CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Analysis of Assembly Bill 56: Mammography

A Report to the 2009-2010 California Legislature
March 16, 2009

CHBRP 09-01

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.

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Analysis of Assembly Bill 56: Mammography

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PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill (AB) 56, a bill to mandate the coverage of mammography and the notification of eligibility when national guidelines recommend breast cancer screening should begin. In response to a request from the California Assembly Committee on Health on January 15, 2009, 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, and Dominique Ritley, MPH, of the University of California, Davis, prepared the medical effectiveness analysis. Penny Coppernoll-Blach, MLIS, of the University of California, San Diego, conducted the literature search. Helen Halpin, ScM, PhD, and Sara McMenamin, MPH, PhD, of the University of California, Berkeley, prepared the public health impact analysis. Nadereh Pourat, PhD, and Meghan Cameron, MPH, of the University of California, Los Angeles, prepared the cost impact analysis. Jay Ripps, FSA, MAAA, of Milliman, provided actuarial analysis. Rebecca Smith-Bindman, MD, of the University of California, San Francisco, provided technical assistance with the literature review and expert input on the analytic approach. John Lewis, MPA of CHBRP staff, prepared the background section and synthesized the individual sections into a single report. Cherie Wilkerson provided editing services. A subcommittee of CHBRP's National Advisory Council (see final pages of this report) and a member of the CHBRP Faculty Task Force, Wayne Dysinger, MD, MPH, of Loma Linda Medical Center, 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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California Health Benefits Review Program Analysis of Assembly 56: Mammography

The California Assembly Committee on Health requested on January 16, 2009, 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) 56. 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 56 requires health insurance policies regulated by the California Department of Insurance (CDI) to provide coverage for mammography upon provider referral. The bill does not alter the similar and already current mammography coverage mandate for Knox-Keene Health Service plans (Health & Safety Code Section 1367.665), which are regulated by the Department of Managed Care (DMHC). For both plans and policies, the bill mandates that every covered woman be notified in writing by her health care service plan or the carrier of her health insurance policy that she is eligible for testing during the year in which national guidelines indicate she should start screening for breast cancer.

Several terms and phrases in the bill are ambiguous, often due to differences in legal and medical terminology. The full text of AB 56 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. CHBRP makes the following assumptions based on conversations with the staff for the Assembly Member[1], discussions with regulatory agencies, including DMHC, and reasonable legal and layperson interpretation of the bill language.

Screening and Diagnosis—the report focuses on "screening," which denotes testing of asymptomatic individuals in order to identify new cases.

National Guidelines—the bill does not specify any particular set of national guidelines. This report is based on the broad agreement between multiple national organizations (e.g., American Cancer Society, American College of Radiology, United States Preventive Services Task Force) that breast cancer screening should begin as early as age 40 years for women of average risk for breast cancer.

Written Notification and "One-Time, Generic Letter"—the bill language does not specify a precise means of compliance, and "written notification" may take many forms. It may be an article in annual newsletter or a tailored letter (which might include the individual's screening history or other detailed information). In broader terms, notification strategies may differ in other important ways. A strategy may use more than written means (including following up by phone). it may be targeted (sent only to women who have not been screened) or comprehensive (sending notification to all women currently eligible for screening). It may be one-time or on-going

[1] Personal communication, Philip Horner, Office of Assembly Member Portantino, January 2009

(occurring every year or in alternate years). Several of the health plans and insurers surveyed by CHBRP indicated use of some strategy for notification. However, the language of the bill specifies that some form of written notification occur and mandates that all female members/enrollees receive that written notification during the year they become eligible for screening according to national guidelines.

For the purpose of anlaysis, CHBRP assumes universal compliance by carriers with an intermediate method of mandated notification, i.e., sending a *one-time, generic letter* (addressed by name and sent though first-class mail service) to each covered woman during the calendar year she reaches age 40.

Alternative notification strategies could lead to higher or lower estimates of cost and public health impacts than those provided in this report.

Medical Effectiveness

The medical effectiveness analysis considers three points in the AB 56 report: (1) does mammography screening reduce mortality due to breast cancer for women of all eligible ages; (2) does mammography screening reduce breast cancer mortality rates for women ages 40-49 years; and (3) does notification of eligibility for mammography increase the rate of completed screenings.

Effectiveness of Mammography

- There is a preponderance of evidence that, among women ages 40 years and older, mammography screening reduces breast cancer mortality by:
    - 15%-26% after 7 to 9 years of follow-up for women ages 50 years and older, and
    - 15%-17% after 10 to 14 years of follow-up for women ages 40 to 49 years.
- The evidence supporting recommended mammography screening for women ages 40-49 years differs from women ages 50 years and older due to the heterogeneity of breast cancer studies, the difference in breast cancer incidence by age cohort, the difference in the accuracy of mammography (due to breast tissue density), and the resulting impact on breast cancer mortality.
- Harms associated with mammography screening are primarily false-positive readings that result in additional outpatient visits, additional diagnostic imaging, and biopsies. After weighing the evidence, seven national organizations determined that the benefits of mammography outweighed the harms. Each organization issued clinical guidelines recommending, for women of average risk for breast cancer, annual or biennial mammography screening beginning at age 40 (with some guidelines recommending that

screening decisions for the 40- to 49-year cohort be based on a woman's breast cancer risk, her preferences, and her provider's recommendation).

Effectiveness of Notification of Eligibility for Mammography Screening

- There is a preponderance of evidence that notifying women through written notice about routine mammography screening can increase the overall mammography screening rate by about one third.

Utilization, Cost, and Coverage Impacts

Coverage

- An estimated 100% of women insured under California Department of Insurance (CDI)-regulated policies in California currently have coverage for breast cancer screening in accordance with USPSTF guidelines. Therefore, there would be no measurable impact on coverage for mammograms as a result of AB 56.
- There are 160,000 women enrolled in CDI and Department of Managed Health Care (DMHC) regulated plans and policies who reach age 40 each year and would be subject to the AB 56 mandate to receive a one-time, generic letter (addressed by name) to inform them of breast cancer screening guidelines. CHBRP's survey of seven major California health plans and insurers indicates that about 35,000 (22%) of these women currently receive a written notification from their plans to inform them of breast cancer screening guidelines and eligibility for the benefit.

Utilization

- Among 41-year-old women, 51% report having received a mammogram within the past year, whereas 30% report never having received a mammogram and 19% had a mammogram over a year ago.
- An estimated 22% of women at age 40 enrolled in CDI- and DMHC-regulated health plans currently receive a written notification from their insurer to receive breast cancer screening based on USPSTF guidelines.
- Among women aged 40 enrolled in CDI- and DMHC-regulated health plans who do not currently receive annual mammograms and do not receive the mandated notification to do so, 32% are expected to receive mammograms after receiving a one-time, generic letter, leading to approximately 20,000 additional mammograms being performed as a result of AB 56; an increase of 0.38% in the total annual number of mammograms performed among women with coverage subject to AB 56.

Costs

- The unit cost of mammograms is estimated at $169, which includes the costs of follow-up biopsies (procedure and lab costs), other noninvasive procedures (repeat mammograms, ultrasounds), and office visits due to false-positive results.
- The cost of mailing a one-time, generic letter (addressed by name) to 160,000 enrolled women who turn age 40 is estimated at $96,000 based on $0.60 per letter.
- The overall increase in total expenditures due to the mandate is estimated at $3,691,000, or an increase of 0.004% in the year following the enactment of the mandate.
- Total premiums are estimated to increase by $0.0090 to $0.0156 per member per month (PMPM) depending on insurance type and market segment. The distribution of the impact on premiums is as follows:
    - Total premiums for private employers are estimated to increase by $2,057,000, or 0.004%.
    - Total employer premium expenditures for California Public Employees' Retirement System (CalPERS) are estimated to increase by $75,000, or 0.002%.
        - Of the amount CalPERS would pay in additional total premium, about 59%, or $44,000, would be the cost borne by the General Fund for CalPERS members who are state employees.
    - Enrollee contributions toward premiums for group insurance are estimated to increase by $537,000, or 0.004%.
    - Individual out-of pocket costs in the form of copayments and deductibles are expected to increase by $287,000 (0.004%).
    - Total premiums for those with individually purchased insurance are estimated to increase by $361,000 (or 0.006%).
    - State expenditures for Medi-Cal are estimated to increase by $374,000, or 0.009%.

Long-term impacts on costs

- Cost-effectiveness studies of mammograms for women ages 40 years and older indicate an incremental cost-effectiveness ratio of $58,000 per quality-adjusted life-year (QALY) for screening annually and $47,000 per QALY for screening every 2 years. These rates were based on the assumption of 100% mammogram rates and would be considerably lower given the current mammogram rates.
- CHBRP projects that AB 56 will have no measurable impact on the number of uninsured due to premium increases.

Public Health Impacts

- Approximately 51% of insured women in California report receiving a mammogram at age 40 years—the age clinical practice guidelines recommend beginning screening with mammography for women of average risk for breast cancer. AB 56 seeks to increase the utilization rate of mammograms through notification of eligibility of such screening through health insurance plans. This mandate, through notification by a one-time, generic letter (addressed by name), is expected to increase the number of women who receive mammograms each year by approximately 20,000.

- The 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 20,000 women with mammography would, over time, prevent approximately 16 deaths per year from breast cancer. It would take approximately 14 years following implementation of AB 56 for this reduction in mortality to be realized, although qualitative improvements, such as a decrease in the aggressiveness of the cancer and less treatment for metastatic disease would be expected sooner.

- Disparities in prevalence of breast cancer exist with the vast majority of the cases (99.4%) occurring among women. In addition, racial and ethnic disparities exist, not only in breast cancer prevalence, but in early diagnoses and mortality rates as well. Non-Hispanic white women have the highest rates of breast cancer, followed by blacks and Asian/Pacific Islanders. Hispanics have the lowest rates. The research on mammography utilization by race/ethnicity suggests that some of the differences in health outcomes among non-white women can be explained by their lower rates of mammography utilization. Therefore, to the extent that notification increases mammography screening among these groups, there is the potential for AB 56 to reduce the racial/ethnic disparities screening rates and health outcomes associated with breast cancer.

- There are approximately 4,200 deaths each year in California due to breast cancer, a rate of 23.2 deaths per 100,000 women. It is estimated 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. An estimated reduction in 16 premature deaths each year due to AB 56 would translate into a savings of 366 life-years and $5.2 million in productivity that would otherwise be lost.

Table 1. Summary of Coverage, Utilization, and Cost Impacts of AB 56

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Coverage				
Total population in plans subject to state regulation (a)	21,340,000	21,340,000	—	0.000%
Total population in plans subject to AB 56	21,340,000	21,340,000	—	0.000%
Percentage of individuals with mandated coverage for mammograms				
Coverage similar to mandated levels: women covered for mammograms by CDI-regulated plans	100%	100%	—	0.000%
No coverage	0%	0%	—	0.000%
Percentage of individuals turning 40 who receive mandated written notification for mammograms				
Coverage similar to mandated levels: women age 40 receiving mammogram notification by CDI and DMHC regulated plans	22%	100%	78%	361.262%
Mandated notification not received	78%	0%	−78%	−100.000%
Number of individuals with mandated coverage for mammograms				
Coverage similar to mandated levels: women covered for mammograms by CDI-regulated plans	1,185,000	1,185,000	—	0.000%
No coverage	—	—	—	0.000%
Number of individuals turning 40 who receive mandated written notification for mammograms				
Coverage similar to mandated levels: women age 40 receiving mammogram notification by CDI- and DMHC-regulated plans	35,000	160,000	125,000	357.143%
Mandated notification not received	125,000	—	−125,000	−100.000%
Utilization and Cost				
Number of mammograms among women in CDI- and DMHC-regulated plans	5,298,000	5,318,000	20,000	0.378%
Average per unit cost- mammograms (including additional services due to false positive results)	$169	$169	$0.00	0.000%
Average per unit cost of one time, personally addressed mammogram notification to women age 40	$0.60	$0.60	$0.00	0.000%

Table 1. Summary of Coverage, Utilization, and Cost Impacts of AB 56 (Cont'd)

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Expenditures				
Premium expenditures by private employers for group insurance	$50,546,208,000	$50,548,265,000	$2,057,000	0.004%
Premium expenditures for individually purchased insurance	$5,944,229,000	$5,944,590,000	$361,000	0.006%
Premium expenditures by individuals with group insurance, CalPERS, Healthy Families, AIM, or MRMIP (b)	$13,475,994,000	$13,476,531,000	$537,000	0.004%
CalPERS employer expenditures (c)	$3,161,160,000	$3,161,235,000	$75,000	0.002%
Medi-Cal state expenditures (d)	$4,112,866,000	$4,113,240,000	$374,000	0.009%
Healthy Families state expenditures	$643,247,000	$643,247,000	$0	0.000%
Individual out-of-pocket expenditures (deductibles, copayments, etc.)	$6,384,067,000	$6,384,354,000	$287,000	0.004%
Out-of-pocket expenditures for noncovered services	$0	$0	$0	0.000%
Total Annual Expenditures	$84,267,771,000	$84,271,462,000	$3,691,000	0.004%

Source: California Health Benefits Review Program, 2009.
Notes: (a) This population includes privately insured (group and individual) and publicly insured (e.g., CalPERS, Medi-Cal, Healthy Families, Access for Infants and Mothers [AIM], Major Risk Medical Insurance Program [MRMIP]) individuals enrolled in health insurance products regulated by DMHC or CDI. Population includes enrollees aged 0-64 years and enrollees 65 years or older covered by employment-sponsored insurance.
(b) Premium expenditures by individuals include employee contributions to employer-sponsored health insurance and member contributions to public insurance.
(c) Of the change in CalPERS employer expenditures, about 59%, or $44,250, would be state expenditures for CalPERS members who are state employees.
(d) Medi-Cal state expenditures for members under 65 years of age include expenditures for MRMIP and AIM program enrollees who will newly receive notification.
Key: CalPERS=California Public Employees' Retirement System; CDI=California Department of Insurance; DMHC=Department of Managed Health Care.

INTRODUCTION

Assembly Bill (AB) 56 contains two separate requirements. The bill requires health insurance policies to provide coverage for mammography upon provider referral. The bill does not alter the similar and already current mammography coverage mandate for Knox-Keene Health Service plans (Health & Safety Code Section 1367.665). In addition, the bill requires both health care service plans and health insurance companies to send a written notice to each female enrollee or policy holder during the calendar year in which national guidelines indicate she should begin breast cancer screening, alerting her that she is eligible for testing.

The California Health Benefits Review Program (CHBRP) undertook this analysis in response to a request from the California Assembly Committee on Health on February 4, 2009. AB 56 was introduced by Assembly Member Anthony Portantino on December 5, 2008.

As a state benefit mandate bill, AB 56 directly affects only insurance coverage that can be influenced by California law. Therefore, AB 56 would affect Knox-Keene Health Service Plans regulated by the Department of Managed Health Care (DMHC) and the health insurance policies regulated by the California Department of Insurance (CDI).[2] As the bill makes no market exclusions, it would affect plans and policies in the large group, small group, and individual markets. Through its impact on the DMHC-regulated plans, AB 56 would also affect the coverage of some (but not all) individuals enrolled in either the California Public Employees' Retirement System (CalPERS), Medi-Cal Managed Care, Healthy Families, or other publicly funded programs. Changes in CDI-regulated health insurance policies would not affect public programs because public programs contract only with DMHC-regulated plans. (Please see Appendix D for a detailed description of the underlying assumptions related to the *Utilization, Cost, and Coverage* section of this analysis.)

AB 56 would not directly affect coverage for populations enrolled in programs or health insurance products not subject to California benefit mandates, such as those enrolled in Medicare Advantage or those who have coverage through self-insured plans (both of which are exempted by federal laws). AB 56 would not directly affect those who are uninsured and have no coverage. Similarly, AB 56 would not directly affect "Every Woman Counts," a program operated by the California Department of Public Health that does not provide health insurance coverage but does provide screening and treatment for breast cancer to the uninsured.

[2] Senate Bill (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, those enrolled in health insurance products offered by health care service plans or health insurers are the portion of the population directly affected by a benefit mandate bill.

Bill Language and Key Assumptions

The full text of AB 56 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. CHBRP makes necessary assumptions regarding the interpretation of bill language in order to conduct its analyses. CHBRP's interpretation of AB 56 is based on conversations[3] with the staff of the Assembly Member who introduced the bill, discussions with regulatory agencies, including the DMHC, and reasonable legal and layperson interpretation of the bill language. These assumptions are as follows:

Screening and Diagnosis—the focus of this report is on "mammography screening," which denotes testing of asymptomatic individuals in order to identify new breast cancer cases. Diagnostic tests, which can be confirmatory or can be used to determine the most appropriate course of treatment, are already broadly covered and are not a source of disagreement across 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 may be consensus driven (which can 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. However, most national guidelines, including those listed below, recommend screening every 1 or 2 years, beginning at age 40 or 50 for those women of average risk for breast cancer.

- United States Preventive Services Task Force (USPSTF)
- American Cancer Society (ACS)
- American College of Obstetricians and Gynecologists (ACOG)
- American College of Physicians (ACP)
- American College of Radiology (ACR)

Guidelines from these respected, national organizations are summarized in Appendix C.

Written Notification and "One-Time, Generic Letter"—the bill language does not specify a precise means of compliance, and "written notification" may take many forms. It may be an article in an annual newsletter or a tailored letter (which might include the individual's screening history or other detailed information). In broader terms, notification strategies may differ in other important ways. They may use more than written means (including following up by phone). They may be targeted (sent only to women who have not been screened) or comprehensive (sent to all women currently eligible for screening). They may be one-time or on-going (occurring

[3] Personal communication, Philip Horner, Office of Assembly Member Portantino, January 2009

every year or in alternate years). Several of the health plans and insurers CHBRP surveyed indicated use of some form of notification. However, the language of the bill references only written notification and only mandates that all female members/enrollees receive a written notification during the year they become eligible for screening according to national guidelines. The bullets below demonstrate a range of potentially compliant carrier actions:

- **Annual Newsletter/Evidence of Coverage**—carriers could, in a newsletter or evidence of coverage (EOC) document annually distributed to all members/enrollees, note that national guidelines suggest women begin breast cancer screening at age 40 years and that members/enrollees are eligible for such screening. None of the literature found by CHBRP assessed the effectiveness of this general outreach method.

- **One-Time, Generic Letter**—carriers could send to each 40-year-old female member/enrollee a one-time, generic letter (addressed by name) noting national guidelines and member/enrollee eligibility. Four studies found through CHBRP's literature search offer comparisons between generic notification compared to no notification or more sophisticated, tailored notification.

- **One-Time, Tailored Letter**—carriers could send to each 40-year-old female member/enrollee a one-time, tailored letter that addresses her by name and addresses specific issues, such as the benefit eligibility, her health beliefs, her perceived barriers to screening, her individual cancer risk assessment, or her screening status/history. Four studies found through CHBRP's literature search offer comparisons between generic notification compared to no notification or more sophisticated, tailored notification.

- **Other Forms of Notification**: The literature also compares written notification to other more detailed or sophisticated methods (including personalized phone calls, personal counseling, and community outreach programs), and several carriers responding to CHBRP's survey did indicate that such outreach strategies were being employed on a more than one-time basis. However, such methods are not mandated by AB 56.

CHBRP's discussions with DMHC[4] suggest that any of the first three scenarios listed above would be compliant with the notification mandate in AB 56.

For the purposes of analysis, CHBRP assumes universal compliance by carriers with an intermediate method of mandated notification, i.e., sending a *one-time, generic letter* (addressed by name and sent though first-class mail service) to each covered woman during the calendar year she reaches age 40.

Alternative notification strategies could lead to higher or lower estimates of cost and public health impacts than those provided in this report.

[4] Personal communication, Sherrie Lowenstein, Department of Managed Health Care, January 2009

Existing California Requirements

AB 56 references mammography testing as well as notification of eligibility at the point when national guidelines recommend that breast cancer screening begin.

Mammography

Existing legislation addresses breast cancer screening for both health care service plans regulated by DMHC and insurance policies regulated by 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, 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 reference age-dependant schedules.

Of the fifty states and the District of Columbia all but one (Texas being the exception) mandate coverage for mammography screening (BCBSA, 2008).

[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

Notification

No current law in California requires plans or insurers to notify female members or enrollees as to when breast cancer screening should begin and CHBRP found no evidence of other states with such a mandate in law.

Background of Disease

Incidence and Prevalence

Breast cancer is one of the most commonly diagnosed cancers in California, with over 21,000 new cases diagnosed annually (CCR, 2008). This translates to an annual incidence rate of 126.7 cases per 100,000 women in California (Kwong et al., 2005). It is estimated that nearly 280,000 Californians alive today have been diagnosed with breast cancer (Hofer et al., 2008). An average woman's lifetime risk of being diagnosed with breast cancer in California is one in nine (i.e., 11.1%) (CCR, 2008).

Although breast cancer is the most common cancer found among women in California, when diagnosed early, survival rates are very high. Overall, the 5-year relative survival rate for breast cancer among women in California is 88% (CCR, 2008). This rate varies with the stage at diagnosis with a 97% 5-year relative survival rate for localized breast cancer (i.e., still confined to the breast), 79% for regional breast cancer (i.e., the tumor has spread to lymph nodes or adjacent tissues), and 20% for distant breast cancer (i.e., the tumor has spread to other parts of the body) (CCR, 2008). In California, 69% of breast cancer is diagnosed at an early stage (in situ, or localized).

In 2008, there were approximately 4,200 deaths due to breast cancer in California (CCR, 2008). This translates into an annual mortality rate of 23.3 per 100,000 women (Kwong et al., 2005). Since 1988, breast cancer mortality among women in California has declined by 27% (CCR, 2008). This decrease is attributed, mostly, to the increased use of mammography screening, as well as to improvements in breast cancer treatments (Berry et al., 2005). It is recommended that women get screened every 1 to 2 years for breast cancer using mammography (USPSTF, 2002). In California, 80.7% of insured women age 40 and older received a mammogram in the past 2 years (CHIS, 2007). Another 12.7% had a mammogram more than 2 years ago, and 6.5% reported never having been screened using a mammogram (CHIS, 2007). Women who do not receive mammograms as recommended in the USPSTF guidelines report that the main reason for not having a mammogram was: laziness (28%), painful or embarrassing (14%), did not know it was needed (14%), financial reasons (5%), and other reasons (39%) (CHIS, 2007). Women who were categorized as "didn't know it was needed" indicated that they did not know the mammogram was needed, the doctor did not tell them it was needed, they have not had any problems with their breasts, or that they were too young to have a mammogram. Other studies have also found that access issues such as insurance status and physician recommendation are significant predictors of mammography utilization (Scheuler et al., 2008).

MEDICAL EFFECTIVENESS

This medical effectiveness analysis considers whether screening mammography reduces mortality due to breast cancer compared to women who are not screened. The potential harms resulting from screening are discussed. This analysis also addresses the medical effectiveness of notifying women when they first become eligible for breast cancer screening and whether notification increases mammography use.

Mammography Screening

Mammography screening applies *only* to asymptomatic women. 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 nondisease. Furthermore, patients who are diagnosed via screening and undergo treatment should achieve better health outcomes compared to patients initiating treatment following presentation of symptoms (without screening) (Bermejo-Perez et al., 2008).

Mortality Benefit Time Frame

Reduction in mortality due to breast cancer is the outcome of primary interest for mammography screening. As with most other preventive services, the benefit of mortality reduction from mammography screening is realized further into the future than the standard 1-year time frame considered in CHBRP reports. For women ages 50 years and older, evidence shows that the mortality benefit is achieved after 7 to 9 years of initiating screening—commonly referred to as "follow-up." The benefit of screening women in their 40s is more limited and slower to appear (10-14 years after follow-up) than for older women. The reduced benefit for this younger age cohort is attributable to their lower incidence of breast cancer and denser breast tissue, which can reduce the sensitivity of mammography (Elmore et al., 2005). Younger women diagnosed with breast cancer can also experience more aggressive breast cancers that appear during the interval between screenings,

Evidence Review Results

The conclusions drawn regarding the medical effectiveness of mammography screening and mammography notification 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 C-1 through C-4, which summarize the studies used for this analysis.

This evidence review considers the effectiveness of three categories: mammography screening for all women 40 years and older; mammography screening for women ages 40-49 years; and notification of women eligible for mammography screening.

Because the medical effectiveness of mammography has been widely acknowledged for more than 20 years, more recent research has progressed to comparing various mammographic modalities and studying subpopulations. AB 56 requires coverage of mammography (of all types), and the older literature cited in this report is the most pertinent to the question at hand: Is mammography effective at reducing mortality from breast cancer?

Eight large, randomized controlled trials (RCTs) conducted in Canada, the United States, and Europe have been conducted on the medical effectiveness of mammography. They provide the foundation for much of the literature reviewed in the AB 56 report. The conclusions about improved mortality reduction have been reached by multiple national (U.S.) organizations (Table2) using these RCTs. These organizations generally give the evidence a "fair" rating based on methodological issues with some studies. In addition, the studies are rated by CHBRP as "somewhat generalizable" (Table 2) because seven of the studies were conducted in Europe or Canada, which are known to have different recall rates than the United States due to medical practice differences (Smith-Bindman et al., 2005).

Epidemiologic Terminology

Sensitivity is defined as the proportion of breast cancers detected when breast cancer is present, or the true-positive rate. The U.S. Agency for Healthcare Research and Quality (AHRQ) sets the desirable sensitivity rate at greater than 85%.

Specificity is defined as the proportion of negative test results 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. The AHRQ sets the desirable specificity rate at greater than 90%.

False-positive rate is defined as the proportion of positive tests that occur in people who do not have the condition. The false-positive rate is equal to 1 − specificity.

Positive Predictive Value (PPV) is defined as the proportion of those testing positive that 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 AHRQ sets the desirable recall rate for screening mammography at less than 10% (Feig, 2007).

Relative Risk (RR) is the ratio of the risk of the outcome (e.g., death from breast cancer) for women who receive the exposure or screening test (e.g., mammography) compared to the risk of the outcome among women who do not receive the exposure.

Screening Studies

Women 40 Years and Older

The medical effectiveness of mammography for screening and diagnosis has been widely recognized in the United States and abroad for more than 25 years. National guidelines, customary practices of care, and current health care coverage, as mandated by existing California statute, all accept mammography as the standard for the screening and diagnosis of breast cancer. The National Cancer Institute (NCI) reports the sensitivity for mammography screening is approximately 75%, but ranges between 54% to 58% in women ages 40-49 years and 81% to 94% in women ages 65+ years (NCI, 2008a).

There are three primary systematic reviews of mammography trials summarized in Table 2. Gøtzsche and Nielsen (2006) updated their first meta-analysis of the eight aforementioned RCTs and state that, despite the studies' shortcomings (all rated fair or poor), mammography screening produces a 15% relative reduction in breast cancer mortality.

Humphrey et al. (2002) performed an extensive systematic review of the effectiveness of mammography screening for the USPSTF. Through a meta-analysis of the eight aforementioned RCTs, the authors report the summary relative risk (RR) estimate of breast cancer mortality is 0.84 (95% credibility interval [CrI], 0.77 to 0.91)[6], equivalent to a 16% relative reduction in mortality risk. The sensitivity for the 1-year screening interval ranges from 71% to 96% and the specificity from 94% to 97%. Finally, the positive predictive value of one-time mammography ranged from 2% to 22%. In their analysis, the authors cite another study of 31,814 average-risk women from California for which the positive predictive value ranges increased from 1% to 4% for ages 40-49 years, to 4% to 9% for ages 50-59 years, to 10% to 19% for ages 60-69 years. Based upon the Humphrey et al. (2002) review, the USPSTF found "fair evidence that mammography screening every 12 to 33 months significantly reduces mortality from breast cancer." (USPSTF, 2002).

Kerlikowske et al. (1995) performed a meta-analysis of nine RCTs and four case-control studies of women ages 40-74 years that estimates the summary relative risk is 0.75 (95% confidence interval [CI], 0.68 to 0.83). Among women ages 50-69 years, screening mammography is shown to reduce breast cancer mortality by 26% (RR=0.74; 95% CI, 17% to 34%) after 7 to 9 years of follow-up. The authors recommend that women ages 50-74 years undergo regular mammography screening.

There is a preponderance of evidence that mammography screening among women ages 40-74 years is effective in reducing mortality due to breast cancer. The mortality benefit for women 50-74 years is seen after 7 to 9 years of follow-up.

[6] CrI=credibility interval, a type of confidence interval used by Bayesian statisticians.

Table 2. Summary of Findings of Medical Effectiveness of Mammography for All Eligible Women

Citation	Research Design[7]	Outcome	Size of Effect	Sensitivity/ Specificity	Generalizability (to Population Affected by Mandate)	Conclusion
Gøtzsche and Nielsen., 2006(a)	**Level I:** Systematic review of 7 trials of 500,000 women ages 40-74 years (the majority of trials enrolled women ages 50-64 years)	Summary RR reduction for breast cancer mortality Absolute risk	15% **RR reduction** **Absolute risk reduction** 0.05%	Not reported	Somewhat generalizable: RCTs, appropriate ages represented in the study; mostly from European countries with lower false-positive rates	Preponderance of evidence that screening likely reduces breast cancer mortality by 15% Over 10 years, 1 of every 2,000 women screened will avoid death due to breast cancer
Humphrey et al., 2002(a)	**Level I:** Systematic review of 8 RCTs and meta-analyses of women ages 40–74 years	Summary RR for breast cancer mortality PPV Sensitivity Specificity	**Summary RR** 0.84 (95% CrI 0.77-0.91) for all women **PPV**=12% for mammography in United States	**Sensitivity**: for first mammogram (1-year interval) ranged from 71%-96% **Specificity**: for single mammogram ranged from 94%-97%	Somewhat generalizable: RCTs, appropriate ages represented in the study; mostly from European countries with lower false-positive rates	Preponderance of evidence that mammography reduces breast cancer mortality rates among women ages 40-74 years. 1,224 women were needed for screening to prevent one death from breast cancer (over 14 years)

[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	Research Design[7]	Outcome	Size of Effect	Sensitivity/ Specificity	Generalizability (to Population Affected by Mandate)	Conclusion
Kerlikowske et al., 1995(a)	**Level I:** Meta-analysis of 9 RCTs, 4 case-control studies of women ages 40-74 years	Summary RR for breast cancer mortality	**Summary RR** 0.75 (95% CI, 0.68 to 0.83) for women ages 40-74 years	Not reported	Somewhat generalizable: appropriate ages represented; mostly from European countries with lower false-positive rates	Preponderance of evidence that screening mammography reduced cancer mortality by 26% in women ages 50-74 years after 7 to 9 years of follow-up.

Note: (a) All three meta-analyses consider the same eight RCTs.
Key: CI=95% confidence intervals; PPV=positive predictive value; RCT=randomized controlled trial; RR=relative risk.

Women Ages 40-49 Years

As noted in this report's screening guidelines summary (Appendix C), the USPSTF, along with the American Cancer Society (ACS) and the American College of Obstetricians and Gynecologists (ACOG), recommend screening mammography for women ages 40 years and older. Many of the guideline sponsors caution that the benefits of screening women ages 40-49 are smaller and the rates of false-positive results are greater.

Four studies that focus on this age cohort all report that the benefits of breast cancer mortality reduction are smaller when weighed against possible harms than they are for women 50 years old and older (Table 3). The systematic review of eight meta-analyses by Armstrong et al. (2007) concludes that routine screening mammography for women ages 40-49 years reduces breast cancer mortality rates by 15% (7% to 23%), but increases the use of unnecessary procedures due to the test's high false-positive rate for that age cohort. This reduction in mortality (RR 0.85; 95% CI: 0.73 to 0.99) occurs after 14 years of follow-up and is less than the 22% reduction in mortality seen among women ages 50 years and older (RR 0.78; 95% CI, 0.70 to 0.87).

The RCT 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 is found (at 10 years' follow-up), but it is 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 ages 40–49 years (Moss et al., 2006).

The Humphrey et al. (2002) review for the USPSTF also considered the effectiveness of mammography screening among the younger subpopulation (ages 40-49 years). The meta-analysis for this age cohort included six RCTs. The summary relative risk is 0.85 (95% CrI, 0.73 to 0.99) after 14 years of follow-up. The sensitivity of mammography screening is lower for this younger cohort (73% to 81%) than compared with women ages 50 years and older (71% to 96%). Mammography sensitivity is thought to be 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.

Kerlikowske (1997) updated the 1995 meta-analysis with a focus on women ages 40-49 years. She found that after 7 to 9 years of follow-up, this younger age cohort receives no reduction in mortality due to mammography screening; however, after 10 to 14 years of follow-up, there is a 16% reduction in mortality due to breast cancer. Kerlikowske explains that the incidence of breast cancer is lower in this age cohort and the benefit from screening is therefore smaller and delayed. The balance of benefits from screening relative to harms from false positives is less favorable in the 40-49–year age group, especially for women at low or average risk of breast cancer.

There is a preponderance of evidence that mammography screening is medically effective for women ages 40-49 years after 10 to 14 years of follow-up, but the reduction in breast cancer mortality is smaller than for women ages 50 years and older, and false-positive results are more frequent in the 40-49 year age group.

Table 3. Summary of Findings of Medical Effectiveness of Mammography for Women Ages 40-49 Years

Citation	Research Design[8]	Outcome	Size of Effect	Sensitivity/ Specificity	Generalizability (to Population Affected by Mandate)	Conclusion
Armstrong et al., 2007	**Level I:** Systematic review of 117, reviews, RCTs, and observational studies 8 Meta-analyses of 8 RCTs of women ages 40-49 yrs	RR for breast cancer mortality False-positive rates	**RR** 0.85 (95% CI, 0.73 to 0.99) for women ages 40-49 years[9] **RR** 0.78 (95% CI, 0.70 to 0.87) for women 50+ years **Cumulative false-positive rate** 30% after 5 mammograms; 56% after 10 mammograms	Not reported	Highly generalizable: randomized trials	Preponderance of evidence that more women 40-49 years than 50+ years have risks that outweigh the benefits of mammography screening The RR is similar to 5 other meta-analyses and is smaller than the RR for women ages 50+ years
Moss et al., 2006	**Level I:** RCT of 160,921 women ages 39–41 years	Summary RR in breast cancer mortality	**Summary RR** 0.83 (95% CI, 0.66 to 1.04; p=0.11) after 10.7 years of follow up	Not reported	Highly generalizable randomized controlled trial of women in the U.K. ages 39 to 41 years	At 10.7 years of follow-up, a 22% reduction in mortality (p=0.11) was found This trial is consistent with findings of other mammography alone trials

[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.

[9] Armstrong et al. (2007) reports the relative risk as stated in the Humphrey et al. (2002) review.

Citation	Research Design[8]	Outcome	Size of Effect	Sensitivity/ Specificity	Generalizability (to Population Affected by Mandate)	Conclusion
Humphrey et al., 2002	**Level I:** Systematic review and meta-analysis of 7 RCTs of 200,000 women ages 40-49 years	Summary RR for breast cancer mortality	**Summary RR** 0.85 (CrI, 0.73 to 0.99) after 14 years of observation	**Sensitivity**: for first mammogram (one year interval) ranged from 71% to 96% **Specificity**: for single mammogram ranged from 94% to 97%	Somewhat generalizable: Randomized trial, different age groups in the study mostly from European countries with lower false-positive rates	Preponderance of evidence that mammography screening reduces breast cancer mortality for women ages 40-49 years This meta-analysis was found to be consistent with most of 7 other meta-analyses
Kerlikowske, 1997	**Level I** Meta-analysis of 9 RCTs, 1 case-control study of women ages 40-49 years	Summary RR for breast cancer mortality	16% **Summary RR** for women ages 40-49 years after 10 to 14 years of follow-up	Not reported	Somewhat generalizable: age ranged between 40-49 years; mostly from European countries with lower false-positive rates	Preponderance of evidence that screening mammography reduces mortality by 16% in women 40-49 years after 10 to 14 years of follow-up

Key: CI=95% confidence intervals; PPV=positive predictive value; RCT=randomized controlled trial; RR=relative risk.

Harms of Screening and Study Limitations

Harms

False-positive screening results are recognized as potentially harmful. Elmore et al. (1998) report that 23.8% of women (ages 40-69 years in a health maintenance organization [HMO]) had at least one false-positive mammogram over a 10-year period. They estimate the cumulative risk of a false-positive result is 49.1% after 10 mammograms (95% CI, 40.3% to 64.1%). False-positive rates on single mammograms increased from 4.2% in 1983-1986 to 7.6% in 1990-1993. False-positive readings may lead to anxiety, unnecessary appointments, additional diagnostic imaging, and biopsies.

The Humphrey et al. (2002) meta-analysis reports a 3% to 6% false-positive rate for single mammography screenings. Their analysis includes one study from the United States and multiple RCTs from Europe, which are known to have lower rates of recall for further evaluation than the United States. Another study finds that 13.3% of U.S. women who underwent mammography for the first time were recalled versus 7.2% of women in the United Kingdom. On subsequent mammograms, 8% of U.S. women were recalled (Smith-Bindman et al., 2005). The single U.S. RCT for effectiveness of mammography screening (Health Insurance Plan of New York) reports a positive predictive value of 12% for mammography screenings requiring further evaluation.

Armstrong et al. (2007) report the findings from the Harvard Pilgrim Health Care Study, which studies the follow-up diagnostic evaluations due to false-positive mammography readings. Among 631 false positives, 162 resulted in additional outpatient visits, 560 resulted in additional diagnostic imaging, and 128 resulted in biopsy. The cumulative risk for a false-positive reading in the Harvard Pilgrim Health Care study was 30% after five mammograms and 56% after 10 mammograms. The authors also considered studies that focus on the outcomes of false-positive readings and found that they had little effect on psychological health or subsequent adherence to mammography.

Brewer et al. (2007) performed a systematic review of 23 correlational studies on the long-term effects of false-positive mammograms. They conclude that European women suffered no long-term harmful effects on obtaining future routine mammography screening after receiving false-positive tests (0.97%; 95% CI, 0.93 to 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; 95% CI, 1.02 to 1.12), unlike Canadian women who were less likely to return (0.63; 95% CI, 0.50 to 0.80). The authors note that smaller study sizes and different surveillance programs may explain the results for the Canadian women.

Risk of breast cancer attributable to radiation from mammography is considered minimal by the medical community, and the benefits of detecting cancer are thought to outweigh the potential risk (Armstrong et al., 2007; Elmore et al., 2005; NCI, 2008b).

Limitations

The quality of studies included in the systematic reviews and meta-analyses are somewhat controversial. Some question validity of the outcome measured, death due to

breast cancer, because differential misclassification of cause of death may bias the results. Also, the reduction in breast cancer mortality rates are not realized until many years after mammography screening begins (Armstrong et al., 2007).

Based on the literature reviewed by CHBRP, false-positive results are more likely in women under 50 years of age due to overall lower disease prevalence and the problems of analyzing the results of mammography due to the denser breast tissue of younger women. False-positive rates are higher in the United States than in Europe/the United Kingdom; false-positive rates are higher for the first mammogram compared with subsequent mammograms; and at least in the 1983-1993 period, false-positive rates increased over time in the United States. This CHBRP analysis assumes a 13.3% false-positive rate for first mammograms, and 8% for subsequent mammograms as a benchmark for more recent U.S. experience.

Medical Effectiveness of Notification of Eligibility for Mammography

AB 56 would require that health plans and insurers send women a one-time, written notice when they first become eligible for testing during the calendar year in which national guidelines indicate that mammography screening for breast cancer should begin. AB 56 language (Appendix A) uses "written notice," which could be interpreted to mean a range of methods, including a note included in a newsletter or evidence of benefits (EOB) document or a detailed, personalized letter tailored to an individual's health and risk[10].

Because most national guidelines (Appendix C) indicate that women should start screening mammography at age 40 years, CHBRP assumes the following midpoint of the possible written methods will satisfy the notification requirement: mailing a one-time, generic letter (addressed by name) to female members/enrollees during the calendar year she turns 40.

For purposes of this report, CHBRP assumes the effect of notification will be realized within a 1-year time frame. Two categories of studies are considered below: effectiveness of notification for preventive health screening and effectiveness of notification for mammography screening.

Evidence Review Results

The literature search from 1995 to present reveals no medical effectiveness studies of "one time" notification of newly eligible women to obtain breast cancer screening service. Furthermore, no studies were found that considered the effectiveness of providing notice in newsletters or EOB documents. Table 4 summarizes the most pertinent studies that consider written notification. Four studies perform systematic reviews or meta-analyses of studies comparing different forms of reminders or notices to women who were due or overdue for mammography screening. All meta-analyses show strong indications that sending reminder letters or postcards for mammography screening is effective in increasing mammography screening rates. The most

[10] The terms *reminders*, *notices*, and *invitations* are used somewhat interchangeably in the literature. *Notification* usually indicates that a woman has had one or more mammograms and is due for mammography screening. *Reminders* generally indicate that a woman has had one or more mammograms and is due or overdue for the next screening test. *Invitation* is usually used in other countries with national screening programs and indicates that a woman is due for mammography screening.

pertinent study compares a mailed reminder to no reminders. The author concludes that notification increases women's adherence to mammography screening (Wagner, 1998) as demonstrated by an adjusted odds ratio (OR) of 1.48 (Mantel-Haenszel chi-square test $[\chi^2_{MH}(1)]=38.27$, $P<0.001$). (The adjusted odds ratio, when converted to a relative risk, indicates that women who receive a reminder are 31.7% more likely to get a mammogram than those who receive no reminder.) Wagner also reports that women receiving tailored letters are 85% more likely to get a mammogram than those receiving a generic reminder (adj. OR 1.87; $\chi^2_{MH}(1)]=4.70$, $P<0.05$). 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. Both Stone et al. (2002) and Sohl and Moyer (2007) report adjusted odds ratios of 2.31 and 1.31, respectively, that indicate written notification is effective in increasing mammography screening rates.

A recently published systematic review by the Federal Task Force on Community Preventive Services reports that strong evidence exists for the effectiveness of client reminders in increasing mammography screening rates (Baron et al., 2008). The authors find that when using simple printed reminders (alone), the median postintervention increase in mammography screening was 3.6 percentage points (interquartile interval=1.8, 14.0). This indicates that an additional 3.6 of 100 women will complete mammography screening due to simple written reminders. This conclusion is considerably different than Wagner's conclusion, which assumes a 32% increase in completed mammography. A possible explanation for the wide variation may be differences in the included studies (United States versus international locations) and differences in the statistical approaches for summarizing the data. Although there are methodologically sound aspects to both the Wagner and Baron et al. studies, Wagner's meta-analysis of U.S.-based studies appears to provide an estimate more directly applicable to the mandate proposed by AB 56.

Ellis et al. (2003) conducted a systematic review for the Agency for Healthcare Research and Quality (AHRQ) that focuses on diffusion of evidence-based cancer control interventions. Based on four studies described in their systematic review, Ellis et al. (2003) concluded that invitations or mailed reminders are consistently effective for increasing mammography. Specifically, Ellis et al. reported that Bonfill et al. (2001), found letters of invitation are effective (adj. OR 1.66; 95% CI, 1.43 to 1.92), and that Shekelle (1999) found that patient reminders are effective (adj. OR 2.57; 95% CI, 2.22 to 2.98). The Ellis et al. (2003) systematic review also included two other reviews of general preventive screening uptake due to notification that concluded, based on fair evidence, that notification does improve rates of uptake (Jepson et al., 2000; Shea et al., 1996). The preventive health screening programs in the Jepson et al. review included cervical cancer, breast cancer, colorectal cancer, and prostate cancer among others. Of the 29 mammography studies they reviewed, 12 RCTs invited women by letter (vs. no letter for control group) for mammograms. Three of the 12 RCTs showed statistically significant effects of the intervention, five showed no effect, and data could not be extracted for four studies (although two report a favorable effect). Jepson et al. concluded that there is evidence of limited effectiveness of reminders for mammograms. The Shea et al. (1996) meta-analysis of 16 RCTs reported that computer-based reminders improved uptake of four of six preventive services, including breast cancer screening. Compared to no intervention, Shea et al. reported an adjusted OR of 1.88 (95%

CI, 1.44 to 2.45; p<.0001) for computer-based reminders and an adjusted OR of 1.63 (95% CI, 1.21 to 2.18, p< .001) for manual reminders.

There is a preponderance of high- to fair-quality evidence that written notification of women who are due for routine mammography screening improves the overall mammography screening rate. There is no evidence found regarding the effectiveness of more generalized notification methods (e.g., newsletters or EOCs). Of the evidence reviewed by CHBRP, the Wagner meta-analysis appears to provide the most relevant information to the AB 56 mandate due to its focus on simple written reminders versus no reminders.

Table 4. Summary of Findings of Medical Effectiveness of Notification for Mammography Screening

Citation	Research Design[11]	Outcome	Findings (Statistical Significance, Direction of Effect)	Generalizability to Population Affected by Mandate	Conclusion
Wagner, 1998	**Level I:** Meta-analysis of 16 RCTs (more than 16,000 women) to compare effectiveness of mailed patient reminders at increasing mammography screening	Increased mammography screening rates for women overdue for screening	Mailed patient reminders are more effective at increasing mammography screening rates than no intervention **Adj. OR 1.48;** $\chi^2_{MH}(1)=38.27, p<0.001$ for mailed print reminders **Adj. OR 1.87;** $\chi^2_{MH}(1)=4.70, p<0.05$ **for tailored letters compared to generic reminders**	Study is highly generalizable because the population is primarily U.S.-based and includes studies with women ages 40+ yrs. Of the studies reviewed, the interventions included in this meta-analysis most closely reflect the AB 56 requirement	Preponderance of evidence that patient reminders for mammography screening increase the number of women completing mammography
Stone et al., 2002[a]	**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.)	Improved adherence to breast cancer screening guidelines for women overdue for screening	Patient reminders are significantly more effective at increasing mammography rates than educational or provider feedback interventions **Adj. OR 2.31 (95% CI, 1.97 to 2.70)** for all forms of patient reminders for mammography	Study is somewhat generalizable because the population is undefined and the interventions are more tailored or detailed than AB 56 requires	Preponderance of evidence that patient reminders for mammography screening increase the number of women completing mammography

[11] 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	Research Design[11]	Outcome	Findings (Statistical Significance, Direction of Effect)	Generalizability to Population Affected by Mandate	Conclusion
Sohl and Moyer, 2007[b]	**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	Improved adherence to mammography screening for women overdue for screening	Women receiving tailored print interventions are significantly more likely to get a mammogram than women in the "usual care" groups **Adj. OR 1.31** for the print reminders based on 14 studies (no CI reported)	Study is somewhat generalizable because mean age is 60 years and women are mostly not from underserved populations. Studies include women nonadherent to screening, and mixed samples of women, but the interventions are more tailored than AB 56 requires	Preponderance of evidence that patient reminders for mammography screening increase the number of women completing mammography
Baron et al., 2008[c]	**Level I:** Systematic review of 19 studies to compare effectiveness of client reminders to increase mammography screening. Reminders were defined as printed (letter or postcard) or telephone messages advising clients that they are due or late for screening. Reminders may be enhanced by tailoring to the individual and additional text or reminders with more detailed information	Increased mammography screening rates for women overdue for screening	When used alone, simple printed reminders result in a **median postintervention increase of 3.6% points** (interquartile interval=1.8, 14.0) (An additional 3.6 women/100 women will obtain mammography screening due to simple client reminders)	Study is somewhat generalizable because, where noted, studies occurred in the United States and Australia; in HMOs and clinical and community settings, and among various races and levels of SES. The print reminders were frequently enhanced by additional or tailored contact (e.g., telephone or follow-up reminders, scheduling assistance, face-to-face counseling)	Preponderance of evidence that patient reminders for mammography screening increase the number of women completing mammography

Notes: [a]The Stone et al (2002) and Wagner (1998) meta-analyses include five of the same studies.
[b]The Sohl and Moyer (2007) and Stone et al. (2002) meta-analyses include two of the same studies.
[c]Two studies overlap in the Baron et al (2008) systematic review and the Sohl and Moyer (2007) analysis. The Baron study also overlaps with the Wagner (1998) meta-analysis on five studies. The Baron study includes three of the same studies as the Stone et al (2002) meta-analysis.
Key: CI=95% confidence interval; OR=odds ratio; χ2MH(1)=Mantel-Haenszel chi-square test; RCT=randomized controlled trial; SES=socioeconomic status.

Summary of Results

The medical effectiveness analysis considers three points in the AB 56 report: (1) does mammography screening reduce mortality due to breast cancer for women of all eligible ages; (2) does mammography screening reduce breast cancer mortality rates for women ages 40-49 years; and (3) does notification of eligibility for mammography increase the rate of completed screenings.

Effectiveness of Mammography

- There is a preponderance of evidence that, among women ages 40 years and older, mammography screening reduces breast cancer mortality by
    - 15%-26% after 7 to 9 years of follow-up for women ages 50 years and older, and
    - 15%-17% after 10 to 14 years of follow-up for women ages 40 to 49 years.
- Harms associated with mammography screening are primarily false-positive readings that result in additional outpatient visits, additional diagnostic imaging, and biopsies. After weighing the evidence, seven national organizations determined that the benefits of mammography for women aged 40 and older outweighed the harms. Each organization issued clinical guidelines recommending, for women of average risk for breast cancer, annual or biennial mammography screening for women beginning at age 40 (with some guidelines recommending that screening decisions for the 40-49–year cohort be based on a woman's breast cancer risk, her preferences, and her provider's recommendation).

Effectiveness of Notification of Eligibility for Mammography Screening

- There is a preponderance of evidence that notifying women through written notice about routine mammography screening can increase the overall mammography screening rate by about one-third.

UTILIZATION, COST, AND COVERAGE IMPACTS

Assembly Bill (AB) 56 would require California Department of Insurance (CDI)-regulated plans to cover mammograms for screening or diagnostic purposes upon referral by a provider. AB 56 would also require that all plans regulated by CDI or Department of Managed Health Care (DMHC) send a one-time, written notice to female policy-holders to indicate that they are eligible for breast cancer screening tests during the calendar year in which national guidelines indicate such screening should begin. For the purpose of this analysis, CHBRP based the cost estimates for notification on a one-time, generic letter (addressed by name) delivered to female members/enrollees of DMHC- and CDI-regulated plans and policies as each woman turns 40.

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 56. Please see Appendix D at the end of this document for further details on the underlying data sources, assumptions, and methods.

Present Baseline Cost and Coverage

Current Coverage of the Mandated Benefit

Coverage of the commercially insured population subject to the mandate

Approximately 21,340,000 individuals in California are enrolled in health plans or policies that would be subject to this mandate. 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 breast cancer screening. All seven health plans and insurers responded to the survey representing approximately 82% of the privately insured enrollees in the CDI-regulated market and approximately 98% in the DMHC-regulated market.[12] Combined, responses to this survey represent 96% of the privately insured market. DMHC-regulated plans represent about 85% of the privately insured market in California, while CDI-regulated plans represent 15%. CHBRP's methods of calculating enrollment in private and public programs that would be affected by the mandate are described in Appendix D.

CHBRP's coverage survey of health plans indicated that all 1,185,000 female enrollees in CDI-regulated plans have coverage for breast cancer screening per United States Preventive Services Task Force (USPSTF) guidelines. Approximately 160,000 enrollees in CDI- and DMHC-regulated plans reach age 40 each year and would receive a one-time, generic letter (addressed by name) about eligibility for breast cancer screening after the passage of AB 56. Of these women, an estimated 22% (35,000) of women turning 40 in DMHC- and CDI-regulated policies already receive written notification from their health plans regarding breast cancer screening and were therefore considered to be in plans compliant with the AB 56 notification mandate (Table

[12] 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.

5); however, this rate differs by market segment. An estimated 20% of DMHC-regulated plans and 23% of CDI-regulated policies send written notification to women aged 40 years to indicate their eligibility for breast cancer screening. Written notification coverage rates for women enrolled in individual policies versus group policies also vary.

Of the portion of the population insured by the California Public Employees' Retirement System (CalPERS) who have coverage subject to AB 56, an estimated 50% receive a written notification. This estimate is based on CHBRP's coverage survey of health plans and insurers in California. Communication with Medi-Cal indicates that they do not require notification of eligibility for mammography screening to enrollees at age 40; however, because Medi-Cal, like CalPERS, contracts with commercial providers for coverage for a portion of its enrollees, CHBRP applied the notification estimates based on the carrier survey to the Medi-Cal, Major Risk Medical Insurance Program (MRMIP), and Access for Infants and Mothers (AIM) populations. Therefore, CHBRP assumed that 20% of the portion of women age 40 years in Medi-Cal, AIM, and MRMIP with coverage subject to AB 56 already receive notification for mammograms.

Table 5. Current Coverage by Market Segment, California, 2009

	Coverage for Mammography Screening	Percent of 40-Year-Old Women Receiving Written Notification for Mammograms
DMHC-Regulated Plans		
Large group	100%	20%
Small group	100%	20%
Individual	100%	22%
All	100%	20%
CDI-Regulated Policies		
Large group	100%	17%
Small group	100%	29%
Individual	100%	22%
All	100%	23%
CalPERS	100%	50%
Medi-Cal	100%	20%
Healthy Families	N/A	N/A
MRMIP	100%	20%
AIM	100%	20%
Total	100%	22%

Source: California Health Benefits Review Program, 2009.

Current Utilization Levels and Costs of the Mandated Benefit

Current Utilization Levels

CHBRP's carrier survey of CDI-regulated policies indicates that an estimated 100% of these plans provide coverage for mammograms as a screening and diagnostic test for breast cancer to women age 18 years and over. Currently, an estimated 51% of women receive a mammogram during their 40th year—the age at which annual screening is recommended to begin. This means that 49% of women do not receive the recommended screening (CHIS, 2007).

CHBRP's carrier survey also indicates that an estimated 22% (35,000) of women age 40 enrolled in CDI- and DMHC-regulated health plans and policies receive a written notification from their health plan or insurer to receive breast cancer screening based on USPSTF guidelines, while the remaining 78% (125,000) do not receive this type of notification from a carrier.

Unit Price

The cost of a single mammogram is estimated at $96.[13] Approximately 13% of first-time mammograms are false positive and are recalled for further evaluation and diagnostic workup (Smith-Bindman et al., 2005). Among these recalls, 20% receive invasive procedures, including biopsies, and 80% receive noninvasive procedures such as clinical breast exam, repeat mammograms, ultrasounds, and office visits. The unit price of a mammogram plus the costs of services due to false-positive test results are estimated at $169. The false-positive rates are higher for women younger than 50 years of age due to a number of factors (further described in the *Medical Effectiveness* section of this report). Thus, the unit price of mammograms calculated by CHBRP may be an underestimation of the true cost of mammograms for women aged 40 years.

AB 56 is not expected to affect the unit cost of mammography. All seven carriers surveyed by CHBRP reported full coverage of mammography as a screening test for breast cancer, and AB 56 is not expected to increase the mammography rate due to increases in coverage. CHBRP estimates that AB 56 will increase utilization as a result of the one-time, generic letter (addressed by name) required under the bill, with the expected total annual number of mammograms increasing by 0.38%, though again, this is not expected to change the unit costs of mammograms.

The baseline costs associated with the mandate, given current utilization and unit price of the screening, are presented in Table 6.

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

[13] This number is obtained from a Milliman database containing 2006 claims data, and is trended forward to 2009 dollars using a rate of 10% per year.

Currently, an estimated 100% of health plans and health insurance policies in the private and public market segments cover mammography as a routine screening test when referred by a provider. Thus, no cost shifting between public and private payers is anticipated as a result of AB 56.

Public Demand for Coverage

As a way to determine whether public demand exists for the proposed mandate (based on criteria specified under Senate Bill 1704 [2007]), CHBRP reports 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.

To further investigate public demand for benefits addressed by the bill, CHBRP utilized a bill specific carrier survey that was fielded after the analysis request was received. Surveyed carriers offering plans or policies to self insured groups were asked whether the relevant benefits differed from those offered in the commercial markets. The responding carriers indicated that there were no substantive differences.

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.[14]

Impacts of Mandated Coverage

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

Impact on Supply and on the Health Benefit

CHBRP does not estimate changes in supply or health benefits of mammograms due to AB 56. There are no supply constraints associated with mammograms, and the estimated increase in the number of mammograms due to AB 56 is not expected to lead to such constraints. AB 56 is not anticipated to change the health benefits of mammograms.

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

Impact on Per-Unit Cost

CHBRP estimates no measurable impact on per-unit costs of mammograms since no changes in supply are anticipated and the increase in total annual utilization of mammograms is 0.38%.

Postmandate coverage

AB 56 is not expected to change coverage of mammograms, since 100% of surveyed health plans and insurers subject to the mandate reported covering mammograms for breast cancer screening upon provider referral.

How Would Utilization Change as a Result of the Mandate?

AB 56 is not estimated to increase utilization of mammograms due to mandated coverage of this service for enrollees of CDI-regulated plans, because 100% of such individuals are currently covered for mammograms. However, AB 56 is expected to increase the number of mammograms due to the mandate requiring plans to send a one-time letter to women when they become eligible for breast cancer screening per national guidelines. Approximately 160,000 women reach age 40 each year and would receive a one-time, generic letter as notification for mammography by their health plan or insurer due to the mandate and concordant with USPSTF guidelines. Of these, currently 22% (35,000) are already receiving notification from their health plans or insurers. Also, an estimated 49% of women did not receive an annual mammogram during their 40th year prior to the mandate (CHIS, 2007). A one-time, generic letter is predicted to lead to an increase of 31.7% in screening (Wagner 1998). After the mandate, an estimated 20,000 additional mammograms will be received by women without previous annual mammograms and without previous health plan or insurer notification, as a result of AB 56.

Increased mammograms due to AB 56 are not expected to substitute or complement other services or lead to changes in delivery or management of mammograms following the mandate. For further discussion of long-term impacts of increased mammograms, see the section titled "Impact on Long-Term Costs," or the *Public Health Impacts* section of this report.

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

The notification requirement of AB 56 will lead to increased administrative costs within both the private and public segments of the market. A written notification in the form of a one-time, generic letter to covered women at age 40 years is estimated to cost $96,000, based on an estimated cost of $0.60 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 costs *as a proportion of premiums* would increase by approximately $389,000 due to the increased utilization of mammograms due to notification and notification costs.

AB 56 is not anticipated to lead to changes in the proportion of premiums paid by employees, employers, policyholders, or public insurers.

Impact of the Mandate on Total Health Care Costs

Changes in total expenditures

AB 56 would increase expenditures in both private and public market segments (Table 7). Total expenditures are estimated to increase by $3,691,000, or 0.004%, including $3,404,000 in total premiums and $287,000 in out-of-pocket expenditures. Employer premium expenditures for group insurance would increase by $2,057,000; premium expenditures by individuals with group insurance, CalPERS, AIM, or MRMIP would increase by $537,000; CalPERS expenditures would increase by $75,000, or 0.002%; and Medi-Cal managed care expenditures would increase by $374,000, or 0.009%.

Offsets

AB 56 is expected to increase the number of mammograms for women 40 years of age by 20,000, or 0.38%. This increase in mammograms is expected to decrease the mortality rate from breast cancer in the long term (as presented in the *Public Health Impacts* section). The average costs for breast cancer treatment are estimated to range from $12,000 to $27,000, depending on the stage of disease at detection (Stout et al., 2006). Early treatment of women with breast cancer found as a result of the mandate may lead to lower average costs of treatment. However, the estimated 13% false positive rate of mammograms will increase the use of unnecessary follow-up services including biopsies, repeat mammograms, ultrasounds, and office visits. Consequently, no net savings are expected due to the increased utilization of mammograms.

Impact on Long-Term Costs

AB 56 is expected 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 implementation of the mandate. A recent cost-effectiveness study of women ages 40 years and older examined the long-term cost savings associated with mammography (Stout et al., 2006). The study identified incremental cost-effectiveness ratios (ICERs) of $58,000 for screening annually and $47,000 for screening every 2 years 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 ICERs assumed that mammogram rates were 100%, and would thus be considerably higher if actual mammogram rates were assumed.

Impacts for Each Category of Payer Resulting from the Benefit Mandate

Changes in Expenditures and per Member per Month (PMPM) Amounts by Payer Category

The impact of AB 56 on total expenditures and PMPM premium amounts for each payer category are displayed in Table 7.

- In the large-group market, total expenditures would increase 0.0040% ($0.0149 PMPM) for DMHC-regulated plans and 0.0031% ($0.0153 PMPM) for CDI-regulated policies. Premiums would increase 0.0040% ($0.0141 PMPM) among DMHC-regulated plans and 0.0031% ($0.0136 PMPM) among CDI-regulated policies.
- In the small-group market, total expenditures would increase 0.0047% ($0.0162 PMPM) for DMHC-regulated plans and 0.0034% ($0.0159 PMPM) for CDI-regulated policies. Premiums would increase 0.0047% ($0.0149 PMPM) for DMHC-regulated plans and 0.0034% ($0.0115 PMPM) for CDI-regulated policies.
- In the individual market, total expenditures would increase 0.0047% ($0.0182 PMPM) for DMHC-regulated plans and 0.0086% ($0.0181 PMPM) for CDI-regulated policies. Premiums would increase 0.0047% ($0.0156 PMPM) for DMHC-regulated plans and 0.0085% ($0.0144 PMPM) among CDI-regulated segments.
- In CalPERS, total expenditures would increase by 0.0024% ($0.0095 PMPM) and premiums would increase by 0.0024% ($0.0090 PMPM).
- Medi-Cal, AIM, and MRMIP total expenditures would to increase by 0.0103% ($0.0133 PMPM).

Changes in Coverage as a Result of Premium Increases

AB 56 is expected to lead to premium increases of less than 1%. Therefore, CHBRP estimates no measurable loss of health insurance coverage as a result of AB 56.[15]

Impact of Changes in Private Coverage on Public Programs

CHBRP estimates that the mandate will produce no measurable impact on enrollment in public insurance programs or on utilization of covered benefits in the public sector.

Impact on Access and Health Service Availability

AB 56 would not impact access to mammograms, because women in all segments of the market are estimated to have coverage for this service. AB 56 is anticipated to increase mammogram

[15] CHBRP estimates the impact on the uninsured, if the mandate will result in a premium increase of greater than 1%. For more information on CHBRP's methodology, see: "Criteria and Methods for Estimating the Impact of Mandates on the Number of Individuals Who Become Uninsured in Response to Premium Increases" available at: http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

utilization due to notification to women age 40 years that do not receive annual mammograms and have not received notification to do so previously. However, this increase in utilization is not a reflection of increased access to services, but is due to an increase in awareness of eligibility and availability of the service. CHBRP assumes that this increase in awareness is uniform across all market segments subject to the mandate.

DMHC's HMO Help Center has logged over 30,000 complaints since its inception in 2001, of which 538 cases reference breast cancer screening[16]. 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 investigative, can appeal disputes to the California Independent Medical Review (IMR). Of 6,231 IMR decisions rendered since 2001, there are references to a variety of breast cancer screening issues, but no IMR decisions were related to mammography.

[16] Personal communication with Sherrie Lowenstein, Department of Managed Health Care, February, 2009

Table 6. Baseline (Premandate) Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2009

	DMHC- Regulated							CDI- Regulated			Total Annual
				CalPERS (b)	Medi-Cal (c)		Healthy Families				
	Large Group	Small Group	Indi-vidual	HMO	Managed Care 65 and Over	Managed Care Under 65	Managed Care	Large Group	Small Group	Indi-vidual	
Total population in plans subject to state regulation (a)	11,100,000	2,844,000	966,000	820,000	159,000	2,366,000	715,000	400,000	932,000	1,038,000	21,340,000
Total population in plans subject to AB 56	11,100,000	2,844,000	966,000	820,000	159,000	2,366,000	715,000	400,000	932,000	1,038,000	21,340,000
Average portion of premium paid by employer	$279.83	$246.48	$0.00	$321.26	$239.00	$128.09	$74.97	$341.25	$288.13	$0.00	$58,443,353,000
Average portion of premium paid by employee	$69.94	$71.52	$330.89	$56.69	$0.00	$0.71	$10.22	$97.61	$54.11	$169.28	$19,440,350,000
Total Premium	$349.77	$318.00	$330.89	$377.95	$239.00	$128.80	$85.19	$438.86	$342.24	$169.28	$77,883,703,000
Member expenses for covered benefits (deductibles, copays, etc.)	$18.90	$24.61	$54.10	$19.49	$0.00	$0.59	$2.32	$53.72	$124.95	$41.39	$6,384,067,000
Member expenses for benefits not covered	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0
Total Expenditures	$368.67	$342.62	$385.00	$397.44	$239.00	$129.39	$87.51	$492.58	$467.19	$210.66	$84,267,770,000

Source: California Health Benefits Review Program, 2009.

Notes: (a) This population includes privately insured (group and individual) and publicly insured (e.g., CalPERS, Medi-Cal, Healthy Families, Access for Infants and Mothers [AIM], Major Risk Medical Insurance Program [MRMIP]) individuals enrolled in health insurance products regulated by DMHC or CDI. Population includes enrollees aged 0-64 years and enrollees 65 years or older covered by employment sponsored insurance.

(b) Of these CalPERS members, about 59%, or 484,000, are state employees.

(c) Medi-Cal state expenditures for members under 65 years of age include expenditures for the MRMIP and the AIM programs**.** Medi-Cal state expenditures for members over 65 years of age include those with Medicare coverage.

Table 7. Impacts of the Mandate on Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2009

	DMHC- Regulated							CDI- Regulated			Total Annual
				CalPERS (b)	Medi-Cal (c)		Healthy Families				
	Large Group	Small Group	Indi-vidual	HMO	Managed Care 65 and Over	Managed Care Under 65	Managed Care	Large Group	Small Group	Indi-vidual	
Total population in plans subject to state regulation (a)	11,100,000	2,844,000	966,000	820,000	159,000	2,366,000	715,000	400,000	932,000	1,038,000	21,340,000
Total population in plans subject to AB 56	11,100,000	2,844,000	966,000	820,000	159,000	2,366,000	715,000	400,000	932,000	1,038,000	21,340,000
Average portion of premium paid by employer	$0.0113	$0.0116	$0.0000	$0.0077	$0.0000	$0.0131	$0.0000	$0.0106	$0.0097	$0.0000	$2,506,000
Average portion of premium paid by employee	$0.0028	$0.0033	$0.0156	$0.0014	$0.0000	$0.0001	$0.0000	$0.0030	$0.0018	$0.0144	$898,000
Total Premium	$0.0141	$0.0149	$0.0156	$0.0090	$0.0000	$0.0132	$0.0000	$0.0136	$0.0115	$0.0144	$3,404,000
Member expenses for covered benefits (deductibles, copays, etc.)	$0.0008	$0.0012	$0.0026	$0.0005	$0.0000	$0.0001	$0.0000	$0.0017	$0.0044	$0.0037	$287,000
Member expenses for benefits not covered	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0
Total Expenditures	$0.0149	$0.0162	$0.0182	$0.0095	$0.0000	$0.0133	$0.0000	$0.0153	$0.0159	$0.0181	$3,691,000
Percentage Impact of Mandate											
Insured premiums	0.0040%	0.0047%	0.0047%	0.0024%	0.0000%	0.0102%	0.0000%	0.0031%	0.0034%	0.0085%	0.0044%
Total expenditures	0.0040%	0.0047%	0.0047%	0.0024%	0.0000%	0.0103%	0.0000%	0.0031%	0.0034%	0.0086%	0.0044%

Source: California Health Benefits Review Program, 2009.

Notes: (a) This population includes privately insured (group and individual) and publicly insured (e.g., CalPERS, Medi-Cal, Healthy Families, Access for Infants and Mothers [AIM], Major Risk Medical Insurance Program [MRMIP]) individuals enrolled in health insurance products regulated by DMHC or CDI. This population includes enrollees aged 0-64 years and enrollees 65 years or older covered by employment sponsored insurance.

(b) Of these CalPERS members, about 59%, or 484,000, are state employees.

(c) Medi-Cal state expenditures for members under 65 years of age include expenditures for the MRMIP and the AIM programs. Medi-Cal state expenditures for members over 65 years of age include those with Medicare coverage.

PUBLIC HEALTH IMPACTS

Impact of the Proposed Mandate on the Public's Health

Impact of Screening with Mammogram

Approximately 51% of insured women in California report receiving a mammogram during their 40th year—the age that clinical practice guidelines recommend screening with mammography begin. As presented in the *Utilization, Cost, and Coverage Impacts* section, all health plans subject to AB 56 currently cover mammography in accordance with national guidelines. AB 56 seeks to increase the utilization rate of mammograms by requiring health insurance plans to notify women at the time they become eligible (per national guidelines) for screening using mammography. This analysis assumes a one-time, generic letter (addressed by name) is sent to enrollees in the year that they turn 40. This mandate, through notification, is expected to increase the number of women who receive mammograms each year by 20,000. Because plans and insurers may do less than is assumed in this analysis to achieve compliance with the notification component of AB 56 (e.g., notification in a quarterly newsletter or evidence of benefit documents), the effect of mandated notification in this analysis should be considered an upper bound estimate.

There are more than 4,200 deaths in California each year due to breast cancer (CCR, 2008). It is estimated that 1,224 women need to be screened with mammography to prevent one death from breast cancer (Humphrey et al., 2002). Of the additional 20,000 women screened with mammograms as a result of AB 56, it is estimated that 16 premature deaths from breast cancer among this population could be prevented over an estimated 14-year time frame, although qualitative improvements, such as a decrease in the aggressiveness of the cancer and less treatment for metastatic disease would be expected sooner.

As presented in the *Medical Effectiveness* section, mammograms are considered to be effective in detecting cancer when done as part of a regular screening program in women ages 40 and older of average risk for breast cancer. As with all screening tests, mammography screening is not perfect, and for first-time mammograms, there is an estimated false-positive rate of 13%. Thus, of the 20,000 additional mammograms, it is estimated that nearly 2,600 would result in false-positive test reports. Evidence exists as to the potential harms associated with increases in false positives, such as increases in biopsies, additional interventions, radiation exposure, and short-term anxiety and discomfort of patients. Despite these inherent risks of population-based screening, there is consensus among the major U.S. national guidelines that the benefits of mammography screening far outweigh the potential harms (see Appendix C).

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

CHBRP investigated the effect that AB 56 would have on health disparities by gender, race, and ethnicity. Evaluating the impact on racial and ethnic disparities is particularly important because racial and ethnic minorities report having poorer health status and worse health indicators (Kaiser, 2007). One important contributor to racial and ethnic health disparities is differential insurance rates, where minorities are more likely than whites to be uninsured; however, disparities still exist within the insured population (Kirby et al 2006, Lillie-Blanton and Hoffman

2005). As such, a literature review was conducted to determine whether there are gender, racial, or ethnic disparities associated with the prevalence, treatment, and outcomes for breast cancer and mammography screening.

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, 2008). Since the subject of AB 56 is breast cancer screening among women, and there are no clinical practice guidelines that recommend breast cancer screening among men, this analysis was limited to breast cancer found in women.

As presented in Table 8, 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), with 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, which are associated with a significant increase in the rates of breast cancer, also vary by race/ethnicity. The highest rates were found among Ashkenazi Jewish women, and the lowest were found among Asian American women (John et al., 2007).

Screening rates using mammography vary by race/ethnicity among women ages 40 years and older. Non-Hispanic white women (82.3%) had the highest rates of breast cancer screening using mammography in the last 2 years, followed by black (81.3%), Hispanic (77.8%), and Asian women (76.1%) (CHIS, 2007). Published studies on mammography utilization by race and ethnicity suggest that the differences in screening rates are even more significant than the CHIS data would indicate (Kagay et al., 2006; Smith-Bindman et al., 2006). These studies found that all groups of non-white women utilize mammography screening at much lower rates compared to white women, and that some differences in health outcomes by race are explained by these differential screening rates (Kagay et al., 2006; Smith-Bindman et al., 2006). 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, 2008). 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 with 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). The research on mammography utilization by race/ethnicity suggests that some of the differences in health outcomes among non-white women can be explained by their lower rates of mammography utilization (Smith-Bindman, 2006). Therefore, to the extent that notification increases mammography screening among these groups, there is the potential for AB 56 to 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.

Although breast cancer is the most common cancer found among women in California, when diagnosed early, the survival rates are very high. The 5-year relative survival rate for breast cancer among women in California is 88% (CCR, 2008). This rate varies with the stage of diagnoses: breast cancer diagnosed at an earlier stage has a higher survival rate. In California, 69% of breast cancer is diagnosed at an early stage—where the 5-year relative survival rate is the highest (97%) compared to diagnoses at later stages.

It is estimated that AB 56 could lead to a reduction in breast cancer–related mortality through increased utilization of mammograms. 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 versus not having such screening (Humphrey et al., 2002). This translates into needing to screen 1,224 women to prevent one death from breast cancer. Of the additional 20,000 women screened with mammograms, it is estimated that 16 premature deaths from breast cancer among this population would be prevented over time.

The data available on lost productivity in California associated with breast cancer suggest 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 $328,000 (converted to 2008 dollars) (Max, 2006). Although it would take an average of 14 years to realize this benefit, a reduction in 16 premature deaths each year would translate into a savings of 366 life-years and $5.2 million in lost productivity.

Long-Term Public Health Impacts

The data presented in the *Public Health Impacts* 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 56.

As presented in the *Utilization, Cost, and Coverage Impacts* section, AB 56 is expected to increase premiums by less than 1%. CHBRP does not estimate loss of coverage as a result of premium increases of less than 1%. Therefore it is unlikely that AB 56 will result in an increase in the uninsured or contribute to the long-term health impacts of being uninsured.

Table 8. 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	80.7% (79.8–81.6)	69%	23.2
Hispanic	87.0	77.8% (74.5–81.0)	63%	16.0
Non-Hispanic white	148.4	82.3% (81.3–83.3)	70%	26.0
Black	118.1	81.3% (77.9–84.8)	61%	33.0
Asian/Pacific Islander	92.9	76.1% (72.6–79.5)	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, 2007. Screening is reported as mammography within the last 2 years for women ages 40 years and older with health insurance.
(c) Data taken from CCR, 2008. Early stage is defined as cancer found in situ or localized.
(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 56 INTRODUCED
BILL TEXT

INTRODUCED BY Assembly Member Portantino

DECEMBER 5, 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 56, as introduced, Portantino. Health care coverage: mammographies.

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. Existing law also requires such plan contracts and policies to cover screenings and diagnosis of breast cancer, consistent with generally accepted medical practice and scientific evidence, upon referral of an enrollee's participating physician.

This bill would 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 cancer. The bill would provide that individual or group policies of health insurance or self-insured employee welfare benefit plans issued, amended, delivered, or renewed on and after July 1, 2010, shall be deemed to provide coverage for mammographies for screening or diagnostic purposes upon referral of a participating nurse practitioner, participating certified nurse-midwife, or participating physician, as specified.

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 that place them at high risk of developing breast cancer during their lives.

(b) In order to protect the health of California citizens, breast cancer screening and diagnostic testing methods must be provided. These diagnostic treatment tools, when used 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~~ *nurse-midwife* , or participating physician, providing care to the patient and operating within the scope of practice provided under existing law.

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

(c) A health care service plan subject to this section or Section 1367.6 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 cancer, 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~~ *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 and over.

(b) On or after July 1, 2010, 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 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.

~~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~~ *nurse-midwife* providing care.

(e) A disability insurer or self-insured employee welfare benefit plan subject to this section or Section 10123.8 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 cancer, 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 56. The literature search included meta-analyses, systematic reviews, randomized controlled clinical trials (RCTs), and clinical practice guidelines. PubMed and the Cochrane Library were searched as well as National Guideline Clearinghouse (NGC), International Network of Agencies for Health Technology Assessment (INAHTA), National Institute for Clinical Excellence (NICE), NHS Centre for Reviews and Dissemination, Agency for Healthcare Research and Quality (AHRQ), National Institutes of Health (NIH), and the Institute for Clinical Systems Improvement (ICSI). Web sites of government agencies and other professional organizations engaged in breast cancer surveillance activities and research were also searched (i.e., American College of Obstetricians and Gynecologists, National Comprehensive Cancer Network, Inc. [NCCN], British National Collaborating Centre for Women's and Children's Health [NCCWCH], American Cancer Society, American College of Radiologists, American College of Obstetricians and Gynecologists, and the American Society of Breast Disease.)

The search was conducted to retrieve literature on four major topics: (1) the effectiveness of mammography screening on breast cancer mortality; (2) the effectiveness of written notification of eligibility for screening on screening rates; (3) the cost effectiveness of mammography screening for breast cancer and notification of eligibility; and (4) the race/ethnicity disparities regarding mammography screening, diagnosis, and notification of eligibility for screening. The medical effectiveness review addressed the first two topics, and the cost and the public health reviews addressed the third and fourth topics, respectively.

The medical effectiveness literature search initially focused on articles published in 2007 to the present for mammography screening and 1990 to present for notification-related literature. For all topics, the literature review was limited to articles published in English and focusing on a target population of all adult women aged 19 years or older. An additional search for articles between 1995 and 2006 was conducted for mammography screening, as the initial search did not yield pertinent studies. All national guidelines were collected through national Web sites, such as the Centers for Disease Control and Prevention and the National Guideline Clearinghouse database.

Four hundred and thirty-two abstracts were reviewed for the literature review for AB 56. 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 for abstracts meeting the criteria, and reviewers reapplied the eligibility criteria. A total of nine studies were included in the medical effectiveness review. Clinical guidelines from eight national organizations were reviewed and included in the medical effectiveness review (three of the eight were footnoted in Table C-1.)

The review of the effectiveness of mammography screening for breast cancer summarized findings from meta-analyses and systematic reviews of primarily RCTs and observational studies. RCTs provide the strongest evidence of effectiveness.

The California Health Benefits Review Program (CHBRP) focused on written notification of routine mammography to eligible women and summarized three meta-analyses of RCTs and one systematic review. 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 AB 56 were as follows:

Search Terms Used:

MeSH Terms
Breast Neoplasms/diagnosis
Breast Neoplasms/prevention and control
Mammography
Mass Screening
Reminder Systems
Insurance Carriers

Health Maintenance Organizations

Keywords
Mammogram*
Mammograph*
Breast Cancer
Newsletter*
Notification
Notify*
Remind*
Letter*
Postcard*
Mail or Mailing or Postal
Communication
Telephone or Phone
Registry
Email*
Intervention

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

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

Databases Searched
PubMed
Cochrane Library
CINAHL
National Guideline Clearinghouse
Grey Literature on Internet (Government websites, Association websites)

Appendix C: Summary of Published Clinical Guidelines and Medical Effectiveness Literature for Mammography Screening

Appendix C summarizes the recommendations of five U.S. organizations issuing clinical guidelines for mammography screening in Table C-1. Table C-2 lists three published systematic reviews and meta-analyses regarding the medical effectiveness of mammography screening for all eligible women (per national guideline recommendations). Table C-3 lists four systematic reviews and meta-analyses of the medical effectiveness of mammography screening for women ages 40–49 years. Table C-4 lists four systematic reviews and meta-analyses of the medical effectiveness of notification for mammography screening.

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

#	Guideline Developer	Evidence or Consensus Based	Issue Year	Screening Age Range for Average-Risk Population	Screening Interval for Average-Risk Population	Comments
1	**U.S. Preventive Services Task Force:** Screening for Breast Cancer: Recommendations and Rationale (USPSTF, 2002)	Evidence based	2002	40 years and older, continuing as long as no comorbid conditions affect life expectancy	Every 12 to 24 months	Breast cancer grows more rapidly in women between ages 40 and 49 years, so shorter screening intervals for mammography have been advocated
2	**American Cancer Society:** Guidelines for Breast Cancer Screening Update 2003 (Smith et al., 2003) [a]	Evidence based	2003	40 years and older, continuing as long as woman is in good health	Annually	Women should be educated about the benefits, limitations, and harms of screening Women at high risk might benefit from other strategies such as earlier screening initiation, shorter screening intervals, or addition of other modalities such as ultrasound or magnetic resonance imaging
3	**American College of Physicians**: Screening Mammography for Women 40–49 Years of Age: A Clinical Practice Guideline (Qaseem et al., 2007)[b]	Evidence based	2007	40-49 years (see Comments)	Clinician should base screening mammography decisions on benefits and harms of screening, a woman's preferences, and her breast cancer risk profile.	Guideline focuses only on mammography in ages 40 to 49 years Clinician should inform patients about potential benefits and harms of screening mammography Screening mammography every 1 to 2 years is reasonable for those women reluctant to discuss screening

#	Guideline Developer	Evidence or Consensus Based	Issue Year	Screening Age Range for Average-Risk Population	Screening Interval for Average-Risk Population	Comments
4	**American College of Obstetrician and Gynecologists:** Breast Cancer Screening (ACOG, 2003)	Evidence based	2003	40-49 yrs 50 years and older	Every 1 to 2 years Annually	
5	**American College of Radiology:** Guidelines for Breast Cancer Screening (Feig et al., 1998)	Evidence based	1997	40 years and older	Annually	Mammographic screening before the age of 40 may benefit those women at high-risk for breast cancer

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

Table C-2. Summary of Published Studies on Effectiveness of Mammography for All Eligible Women

Citation	Type of Study	Study Objective	Population Studied	Location
Gøtzsche and Nielsen, 2006[a]	Systematic review of 7 RCTs	Assess effectiveness of screening mammography on breast cancer mortality and morbidity	Approximately 500,000 women ages 40 to 74 years	North American and Europe
Humphrey et al., 2002 [a]	Systematic review and meta-analysis of 8 RCTs	Assess effectiveness of screening mammography on breast cancer mortality	Women ages 40 to 74 years	North America and Europe
Kerlikowske et al., 1995[a]	Systematic review and meta-analysis of 9 RCTs and 4 case-control studies	Assess effectiveness of screening mammography on breast cancer mortality	Women ages 35 to 74 years	North America and Europe

Note: [a]All meta-analyses consider the same eight RCTs.
Key: RCT=randomized controlled trial.

Table C-3. Summary of Published Studies on Effectiveness of Mammography for Women Ages 40-49 Years

Citation	Type of Study	Study Objective	Population Studied	Location
Armstrong et al., 2007	Systematic review of 7 RCTs	Assess effectiveness of screening mammography on breast cancer mortality and morbidity	Approximately 500,000 women ages 40 to 74 years	North American and Europe
Moss et al., 2006	RCT	Assess effectiveness of screening mammography on breast cancer mortality	160,921 women ages 39 to 41 years	North America and Europe
Humphrey et al., 2002	Systematic review and meta-analysis of 7 RCTs	Assess effectiveness of screening mammography on breast cancer mortality	200,000 women ages 35 to 74 years	North America and Europe
Kerlikowske et al., 1997	Meta-analysis of 9 RCTs and 4 case-control studies	Assess effectiveness of screening mammography on breast cancer mortality	Women ages 40 to 49 years	North America and Europe

Key: RCT=randomized controlled trial.

Table C-4. Summary of Published Studies of Medical Effectiveness of Notification for Mammography Screening

Citation	Type of Study	Study Objective	Population Studied	Location
Wagner, 1998	Meta-analysis of 16 RCTs	To compare effectiveness of mailed patient reminders at increasing mammography screening	Approximately 16,000 women ages 40+ years Interventions most closely reflect the AB 56 requirement.	United States, Australia, New Zealand
Stone et al., 2002[a]	Meta-analysis of 29 RCTs and controlled clinical trials	To compare relative effectiveness of patient reminders	Study is somewhat generalizable because the population is undefined Interventions are more tailored or detailed than AB 56 requires	United States and abroad (unspecified)
Sohl and Moyer, 2007[b]	Meta-analysis of 28 RCTs	To compare effectiveness of tailored interventions including print reminders compared to "usual care" control groups	33,227 women (mean age is 60 years) who are mostly not from underserved populations, include women nonadherent to screening, and mixed samples of women Interventions are more tailored than AB 56 requires	Not stated
Baron et al., 2008[c]	Systematic review of 19 studies	To compare effectiveness of client reminders to improve adherence to mammography screening	Women in HMOs and clinical and community settings, and among various races and levels of SES	Where noted, studies occurred in the United States and Australia

Notes: [a]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.
[b]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.
[c]The following studies in the Baron et al (2008) systematic review overlap with the Sohl and Moyer (2007) analysis: Davis, 1997; Saywell, 2003. The Baron study also overlapped with the Wagner (1998) meta-analysis on five studies: Irwig, 1990; King, 1994; Landis, 1992; Lantz, 1995; and Turnbull, 1991. The Baron study overlapped with the Stone et al. (2002) meta-analysis on three studies: Hogg, 1998; Lantz, 1995; and Landis, 1992.
Key: HMO=health maintenance organization; RCT=randomized controlled trial; SES=socioeconomic status.

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

This appendix describes data sources, as well as general and mandate-specific caveats and assumptions, used in conducting the cost impact analysis. For additional information on the cost model and underlying methodology, please refer to the CHBRP Web site at 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 that provides data and analyses per the provisions of CHBRP's authorizing legislation.

Data Sources

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

Private Health Insurance

1. The latest (2007) California Health Interview Survey (CHIS), which is used 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 approximately 53,000 households. More information on CHIS is available at www.chis.ucla.edu/

2. The latest (2008) California Employer Health Benefits Survey is used 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] and point of service plans [POS]),
    - premiums for policies regulated by the California Department of Insurance (CDI) (primarily preferred provider organizations [PPOs] and fee-for-service plans [FFS]), and
    - premiums for high-deductible health plans (HDHPs) for the California population covered under employment-based health insurance.

    This annual survey is currently released by the California Health Care Foundation/National Opinion Research Center (CHCF/NORC) and is similar to the national employer survey released annually by the Kaiser Family Foundation and the Health Research and Educational Trust. Information on the CHCF/NORC data is available at: www.chcf.org/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, Blue Cross 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.
- 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 95.5% of the privately insured market: 98.0% of privately insured enrollees in full-service health plans regulated by DMHC and 81.7% of enrollees in privately insured health insurance products regulated by CDI.

Public Insurance

5. Premiums and enrollment in DMHC- and CDI-regulated plans by self-insured status and firm size are obtained annually from 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 licensed health care service plans covering non-Medicare beneficiaries—comprising 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.dhcs.ca.gov/dataandstats/statistics/Pages/BeneficiaryDataFiles.aspx.

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 Managed 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-MRMIP 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 mandated benefits 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 products subject to state-mandated health insurance benefits.
- Cost impacts are only for the first year after enactment of the proposed mandate
- Employers and employees will share proportionately (on a percentage basis) in premium rate increases resulting from the mandate. In other words, the distribution of premium paid by the subscriber (or employee) and the employer will be unaffected by the mandate.
- For state-sponsored programs for the uninsured, the state share will continue to be equal to the absolute dollar amount of funds dedicated to the program.
- When cost savings are estimated, they reflect savings realized for one year. Potential long-term cost savings or impacts are estimated if existing data and literature sources are available and provide adequate detail for estimating long-term impacts. For more information on CHBRP's criteria for estimating long-term impacts please see: http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

- Several 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% 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

- For this analysis, a 1.48 odds ratio (OR) or an increase of 31.7% for mammography after notification was applied to everyone not currently receiving a notification from their health plan. In the analysis of the impact of AB 2234 in 2008, CHBRP excluded women who receive notification from their medical groups from those who would receive screening due to health plan notification. CHBRP has evidence that suggests a number of medical groups and independent practice associations (IPAs) in California send out their own notifications to women for mammography screening (unpublished data, the National Study of Physician Organizations, UC Berkeley School of Public Health). Similarly, individual physicians may also send reminders to notify women to receive mammograms. It is likely that some women may receive more than one notification from multiple sources and more frequently than AB 56 mandates, though the extent of this overlap is unknown.

  CHBRP did not exclude women who may have received notification from other sources in the current report for the following reasons. CHBRP was not able to obtain detailed information on the nature of medical groups and IPAs notifications and was not able to get any information on notifications sent by physicians within its 60-day timeline. Existing data on notification from medical groups and IPAs were for women aged 50 and older; an entirely different cohort from the cohort of women turning 40 in this mandate analysis. Finally, the studies identified in the *Medical Effectiveness* section did not show a statistically significant difference in the OR of a single notification versus more than one notification for mammography screening. As a result, CHBRP did not incorporate the impact of notification from sources other than the health plan. Consequently, the estimates of the number of women who receive notification for the first time as a result of the mandate may be overestimated.

- The estimates of mammography screening rates obtained from survey data are shown to be significantly larger than those obtained from claims data among elderly women in U.S. (Kagay, et al, 2006). CHBRP did not have data on the potential extent of over-reporting of screening among women age 40 years who are subject to AB 56. However, potential over-reporting is not expected to impact the estimated change in utilization rates provided in this report, since such a bias is likely to exist before and after AB 56.

- The cost and utilization estimates provided in this report are based on the assumption that health plans subject to AB 56 will send a one-time written notification for mammogram screening to women age 40 years. Health plans may comply with AB 56 by sending a written notification to all women eligible for screening. AB 56 may lead to a small increase in mammograms among women older than 40 years of age who receive such notification for the first time. CHBRP did not estimate the extent of such potential

increase in cost and utilization since the way in which plans may comply with the notification requirement is not specified by AB 56. Such an increase is likely to be negligible.

Appendix E: Information Submitted by Outside Parties

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

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 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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