancer surveillance including mammography, ultrasound, MRI, and clinical breast exam	A surveillance study of 236 women aged 26-65 yrs (mean age 47 yrs) with *BRCA1* or *BRCA2* mutation with 1 to 3 annual screening(s) for breast cancer	Canada
Berg et al., 2008	Prospective diagnostic test evaluation study	Compare performance of screening with ultrasound and mammography compared to mammography alone in women at elevated risk of breast cancer	2,809 women, with at least heterogeneously dense breast tissue in at least 1 quadrant	USA
Peters et al., 2008, and Saunders et al., 2009 (a)	Prospective diagnostic test evaluation study	Four methods of breast cancer surveillance, including mammography, ultrasound, MRI, and clinical breast exam; participants were screened once per year for 2 years	Study enrolled 72 women at potentially high risk of breast cancer due to their family history, including known gene mutations and those at high risk due to previously diagnosed breast conditions (such as atypical ductal hyperplasia or ductal carcinoma in situ) All women were aged 50 years or under at study entry.	Australia
Nothacker et al., 2009	Systematic review of 6 cohort studies	Examined studies in which breast ultrasound was used as supplemental examination to negative mammography results in women with dense breasts	Asymptomatic women with negative breast exam and breast density ACR 2-4 who ranged in age from their 30s to their 80s.	Belgium, United States, Italy, Austria, Israel
Kelly et al., 2010	Randomized control trial	Compared the performance and diagnostic yield of mammography alone versus an automated whole breast ultrasound and mammography	4,419 women either with a family history, dense breasts, or over 35 yrs old.	United States
Trop et al., 2010	Prospective comparative trial.	Evaluated the performance of mammography, ultrasonography, and magnetic resonance imaging screening in high-risk women; participants underwent 1-3 yearly screening rounds	184 asymptomatic women either confirmed as *BRCA1/2* carriers, or having a greater than 30% probability of being so as estimated by BRCAPRO	Canada

Sources: Berg et al., 2008; Kelly et al., 2010; Nothacker et al., 2009; Saunders et al., 2009; Trop et al., 2010; Warner et al., 2004.
(a) Peters et al., 2008, and Saunders et al., 2009, presented findings from the first and second years of the same study.

Appendix D: Cost Impact Analysis: Data Sources, Caveats, and Assumptions

This appendix describes data sources, as well as general and mandate-specific caveats and assumptions used in conducting the cost impact analysis. For additional information on the cost model and underlying methodology, please refer to the CHBRP Web site at: www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

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

Data Sources

In preparing cost estimates, the cost team relies on a variety of data sources as described 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 payor (i.e., employment-based, individually purchased, or publicly financed). The biennial CHIS is the largest state health survey conducted in the United States, collecting information from approximately 50,000 households. More information on CHIS is available at: www.chis.ucla.edu.

2. The latest (2010) California Employer Health Benefits Survey is used to estimate:

    - size of firm,
    - percentage of firms that are purchased/underwritten (versus self-insured),
    - premiums for health care service plans regulated by the Department of Managed Health Care (DMHC) (primarily health maintenance organizations [HMOs] and Point of Service Plans [POS]),
    - premiums for health insurance policies regulated by the California Department of Insurance (CDI) (primarily preferred provider organizations [PPOs] and fee-for-service plans [FFS]), and
    - premiums for high deductible health plans (HDHPs) for the California population with employment-based health insurance.
    - This annual survey is currently released by the California Health Care Foundation/National Opinion Research Center (CHCF/NORC) and is similar to the national employer survey released annually by the Kaiser Family Foundation and the Health Research and Educational Trust. Information on the CHCF/NORC data is available at: 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 healthcare plans, generally those characterized as preferred provider plans, or PPOs. The HCGs currently include claims drawn from plans covering 4.6 million members. In addition to the Milliman HCGs, CHBRP's utilization and cost estimates draw on other data, including the following:

    - The MarketScan Database, which includes demographic information and claim detail data for approximately 13 million members of self-insured and insured group health plans.

    - An annual survey of HMO and PPO pricing and claim experience. The most recent survey (2010 Group Health Insurance Survey) contains data from seven major California health plans regarding their 2010 experience.

    - Ingenix MDR Charge Payment System, which includes information about professional fees paid for healthcare services, based upon approximately 800 million claims from commercial insurance companies, HMOs, and self-insured health plans.

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

4. An annual survey by CHBRP of the seven largest providers of health insurance in California (Aetna, Anthem Blue Cross of California, Blue Shield of California, CIGNA, Health Net, Kaiser Foundation Health Plan, and PacifiCare) to obtain estimates of baseline enrollment by purchaser (i.e., large and small group and individual), type of plan (i.e., DMHC- or CDI-regulated), cost-sharing arrangements with enrollees, and average premiums. Enrollment in plans or policies offered by these seven firms represents an estimated 93.7% of the persons with health insurance subject to state mandates. This figure represents an estimated 94.4% of enrollees in full service (nonspecialty) DMHC-regulated health plans and an estimated 90.1% of enrollees in full service (nonspecialty) CDI-regulated policies.[37]

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

Publicly funded insurance subject to state benefit mandates

5. Premiums and enrollment in DMHC-regulated health plans and CDI-regulated policies by self-insured status and firm size are obtained annually from CalPERS for active state and local government public employees and their dependents who receive their benefits through CalPERS. Enrollment information is provided for DMHC-regulated health care service plans covering non-Medicare beneficiaries—about 74% of CalPERS total enrollment. CalPERS self-funded plans—approximately 26% of enrollment—are not subject to state mandates. In addition, CHBRP obtains information on current scope of benefits from evidence of coverage (EOCs) documents publicly available at: www.calpers.ca.gov.
6. Enrollment in Medi-Cal Managed Care (beneficiaries enrolled in Two-Plan Model, Geographic Managed Care, and County-Operated Health System plans) is estimated based on CHIS and data maintained by the Department of Health Care Services (DHCS). DHCS supplies CHBRP with the statewide average premiums negotiated for the Two-Plan Model, as well as generic contracts that summarize the current scope of benefits. CHBRP assesses enrollment information online at: www.dhcs.ca.gov/dataandstats/statistics/Pages/RASS_General_Medi_Cal_Enrollment.aspx..
7. Enrollment data for other public programs—Healthy Families Program (HFP), Access for Infants and Mothers (AIM), and the Major Risk Medical Insurance Program (MRMIP)—are estimated based on CHIS and data maintained by the Managed Risk Medical Insurance Board (MRMIB). The basic minimum scope of benefits offered by participating health plans under these programs must comply with all requirements for DMHC-regulated health plans, and thus these plans are affected by state-level benefit mandates. CHBRP does not include enrollment in the Post-MRMIP Guaranteed-Issue Coverage Products as these persons are already included in the enrollment for individual market health insurance offered by DMHC-regulated plans or CDI-regulated insurers. Enrollment figures for AIM and MRMIP are included with enrollment for Medi-Cal in presentation of premium impacts. Enrollment information is obtained online at: www.mrmib.ca.gov/. Average statewide premium information is provided to CHBRP by MRMIB staff.

General Caveats and Assumptions

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

- Prevalence of mandated benefits before and after the mandate may be different from CHBRP assumptions.
- Utilization of mandated benefits (and, therefore, the services covered by the benefit) before and after the mandate may be different from CHBRP assumptions.
- Random fluctuations in the utilization and cost of health care services may occur.

Additional assumptions that underlie the cost estimates presented in this report are:

- Cost impacts are shown only for plans and policies subject to state benefit mandate laws.
- Cost impacts are only for the first year after enactment of the proposed mandate.
- Employers and employees will share proportionately (on a percentage basis) in premium rate increases resulting from the mandate. In other words, the distribution of premium paid by the subscriber (or employee) and the employer will be unaffected by the mandate.
- For state-sponsored programs for the uninsured, the state share will continue to be equal to the absolute dollar amount of funds dedicated to the program.
- When cost savings are estimated, they reflect savings realized for one year. Potential long-term cost savings or impacts are estimated if existing data and literature sources are available and provide adequate detail for estimating long-term impacts. For more information on CHBRP's criteria for estimating long-term impacts please see: www.chbrp.org/analysis_methodology/cost_impact_analysis.php.
- Several recent studies have examined the effect of private insurance premium increases on the number of uninsured (Chernew, et al., 2005; Glied and Jack, 2003; Hadley, 2006). Chernew et al. (2005) estimate that a 10% increase in private premiums results in a 0.74 to 0.92 percentage point decrease in the number of insured, while Hadley (2006) and Glied and Jack (2003) estimate that a 10% increase in private premiums produces a 0.88 and 0.84 percentage point decrease in the number of insured, respectively. The price elasticity of demand for insurance can be calculated from these studies in the following way. First, take the average percentage point decrease in the number of insured reported in these studies in response to a 1% increase in premiums (about −0.088), divided by the average percentage of insured persons (about 80%), multiplied by 100%, i.e., ({[−0.088/80] × 100} = −0.11). This elasticity converts the *percentage point* decrease in the number of insured into a *percentage* decrease in the number of insured persons for every 1% increase in premiums. Because each of these studies reported results for the large-group, small-group, and individual insurance markets combined, CHBRP employs the simplifying assumption that the elasticity is the same across different types of markets. For more information on CHBRP's criteria for estimating impacts on the uninsured please see: www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

There are other variables that may affect costs, but which CHBRP did not consider in the cost projections presented in this report. Such variables include, but are not limited to:

- Population shifts by type of health insurance: If a mandate increases health insurance costs, some employer groups and individuals may elect to drop their health insurance. Employers may also switch to self-funding to avoid having to comply with the mandate.
- Changes in benefit plans: To help offset the premium increase resulting from a mandate, subscribers/policyholders may elect to increase their overall plan deductibles or copayments. Such changes would have a direct impact on the distribution of costs between the health plan and policies and enrollees, and may also result in utilization reductions (i.e., high levels of patient cost sharing result in lower utilization of health care

services). CHBRP did not include the effects of such potential benefit changes in its analysis.

- Adverse selection: Theoretically, individuals or employer groups who had previously foregone health insurance may now elect to enroll in a health plan or policy, postmandate, because they perceive that it is to their economic benefit to do so.
- Medical management: Health plans and insurers may react to the mandate by tightening medical management of the mandated benefit. This would tend to dampen the CHBRP cost estimates. The dampening would be more pronounced on the plan types that previously had the least effective medical management (i.e., PPO plans).
- Geographic and delivery systems variation: Variation in existing utilization and costs, and in the impact of the mandate, by geographic area and delivery system models: Even within the health insurance types CHBRP modeled (HMO—including HMO and point of service [POS] plans—and non-HMO—including PPO and fee for service [FFS] policies), there are likely variations in utilization and costs by type. Utilization also differs within California due to differences in the health status of the local population, provider practice patterns, and the level of managed care available in each community. The average cost per service would also vary due to different underlying cost levels experienced by providers throughout California and the market dynamic in negotiations between providers and health plans or insurers. Both the baseline costs prior to the mandate and the estimated cost impact of the mandate could vary within the state due to geographic and delivery system differences. For purposes of this analysis, however, CHBRP has estimated the impact on a statewide level.
- Compliance with the mandate: For estimating the postmandate coverage levels, CHBRP typically assumes that plans and policies subject to the mandate will be in compliance with the coverage requirements of the bill. Therefore, the typical postmandate coverage rates for populations subject to the mandate are assumed to be 100%.

Potential Effects of the Federal Affordable Care Act

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

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

1. The number of covered lives in California, and specifically the makeup of the population with health insurance subject to state mandates;
2. Baseline premiums and expenditures for health insurance subject to state mandates; and

3. Benefits required to be covered in various health insurance plans subject to state mandates.

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

Coverage for adult children

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

Minimum medical loss ratio requirement

PPACA Section 2718 requires health plans offering health insurance in group and individual markets to report to the Secretary of Health and Human Services the amount of premium revenue spent on clinical services, activities to improve quality, and other non-claim costs. Beginning in 2011, large-group plans that spend less than 85% of premium revenue and small-group/individual market plans that spend less than 80% of premium revenue on clinical services and quality must provide rebates to enrollees. According to the Interim Final Rule, (45 CFR Part 158) "Issuers will provide rebates to enrollees when their spending for the benefit of policyholders on reimbursement for clinical services and quality improvement activities, in relation to the premiums charged, is less than the MLR standards established pursuant to the statute."[38] The requirement to report medical loss ratio is effective for the 2010 plan year, while

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

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

Pre-Existing Condition Insurance Plan

PPACA Section 1101 establishes a temporary high-risk pool for individuals with pre-existing medical conditions, effective 90 days following enactment until January 1, 2014. In 2010, California enacted AB 1887 and SB 227, providing for the establishment of the California Pre-existing Conditions Insurance Plan (PCIP) to be administered by the Managed Risk Medical Insurance Board (MRMIB) and federally funded per Section 1101. MRMIB has projected average enrollment of 23,100 until the end of 2013, when the program will expire. As of December 2010, there were approximately 1,100 subscribers.[39] The California PCIP is not subject to state benefit mandates,[40] and therefore, this change does not directly affect CHBRP's Cost and Coverage Model. CHBRP has revised its annual update of *Estimates of the Sources of Health Insurance in California.*[41] to reflect that a slight increase in the number of those who are insured under other public programs that are not subject to state-level mandates.

Prohibition of pre-existing condition exclusion for children

PPACA Sections 1201& 10103(e): Prohibits pre-existing condition exclusions for children. This provision was effective upon enactment). California's recently enacted law, AB 2244 (2010) implements this provision. AB 2244 also prohibits carriers that sell individual plans or policies from refusing to sell or renew policies to children with pre-existing conditions. Carriers that do not offer new plans for children are prohibited from offering for sale new individual plans in California for 5 years.[42] This provision could have had significant premium effects, especially for the DMHC- and CDI-regulated individual markets. The premium information is included in the responses to CHBRP's Annual Enrollment and Premium Survey. Thus the underlying data used in CHBRP annual model updates captured the effects of this provision.

Prohibition of lifetime limits and annual benefit limit changes

PPACA Section 2711 prohibits individual and group health plans from placing lifetime limits on the dollar value of coverage, effective September 23, 2010. Plans may only impose annual limits on coverage and these annual limits may be no less than $750,000 for "essential health benefits." The minimum annual limit will increase to $1.25 million on Sept. 23, 2011, and to $2 million

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

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

[41] See: http://www.chbrp.org/other_publications/index.php.

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

September 23, 2012. Earlier in 2010, CHBRP conducted an analysis of SB 890 which sought to prohibit lifetime and annual limits for "basic health care services" covered by CDI-regulated policies. CHBRP's indicated that DMHC-regulated plans were generally prohibited from having annual or lifetime limits. The analysis also indicated that less than 1% of CDI-regulated policies in the state had annual benefit limits and of those, the average annual benefit limit was approximately $70,000 for the group market and $100,000 for the individual market. Almost all CDI-regulated policies had lifetime limits in place, and the average lifetime limit was $5 million. After the effective date of the PPACA Section 2711, removal of these limits may have had an effect on premiums. As mentioned, premium information is included in the responses to CHBRP's Annual Enrollment and Premium Survey. Thus, the underlying data used in CHBRP's annual model updates captured the effects of this provision to remove lifetime limits and to increase annual limits for those limited number of policies that had annual limits that fell below $750,000.

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

Although the PPACA allows states the option to expand coverage to those not currently eligible for Medicaid (Medi-Cal in California), large-scale expansions are not expected to be seen during 2011. However, as a result of the 2010-2011 California Budget Agreement, there are expected to be shifts in coverage for seniors and persons with disabilities. Specifically, "Seniors and persons with disabilities who reside in certain counties which have managed care plans, and who are not also eligible to enroll in Medicare, will be required to enroll in a managed care plan under a phased-in process."[43] The Medi-Cal Managed Care enrollment in CHBRP's 2011 Cost and Coverage Model has been adjusted to reflect this change. Baseline premium rates have also been adjusted to reflect an increase in the number of seniors and persons with disabilities in Medi-Cal Managed Care. Information from DHCS indicates these changes will go into effect July 1, 2011, and would affect approximately 427,000 Medi-Cal beneficiaries.[44] CHBRP used data from DHCS to adjust enrollment in Medi-Cal Managed Care, and to adjust premiums to account for the change in acuity in the underlying populations.[45]

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

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

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

Appendix E: Information Submitted by Outside Parties

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

The following information was submitted by the Office of Assembly Member Jared Huffman submitted the following information in March 2010.

Boyd et al. Mammographic Density and the Risk and Detection of Breast Cancer. *The New England Journal of Medicine.* January 18, 2007: p. 228.

Lindström et al. Common Variants in *ZNF365* Are Associated With Both Mammographic Density and Breast Cancer Risk. *Nature Genetics*. Published online: 30 January 2011; doi:10.1038/ng.760

Rhodes et al. Dedicated Dual-Head Gamma Imaging for Breast Cancer Screening in Women with Mammographically Dense Breasts. *Journal of Radiology.* January 2011; 258: p. 106-118.

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

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A group of faculty and staff undertakes most of the analysis that informs reports by the California Health Benefits Review Program (CHBRP). The CHBRP **Faculty Task Force** comprises rotating representatives from six University of California (UC) campuses and three private universities in California. In addition to these representatives, there are other ongoing contributors to CHBRP from UC. This larger group provides advice to the CHBRP staff on the overall administration of the program and conducts much of the analysis. The **CHBRP staff** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and coordinates all external communications, including those with the California Legislature. The level of involvement of members of the CHBRP Faculty Task Force and staff varies on each report, with individual participants more closely involved in the preparation of some reports and less involved in others. As required by CHBRP's authorizing legislation, UC contracts with a certified actuary, Milliman Inc., to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit. Milliman also helped with the initial development of CHBRP methods for assessing that impact. The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance and thoughtful critiques provided by the members of the National Advisory Council. However, the Council does not necessarily approve or disapprove of or endorse this report. CHBRP assumes full responsibility for the report and the accuracy of its contents.

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