



CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Executive Summary
Analysis of Senate Bill 173:
Mammograms

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

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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Senate Bill 173

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

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

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

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

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

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

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

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

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

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

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

⁵ Health & Safety Code Section 1367.6 and Insurance Code Section 10123.8; also Basic Health Care Services; California Health and Safety Code, Section 1345 and Section 1300.67 of the California Code of Regulations, Title 28; Cancer Screening; Health and Safety Code Section 1367.665 and Insurance Code Section 10123.20.

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

SB 173 would require DMHC-regulated plans and CDI-regulated policies to cover “comprehensive breast cancer screening” for enrollees whose mammograms indicate they have dense or heterogeneous breast tissue and for enrollees “believed to be” at increased risk for breast cancer. SB 173 does not further define “comprehensive breast cancer screening.” As previously noted, current code already requires coverage for all generally medically accepted cancer screening tests. Based on review by one of the two regulators⁶ and legal counsel,⁷ CHBRP assumes that plans and insurers would still retain the ability to conduct utilization review and to base coverage decisions on medical necessity and that coverage would remain the same. Therefore, CHBRP assumes that SB 173 would not expand benefit coverage for breast cancer screening.

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

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

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

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

Medical Effectiveness

- The medical effectiveness analysis addressed two questions.
 - Did the modality detect more cancers?
 - Did the modality result in fewer cancer deaths or better health outcomes?
- Three modalities are used to screen asymptomatic women for breast cancer: mammography, breast magnetic resonance imaging (BMRI), and ultrasound. A new modality, breast tomosynthesis (also referred to as three-dimensional mammography), was recently approved by the U.S. Food and Drug Administration (FDA).

⁶ Personal communication, A. Abu-Rahma, California Department of Managed Health Care (DMHC), February 2011.

⁷ Personal communication, Office of the General Counsel, University of California, Office of the President, March 2011.

- The medical effectiveness of mammography for breast cancer screening is well established. Multiple randomized controlled trials (RCTs) have found that mammography screening reduces breast cancer mortality, especially among women aged 50 to 74 years.
- The medical effectiveness review for SB 173 focused on evidence of the effectiveness of BMRI and ultrasound. No studies of the effectiveness of breast tomosynthesis were identified, most likely because this screening modality was only recently approved by the FDA. The literature regarding the efficacy of BMRI and ultrasound encompasses primarily observational studies, including those analyzed in systematic reviews and meta-analyses.
- Studies of BMRI
 - Most studies found that the high sensitivity of BMRI may be useful to identify breast cancers in a *targeted population of high-risk women*.
 - False-positive rates for BMRI were higher than false-positive rates for mammography; a meta-analysis of eight studies estimated that the false-positive rate for BMRI was twice as high as the false-positive rate for mammography.
 - There is insufficient evidence that BMRI screening decreases breast cancer mortality or improves health outcomes.
- Studies of Breast Ultrasound
 - There is insufficient evidence that ultrasound improves the sensitivity of breast cancer screening when it is used to screen asymptomatic women with dense breast tissue or those considered at high risk for breast cancer (e.g., women ages 40–49 years).
 - False-positive rates for breast ultrasound were higher than false-positive rates for mammography; a large observational study reported that the false-positive rate for breast ultrasound was twice as high as the false-positive rate for mammography.
 - There is insufficient evidence that breast ultrasound decreases breast cancer mortality or improves health outcomes.
- Benefits and Harms of BMRI and Breast Ultrasound Screening
 - The lack of evidence of improvement in sensitivity suggests that breast ultrasound is no more effective than mammography for screening asymptomatic women.
 - The higher sensitivity of BMRI relative to mammography for detecting breast cancer among asymptomatic high-risk women must be weighed against the harms associated with higher false-positive rates.
 - Higher false-positive rates increase the numbers of unnecessary follow-up testing and biopsies, which can cause anxiety and discomfort and may result in overdiagnosis and overtreatment.
 - It is unknown whether the benefits of BMRI and breast ultrasound screening outweigh the harms because no studies of their impact on survival or other health outcomes were identified.

Benefit Coverage, Utilization, and Cost Impacts

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

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

Public Health Impacts

- SB 173 is not expected to impact utilization of comprehensive breast cancer screening; therefore, no public health impact is expected.
- Gender and racial/ethnic disparities in breast cancer prevalence and screening patterns exist in California. However, utilization for comprehensive breast cancer screening is not expected to change as a result of SB 173. Therefore, SB 173 would not impact gender, racial, or ethnic disparities in breast cancer screening, early diagnosis, or mortality rates.
- There are more than 4,200 deaths in California each year due to breast cancer, but since SB 173 is not estimated to impact utilization of comprehensive breast cancer screening, no impact on premature mortality due to breast cancer is estimated.

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

Potential Effects of the Federal Affordable Care Act

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

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

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

- differences in the scope of benefits in the final EHB package and the scope of mandated benefits in SB 173;
- the number of enrollees in QHPs; and
- the methods used to define and calculate the cost of additional benefits.

EHBs may all be considered to include benefits and services mandated by SB 173. In addition, HHS when promulgating regulations on EHBs is to ensure that the EHB floor “is equal to the scope of benefits provided under a typical employer plan.” Virtually all employers provide coverage for services mandated under SB 173. Because mammography services as defined under

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

⁹ Affordable Care Act, 1311(d)(3)(B).

SB 173 is considered standard coverage for employer-based plans, and because it is likely to be considered part of EHBs, it is unlikely that there would be any additional fiscal liability to the state for qualified health plans offered in the Exchange as a result of this mandate.

Preventive Services Required Under ACA and SB 173

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

ACKNOWLEDGMENTS

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

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

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

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California Health Benefits Review Program Committees and Staff

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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