CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Analysis of Assembly Bill 2234: Health Care Coverage: Breast Conditions

A Report to the 2007–2008 California Legislature
April 3, 2008

CHBRP 08-01

The California Health Benefits Review Program (CHBRP) responds to requests from the State Legislature to provide independent analyses of the medical, financial, and public health impacts of proposed health insurance benefit mandates and proposed repeals of health insurance benefit mandates. In 2002, CHBRP was established to implement the provisions of Assembly Bill 1996 (California Health and Safety Code, Section 127660, et seq.) and was reauthorized by Senate Bill 1704 in 2006 (Chapter 684, Statutes of 2006). The statute defines a health insurance benefit mandate as a requirement that a health insurer or managed care health plan (1) permit covered 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.

A small analytic staff in the University of California's Office of the President supports a task force of faculty from several campuses of the University of California, as well as Loma Linda University, the University of Southern California, and Stanford University, to complete each analysis within a 60-day period, usually before the Legislature begins formal consideration of a mandate bill. A certified, independent actuary helps estimate the financial impacts, and a strict conflict-of-interest policy ensures that the analyses are undertaken without financial or other interests that could bias the results. A National Advisory Council, drawn from experts from outside the state of California and designed to provide balanced representation among groups with an interest in health insurance benefit mandates, reviews draft studies to ensure their quality before they are transmitted to the Legislature. Each report summarizes scientific evidence relevant to the proposed mandate, or proposed mandate repeal, but does not make recommendations, deferring policy decision making to the Legislature. The State funds this work through a small annual assessment on health plans and insurers in California. All CHBRP reports and information about current requests from the California Legislature are available at the CHBRP Web site, www.chbrp.org.

A Report to the 2007–2008 California State Legislature

Analysis of Assembly Bill 2234
Health Care Coverage: Breast Conditions

April 3, 2008

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Suggested Citation:

California Health Benefits Review Program (CHBRP). (2008) *Analysis of Assembly Bill 2234: Health Care Coverage: Breast Conditions.* Report to California State Legislature. Oakland, CA: CHBRP. 08-01.

PREFACE

This report provides an analysis of the medical, financial, and public health impacts of AB 2234, a bill to mandate coverage of tests necessary for the screening and diagnosis of breast conditions, in accordance with national guidelines. The bill also mandates that every covered women be notified by the health care service plan or insurer in writing, during the year when national guidelines indicate she should start undergoing tests for screening or diagnosis of breast conditions, that she is eligible for testing covered by her health care service plan or health insurance. In response to a request from the California Assembly Committee on Health on February 1, 2008, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the provisions of Senate Bill 1704 (Chapter 684, Statutes of 2006) as chaptered in Section 127600, et seq. of the California Health and Safety Code.

Joy Melnikow, MD, MPH, Dominique Ritley, MPH, Stephen A. McCurdy, MD, MPH, Banafsheh Sadeghi, MD, all of University of California, Davis, prepared the literature analysis and review of medical effectiveness of the benefit mandate. Penny Copernoll-Blach of the University of California, San Diego, conducted the literature search. Rebecca Smith-Bindman, MD, of the University of California, San Francisco, as well as Diana L. Miglioretti, PhD, and Deborah J. Seger, both of Group Health Center for Health Studies, provided technical assistance with the literature review and expert input on the analytic approach. Helen Halpin, ScM, PhD, and Sara McMenamin, MPH, PhD, prepared the public health impact analysis. Gerald Kominski, PhD, and Nadereh Pourat, PhD, of the University of California, Los Angeles, prepared the cost impact analysis. Jay Ripps, FSA, MAAA, of Milliman, provided actuarial analysis. John Lewis, MPA, of CHBRP staff prepared the background section and synthesized the individual sections into a single report. Cherie Wilkerson, BA, provided editing services. A subcommittee of CHBRP's National Advisory Council (see final pages of this report) and a member of the CHBRP Faculty, 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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The California Assembly Committee on Health requested on February 1, 2008, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 2234. In response to this request, CHBRP undertook this analysis pursuant to the provisions of Senate Bill 1704 (Chapter 684, Statutes of 2006) as codified in Section 127600, et seq. of the California Health and Safety Code.

AB 2234 requires health care service plans and insurance policies to cover tests necessary for the screening and diagnosis of breast conditions, in accordance with national guidelines. It specifies coverage of tests consistent with national guidelines, including but not limited to mammography, magnetic resonance imaging (MRI), ultrasound, and computer-aided detection. The bill also mandates that every covered woman be notified in writing by her health care service plan or health insurance that she is eligible for testing during the year in which national guidelines indicate she start undergoing tests for screening or diagnosis of breast conditions.

Several terms and phrases in the bill are ambiguous, often due to differences in legal and medical terminology. The full text of AB 2234 can be found in Appendix A of this report. The scope and intent of a bill must be defined to conduct an analysis of the bill. This report assumes the following medical/clinical interpretations. CHBRP's interpretations are based on conversations[1] with the staff for the Assemblymember, discussions with regulatory agencies, including the DMHC, and reasonable legal and layperson interpretation of the bill language.

Breast Conditions—the report focuses on breast cancer, the only "breast condition" for which screening is recommended.

Screening and Diagnosis—the report focuses on "screening," which denotes testing of asymptomatic individuals in order to identify new cases. Coverage for diagnostic tests (which may be confirmatory or used to determine the most appropriate course of treatment) is broad and there are no significant disagreements in this area between sets of national guidelines.

National Guidelines—the bill does not specify but this report focuses on two prominent sets of breast cancer screening guidelines: those promulgated by the Unites States Preventive Services Task Force (USPSTF, 2002) and those of the American Cancer Society (ACS, 2007). Other organizations' guidelines are also summarized in the Medical Effectiveness Section of this report.

[1] Personal communication, Philip Horner, Office of Assemblymember Portantino, February 2008

Written Notification—the bill does not specify but this report makes the simplifying assumption that a single notification in the form of letter sent to each covered woman when she reaches age 40 years is the minimum needed.

Screening Tests—the bill mandates coverage of computer-aided detection (CAD), digital mammography, ultrasound, and breast magnetic resonance imaging (BMRI). Ultrasound is only summarized in an appendix because no current national guidelines recommend its singular use for screening. CAD and digital mammography are understood to be included in mammography guidelines. BMRI, as an adjuvant technology to mammography for high-risk women, is explicitly recommended by the ACS national guidelines. As the BMRI recommendation is a somewhat controversial and costly addition to standard mammography screening, the Utilization, Cost and Coverage and the Public Health sections focus their analyses on this newly recommended adjuvant technology.

Existing California law mandates coverage for cancer screening and, even more specifically, breast cancer screening. Health care service plans regulated by the Department of Managed Health Care (DMHC) and insurance policies regulated by the California Department of Insurance (CDI), are mandated to cover breast cancer screening with mammography specified as a screening test.[2] Current requirements do not explicitly list the other tests or link coverage of tests to national guidelines. Current requirements do not mandate written notifications related to breast cancer screening or related guidelines.

In California, a woman has a one in nine chance of being diagnosed with breast cancer in her lifetime. Thus, the average lifetime risk of being diagnosed with breast cancer in California is 11%. It is estimated that 3.5% of women ages 30–64 years are at "high risk" for breast cancer based on having one or more of the following factors: *BRCA1* or *BRCA2* gene mutation and first degree relatives, Li-Fraumeni syndrome and first degree relatives, Cowden and Bannayan-Riley-Ruvalcaba syndromes and first degree relatives, chest irradiation between age 10 and 30 years (e.g., Hodgkins disease treatment), or a lifetime risk of being diagnosed with breast cancer of >20% as defined by risk assessment tools. The average annual incidence of breast cancer among women in California is 126.7 per 100,000 women, resulting in approximately 21,000 new cases and 4,200 deaths each year.

Medical Effectiveness

Effectiveness of Breast Cancer Screening Modalities

The literature regarding the efficacy of adjunct breast cancer screening modalities (mammography with computer-aided detection [CAD], digital mammography, ultrasound, and breast magnetic resonance imaging [BMRI]) encompasses primarily

[2] California Health and Safety Code, Section 1345 and Section 1300.67 of the California Code of Regulations, Title 28

observational studies, including those analyzed in systematic reviews and meta-analyses. (The exception is two randomized controlled trials [RCTs] regarding digital mammography that did not measure breast cancer mortality or health outcomes.)

Two points were under consideration in the medical effectiveness analysis: (a) did the modality detect more cancers; and (b) did the modality result in fewer cancer deaths or better health outcomes? Although observational studies suggest higher test sensitivity for women at increased risk of breast cancer, the increased cancer detection produces additional false-positive biopsies. No studies to date have evaluated whether the adjunct modalities decrease the breast cancer mortality rate or otherwise affect breast cancer outcomes.

- Ultrasound: Although ultrasound is not recommended by national guidelines as a breast cancer screening technology, bill language prompted CHBRP to review its medical effectiveness as a screening tool. (a) There is insufficient evidence that ultrasound improves the sensitivity of breast cancer screening when it is used in women with dense breast tissue or those considered at high risk for breast cancer (e.g., women ages 40–49 years). (b) There is insufficient evidence that this modality decreases breast cancer mortality or improves health outcomes.

- CAD: There is a preponderance of evidence that CAD has little to no effect in increasing the accuracy of mammography screening.

- Digital mammography: (a) There is a preponderance of evidence that digital mammography improves the rate of cancer detection in *women with radiologically dense breasts, among pre- and perimenopausal women and women younger than age 50 years*. (b) There is insufficient evidence that this modality decreases breast cancer mortality or improves health outcomes.

- BMRI: (a) Most studies found that the high sensitivity of BMRI may be useful to identify breast cancers in a *targeted population of high-risk women*. (b) There is insufficient evidence that BMRI screening decreases breast cancer mortality or improves health outcomes.

- Harms associated with screening are primarily related to false-positive readings that result in a higher rate of benign biopsies. Among the five BMRI studies, the false-positive rates for BMRI ranged between 4% and 23%. No studies calculated pooled estimates due to the heterogeneity of the study populations.

- The medical effectiveness literature provides insufficient evidence to support the use of mammographic adjunct modalities for women at high risk for breast cancer.

- Of the six organizations with breast cancer screening guidelines, only the American Cancer Society (ACS) specifically recommends adjunct BMRI for women at high risk of breast cancer. All organizations, including the United

States Preventive Services Task Force (USPSTF), recommend mammograms every 12–24 months for women over age 50 years, and five organizations recommend starting screening at age 40.

Effectiveness of Breast Cancer Screening Invitations

- Notification: There is a preponderance of evidence that notifying women about routine mammography screening improves the overall mammography screening rate.

Utilization, Cost, and Coverage Impacts

Coverage

- About 6,775,000 women aged 30–64 years are enrolled in plans or policies that would be affected by AB 2234.
- Based on CHBRP's survey of seven major California health plans and insurers, all of these women are estimated to have coverage for mammography screening and other screening modalities specified in AB 2243, including BMRI, digital mammography, ultrasound, and CAD. However, of the 6,775,000 insured women ages 30–64 years, 24% (1,608,000) have coverage for BMRI as a routine screening test.

Utilization

- Of the 6,775,000 women aged 30–64 years, 3.5% are estimated to be at high-risk for breast cancer. The 2007 ACS guidelines recommend BMRI as the routine annual screening test in conjunction with a mammogram for these women. Approximately 78% of these women currently receive mammogram tests and are expected to also receive BMRI if AB 2234 were to be enacted.
- An estimated 18% of women are at above-average risk of breast cancer. The ACS guidelines recommend that BMRI screening among these women should be based on the mutual decision with their physician. The estimates in this report do not include women is this risk category. However, increases in routine BMRI screening among these women are possible.
- CHBRP estimates that currently about 39,000 BMRIs are performed as a screening test for a targeted population of high-risk women or as a follow-up diagnostic test in California.
- If AB 2234 were to be enacted, the number of BMRIs is estimated to increase by 131,000, a 336% increase based on the assumptions or prevalence and premandate screening rates described above. Direct to consumer advertising and

advocacy efforts may substantially increase BMRI utilization level among women at above-average risk and high-risk women.

- About 168,000 women age 40 years will receive notification for mammography due to the mandate. Of these women, 19,000 are estimated to receive mammography after the mandate due to notification, excluding women who already receive mammograms and notifications prior to the mandate.

Costs

- The unit cost of BMRI is estimated at $1,282, including the costs of office visits, follow-up biopsies (procedure and lab costs), and follow-up BMRIs due to false-positive results.
- The overall increase in total expenditures due to the mandate is estimated at $252,174,000, or an increase of 0.32% in total expenditures in the year following the enactment of the mandate. Total expenditures may be substantialy higher in response to advocacy and direct to consumer advertising for BMRI.
- The estimated increase in expenditures includes $36,635,000 in administrative costs, of which $84,000 is the annual cost of sending a single notification letter to covered women when they reach age 40 years and become eligible for covered screening tests.
- The increase in expenditures includes an increase of $243,469,000 in insured premiums and is largest in the DMHC-regulated private markets.
- Employee share of group insurance premiums is estimated to increase by $40,029,000 (or 0.31%). Premiums paid by consumers for individually purchased insurance are estimated to increase by $24,672,000 (or 0.40%). Individual out-of-pocket costs in the form of copayments and deductibles are expected to increase by $13,456,000 (0.24%).
- Total premiums will increase by $0.74 - $1.07 per member per month (PMPM), depending on insurance type and market segment (for example, the DMHC-regulated small group market is expected to face $1.07 PMPM increase and the CDI-regulated individual market is expected to face $0.97 PMPM increase.

Long-term impacts on costs

- Cost-effectiveness studies of BMRI for high-risk women are rare. CHBRP does not estimate long-term costs or savings due to AB 2234.
- Cost-effectiveness studies of mammograms for women ages 40 and older indicate an incremental cost-effectiveness ratio of $58,000 for screening in every two years and $47,000 for annual screening per quality-adjusted life-year (QALY) saved. These rates were based on the assumption of 100% mammogram rates and would be considerably lower given the current mammogram rates.

Public Health Impacts

- AB 2234 is expected to increase utilization of BMRI screening of women at high risk for breast cancer, in conjunction with their regular mammogram, resulting in 131,000 additional BRMI screenings each year. There is insufficient evidence to determine whether BRMI screening used as an adjunct to mammography for high-risk women leads to improved health outcomes. Therefore, there is insufficient evidence to draw a conclusion as to the potential public health benefit of the mandate.

- The use of BMRI as an adjunct to mammography increases the rates of false-positive breast cancer diagnoses. Of the 131,000 additional BMRI screenings, it is estimated that nearly 17,700 would result in false-positive test results. Evidence does exist as to the potential harms associated with the increases in false positives, such as: increases in benign biopsies, additional interventions, radiation exposure, anxiety, and discomfort of patients.

- AB 2234 is expected to increase the number of women who receive mammograms each year by 19,000. The United States Preventive Services Task Force (USPTF) concluded that 1,224 women need to be screened to prevent one death from breast cancer. Therefore, it is estimated that screening an additional 19,000 women with mammography would, over time, prevent approximately 16 deaths per year from breast cancer (this benefit is expected to be realized 14 years following implementation of AB 2234).

- A total of 99.4% of cases of breast cancer occur in women, with approximately 130 cases diagnosed among men in California each year. In addition, non-Hispanic white women have the highest rates of breast cancer, followed by blacks and Asian/Pacific Islanders. Hispanics have the lowest rates. Despite reporting receiving mammography screening at average rates, black women have the lowest rates of early breast cancer diagnosis and higher mortality rates compared to other racial and ethnic groups. There is insufficient evidence to determine whether AB 2234 would impact the racial/ethnic disparities in screening rates and associated breast cancer health outcomes.

- There are an estimated 4,200 deaths each year in California due to breast cancer. An estimated reduction in 16 premature deaths each year would translate into a savings of 366 life years and 4.4 million dollars in lost productivity.

Table 1. Summary of Coverage, Utilization, and Cost Impacts of AB 2234

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Coverage				
Number of woman aged 30–64 years enrolled in plans or polices affected by AB 2234	6,775,000	6,775,000	—	0.00%
Percentage with coverage				
Coverage for mammogram and ultrasound tests[a]	100%	100%	0%	0.00%
Coverage for MRI tests	24%	100%	76%	321.28%
Number with coverage				
Coverage for mammogram and ultrasound tests	6,775,000	6,775,000	—	0.00%
Coverage for BMRI tests	1,608,000	6,775,000	5,167,000	321.33%
Utilization and cost				
Number of mammogram & ultrasound tests	5,918,000	5,937,000	19,000	0.32%
Number of BMRI tests	39,000	170,000	131,000	335.90%
Average cost of benefit				
Mammogram & ultrasound tests	$87.00	$87.00	$0.00	0.00%
BMRI tests (including additional services due to false-positive results)	$1,282.00	$1,282.00	$0.00	0.00%
Expenditures				
Premium expenditures by private employers for group insurance	$47,088,966,000	$47,238,980,000	$150,014,000	0.32%
Premium expenditures for individually purchased insurance	$6,158,288,000	$6,182,960,000	$24,672,000	0.40%
Premium expenditures by individuals with group insurance, CalPERS, Healthy Families, AIM, or MRMIP	$12,819,308,000	$12,859,337,000	$40,029,000	0.31%
CalPERS employer expenditures[b]	$2,942,984,000	$2,949,339,000	$6,355,000	0.22%
Medi-Cal state expenditures[c]	$4,044,192,000	$4,066,593,000	$22,401,000	0.55%
Healthy Families state expenditures	$644,074,000	$644,074,000	$0	0.00%
Individual out-of-pocket expenditures (deductibles, copayments, etc.)	$5,602,060,000	$5,615,516,000	$13,456,000	0.24%
Out-of-pocket expenditures for noncovered services	$4,753,000	$0	–$4,753,000	–100.00%
Total annual expenditures[d]	$79,304,625,000	$79,556,799,000	$252,174,000	0.32%

Source: California Health Benefits Review Program, 2008.
Notes: The population includes employees and dependents covered by employer-sponsored insurance (including CalPERS), individually purchased insurance, and public health insurance provided by a health plan subject to the requirements of the Knox-Keene Health Care Service Plan Act of 1975. Health maintenance organizations in California are licensed under the Knox-Keene Health Care Services Plan Act, which is part of the California Health and Safety Code. Premium expenditures by individuals include employee contributions to employer-sponsored health insurance and member contributions to public health insurance.

[a]Of the CalPERS employer expenditure, about 60% of the increase, or $3,813,000, would be State expenditures for CalPERS members who are State employees
[b]Medi-Cal state expenditures for members under 65 years of age include expenditures for the Major Risk Medical Insurance Program (MRMIP) and Access for Infants and Mothers (AIM) program.
[c]This includes administrative expenses of $11,323,927,000 before the mandate and $11,361,562,000 after the mandate, an increase of $37,635,000, of which approximately $84,000 is the estimated cost of health plan notification to women who became eligible for covered screening tests.
Key: CalPERS=California Public Employees' Retirement System; MRI=magnetic resonance imaging.

INTRODUCTION

Assembly Bill (AB) 2234 requires health care service plans and health insurance policies to cover tests necessary for the screening and diagnosis of breast conditions, in accordance with national guidelines. It also requires that every covered women be notified by the health care service plan or insurer in writing, during the year when national guidelines indicate she should start undergoing tests for screening or diagnosis of breast conditions, that she is eligible for testing covered by her health care service plan or health insurance.

The California Health Benefits Review Program (CHBRP) undertook this analysis in response to a request from the California Assembly Committee on Health on February 1, 2008. AB 2234 was introduced by Assembly Member Portantino on February 20, 2008.

As a benefit mandate bill, AB 2234 affects insurance coverage that can be influenced by California law. Specifically, AB 2234 would affect the markets regulated by the Department of Managed Health Care (DMHC) and the California Department of Insurance (CDI), including large groups, small groups and individual market policies. The bill does not exempt the California Public Employees' Retirement System (CalPERS) or Medi-Cal Managed Care, Healthy Families or other publicly funded insurances. Therefore, AB 2234 would affect members enrolled in these programs through its impact on the DMHC-regulated plans. Changes in CDI-regulated policies would not affect public programs because those programs contract only DMHC-regulated plans. (Please see Appendix D for a detailed description the underlying assumptions related to the Utilization, Coverage and Cost section of this analysis.) AB 2234 would not directly affect populations that are enrolled in health insurance products not subject to California benefit mandates, such as those enrolled in Medicare Advantage or in self-insured plans (both of which are exempted by federal laws) or those who are uninsured.[3] Nor would the bill directly affect "Every Woman Counts," a program operated by the California Department of Public Health that provides screening and treatment for breast cancer to the uninsured.

Bill Language and Key Assumptions

The full text of AB 2234 can be found in Appendix A of this report.

Several terms and phrases in the bill are ambiguous, often due to the differences in legal and medical terminology. The scope and intent of a bill must be defined to conduct an analysis of the bill. This report assumes the following medical/clinical interpretations.

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

CHBRP's interpretations are based on conversations[4] with the staff for the Assemblymember, discussions with regulatory agencies, including the DMHC, and reasonable legal and layperson interpretation of the bill language.

Breast Conditions— the focus of this report is on breast cancer, the only "breast condition" for which screening is recommended.

Screening and Diagnosis—the focus of this report is on "screening," which denotes testing of asymptomatic individuals in order to identify new cases. Diagnostic tests, which can be confirmatory or be used to determine the most appropriate course of treatment are already broadly covered and are not a source of disagreement between sets of national guidelines.

National Guidelines—the bill does not identify which set or what kind of guidelines must be referenced by regulators, plans or policies. Guidelines may be evidence-based or consensus driven (which may entail a less rigorous review process). Guidelines may be issued by federal bodies, advocates, professional organizations, or manufacturers. Furthermore, even when two organizations view the same evidence, their recommendations may differ. This report focuses on two of the most respected sets of breast cancer screening guidelines: those promulgated by the United States Preventive Services Task Force (USPSTF, 2002) and those of the American Cancer Society (ACS, 2007). Several other organizations' guidelines are also summarized in the Medical Effectiveness Section of this report.

Written Notification—the bill requires written notification, but does not specify the exact means of achieving compliance. Written notification could take many forms, from a relatively inexpensive notice in an annual newsletter to a more costly strategy using personalized letters or reminder cards. For the purpose of assessing the cost and public health impacts, CHBRP makes the simplifying assumption that a single notification in the form of letter sent to each covered woman when she reaches age 40 years is considered the minimum action needed to achieve compliance. Although less aggressive notification strategies might be effective, this form of notification identified in this report is probably a minimum needed to achieve an impact.

Screening Tests—the bill mandates coverage of computer-aided detection (CAD), digital mammography, ultrasound, and BMRI for screening and diagnosis of breast cancer. CHBRP included these four technologies in the Medical Effectiveness section, but the medical effectiveness of ultrasound is only summarized in an appendix because no current national guidelines recommend its singular use for screening. CAD and digital mammography, while not explicitly recommended in any national guideline, are closely related to mammography and are understood to be included in those guidelines. BMRI, as an adjuvant technology to mammography for high-risk women, is explicitly recommended by the ACS national guidelines. As the BMRI recommendation is a somewhat controversial and costly addition to standard mammography screening, the

[4] Personal communication, Philip Horner, Office of Assemblymember Portantino, February 2008

Utilization, Cost and Coverage and the Public Health sections focus their analyses on this newly recommended adjuvant technology.

Existing California Requirements

Existing legislation addresses breast cancer screening for both health care service plans regulated by the DMHC and insurance policies regulated by the CDI.

DMHC-regulated plans are 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 services for the detection of asymptomatic diseases), which shall include, under a physician's supervision…(1) reasonable health appraisal examinations on a periodic basis."[5] Laws related to CDI-regulated policies do not have a similar set of broad "basic health care services" requirements.

Existing requirements mandate that both DMHC-regulated plans and CDI-regulated policies cover breast cancer screening. Health & Safety Code Section 1367.665 requires "Every individual or group health care service plan contract, except for a specialized health care service plan contract, that is issued, amended, delivered, or renewed on or after July 1, 2000, shall be deemed to provide coverage for all generally medically accepted cancer screening tests, subject to all terms and conditions that would otherwise apply." Insurance Code Section 10123.20 requires "Every individual or group disability insurance policy that covers hospital, medical, or surgical expenses that is issued, amended, delivered, or renewed on or after July 1, 2000, shall be deemed to provide coverage for all generally medically accepted cancer screening tests, subject to all other terms and conditions that would otherwise apply."

For both DMHC-regulated plans and CDI-regulated policies, breast magnetic resonance imaging (BMRI), ultrasound, and national guidelines are mentioned only in the intent sections of the laws related to breast cancer screening. For both, mammography is specified in the code. For CDI-regulated policies, the law makes further specifications, requiring the policies to provide mammography on an age-dependent schedule. For women aged 35–39 years, coverage of a baseline mammography is required. For women aged 40–49, coverage for a mammography every 1–2 years (or more frequently, if recommended by a physician) is required. For women aged 50 or more, coverage for an annual mammography is required. Breast cancer screening laws related to DMHC-regulated plans do not detail similar mammography specifications.

The vast majority of states mandate coverage for breast cancer screening, and two states, Rhode Island and Kansas, specify compliance with ACS recommendations (ACS, 2006).

[5] 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 10123.8

State mandates generally specify age ranges and frequency minimums for mammography (BCBSA, 2007). Compliance with ACS recommendations would include coverage for BMRI for women the ACS describes as at high risk for breast cancer.

Background of Disease

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, 2008b). 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, 2008d).

Invasive ductal carcinoma (IDC) or invasive lobular carcinoma (ILC) has progressed beyond the walls of origin and spread into the fatty tissue of the breast, and perhaps the lymphatic or blood vessels. These cancers may spread to other parts of the body. Approximately 80% of breast cancer is classified as IDC, and 10%–15% are classified as ILC (NCI, 2008d)

Incidence and Prevalence

Although breast cancer can occur in men, women are the population predominantly affected and women are the population for whom screening is recommended. According to the American Cancer Society (ACS), breast cancer is the most common cancer among women in the United States (other than skin cancer) and is the second leading cause of cancer death in women, after lung cancer.

Breast cancer is one of the most commonly diagnosed cancers in California, with over 21,000 new cases diagnosed annually (CCR, 2007). The average annual incidence rate of female breast cancer in California is 126.7 cases per 100,000 women (Kwong et al., 2005). An average woman's lifetime risk of being diagnosed with breast cancer in California is one in nine (i.e., 11.1%) (CCR, 2007).

Among California women, the 5-year relative survival rate for breast cancer is 88% (CCR, 2007). This rate varies with the stage at diagnosis with a 97% 5-year relative survival rate for localized breast cancer (most often DCIS), 79% for regional breast cancer (IDC/ILC), and 20% for distant breast cancer (IDC/ILC) (CCR, 2007). In

California, 69% of breast cancer is diagnosed in the early stages (CCR, 2007). The annual death rate from breast cancer in California is 23.2 deaths per 100,000 women (Kwong et al., 2005). This translates into more than 4,200 deaths in California in 2008 (CCR, 2007).

A sustained decrease in breast cancer mortality in the United States and California during the last 18 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. The National Cancer Institute estimated that screening reduced the total breast cancer mortality by 28%–65%, with treatment contributing to the rest of the reduction (NCI, 2008c).

Assessing Breast Cancer Risk

Several algorithms have been developed to estimate a woman's risk of breast cancer. The best known and most widely accessible is the Breast Cancer Risk Assessment Tool (NCI, 2008a) which can be found online at: www.cancer.gov/bcrisktool/. This tool uses the following personal information to calculate a woman's risk for breast cancer:

- Family history of breast cancer in a first degree relative
- Personal history of breast cancer, including DCIS or LCIS
- Age
- Age at onset of menarche
- Age at first live birth
- Ever had a biopsy (how many, atypical hyperplasia)
- Race/ethnicity

The lifetime average risk of breast cancer for all women is about 12% in the United States and 11% in California. Those women with 15%-20% lifetime risk are considered "above-average risk."

The ACS recommends annual BMRI screening for those women classified as "high risk" for breast cancer. Women with one or more of the following factors are classified as "high-risk" by the ACS:

Genetic

- *BRCA1* or *BRCA2* gene mutation
- Li-Fraumeni syndrome and first-degree relatives
- Cowden and Bannayan-Riley-Ruvalcaba syndromes and first-degree relatives

Family History

- First-degree relative of *BRCA* carrier, but untested

Clinical History

- Chest irradiation between age 10 and 30 years (e.g., Hodgkins disease treatment)

High estimated lifetime risk

- Lifetime risk of >20% as defined by risk assessment tool[6]

In this analysis, "high-risk" women are defined as those women who meet the ACS recommendation for BMRI screening. CHBRP estimates that 3.5% of women ages 30–64 years would be classified as high risk based on having one or more of the ACS-identified factors. Information regarding the methods used in this estimation is provided in the Cost, Utilization, and Coverage Impact section and Appendix D.

Breast Cancer Screening Guidelines

Although some controversy continues about the appropriate age to begin screening and the frequency of breast cancer screening with mammography for women of higher than average risk, there is agreement between the major guideline sponsors regarding the age to begin screening for average-risk women.

Women With *Average Risk* of Breast Cancer: Ages 50 Years and Older

All guidelines recommend annual or biennial breast cancer screening by mammography for women aged 50 years and older at average risk for breast cancer. None of the guidelines recommends any other modalities for screening, such as breast magnetic resonance imaging (BMRI) or ultrasound.

Women With *Average Risk* of Breast Cancer: Ages 40–49 Years

For women at average risk of breast cancer between 40 and 49 years old, the United States Preventive Services Task Force (USPSTF), the ACS, and the American College of Obstetricians and Gynecologists (ACOG) recommend screening mammography every 12 to 24 months. The American College of Physician (ACP) recommends screening mammography only as an opt-in test based on the clinician and patient's decision.

Women With *Above-Average* Risk of Breast Cancer

Several national guidelines suggest early start of mammography screening with or without shorter screening intervals for women with above-average risk of breast cancer. However, due to lack of evidence, none of the guidelines recommend a specific age to begin screening. ACS specifically recommends that for women with a 15%–20% lifetime risk, a mutual decision should be made between a patient and her clinician regarding annual adjuvant BMRI. Another organization (the American Society of Clinical Oncology [ASCO, 2006]) wrote a specific guideline for follow-up of women with a history of breast cancer.

Women at *High Risk* of Breast Cancer

The ACS recommends that the decision of when to initiate mammography screening for women age 30 years and older at high risk for breast cancer be based on shared decision-

[6] The "lifetime risk of >20%" group comprises the largest group of women at high risk. Those women who are high risk because of genetic, family history, or clinical history comprise a very minor portion of the high-risk population.

making, taking into consideration individual circumstances. ACS also recommends an annual adjuvant screening with BMRI if the woman has a lifetime risk of breast cancer of more than 20% or has a *BRCA* mutation. The American Society of Breast Disease concurs with the ACS BMRI recommendation. All guidelines are summarized in Appendix C, Table C-1.

In California, it is estimated that among women ages 40–64 years with health insurance, 80.5% are screened at least every 2 years with mammography (CHIS, 2005). The rates at which high-risk women are being screened with BMRI since the guideline was published are unknown.

MEDICAL EFFECTIVENESS

The medical effectiveness of breast cancer screening with mammography and diagnostic testing has been established for decades, however, controversy surrounding the appropriate age to begin screening and the effectiveness of newer technologies continues. This debate includes the effectiveness of screening high-risk women younger than 40 years and the appropriate method for screening high-risk women, specifically the effectiveness of mammography with magnetic resonance imaging (MRI) (Trop, 2006).

This medical effectiveness analysis focuses on the changes to current practice with the passage of AB 2234: the possible increased use of adjuvant computer-aided detection (CAD), digital mammography, and magnetic resonance imaging of the breast (BMRI). It also addresses the medical effectiveness of notifying women of their eligibility for breast cancer screening.

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, 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). Other screening modalities used in conjunction with mammography include CAD, digital mammography, magnetic resonance imaging of the breast (BMRI), and ultrasound/ultrasonography. It should be noted that typically ultrasound is used as a diagnostic tool once abnormalities are discovered using mammography, but the studies summarized in this section focus on the effectiveness of this modality as a screening tool.

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 AB 2234, CBE is not within the scope of the bill, as this exam is generally covered during a woman's periodic preventive health care visit to her physician. For the purposes of this analysis, a review of CBE evidence-based studies is limited to the clinical screening guidelines summarized previously in this report. Evidence is inconclusive regarding the effectiveness of CBE and is so noted by all clinical guidelines that state varying degrees of support for recommending CBE as standard practice (Smith, 2003; USPTF, 2003).

CHBRP chose to include ultrasound in its medical effectiveness analysis because of specific language in AB 2234. Although national guidelines do not recommend ultrasound for screening, it is sometimes used as adjuvant modality with mammography (similar to the way BMRI is used). Echoes from high-frequency sound waves directed at the breast through a transducer 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.

CHBRP found that overall, there is insufficient evidence that ultrasound (as an adjunct to mammography) improves the sensitivity of breast cancer screening when it is used in women with dense breast tissue or those considered at high-risk for breast cancer (e.g., women ages 40–49 years), or that its use reduces breast cancer mortality or otherwise improves breast cancer outcomes. The three key diagnostic evaluation studies that considered the efficacy of ultrasound screening focused on women with high-density breast tissue (see Appendix D for Summary Findings of Medical Effectiveness of Ultrasound/Ultrasonography). One of the studies by Warner et al. (2004) explored use of ultrasound in women at high risk of breast cancer due to gene mutation in *BRCA1/2*. They compared the performance of ultrasound with BMRI and mammography, and found that BMRI was more sensitive for detecting breast cancers than mammography or ultrasound. In this population of women, ultrasound showed a very low sensitivity (33%). Chan et al. (2007) found that ultrasound had a higher sensitivity than mammogram alone when applied in women with mammographically occult breast cancer (91% vs. 78%) and improved the cancer detection rate by 14.3%. However, ultrasound also had a lower sensitivity in detecting nonpalpable/noninvasive cancer than mammograms (62% vs. 78%). Another study (Corsetti et al., 2008) showed that in women with dense breasts and at increased risk for breast cancer (especially those younger than age 50 years), ultrasound enhances cancer detection rates.

Film Mammography With CAD

Film mammography is the most common method of breast cancer screening. The breast is compressed between a plastic plate, and an x-ray cassette that contains x-ray film that is developed into a large film-screen. Routine screening involves two views of the breast, mediolateral oblique and craniocaudal. Two-view mammograms reduce the recall rate associated with single views incorrectly identifying normal breast structure variations as suspicious (NCI, 2008b). One (or two) radiologist(s) review the films for abnormalities.

CAD refers to sophisticated pattern-recognition computer software that radiologists use to assist in identifying suspicious features on digital images, with the goal of decreasing false-positive readings. It does not replace the imaging (mammography) technology; rather it is an interpretive aid to be used during image review. Radiologists review a mammogram and then activate the CAD software and re-evaluate the marked area(s) before issuing a final report. Film images must be digitally scanned before CAD can be activated, whereas digital mammography images are already downloaded into the computer for CAD.

Digital Mammography (With or Without CAD)

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.

Mammography With MRI of the Breast (BMRI)

BMRI is used as an adjuvant technology with mammography. 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, is administered to the patient by intravenous injection. The images are transferred from the MRI machine into a computer for the radiologist to study. BMRI is sometimes used in conjunction with mammography to increase test sensitivity for women with high-density breasts or for viewing palpable abnormalities that cannot be detected by mammography or ultrasound (NCI, 2008f). BMRI is the only adjuvant technology to mammography that is specifically recommended by any national guideline for breast cancer screening.

Evidence Review Results

Screening Studies

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. Unpublished studies are not reviewed because the results of such studies, if they exist, cannot be obtained within the 60-day timeframe for this report. Appendix B describes the literature search specifications in detail, and Appendix C provides Tables C1–C6, which summarize the studies used for this analysis.

The literature regarding the medical effectiveness of screening for breast cancer is vast. This report provides only a brief summary of the medical effectiveness of conventional mammography screening due to its already widely instituted use throughout the United States for the last 25 years. The medical effectiveness team chose to highlight those breast screening modalities that are newer and more controversial in current practice and in current screening guidelines. The following modalities all relate to mammography: mammography with CAD, digital mammography (with or without CAD), and BMRI adjuvant to mammography. It is important to understand that the evidence to evaluate most of these newer modalities as screening tests is much more limited than the volume of evidence regarding the effectiveness of screening mammography. Unlike conventional film mammography and digital mammography, there are no randomized trials of CAD or BMRI as breast cancer screening modalities. Tables 2–4 focus on three modalities.

Conventional film mammography

National guidelines, standard practices of care, and current health plan/insurer coverage as mandated by existing California statute all recognize mammography as the accepted standard for screening for breast cancer.

Breast cancer screening guidelines are generally developed based on systematic review of available research. The United States Preventive Services Task Force (USPSTF) performed an extensive systematic review of the effectiveness of mammography screening in 2001. Through a meta-analysis of eight RCTs, the USPSTF found "fair evidence that mammography screening every 12 to 33 months significantly reduces mortality from breast cancer," (USPSTF, 2002). As noted in the screening guidelines summary, USPSTF, along with the American Cancer Society (ACS) and the American College of Obstetricians and Gynecologists (ACOG), recommend screening mammography for women aged 40 years and older based on their systematic reviews.

In general, sensitivity for conventional mammography is approximately 75%, but ranges between 54% to 58% in women aged 40–49 years and 81% to 94% in women aged 65+ years (NCI, 2008b). The sensitivity of mammography is inversely related to breast density, which decreases as a woman ages. Thus, mammography screening is more effective for women with less-dense breast tissue, (generally ages 50 years and older) and is less helpful in detecting cancer in women younger than 50 years.

One randomized controlled trial on the effect of mammography screening for average-risk women aged 40 to 48 years has been published since the USPSTF and ACS breast cancer screening guidelines were released. The findings from Moss et al. (2006) are consistent with the efficacy results of multiple trials of mammography alone for this age group: a reduction in breast cancer mortality was found (at 10 years' follow-up), but it was not statistically significant. However, the authors conclude that through a meta-analysis of nine studies (including their own), mammography screening could reduce breast cancer mortality 15% to 17% for women aged 40–49 years (Moss et al., 2006).

Regarding potential harms from mammography screening, Brewer et al., 2007 performed a systematic review of 23 correlational studies on the long term effects of false-positive mammograms. They concluded that there were no long-term effects for European women on obtaining future routine mammography screening after receiving false-positive tests (0.97%, 95% confidence interval [CI] 0.93–1.01). Women in the United States were slightly more likely to return for their next routine mammography screening after false-positive tests (1.07, CI 1.02–1.12), unlike Canadian women who were less likely to return (0.63, CI 0.50–0.80), although the authors caution that smaller study sizes and different surveillance programs may explain the different results for the Canadian women.

Note: **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 normal 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. The American College of Radiology sets the desirable recall rate for screening mammography at less than 10%.

Mammography with CAD

Table 2 summarizes five large studies that evaluated CAD performance in breast cancer detection. All of these studies are observational. Most studies found mixed results, with increased cancer detection rates and no change in positive predictive value for biopsy. None of them demonstrated strong evidence for recommending CAD in breast cancer screening (see Appendix C). For example, Fenton et al. (2007) used 429,345 mammograms from 222,135 women from 43 facilities (in three states) and found that CAD increased the sensitivity of mammography from 80.4% to 84.0%, but this increase was not statistically significant. The study authors noted there was no improvement in specificity with CAD or in the positive predictive value of biopsy. Of the five studies, only Fenton et al. reported specificity. They also found the cancer detection rate change was not statistically significant.

Dean and Ilvento (2006) used one radiologist to review 9,520 mammograms. They found that the increased positive predictive value using CAD was not statistically significant. Screening-detected cancers increased 13.3% with CAD. The Freer and Ulissey study (2001) interpreted 12,860 screening mammograms with and without CAD, and reported that the proportion of benign and malignant lesions sampled at biopsy (positive predictive value) were unaffected by the use of CAD. They found the incremental yield for cancer detection was 19.5%, with a recall rate increase from 6.5% to 7.7%. They recommend further studies of CAD. In their evaluation of a noncommercial CAD program, Helvie et al. (2004) reported a sensitivity of 92% for CAD by means of screening mammograms of 2,389 patients. Morton et al. (2006) found that CAD improved the detection of breast cancer by 7.62%, with a recall rate increase of 0.93% and no change in the positive predictive value for biopsy.

A lack of large clinical trials or consistent statistically significant measures in the CAD mammography studies result in the preponderance of evidence that CAD has little to no effect in increasing the accuracy of mammography screening.

Table 2. Summary of Findings of Medical Effectiveness of Computer-Aided Detection (CAD) in Breast Cancer Screening

Citation	**Outcome**	**Research Design**[7]	**Sensitivity/ Specificity PPV**	**Recall Rate/ Cancer Detection Rate**	**Generalizability** (to Population Affected by Mandate) **Size of Effect**	**Conclusion**
Fenton et al., 2007	Sensitivity Specificity Positive predictive value Overall accuracy	**Level III**: Retrospective study of association between use of CAD at mammography facilities and performance of screening mammography with or without CAD. 222,135 women aged 40+ yrs	Without CAD: Sensitivity: 80.4% Specificity: 90.2% With CAD Sensitivity: 84.0% (P=0.32) Specificity: 87.2% (P<0.001) Positive predictive value decreased from 4.1% to 3.2% (P=0.01)	Recall rate increased 3.1% with CAD P<0.001 Change in cancer-detection rates was not significant: 4.15 cases/1,000 screened without CAD 4.20 cases/1,000 screened with CAD (P=0.90)	Highly generalizable due to large population size of women in proper age range No clinically meaningful effect was found	CAD appeared to be increasing detection of in-situ cancers but not invasive cancers Use of CAD is associated with reduced accuracy of interpretation of screening mammograms Incremental yield of additional cancers detected: not significant
Morton et al., 2006	Recall rate Positive predictive value Cancer detection rate	**Level III:** Prospective study of radiologists' interpretation of mammograms with and without	Without CAD Positive predictive value for biopsy: 40.0% With CAD	Recall rate increased 0.93% with CAD Incremental yield of additional cancers detected:	Highly generalizable due to large population size of women in proper age range	Use of CAD improved detection of breast cancer with an acceptable increase in recall rates and minimal increase in number of benign biopsy results

[7] 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.

Citation	Outcome	Research Design[7]	Sensitivity/ Specificity PPV	Recall Rate/ Cancer Detection Rate	Generalizability (to Population Affected by Mandate) Size of Effect	Conclusion
		CAD 18,096 women aged 23–98 yrs	Positive predictive value for biopsy: 40.8%	7.62% Change in positive predictive value was not significant	The positive predictive value did not change significantly so no clinically meaningful effect was found	
Helvie et al., 2004	Sensitivity Positive predictive value Overall accuracy	**Level III**: Prospective pilot clinical trial assessing CAD sensitivity 2,389 women of any age	<u>Without CAD</u> Sensitivity: 91% Positive predictive value for biopsy: 27.0% <u>With CAD</u> Sensitivity: 91% (CI 74–100) Positive predictive value for biopsy: 27.5%	Recall rate increased 1.4% with CAD Incremental yield of additional cancers detected: 9%	Somewhat generalizable due to trial occurring with volunteers at academic medical centers (ages unknown) No change in sensitivity or positive predictive value No clinically meaningful effect was found	High sensitivity (91%) for cancer detection with an increased biopsy rate (8%) and higher recall rate
Dean and Ilvento, 2006	Recall rates Positive predictive value	**Level IV**: Prospective observational trial of cancer detections based on one radiologist's	<u>Without CAD</u> Positive predictive value for biopsy: 21.9% <u>With CAD</u>	Recall rate increased 1.6% with CAD Cancer detected only with CAD assistance were	Somewhat generalizable due to difference in purpose of mammograms: 60% for screening; 40% for diagnosis	CAD resulted in detection of more cancers in screening and diagnostic patients with increased recall rate, but no deterioration in positive predictive value of biopsy Additional cancers detected by CAD

Citation	Outcome	Research Design[7]	Sensitivity/ Specificity PPV	Recall Rate/ Cancer Detection Rate	Generalizability (to Population Affected by Mandate) Size of Effect	Conclusion
		interpretation of mammograms with and without CAD 9,520 women aged 32–94 yrs	Positive predictive value for biopsy: 26.3% (not significant)	9.6% of all cancers Incremental yield of additional cancers detected: 13.3%	Included women aged 34–92 yrs (mean age 58.5 yrs) A clinically meaningful effect was found	were significantly smaller in size
Freer and Ulissey, 2001	Recall rate Positive predictive value Cancer detection rate	**Level IV:** Prospective study of radiologists' interpretation of mammograms with and without CAD 12,860 women aged 26–88 yrs	<u>With CAD</u> Positive predictive value for biopsy: 38% (no change)	Recall rate increased 1.2% with CAD Incremental yield of additional cancers detected 19.5%	Highly generalizable due to similar population: women aged 26–88 yrs (mean age 49 yrs) who were screened according to routine screening guidelines A clinically meaningful effect was found	CAD increased proportion of early stage malignancies detected from 73% to 78% No change in positive predictive rate for biopsy

Source: California Health Benefits Review Program, 2008
Key: CAD=computer-aided detection.

Digital mammography (with or without CAD)

Skaane et al. (2007) conducted a large randomized trial comparing screen-film mammography (SFM) with full-field digital mammography (FFDM). The FFDM resulted in a statistically significantly higher cancer detection rate than did SFM; however, the positive predictive values were comparable for the two imaging modalities. Another study by the same group showed that FFDM may marginally enhance cancer detection in women over 50 years (Skaane et al., 2004). In another nonrandomized large study, however, the overall diagnostic accuracy of digital and film mammography as a means of screening for breast cancer was similar, but digital mammography was more accurate in women under 50 years—women with radiographically dense breasts, and premenopausal or perimenopausal women (Table 3).

Digital mammography is a relatively new technology. There is still insufficient evidence that its large-scale use for screening reduces breast cancer mortality or otherwise improves breast cancer outcomes. There is a preponderance of evidence from randomized clinical trials that digital mammography improves the rate of cancer detection in women with radiologically dense breasts.

Table 3. Summary of Findings of Medical Effectiveness of Screen Film Mammography vs. Full-Field Digital Mammography

Citation	Outcome	Research Design[8]	Sensitivity/ Specificity PPV	Recall Rate/ Cancer Detection Rate	Generalizability (to Population Affected by Mandate) And Size of Effect	Conclusion
Skaane et al., 2007	Sensitivity Specificity	**Level I:** Large-scale, well-designed randomized trial adjusted for age and area of residence; the cases were followed up to 2 yrs 23,929 women aged 45–69 yrs	FFDM Sensitivity: 77.4% (CI 63.4–87.3) Specificity: 96.5% (CI 96.0–96.9) SFM Sensitivity: 61.5% (CI 51.5–70.8) (P=0.07) Specificity: 97.9%, (CI 97.8–98.1) (P<0.005)	Recall Rate FFDM: 4.2% SFM: 2.5% P<0.001) Cancer detection rate FFDM: 0.59% SFM: 0.38% P<0.02 No significant different in positive predictive value	Highly generalizable: randomized trial with a two specific age ranges in the study A small, clinically meaningful effect was found	FFDM resulted in a significantly higher cancer detection rate than did SFM. The positive predictive values were comparable for the two imaging modalities
Pisano et al., 2005	Differences in ROCs for the two different techniques	**Level III**: Study of asymptomatic women undergoing both digital and film screening mammography for the purpose of comparing these	• Entire population: Difference in area under ROC curve, 0.03; 95% CI, –0.02 to 0.08; P=0.18 • Women under the age of 50 yrs:	335 cancers detected with SFM and FFDM	Highly generalizable: randomized trial with a mean age of 55 yrs	The diagnostic accuracy of FFDM was similar to that of SFM in the overall population

[8] 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.

Citation	Outcome	Research Design[8]	Sensitivity/ Specificity PPV	Recall Rate/ Cancer Detection Rate	Generalizability (to Population Affected by Mandate) And Size of Effect	Conclusion
		two techniques 42,760 women mean age of 55 yrs	Difference in area under ROC, 0.15; 95% CI, 0.05–0.25; P=0.002 • Women with heterogeneously dense or extremely dense breasts: Difference in area under ROC was 0.11; 95% CI, 0.04–0.18; P=0.003), • Premenopausal or perimenopausal women: Difference in area under ROC, 0.15; 95% CI, 0.05–0.24; P=0.002)		A clinically meaningful effect was found for younger women and women with dense breasts	The diagnostic accuracy of FFDM was significantly higher than SFM among women under age 50, women with dense breast tissue and pre- and perimenopausal women
Skaane and Skjennald, 2004	Cancer detection rates Positive predictive values	**Level I:** Large-scale, well-designed randomized trial adjusted for age and area of	SFM PPV: 22.1% FFDM PPV: 21.6% P>0.05	Incremental cancer detection rate: SFM=0.41% FFDM=0.59%; P=0.06	Highly generalizable: Randomized trial, different age groups in the study	FFDM allowed a higher cancer detection rate than did SFM in the group aged 50–69 yrs, although the

Citation	Outcome	Research Design[8]	Sensitivity/ Specificity PPV	Recall Rate/ Cancer Detection Rate	Generalizability (to Population Affected by Mandate) And Size of Effect	Conclusion
		residence 25,263 women aged 45–69 yrs	Positive predictive values were not significant within each age group	Incremental cancer detection in ages 50–69 yrs: SFM=0.54% FFDM=0.83%; P=0.053 Incremental cancer detection in ages 45–49 yrs: SFM=0.22% FFDM=0.27%; SFM PPV: 7.4% FFDM PPV: 7.1% P>0.05	A small, possibly clinically meaningful effect was found, but differences in the cancer detection rates overall and for subgroups was not statistically significant	difference was not statistically significant. The detection rate was nearly identical for ages 45–49 yrs for both modalities

Source: California Health Benefits Review Program, 2008
Key: CI=95% confidence intervals; FFDM=full field digital mammography; ROC=receiver operating curve; PPV=positive predictive value; SFM=screen-film mammography.

Breast MRI (BMRI) with mammography
BMRI is approved by the FDA only for diagnostic purposes related to breast cancer. Nevertheless, there is research on the effectiveness of this modality as a screening tool, and one national organization released screening guidelines recommending its use for screening high-risk women. The medical effectiveness literature review revealed five key studies related to the use of BMRI in breast cancer screening (Table 4). The ACS recommends BMRI for women ages 30 years and older at high risk (>20% lifetime) for breast cancer. Several of the following studies include women younger than 40 years. BMRI is not recommended for women at average risk for breast cancer due to its high cost and low specificity.

Lord et al. (2007) performed a systematic review of the effectiveness of BMRI in addition to mammography and ultrasound in screening women at high risk. No randomized clinical trials were available for review. They report 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%) 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% and that test recall rates were three to five times higher when MRI was added to mammography versus mammography alone. This indicates that an additional 71–74 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.

Kriege et al. (2004) conducted a prospective study with 1,909 women comparing BMRI to mammography alone and found that MRI sensitivity was higher (71.1% versus 40.0%), but the specificity and positive predictive value were lower. The MRI led to twice as many unneeded additional examinations compared to mammography and three times as many unneeded biopsies. 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 MRI with conventional screening achieved the highest diagnostic performance for all women (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. Ultimately, the authors note, MRI has not been proven to reduce breast cancer mortality, and it is uncertain whether the benefits of treatment at an early stage (due to MRI diagnosis) outweigh the harm of over-detection of cancers that would never have manifested clinically. Hagen et al. (2007) also consider *BRCA*-associated cancers in their prospective study of 491 women. They concluded that BMRI had high sensitivity to diagnosing early-stage cancer (86% versus 50% for mammography alone), but they are unsure whether this will ultimately lead to a reduction in breast cancer mortality.

Finally, Lehman et al. (2007) took a slightly different view of BMRI in evaluating the effectiveness of screening the contralateral breast in 969 women diagnosed with breast cancer. They found that BMRI detects occult cancers undetected by mammography and ultrasound at the initial breast cancer diagnosis (91% sensitivity and 88% specificity). The increase in detection rate was accompanied by a false-positive rate of 10.9% and a "relatively low rate" of 9.4% of detecting benign disease on biopsy.

Harms associated with screening are primarily related to false-positive readings that result in a higher rate of benign biopsies. Among the five BMRI studies in Table 4, the false-positive rates for BMRI ranged between 4% and 23%. None of the studies calculated pooled estimates due to the heterogeneity of the study populations.

Limited 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 studies and an increase in false-positive biopsies. Most studies reference the high cost associated with BMRI, but state that the high sensitivity of the screening test may be useful in a targeted population of *high-risk women*.

Table 4. Summary of Findings of Medical Effectiveness of Breast MRI Screening Studies

Citation	Outcome	Research Design[9]	Sensitivity/ Specificity PPV	Recall Rate/ Cancer Detection Rate	Generalizability (to Population Affected by Mandate) And Size of Effect	Conclusion
Lord et al., 2007	Sensitivity	**Level III:** Five studies including 2,059 women at high risk for breast cancer screened by BMRI and reporting sensitivity for each study. 2,059 women (mean age range 40–47 yrs	Range for MRI from five studies: Sensitivity: 93%–100% Specificity: 77%–96% Pooled estimate of three studies showed: <u>MRI+mammogram</u>: 94% (CI 86–98) <u>Incremental MRI</u>: 58% (CI 47–70)	Recall rate for three 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	Highly generalizable because the population in each study has a high lifetime breast cancer risk, and the mean age range is pertinent to this population A clinically meaningful effect was found for young women undergoing MRI	Adding BMRI in five studies showed consistently higher sensitivity (93% to 100%) compared with mammography alone (25% to 59%) or mammography plus ultrasound ± CBE (49% to 67%)
Kriege et al., 2004	Sensitivity Specificity	**Level III**: Prospective study comparing mammography to BMRI screening in women with family history or genetic predisposition to	<u>MRI:</u> Sensitivity: 71.1% Specificity: 89.8% (Positive predictive value 7.1% at BI-RADS 3+ cutoff) <u>Mammography</u>	MRI led to twice as many unneeded exams and three times as many unneeded biopsies	Highly generalizable because the population in each study has a high lifetime breast cancer risk, and the mean age range is pertinent to this population	Sensitivity of MRI for *any* breast cancer MRI screening can detect breast cancer at an early stage in women at risk

[9] 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.

Citation	Outcome	Research Design[9]	Sensitivity/ Specificity PPV	Recall Rate/ Cancer Detection Rate	Generalizability (to Population Affected by Mandate) And Size of Effect	Conclusion
		breast cancer 1,909 women aged 19–72 yrs	Sensitivity: 40% Specificity: 95.0% (Positive predictive value 8.0% at BI-RADS 3+ cutoff)		A clinically meaningful effect was found for women at high-risk	
Bermejo-Perez, et al., 2008[a]	Sensitivity Specificity	**Level III:** Eight prospective and retrospective studies looking at BRCA1/2 carriers who were screened with BMRI to evaluate diagnostic performance. Women with a mean age of 46 years or less	Range from 8 studies: <u>Sensitivity</u> MRI: 77%–100% Mammography: 20%–50% <u>Specificity</u> MRI: 81%–97.5% Mammography: +96% (Positive predictive value 12.5%–66.7%) (No pooled estimates calculated)	61 cancers detected in all 8 studies	Somewhat generalizable because the population is limited to women at high risk due to *BRCA1/2* genes A small clinically meaningful effect was found for women at high risk	Screening BMRI had the highest sensitivity of all screening methods False positive rates result in unnecessary biopsies Uncertain if treatment benefits outweigh harm of overdetection of cancer by MRI screening

Citation	Outcome	Research Design[9]	Sensitivity/ Specificity PPV	Recall Rate/ Cancer Detection Rate	Generalizability (to Population Affected by Mandate) And Size of Effect	Conclusion
Hagen, et al., 2007	Sensitivity	**Level III:** Nonrandomized study of BMRI vs. conventional screening in 491 women with *BRCA1/2* mutation to explore the sensitivity in early diagnosis of breast cancer 491 women aged 18–79 yrs	Sensitivity BMRI: 86% Mammography: 50% (Overall sensitivity of BMRI and mammography)	25 cancers detected	This study is somewhat generalizable because the study population is at increased risk due to *BRCA1/2* mutation as are some in the general population	Breast MRI had increased sensitivity compared to mammography to diagnose early *BRCA*-associated cancers
Lehman et al., 2007)	Sensitivity Specificity Negative predictive value	**Level III**: 969 women with a recent diagnosis of unilateral breast cancer and no abnormalities on mammographic and clinical examination underwent BMRI	Sensitivity BMRI: 91% Specificity BMRI:88% (Negative predictive value: 99%)	BMRI recall rate:13.9% BMRI cancer detection rate: 3.1%	This study is somewhat generalizable because the population is women with known breast cancer at a mean age of 53 yrs	BMRI detected clinically and mammographically occult breast cancer in the contralateral breast in 3.1% of cases

Source: California Health Benefits Review Program, 2008

[a]Bermejo-Perez et al. (2008) shares two studies in common with the Lord et al. (2007) study.

Key: BI-RADS=Breast Imaging–Reporting and Data System; BMRI=breast magnetic resonance imaging; CBE=clinical breast exam; MRI=magnetic resonance imaging.

Limitations and 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 diagnose 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.

Most of the studies summarized in Tables 2–4 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.

Randomized controlled trials 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 over-represents less-aggressive disease), over diagnosis bias (diagnosing disease that will not cause symptoms or death), and healthy volunteer bias (patient selection bias) (Moses, 2008). The relatively small study populations also negatively affect the strength of the studies summarized.

Medical Effectiveness of Notification of Eligibility for Breast Cancer Screening and Diagnostic Testing

The literature search from 2002 to present revealed that there are no medical effectiveness studies of "one time" notification of newly eligible women to obtain breast cancer screening services, though one systematic review from 2007 includes tailored print notification. A literature review through 1995 revealed several studies related to this particular method of notification. Table 5 (notification) summarizes the most pertinent studies that use written notification. All three studies performed a meta-analysis of studies comparing different forms of reminders or notices to women about mammography screening. All showed strong indications that providing some form of written notification to remind women of mammography screening was effective in increasing mammography screening rates. The most pertinent study is from 1998 where one mailed reminder was compared with no reminders and the effect was statistically significantly in increasing women's adherence to mammography screening (Wagner et al., 1998), as demonstrated by an odds ratio of 1.48 (Mantel-Haenszel chi-square test $[\chi^2_{MH}(1)]=38.27$, $P<0.001$). The other two studies consider more sophisticated communication methods such as tailored phone calls and tailored written material, and compare to "usual care" groups that may or may not receive a simple written reminder.

There is a preponderance of evidence that notifying women about routine mammography screening improves the overall mammography screening rate.

Table 5. Summary of Findings of Medical Effectiveness of Notification or Reminders for Breast Cancer Screening

Citation	Outcome	Research Design[10]	Findings (Statistical Significance, Direction of Effect)	Generalizability to Population Affected by Mandate
Sohl and Moyer., 2007[a]	Improved adherence to mammography screening	**Level I**: Meta-analysis of 28 RCTs (33,227 women) to compare effectiveness of tailored interventions including print reminders compared to "usual care" control groups	Women receiving tailored print interventions were significantly more likely to get a mammogram than women in the "usual care" groups OR 1.31 for the print reminders based on 14 studies (no CI reported)	These studies are highly generalizable because mean age was 60 yrs and women were mostly not from underserved populations and were both nonadherent to screening and mixed samples of women
Wagner, 1998	Increased mammography screening rates	**Level I**: Meta-analysis of 11 RCTs (more than 16,000 women) to compare effectiveness of mailed patient reminders at increasing mammography screening	Mailed patient reminders were more effective at increasing mammography screening rates than no intervention OR 1.48; $\chi^2_{MH}(1)=38.27$, $P<0.001$ for mailed print reminders	These studies are highly generalizable because the population is U.S. based and includes studies with women ages 40+ yrs
Stone et al., 2002[b]	Improved adherence to breast cancer screening guidelines	**Level I**: Meta-analysis of 29 RCTs and controlled clinical trials to compare relative effectiveness of patient reminders (delivered verbally, on paper, or by computer screen) to other interventions (e.g., organizational change, education, financial incentives, etc.)	Patient reminders were significantly more effective at increasing mammography rates than educational or provider feedback interventions OR 2.31 (CI 1.97–2.70) for all forms of patient reminders for mammography	These studies are somewhat generalizable because the population is undefined

Source: California Health Benefits Review Program, 2008

[a]The Sohl and Moyer (2007) and Stone et al. (2002) meta-analyses both include studies by Davis et al., 1997, and Janz et al., 1997.

[b]The Stone et al. (2002) and Wagner (1998) meta-analyses both include studies by Lantz et al., 1995; Landis et al., 1992; Mandelblatt and Kanesky, 1995; and Taplin et al., 1994.

Key: CI=95% confidence interval; OR=odds ratio; χ2MH(1)=Mantel-Haenszel chi-square test; RCT=randomized controlled trial.

[10] 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.

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. Due to limitations in the technology associated with mammography, this screening test appears to be most effective in women older than 50 years and those with less-dense breast tissue.

The evidence on the effectiveness of breast cancer screening with CAD, ultrasound, and MRI is limited by the lack of randomized controlled trials. No studies have yet shown that screening tests other than mammography find cancer at an earlier stage, reduce breast cancer mortality, or otherwise improve outcomes for women at high risk for breast cancer.

Current evidence suggests that mammography, ultrasound, and MRI complement each other by detecting cancers undetected by their counterparts. However, such screening modalities are expensive and lead to higher recall rates and increased benign biopsy rates. The medical effectiveness literature provides insufficient evidence at this time to document the benefit of mammographic adjunct modalities for women at high risk for breast cancer.

There is a convincing preponderance of evidence to support the effectiveness of a one-time invitation to participate in mammography screening to increase screening participation by eligible women (those women aged 40 years each calendar year per national guidelines in 2008).

UTILIZATION, COST, AND COVERAGE IMPACTS

AB 2234 would require Department of Managed Health Care (DMHC)- and California Department of Insurance (CDI)-regulated plans to cover breast cancer screening, consistent with national guidelines, and including, but not limited to, mammography, magnetic resonance imaging of the breast (BMRI), ultrasound, and computer-aided detection. The latest American Cancer Society (ACS) guidelines additionally recommend BMRI in conjunction with mammogram for screening of women at high-risk of breast cancer. This recommendation is not currently present in any other national guidelines. Thus, the following analyses reflect the cost impact of compliance with ACS guidelines, as well as the cost impact of one-time notification of women age 40 to receive mammograms.

This section presents the current, or baseline, costs and coverage related to breast cancer screening, and then presents the estimated utilization, cost, and coverage impacts of AB 2234. For further details on the underlying data sources, assumptions, and methods, please see Appendix E at the end of this document.

Present Baseline Cost and Coverage

Current Coverage of the Mandated Benefit

Coverage of the commercially insured population subject to the mandate
Approximately 22,362,000 individuals in California are enrolled in health plans or policies that would be subject to this mandate. An estimated 6,775,000 are insured women aged 30 to 64 years.

A survey of the seven largest health plans and insurers in California was conducted by the California Health Benefits Review Program (CHBRP) to examine current coverage levels for screening of breast conditions. The survey also included questions related to the guidelines used to make coverage determinations since AB 2234 specifies that coverage must be in accordance with "national guidelines." Six of the seven health plans and insurers responded to the survey representing approximately 83% of the privately insured enrollees in the CDI-regulated market and approximately 94% in the DMHC-regulated market.[11]

DMHC-regulated plans represent about 89.6% of the privately insured market in California, while CDI-regulated plans represent 10.4%. CHBRPS's methods of calculating enrollment in private and public programs that would be affected by the

[11] CHBRP analysis of the share of insured members included in CHBRP's 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, 2006 by the California Department of Insurance, Statistical Analysis Division and data retrieved from The Department of Managed Health Care's interactive web site "Health Plan Financial Summary Report," December, 2007.

mandate are described in Appendix E. CHBRP's coverage survey of health plans indicated that all enrollees in DMHC-regulated plans and CDI-regulated insurers have coverage for screening of breast cancer per *at least one existing* national guideline.

However, according the survey responses, 24% of insured women aged 30 to 64 years or 1,608,000 women had coverage for BMRI, *in accordance with 2007 ACS guidelines*. This rate differs by market segment and DMHC- or CDI-regulated policies. Coverage of BMRI as a routine screening test was estimated at 25% for DMHC-regulated plans and 37% for CDI-regulated policies. Coverage rates for women enrolled in individual policies versus group policies also varied. Table 6 shows the variation in coverage by market segment.

Table 6. Current Coverage by Market Segment, California, 2008

	Mammography Screening Tests	BMRI Screening Tests, in accordance with ACS, 2007 guidelines
DMHC-regulated plans		
Large group	100%	24%
Small group	100%	22%
Individual	100%	37%
Total	100%	25%
CDI-regulated policies		
Large group	100%	31%
Small group	100%	42%
Individual	100%	33%
Total	100%	37%
CalPERS	100%	48%
Medi-Cal Managed Care	100%	0%
Total	100%	24%

Source: California Health Benefits Review Program, 2008.
Notes: Medi-Cal Managed Care includes coverage estimates for AIMS and MRMIP.
Key: CalPERS=California Public Employees' Retirement System; CDI=California Department of Insurance; DMHC=Department of Managed Health Care; MRI=magnetic resonance imaging.

Coverage of the publicly insured population subject to the mandate
Approximately 48% of the population insured by the California Public Employees' Retirement System (CalPERS) and none of those covered by other Medi-Cal, Access for Infants and Mothers (AIM), and Major Risk Medical Insurance Board (MRMIB) have coverage for BMRI in accordance with ACS guidelines.

Current Utilization Levels and Costs of the Mandated Benefit

Current utilization levels
Utilization of BMRI reflects factors such as current coverage levels, BMRI for high-risk women, physician assessment of patients' risk levels, the awareness of women of their breast cancer risk levels, the availability of scanners capable of BMRI screening, and the capacity of magnetic resonance imaging (MRI) scanners for breast screening rather than other types of tests. For the purposes of this analysis, CHBRP assumes all other factors, except coverage levels and patient awareness, to be held constant since AB 2234 includes provisions related to coverage and notification.

As discussed, the 2007 ACS guideline recommends BMRI as the preferred method of routine annual screening in conjunction with a mammogram for high-risk women. The guidelines also recommend that screenings for women with above-average risk (see Medical Effectiveness for definitions of risk) should be based on a mutual decision with the physician. CHBRP estimates that about 3.5% of women aged 30–64 years are high risk in California. (See Appendix D for a discussion of the estimated rate of above-average risk and high-risk women.) Another 18.1% of the California population of women 30–64 years of age is at above-average risk of breast cancer. The majority of the analyses in this report is focused on high-risk women. CHBRP estimated utilization and total expenditures for some women at above-average risk to assess the potential impact of raised awareness.

CHBRP estimates that approximately 39,000 BMRIs were performed in 2006, the most recent year of available data. The utilization of BMRI is assumed to be the same as their current mammogram rates of 78%. These BMRIs were performed for diagnosis and screening for women at high risk for breast cancer. It is possible that this estimate may be low for 2007 (when this report was produced) since more providers may have begun to apply the ACS guidelines from early 2007, and coverage of BMRI as a routine screening test would increase by the AB 2234 effective date of January 2009. Thus, the BMRI coverage and utilization rate are dynamic, most likely increasing, and have not yet reached equilibrium.

The survey of health plans indicated that none send a single notification to women age 40 years to receive cancer screening. The percentage of providers or medical groups within each health plan that may send reminders to women independent of the health plan is unknown, but such practices are relatively common. It is estimated that 51% of medical groups and independent practice associations (IPAs) nationally send annual mammogram reminders for women aged 50 and up (Schmittdiel et al., 2004).

Unit price
AB 2234 is not expected to affect the cost of mammography, since the estimated percentage increase in utilization rates of mammography due to the one-time notification required under the bill is very low at 0.32% and is not estimated to change the unit costs of mammograms. The average cost of a BMRI test is estimated at $1,282, including the costs of office visits, follow-up biopsies (procedure and lab costs), and follow-up BMRIs due to false-positive results. The evidence on the specificity or the false-positive rate of BMRI tests is tenuous, since most studies of the effectiveness of BMRI are based on

specific subgroups of the general population of women at risk of breast cancer, and their generalizability varies (see the Medical Effectiveness section). The false-positive rates of BMRI range from 4%–23% in existing studies, and CHBRP has estimated that approximately 13.5% of BMRIs would have false-positive results based on findings of the Medical Effectiveness section. This rate is somewhat higher than studies cited by the American Cancer Society, with BMRI specificity rates ranging from 80%–99% in primarily European studies with varying samples and generalizability to U.S. populations of women (Saslow et al., 2007) The false-positive rates are assumed to be the same for private and public sector.

The baseline costs associated with the mandate, given current utilization and unit price of the screening, are presented in Table 7.

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

Currently, approximately 24% of health plans and health insurance policies in the private and public market segments cover BMRI as a routine screening test. All plans appear to cover BMRIs as a diagnostic or screening test, when indicated by evidence-based guidelines.

Public Demand for Coverage

As a way to determine whether public demand exists for the proposed mandate (based on criteria specified under Senate Bill [SB] 1704 [2007]), CHBRP is to report on the extent to which collective bargaining entities negotiate for, and the extent to which self-insured plans currently have, coverage for the benefits specified under the proposed mandate. Currently, the largest public self-insured plans are the preferred provider organization (PPO) plans offered by CalPERS. These plans provide coverage similar to that of the privately self-insured plans. CalPERS PPO plans are administered by Blue Cross. The plans cover screening and diagnostic tests that are medically necessary as defined by Blue Cross of California's Medical Policy. For cancer screening tests, Blue Cross' Medical Policy relies on the American Cancer Society's Cancer Detection guidelines. Based on conversations with the largest collective bargaining agents in California, CHBRP concluded that unions currently do not include cost-sharing arrangements in their health insurance policy negotiations. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and coinsurance levels.[12]

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

Impacts of Mandated Coverage

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

Impact on per-unit cost
AB 2234 is not expected to change the per unit cost of mammograms, since the mandate is not expected to change the rate of mammography screening. However, the mandate is expected to increase the number of BMRIs. The current supply of MRI machines may not be sufficient to respond to the future demand for BMRI; however, this supply may already be increasing due to the 2007 ACS guidelines and may continue to increase before and after the mandate's effective date. It is likely that the rate of the growth in the number of MRI machines post AB 2234 may increase. By the same token, full compliance with the 2007 ACS guidelines would not occur immediately post AB 2234, and CHBRP estimates that the supply and demand for BMRI would grow at roughly the same rates and maintain equilibrium without increasing the unit price of BMRIs.

CHBRP does not assume a significant increase in the unit price of BMRI due to AB 2234 because of the trends described above.

Postmandate coverage
AB 2234 would not affect the coverage of mammography screening of women for breast conditions. However, the mandate is expected to significantly increase coverage of BMRI for high risk women 30–64 years of age as per the 2007 ACS guidelines. This coverage is estimated to change from 25% in the DMHC-regulated and from 37% in the CDI-regulated private market to 100%. Coverage is expected to increase from 48% in CalPERS and from 0% in the Medi-Cal managed care market to 100%.

Changes in coverage as a result of premium increases
AB 2234 would mandate coverage of this screening for both public and private market segments, raising the coverage level to 100%. The estimated increase in the private market premiums is less than 1%, and CHBRP does not estimate loss of coverage as a result of per member per month (PMPM) premium increases less than 1%.

AB 2234 is not expected to affect the health benefits of BMRI. The Medical Effectiveness section of this report does not identify conclusive evidence on benefits of BMRI as a routine screening test for high-risk women in conjunction with mammography. Furthermore, BMRI has a 13.5% false-positive rate, leading to increased utilization and potentially harmful and unnecessary follow-up procedures.

How Will Utilization Change as a Result of the Mandate?

Utilization for BMRI is expected to increase as a result of AB 2234 because the mandate would increase the number of women who have coverage for BMRI per ACS guidelines.

Implicit is the assumption that, postmandate, all high-risk women who were screened by mammograms previously would also receive a BMRI.

The number of BMRIs is estimated to increase from 39,000 per year to 170,000 per year, an increase of 131,000 new BMRIs, based on the assumption that 78% of high-risk women currently receive mammograms and would also receive BMRIs after the mandate. In terms of utilization per *covered member*, CHBRP estimates that BMRI screenings per 1,000 covered members would increase from 1.8 to 8.7 post-mandate.

It is likely that advocacy and direct-to-consumer advertising would increase the rates of BMRI among high-risk and lower-risk women. An unknown percentage of women not at average risk may request BMRI screening. However, they are unlikely to receive coverage for BMRI because utilization review by health plans is likely to deny BMRIs that are not in concordance with the 2007 ACS guidelines. These women may pay for these services out of pocket, and their costs are not estimated by CHBRP. All those at high risk who did not receive mammograms prior to the mandate (an additional 22% of high-risk women) may receive mammograms and BMRIs due to raised awareness and increased anxiety of cancer risk (an upper-bound estimate). Similarly, among women with above-average-risk, an estimated 62% are currently receiving mammograms and may receive BMRI in conjunction with mammography, leading to an estimated increase of 588,000 mammograms and 700,000 BMRIs due to the mandate. However, increases in BMRI rates may be dampened by the higher levels of cost sharing for BMRI, especially among individuals with PPO coverage. CHBRP does not estimate the potential decrease in utilization due to cost sharing for BMRI due to lack of data for such an assumption.

The postmandate BMRI utilization rates are also assumed to be similar among the group (large and small) and individual market segments. The BMRI rates for CalPERS are assumed to be similar to that of the relevant private sector health plans. For a detailed examination of the methods, refer to Appendix D.

The number of mammograms is also expected to increase due to the mandate requiring plans to send a one-time notification letter to women when they turn 40. Approximately 168,000 women age 40 are estimated to receive notification for mammography by their health plan due to the mandate. Of these women, an estimated 49% did not receive annual mammography prior to the mandate (based on analysis of the 2005 California Health Interview Survey) and another 49% did not receive notification to do so (Schmittdiel et al., 2004). Approximately 48% (see the Medical Effectiveness section) or 19,000 of these women (without previous mammograms and notification) are estimated to receive mammography after the mandate due to notification.

The utilization of other screening modalities are expected to remain unchanged because the 2007 ACS guidelines do not recommend changes in such modalities. Furthermore, the rates of BMRI for screening and diagnosis of women with a previous history of breast cancer are expected to remain unaffected by this mandate because the 2007 ACS guidelines do not recommend changes in screening and diagnosis for these women.

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

AB 2234 requires insurers and health plans subject to this mandate to send each covered woman a written notice of her eligibility for testing during the calendar year for which she becomes eligible for screening (age 40 years). CHBRP has assumed this to be a single notification in the form of an individual letter sent to each covered woman when she reaches age 40, following the 2007 ACS guidelines for screening of average-risk women. The cost of this notification is estimated as $84,000, based on an estimated cost of $0.50 per letter for postage, supplies, and labor. The cost of the notification is based on information provided through the CHBRP survey of health plans and insurers in California.

In addition, CHBRP assumes that if health care costs increase as a result of increased utilization or changes in unit costs, there is a corresponding proportional increase in administrative costs. CHBRP assumes that the administrative cost *proportion of premiums* would increase by the magnitude of $37,635,000 due to the increased utilization of BMRIs and notification costs.

Impact of the Mandate on Total Health Care Costs

Changes in total expenditures

This mandate would increase expenditures in both private and public market segments (Table 8). CHBRP estimates that total expenditures would increase by $252,174,000, or 0.32%, including $243,469,000 in total premiums and $13,456,000 in out-of-pocket expenditures. In the private market, the total estimated expenditure increase varies from 0.56% ($1.12 PMPM) in the individual CDI-regulated market to 0.20% ($0.90 PMPM) in the small-group CDI-regulated market. The highest PMPM increases are estimated within the DMHC-regulated plans in the small-group ($1.12 PMPM, 0.30%) and individual CDI-regulated ($1.12 PMPM, 0.56%) markets. CalPERS expenditures are estimated to increase by 0.21% ($0.77 PMPM), and Medi-Cal managed care expenditures are estimated to increase by 0.59% ($0.72 PMPM).

CHBRP estimates that the total expenditures may increase by $1,161,448,000 or 1.46% if direct-to-consumer advertising and awareness levels led to an increased rate of BMRI among high-risk women from 78% to 100% and an increased rate of BMRI among above-average risk to 62% (their current estimated rate of mammogram). This estimated increase in total expenditures reflects additional BMRIs, additional mammograms, and additional follow-up tests and office visits due to false-positive results. However, the increase in rates of BMRI due to such secondary effects may be dampened by other factors such as potentially higher cost-sharing levels for high-risk women not estimated in this analysis.

Offsets

AB 2234 is expected to increase the number of mammograms for women 40 years of age who would receive a one-time notification by 19,000 or 0.32%. This increase in mammograms may lead to a decrease in the mortality rates from breast cancer screening (see the Public Health Section). The average costs of breast cancer treatment are estimated at $12,000 to $27,000 depending on stage at detection disease. Early treatment of women found with breast cancer due to the mandate may lead to a lower range increase in costs of treatment.

No offset are expected due to the increased utilization of BMRI, such as reductions in costs of other services (e.g., doctor visits or hospitalization) due to a decrease in morbidity or mortality from breast cancer. CHBRP estimates that, due to the high rate of false-positive BMRIs, the rates of unnecessary office visits and biopsies would increase.

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

The overall impact of AB 2234 on total premiums is an increase of $243,469,000 in the year following the mandate. This increase varies by market segment. In the private market, this increase translates from the highest estimated premium increase of 0.61% ($0.97 PMPM) in the individual CDI-regulated market to an estimated increase of 0.31% ($1.07 PMPM) in the small-group CDI-regulated market. The highest PMPM increases is estimated in the DMHC-regulated plans in the small-group ($0.89 PMPM, 0.22%) market. CalPERS premiums are estimated to increase by 0.22% ($0.76 PMPM), and Medi-Cal managed care premiums are estimated to increase by 0.61% ($0.74 PMPM).

Of the total increase in expenditures, $150,014,000 is attributable to increases in premiums paid by employers, $24,672,000 to increases in premiums by those purchasing individual policies, and $40,029,000 in an increased share of premiums paid by employees and those insured in the public sector (Table 8). The mandate may increase the supply of MRIB machines to address increased demand for this screening, as discussed previously.

Impact on Long-Term Costs

AB 2234 is estimated to increase health care expenditures and premiums in both public and private markets in California. CHBRP estimates this increase to be relatively constant over the long term in the years following 2009.

Cost-effectiveness studies of BMRI for high-risk women are rare. CHBRP did not find evidence that BMRI is cost effective for women at high risk. Thus, the use of BMRI as a routine screening test for high-risk women is not estimated to lead to long-term cost savings, in the absence of evidence of clear medical effectiveness or public health benefits.

A recent cost-effectiveness study of women ages 40 years and older examines the long-term cost savings associated with mammography (Stout et al., 2006). The study identified

an incremental cost-effectiveness ratio (ICER) of $58,000 for screening in every two years and $47,000 for annual screening per quality-adjusted life-year (QALY) saved. These estimates mean that the net cost, after accounting for all savings associated with the reductions in adverse health events, ranges from about $58,000 to $47,000 per additional QALY saved. Although there is no consensus about the most appropriate threshold, policy makers have routinely accepted technologies with estimated ICERs much higher than these. These rates were based on the assumption of 100% mammogram rates and would be considerably lower given the current mammogram rates.

Impact on Access and Health Service Availability

AB 2234 would significantly improve access to BMRI as a routine screening test for women aged 30–64 years should they be identified as high-risk. AB 2234 may increase availability of BMRI services; however, the increase in this service would have already begun prior to the mandate. CHBRP did not have sufficient evidence to distinguish the additional increase in service availability due to AB 2234.

DMHC's HMO Help Center has logged over 30,000 complaints since its inception in 2001, of which 348 are complaints related to breast cancer screening[13]: 48 complaints reference mammography, 75 referenced MRI, 6 referenced ultrasound, and none referenced computer-aided detection. Lack of case detail precludes CHBRP from drawing any conclusions on what procedures are being denied. Patients, who dispute health plan denials because procedures are not considered medically necessary or they are considered experimental or investigations, can appeal disputes to the California Independent Medical Review (IMR). Out of 6,231 IMR decisions rendered since 2001, 15 disputes were related to MRI and breast cancer screening, the majority in connection with post-diagnosis use of the test. No IMR decisions were related to mammography, ultrasound or computer-aided detection.

The following tables provide a review of the information the Cost Impact Team included in the analysis.

[13] Personal communication with S. Lowenstein, DMHC, March 2008.

Table 7. Baseline (Premandate) Per Member Per Month Premium and Expenditures by Insurance Plan Type, California, 2008

	Large Group		Small Group		Individual		CalPERS	Medi-Cal		Healthy Families	
	DMHC-Regulated	CDI-Regulated	DMHC-Regulated	CDI-Regulated	DMHC-Regulated	CDI-Regulated	HMO[a]	Managed Care 65 yrs and Over	Managed Care Under 65 yrs	Managed Care	Total Annual
Population currently covered	11,721,000	342,000	3,256,000	728,000	1,299,000	812,000	815,000	172,000	2,532,000	685,000	22,362,000
Average portion of premium paid by employer	$238.92	$315.18	$245.82	$296.00	$0.00	$0.00	$300.92	$181.00	$120.01	$78.35	$54,695,911,000
Average portion of premium paid by employee	$54.60	$86.99	$93.75	$62.26	$294.46	$160.95	$53.10	$0.00	$0.80	$6.81	$19,001,902,000
Total premium	$293.53	$402.17	$339.57	$358.26	$294.46	$160.95	$354.02	$181.00	$120.81	$85.17	$73,697,813,000
Member expenses for covered benefits (deductibles, copays, etc.)	$15.78	$45.50	$24.95	$95.56	$50.61	$39.36	$18.26	$0.00	$0.56	$2.32	$5,602,060,000
Member expenses for benefits not covered	$0.02	$0.02	$0.02	$0.02	$0.02	$0.02	$0.02	$0.00	$0.02	$0.00	$4,753,000
Total expenditures	$309.32	$447.69	$364.54	$453.84	$345.08	$200.33	$372.30	$181.00	$121.38	$87.49	$79,304,626,000

Source: California Health Benefits Review Program, 2008.

Notes: The population includes individuals and dependents in California who have private insurance (group and individual) or public insurance (e.g., CalPERS, Medi-Cal, Healthy Families, Access for Infants and Mothers [AIM], Major Risk Medical Insurance Program [MRMIP]) under health plans or policies regulated by DMHC or CDI. All population figures include enrollees aged 0–64 years and enrollees 65 years or older covered by employment-based coverage.

[a]Of these CalPERS members, about 60% or 489,000 are state employees whose cost is borne by the General Fund.

Key: CalPERS=California Public Employees' Retirement System; CDI=California Department of Insurance; DMHC=Department of Managed Health Care; HMO=health maintenance organization and point of service plan.

Table 8. Postmandate Impacts on Per Member Per Month and Total Expenditures by Insurance Plan Type, California 2008

	Large Group		Small Group		Individual		CalPERS	Medi-Cal		Healthy Families	
	DMHC-Regulated	CDI-Regulated	DMHC-Regulated	CDI-Regulated	DMHC-Regulated	CDI-Regulated	HMO[a]	Managed Care 65 yrs and Over	Managed Care Under 65 yrs	Managed Care	Total Annual
Population currently covered	11,721,000	342,000	3,256,000	728,000	1,299,000	812,000	815,000	172,000	2,532,000	685,000	22,362,000
Average portion of premium paid by employer	$0.79	$0.70	$0.77	$0.64	$0.00	$0.00	$0.65	$0.00	$0.73	$0.00	$178,621,000.00
Average portion of premium paid by employee	$0.18	$0.19	$0.29	$0.14	$0.97	$0.97	$0.11	$0.00	$0.00	$0.00	$64,849,000.00
Total premium	$0.97	$0.89	$1.07	$0.78	$0.97	$0.97	$0.76	$0.00	$0.74	$0.00	$243,469,000.00
Member expenses for covered benefits (deductibles, copays, etc.)	$0.04	$0.08	$0.06	$0.14	$0.12	$0.17	$0.03	$0.00	$0.00	$0.00	$13,457,000.00
Member expenses for benefits not covered	–$0.02	–$0.02	–$0.02	–$0.02	–$0.02	–$0.02	–$0.02	$0.00	–$0.02	$0.00	–$4,753,000.00
Total expenditures	$0.99	$0.95	$1.11	$0.90	$1.07	$1.12	$0.77	$0.00	$0.72	$0.00	$252,173,000.00
Percentage impact of mandate											
Insured premiums	0.33%	0.22%	0.31%	0.22%	0.33%	0.61%	0.22%	0.00%	0.61%	0.00%	0.33%
Total expenditures	0.32%	0.21%	0.30%	0.20%	0.31%	0.56%	0.21%	0.00%	0.59%	0.00%	0.32%

Source: California Health Benefits Review Program, 2008.

Notes: The population includes individuals and dependents in California who have private insurance (group and individual) or public insurance (e.g, CalPERS, Medi-Cal, Healthy Families, Access for Infants and Mothers [AIM], Major Risk Medical Insurance Program [MRMIP]) under health plans or policies regulated by DMHC or CDI. All population figures include enrollees aged 0–64 years and enrollees 65 years or older covered by employment-based coverage.
[a]Of these CalPERS members, about 60% or 489,000, are state employees whose cost is borne by the General Fund.
Key: CalPERS=California Public Employees' Retirement System; CDI=California Department of Insurance; DMHC=Department of Managed Health Care; HMO=health maintenance organization and point of service plan.

PUBLIC HEALTH IMPACTS

Impact of the Proposed Mandate on the Public's Health

Impact of Screening with BMRI

As presented in the Utilization, Cost, and Coverage Impacts section, AB 2234 would be expected to increase utilization of BMRI screening of women at high-risk for breast cancer by 131,000. As presented in the Medical Effectiveness section, the use of BMRI 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 high-risk women, reduces breast cancer mortality or improves health outcomes.

As presented in the Medical Effectiveness section, screening with BMRI increases the rate of false-positive breast cancer diagnoses. The false-positive rates for BMRI range between 4% and 23%. Thus, of the 131,000 additional BMRI screenings, it is estimated that nearly 17,700 would result in false positive test results.[14] Evidence exists as to the potential harms associated with increases in false positives, such as increases in benign biopsies, additional interventions, radiation exposure, and anxiety and discomfort of patients. Furthermore, one study concluded that BMRI led to twice as many unneeded additional examinations as did mammography and three times as many unneeded biopsies (Kriege et al, 2004).

Therefore, there is insufficient evidence to draw a conclusion as to the potential public health benefit of AB 2234, whereas some evidence exists as to the potential harms associated with increases in false positives and benign biopsies resulting from increased BMRI screening.

Impact of Screening with Mammogram

As presented in the Utilization, Cost, and Coverage Impacts section, all health plans subject to AB 2234 currently cover mammography in accordance with national guidelines. It is estimated that there would be an increase in the utilization rate of mammography among 40-year-old women as the notification requirement of AB 2234 is enacted. It is estimated that 19,000 additional women receive mammograms each year. Because plans and insurers may be required to do less than assumed in this analysis to achieve compliance with the notification component of AB 2234, the effect of the notification in this analysis should be considered an upper bound estimate.

A meta-analysis compiled by the USPSTF on the effectiveness of breast cancer screening with mammograms concluded that the relative risk of breast cancer mortality was 0.84

[14] A false-positive rate of 13.5% was used in this calculation.

(Humphrey et al., 2002). This translates into needing to screen 1,224 women to prevent one death from breast cancer. Using these data, it is estimated that screening an additional 19,000 women with mammography would, over time, prevent nearly 16 deaths per year from breast cancer in this group of women (this benefit would not be realized until 14 years following the implementation of AB 2234).

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

Breast cancer overwhelmingly affects women, although a small number of cases are diagnosed in men, as well. In California, it is estimated that 0.6% of cases of breast cancer occur in men—about 130 cases and 30 deaths each year (CCR, 2007).

As presented in Table 9, the incidence of breast cancer in California varies by race/ethnicity, with non-Hispanic whites having the highest rates (148.4 per 100,000 women), followed by blacks (118.1 per 100,000 women), and Asian/Pacific Islanders and Hispanics having the lowest rates (92.9 and 87.0 per 100,000 women, respectively) (Kwong et al., 2005). 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).

Screening rates using mammography vary by race/ethnicity among insured women ages 40–64 years. Black (83.4%) and non-Hispanic white (82.5%) women report breast cancer screening using mammography in the last 2 years at significantly higher rates compared to Hispanic women (74.8%) (CHIS, 2005). There are 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 (61%) and Hispanics (63%) having lower rates of early diagnosis compared to non-Hispanic whites (71%) or Asian/Pacific Islanders (70%) (CCR, 2007). Mortality rates from breast cancer vary by race/ethnicity, with blacks having the highest rates (33.0 per 100,000 women), followed by non-Hispanic whites (26.0 per 100,000 women), and Hispanics and Asian/Pacific Islanders having the lowest mortality rates (16.0 and 14.7 per, 100,000 women, respectively) (Kwong et al., 2005).

There is no published research that examines the effects of one time written notification on mammography screening rates across different racial and ethnic groups (Wagner, 1998). Therefore, there is insufficient evidence to determine whether AB 2234 would reduce the racial/ethnic disparities screening rates and health outcomes associated with breast cancer.

Extent to Which the Proposed Service Reduces Premature Death and the Economic Loss Associated with Disease.

There are more than 4,200 deaths in California each year due to breast cancer (CCR, 2007). As discussed elsewhere in this report, it is estimated that AB 2234 could lead to a reduction in breast-cancer–related mortality through increased utilization of mammograms. Of the additional 19,000 women screened each year with mammograms,

it is estimated that 16 premature deaths from breast cancer among this population would be prevented every year over time. 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 loss of 22.9 life-years and a cost of lost productivity of $272,000 in 2001 dollars (Max, 2006). A reduction in 16 premature deaths each year (this benefit would not be realized until 14 years following implementation of AB 2234) would translate into a savings of 366 life-years and 4.4 million dollars in lost productivity.

Long-Term Public Health Impacts

The data presented in the public health impact section assume a time frame of more than 1 year to realize a reduction in premature death from an increase in mammography screening. In the meta analysis conducted by the USPSTF, an average of 14 years of follow-up were used to assess related breast cancer mortality among women in mammography screening trials (Humphrey et al., 2002). Therefore, it would take an average of 14 years to see the reduction in 16 deaths per year as a result of increased mammography screening occurring following implementation of AB 2234.

Table 9. Incidence, Mortality, and Screening for Breast Cancer Overall and by Race/Ethnicity in California

Population	Incidence Rate[a]	Screening Rate[b]	Cancer Found at an Early Stage[c]	Mortality Rate[d]
Overall	126.7	80.5% (79.5–81.6)	69%	23.2
Hispanic	87.0	74.8% (71.1–78.4)	63%	16.0
Non-Hispanic white	148.4	82.5% (81.3–83.7)	71%	26.0
Black	118.1	83.4% (79.7–87.2)	61%	33.0
Asian/Pacific Islander	92.9	78.2% (74.9–81.5)	70%	14.7

Sources and Notes: [a]Data taken from Kwong et al., 2005. Incidence rate is defined as number of cases per 100,000 women in California in 2002.
[b]Data taken from CHIS, 2005. Screening is reported as mammography within the last 2 years for women ages 40–64 years with health insurance.
[c]Data taken from CCR, 2007. Early stage is defined as cancer found in situ or localized. Data is for 2004.
[d]Data taken from Kwong et al., 2005. Mortality rate is defined as number of deaths per 100,000 women in California in 2002.

APPENDICES

Appendix A: Text of Bill Analyzed

BILL NUMBER: AB 2234 INTRODUCED
BILL TEXT

INTRODUCED BY Assembly Members Portantino and Wolk
(Principal coauthor: Senator Negrete McLeod)
(Coauthors: Assembly Members Berg and Dymally)

FEBRUARY 20, 2008

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.

LEGISLATIVE COUNSEL'S DIGEST

AB 2234, as introduced, Portantino. Health care coverage: breast conditions.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Under existing law, a health care service plan contract, except a specialized health care service plan contract, that is issued, amended, delivered, or renewed on or after January 1, 2000, is deemed to provide coverage for mammography for screening or diagnostic purposes upon referral by a participating nurse practitioner, participating certified nurse midwife, or participating physician, providing care to the patient and operating within the scope of practice provided under existing law. Under existing law, an individual or group policy of disability insurance or self-insured employee welfare benefit plan that is issued, amended, delivered, or renewed on or after January 1, 2000, is deemed to provide specified coverage based upon age for mammography for screening or diagnostic purposes upon referral by a participating nurse practitioner, participating certified nurse midwife, or participating physician, providing care to the patient and operating within the scope of practice provided under existing law.

This bill would provide that such plans or policies issued, amended, delivered, or renewed on and after January 1, 2009, shall be deemed to provide coverage for tests necessary for screening or diagnoses, as specified, of breast conditions upon referral of a participating nurse practitioner, participating certified nurse midwife, or participating physician, providing care to the patient and operating within the scope of practice provided under existing law and in accordance with national guidelines. The bill would also require these plans and insurers to send female enrollees or policyholders a written

notice, as specified, regarding eligibility for tests for screening or diagnosis of breast conditions.

Because this bill would specify an additional requirement for a health care service plan, the willful violation of which would be a crime, it would impose a state-mandated local program.

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

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

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

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. The Legislature hereby finds and declares the following:

(a) It is the intent of the Legislature to ensure that all women have access to medically appropriate breast cancer screening and diagnostic tests, especially those women who possess risk factors, including any of the following:

(1) A woman who has had a personal history of breast cancer, including ductal carcinoma in situ (DCIS).

(2) A woman who has been identified as having the BRCA1 or BRCA2 gene mutation or is a first degree relative of someone identified as having the BRCA1 or BRCA2 gene mutation.

(3) A woman who has two or more first degree relatives with breast cancer diagnosed before 50 years of age.

(4) A woman who has been diagnosed with Li-Fraumeni syndrome (LFS), Cowden syndrome, or Bannayan-Riley-Ruvalcaba syndrome (BRRS), or who has a first degree relative who has been diagnosed with one of those syndromes.

(5) A woman identified with a lifetime risk of breast cancer of 20 percent or greater, as defined by the BRCAPRO model or other models that are largely dependent upon family history.

(6) A woman who has experienced radiation to her chest between 10 to 30 years of age, inclusive.

(7) A woman who has been diagnosed with lobular carcinoma in situ (LCIS) or atypical lobular hyperplasia (ALH).

(8) A woman who has been diagnosed with atypical ductal hyperplasia (ADH).

(9) A woman with heterogeneously or extremely dense breast tissue on mammography.

(b) In order to protect the health of California citizens, breast cancer diagnostic methods such as mammography, magnetic resonance imaging (MRI), and ultrasound must be provided. These diagnostic treatment tools, when used together in accordance with nationally accepted guidelines, offer the best chance for the detection and timely, cost-effective treatment of breast cancer.

SEC. 2. Section 1367.65 of the Health and Safety Code is amended to read:

1367.65. (a) On or after January 1, 2000, every health care service plan contract, except a specialized health care service plan contract, that is issued, amended, delivered, or renewed shall be deemed to provide coverage for mammography for screening or diagnostic purposes upon referral by a participating nurse practitioner, participating certified nurse midwife, or participating physician, providing care to the patient and operating within the scope of practice provided under existing law.

(b) On or after January 1, 2009, every health care service plan contract, except for a specialized health care service plan contract, that is issued, amended, delivered, or renewed shall be deemed to provide coverage for tests necessary for screening or diagnoses of breast conditions, upon referral. Necessary tests shall encompass those tests consistent with national guidelines and shall include, but not be limited to, mammography, magnetic resonance imaging, ultrasound, and computer-aided detection. Referral shall be made by a participating nurse practitioner, participating certified nurse midwife, or participating physician, providing care to the patient and operating within the scope of practice provided under existing law and in accordance with national guidelines.

~~(b)~~

(c) Nothing in this section shall be construed to prevent application of copayment or deductible provisions in a plan, nor shall this section be construed to require that a plan be extended to cover any other procedures under an individual or a group health care service plan contract. Nothing in this section shall be construed to authorize a plan enrollee to receive the services required to be covered by this section if those services are furnished by a nonparticipating provider, unless the plan enrollee is referred to that provider by a participating physician, nurse practitioner, or certified nurse midwife providing care.

(d) A health care service plan subject to this section shall send a female enrollee a written notice, during the calendar year in which national guidelines indicate she should start undergoing tests for screening or diagnosis of breast conditions, notifying her that she is eligible for testing.

SEC. 3. 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, 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 *years* and over.

(b) On or after January 1, 2009, every individual or group policy of health insurance or self-insured employee welfare benefit plan that is issued, amended, delivered, or

renewed, shall be deemed to provide coverage for tests necessary for screening or diagnoses of breast conditions, upon referral. Necessary tests shall encompass those tests consistent with national guidelines and shall include, but not be limited to, mammography, magnetic resonance imaging, ultrasound, and computer-aided detection. Referral shall be made by a participating nurse practitioner, participating certified nurse midwife, or participating physician, providing care to the patient and operating within the scope of practice provided under existing law and in accordance with national guidelines.

~~Nothing~~

(c) 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~~

(d) 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, nurse practitioner, or certified nurse midwife providing care.

(e) A disability insurer or self-insured employee welfare benefit plan subject to this section shall send a female policyholder a written notice, during the calendar year in which national guidelines indicate she should start undergoing tests for screening or diagnosis of breast conditions, notifying her that she is eligible for testing.

(f) This section shall not apply to Medicare supplement, vision-only, dental-only, or Champus-supplement insurance, or to hospital indemnity, accident-only, or specified disease insurance that does not pay benefits on a fixed-benefit, cash payment only basis.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Appendix B: Literature Review Methods

Appendix B describes methods used in the medical effectiveness literature review for AB 2234. The literature search included meta-analyses, systematic reviews, randomized controlled clinical trials (RCTs), and observational studies. PubMed and the Cochrane library were searched. Web sites of government agencies and other organizations engaged in breast cancer surveillance activities and research were also searched.

The search was conducted to retrieve literature on four major topics: (1) the effectiveness of screening tests for breast cancer; (2) the effectiveness of notification of eligibility for screening; (3) the cost effectiveness of screening tests for breast cancer and notification; and (4) the public health effects of screening tests for breast cancer and notification of eligibility for screening. The medical effectiveness review addressed the first two topics, and the cost and public health reviews addressed the third and fourth topics, respectively.

The medical effectiveness literature search focused on articles published since 2002 to the present. For all topics, the literature review was limited to articles published in English and focusing on a target population of all adult women. An additional search between 1995 and 2002 was conducted for notification studies, as the initial search did not yield pertinent studies. Furthermore, all the national guidelines were collected through national Web sites such as the Centers for Disease Control and Prevention and the National Guideline Clearinghouse database.

Three hundred and ten abstracts were reviewed for the literature review for AB 2234. At least two reviewers screened the title and abstract of each citation returned by the literature search to determine eligibility for inclusion. Full-text articles were obtained, and reviewers reapplied the initial eligibility criteria. A total of 20 studies were included in the medical effectiveness review, including the notification studies and one RCT regarding conventional mammography.

Out of 25 obtained guidelines, eight guidelines were included in the medical effectiveness review.

The review of the effectiveness of screening tests for breast cancer summarized findings from meta-analyses and systematic reviews of primarily observational studies and RCTs as well as three RCTs that were not included in the meta-analyses and systematic reviews. RCTs provide the strongest evidence of effectiveness.

The California Health Benefits Review Program (CHBRP) focused on four major screening modalities, including computer-aided detection mammography, screen-film mammography versus full-field digital mammography, ultrasound, and breast magnetic resonance imaging (MRI). These are relatively new techniques for screening, and with the exception of two RCTs for digital mammography, there are no randomized trials in this area. Additionally, CHBRP focused on written notification of routine mammography to eligible women and summarized three meta-analyses of RCTs.

In making a “call” for each outcome measure, the team 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,
- 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.

The search terms used to locate studies relevant to the AB 2234 were as follows:

MeSH Terms
Breast Neoplasms
Breast Neoplasms/diagnosis
Breast Neoplasms/ultrasonography
Mammography
Ultrasonography, Mammary
Xeromammography
Biopsy, Needle
Biopsy, Fine-Needle
Magnetic Resonance Imaging

Image Interpretation, Computer-Assisted
Radiographic Image Interpretation, Computer-Assisted
Diagnosis, Computer Assisted
Mass Screening
Insurance Carriers
Costs and Cost Analysis

Keywords
Screen?
Notify or Notification?
Remind or Reminder?
Insurance Costs
MRI
Breast Cancer
Mammogram?
Ultrasound

? Indicates truncation of the word stem

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

Appendix C: Summary Findings on Medical Effectiveness

Description of Studies on Medical Effectiveness of Breast Cancer Screening Modalities and Written Notification of Eligibility for Screening

Appendix C describes the meta-analyses, systematic reviews, and individual studies on breast cancer screening modalities and written notification of eligibility for screening that were analyzed by the medical effectiveness team. In addition to the tables, one RCT regarding conventional mammography (Moss et al., 2006) was included in the text of the Medical Effectiveness analysis. Table C-1 summarizes national breast cancer screening guidelines. Tables C-2 through C-6 present information regarding the citation, type of study, intervention and comparison groups, population studied, and the location at which the study was conducted. Table C-2 lists studies that assessed the effectiveness of computer-aided detection (CAD). Table C-3 lists studies that assessed the effectiveness of digital mammography. Table C-4 lists studies that assessed the effectiveness of ultrasound. Table C-5 lists studies that assessed the effectiveness of breast magnetic resonance imaging (BMRI). Table C-6 lists studies that assessed the effectiveness of written notification on mammography screening rates.

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

#	Guideline Developer	Evidence or Consensus Based	Issue Year	Screening Age Range for Average-Risk Population	Screening Interval for Average-Risk Population	Factors Elevating Risk for Breast Cancer	Screening Age Range (for High-Risk Population)	Screening Interval (for High-Risk Population)	Note
1	**US Preventive Services Task Force:** Screening for Breast Cancer: Recommendations and Rationale (USPSTF, 2002)	Evidence based	2002	40 + yrs and continuing as long as no comorbid conditions affect life expectancy	Every 12 to 24 months	Women with factors contributing to increased risk (family history, atypical hyperplasia, first birth after 30 yrs) are more likely to benefit from mammography screening than those at average risk	No specific recommendation	No specific recommendation	Breast cancer grows more rapidly in women between ages 40 and 49 yrs, so shorter intervals have been advocated for mammography

#	Guideline Developer	Evidence or Consensus Based	Issue Year	Screening Age Range for Average-Risk Population	Screening Interval for Average-Risk Population	Factors Elevating Risk for Breast Cancer	Screening Age Range (for High-Risk Population)	Screening Interval (for High-Risk Population)	Note
2	**American Cancer Society**: Guidelines for Breast Cancer Screening Update 2003 (Smith et al., 2003)	Evidence based	2003	40 + yrs and continuing as long as woman is in good health	Annually	*BRCA1* or *BRCA2* mutation; 2 or more relatives with BC or ovarian cancer BC occurring before age 50 yrs in an affected relative; relative with both breast and ovarian cancer One or more relative with two cancers Male relative with BC A family history of breast cancer or ovarian cancer and Ashkenazi Jewish heritage Previous treatment with chest irradiation Personal history of breast cancer Family history of diseases such as Li-Fraumeni or Cowden syndrome	30 yrs, depending on risk factors (see Notes)	Points of discussion developed for patient and physician to consider when weighing screening options. See (2a) 2007 revision	Women should be educated about the benefits, limitations, and harms of screening Women at high-risk might benefit from other strategies such as earlier screening initiation, shorter screening intervals, or addition of other modalities such as ultrasound, MRI*

#	Guideline Developer	Evidence or Consensus Based	Issue Year	Screening Age Range for Average-Risk Population	Screening Interval for Average-Risk Population	Factors Elevating Risk for Breast Cancer	Screening Age Range (for High-Risk Population)	Screening Interval (for High-Risk Population)	Note
2a	**American Cancer Society**: Guidelines for Breast Cancer Screening With MRI as an Adjunct to Mammography[a] (Saslow et al., 2007)	Evidence based and consensus based	2007	Same as 2003	Same as 2003	*BRCA1* or *BRCA2* mutation First degree relative of *BRCA* carrier, but untested Lifetime risk >20% (women with 15%–20% lifetime risk should consult their physician about benefits/risks to adding BMRI	30–69 yrs	Mammography with adjunct breast MRI annually for women with risk greater than 20%	Women with lifetime risk 15%–20% should be advised on benefits and risks of MRI MRI not recommended for those with lifetime risk less than 15%
3	**American College of Physicians**: Screening Mammography for Women 40–49 Years of Age: A Clinical Practice Guideline (Qauseem et al., 2007)	Evidence based	2007	40–49 yrs (see Notes)	Clinician perform risk assessment for breast cancer every 1 to 2 years Clinician inform patients about potential benefits and harms of screening mammography	Older age Family history. Older age at the time of first birth Younger age at menarche History of breast biopsy Women 40–49 yrs with any of the below have a higher risk of breast cancer than the average 50-yr-old woman: Two first-degree relatives with breast cancer Two previous breast biopsies			Guideline focuses only on mammography in ages 40 to 49 yrs Seven out of eight meta-analyses used in the guideline estimated that mammography screening in ages 40 to 49 yrs reduced breast cancer mortality rate, but only three studies found statistically significant results

#	Guideline Developer	Evidence or Consensus Based	Issue Year	Screening Age Range for Average-Risk Population	Screening Interval for Average-Risk Population	Factors Elevating Risk for Breast Cancer	Screening Age Range (for High-Risk Population)	Screening Interval (for High-Risk Population)	Note
						One first-degree relative with breast cancer and one previous breast biopsy Previous diagnosis of breast cancer Ductal carcinoma in situ or atypical hyperplasia Previous chest irradiation or *BRCA1* or *BRCA2* mutation			
4	**American College of Obstetrician and Gynecologists**: Breast Cancer Screening (ACOG, 2003)	Evidence based	2003	40–49 yrs 50+ yrs	Every 1 to 2 years Annually	No recommendation	No recommendation	No recommendation	
5	**American Society of Clinical Oncology**: 2006 Update of the Breast Cancer Follow-Up and Management Guidelines in the Adjuvant	Evidence based	2006	Guideline for those with history of breast cancer	—	Guideline only about patients with the history of breast cancer	Only those with history of breast cancer	Mammography[b] year after breast-conserving surgery and at least 6 months after completion of radiation therapy. Annual mammography thereafter unless otherwise	Use of complete blood counts, chemistry panels, bone scans, chest radiographs, liver ultrasounds, CT scans, MRI,or tumor markers are not recommended for routine breast cancer follow-up.

#	Guideline Developer	Evidence or Consensus Based	Issue Year	Screening Age Range for Average-Risk Population	Screening Interval for Average-Risk Population	Factors Elevating Risk for Breast Cancer	Screening Age Range (for High-Risk Population)	Screening Interval (for High-Risk Population)	Note
	Setting (ASCO, 2006)							indicated	
6	**American Society of Breast Disease**: Use of Magnetic Resonance Imaging of the Breast (MRIB) for Screening Women at High Risk of Breast Cancer (ASBD, 2004)	Evidence based	2004	No recommendations for average-risk women	—	No data on BMRI in women with these risk factors: Personal history of breast cancer Previous chest radiation Lobular carcinoma in situ Atypical hy/perplasia Mutations other than *BRCA*	Use of BMRI for screening of women at high risk of breast cancer based on family history or *BRCA* mutation	The appropriate interval for BMRI is not determined yet based on literature	

Source: California Health Benefits Review Program, 2008

[a]MRI screening recommendations are new from 2003.

[b]Gail model: The Gail model uses risk factors such as age, family history of breast cancer, age of the first menstrual period and first pregnancy, and number of breast biopsies to calculate a woman's risk of developing breast cancer within the next 5 years.

Key: BC=breast cancer; CT=computed tomography; MRI=magnetic resonance imaging.

Table C-2. Summary of Published Studies on Effectiveness of Computer-Aided Detection (CAD) in Breast Cancer Screening

Citation	Type of Study	Intervention vs. Control Group	Population Studied	Location
Fenton et al., 2007	Retrospective diagnostic test evaluation	Compared screening mammography with and without CAD	222,135 women aged 40+ yrs with no history of breast cancer for routine screening mammography (429,345 mammograms studied from 43 facilities)	United States (three states)
Morton et al., 2006	Prospective diagnostic test evaluation	Compared screening mammography with and without CAD	18,096 asymptomatic women ages 23–98 yrs (mean age 60 yrs)	Rochester, MN
Helvie et al., 2004	Prospective diagnostic test evaluation (pilot trial)	Compared screening mammography with and without CAD	2,389 patients of any age undergoing routine mammography screening	United States (two academic medical centers)
Dean and Ilvento, 2006	Prospective diagnostic test evaluation	Compared screening mammography with and without CAD	9,520 consecutive mammograms (screening and diagnostic) of women aged 32–94 yrs (mean age 58 yrs)	United States (single site)
Freer and Ulissey, 2001	Prospective diagnostic test evaluation	Compared screening mammography with and without CAD	12,860 consecutive screening mammograms of women aged 26–88 yrs (mean age 49 yrs) with and without CAD	Texas (single site)

Source: California Health Benefits Review Program, 2008.
Key: CAD=computer-assisted detection.

Table C-3. Summary of Published Studies on Effectiveness of Screen Film Mammography vs. Full-Field Digital Mammography

Citation	Type of Study	Intervention vs. Control Group	Population Studied	Location
Skaane et al., 2007	Randomized clinical trial	A prospective study of screen-film mammography (SFM) vs. full-field digital mammography (FFDM) with soft copy	23,929 women aged 45–69 yrs were assigned to undergo SFM (n=16,985) or FFDM (n=6,944). Women aged 45–49 yrs were followed up for 1.5 yrs, and women aged 50–69 yrs were followed up for 2.0 yrs	Norway (2 sites)
Pisano et al., 2005	Prospective diagnostic test evaluation	Applying both digital and film mammography for all the subjects	42,760 asymptomatic women with a mean age of 55 yrs presenting for screening mammography were followed for 15 months	United States, Canada (33 sites)
Skaane and Skjennald, 2004	Randomized clinical trial	A screening program with SFM vs. FFDM with soft copy	43,429 women invited, 25,263 women aged 45–69 yrs were randomized, with adjustments for age and area of residence, to undergo SFM or FFDM in a population-based screening program	Norway

Source: California Health Benefits Review Program, 2008.

Table C-4. 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 one to three annual screening(s) for breast cancer	Canada
Chan et al., 2007	Prospective diagnostic test evaluation study	Compared patient age and size of tumor detected by mammography alone and by ultrasound alone in women with clinically and mammographically occult breast cancer	1,485 cases of confirmed breast cancer in women aged 24–91 yrs (mean age 49 yrs)	Hong Kong
Corsetti et al., 2008	Prospective diagnostic test evaluation study	Ultrasound for women with mammographically occult breast cancer	9,157 women with dense breast tissue and negative mammograms	Italy

Source: California Health Benefits Review Program, 2008.
Key: MRI=magnetic resonance imaging.

Table C-5. 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 five 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 eight 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 Kingsom, United States, other
Lehman et al., 2007	Prospective diagnostic test evaluation	Clinical breast examination and mammography vs. BMRI	969 women with a recent diagnosis of unilateral breast cancer and no abnormalities on mammographic and clinical examination of the contralateral breast	United States
Hagen et al., 2007	Prospective diagnostic test evaluation	BMRI vs. conventional screening (mammography ± ultrasound)	445 women with *BRCA1* and 46 women with *BRCA2* mutation (age range 18–79 years; mean age 41 yrs)	Norway
Kriege et al., 2004	Prospective diagnostic test evaluation	BMRI vs. mammography	1,909 women with >15% lifetime risk for breast cancer (age range 19–72 yrs; mean age 40 yrs)	Netherlands

Source: California Health Benefits Review Program, 2008.
[a]All studies included in the Lord et al. (2007) meta-analysis are included in the American Cancer Society 2007 review for MRI Screening Guidelines.
[b]Two studies included in the Bermejo-Perez et al. (2008) systematic review are included in the ACS-NCCN review for MRI Screening Guidelines. Three studies in the Bermejo-Perez et al. (2008) study are also included in the Lord et al. (2007) meta-analysis.
Key: BMRI=breast magnetic resonance imaging; CBE=clinical breast exam.

Table C-6. Summary of Published Studies on Effectiveness of Notification or Reminders for Breast Cancer Screening

Citation	Type of Study	Intervention vs. Control Group	Population Studied	Location
Sohl and Moyer, 2007[a]	Meta-analysis of 28 RCTs	Tailored interventions including print reminders compared to "usual care" control groups	33,227 women eligible for mammography screening	Not stated
Wagner, 1998	Meta-analysis of 11 RCTs	Mailed patient reminders at increasing mammography screening	More than 16,000 women eligible for mammography screening	U.S.
Stone et al., 2002[b]	Meta-analysis of 29 RCTs about interventions increasing use of adult immunization and cancer screening services	Patient reminders (delivered verbally, on paper, or by computer screen) compared to other interventions (e.g., organizational change, education, financial incentives, etc.)	Population undefined	U.S.

Source: California Health Benefits Review Program, 2008.
[a]The Sohl and Moyer (2007) and Stone et al. (2002) meta-analyses both include studies by Davis et al., 1997 and Janz et al., 1997.
[b]The Stone et al. (2002) and Wagner (1998) meta-analyses both include studies by Lantz et al., 1995; Landis et al., 1992; Mandelblatt and Kanesky, 1995; and Taplin et al., 1994.
Key: RCT=randomized controlled clinical trial.

Appendix D: Summary Findings on Medical Effectiveness of Ultrasound/Ultrasonography

Table D-1. Summary of Findings of Medical Effectiveness of Ultrasound for Breast Cancer Screening

Citation	Outcome	Research Design	Sensitivity/ Specificity PPV	Recall Rate/ Cancer Detection Rate	Generalizability (to Population Affected by Mandate) And Size of Effect	Conclusion
Warner et al., 2004	Sensitivity Specificity	**Level III:** An observational study to evaluate of 236 women aged 25 to 65 with *BRCA1* or *BRCA2* mutation 236 women aged 26 to 65 yrs	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	Somewhat generalizable since the study focused only on women with *BRCA1/2* mutation carrier No clinically meaningful effect was found	In *BRCA1* and *BRCA2* mutation carriers, MRI is more sensitive for detecting breast cancers than mammography, ultrasound, or CBE alone
Chan et al., 2007	Sensitivity	**Level III:** An observational study to evaluate the performance of high-resolution ultrasonography in the detection of clinically and mammographically occult breast cancer 1,379 women aged 24–91 yrs	Mammography and ultrasound: 94% Mammography only: 78% Ultrasound only: 91% P=0.001	Improved cancer detection rate by 14.3%	Somewhat generalizable due to target population of the study (those with clinically and mammographically occult breast cancer) A small, clinically meaningful effect was found for younger women and women with dense breasts	The use of ultrasonography may lead to detection of a significant number of occult cancers that are no different in size from nonpalpable mammographically detected lesions

Citation	Outcome	Research Design	Sensitivity/ Specificity PPV	Recall Rate/ Cancer Detection Rate	Generalizability (to Population Affected by Mandate) And Size of Effect	Conclusion
Corsetti et al., 2008	Incremental cancer detection rate	**Level III:** An observational study to evaluate the performance of ultrasonography in women with dense breasts and breast cancer not detected with standard mammography 9,157 women		Ultrasound incremental cancer detection rate[1]: Overall: 0.40% (CI 0.39–0.41%) Women <50 yrs: 0.33% Women 50+yrs: 0.51%	Somewhat generalizable due to study population which comprises women with dense breasts and breast cancer not detected with standard mammography A small, clinically meaningful effect was found for women with mammography-negative dense breasts	Ultrasound detects early-stage cancers in women with mammography-negative dense breasts, with higher contribution in women younger than 50 yrs. The additional false-positive biopsy rate was lower than other studies

Source: California Health Benefits Review Program, 2008
[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.

Appendix E: 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, http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

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

Data Sources

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

Private health insurance

1. The latest (2005) California Health Interview Survey (CHIS), which is utilized to estimate insurance coverage for California's population and distribution by payer (i.e., employment-based, privately purchased, or publicly financed). The biannual CHIS is the largest state health survey conducted in the United States, collecting information from over 40,000 households. More information on CHIS is available at www.chis.ucla.edu/

2. The latest (2007) California Employer Health Benefits Survey is utilized to estimate:

   - size of firm,
   - percentage of firms that are purchased/underwritten (versus self-insured),
   - premiums for plans regulated by the Department of Managed Health Care (DMHC) (primarily health maintenance organizations [HMOs]),
   - premiums for policies regulated by the California Department of Insurance (CDI) (primarily preferred provider organizations [PPOs]), and
   - premiums for high-deductible health plans (HDHP) for the California population covered under employment-based health insurance.

   This annual survey is 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 are available at: http://www.chcf.org/topics/healthinsurance/index.cfm?itemID=133543.

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

- The MEDSTAT 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 (2006 Group Health Insurance Survey) contains data from seven major California health plans regarding their 2005 experience.
- Ingenix MDR Charge Payment System, which includes information about professional fees paid for health care 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, Blue Cross of California, Blue Shield of California, CIGNA, Health Net, Kaiser Foundation Health Plan, and PacifiCare) to obtain estimates of baseline enrollment by purchaser (i.e., large and small group and individual), type of plan (i.e., DMHC- or CDI-regulated), cost-sharing arrangements with enrollees, and average premiums. Enrollment in these seven firms represents 85% of enrollees in full-service health plans regulated by DMHC and 94% of lives covered by comprehensive health insurance products regulated by CDI.[15]

Public health insurance

5. Premiums and enrollment in DMHC- and CDI-regulated plans by self-insured status and firm size are obtained annually from the California Public Employees' Retirement System (CalPERS) for active state and local government public employees and their family members who receive their benefits through CalPERS. Enrollment information is provided for fully funded, Knox-Keene

[15] CHBRP analysis of the share of insured members included in CHBRP's 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, 2006 by the California Department of Insurance, Statistical Analysis Division and data retrieved from The Department of Managed Health Care's interactive web site "Health Plan Financial Summary Report," December, 2007.

licensed health care service plans covering non-Medicare beneficiaries—which is about 75% of CalPERS total enrollment. CalPERS self-funded plans—approximately 25% of enrollment—are not subject to state mandates. In addition, CHBRP obtains information on current scope of benefits from health plans' evidence of coverage (EOCs) publicly available at www.calpers.ca.gov.

6. Enrollment in Medi-Cal Managed Care (Knox-Keene licensed plans regulated by DMHC) is estimated based on CHIS and data maintained by the Department of Health Care Services (DHCS). DHCS supplies CHBRP with the statewide average premiums negotiated for the Two-Plan Model, as well as generic contracts that summarize the current scope of benefits. CHBRP assesses enrollment information online at www.dhs.ca.gov/admin/ffdmb/mcss/RequestedData/Beneficiary%20files.htm.

7. Enrollment data for other public programs—Healthy Families, Access for Infants and Mothers (AIM), and the Major Risk Medical Insurance Program (MRMIP)—are estimated based on CHIS and data maintained by the Major Risk Medical Insurance Board (MRMIB). The basic minimum scope of benefits offered by participating plans under these programs must comply with all requirements of the Knox-Keene Act, and thus these plans are affected by changes in coverage for Knox-Keene licensed plans. CHBRP does not include enrollment in the Post-MRMIB Guaranteed-Issue Coverage Products as these individuals are already included in the enrollment for individual health insurance products offered by private carriers. Enrollment figures for AIM and MRMIP are included with enrollment for Medi-Cal in presentation of premium impacts. Enrollment information is obtained online at www.mrmib.ca.gov/. Average statewide premium information is provided to CHBRP by MRMIB staff.

General Caveats and Assumptions

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

- Prevalence of breast cancer, the proportion of women at high risk for breast cancer, and the use of BMRIs before and after the mandate may be different from CHBRP assumptions.
- Utilization of mandated services before and after the mandate may be different from CHBRP assumptions.
- Random fluctuations in the utilization and cost of health care services may occur.

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

- Cost impacts are shown only for people with insurance and only for the first year after enactment of the proposed mandate.

- The projections do not include people covered under self-insured employer plans because those plans are not subject to state-mandated minimum benefit requirements.
- Employers and employees will share proportionately (on a percentage basis) in premium rate increases resulting from the mandate. In other words, the distribution of premium paid by the subscriber (or employee) and the employer will be unaffected by the mandate.
- For state-sponsored programs for the uninsured, the state share will continue to be equal to the absolute dollar amount of funds dedicated to the program.
- When cost savings are estimated, they reflect savings realized for 1 year. Potential long-term cost savings or impacts are estimated if existing data and literature sources are available and provide adequate detail for estimating long-term impacts. For more information on CHBRP's criteria for estimating long-term impacts please see: http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php
- Several recent studies have examined the effect of private insurance premium increases on the number of uninsured (Chernew et al., 2005; Glied and Jack, 2003; Hadley, 2006). Chernew et al. estimate that a 10-percent 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 individuals (about 80%), multiplied by 100%, i.e., ({[–0.088/80] × 100} = –0.11). This elasticity converts the *percentage point* decrease in the number of insured into a *percentage* decrease in the number of insured for every 1% increase in premiums. Because each of these studies reported results for the large-group, small-group, and individual insurance markets combined, CHBRP employs the simplifying assumption that the elasticity is the same across different types of markets. For more information on CHBRP's criteria for estimating impacts on the uninsured, please see: http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php

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

- Population shifts by type of health insurance coverage: If a mandate increases health insurance costs, then some employer groups and individuals may elect to drop their coverage. Employers may also switch to self-funding to avoid having to comply with the mandate.
- Changes in benefit plans: To help offset the premium increase resulting from a mandate, health plan members may elect to increase their overall plan deductibles or copayments. Such changes would have a direct impact on the distribution of

costs between the health plan and the insured person, and may also result in utilization reductions (i.e., high levels of patient cost sharing result in lower utilization of health care services). CHBRP did not include the effects of such potential benefit changes in its analysis.

- Adverse selection: Theoretically, individuals or employer groups who had previously foregone insurance may now elect to enroll in an insurance plan postmandate because they perceive that it is to their economic benefit to do so.
- Health plans may react to the mandate by tightening their medical management of the mandated benefit. This would tend to dampen the CHBRP cost estimates. The dampening would be more pronounced on the plan types that previously had the least effective medical management (i.e., PPO plans).
- Variation in existing utilization and costs, and in the impact of the mandate, by geographic area and delivery system models: Even within the plan types CHBRP modeled (HMO—including HMO and 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 these plan types. Utilization also differs within California due to differences in the health status of the local commercial population, provider practice patterns, and the level of managed care available in each community. The average cost per service would also vary due to different underlying cost levels experienced by providers throughout California and the market dynamic in negotiations between health plans and providers. Both the baseline costs prior to the mandate and the estimated cost impact of the mandate could vary within the state due to geographic and delivery system differences. For purposes of this analysis, however, CHBRP has estimated the impact on a statewide level

Bill Analysis-Specific Caveats and Assumptions

No studies of the percentage of the general population of insured women between the ages of 30–64 years at over 20% lifetime risk of breast cancer were available for these analyses. The estimated 3.5% of the population at this level of risk was calculated by the content expert using a number of data sources. These data sources included:

(1) A study of the prevalence of *BRCA1/2* by Harvey A. Risch, et al. Population *BRCA1* and *BRCA2* Mutation Frequencies and Cancer Penetrances: A Kin–Cohort Study in Ontario, Canada (Risch et al., 2006).

(2) Lifetime risk of 20% based on the Gail model using analyses of data from the Group Health of Puget Sound collected by Diana Buist. The data from this study included a random survey of women ages 40 years and older in the enrolled population as well as at the women obtaining mammography. The estimate for women age 30–39 years was extrapolated from women 40–49 years old.

(3) Personal History of Cancer: Breast Cancer Surveillance Consortium, Unpublished surveillance data from Diana Miglioretti.

These calculations only include women with “dense breasts” who are considered highest risk. Women with “heterogeneously dense breast tissue” were not included

because approximately half of all women have heterogeneously dense breasts and would not be considered high risk without other risk factors. Others with risk factors including Li Fraumeni, Cowden, Bannayan-Riley-Ruvalcaba, radiation exposure, lobular carcinoma in situ (LCIS), and atypical ductal hyperplasia were not included in these estimates due to lack of such data. However, the prevalence of these conditions is very small and not expected to significantly increase the percentage of women eligible for BMRI in these analyses.

Appendix F: Information Submitted by Outside Parties

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

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

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

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A group of faculty and staff undertakes most of the analyses that inform 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 analyses. The CHBRP **staff** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and coordinates all external communications, including those with the California Legislature. The level of involvement of members of the CHBRP Faculty Task Force and staff varies on each report, with individual participants more closely involved in the preparation of some reports and less involved in others.

As required by the CHBRP authorizing legislation, UC contracts with a certified actuary, Milliman Inc. (Milliman), to assist in assessing the financial impact of each benefit mandate bill. Milliman also helped with the initial development of CHBRP methods for assessing that impact.

The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance and thoughtful critiques provided by the members of the National Advisory Council. However, the Council does not necessarily approve or disapprove of or endorse this report. CHBRP assumes full responsibility for the report and the accuracy of its contents.

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The California Health Benefits Review Program is administered by the Division of Health Affairs at the University of California Office of the President, Wyatt R. Hume, DDS, PhD, Provost and Executive Vice President - Academic and Health Affairs.