



CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Analysis of Assembly Bill 137: Mammography

A Report to the 2011-2012 California Legislature
March 18, 2011

CHBRP 11-01



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

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

A Report to the 2011-2012 California State Legislature

Analysis of Assembly Bill 137 Mammography

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PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill 137. In response to a request from the California Assembly Committee on Health on January 14, 2011, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the program's authorizing statute.

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

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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Assembly Bill 137

The California Assembly Committee on Health requested on January 14, 2011, 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) 137 Mammography, a bill that would impose a health benefit mandate. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.¹

Approximately 21.9 million Californians (59%) have health insurance that may be subject to a health benefit mandate law passed at the state level.² Of the rest of the state's population, a portion is uninsured (and so has no health insurance subject to any benefit mandate) and another portion has health insurance subject to other state law or only to federal laws. Similarly, AB 137 would not directly affect "Every Woman Counts," a program operated by the California Department of Public Health that does not provide health insurance coverage but does provide screening for breast cancer to the uninsured.

Uniquely, California has a bifurcated system of regulation for health insurance subject to state-level benefit mandates. The California Department of Managed Health Care (DMHC)³ regulates health care service plans, which offer benefit coverage to their enrollees through health plan contracts. The California Department of Insurance (CDI) regulates health insurers⁴, which offer benefit coverage to their enrollees through health insurance policies.

DMHC-regulated plans and/or CDI-regulated policies would be subject to AB 137. Therefore, the mandate would affect the health insurance of approximately 21.9 million Californians (59%).

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

AB 137 contains two separate mandates, one involving mammography coverage and the other related to notification regarding timelines for breast cancer screening.

AB 137 would require CDI-regulated policies to cover medically necessary mammography upon a provider's referral. The bill does not alter the current requirement for DMHC-regulated plans to do the same. The current Insurance Code requires CDI-regulated policies to cover mammography for women at particular ages and specifies particular frequencies (one test

¹ CHBRP's authorizing statute is available at: www.chbrp.org/documents/authorizing_statute.pdf.

² CHBRP's estimates are available at http://www.chbrp.org/other_publications/index.php.

³ DMHC was established in 2000 to enforce the Knox-Keene Health Care Service Plan Act of 1975; see Health and Safety Code, Section 1340.

⁴ CDI licenses "disability insurers." Disability insurers may offer forms of insurance that are not health insurance. This report considers only the impact of the benefit mandate on health insurance policies, as defined in Insurance Code, Section 106(b) or subdivision (a) of Section 10198.6.

between the ages of 35 and 39; one test every 2 years between the ages of 40 and 49; annual tests at age 50 and beyond).

AB 137 would also require that both DMHC-regulated plans and CDI-regulated policies notify subscribers/policyholders regarding recommended timelines for an individual to undergo tests for the screening or diagnosis of breast cancer. The bill indicates that the information may be provided by written letter, by publication in a newsletter, by publication in evidence of coverage (EOC) document, by direct telephone call, by electronic transmission, by Web-based portal, or by any other means that will reasonably notify the subscriber or policyholder of the recommended timelines for testing. In prior years, CHBRP analyzed bills (AB 2234 in 2008 and AB 56 in 2009), that would have placed different and more specific information requirements on plans and policies.

The notification requirement in AB 137 is much less prescriptive than the notification requirements contained in the 2008⁵ and 2009⁶ bills, that CHBRP projects no measurable notification-related utilization, cost, and public health impacts for AB 137.

CHBRP is aware that most states have mammography requirements but is unaware of any states that require plans or insurers to provide notification regarding the timelines for breast cancer screening.

Medical Effectiveness

The medical effectiveness analysis addresses three questions pertinent to AB 137:

- Does mammography screening (i.e., providing mammograms to asymptomatic women) reduce mortality due to breast cancer for women of all eligible ages?
- Does mammography screening reduce breast cancer mortality rates for women ages 40-49 years?
- Does notification of recommended timelines for mammography screening increase the rate at which women are screened?

Effectiveness of Screening Mammography

- There is a preponderance of evidence that, among women ages 40 years and older, mammography screening reduces breast cancer mortality by:
 - 15% for women age 39 to 49 years (need to invite 1,904 women for screening to avoid 1 death)
 - 14% for women age 50 to 59 years (need to invite 1,339 women for screening to avoid 1 death)

⁵ See: http://www.chbrp.org/completed_analyses/index.php.

⁶ See: http://www.chbrp.org/completed_analyses/index.php.

- 32% for women age 60 to 69 years (need to invite 377 women for screening to avoid 1 death)
- The evidence does not support mammography screening for most women under age 40 years.
- There is insufficient evidence to determine whether mammography screening is effective for women over age 74 years.
- The evidence supporting recommended mammography screening differs by age cohort due to the heterogeneity of breast cancer studies, the greater incidence of breast cancer among older women, the difference in the accuracy of mammography (due to breast tissue density), and the resulting impact of screening 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. The estimated risk of a false-positive reading after 10 screening mammograms is 63%.

Effectiveness of Notification Regarding Recommended Timelines for Breast Cancer Screening

- No studies were identified that assessed the effectiveness of providing subscribers, regardless of age or gender, with information about recommended timelines for mammography screening on screening rates.
- No studies were identified that examined the effectiveness of providing notification of recommended timelines for breast cancer screening in newsletters, evidence of coverage documents, or Web portals.
- There is a preponderance of evidence that for women for whom national guidelines recommend mammography screening, notification through written notices or telephone calls increases the percentage of eligible women screened.

Benefit Coverage, Utilization, and Cost Impacts

- The provision of medically necessary mammography upon provider referral is estimated to be already compliant with AB 137 among DHMC-regulated plans and CDI-regulated policies. Therefore, no measurable change is expected.
- Notification regarding timelines for breast cancer screening is estimated to be already compliant with AB 137 among both DHMC-regulated plans and CDI-regulated policies. Therefore, no measurable change is expected.
- Approximately 4.7 million women receive mammograms each year. The average per unit cost of mammograms (including additional services due to false positive results) is \$190.

- As no measurable change in benefit coverage is expected, no measurable change in utilization is projected.
- As no measurable change in benefit coverage is expected, no measurable change in cost is expected.
- As no measurable change in benefit coverage or cost is expected, no measurable change in the number of uninsured persons is expected.

Public Health Impacts

- In California, 84.6% of women aged 40-64 years with health insurance had a mammogram within the last 2 years. There is evidence that mammography can reduce mortality from breast cancer; however, no public health impact is projected due to the implementation of AB 137.
- There is evidence to suggest that the use of mammography is not without risk, and there are potential harms of this screening procedure, such as discomfort and pain during the procedure, consequences of false-positive and false-negative tests, overdiagnosis, and radiation exposure. However, there are no estimated increases in harms as a result of AB 137 due to no changes in utilization or coverage.
- The vast majority of breast cancer cases (99.3%) occur among women. Racial and ethnic disparities exist, not only in breast cancer prevalence, but also in early diagnoses and mortality rates as well. 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. However, since AB 137 is not expected to increase the utilization of mammography, AB 137 would not impact these disparities.
- There are approximately 4,200 deaths each year in California due to breast cancer, a rate of 21.4 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. Although breast cancer is related to economic loss, AB 137 is not estimated to change the utilization of mammography or result in a corresponding reduction in economic loss.

Potential Effects of the Federal Affordable Care Act

The federal “Patient Protection and Affordable Care Act” (P.L.111-148) and the “Health Care and Education Reconciliation Act” (H.R.4872) were enacted in March 2010. These laws

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

A number of ACA provisions will need to be further clarified through guidance or regulation. One example is the ACA’s requirement for certain health insurance to cover “essential health benefits.” Effective 2014, Section 1302(b) will require small group and individual health insurance, including “qualified health plans” (QHPs) that will be sold in the California Exchange, to cover specified categories of benefits. These essential health benefits (EHBs) are defined as ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care. The Secretary of Health and Human Services (HHS) is charged with defining these categories through regulation, ensuring that the EHB floor “is equal to the scope of benefits provided under a typical employer plan.” In addition, the ACA would allow a state to “require that a qualified health plan offered in [the Exchange] offer benefits in addition to the essential health benefits.” If the state does so, the state must make payments to defray the cost of those additionally mandated benefits, either by paying the individual directly, or by paying the qualified health plan (QHP). This ACA requirement could interact with existing and proposed California benefit mandates, especially if California decided to require qualified health plans to cover California-specific mandates, and those mandates were determined to go beyond the EHB floor. Federal regulations regarding which benefits are to be covered under these broad EHB categories and other details, such as how the subsidies for purchasers of qualified health plans are structured, are forthcoming.⁷

Essential health benefits included in qualified health plans in the Exchange and potential interactions with AB 137

As noted, EHBs are defined to include ambulatory patient services; laboratory services; and preventive and wellness services and chronic disease management. In addition, HHS, when promulgating regulations on EHBs is to ensure that the EHB floor “is equal to the scope of benefits provided under a typical employer plan.” Virtually all employer-based plans provide coverage for mammography services. As mentioned, the ACA requires states, beginning 2014, to “make payments...to defray the cost of any additional benefits” required of QHPs sold in the Exchange.⁸ This potential liability would depend on three factors:

⁷ For further discussion on EHBs and potential interaction with state mandates, please see, *California's State Benefit Mandates and the Affordable Care Act's "Essential Health Benefits"* available here: http://www.chbrp.org/other_publications/index.php.

⁸ Affordable Care Act, 1311(d)(3)(B).

- differences in the scope of “benefits in the final EHB package and the scope of mandated benefits in AB 137;
- the number of enrollees in QHPs; and
- the methods used to define and calculate the cost of additional benefits.

Because mammography services as defined under AB 137 is considered standard coverage for employer-based plans, and because it is likely to be considered part of EHBs, it is unlikely that there would be any additional fiscal liability to the state as a result of this mandate.

Preventive Services Required under ACA and AB 137

“New plans” (i.e., those not covered under the ACA’s “grandfather” provisions) were required to cover certain preventive services zero cost sharing beginning September 23, 2010. The U.S. Preventive Services Task Force (USPSTF) recommends screening every 2 years for women age 50 to 74 years. For women age 40 to 49 years, the USPSTF recommends that the decision to initiate biennial screening be made by individual women on the basis of their level of risk for breast cancer and their values regarding the benefits and harms of screening. Mammography, therefore, can be considered one of the preventive benefits that must be covered at zero cost sharing per the ACA. Based on CHBRP’s analysis of current coverage rates, virtually all health plans and policies have coverage for mammography services. AB 137 does not affect the cost sharing of mammography services. Any premium impacts resulting from the ACA’s requirements to cover preventive services at zero cost sharing is already reflected in the baseline premiums presented in this report and does not affect the marginal impact of AB 137.

INTRODUCTION

The California Assembly Committee on Health requested on January 14, 2011, 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) 137: Mammography, a bill that would impose a health benefit mandate. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.⁹

Approximately 21.9 million Californians (59%) have health insurance that may be subject to a health benefit mandate law passed at the state level.¹⁰ Of the rest of the state's population, a portion is uninsured (and so has no health insurance subject to any benefit mandate) and another portion has health insurance subject to other state law or only to federal laws. AB 137 would not directly affect "Every Woman Counts," a program operated by the California Department of Public Health that does not provide health insurance coverage but does provide screening for breast cancer to the uninsured.

Uniquely, California has a bifurcated system of regulation for health insurance subject to state-level benefit mandates. The California Department of Managed Health Care (DMHC)¹¹ regulates health care service plans, which offer benefit coverage to their enrollees through health plan contracts. The California Department of Insurance (CDI) regulates health insurers,¹² which offer benefit coverage to their enrollees through health insurance policies.

DMHC-regulated plans and/or CDI-regulated policies would be subject to AB 137. Therefore, the mandate would affect the health insurance of approximately 21.9 Californians (59%).

Bill language

The full text of AB 137 can be found in Appendix A.

AB 137 contains two separate mandates, one involving mammography coverage and the other related to information regarding timelines for breast cancer screening.

AB 137 would require CDI-regulated policies to cover medically necessary mammography upon a provider's referral. The bill does not alter the current requirement for DMHC-regulated plans

⁹ CHBRP's authorizing statute is available at: www.chbrp.org/documents/authorizing_statute.pdf.

¹⁰ CHBRP's estimates are available at: http://www.chbrp.org/other_publications/index.php.

¹¹ DMHC was established in 2000 to enforce the Knox-Keene Health Care Service Plan Act of 1975; see Health and Safety Code, Section 1340.

¹² CDI licenses "disability insurers." Disability insurers may offer forms of insurance that are not health insurance. This report considers only the impact of the benefit mandate on health insurance policies, as defined in Insurance Code, Section 106(b) or subdivision (a) of Section 10198.6.

to do the same. The current Insurance Code requires CDI-regulated policies to cover mammography for women at particular ages and specifies particular frequencies (one test between the ages of 35 and 39; one test every two years between the ages of 40 and 49; annual tests at age 50 and beyond).

AB 137 would require that both DMHC-regulated plans and CDI-regulated policies notify subscribers/policyholders regarding recommended timelines for an individual to undergo tests for the screening or diagnosis of breast cancer. The bill indicates that the information may be provided by written letter, by publication in a newsletter, by publication in evidence of coverage (EOC) document, by direct telephone call, by electronic transmission, by Web-based portal, or by any other means that will reasonably notify the subscriber or policyholder of the recommended timelines for testing.

Analytic approach and key assumptions

In prior years, CHBRP analyzed bills (AB 2234 in 2008¹³ and AB 56 in 2009¹⁴) that would have placed very different information requirements on plans and policies. The 2008 and 2009 bills would have required that DMHC-regulated plans and CDI-regulated insurers send a female enrollee a written notice during the calendar year in which national guidelines indicated she should start undergoing test for breast cancer screening, notifying her that she was eligible for testing.

The notification requirement in AB 137 is much less prescriptive than the notification requirements contained in the 2008¹⁵ and 2009¹⁶ bills, such that CHBRP projects no measurable notification-related utilization, cost, and public health impacts for AB 137.

AB 137 indicates only that information on timelines for breast cancer screening will be provided to policyholders and subscribers. CHBRP cannot predict what screening timelines plans and insurers will provide. 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.

- American Cancer Society (ACS)
- American College of Obstetricians and Gynecologists (ACOG)
- American College of Physicians (ACP)
- American College of Radiology (ACR)

¹³ See: http://www.chbrp.org/completed_analyses/index.php

¹⁴ See: http://www.chbrp.org/completed_analyses/index.php

¹⁵ See: http://www.chbrp.org/completed_analyses/index.php

¹⁶ See: http://www.chbrp.org/completed_analyses/index.php

As previously mentioned, the U.S. Preventive Services Task Force (USPSTF) recommends screening every 2 years for women age 50 to 74 years. For women age 40 to 49 years, the USPSTF recommends that the decision to initiate biennial screening be made by individual women on the basis of their level of risk for breast cancer and their values regarding the benefits and harms of screening.

Guidelines from these national organizations are summarized in Appendix C.

Existing California requirements

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.”¹⁷ 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, coverage for mammography is specified in statute. For CDI-regulated policies, the law makes further specifications, requiring the policies to cover mammography on an age-dependent schedule. For women aged 35-39 years, coverage of a baseline mammography is required. For women aged 40-49, coverage for a mammography every 1-2 years (or more frequently, if recommended by a physician) is required. For women aged 50 or more, coverage for an annual mammography is required. Breast cancer screening laws related to DMHC-regulated plans do not reference age-dependant schedules.

CHBRP is unaware of any existing law that requires plans or insurers to provide information on timelines for breast cancer screening to subscribers or policyholders.

¹⁷ 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.

Requirements in other states

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

CHBRP is unaware of any existing law in another state that requires plans or insurers to provide notification on timelines for breast cancer screening to subscribers or policyholders.

Potential Effects of Federal Affordable Care Act

The federal “Patient Protection and Affordable Care Act” (P.L.111-148) and the “Health Care and Education Reconciliation Act” (H.R.4872) were enacted in March 2010. These laws (together referred to as the “Affordable Care Act [ACA]”) are expected to dramatically affect the California health insurance market and its regulatory environment, with most changes becoming effective in 2014. How these provisions are implemented in California will largely depend on pending legal actions, funding decisions, regulations to be promulgated by federal agencies, and statutory and regulatory actions to be taken by California state government.

The provisions that go into effect during the transitional years (2011-2013) would affect the baseline, or current enrollment, expenditures, and premiums. It is important to note that CHBRP’s analysis of specific mandate bills typically address the marginal effects of the mandate bill—specifically, how the proposed mandate would impact benefit coverage, utilization, costs, and public health, holding all other factors constant. CHBRP’s estimates of these marginal effects are presented in this report. Each of the provisions that have gone into effect by January 2011 has been considered to determine whether they may affect CHBRP’s 2011 Cost and Coverage Model. There are still a number of provisions that have gone into effect for which data are not yet available. Where data allows, CHBRP has made adjustments to the Cost and Coverage model to reflect changes in enrollment and/or baseline premiums. These adjustments are discussed in further detail in Appendix D.

A number of ACA provisions will need regulations and further clarity. One example is the ACA’s requirement for certain health insurance to cover “essential health benefits.” Effective 2014, Section 1302(b) will require small group and individual health insurance, including “qualified health plans” that will be sold in the California Exchange, to cover specified categories of benefits. These essential health benefits (EHBs) are defined as ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care. The Secretary of Health and Human Services (HHS) is charged with defining these categories through regulation, ensuring that the EHB floor “is equal to the scope of benefits provided under a typical employer plan.” In addition, the ACA would allow a state to “require that a qualified health plan offered in [the Exchange] offer benefits in addition to the essential health benefits.” If the state does so, the state must make payments to defray the cost of those additionally mandated benefits, either by paying the individual directly, or by paying the qualified health plan. This ACA requirement could interact with existing and proposed California benefit mandates, especially if California decided to require qualified health plans to cover California-specific

mandates, and those mandates were determined to go beyond the EHB floor. Federal regulations regarding which benefits are to be covered under these broad EHB categories and other details, such as how the subsidies for purchasers of qualified health plans are structured, are forthcoming.¹⁸

Essential health benefits included in qualified health plans in the Exchange and potential interactions with AB 137

As noted, EHBs are defined to include ambulatory patient services; laboratory services; and preventive and wellness services and chronic disease management. In addition, HHS, when promulgating regulations on EHBs is to ensure that the EHB floor “is equal to the scope of benefits provided under a typical employer plan.” Virtually all employer-based plans provide coverage for mammography services. As mentioned, the ACA requires states, beginning 2014, to “make payments...to defray the cost of any additional benefits” required of QHPs sold in the Exchange.¹⁹ This potential liability would depend on three factors:

- differences in the scope of “benefits in the final EHB package and the scope of mandated benefits in AB 137;
- the number of enrollees in QHPs; and
- the methods used to define and calculate the cost of additional benefits.

Because mammography services as defined under AB 137 is considered standard coverage for employer-based plans, and because it is likely to be considered part of EHBs, it is unlikely that there would be any additional fiscal liability to the state as a result of this mandate.

Preventive Services Required under ACA and AB 137

“New plans” (i.e., those not covered under the ACA’s “grandfather” provisions) were required to cover certain preventive services zero cost sharing beginning September 23, 2010. The U.S. Preventive Services Task Force (USPSTF) recommends screening every 2 years for women age 50 to 74 years. For women age 40 to 49 years, the USPSTF recommends that the decision to initiate biennial screening be made by individual women on the basis of their level of risk for breast cancer and their values regarding the benefits and harms of screening. Mammography, therefore, can be considered one of the preventive benefits that must be covered at zero cost sharing per the ACA. Based on CHBRP’s analysis of current coverage rates, virtually all health plans and policies have coverage for mammography services. AB 137 does not affect the cost sharing of mammography services. Any premium impacts resulting from the ACA’s requirements to cover preventive services at zero cost sharing is already reflected in the baseline premiums presented in this report and does not affect the marginal impact of AB 137.

¹⁸ For further discussion on EHBs and potential interaction with state mandates, please see, *California's State Benefit Mandates and the Affordable Care Act's "Essential Health Benefits"* available here:

http://www.chbrp.org/other_publications/index.php.

¹⁹ Affordable Care Act, 1311(d)(3)(B).

Background on breast cancer

Breast cancer is one of the most commonly diagnosed cancers in California, with approximately 23,600 (excluding *in situ*²⁰ cancers) new cases diagnosed annually in women (ACS et al., 2010a). This translates to an annual incidence rate of 123.1 cases of invasive breast cancer, or 153.09 cases of all breast cancer incidence, per 100,000 women in California (CCR, 2011). It is estimated that more than 280,000 Californian women alive today are breast cancer survivors (excluding *in situ* cancers) (Hofer et al., 2010). An average newborn girl's chance of eventually being diagnosed with invasive breast cancer in California is approximately one in eight (i.e., 12%) (ACS et al., 2010a).

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

Population	Incidence Rate (a)	Screening Rate (b)	% Cancers Diagnosed at an Early Stage (c)	Mortality Rate (d)
Overall	153.09	84.6% (83.3–85.9)	71%	21.36
Hispanic/Latina	108.86	83.7% (80.2–87.1)	64%	16.59
White (Non-Hispanic)	174.75	85.6% (84.3–86.8)	72%	23.69
African American (Non-Hispanic)	154.90	85.1% (80.6–89.6)	63%	31.94
Asian/Pacific Islander	129.19	82.5% (77.4–87.6)	73%	13.27

Sources and Notes: (a) Data from the California Cancer Registry. Data are age adjusted to the 2000 U.S. Standard Million Population and reflect all breast cancer incidence including *in-situ* cancers. Rates are per 100,000 women in California in 2008.

(b) Data taken from CHIS, 2009. Screening is reported as mammography within the last 2 years for women ages 40 - 64 years old with health insurance. The CHIS Asian category does not include Pacific Islanders.

(c) Data from *California Cancer Facts and Figures 2011* (ACS et al., 2010a) and reflect cases reported to the California Cancer Registry in 2008. Early stage is defined as *in situ* or localized.

(d) Data from the California Cancer Registry. Data are age adjusted to the 2000 U.S. Standard Million Population. Rates are per 100,000 women in California in 2008.

Although breast cancer is the most common cancer found among women in California, when diagnosed early, survival rates are high. Overall, the 5-year relative survival rate for breast cancer among women in California is 91% (ACS et al., 2010a). This rate varies with the stage at diagnosis, with a 99% 5-year relative survival rate for localized breast cancer (i.e., still confined to the breast, including *in situ* cancers), 85% for regional breast cancer (i.e., the tumor has spread to lymph nodes or adjacent tissues), and 25% for distant breast cancer (i.e., the tumor has spread to other parts of the body) (ACS et al., 2010a). In California, 71% of breast cancer is diagnosed at an early stage (*in situ*, or localized) (ACS et al., 2010a).

²⁰ *In situ* cancer refers to cancer cells that are confined to the ducts or lobules of the breast and have not invaded deeper tissues in the breast or spread to other organs. *In situ* breast cancer is sometimes referred to as non-invasive or pre-invasive breast cancer (ACS, 2010b).

In 2008, there were approximately 4,200 deaths of women due to breast cancer in California, equivalent to an annual mortality rate of 21.4 per 100,000 women (CCR, 2011). Since 1988, breast cancer mortality among women in California has declined by 32% (ACS et al., 2010a). This decrease is attributed, mostly, to the increased use of mammography screening, as well as improvements in breast cancer treatments (Berry et al., 2005). Some of this decrease in mortality, however, is due to the fact that mammography detects *in situ* cancers that previously wouldn't have been detected or caused death (Kerlikowske, 2010). Although different organizations have different guidelines, age 40 has been traditionally regarded as an age at which women should be offered annual screening for breast cancer with mammography (ACS et al., 2010a). In California, 84.6% of women aged 40-64 years with health insurance had a mammogram within the last 2 years (CHIS, 2009). Another 8.6% had a mammogram more than 2 years ago, and 6.8% reported never having had a mammogram (CHIS, 2009). Women who have not had a mammogram report that the main reason for not having had one was: laziness (23.2%), painful or embarrassing (10.6%), did not know it was needed (13.8%), financial reasons (6.7%), and other reasons (39.5%) (CHIS, 2009). Women who were categorized as "didn't know it was needed" indicated that they did not know the mammogram was needed, the doctor did not tell them it was needed, they have not had any problems with their breasts, or that they were too young to have a mammogram. Other studies have found that insurance status and physician recommendation are significant predictors of mammography utilization (Scheuler et al., 2008).

Breast cancer is a disease that affects primarily women. In terms of disparities, there are racial/ethnic disparities both in stage at diagnosis and mortality rates. African Americans and Hispanics both have lower rates of early diagnosis (*in situ* or localized) (63% and 64%, respectively) compared to Non-Hispanic Whites or Asian/Pacific Islanders (72% and 73%, respectively). Mortality rates from breast cancer also suggest that African Americans have the highest rates of mortality, followed by Non-Hispanic Whites (Table 1).

MEDICAL EFFECTIVENESS

This medical effectiveness analysis considers whether screening mammography reduces mortality due to breast cancer among screened women 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.

The medical effectiveness analysis addresses three questions pertinent to AB 137:

- Does mammography screening (i.e., providing mammograms to asymptomatic women) reduce mortality due to breast cancer for women of all eligible ages?
- Does mammography screening reduce breast cancer mortality rates for women ages 40-49 years?
- Does notification of eligibility for mammography screening increase the rate at which women are screened?

Effectiveness of Mammography Screening

Mammography screening applies *only* to asymptomatic women.²¹ To be effective, screening tests must be able to detect a disease earlier than it would be detected in the absence of screening, and must be able to distinguish persons who have a disease from persons who do not have the disease. Furthermore, patients whose disease is detected via screening and who 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 7 to 9 years after initiating screening. The benefit of screening women in their 40s is more limited and slower to appear (10-14 years after initiating screening) than for older women. The reduced benefit for women in this younger age cohort is attributable to their lower incidence of breast cancer and denser breast tissue, which can reduce the sensitivity of mammography (Carney et al., 2003; Elmore et al., 2005). Younger women diagnosed with breast cancer can also experience more aggressive breast cancers that appear during the interval between screenings (Buist et al., 2004).

²¹ Mammography is also used to diagnose women and men with symptoms suggestive of breast cancer. Additional diagnostic tests and/or biopsies are usually conducted to make a definitive diagnosis.

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. Studies of the effects of mammography screening were identified through searches of PubMed and the Cumulative Index to Nursing and Allied Health 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. The search was limited to abstracts of peer-reviewed research studies that were published in English from 2009 to present, because CHBRP had previously conducted thorough searches of literature on the effectiveness of mammography and notification of eligibility for mammography screening in 2009 for its report on AB 56. A total of 13 studies were included in the medical effectiveness review for AB 137, including 7 studies from the AB 56 review. A more thorough description of the methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure is presented in Appendix B: Literature Review Methods.

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 137 requires coverage of mammography (and does not specify modalities), 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.²² Organizations that have reviewed these RCTs have generally rated the evidence as “fair” based on methodological issues with some studies. In addition, the studies are rated by CHBRP as “somewhat generalizable” because seven were conducted in Europe or Canada, which are known to have different recall rates than the United States due to differences in medical practice (Smith-Bindman et al., 2005).

Epidemiologic Terminology²³

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%.

²² One of these RCTs is sometimes characterized as two separate RCTs because the authors reported findings separately for women from the two counties in Sweden in which the RCT was conducted. Another RCT conducted in Canada is also sometimes characterized as two separate RCTs because the authors reported findings separately for women age 40 to 49 years and women age 50 to 59 years (Gøtzsche and Nielsen, 2011).

²³ Carney et al. (2010) has identified minimally acceptable criteria for performance of screening mammography. Carney PA, Sickles EA, Monsees BS, et al. Identifying minimally acceptable interpretive performance criteria for screening mammography. *Radiology*. 2010;255:354-361

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 $1 - \text{specificity}$.

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 under 40 years

Screening mammography is not recommended for most women under age 40 years because they are more likely to have dense breast tissue and because their incidence of breast cancer is low. There is also concern about the cumulative dose of radiation women receive if they begin mammography screening before age 40. Exceptions would be women who were previously diagnosed with breast cancer or who are at very high risk.

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).

Table 2 summarizes findings from the three primary meta-analyses of RCTs of mammography screening.

Gøtzsche and Nielsen (2011) updated their previous meta-analyses of the eight aforementioned RCTs. They omitted one RCT in which subjects were not adequately randomized and state that, despite the studies' shortcomings (all rated fair or poor), mammography screening produces a 19% relative reduction in breast cancer mortality (relative risk = 0.81 [95% confidence interval 0.74 to 0.87]).

Humphrey et al. (2002) performed a meta-analysis of six of the eight aforementioned RCTs for the US Preventive Services Task Force (USPSTF).²⁴ 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)²⁵, equivalent to a 16% relative reduction in breast cancer 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%. Findings from observational studies suggest that the positive predictive value of mammography screening increases with age. In their analysis, Humphrey et al. (2002) cite a 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, and to 18% to 20% for age 70 and older.

Nelson et al. (2009) updated Humphrey et al. (2002)'s meta-analysis for the USPSTF. Their update focused on the effectiveness of mammography screening for women age 40 to 49 years and for women age 70 or older. The authors report the summary RR estimate of breast cancer mortality for women age 40 to 49 years is 0.85 (95% CrI, 0.77 to 0.91), equivalent to a 15% relative reduction in breast cancer mortality risk. The impact of mammography screening on the relative risk of breast cancer mortality for women age 40 to 49 years is similar to the impact on women age 50 to 59 years (0.86, [95% CrI, 0.75 to 0.99]). However, the number of women who need to be invited for screening to prevent one breast cancer death is substantially larger for women age 40 to 49 years than for women age 50 to 59 years, because the incidence of breast cancer is smaller among women in their 40s than among women in their 50s (Kerlikowske, 1997). Nelson et al. (2009) estimated that the number of women age 40 to 49 who need to be invited for screening to prevent one breast cancer death is 1,904 (95% CrI, 929 to 6,378), whereas the number needed to screen for women age 50 to 59 years is 1,339 (95% CrI, 322 to 7,455).

Nelson et al. (2009) also analyzed findings from two RCTs that enrolled women over age 59 years. The pooled relative risk for breast cancer mortality from these two RCTs is 0.68 (95% CrI, 0.54 to 0.87) for women age 60 to 69 years, equivalent to a 32% reduction. The one RCT to enroll women age 70 to 74 years found no statistically significant difference in breast cancer mortality between women invited for mammography screening and the control group. No RCTs have enrolled women over age 74 years.

Kerlikowske et al. (1995) performed a meta-analysis of seven RCTs²⁶ 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 50-74 years, mammography screening is shown to reduce breast cancer mortality by 26% (RR=0.74; 95% CI, 0.66 to 0.83) within 7 to 9 years of initial mammogram.

²⁴ Humphrey et al. (2002) omitted the same RCT as Gøtzsche and Nielsen (2011). The eighth RCT was not published until after Humphrey et al. (2002) had completed their meta-analysis.

²⁵ CrI=credibility interval, a type of confidence interval used in Bayesian statistical analyses.

²⁶ Kerlikowske and colleagues (1995) state that they analyzed nine RCTs because they counted the Swedish two-county trial as two RCTs and also counted the Canadian trial as two RCTs.

A recent nonrandomized study with comparison groups have suggested that the reduction in breast cancer mortality associated with mammography screening may be lower than estimates from RCTs suggest (Kalager et al., 2010). This study conducted in Norway, a country in which mammography screening was phased in gradually, which enabled the authors to compare women who were offered screening with those who were not at a single point in time. The authors' findings suggest that mammography screening is associated with a 10% reduction in breast cancer mortality, a much lower percentage than the estimates from the meta-analyses of RCTs conducted for the Cochrane review and the USPSTF (Gøtzsche and Nielsen, 2011; Nelson et al., 2009). An editorial that accompanied the journal article summarizing the study's findings noted that several factors may account for the lower reduction in breast cancer mortality attributed to screening (Welch, 2010). The Norwegian study was conducted more recently than the RCTs. The implementation of mammography screening in Norway coincided with the establishment of multidisciplinary treatment teams, which may have improved the quality of care for women with breast cancer. Increased awareness of breast cancer may have led women with breast abnormalities to seek care sooner. The findings may also be understated if large numbers of women in the comparison group received mammograms. In addition, these findings from a Scandinavian country may not be fully generalizable to California's racially and ethnically diverse population.

There is a preponderance of evidence that mammography screening among women ages 40-74 years is effective in reducing mortality due to breast cancer. There is a mortality benefit for women age 50-74 years after 7 to 9 years of follow-up. The benefit of mammography screening is greater for women age 50-74 years than for women age 40-49 years because breast cancer incidence increases with age and because younger women tend to have more aggressive cancers that may become symptomatic between screening intervals. There is insufficient evidence to determine whether mammography screening is effective for women over age 74 years.

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

Citation	Research Design ²⁷	Outcome	Size of Effect	Sensitivity/ Specificity	Generalizability (to Population Affected by Mandate)	Conclusion
Gøtzsche and Nielsen, 2011	Level I Meta-analysis of 7 trials of 600,000 women ages 40-74 years (the majority of trials enrolled women ages 45-64 years) ²⁸	Summary RR reduction for breast cancer mortality Absolute risk	19% RR reduction Deaths due to breast cancer: RR was 0.81 (95% CI, 0.72 to 0.90) after 7 years and RR 0.81 (95% CI, 0.74 to 0.87) after 13 years 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

²⁷ 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.

²⁸ The authors excluded one RCT in which subjects were not adequately randomized to the intervention and control groups.

Table 2. Summary of Findings of Medical Effectiveness of Mammography for All Eligible Women (Cont'd)

Citation	Research Design ²⁹	Outcome	Size of Effect	Sensitivity/ Specificity	Generalizability (to Population Affected by Mandate)	Conclusion
Nelson et al., 2009 ³⁰	Level I: Meta-analysis of 7 RCTs that enrolled women ages 40 to 49 years or 70 years and older	Summary RR for breast cancer mortality PPV Sensitivity Specificity	Summary RR 0.85; (95% CI 0.75 to 0.96); 8 trials for women ages 39-49 0.86 (95% CI 0.75 to 0.99) for women ages 50-59 0.68 (95% CI 0.54 to 0.87) for women ages 60-69 1.12 (95% CI 0.73 to 1.72) for women >70 PPV =15% for mammography in United States	Sensitivity: for first mammogram (1-year interval) ranged from 77%-95% 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 40-69 years 1,904 women were needed for screening to prevent one death from breast cancer (over 11-20 years of follow-up) for women ages 39-49. 1,339 women were needed for screening to prevent one death from breast cancer (over 11-20 years of follow-up) for women ages 50-59 370 women were needed for screening to prevent one death from breast cancer (over 11-20 years of follow-up) for women ages 60-69

²⁹ 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.

³⁰ Updates Humphrey et al., 2002.

Table 2. Summary of Findings of Medical Effectiveness of Mammography for All Eligible Women (Cont'd)

Citation	Research Design ³¹	Outcome	Size of Effect	Sensitivity/ Specificity	Generalizability (to Population Affected by Mandate)	Conclusion
Kerlikowske et al., 1995	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

Sources: Gøtzsche and Nielsen, 2011; Kerlikowske et al., 1995; Nelson et al., 2009.

Note: 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.

³¹ 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.

Women Ages 40-49 Years Three studies that focus on women age 40 to 49 years 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 mammography screening for women ages 40-49 years reduces breast cancer mortality rates by 7% to 23%, but increases the use of unnecessary procedures due to the test's high false-positive rate for that age cohort. Armstrong et al. (2007) cite findings from Humphrey et al. (2002) to compare the effects of mammography screening on breast cancer mortality for women age 40 to 49 years and 50 to 59 years. Humphrey et al. (2002) reported a 15% reduction in breast cancer mortality (RR, 0.85; 95% CrI, 0.73 to 0.99) for women age 40 to 49 years that 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% CrI, 0.70 to 0.87).

As noted previously, Nelson et al.'s (2009) update of Humphrey et al. (2002)'s meta-analysis for the USPSTF focused on the effectiveness of mammography screening for women age 40 to 49 years and for women age 70 or older. The authors report the summary relative risk (RR) estimate of breast cancer mortality for women age 40 to 49 years is 0.85 (95% CrI, 0.77 to 0.91), equivalent to a 15% relative reduction in breast cancer mortality risk. The impact of mammography screening on the relative risk of breast cancer mortality for women age 40 to 49 years is similar to the impact on women age 50 to 59 years (RR, 0.86, [95% CrI, 0.75 to 0.99]), but the number of women who need to be invited for screening to prevent one breast cancer death is substantially larger for women age 40 to 49 years than for women age 50 to 59 years. The number of women age 40 to 49 who need to be invited for screening to prevent one breast cancer death is 1,904 (95% CrI, 929 to 6,378), whereas the number needed to invite for screening among women age 50 to 59 years is 1,339 (95% CrI, 322 to 7,455).

Mammography sensitivity is inversely related to breast density, which decreases as a woman ages (Carney et al., 2003). 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.

A recent nonrandomized study with comparison groups evaluated the impact of mammography screening among women age 40 to 49 years. The authors compared breast cancer mortality among Swedish women invited for mammography screening and a comparison group of women not invited for mammography screening (Hellquist et al., 2011). They found that mammography

was associated with a 26% reduction in the relative risk for breast cancer mortality (RR, 0.74, 95% CI, 0.66 to 0.83).

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 ³²	Outcome	Size of Effect	Sensitivity/ Specificity	Generalizability (to Population Affected by Mandate)	Conclusion
Armstrong et al., 2007	<p>Level I: Systematic review of 117, reviews, RCTs, and observational studies</p> <p>8 Meta-analyses of 8 RCTs of women ages 40-49 yrs</p>	<p>RR for breast cancer mortality</p> <p>False-positive rates</p>	<p>RR 0.85 (95% CI, 0.73 to 0.99) for women ages 40-49 years</p> <p>RR 0.78 (95% CI, 0.70 to 0.87) for women 50+ years</p> <p>Cumulative false-positive rate 30% after 5 mammograms; 56% after 10 mammograms</p>	Not reported	Highly generalizable: randomized trials	<p>Preponderance of evidence that more women 40-49 years than 50+ years have risks that outweigh the benefits of mammography screening</p> <p>The RR is similar to 5 other meta-analyses and is smaller than the RR for women ages 50+ years</p>

³² 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.

Table 3. Summary of Findings of Medical Effectiveness of Mammography for Women Ages 40-49 Years (Cont'd)

Citation	Research Design ³³	Outcome	Size of Effect	Sensitivity/ Specificity	Generalizability (to Population Affected by Mandate)	Conclusion
Nelson et al., 2009	Level I: Systematic review of 8 RCTs and meta-analyses of women ages 40 to 49.	Summary RR for breast cancer mortality PPV Sensitivity Specificity	Summary RR 0.85; 95% CI 0.75 to 0.96; 8 trials for women ages 39-49. PPV =15% for mammography in United States	Sensitivity: for first mammogram (1-year interval) ranged from 77%-95% 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 39-49 years. 1,904 women were needed for screening to prevent one death from breast cancer (over 11-20 years of follow-up)
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

Sources: Armstrong et al., 2007; Kerlikowske, 1997; Nelson et al., 2009.

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

³³ 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.

Harms of Screening

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 studied 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.

Nelson et al. (2009) analyzed data on false-positive mammograms from the Breast Cancer Surveillance Consortium, a collaborative network of seven mammography registries in the United States. The authors found that false-positive mammograms are more common among women age 40 to 49 years than among older women. The rate of false-positive mammograms for women in this age group was 97.8 per 1,000 mammograms performed during a single round of screening. The authors conclude that for every case of invasive breast cancer detected by screening mammography among women age 40 to 49 years, 556 women undergo mammography, 47 complete additional imaging tests, and 5 receive biopsies.

The most recent estimates of the cumulative risk of having a false-positive mammogram are based on data from the Age RCT conducted in the United Kingdom (Johns et al., 2010) and from the Breast Cancer Surveillance Consortium in the United States (Hubbard et al., 2010). The Age RCT enrolled women in their 40s. The authors found that 14.6% of the women in the intervention arm of the RCT (i.e., those who were invited to obtain a screening mammogram) had at least one false positive mammogram during the 13 years of the trial. Among women who were screened seven times during the RCT, the cumulative false positive rate was 20.5% (Johns et al., 2010). Analysis of data from the Breast Cancer Surveillance Consortium, which collects data on all mammograms performed in seven communities across the United States, suggests that the cumulative false positive rate in the United States may be higher than in the United

Kingdom. Using 13 years of data from the Breast Cancer Surveillance Consortium, Hubbard et al. (2010) estimated that the risk of a false positive mammogram after 10 mammograms is 63% (range = 58% to 77%).

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.

Some women who obtain screening mammograms may be overdiagnosed and overtreated. Estimates of rates of overdiagnosis vary from <1 to 30%, with most between 1% to 10% (Nelson et al., 2009). A substantial percentage of women who are screened and subsequently diagnosed with ductal carcinoma in situ (DCIS) have cancers that will not progress to invasive breast cancer. However, physicians are unable to determine which women diagnosed with DCIS are at risk for invasive breast cancer if not treated. In the absence of such information, physicians tend to treat all women with DCIS or other forms of breast cancer aggressively.

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).

Study 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 studies of mammography screening may not have accurately recorded causes of death (Gøtzsche and Nielsen, 2011). 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 difficulty of interpreting 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 Regarding Timelines for Breast Cancer Screening

AB 137 would require that both DMHC-regulated plans and CDI-regulated policies provide subscribers/policyholders with information regarding recommended timelines for an individual to undergo tests for the screening or diagnosis of breast cancer. The bill indicates that the information may be provided by written letter, by publication in a newsletter, by publication in evidence of coverage (EOC) document, by direct telephone call, by electronic transmission, by Web-based portal, or by any other means that will reasonably notify the subscriber or policyholder of the recommended timelines for testing.

Evidence Review Results

No studies were identified that assessed the impact of providing subscribers regardless of age or gender with information about recommended timelines for mammography screening on the rate at which eligible women are screened. Most studies of interventions to increase screening rates have focused on providing information to women who are eligible for an initial or repeat mammogram.

*No studies were found that evaluated the effectiveness of providing information about recommended timelines for mammography screening through newsletters, evidence of coverage materials, and Web portals.*³⁴

The literature search conducted for AB 56 identified no medical effectiveness studies of “one-time” notification of newly eligible women to obtain breast cancer screening service. The literature search was updated for AB 137, and once again no studies of “one-time” notification were identified. Rather, most studies examine the effectiveness of reminding women who are due or overdue for screening mammograms.

Most of the literature on notification has examined the effectiveness of written reminders to women due or overdue for mammography. Table 4 summarizes the most pertinent studies that consider written notification. Five studies are 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 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 32% 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 three 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.

³⁴ One new RCT used the furnishing of notification in newsletters and pamphlets as a control condition (Ahmed et al., 2010).

(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. The Krebs et al. (2010) meta-analysis synthesized findings from 12 studies of computer-tailored interventions aimed at increasing mammography screening rates. Women who received computer-tailored notification were more likely to obtain mammograms biannually than women in control groups (56% vs. 50%; mean effect size of $g=0.13$ [95% CI, 0.08 to 0.18, $p>0.001$]). Dynamic tailoring (i.e., iterative assessments and feedback) was associated with larger mean effect sizes ($g=0.19$) than static tailoring ($g=0.14$, $p=0.01$).

A recently published systematic review by the 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 post intervention 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 the 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 137.

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 et al. (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; $p<0.0001$) for computer-based reminders and an adjusted OR of 1.63 (95% CI, 1.21 to 2.18, $p<0.001$) for manual reminders.

Studies have also assessed the effectiveness of notification by telephone. A systematic review completed by Bonfil et al. (2001) found that women who received telephone calls reminding

them that they were due or overdue for mammography screening were more likely to be screened (OR, 1.94; 95% CI, 1.70 to 2.23). DeFrank et al. (2009) conducted a RCT of 3,547 women that compared automated telephone reminders to printed enhanced usual care reminders and enhanced letter reminders. Automated telephone reminders were automated phone calls using a real women's voice with "due for mammogram" as the key message. Printed enhanced usual care reminders were mailed letters with information about the women's last mammogram, benefits of mammograms, and recommended guidelines. Enhanced letter reminders contained the same information as the other interventions plus a four-page informational booklet, statistics about the severity of breast cancer, contact information, and reminder stickers. All three types of notification were effective in promoting repeat mammography. However, women who received automated telephone reminders were significantly more likely to have had a repeat mammogram than those who received enhanced printed reminders ($p=0.014$).

Several recent studies have examined the effectiveness of "stepped" interventions that combine written notification with telephone calls. Bowen and Powers (2010) conducted a RCT of 1,336 women assigned to an intervention or control group that received no intervention. The intervention group received stepwise mammogram reminders (i.e., additional type of reminder provided if no response to previous reminder) which included mailings, telephone calls, and counseling (where appropriate). Participants in the intervention group significantly increased their mammography use by 12% ($p<0.01$) from baseline to follow up compared to those in the control group. Ahmed et al. (2010) conducted a RCT of 2,357 insured, very low-income women assigned one of three intervention groups: usual care (written messages in newsletters and pamphlets), simple intervention (letter from medical director), and stepwise intervention that consisted of a letter from the medical director, then a follow-up letter from the primary care physician, and finally, telephone contact and counseling by a lay health worker for women who did not respond to the letters. Compared with the control, receipt of the primary care physician letter increased the likelihood of screening by 80% (RR, 1.80; $p<0.001$), and receipt of counseling tripled the likelihood of screening (RR, 3.11; $p<0.001$). The letter from the medical director alone did not achieve statistically significant higher rates of screening than usual care. However, the generalizability of this study to women with health plans and health insurance policies that would be affected by AB 137 is limited because it only included low-income women not accustomed to accessing preventive health services. It is also important to note that the intervention groups evaluated in all of three of these studies received more intensive forms of notification than AB 137 would require.

There is no evidence found regarding the effectiveness of more generalized notification methods (e.g., newsletters or EOCs) or of providing notification of recommended timelines for breast cancer screening to all subscribers regardless of age or gender. There is a preponderance of high-to fair-quality evidence that providing written notification or telephone calls to women who are due for routine mammography screening improves the overall mammography screening rate.

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

Citation	Research Design ³⁵	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	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

Notes: The Stone et al (2002) and Wagner (1998) meta-analyses include five of the same studies.

³⁵ 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.

Table 4. Summary of Findings of Medical Effectiveness of Notification for Mammography Screening (Cont'd)

Citation	Research Design	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 post-intervention 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: ^bThe Sohl and Moyer (2007) and Stone et al. (2002) meta-analyses include two of the same studies.

^cTwo 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.

Table 4. Summary of Findings of Medical Effectiveness of Notification for Mammography Screening (Cont'd)

Citation	Research Design	Outcome	Findings (Statistical Significance, Direction of Effect)	Generalizability to Population Affected by Mandate	Conclusion
Krebs et al., 2010 ^{d,e}	Level I: Meta-analysis of 88 studies that look at computer tailored interventions for 4 health related behaviors including mammography. Behavior specific analyses representing 106,243 participants. 12 studies examined computer tailored mammography interventions	Improved adherence to bi-annual mammography screening	Twelve studies reported the percentage of participants adherent to mammography recommendations. The mean effect size was $g=0.13$ (95% CI, 0.08–0.18, pb.001). In terms of communication channel (i.e. print, computer, telephone, etc), effect sizes ranged from 0.16 to 0.21 with no significant difference noted ($p=0.89$). Additionally, across all health behaviors only dynamic tailoring remained significant at long-term follow-up	Study is somewhat generalizable because the population is undefined and the interventions are more tailored or detailed than AB 137 requires	This study demonstrates that computer-tailored interventions have the potential to improve health behaviors and suggests strategies that may lead to greater effectiveness of these techniques
Bowen and Powers, 2010	Level I: RCT of 1336 women assigned to an intervention group that consisted of mailings, telephone calls, and counseling (where appropriate) or a no intervention group	Improved adherence to mammography screening; improved quality of life	Participants in the intervention group significantly ($p<0.001$) increased their mammography use from baseline to follow up compared to those in control group	Study is somewhat generalizable because participants ages were 18 to 74 years and women are mostly not from underserved populations. However, participants were only from Northwest and results are self reported. The nature of the study eliminates inclusion of very poor or illiterate women. Intervention more intensive than AB 137 requires	The intervention was successful in increasing mammography over the 1 yr intervention period. Preponderance of evidence that patient reminders for mammography screening increase the number of women completing mammography

Notes ^dThe Sohl and Moyer (2007) and Krebs et al. (2010) meta-analyses include eight of the same studies.

^eThe Krebs et al. (2010) and Wagner (1998) meta-analyses include one of the same studies.

Table 4. Summary of Findings of Medical Effectiveness of Notification for Mammography Screening (Cont'd)

Citation	Research Design	Outcome	Findings (Statistical Significance, Direction of Effect)	Generalizability to Population Affected by Mandate	Conclusion
DeFrank et al., 2009	Level I: RCT of 3547 women randomly assigned 3 groups for mammogram reminders: EUCR(enhanced usual care reminders), ATR(automated telephone reminders), and ELR (enhanced letter reminders)	Improved adherence to repeat mammography screening	All three types of reminders were associated with increase in repeat mammography screening (p=0.0001). Women assigned automated telephone reminders were significantly more likely to have repeat mammograms than women assigned to printed enhanced usual care reminders. (p=0.014)	Study is somewhat generalizable because participants ages were 40-75 years and women are mostly not from underserved populations Study includes women that have already had a mammogram in the last 10-14 months	Evidence that all three interventions increase repeat mammography with telephone patient reminders as the most effective way to increase the number of women completing mammography screening. This was also the lowest in cost
Ahmed et al., 2010	Level I: RCTs of 2357 very low income insured women assigned one of three intervention groups: usual care (no intervention), simple interventions(letter from medical director, and "stepwise intervention"	Improved adherence to mammography screening	Women receiving stepwise interventions are twice as likely to receive screening as the control group (RR=1.69;95%CI,1.64-2.51) and 69% more likely than women in the simple intervention group(RR=1.69;95%CI,1.39-2.06). The simple intervention did not achieve statistically significant higher rates of screening than usual care	Study is somewhat generalizable to low income populations. Study population is women over 40. Studies include low SES women not accustomed to accessing preventative health services. Even the usual care group received written messages in newsletters and breast cancer awareness pamphlets were mailed to all participants, more than required by AB 137	Preponderance of evidence that patient reminders for mammography screening increase the number of women completing mammography

Sources: Ahmed et al., 2010; Baron et al., 2008; Bowen and Powers, 2010; DeFrank et al., 2009; Krebs et al., 2010; Sohl and Moyer, 2007; Stone et al., 2002; Wagner, 1998.

Key: CI=95% confidence interval; OR=odds ratio; χ^2 MH(1)=Mantel-Haenszel chi-square test; RCT=randomized controlled trial; SES=socioeconomic status.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

Assembly Bill (AB) 137 would require California Department of Insurance (CDI)-regulated policies to cover medically necessary mammography upon a provider's referral. AB 137 would change the mammography requirement for CDI-regulated health policies, making mammography requirements equivalent to what is currently required of DMHC-regulated health plans. AB 137 would require that both DMHC-regulated plans and CDI-regulated policies provide subscribers/policyholders with notification regarding recommended timelines for breast cancer screening. The bill indicates that the notification may be provided by written letter, by publication in a newsletter, by publication in evidence of coverage (EOC) document, by direct telephone call, by electronic transmission, by Web-based portal, or by any other means that will reasonably notify the subscriber or policyholder of the recommended timelines for testing.

This section presents the current, or baseline, costs and benefit coverage related to mammography, and the estimated utilization, cost and benefit coverage impacts if AB 137 is enacted. For further details on the underlying data sources and methods, please see Appendix D at the end of this document.

Current (Baseline) Benefit Coverage, Utilization and Cost

Current Coverage of the Mandated Benefit

Approximately 21,902,000 persons in California are enrolled in health plans or policies that would be subject to the mandate. Of these 21.9 million enrollees, 2,858,000 are in CDI-regulated plans. Current mammography coverage was determined by a survey of the seven largest providers of health insurance in California.³⁶ CHBRP surveys the largest major health plans and insurers about coverage. Responses to this survey represented 85.16% of the privately funded, CDI-regulated market and 88.53% of the privately funded, DMHC-regulated market. Combined, responses to this survey represent 87.83% of the privately funded market subject to state mandates.

Based on this survey, CHBRP estimates that 100% of female enrollees in DMHC-regulated plans and CDI-regulated policies have benefit coverage compliant with AB 137 and that all plans and insurers are compliant with some form of notification. Publicly funded plans such as the California Public Employees' Retirement System (CalPERS HMOs), Medi-Cal Managed Care Plans, Healthy Families Program (HFP), Access for Infants and Mothers (AIM), and Major Risk Medical Insurance Program (MRMIP) have mammography coverage compliant with AB 137.

³⁶ CHBRP analysis of the share of enrollees included in CHBRP's Bill-Specific Coverage Survey of the major carriers in the state is based on "CDI Licenses with HMSR Covered Lives Greater than 100,000" as part of the Accident and Health Covered Lives Data Call, December 31, 2009, by the California Department of Insurance, Statistical Analysis Division, data retrieved from the Department of Managed Health Care's interactive Web site "Health Plan Financial Summary Report," July-September, 2010, and CHBRP's Annual Enrollment and Premium Survey.

AB 137 would require notification regarding timelines for breast cancer screening be provided though any one of the following forms: by written letter, by publication in a newsletter, by publication in evidence of coverage (EOC) document, by direct telephone call, by electronic transmission, by Web-based portal, or by any other means that will reasonably notify the subscriber or policyholder of the recommended timelines for testing. CHBRP estimates that about 100% of enrollees currently receive such notification in at least one form of communication stated by the bill based on the bill specific coverage survey.

Current Utilization Levels

CHBRP's bill-specific coverage survey found that 100% of enrollees in CDI-regulated policies have benefit coverage for mammograms as a screening and diagnostic test for breast cancer. Baseline utilization of women receiving mammograms is approximately 4.7 million. The mandate is not expected to change the number of women receiving mammograms nor the number of individuals with mandated coverage of mammograms. The specific number of enrollees utilizing each type of notification considered by AB 137 (i.e., written letter, by publication in a newsletter, by publication in evidence of coverage [EOC] document, by direct telephone call, by electronic transmission, by Web-based portal, or by any other means that will reasonably notify the subscriber or policyholder) cannot be estimated with available data sources. Some forms of notification have been identified by the literature to increase utilization as analyzed in the *Medical Effectiveness* section.

Per-Unit Cost

The cost per mammogram is estimated at \$190, which includes the follow-up costs, other noninvasive procedures, and office visits due to false-positive results. AB 137 is not expected to affect the per-unit cost of mammography or of notification regarding timelines for breast cancer screening because an estimated 100% of enrollees have mammography coverage and receive notification in compliance with AB 137. Considering the diversity of notifications and the confounding effects associated to them, it is not possible to estimate its per-unit cost.

Current (Baseline) Premiums and Expenditures

Per member per month (PMPM) premiums for CDI-regulated policies prior to the mandate are \$497.52 in large group policies, \$334.45 in small-group policies, and \$199.13 in individual policies.

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

An estimated 100% of enrollees in DMHC-regulated plans and CDI-regulated policies are covered for mammography as a routine screening test when referred by a provider, as would be required by AB 137. Therefore, CHBRP estimates no cost shifting as a result of AB 137.

As AB 137 would have no measurable impact on benefit coverage or utilization, AB 137 would not directly affect “Every Woman Counts,” a program operated by the California Department of Public Health that does not provide health insurance coverage but does provide screening for breast cancer to the uninsured.

Public Demand for Benefit Coverage

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

On the basis of conversations with the largest collective bargaining agents in California, CHBRP concluded that mammography is a covered benefit for the members of at least one large union.³⁷

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

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

Based on coverage levels of self-insured plans and responses from large unions, CHBRP concludes that there may be some public demand for mammography screening by collective bargaining agents and by self-insured plans.

Impacts of Mandated Benefit Coverage

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

Impact on access and health treatment/service availability

CHBRP does not estimate changes in supply or health benefits of mammograms due to AB 137. No supply constraints are currently associated with mammograms. AB 137 is not expected to change access to mammography screening among female enrollees of CDI-regulated plans. The

³⁷ Personal communication, S Flocks, California Labor Federation, March 2011.

diversity of notification services considered to be in compliance with AB 137 would be unlikely to change the current notification mechanisms of CDI-regulated insurers and DMHC-regulated health plans. Therefore, no new notification impact mammography screening rates is expected as a consequence of AB 137.

Impact on the health benefit of the newly covered treatment/service

AB 137 would not be expected to change coverage of mammography screening since CHBRP estimates that 100% of enrollees in DMHC-regulated plans and CDI-regulated policies already have coverage for medically necessary mammography upon a provider's referral.

Impact on per-unit cost

CHBRP estimates no measurable effects on per-unit cost of mammograms since no changes in coverage are anticipated as a result of this mandate.

How Would Utilization Change as a Result of the Mandate?

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

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

This mandate would not be expected to increase administrative expenses for health plans and insurers for mammography coverage since health plans and insurers that would be subject to AB 137 already cover an estimated 100% of enrollees in a compliant fashion. AB 137 would not be likely to increase administrative costs due to notification of recommended timelines for breast cancer screening because 100% of enrollees with benefit coverage are already notified by at least one mechanism considered compliant by AB 137.

It is not expected that AB 137 would increase the share of premiums paid by employees, employers, policyholders, or public agencies that enroll their beneficiaries in DMHC-regulated plans.

Impact of the Mandate on Total Health Care Costs

Changes in total expenditures

AB 137 would not be expected to increase total expenditures of employees with DMHC-regulated health plans or CDI-regulated health policies. Likewise, AB 137 would not be expected to increase total expenditures of employers in the small, large, or individual markets. State plans (i.e., CalPERS, HMOs, Medi-Cal Managed Care Plans, HFP, AIM, MRMIP) would be unaffected as well.

Potential cost offsets or savings in the short term

AB 137 would not be expected to change coverage of mammography screening by a measurable amount because a 100% of enrollees in plans subject to the mandate are estimated to be covered. Health plans and insurers subject to the mandate are already compliant of at least one notification mechanism considered by AB 137. Since no changes in the coverage of mammograms or notifications of mammography eligibility are expected no cost offsets or savings are expected in the short term.

Impacts on long-term costs

AB 137 would not change PMPM premiums or total expenditures of employers and employees with DMHC-regulated health plans or CDI-regulated health policies, including publicly purchased plans. Since no changes in the coverage of mammograms or notifications would be expected, no cost offsets no effects on long-term costs are expected.

Impacts for Each Category of Payor Resulting from the Benefit Mandate

Changes in expenditures and PMPM amounts by payor category

AB 137 would not be expected to increase total expenditures and PMPM premiums in the large-group, small-group, or individual markets for DMHC-regulated plans or CDI-regulated policies. Total expenditures and PMPM premiums in CalPERS HMOs, Medi-Cal Managed Care, and MRMIB plans are not expected to increase.

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

Changes in the number of uninsured persons as a result of premium increases

Since AB 137 would not be expected to lead to premium increases, CHBRP estimates no measurable loss of health insurance coverage as a result of AB 137. CHBRP's method for estimating the impact of premium increases on the number of individuals who drop their private insurance is described on CHBRP's Web site.³⁸

Impact on public programs as a result of premium increases

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

³⁸ CHBRP's method for estimating the effect of premium increases on the number of individuals who drop their private insurance is described on CHBRP's Web site at: www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

PUBLIC HEALTH IMPACTS

Assembly Bill (AB) 137 would require California Department of Insurance (CDI)-regulated policies to cover medically necessary mammography upon a provider's referral. AB 137 would change the mammography requirement for CDI-regulated health policies, making mammography requirements equivalent to what is currently required of DMHC-regulated health plans. AB 137 would require that both DMHC-regulated plans and CDI-regulated policies provide subscribers/policyholders with notification regarding recommended timelines for breast cancer screening. The bill indicates that the notification may be provided by written letter, by publication in a newsletter, by publication in evidence of coverage (EOC) document, by direct telephone call, by electronic transmission, by Web-based portal, or by any other means that will reasonably notify the subscriber or policyholder of the recommended timelines for testing.

This section presents the public health impacts of mammography and breast cancer, as well as the public health impacts of AB 137, if enacted. This section also discusses the potential impact of the bill on racial disparities related to breast cancer and mammography, and any impact AB 137 might have on premature death and economic loss, if enacted.

CHBRP's analysis finds that AB 137 would have no public health impact due to no anticipated change in utilization or coverage of mammography.

Public Health Impacts

As presented in the *Medical Effectiveness* section, there is a preponderance of evidence that mammography screening among women aged 40-74 years is effective in reducing mortality due to breast cancer. There is also 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.

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, no measurable impact on mammogram coverage is expected as a consequence of AB 137. Approximately 100% of female enrollees in DMHC-regulated plans and CDI-regulated policies are currently covered for breast cancer screening in compliance with the mandate AB 137 would impose. Moreover, the majority of California's health plans and insurers are currently notifying their members regarding recommended timelines for the screening of breast cancer. Therefore, no changes in utilization or coverage are anticipated as a result of this bill. Consequently, this bill is not expected to impact public health.

As noted in the *Medical Effectiveness* section, there is evidence to suggest that the use of mammography is not without risk, and there are potential harms of this screening procedure, such as discomfort and pain during the procedure, consequences of false-positive and false-negative tests, overdiagnosis, and radiation exposure (Armstrong et al., 2007; Elmore et al., 2008; Hubbard et al., 2010; Humprey et al., 2002; NCI, 2008b; Nelson et al., 2009; USPSTF, 2009). Despite the inherent risks of population-based screening, there is consensus among the major U.S. national guidelines that the benefits of mammography screening outweigh the potential harms for average-risk women aged 50-75 years. Furthermore, as presented in the

Benefit Coverage, Utilization, and Cost Impacts section, no increase in utilization of mammography is expected from AB 137.

Impact on Gender and Racial Disparities

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

CHBRP investigated the effect that AB 137 would have on health disparities by gender, race, and ethnicity. Evaluating the impact on racial and ethnic disparities is particularly important because racial and ethnic minorities report having poorer health status and worse health indicators (KFF, 2007). One important contributor to racial and ethnic health disparities is differential rates of insurance, where minorities are more likely than Whites to be uninsured; however disparities still exist within the insured population (Kirby et al, 2006; Lillie-Blanton and Hoffman, 2005). Since AB 137 would only affect persons enrolled in DMHC-regulated plans or CDI-regulated policies, a literature review was conducted to determine whether there exist gender, racial, or ethnic disparities associated with the prevalence, treatment, and outcomes for breast cancer and mammography screening outside of disparities attributable to differences between insured and uninsured populations.

Breast cancer overwhelmingly affects women, although a small number of cases are diagnosed in men as well. In California, it is estimated that 0.7% of cases of breast cancer occur in men—about 165 cases and 30 deaths each year (ACS et al., 2010a). Since the subject of AB 137 is breast cancer screening, and there are no clinical practice guidelines that recommend breast cancer screening for men, this analysis was limited to breast cancer found in women.

Impact on Racial/Ethnic Disparities

Racial and ethnic disparities in the prevalence, treatment, and outcomes for breast cancer and mammography screening exist in California. As presented in Table 1 (in the *Introduction* section), the incidence of breast cancer (including *in situ* cancers) in California varies by race/ethnicity, with Non-Hispanic Whites having the highest rates in 2008 (174.8 per 100,000 women), followed by Blacks (154.9 per 100,000 women), with Asian/Pacific Islanders and Hispanics having the lowest rates (129.2 and 108.9 per 100,000 women, respectively) (CCR, 2011). Research suggests that prevalence of mutations in the *BRCA1* gene, 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).

Self-reported screening rates using mammography vary by race/ethnicity among women aged 40-64 years. Of the four populations identified in Table 1, non-Latina White women had the highest rates of breast cancer screening using mammography in the last 2 years (85.6%), followed by African American (85.1%), Latina (83.7%), and Asian women (82.5%) (CHIS, 2009). Published studies on mammography utilization by race and ethnicity suggest that the differences in screening rates are 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 African Americans (63%) and Hispanics (64%) having lower rates of early diagnosis compared to Non-Hispanic Whites (72%) or Asian/Pacific Islanders (73%) (ACS, et al., 2010a). Mortality rates from breast cancer vary by race/ethnicity, with African Americans having the highest rates (31.9 per 100,000 women), followed by Non-Hispanic Whites (23.7 per 100,000 women), and with Hispanics and Asian/Pacific Islanders having the lowest mortality rates (16.7 and 13.3 per 100,000 women, respectively) (ACS et al., 2010a). However, for each of these disparities (screening, stage of diagnosis, mortality), AB 137 is not anticipated to have an effect due to no projected changes in mammography utilization or coverage.

Impacts on Premature Death and Economic Loss

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

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

Premature Death

Although breast cancer is related to premature death and there is a preponderance of evidence presented in the *Medical Effectiveness* section that indicates mammography is effective at screening for breast cancer, AB 137 is not estimated to measurably change the utilization of mammography nor result in a measurable reduction in premature deaths.

Breast cancer is the most common cancer found among women in California; however, when diagnosed early, the survival rates are high. The 5-year relative survival rate for breast cancer among women in California is 91% (ACS et al., 2010a). This rate varies with the stage of diagnosis: breast cancer diagnosed at an earlier stage has a higher survival rate. In California, 71% of breast cancer is diagnosed at an early stage—in which the 5-year relative survival rate is the highest (99%) compared to diagnoses at later stages (ACS et al., 2010a).

Economic Loss

Although breast cancer is related to economic loss, AB 137 would not be estimated to measurably change the utilization of mammography nor result in a measurable reduction in economic loss.

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 \$272,000 (Max, 2006).

APPENDICES

Appendix A: Text of Bill Analyzed

On January 14, 2011, the Assembly Committee on Health requested that CHBRP analyze AB 137.

BILL NUMBER: AB 137 INTRODUCED
BILL TEXT

INTRODUCED BY Assembly Member Portantino

JANUARY 12, 2011

An act to amend Section 1367.65 of, and to add Section 1367.651 to, the Health and Safety Code, and to amend Section 10123.81 of, and to add Section 10123.815 to, the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 137, 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 that is issued, amended, delivered, or renewed on or after January 1, 2000, is deemed to provide specified coverage based upon age for mammography for screening or diagnostic purposes upon referral by a participating nurse practitioner, participating certified nurse-midwife, or participating physician, providing care to the patient and operating

within the scope of practice provided under existing law.

This bill would provide that health care service plan contracts and individual or group policies of health insurance issued, amended, delivered, or renewed on or after July 1, 2012, shall be deemed to provide coverage for mammographies for screening or diagnostic purposes upon referral of a participating nurse practitioner, participating certified nurse-midwife, participating physician assistant, or participating physician, as specified. The bill would, commencing July 1, 2012, require plans and insurers subject to these provisions to provide subscribers or policyholders with information regarding recommended timelines for an individual to undergo tests for the screening or diagnosis of breast cancer, as specified.

Because this bill would specify additional requirements for health care service plans, 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. Section 1367.65 of the Health and Safety Code is amended to read:

1367.65. (a) *Until June 30, 2012, every health care service plan contract, except a specialized health care service plan contract, that is issued, amended, delivered, or renewed shall be deemed to provide coverage for mammography for screening or diagnostic purposes upon referral by a participating nurse practitioner, participating certified nurse-midwife, or participating physician, providing care to the patient and operating within the scope of practice provided under existing law.*

(b) On or after ~~January~~
~~July 1, 2000~~ 2012, 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,~~ participating physician assistant, or participating physician, providing care to the patient and

operating within the scope of practice provided under existing law.

—(b)

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

SEC. 2. Section 1367.651 is added to the Health and Safety Code, to read:

1367.651. Commencing July 1, 2012, a health care service plan subject to Section 1367.6 or 1367.65 shall provide a subscriber with information regarding recommended timelines for an individual to undergo tests for the screening or diagnosis of breast cancer. This information may be provided by written letter sent to the subscriber, by publication in a newsletter sent to the subscriber, by publication in evidence of coverage, by direct telephone call to the subscriber, by electronic transmission, by Web-based portal containing various plan and benefit information if the subscriber has access to that portal, or by any other means that will reasonably notify the subscriber of the recommended timelines for testing. Communications made by a plan's contracted providers that satisfy the requirements of this section shall constitute compliance by the plan with this section.

SEC. 3. Section 10123.81 of the Insurance Code is amended to read:

—10123.81. On or after January 1, 2000,

10123.81. (a) Until June 30, 2012, 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, 2012, every individual or group policy of health insurance 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, participating physician assistant, 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~~ provider identified in subdivision (a) or (b), as applicable, providing care to the patient .

(e) *This section shall not apply to specialized health insurance, Medicare supplement insurance, short-term limited duration health insurance, CHAMPUS supplement insurance, TRI-CARE supplement insurance, or to hospital indemnity, accident-only, or specified disease insurance.*

SEC. 4. Section 10123.815 is added to the Insurance Code, to read:

10123.815. (a) Commencing July 1, 2012, a health insurer subject to Section 10123.8 or 10123.81 shall provide a policyholder with information regarding recommended timelines for an individual to undergo tests for the screening or diagnosis of breast cancer. This information may be provided by written letter sent to the policyholder, by publication in a newsletter sent to the policyholder, by publication in evidence of coverage, by direct

telephone call to the policyholder, by electronic transmission, by Web-based portal containing various plan or policy and benefit information if the policyholder has access to that portal, or by any other means that will reasonably notify the policyholder of the recommended timelines for testing. Communications made by an insurer's contracted providers that satisfy the requirements of this section shall constitute compliance by the insurer with this section.

(b) This section shall not apply to specialized health insurance, Medicare supplement insurance, short-term limited duration health insurance, CHAMPUS supplement insurance, TRI-CARE supplement insurance, or to hospital indemnity, accident-only, or specified disease insurance.

SEC. 5. 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 conducted for AB 137. A discussion of CHBRP's system for grading evidence, as well as lists of MeSH Terms, Publication Types, and Keywords, follows.

The literature search for AB 137 updates literature searches performed in 2008 for AB 2234 and in 2009 for AB 56. Although there are important differences among these three bills, all address coverage for mammography screening. The literature search was limited to studies published in English from January 2009 to present. The following databases of peer-reviewed literature were searched: MEDLINE (PubMed), the Cochrane Database of Systematic Reviews, the Cochrane Register of Controlled Clinical Trials, the Cumulative Index of Nursing and Allied Health Literature, Web of Science, EconLit, and Business Source Complete. In addition, Web sites maintained by the following organizations that index or publish systematic reviews and evidence-based guidelines were searched: Agency for Healthcare Research and Quality, International Network of Agencies for Health Technology Assessment, the National Cancer Institute's Physician Data Query, National Health Service Centre for Reviews and Dissemination, National Institute for Health and Clinical Excellence, and the Scottish Intercollegiate Guideline Network.

For its review of literature on the effectiveness of mammography screening, CHBRP reviewed meta-analyses and systematic reviews as well as randomized controlled trials (RCTs) and nonrandomized studies with comparison groups that were published after the studies included in the meta-analyses and systematic reviews. Owing to the large volume of literature, the review of literature on the effectiveness of notification regarding recommended mammography screening was limited to meta-analyses, systematic reviews, and RCTs published after the studies included in the meta-analyses and systematic reviews.

Two reviewers screened the title and abstract of each citation retrieved by the literature search to determine eligibility for inclusion. The reviewers acquired the full text of articles that were deemed eligible for inclusion in the review and reapplied the initial eligibility criteria. Abstracts for 454 articles were identified. Nine meta-analyses, systematic reviews, RCTs, and nonrandomized studies with comparison groups were retrieved and reviewed.

Evidence Grading System

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

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

- size of effect, and
- generalizability of findings.

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

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

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

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

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

The category “insufficient evidence” of an intervention’s effect is used when there is little if any evidence of an intervention’s effect.

Search Terms

The search terms used to locate studies relevant to AB 137 were as follows:

Medical Subject Headings (MeSH) Terms—PubMed

Breast Neoplasms
 Breast Neoplasms/diagnosis
 Breast Neoplasms/prevention and control
 Breast Neoplasms/radiography
 Costs and Cost Analysis
 Ethnic Groups

Healthcare Disparities
Image Interpretation, Computer-Assisted
Insurance Carriers
Magnetic Resonance Imaging
Mammography
Ultrasonography, Mammary

Keywords—PubMed, Business Source Complete, CINAHL, Cochrane, and PDQ

Absenteesim
Breast Cancer
Cost of Illness
Costs
Economic Burden
Economic Evaluations
Economic Loss
Economics
Email?
Expenditures Per Quality of Life Year Gained
Harms
Healthcare Disparities
Insurance Costs
Long-term Impact
Mammogram?
Mortality
Newsletter
Notif? or Notification?
Premature Death
Productivity
Quality of Life
Quality adjusted life years
Race/ethnicity disparities
Remind or Reminder?
Phone?
Postcard?
Questionnair?
Screen?
Screening Rates
Socioeconomic Factors
Telephone
Ultrasound
Utilization
Years of Potential Life

(? Indicates truncation of the word stem)

Publication Types

Meta-Analysis

Practice Guideline

Randomized Controlled Trial

Review

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, 2009)	Evidence based	2009	50 to 74 years	Every 2 years	<p>The decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take patient context into account, including the patient's values regarding specific benefits and harms</p> <p>There is insufficient evidence to assess the benefits and harms of screening mammography for women age 75 years or older</p>

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

2	American Cancer Society: Guidelines for Breast Cancer Screening Update 2003 (Smith et al., 2011) ^a	Evidence based	2003	40 years and older, continuing as long as woman is in good health	Annually	Women should be educated about the benefits, limitations, and harms of screening Women at high risk might benefit from other strategies such as earlier screening initiation, shorter screening intervals, or addition of other modalities such as ultrasound or magnetic resonance imaging
3	American College of Physicians: Screening Mammography for Women 40–49 Years of Age: A Clinical Practice Guideline (Qaseem et al., 2007) ^b	Evidence based	2007	40-49 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
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	In 2009, the American College of Obstetricians and Gynecologists (ACOG) maintained its current advice that women in their 40s continue mammography screening every one to two years and women age 50 or older continue annual screening.
5	American College of Radiology: Guidelines for Breast Cancer Screening (Lee et al., 2010)	Evidence based	2010	40 years and older	Annually	Mammographic screening before the age of 40 may benefit those women at high-risk for breast cancer

Notes: ^aAmerican Medical Association and American College of Radiology concur with American Cancer Society (ACS) guidelines.

^bAmerican 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, 2011	Systematic review of 7 RCTs	Assess effectiveness of screening mammography on breast cancer mortality and morbidity	Approximately 600,000 women ages 40-74 years (the majority of trials enrolled women ages 45-64 years)	North American and Europe
Nelson et al., 2009	Systematic review and meta-analysis of 8 RCTs	Assess effectiveness of screening mammography on breast cancer mortality	Women ages 40 to 49 and 70 and older.	North America and Europe
Kerlikowske et al., 1995	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

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
Nelson et al., 2009	Systematic review and meta-analysis of 8 RCTs	Assess effectiveness of screening mammography on breast cancer mortality	Women ages 40 to 49 and 70 and older.	North America and Europe
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
Kerlikowske., 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
Krebs et al., 2010 ^{d,e}	Meta-analysis of 88 studies, including 12 on mammography screening	To compare effectiveness of computer tailored reminders to improve adherence to mammography screening.	21,292 women	United States, Europe, Australia, and New Zealand

Table C-4. Summary of Published Studies of Medical Effectiveness of Notification for Mammography Screening (Cont'd)

Citation	Type of Study	Study Objective	Population Studied	Location
Ahmed et al., 2010	RCT	To compare effectiveness of usual care (no intervention), simple intervention (letter from medical director), and a “stepwise intervention” (letter from medical director, letter from personal physician, counseling by outreach workers)	2,357 low-income women age 40 years or older who were enrolled in a managed care organization who had not had a mammogram in the previous 2 years (women age 50 years or older) or 3 years (women age 40-49 years)	Tennessee
Bowen and Powers, 2010	RCT	To compare effectiveness of stepped-intensity interventions including print reminders, telephone counseling, in-person counseling, and (if appropriate) genetic counseling and testing compared to a control group that received usual care	1,336 women aged 18 to 74 years	Pacific Northwest.
DeFrank et al., 2009	RCT	To compare effectiveness of three types of reminders enhanced usual care reminders, automated telephone reminders, and enhanced letter reminders to improve adherence to recommendations for repeat mammography screening	3,547 women age 40-75 years enrolled in a health plan for teachers and state employees who were due for their next mammogram	North Carolina

Notes: ^aThe 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.

^bThe Sohl and Moyer (2007) and Stone et al. (2002) meta-analyses both include studies by Davis et al., 1997, and Janz et al., 1997.

^cThe 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.

^dThe Sohl and Moyer (2007) and Krebs et al. (2010) meta-analyses include eight of the same studies. The Krebs et al. (2010) and Wagner (1998) meta-analyses include one of the same studies.

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

Data Sources

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

Health insurance

1. The latest (2009) California Health Interview Survey (CHIS), which is used to estimate health insurance for California's population and distribution by payor (i.e., employment-based, individually purchased, or publicly financed). The biennial CHIS is the largest state health survey conducted in the United States, collecting information from approximately 50,000 households. More information on CHIS is available at: www.chis.ucla.edu.
2. The latest (2010) California Employer Health Benefits Survey is used to estimate:
 - size of firm,
 - percentage of firms that are purchased/underwritten (versus self-insured),
 - premiums for health care service plans regulated by the Department of Managed Health Care (DMHC) (primarily health maintenance organizations [HMOs] and Point of Service Plans [POS]),
 - premiums for health insurance policies regulated by the California Department of Insurance (CDI) (primarily preferred provider organizations [PPOs] and fee-for-service plans [FFS]), and
 - premiums for high deductible health plans (HDHPs) for the California population with employment-based health insurance.
 - This annual survey is currently released by the California Health Care Foundation/National Opinion Research Center (CHCF/NORC) and is similar to the national employer survey released annually by the Kaiser Family Foundation and the Health Research and Educational Trust. Information on the CHCF/NORC data is available at: www.chcf.org/publications/2010/12/california-employer-health-benefits-survey.

3. Milliman data sources are relied on to estimate the premium impact of mandates. Milliman's projections derive from the Milliman Health Cost Guidelines (HCGs; Milliman, 2010). The HCGs are a health care pricing tool used by many of the major health plans in the United States. See: www.milliman.com/expertise/healthcare/products-tools/milliman-care-guidelines/index.php. Most of the data sources underlying the HCGs are claims databases from commercial health insurance plans. The data are supplied by health insurance companies, Blues plans, HMOs, self-funded employers, and private data vendors. The data are mostly from loosely managed healthcare plans, generally those characterized as preferred provider plans or PPOs. The HCGs currently include claims drawn from plans covering 4.6 million members. In addition to the Milliman HCGs, CHBRP's utilization and cost estimates draw on other data, including the following:
 - The MarketScan Database, which includes demographic information and claim detail data for approximately 13 million members of self-insured and insured group health plans.
 - An annual survey of HMO and PPO pricing and claim experience. The most recent survey (2010 Group Health Insurance Survey) contains data from seven major California health plans regarding their 2010 experience.
 - Ingenix MDR Charge Payment System, which includes information about professional fees paid for healthcare services, based upon approximately 800 million claims from commercial insurance companies, HMOs, and self-insured health plans.
 - These data are reviewed for applicability by an extended group of experts within Milliman but are not audited externally.
4. An annual survey by CHBRP of the seven largest providers of health insurance in California (Aetna, Anthem Blue Cross of California, Blue Shield of California, CIGNA, Health Net, Kaiser Foundation Health Plan, and PacifiCare) to obtain estimates of baseline enrollment by purchaser (i.e., large and small group and individual), type of plan (i.e., DMHC- or CDI-regulated), cost-sharing arrangements with enrollees, and average premiums. Enrollment in plans or policies offered by these seven firms represents an estimated 93.7% of the persons with health insurance subject to state mandates. This figure represents an estimated 94.4% of enrollees in full service (non-specialty) DMHC-regulated health plans and an estimated 90.1% of enrollees in full service (non-specialty) CDI-regulated policies.³⁹

Publicly funded insurance subject to state benefit mandates

5. Premiums and enrollment in DMHC-regulated health plans and CDI-regulated policies by self-insured status and firm size are obtained annually from CalPERS for active state and local government public employees and their dependents who receive their benefits through CalPERS. Enrollment information is provided for DMHC-regulated health care service plans covering non-Medicare beneficiaries—about 74% of CalPERS total enrollment. CalPERS

³⁹ CHBRP analysis of the share of enrollees included in CHBRP's Bill-Specific Coverage Survey of the major carriers in the state is based on "CDI Licenses with HMSR Covered Lives Greater than 100,000" as part of the Accident and Health Covered Lives Data Call, December 31, 2009 by the California Department of Insurance, Statistical Analysis Division, data retrieved from The Department of Managed Health Care's interactive Web site "Health Plan Financial Summary Report," July-September 2010," and CHBRP's Annual Enrollment and Premium Survey.

self-funded plans—approximately 26% of enrollment—are not subject to state mandates. In addition, CHBRP obtains information on current scope of benefits from evidence of coverage (EOCs) documents publicly available at: www.calpers.ca.gov.

6. Enrollment in Medi-Cal Managed Care (beneficiaries enrolled in Two-Plan Model, Geographic Managed Care, and County Operated Health System plans) is estimated based on CHIS and data maintained by the Department of Health Care Services (DHCS). DHCS supplies CHBRP with the statewide average premiums negotiated for the Two-Plan Model, as well as generic contracts that summarize the current scope of benefits. CHBRP assesses enrollment information online at: www.dhcs.ca.gov/dataandstats/statistics/Pages/RASS_General_Medi_Cal_Enrollment.aspx.
7. Enrollment data for other public programs—Healthy Families Program (HFP), Access for Infants and Mothers (AIM), and the Major Risk Medical Insurance Program (MRMIP)—are estimated based on CHIS and data maintained by the Managed Risk Medical Insurance Board (MRMIB). The basic minimum scope of benefits offered by participating health plans under these programs must comply with all requirements for DMHC-regulated health plans, and thus these plans are affected by state-level benefit mandates. CHBRP does not include enrollment in the Post-MRMIP Guaranteed-Issue Coverage Products as these persons are already included in the enrollment for individual market health insurance offered by DMHC-regulated plans or CDI-regulated insurers. Enrollment figures for AIM and MRMIP are included with enrollment for Medi-Cal in presentation of premium impacts. Enrollment information is obtained online at: www.mrmib.ca.gov/. Average statewide premium information is provided to CHBRP by MRMIB staff.

General Caveats and Assumptions

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

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

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

- Cost impacts are shown only for plans and policies subject to state benefit mandate laws.
- Cost impacts are only for the first year after enactment of the proposed mandate.
- Employers and employees will share proportionately (on a percentage basis) in premium rate increases resulting from the mandate. In other words, the distribution of premium paid by the subscriber (or employee) and the employer will be unaffected by the mandate.
- For state-sponsored programs for the uninsured, the state share will continue to be equal to the absolute dollar amount of funds dedicated to the program.

- When cost savings are estimated, they reflect savings realized for one year. Potential long-term cost savings or impacts are estimated if existing data and literature sources are available and provide adequate detail for estimating long-term impacts. For more information on CHBRP's criteria for estimating long-term impacts please see: http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.
- Several recent studies have examined the effect of private insurance premium increases on the number of uninsured (Chernew, et al., 2005; Glied and Jack, 2003; Hadley, 2006). Chernew et al. (2005) estimate that a 10% increase in private premiums results in a 0.74 to 0.92 percentage point decrease in the number of insured, whereas Hadley (2006) and Glied and Jack (2003) estimate that a 10% increase in private premiums produces a 0.88 and 0.84 percentage point decrease in the number of insured, respectively. The price elasticity of demand for insurance can be calculated from these studies in the following way. First, take the average percentage point decrease in the number of insured reported in these studies in response to a 1% increase in premiums (about -0.088), divided by the average percentage of insured persons (about 80%), multiplied by 100%, i.e., ($\{-0.088/80\} \times 100 = -0.11$). This elasticity converts the *percentage point* decrease in the number of insured into a *percentage* decrease in the number of insured persons for every 1% increase in premiums. Because each of these studies reported results for the large-group, small-group, and individual insurance markets combined, CHBRP employs the simplifying assumption that the elasticity is the same across different types of markets. For more information on CHBRP's criteria for estimating impacts on the uninsured please see: http://www.chbrp.org/other_publications/index.php.

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

- Population shifts by type of health insurance: If a mandate increases health insurance costs, some employer groups and individuals may elect to drop their health insurance. Employers may also switch to self-funding to avoid having to comply with the mandate.
- Changes in benefit plans: To help offset the premium increase resulting from a mandate, subscribers/policyholders may elect to increase their overall plan deductibles or copayments. Such changes would have a direct impact on the distribution of costs between the health plan and policies and enrollees, and may also result in utilization reductions (i.e., high levels of patient cost sharing result in lower utilization of health care services). CHBRP did not include the effects of such potential benefit changes in its analysis.
- Adverse selection: Theoretically, individuals or employer groups who had previously foregone health insurance may now elect to enroll in a health plan or policy, postmandate, because they perceive that it is to their economic benefit to do so.
- Medical management: Health plans and insurers may react to the mandate by tightening medical management of the mandated benefit. This would tend to dampen the CHBRP cost estimates. The dampening would be more pronounced on the plan types that previously had the least effective medical management (i.e., PPO plans).
- Geographic and delivery systems variation: Variation in existing utilization and costs, and in the impact of the mandate, by geographic area and delivery system models: Even within the health insurance types CHBRP modeled (HMO—including HMO and point of

service [POS] plans—and non-HMO—including PPO and fee for service [FFS] policies), there are likely variations in utilization and costs by type. Utilization also differs within California due to differences in the health status of the local population, provider practice patterns, and the level of managed care available in each community. The average cost per service would also vary due to different underlying cost levels experienced by providers throughout California and the market dynamic in negotiations between providers and health plans or insurers. Both the baseline costs prior to the mandate and the estimated cost impact of the mandate could vary within the state due to geographic and delivery system differences. For purposes of this analysis, however, CHBRP has estimated the impact on a statewide level.

- Compliance with the mandate: For estimating the postmandate coverage levels, CHBRP typically assumes that plans and policies subject to the mandate will be in compliance with the coverage requirements of the bill. Therefore, the typical postmandate coverage rates for populations subject to the mandate are assumed to be 100%.

Potential Effects of the Federal Affordable Care Act

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

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

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

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

Coverage for adult children

PPACA Section 2714, modified by HR 4872, Section 2301, requires coverage for adult children up to age 26 as dependants to primary subscribers on all individual and group policies, effective September 23, 2010. California's recently enacted law SB 1088 (2010) implements this provision. This could potentially affect both premiums and enrollment in 2011. According to the California Health Interview Survey (CHIS), approximately 22% of Californians aged 19-25 years (1,063,000) were estimated to be uninsured at some point in 2009. As a result of the ACA, many of these young adults will likely gain access to health insurance through a parent. This

dynamic may diminish the number of uninsured and may also shift some young adults from the individually purchased health insurance market into the group market. The Departments of Treasury, Labor, and Health and Human Services estimate, for 2011, the number of young adults newly covered by his/her parent's plan would be about 0.78 to 2.12 million (using high and low take-up rate assumptions, respectively). Of these young adults, about 0.2 to 1.64 million would have previously been uninsured. The corresponding incremental cost impact to group insurance policies is estimated to be a premium increase of 0.5% to 1.2%. Based on the responses to the Annual Enrollment and Premium survey, there has been an increase of 1% to 1.5% in enrollment for the 19-25 year olds, and the increase varies depending on whether the parents were enrolled in the large-group, small-group, or individual market. Based on analysis of the estimates from the Departments of Treasury, Labor, and Health and Human Services, as well as CHIS 2009 data, approximately 25% of the increase in enrollment represents a shift from the individual market, and approximately 75% were previously uninsured. CHBRP took these estimates into account and adjusted underlying population data since source data did not reflect the effects of this provision, because shift in populations were expected to be significant, and to account for potential lags in enrollment (e.g., due to awareness).

Minimum medical loss ratio requirement

PPACA Section 2718 requires health plans offering health insurance in group and individual markets to report to the Secretary of Health and Human Services the amount of premium revenue spent on clinical services, activities to improve quality, and other non-claim costs. Beginning in 2011, large group plans that spend less than 85% of premium revenue and small-group/individual market plans that spend less than 80% of premium revenue on clinical services and quality must provide rebates to enrollees. According to the Interim Final Rule, (45 CFR Part 158) "Issuers will provide rebates to enrollees when their spending for the benefit of policyholders on reimbursement for clinical services and quality improvement activities, in relation to the premiums charged, is less than the MLR standards established pursuant to the statute."⁴⁰ The requirement to report medical loss ratio is effective for the 2010 plan year, whereas the requirement to provide rebates is effective January 1, 2011. The MLR requirement, along with the rebate payment requirement, will affect premiums for 2011, but the effects are unknown and data are not yet available. There is potential for substantial impact on markets with higher administrative costs, including the small and individual group markets. Responses to CHBRP's Annual Enrollment and Premiums Survey indicate that carriers intend to be in compliance with these requirements. For those that may not be in compliance, the requirement to pay rebates is intended to align the MLR retrospectively. Therefore for modeling purposes, CHBRP has adjusted administrative and profit loads to reflect MLRs that would be in compliance with this provision.

Pre-Existing Condition Insurance Plan (PCIP)

PPACA Section 1101 establishes a temporary high-risk pool for individuals with pre-existing medical conditions, effective 90 days following enactment until January 1, 2014. In 2010, California enacted AB 1887 and SB 227, providing for the establishment of the California Pre-Existing Conditions Insurance Plan (PCIP) to be administered by the Managed Risk Medical Insurance Board (MRMIB) and federally funded per Section 1101. MRMIB has projected average enrollment of 23,100 until the end of 2013, when the program will expire. As of

⁴⁰ Department of Health and Human Services, *Interim Final Rule: Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act*. 45 CFR Part 158. December 1, 2010.

December 2010, there were approximately 1,100 subscribers.⁴¹ The California PCIP is not subject to state benefit mandates,⁴² and therefore this change does not directly affect CHBRP's Cost and Coverage Model. CHBRP has revised its annual update of *Estimates of the Sources of Health Insurance in California*.⁴³ to reflect a slight increase in the number of those who are insured under other public programs that are not subject to state-level mandates.

Prohibition of pre-existing condition exclusion for children

PPACA Sections 1201& 10103(e): Prohibits pre-existing condition exclusions for children. This provision was effective upon enactment). California's recently enacted law, AB 2244 (2010) implements this provision. AB 2244 also prohibits carriers that sell individual plans or policies from refusing to sell or renew policies to children with pre-existing conditions. Carriers that do not offer new plans for children are prohibited from offering for sale new individual plans in California for 5 years.⁴⁴ This provision could have had significant premium effects, especially for the DMHC- and CDI-regulated individual markets. The premium information is included in the responses to CHBRP's Annual Enrollment and Premium Survey. Thus the underlying data used in CHBRP annual model updates captured the effects of this provision.

Prohibition of lifetime limits and annual benefit limit changes

PPACA Section 2711 prohibits individual and group health plans from placing lifetime limits on the dollar value of coverage, effective September 23, 2010. Plans may only impose annual limits on coverage and these annual limits may be no less than \$750,000 for "essential health benefits." The minimum annual limit will increase to \$1.25 million on September 23, 2011, and to \$2 million September 23, 2012. Earlier in 2010, CHBRP conducted an analysis of SB 890 that sought to prohibit lifetime and annual limits for "basic health care services" covered by CDI-regulated policies. CHBRP's report indicated that DMHC-regulated plans were generally prohibited from having annual or lifetime limits. The analysis also indicated that less than 1% of CDI-regulated policies in the state had annual benefit limits, and of those, the average annual benefit limit was approximately \$70,000 for the group market and \$100,000 for the individual market. Almost all CDI-regulated policies had lifetime limits in place, and the average lifetime limits was \$5 million. After the effective date of the PPACA Section 2711, removal of these limits may have had an effect on premiums. As mentioned, premium information is included in the responses to CHBRP's Annual Enrollment and Premium Survey. Thus, the underlying data used in CHBRP annual model updates captured the effects of this provision to remove lifetime limits and to increase annual limits for those limited number of policies that had annual limits that fell below \$750,000.

Medi-Cal Managed Care Enrollment: Seniors and Persons with Disabilities

Although the PPACA allows states the option to expand coverage to those not currently eligible for Medicaid (Medi-Cal in California), large-scale expansions are not expected to be seen during 2011. However, as a result of the 2010-2011 California Budget Agreement, there are expected to be shifts in coverage for seniors and persons with disabilities. Specifically, "Seniors and persons

⁴¹ Enrollment report presented at the Managed Risk Medical Insurance Board Meeting, January 19, 2010. Available at: www.mrmib.ca.gov/MRMIB/Agenda_Minutes_011911/Agenda_Item_9.a_PCIP_Board_Report_for_Dec_2010_FI_NAL.pdf.

⁴² Correspondence with John Symkowick, Legislative Coordinator, MRMIB, October 19, 2010.

⁴³ See: http://www.chbrp.org/other_publications/index.php.

⁴⁴ See enacted language at: www.leginfo.ca.gov/pub/09-10/bill/asm/ab_2201-2250/ab_2244_bill_20100930_chaptered.pdf.

with disabilities who reside in certain counties which have managed care plans, and who are not also eligible to enroll in Medicare, will be required to enroll in a managed care plan under a phased-in process.”⁴⁵ The Medi-Cal Managed Care enrollment in CHBRP’s 2011 Cost and Coverage Model has been adjusted to reflect this change. Baseline premium rates have also been adjusted to reflect an increase in the number of seniors and persons with disabilities in Medi-Cal Managed Care. Information from DHCS indicate these changes will go into effect July 1, 2011 and would affect approximately 427,000 Medi-Cal beneficiaries.⁴⁶ CHBRP used data from DHCS to adjust enrollment in Medi-Cal Managed Care, and to adjust premiums to account for the change in acuity in the underlying populations.⁴⁷

Bill Analysis-Specific Caveats and Assumptions

Changes in mammography utilization as a result of a written letter, by publication in a newsletter, by publication in evidence of coverage (EOC) document, by direct telephone call, by electronic transmission, by Web-based portal, or by any other means is not considered in the cost analyses since health plans and insurers subject to AB 137 are already compliant of this provision.

The cost per mammogram is estimated using 2006 claims from Milliman, and it is trended forward to 2010 dollars using a rate of 10% per year.

⁴⁵ Taylor, M. Legislative Analyst, *The Budget Package 2010-11 California Spending Plan*. LAO: November, 2010. Available at:

www.lao.ca.gov/reports/2010/bud/spend_plan/spend_plan_110510.pdf.

⁴⁶ Data from the Department of Health Care Services, Medi-Cal Managed Care Division. Received January 14, 2011.

⁴⁷ See the study conducted for DHCS by Mercer on this topic: Mercer, *Medi-Cal Acuity Study: Seniors and Persons with Disabilities*. September 28, 2010. Available at:

www.dhcs.ca.gov/provgovpart/Documents/Waiver%20Renewal/SPD_Study_092810.pdf.

Appendix E: Information Submitted by Outside Parties

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

No information was submitted 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 CHBRP's authorizing legislation, UC contracts with a certified actuary, Milliman Inc., to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit. Milliman also helped with the initial development of CHBRP methods for assessing that impact.

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

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