CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

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

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

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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Assembly Bill 2234

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.

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.

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

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 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.)

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

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.

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

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A group of faculty and staff undertakes most of the analysis that informs reports by the California Health Benefits Review Program (CHBRP). The CHBRP **Faculty Task Force** comprises rotating representatives from six University of California (UC) campuses and three private universities in California. In addition to these representatives, there are other ongoing contributors to CHBRP from UC. This larger group provides advice to the CHBRP staff on the overall administration of the program and conducts much of the analysis. The CHBRP **staff** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and coordinates all external communications, including those with the California Legislature. The level of involvement of members of the CHBRP Faculty Task Force and staff varies on each report, with individual participants more closely involved in the preparation of some reports and less involved in others.

As required by 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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