

California Health Benefits Review Program

Analysis of California Assembly Bill (AB) 2764 Health Care Coverage: Mammography

A Report to the 2015-2016 California State Legislature

May 6, 2016



Key Findings:

Analysis of California Assembly Bill (AB) 2764 Mammography

Summary to the 2015-2016 California State Legislature, May 2016



AT A GLANCE

AB 2764 would mandate coverage for digital mammography and digital breast tomosynthesis (DBT).

Enrollees covered. CHBRP estimates that in 2016, 25.2 million Californians have state-regulated coverage that would be subject to AB 2764.

- **Background.** Digital mammography is frequently used as a breast cancer screening test. Less frequently, DBT is added to digital mammography when screening for breast cancer.
- **Medical effectiveness.** There is *clear and convincing* evidence that compared to no screening digital mammography alone leads to reduced breast cancer–related mortality, and may detect breast cancer at an earlier stage among some subgroups of women. There is insufficient evidence to indicate whether adding DBT to digital mammography for breast cancer screening would alter these key clinical outcomes.
- **Benefit coverage.** AB 2764 would not alter the fact that 100% of enrollees have coverage for digital mammography but would increase coverage for DBT (from 61% of enrollees to 100%).
- **Utilization.** Utilization of screening digital mammography would increase by 4% and utilization of DBT would increase by 91%.
- **Expenditures.** AB 2764 would increase total expenditures (premiums and cost sharing) by \$39,500,000 (0.03%).
- **Public Health.** Due to 100% coverage, CHBRP projects no impacts on health outcomes attributable to digital mammography. Due to insufficient evidence of increased medical effectiveness for use of DBT, CHBRP finds impacts on health outcomes attributable to DBT to be unknown.
- **Long Term Impacts.** AB 2764’s impacts on utilization and expenditures would increase after the first postmandate year, as DBT technology becomes more available. However, the impact on health outcomes of the later years’ increased DBT utilization is unknown.

BACKGROUND

Mammography provides an x-ray picture of the breast, and can be conducted as a screening or diagnostic test. As a screening test, its purpose is to identify potentially cancerous abnormalities in asymptomatic women. As a diagnostic test, it further investigates identified abnormalities or checks for abnormalities among women previously treated for breast cancer.

CHBRP’s full report discusses diagnostic tests, but this key findings section focuses on breast cancer screening and the related impacts that would result from AB 2764.

Film and digital mammography are frequently used as breast cancer screening tests. Both produce two-dimensional images. In recent years, digital mammography has become the much more commonly used form. Digital breast tomosynthesis (DBT) takes multiple cross-sectional images of the breast and then uses a computer algorithm to reconstruct a three-dimensional image. DBT images for screening are generally obtained in combination with digital mammography. Breast cancer screening generally consists of digital mammography alone although it is sometimes accompanied by DBT.

In either case, when results indicate an abnormality that may be breast cancer, additional tests (additional mammographic views and/or other tests - possibly breast ultrasound, and/or biopsies) may also be performed to verify the presence of cancer.

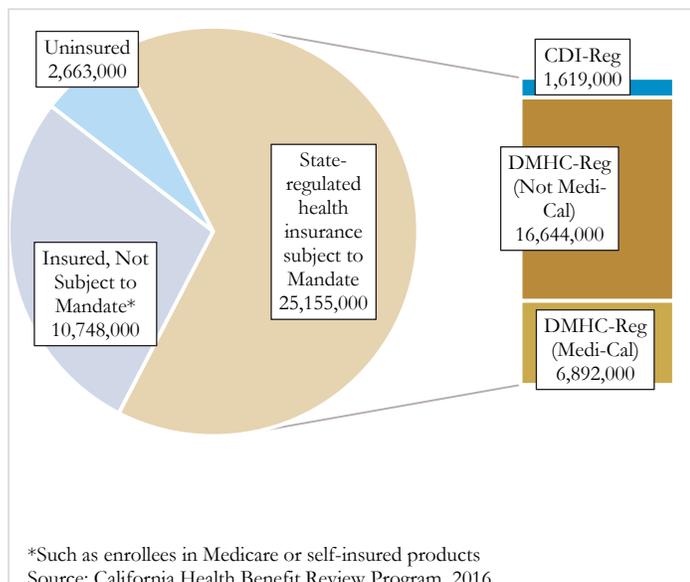
BILL SUMMARY

AB 2764 would amend a current benefit mandate law to specify “mammography” as inclusive of both digital mammography, which is generally covered, as well as DBT, which is frequently not covered. Both can be used as screening and/or diagnostic tests for breast cancer.

AB 2764, as noted in Figure 1, would affect the health insurance of enrollees in plans regulated by the California Department of Managed Health Care (DMHC) as well as

the health insurance of enrollees in policies regulated by the California Department of Insurance (CDI).

Figure 1. Health Insurance in CA and AB 2764



Medical Effectiveness

Film and digital mammography are comparable as breast cancer screening tests for “average-risk women.” Numerous clinical guidelines recommend film or digital mammography as breast cancer screening tests. Examples include current guidelines and recommendations issued by the following national sources:

- American Academy of Family Physicians (AAFP)
- American Congress of Obstetrics and Gynecology (ACOG)
- American College of Radiology (ACR)
- American Cancer Society (ACS)
- National Comprehensive Cancer Network (NCCN)
- United States Preventive Services Task Force (USPSTF)

The 2016 USPSTF recommendations noted evidence that screening mammography (film or digital) impacts clinically significant health outcomes, reducing breast-cancer specific mortality among women aged 40 to 74 years and also reducing cancer stage at diagnosis among women aged 50 years and older. Although the ACR concludes that DBT is no longer an investigational modality and “improves key screening parameters compared to digital mammography,” the ACS, as well as the AAFP, ACOG,

NCCN, and USPSTF, citing insufficient evidence, have not recommended DBT as a screening tool for breast cancer.

For its analysis of AB 2764, CHBRP focused on reviewing the comparative effectiveness for breast cancer screening of (1) digital mammography alone and (2) digital mammography with DBT.

The previously mentioned guidelines and recommendations, as well as a number of systematic evidence reviews, provide *clear and convincing* evidence that digital mammography alone, leads, to reduced breast cancer-related mortality, and may detect breast cancer at an earlier stage among some subgroups of women.

As noted most guidelines and recommendations cite insufficient evidence to recommend DBT as an addition to digital mammography. In addition, CHBRP located no studies of digital mammography with DBT that evaluated key clinical outcomes such as reduced breast cancer-related mortality or earlier stage diagnosis. Therefore, CHBRP concludes that there is *insufficient* evidence to determine the effectiveness of adding DBT to screening digital mammography on key clinical outcomes.

There is *preponderance* of evidence, from low- to moderate-quality studies, that in comparison to digital mammography alone, digital mammography with DBT may reduce recall (for further testing) by 1.6-2.6%, decreasing to 6.4% to 13.6% with the addition of DBT to digital mammography from 9.3% to 16.2% with digital mammography alone, and that the addition of DBT may increase breast cancer detection by as many as 1 per 1,000 tests, from 4 cancers per 1,000 exams to 5 cancers per 1,000 exams. However, there is insufficient long-term follow up evidence to conclude that the additional tests led to improved outcomes.

Although screening mammography (generally digital mammography alone) reduces mortality from breast cancer in women aged 40 to 75 years, it is associated with some harms. The USPSTF cites the key harm as overdiagnosis (diagnosis of a cancer that would not have progressed to clinical significance) and subsequent overtreatment.

In addition to the previously described harms associated with digital mammography, DBT, like digital mammography, involves radiation exposure. Although the exposure for both is limited, DBT and digital mammography together result in greater radiation exposure than does digital mammography alone.

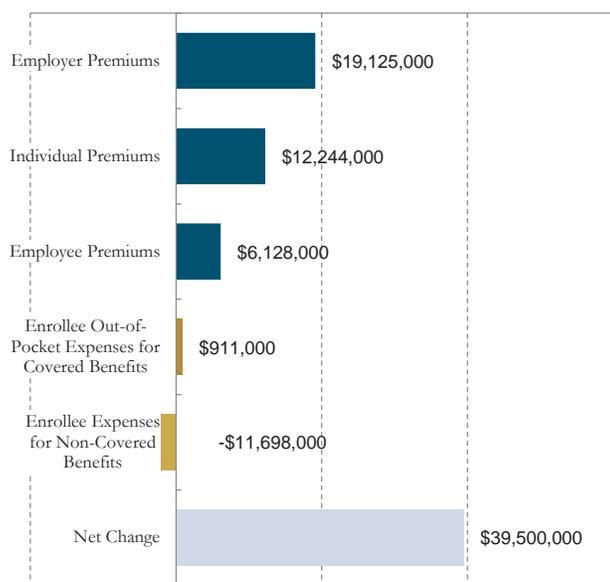
Benefit Coverage

Although 100% of enrollees in DMHC-regulated plans and CDI-regulated policies have coverage for digital mammography, premandate only 61% of these enrollees have coverage for DBT. AB 2764 would increase the second figure to 100%.

Utilization

In 2017, among enrollees with health insurance that could be subject to AB 2764, CHBRP estimates that there would be 2,832,000 screening digital mammograms, and that 862,000 of those would be accompanied by DBT tests. Postmandate, both figures would rise, screening digital mammograms to 2,950,000 (an increase of 4%), a hastening of the general trend away from film mammography to digital mammography. Accompanying DBT tests would also increase, to 1,646,000 (an increase of 91%).

Figure 2. Impacts on Premiums and Cost Sharing



Expenditures

As detailed in Figure 2, as a result of the increased utilization, total expenditures (premiums and cost sharing) would increase \$39,499,000 (0.03%). This figure assumes cost sharing only for diagnostic digital/film mammography and DBT (no cost sharing for screening test) and represents a reduction in payments by enrollees for non-covered DBT.

Public health

Because the review found insufficient evidence to suggest that the use of DBT in addition to digital mammography would improve clinically meaningful health outcomes (i.e., breast cancer-related morbidity and mortality), the public health impact in the first year, postmandate, is unknown. Please note that the absence of evidence is not “evidence of no effect.” Impacts — desirable and/or undesirable — could result, but current evidence is insufficient to inform an estimate.

Long-Term Impacts

Impacts on utilization during the 12 months following enactment of AB 2764 would be constrained by availability of DBT technology, but CHBRP would expect, postmandate, for DBT to accompany over half of digital mammograms postmandate (an increase from a premandate estimate of one third). In later years, as DBT technology is made more accessible, impacts could increase so that over 90% of enrollees utilizing screening digital mammography may simultaneously utilize DBT. Such an increase in utilization would be expected to have concomitant impacts on expenditures. However, the impact on meaningful health outcomes of the additional utilization is unknown.

A Report to the California State Legislature

Analysis of California Assembly Bill (AB) 2764 Health Care Coverage: Mammography

May 6, 2016

California Health Benefits Review Program
1111 Broadway, Suite 1400
Oakland, CA 94607
Tel: 510.287.3876
Fax: 510.763.4253
www.chbrp.org

ABOUT CHBRP

The California Health Benefits Review Program (CHBRP) was established in 2002 to provide the California Legislature with independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit mandates and repeals, per its authorizing statute. The state funds CHBRP through an annual assessment on health plans and insurers in California.



An analytic staff in the University of California's Office of the President supports a task force of faculty and research staff from several campuses of the University of California to complete each CHBRP analysis. A strict conflict-of-interest policy ensures that the analyses are undertaken without bias. A certified, independent actuary helps to estimate the financial impact, and content experts with comprehensive subject-matter expertise are consulted to provide essential background and input on the analytic approach for each report.

More detailed information on CHBRP's analysis methodology, as well as all CHBRP reports and publications are available at www.chbrp.org.

TABLE OF CONTENTS

About CHBRP	v
List of Tables and Figures.....	vii
Policy Context	1
Medical Effectiveness	4
Research Approach and Methods.....	4
Findings Related to the Effectiveness of Screening Mammography for Breast Cancer	5
Findings Related to the Effectiveness of Mammography in Diagnostic Imaging for Breast Cancer.....	9
Findings Related to the Harms of Digital Mammography With and Without DBT	10
Benefit Coverage, Utilization, and Cost Impacts.....	12
Benefit Coverage.....	12
Utilization	13
Per-Unit Cost	16
Premiums and Expenditures	16
Related Considerations for Policymakers	18
Public Health Impacts	23
Estimated Public Health Outcomes.....	23
Social Determinants of Health and Disparities	24
Potential Harms from DBT	25
Financial Burden.....	25
Long-Term Impact of AB 2764.....	26
Long-Term Utilization and Cost Impacts	26
Long-Term Public Health Impacts	27
Appendix A Text of Bill Analyzed.....	A-1
Appendix B Literature Review Methods	B-1
Appendix C Cost Impact Analysis: Data Sources, Caveats, and Assumptions.....	C-1

References

California Health Benefits Review Program Committees and Staff

Acknowledgements

LIST OF TABLES AND FIGURES

Table 1. AB 2764 Impacts on 2017 Benefit Coverage, Utilization, and Cost	viii
Table 2. Premandate and Postmandate Utilization of Breast Imaging Exams	15
Table 3. 2017 Baseline (Premandate) Per Member Per Month Premiums and Total Expenditures by Market Segment, California	19
Table 4. 2017 Postmandate Impacts of the Mandate on Per Member Per Month Premiums and Total Expenditures by Market Segment, California	21
Table 5. Data for 2017 Projections	C-1
Figure 1. Health Insurance in CA and AB 2764	ii
Figure 2. Impacts on Premiums and Cost Sharing	iii
Figure 3. Summary of Findings Related to the Effect of Digital Mammography on Screening for Breast Cancer.....	6
Figure 4. Summary of Findings related to the effect of digital mammography on diagnostic imaging for breast cancer	9

Table 1. AB 2764 Impacts on 2017 Benefit Coverage, Utilization, and Cost

	Premandate	Postmandate	Increase/ Decrease	Change
Benefit coverage				
Total enrollees with health insurance subject to state benefit mandates ^(a)	25,155,000	25,155,000	--	--
Total enrollees with health insurance subject to AB 2764	25,155,000	25,155,000	--	--
Number of enrollees with health insurance fully compliant with AB 2764 ^(b)	15,378,000	25,155,000	9,777,000	63.6%
Percentage of enrollees with health insurance fully compliant with AB 2764	61%	100%	39%	
Utilization and cost				
Total enrollees using mammography services	2,051,000	2,051,000	--	--
Total digital mammography screening exams (units)	2,832,000	2,950,000	118,000	4.16%
Total digital breast tomosynthesis (DBT) screening exams	862,000	1,646,000	784,000	91.0%
Total digital mammography diagnostic exams	748,000	778,000	30,000	4.05%
Total DBT diagnostic exams	303,000	464,000	161,000	52.9%
Screening digital mammography unit cost	\$182.37	\$182.37	--	--
Screening DBT unit cost	\$63.49	\$63.49	--	--
Diagnostic digital mammography unit cost	\$178.51	\$178.51	--	--
Diagnostic DBT unit cost	\$59.44	\$59.44	--	--
Expenditures				
<u>Premium expenditures by payer</u>				
Private employers for group insurance	\$64,837,024,000	\$64,854,749,000	\$17,725,000	0.03%
CalPERS HMO employer expenditures ^(c)	\$4,756,143,000	\$4,757,543,000	\$1,400,000	0.03%
Medi-Cal Managed Care Plan expenditures ^(d)	\$16,670,700,000	\$16,683,490,000	\$12,790,000	0.08%
Enrollees for individually purchased insurance — Outside Exchange	\$10,875,864,000	\$10,882,279,000	\$6,415,000	0.06%
Enrollees for individually purchased insurance — Covered California	\$11,197,252,000	\$11,203,081,000	\$5,829,000	0.05%
Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care ^{(a) (g)}	\$20,496,488,000	\$20,502,616,000	\$6,128,000	0.03%
<u>Enrollee out-of-pocket expenses</u>				
Enrollee cost-sharing expenses for covered benefits (deductibles, copayments, etc.) ^(e)	\$16,248,327,000	\$16,249,238,000	\$911,000	0.01%
Enrollee expenses for noncovered diagnostic DBT exams ^(f)	\$11,698,000	\$0	-\$11,698,000	-100.00%
Total expenditures	\$145,093,495,000	\$145,132,996,000	\$39,499,000	0.03%

Source: California Health Benefits Review Program, 2016.

Notes: (a) This population includes persons with privately funded (including Covered California) and publicly funded (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans) health insurance products regulated by DMHC or CDI.

Population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employer-sponsored health insurance.

(b) Fully compliant health insurance covers both digital mammography and DBT. Noncompliant health insurance covers digital mammography (but does not cover DBT).

(c) Of the increase in CalPERS employer expenditures, about 56.7% or \$3,455,000 would be state expenditures for CalPERS members who are state employees or their dependents.

(d) Does not include enrollees in COHS.

(e) Health plans are prohibited from applying cost sharing (i.e., co-payments, deductibles) to screening digital mammography exams but do apply cost sharing for diagnostic digital mammography exams. Likewise, health insurance plans that currently provide coverage for digital breast tomosynthesis (DBT) also do not apply cost sharing when DBT is performed in conjunction with screening digital mammography but do apply cost sharing when DBT is performed with digital diagnostic mammography.

(f) When a health insurance plan does not provide coverage for digital breast tomosynthesis (DBT), providers directly charge enrollees a fee for DBT services.

(g) Premium expenditures by enrollees include employee contributions to employer-sponsored health insurance and enrollee contributions for publicly purchased insurance.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DBT = digital breast tomosynthesis; DMHC = Department of Managed Health Care; OPD= Outpatient Drug Benefit; COHS = County Operated Health System

POLICY CONTEXT

The California Assembly Committee on Health has requested that the California Health Benefits Review Program (CHBRP)¹ conduct an evidence-based assessment of the medical, financial, and public health impacts of (AB) 2764, Mammography.

If enacted, (AB) 2764 would affect the health insurance of approximately 25.2 million enrollees (65% of all Californians). This represents 100% of the 25.2 million Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law — health insurance regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI). If enacted, the law would affect the health insurance of enrollees in DMHC-regulated plans and CDI-regulated policies.

Bill Language

A current law² requires DMHC-regulated plans and CDI-regulated policies to cover mammography for both screening and diagnostic purposes, but does not specify that digital mammography must be covered. AB 2764 would amend a current benefit mandate law to specify that “mammography” includes both digital mammography, which is generally covered, as well as digital breast tomosynthesis (DBT), which is frequently not covered.

Mammography can be done using either digital or film technology. In recent years, digital mammography has become the much more common form comprising approximately 93% of exams.

DBT is another digital test, one that can create three-dimensional images. It is typically performed as an addition to a digital mammogram and is produced by the same machine.

Analytic Approach and Key Assumptions

CHBRP has assumed that AB 2764 would not affect the coverage of breast cancer screening and diagnostic tests not considered “mammography,” such as ultrasound but may impact utilization of these other tests (see Table 2 in the *Benefit Coverage, Utilization, and Cost Impacts* section).

CHBRP is aware that the California Department of Health Care Services (DHCS) expects DBT to be covered for Medi-Cal beneficiaries enrolled in DMHC-regulated plans,³ but has assumed enactment of AB 2764 would bring additional clarity and so impact the health insurance of a portion of these enrollees.

CHBRP has assumed that cost-sharing for DBT and other forms of mammography would be similar.

General Caveat for All CHBRP Analyses

It is important to note that CHBRP’s analysis of proposal benefit mandate bills address incremental effects — how the proposed legislation would impact benefit coverage, utilization, costs, and public health. CHBRP’s estimates of these incremental effects are presented in this report.

¹ CHBRP’s authorizing statute is available at www.chbrp.org/docs/authorizing_statute.pdf.

² Health & Safety Code 1367.65 and Insurance Code 10123.81

³ Personal Communication, D. Adler, DHCS, May 2016

Interaction with Existing Requirements

Health benefit mandates may interact and align with the following state and federal mandates or provisions.

State Requirements

California law and regulations

In addition to the mammography-specific mandate that AB 2764 would amend, another current law⁴ broadly requires coverage for breast cancer screening, diagnosis, and treatment. To date, neither law has been interpreted as requiring coverage for DBT, which is classified as experimental/investigational in the independent medical review (IMR) database maintained by DMHC.

Similar requirements in other states

Although bills mandating coverage for mammography are present in the majority of states (BCBSA, 2015), CHBRP is aware of only two — Pennsylvania (as of 2015) and Illinois (as of 2016) — requiring coverage for DBT.

Federal Requirements

A number of Affordable Care Act (ACA) provisions have the potential to or do interact with state benefit mandates. Below is an analysis of how AB 2764 may interact with requirements of the ACA.

Essential Health Benefits

State health insurance marketplaces, such as Covered California, are responsible for certifying and selling qualified health plans (QHPs) in the small-group and individual markets. Health insurance offered in Covered California is required to at least meet the minimum standard of benefits as defined by the ACA as essential health benefits (EHBs),⁵ and available in the Kaiser Foundation Health Plan Small Group Health Maintenance Organization (HMO) 30 plan, the state's benchmark plan for federal EHBs.^{6,7}

States may require such QHPs to offer benefits that exceed EHBs.⁸ However, a state that chooses to do so must make payments to defray the cost of those additionally mandated benefits, either by paying the purchaser directly or by paying the QHP.^{9,10} On the other hand, "state rules related to provider types,

⁴ Health & Safety Code 1367.6 and Insurance Code 10123.8

⁵ The ACA requires nongrandfathered small-group and individual market health insurance — including, but not limited to, QHPs sold in Covered California — to cover 10 specified categories of EHBs. Resources on EHBs and other ACA impacts are available on the CHBRP website: http://www.chbrp.org/other_publications/index.php.

⁶ The U.S. Department of Health and Human Services (HHS) has allowed each state to define its own EHBs for 2014 and 2015 by selecting one of a set of specified benchmark plan options. CCIIO, Essential Health Benefits Bulletin. Available at: cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf.

⁷ H&SC § 1367.005; IC § 10112.27.

⁸ ACA § 1311(d)(3).

⁹ State benefit mandates enacted on or before December 31, 2011, may be included in a state's EHBs, according to the U.S. Department of Health and Human Services (HHS). Patient Protection and Affordable Care Act: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. Federal Register, Vol. 78, No. 37. February 25, 2013. Available at: www.gpo.gov/dfsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.

cost-sharing, or reimbursement methods” would *not meet* the definition of state benefit mandates that could exceed EHBs.¹¹

“AB 276 requires coverage beyond the current mandate to cover digital mammography and would require, in addition to digital mammography, DBT. However, because DBT would be considered part of mammography coverage which is an essential health benefit, it would not trigger the requirement that the state pay for benefits beyond EHBs”).¹² For this reason, the benefit coverage that would be mandated by (AB) 2764 appear not to Exceed EHBs, and therefore would not trigger the ACA requirement that the state defray the cost of additional benefit coverage for enrollees in qualified health plans (QHPs)¹³ in Covered California.

Preventive Services

Separately from requirements regarding EHBs, the ACA requires that nongrandfathered group and individual health insurance plans and policies cover certain preventive services without cost sharing when delivered by in-network providers and as soon as 12 months after a recommendation appears in any of the following:¹⁴

- The United States Preventive Services Task Force (USPSTF) A and B recommendations;
- The Health Resources and Services Administration (HRSA)-supported health plan coverage guidelines for women’s preventive services;
- The HRSA-supported comprehensive guidelines for infants, children, and adolescents, which include:
 - The Bright Futures Recommendations for Pediatric Preventive Health Care; and
 - The recommendations of the Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children; and
- The Advisory Committee on Immunization Practices (ACIP) recommendations that have been adopted by the Director of the Centers for Disease Control and Prevention (CDC).

Although a number of these sources recommend film and/or digital mammography, none of these sources recommend use of DBT as a breast cancer screening test. For this reason, it is unclear whether or not the prohibition on cost sharing for screening would be applicable to DBT.¹⁵ However, since screening film and digital mammography are often performed without any applicable cost sharing, in this analysis CHBRP has assumed no cost sharing would be applicable when DBT is performed as a screening test if AB 2764 were enacted to define mammography as inclusive of DBT.

¹⁰ However, as laid out in the Final Rule on EHBs HHS released in February 2013, state benefit mandates enacted on or before December 31, 2011, would be included in the a state’s EHBs and there would be no requirement that the state defray the costs of those state mandated benefits. For state benefit mandates enacted after December 31, 2011, that are identified as exceeding EHBs, the state would be required to defray the cost.

¹¹ Essential Health Benefits. Final Rule. A state’s health insurance marketplace would be responsible for determining when a state benefit mandate exceeds EHBs, and QHP issuers would be responsible for calculating the cost that must be defrayed.

¹² Personal communication, R. Arnold, DMHC, April 2016.

¹³ In California, QHPs are non-grandfathered small-group and individual market DMHC-regulated plans and CDI-regulated policies sold in Covered California, the state’s health insurance marketplace.

¹⁴ A resource on this ACA requirement is available on the CHBRP website: www.chbrp.org/other_publications/index.php.

¹⁵ Personal communication, R. Arnold, DMHC, April 2016.

MEDICAL EFFECTIVENESS

As discussed previously, AB 2764 would require plans and policies to cover both digital mammography and digital breast tomosynthesis (DBT). The medical effectiveness review summarizes findings from the literature on the effectiveness of digital mammography and DBT in screening for and diagnosis of breast cancer.

Mammography provides an x-ray picture of the breast, and can be conducted as a screening mammogram (to identify potentially cancerous lesions in the breast in asymptomatic women) or as a diagnostic mammogram (to investigate an abnormality identified on a screening mammogram or a breast symptom [such as a lump or nipple discharge], or to screen for abnormalities among women previously treated for breast cancer) (ACS, 2015c). A mammogram may be done as a film-screen mammogram or as a 2D digital mammogram. In film mammography, the x-ray image is stored directly on film, whereas digital mammography stores an electronic image, allowing the radiologist to manipulate or enhance the image for assessment (NCI, 2014). The medical effectiveness review did not review studies comparing the effectiveness of film vs. digital mammography for breast cancer screening, due to the existence of numerous high-quality systematic reviews (Iared et al., 2011; Souza et al., 2013) and large cohort studies (Kerlikowske et al., 2011; Pisano et al., 2005) which have found that the two modalities (film and digital mammography) are comparable for “average-risk women.” Digital mammography has been shown to have higher sensitivity in younger women and women with dense breasts (Pisano et al., 2005). However, one major limitation of both film and digital mammography is the potential for overlapping tissue in the digital image, resulting in obscured areas and potentially leading to false findings.

DBT, also known as 3D mammography, attempts to address this limitation by taking multiple low-dose, cross-sectional digital images of the entire breast. Then, a computer algorithm reconstructs the images into a 3D estimation of tissue distribution. DBT images for breast cancer screening are obtained in combination with 2D digital mammography or synthetically reconstructed 2D images (Peppard et al., 2015).

Mammography is a critical first step in the detection of breast cancers. Patients with abnormalities upon imaging and/or clinical exam may undergo additional imaging with other modalities such as ultrasound, or will directly undergo a biopsy of the suspicious area(s) to confirm whether there is a malignancy in the breast tissue. It should be noted that although clinical terminology refers to imaging exams as “diagnostic,” breast cancer is diagnosed based on examination of breast tissue pathology (usually from biopsy). Breast tissue pathology is used to classify cancers as non-invasive or invasive. Non-invasive breast cancers are limited to specific types of cells within the breast tissue; treatment is limited and prognosis is highly favorable (NCCN, 2014b). Invasive breast cancers have or may spread to other parts of the breast tissue and body. Treatment and prognosis of invasive breast cancers are guided by multiple factors, including biological characteristics of the cancer and the stage of disease, which is determined after surgery to remove the lump or whole breast and excision of a sample of nearby lymph nodes. By enabling the detection of certain forms of invasive cancer at an earlier stage of disease, breast imaging exams have the potential to reduce breast cancer morbidity and mortality.

Research Approach and Methods

Given the widespread use of digital mammography in clinical practice (estimated 93% of mammograms are with digital mammography; see the *Benefit Coverage, Utilization, and Cost Impacts* section for further details) and its comparable performance to film mammography, this medical effectiveness review briefly describes the literature on the effectiveness of digital mammography and then focuses primarily on comparisons of digital mammography with and without the addition of DBT. Studies of breast cancer

screening and diagnosis using digital mammography and DBT were identified through searches of relevant databases of peer-reviewed literature listed in Appendix B. For the comparative medical effectiveness of digital mammography with and without DBT on breast cancer screening, CHBRP relied on a US Preventive Services Task Force (USPSTF) systematic review on DBT that searched the literature through October 2015, and CHBRP reviewed abstracts of studies published from September 2015 to the present. For the effectiveness of DBT in the diagnosis of breast cancer, abstracts published from January 2010 to present were reviewed. Of the 481 articles identified in the literature search, 127 were reviewed as potentially relevant for inclusion in this report. Studies were eliminated because they did not include a comparison arm (i.e., only looked at outcomes among women receiving digital mammography and DBT); only analyzed outcomes related to radiology/reader performance, or; for studies of screening did not represent a true screening population, such as studies that included both asymptomatic and symptomatic women.

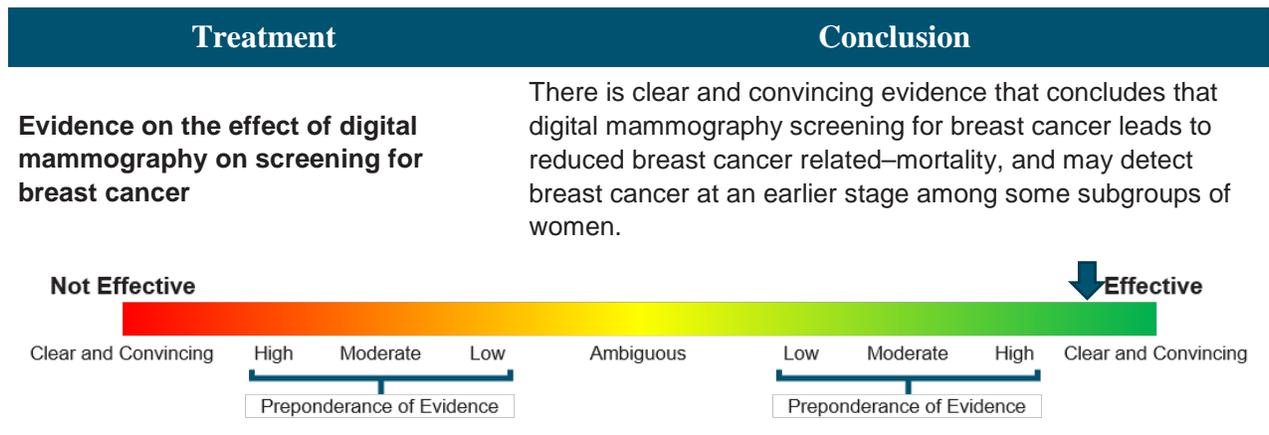
Findings Related to the Effectiveness of Screening Mammography for Breast Cancer

Effectiveness of Digital Mammography in Screening for Breast Cancer

Clinical guidelines from the American Academy of Family Physicians (AAFP), American Congress of Obstetrics and Gynecology (ACOG), American College of Radiology (ACR), American Cancer Society (ACS), National Comprehensive Cancer Network (NCCN), and the United States Preventive Services Task Force (USPSTF) all recommend mammography for breast cancer screening (AAFP, 2016; ACS, 2015a; ACR, 2014a; ACOG, 2011; NCCN, 2014d; Siu, 2016). However, only the USPSTF recommendation notes that digital mammography is widely used in the United States and has similar diagnostic accuracy as film-screen mammography overall, and higher sensitivity in women under 50 years of age (Siu, 2016).

The recent USPSTF recommendations on breast cancer screening were based on systematic evidence reviews, which found that mammography screening reduces breast cancer–specific mortality (but not all-cause mortality) among women ages 40 to 74 years (Nelson et al., 2016). Other recent systematic reviews, including a review by ACS, have reached similar conclusions (Myers et al., 2015; Oeffinger et al., 2015). The USPSTF review found that screening mammography reduced cancer stage at diagnosis among women aged 50 years and older (Nelson et al., 2016). Based on the review, the USPSTF recommends screening on an individual basis among women aged 40 to 49 years (based on family history and personal preference) and screening every 2 years for women aged 50 to 74 years. The ACS recommendations differ slightly, recommending screening on an individual basis among women aged 40 to 44 years, annual screening mammography among women aged 45 to 54 years, and screening every 2 years among women aged 55 years and older (ACS, 2015a).

Figure 3. Summary of Findings Related to the Effect of Digital Mammography on Screening for Breast Cancer



Effectiveness of Digital Mammography Plus DBT in Screening for Breast Cancer, Compared to Digital Mammography Alone

No studies of digital mammography with DBT evaluated the important clinical outcomes such as morbidity, disease-free survival, or mortality (all-cause or breast cancer–specific) attributable to the addition of DBT to digital mammography. The majority of studies include only one year of clinical follow-up, and none followed women beyond either their breast cancer diagnosis or confirmation of negative mammogram.

Currently, there are no clinical guidelines recommending the use of DBT for breast cancer screening or diagnosis. The ACR has found that DBT is no longer an investigational modality and “improves key screening parameters compared to digital mammography” (ACR, 2014b), but the recent ACS guidelines (released in October 2015), as well as recommendations from AAFP, ACOG, NCCN, and USPSTF have cited insufficient evidence to recommend the use of DBT as a screening tool for breast cancer (AAFP, 2016; ACS, 2015b; ACOG, 2014; NCCN, 2014a; Siu, 2016).

CHBRP concludes that there is insufficient evidence to determine the medical effectiveness of digital mammography with DBT on breast cancer morbidity, disease-free survival, or mortality.

Screening performance of digital mammography with DBT, compared to digital mammography alone

Since CHBRP identified no literature addressing important clinical outcomes such as morbidity, disease-free survival, or mortality attributable to the addition of DBT to digital mammography, the medical effectiveness review also reviewed the literature on more proximate breast cancer screening outcomes: test performance, recall and biopsy rates, and cancer detection.

Three cohort studies¹⁶ of breast cancer screening reported on test performance characteristics of digital mammography with and without DBT (Ciatto et al., 2013; Conant et al., 2016; Houssami et al., 2014;

¹⁶ Houssami et al. (2014) and Ciatto et al. (2013) each reported on results from the Screening with Tomosynthesis or Standard Mammography (STORM) trial. For the purpose of this review, we only report results from the later Houssami (2014) publication

Lourenco et al., 2015). Twelve cohort studies¹⁷ of breast cancer screening also reported on recall and cancer detection rates for digital mammography with or without DBT (Conant et al., 2016; Destounis et al., 2014; Durand et al., 2015; Friedewald et al., 2014; Greenberg et al., 2014; Haas et al., 2013; Lang et al., 2016; McCarthy et al., 2014; McDonald et al., 2016; Rose et al., 2013; Sharpe et al., 2016; Skaane et al., 2013). These studies compared findings within a single cohort of women undergoing both studies or compared two screening cohorts, one undergoing digital mammography only compared to a cohort undergoing digital mammography and DBT. The majority of studies (9/12) were conducted in the United States, primarily within academic health systems; the remaining three were cohorts of women from population-based screening programs in Italy, Norway, and Sweden. Four of the studies were large cohort studies set in the United States including more than 10,000 women or exams in both the digital mammography and digital mammography with DBT arms (Conant et al., 2016; Friedewald et al., 2014; Greenberg et al., 2014; Lourenco et al., 2015).

Test performance characteristics

The medical effectiveness review identified three cohort studies reporting on test performance characteristics of digital mammography with and without DBT (Conant et al., 2016; Houssami et al., 2014; Lourenco et al., 2015). Test performance characteristics, which include sensitivity¹⁸, specificity¹⁹, positive predictive value (PPV)²⁰, and negative predictive value (NPV)²¹, assess the ability of a screening test to differentiate between individuals with a disease and those without the disease. Two of the three studies reported the sensitivity of digital mammography with and without DBT. Conant (2016), conducted in the United States, found similar results between the two modalities (90.6% for digital mammography and 90.9% with the addition of DBT) and the study conducted in Italy (Houssami, 2014) found that digital mammography with DBT was more sensitive (85%) compared to digital mammography alone (54%). All three studies reported on the specificity between the two modalities. Lourenco (2015) found that digital mammography with DBT had higher specificity than digital mammography alone (94% vs. 91%), while Conant (2016) also found higher specificity for digital mammography with DBT than with digital mammography alone (91.3% vs. 89.7%). Houssami (2014) found that the specificity for digital mammography with and without DBT was similar (97.1% vs. 96.2%). All three studies reported on the PPV of digital mammography with and without DBT. Houssami (2014) reported a PPV of 21% with DBT and 11% without, Lourenco (2015) reported a PPV of 6.2% with DBT and 5.2% without, and Conant (2016) reported a PPV of 6.4% with DBT combined with digital mammography and 4.1% with digital mammography alone.

CHBRP concludes that there is limited and ambiguous evidence on the test performance of digital mammography used with DBT, in comparison to the performance of digital mammography alone.

¹⁷ The study reported by Conant et al. (2016) reflects a large, multisite prospective cohort. The results from one of those sites (Pennsylvania) are reported separately by McDonald et al. (2016) and McCarthy et al. (2014). For the purposes of this review, we have not reported out the site-specific results, and only report results from the Conant et al. (2016) publication.

¹⁸ Sensitivity represents the “true positives,” or the proportion of women with breast cancer who have been correct identified

¹⁹ Specificity represents the “true negatives,” or the proportion of women who do not have breast cancer who have been correctly identified

²⁰ PPV represents the likelihood that a woman with a positive screening mammogram will have breast cancer.

²¹ NPV represents the likelihood that a woman with a negative screening mammogram will not have breast cancer.

Recall and biopsy rates

In most studies, compared to digital mammography alone, digital mammography with DBT was associated with reduced recall rates²² (Conant et al., 2016; Destounis et al., 2014; Durand et al., 2015; Friedewald et al., 2014; Greenberg et al., 2014; Haas et al., 2013; Lourenco et al., 2015; Rose et al., 2013) but was similar to digital mammography alone in a few studies (Houssami et al., 2014; Skaane et al., 2013). In the four large, US-based cohort studies, the recall rates decreased when DBT was added to digital mammography by an absolute difference of 1.6% to 2.6% compared with digital mammography alone. Recall rates ranged for digital mammography with DBT from 6.4% to 13.6%, and with digital mammography alone the recall rates ranged from 9.3% to 16.2%.

Only three studies reported reasons for recall for digital mammography with or without DBT. In all three studies, digital mammography with DBT was more likely to lead to a recall for a mass or microcalcification, and less likely to lead to a recall for asymmetry (Destounis et al., 2014; Durand et al., 2015; Lourenco et al., 2015). Across the three studies, DBT increased recall for masses and for microcalcifications, and decreased recall for asymmetry. Durand (2015) found the odds of recall in the digital mammography group due to an asymmetry finding were 2.7 times higher than the arm including DBT. Destounis (2014) also found that DBT decreased recalls due to overlapping tissue.

In four of the eight studies reporting biopsy rates, the biopsy rate was slightly higher with DBT compared to digital mammography alone (Conant et al., 2016; Greenberg et al., 2014; Lourenco et al., 2015; McCarthy et al., 2014; McDonald et al., 2015). Similarly, in the four of the five large, US-based cohort studies, the biopsy rate was slightly higher (an average of 0.2 percentage points higher), with the exception of Friedewald (2014), which saw a 0.9% decrease in biopsy rates among women receiving digital mammography with DBT. However, whether these changes in biopsy rates are statistically significant or clinically meaningful is unknown.

There is a preponderance of evidence from low- to moderate-quality studies that compared to digital mammography alone, digital mammography performed with DBT reduces recall by an absolute difference of 1.6% to 2.6%, decreasing to 6.4% to 13.6% with the addition of DBT to digital mammography from 9.3% to 16.2% with digital mammography alone to.

Cancer detection

In most of the included studies (11/13), digital mammography plus DBT was associated with an increase in breast cancer detection rates (including both invasive cancer and ductal carcinoma in situ [DCIS]) compared to digital mammography alone. In four of the five large, US-based cohort studies, digital mammography plus DBT resulted in approximately one additional cancer detected per 1,000 women or exams, from approximately 4 cancers per 1,000 exams to 5 cancers per 1,000 exams (Conant et al., 2016; Friedewald et al., 2014; Greenberg et al., 2014; McCarthy et al., 2014; McDonald et al., 2015).

There is a preponderance of evidence from low- to moderate-quality studies that compared to digital mammography alone, digital mammography performed with DBT is associated with an increase in cancer detection of about 1 per 1,000 exams, from approximately 4 cancers per 1,000 exams to 5 cancers per 1,000 exams. However, due to a lack of studies with long-term follow-up, it is unknown whether this

²² Recall rate is generally defined as the proportion of women recommend for further evaluation due to an abnormality identified on the screening mammogram. However, within the included studies, definitions of recall were absent or inconsistent (e.g., whether recall rates include only those recalled for more imaging or also including imaging with other modalities or biopsies).

increase in cancer detection represents earlier diagnosis leading to improved outcomes, earlier diagnosis with similar outcomes to later detection by digital mammography, or overdiagnosis and unnecessary treatment.

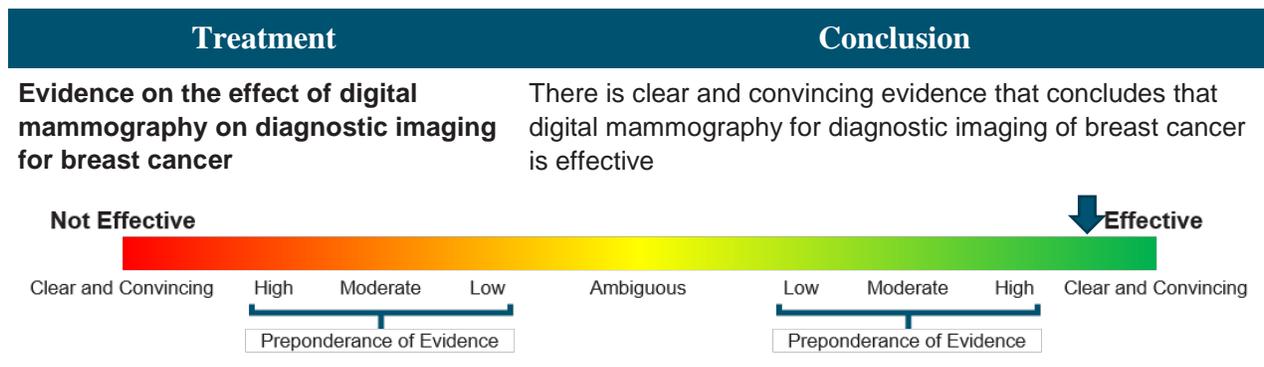
Findings Related to the Effectiveness of Mammography in Diagnostic Imaging for Breast Cancer

As described above, diagnosis of breast cancer is based on a tissue sample obtained by biopsy. Diagnostic imaging is used to further evaluate an abnormality to determine if biopsy is needed.

Effectiveness of Digital Mammography in Diagnostic Imaging for Breast Cancer

Diagnostic mammography is frequently used to evaluate abnormal areas on a screening mammogram or to evaluate a mass felt on clinical examination. Film mammography has been employed for this purpose for many years, and with the transition to widespread use of digital mammography over the past 10 years, this modality has largely replaced film mammography for screening and diagnosis. Initial studies done for FDA approval of digital mammography systems compared digital mammography with film mammography for diagnosis of breast cancer and found that digital mammography had similar diagnostic performance (Pisano and Yaffe, 2005). The large studies showing screening digital mammography to perform as well as film cited above provided additional justification for the use of digital mammography for diagnostic purposes (Kerlikowske et al., 2011; Pisano et al., 2005).

Figure 4. Summary of Findings related to the effect of digital mammography on diagnostic imaging for breast cancer



Effectiveness of Diagnostic Mammogram Plus DBT in Diagnostic Imaging for Breast Cancer, Compared to Diagnostic Mammogram Alone

The medical effectiveness review identified 10 studies that enrolled cohorts of women recalled from breast cancer screening who underwent diagnostic mammography with or without DBT, or whose diagnostic images were read with or without the DBT images (Cornford et al., 2016; Fornvik et al., 2010; Gennaro et al., 2010; Gilbert et al., 2015; Michell et al., 2012; Noroozian et al., 2012; Tagliafico et al., 2012; Teertstra et al., 2010; Waldherr et al., 2013; Zuley et al., 2013). This section will focus primarily on results from Gilbert (2015), which reported on results from a multicenter, large retrospective cohort (over 7,000 cases) in the UK, and results from Zuley and colleagues (2013), which was the only study set in the United States. All other studies were smaller cohorts conducted in Europe.

Test performance characteristics

Seven studies reported on the sensitivity and specificity of diagnostic mammography with and without DBT. Sensitivity of diagnostic digital mammography ranged from 74% to 100% and specificity ranged from 51% to 94%. With the addition of DBT, sensitivity ranged from 70% to 100%, and specificity ranged from 69% to 100%. Five studies reported on the PPV and NPV of diagnostic mammography with and without DBT. For diagnostic digital mammography, the PPV ranged from 42% to 100% and NPV ranged from 82% to 98.9%. With the addition of DBT, PPV ranged from 44% to 100%, and NPV ranged from 86% to 100%.

In Gilbert (2015), the sensitivity of diagnostic digital mammography increased from 87% to 89% with the addition of DBT, but this difference was not statistically significant. Specificity increased from 58% to 69% with the addition of DBT, a statistically significant difference. The addition of DBT to diagnostic digital mammography increased specificity across all age groups, breast densities, and radiologic features (soft-tissue mass, microcalcifications, and distortion or asymmetrical density). Zuley (2013) found that with the addition of DBT to diagnostic digital mammography, the false-positive rate²³ for lesions categorized as BI-RADS 3, 4, or 5 (recommended for follow-up or biopsy) decreased from 85% to 74%, and the false-positive rate for lesions categorized as BI-RADS 4 or 5 (recommended for biopsy) decreased from 57% to 48%.

There is limited evidence that concludes that compared to diagnostic digital mammography alone, digital mammography performed with DBT in a diagnostic setting leads to an increase in test specificity.

Findings Related to the Harms of Digital Mammography With and Without DBT

Harms of Digital Mammography

Screening mammography reduces mortality from breast cancer in women aged 40 to 75 years (Nelson et al., 2016), but is associated with some harms. According to the 2016 USPSTF recommendation, the most important harm related to breast cancer screening (with digital or film mammography) is overdiagnosis, meaning the diagnosis of a cancer that would not have progressed to clinical significance (Siu, 2016). Overdiagnosis exposes women to potential harms (e.g., complications, side effects) associated with treatment. The recommendation also notes the potential for false-positive and false-negative results, which can not only cause some short-term psychological harms, but in the case of false positives can also lead to unnecessary diagnostic procedures (Siu, 2016). A systematic review by Nelson (2016) found a range of overdiagnosis of 11% to 22% in published RCTs and estimated the 10-year cumulative false-positive rate for mammography at 61%. In addition, mammography exposes women to additional radiation over the course of many years, and modeling suggests that this could lead to radiation-induced breast cancers; however, the incidence of these cancers is estimated to be very low relative to breast cancer deaths averted (Miglioretti et al., 2016).

Harms of Digital Mammography with DBT

In addition to the previously described harms associated with digital mammography, the combined use of digital mammography with DBT can increase the radiation exposure. While radiation dose from DBT is slightly higher than that of digital mammography, it is most commonly used in addition to digital

²³ False-positives refer to women who were incorrectly identified as requiring additional imaging or diagnostic testing.

mammography, resulting in over twice the radiation; however, this risk remains very low relative to breast cancer deaths averted (Miglioretti et al., 2016; Svahn et al., 2015).

In 2013, the U.S. Food and Drug Administration (FDA) approved the use of synthetic 2D images to take the place of standard 2D, two-view digital mammography (allowing the 2D images to be reconstructed from the 3D DBT images). While this technology eliminates the additional radiation of a digital mammogram, it is currently not known how frequently synthetic views are used (Gur et al., 2012). A General Electric tomosynthesis system was approved by the FDA in September 2014 (FDA, 2014) and a single 3D view from this system is reported to have a similar radiation dose as a standard two-view digital mammography examination (GE Healthcare, 2014). However, it is not yet clear how broadly this system will be used in practice.

In addition, the use of DBT with mammography increases cancer detection; however, it is unknown whether this increase in cancer detection represents earlier diagnosis leading to improved outcomes, earlier diagnosis with similar outcomes to later detection by digital mammography, or overdiagnosis and unnecessary treatment.

As previously mentioned, the use of digital mammography with DBT leads to a reduction in recall for further imaging, which may lead to a reduction in some of the short-term psychological harms, such as anxiety associated with recall (Lampic et al., 2001).

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

AB 2764 would require that DMHC-regulated health plans and CDI-regulated policies provide coverage for digital mammography and digital breast tomosynthesis (DBT). This section reports the potential incremental impact of AB 2764 on estimated baseline benefit coverage, utilization, and overall cost. The analysis in this section was conducted with a few underlying assumptions.

First, although AB 2764 does not address clinical indications for use of digital mammography and DBT, the CHRBP analysis accounts for utilization and cost when these exams are used for screening and diagnostic applications. CHRBP employs this approach because utilization and costs differ by clinical indication.

Second, and related to the first assumption, CHRBP expects cost sharing to vary by screening versus diagnostic exams. CHRBP assumes that AB 2764 does not prevent health plans from applying cost sharing or deductibles to digital mammography or DBT. However, currently Medicare covers both exams without cost sharing when performed for screening indications (CMS, 2015). In contrast, cost sharing is applied when either exam is performed for diagnostic indications. CHRBP assumes that postmandate, health insurance plans would be consistent with Medicare premandate practices, i.e., that health insurance plans would only apply cost sharing to digital mammography and DBT for diagnostic indications.

Third, based upon survey responses from the health insurance plans, CHRBP estimates that 100% of enrollees have health insurance coverage for digital mammography. Therefore, CHRBP's analysis focuses on impacts related to expanded coverage for DBT.

Fourth, as discussed in the *Medical Effectiveness* analysis, there are no current recommendations for use of DBT without digital mammography. Furthermore, Current Procedural Terminology codes (reported for health insurance reimbursement) are only applied for DBT when combined with mammography (CMS, 2015). Therefore, CHRBP's analysis will address impacts related to the addition of DBT to digital mammography exams, not utilization of DBT alone.

For further details on the underlying data sources and methods, please see Appendix C.

Benefit Coverage

Premandate (Baseline) Benefit Coverage

CHRBP estimates there will be 25,155,000 enrollees with health insurance subject to AB 2764. CHRBP estimates that 100% of enrollees have coverage for digital mammography premandate, and 61% or 15,378,000, enrollees have health insurance coverage for DBT.

Current coverage of digital mammography and DBT was determined by a survey of the seven largest providers of health insurance in California. Responses to this survey represent:

- 74% of enrollees in the privately funded market subject to state mandates, including
- 79% of enrollees in DMHC-regulated plans; and
- 42% of enrollees in CDI-regulated policies

Postmandate Benefit Coverage

Postmandate, 100% of enrollees in DMHC-regulated plans and CDI-regulated policies would have mandate-compliant coverage of digital mammography and DBT (see Table 1).

Postmandate, an estimated 9,777,000 enrollees would gain coverage for DBT.

Utilization

Premandate (Baseline) Utilization

Utilization of digital mammography

Based on the MarketScan® Commercial Claims and Encounters Database, CHBRP estimates that premandate, 2,015,100 covered enrollees would receive mammography services. Of those, CHBRP estimates digital mammography would comprise 93% of exams (the remaining 7% would be film mammography) (See Appendix C for detail). CHBRP estimates that premandate, enrollees would use 2,832,000 screening digital mammography exams and 748,000 diagnostic digital mammography exams.

Utilization of digital breast tomosynthesis as an addition to digital mammography

There is no available data or peer-reviewed literature to quantify baseline utilization of DBT. Based upon content expert input and a survey conducted by the Society for Breast Imaging (Hardesty et al., 2014), CHBRP estimates that premandate, 30% of enrollees would add DBT to screening digital mammography exams, or 862,000 screening DBT exams, and 40% would add DBT to diagnostic digital mammography exams, or 303,000 of diagnostic DBT exams (See Appendix C for detail).

Postmandate Utilization

Utilization of screening digital mammography

As noted above, CHBRP estimates 100% of health insurance plans already cover digital mammography. Furthermore, 97% of mammography facilities in the U.S. currently utilize digital technology (FDA, 2016). CHBRP assumes that postmandate, additional coverage for DBT would encourage film providers to invest in digital technology that performs both digital mammography and DBT. CHBRP estimates that utilization of digital mammography would increase to 97% of all mammography exams (film mammography decreases to 3%) (See Appendix C for detail). CHBRP estimates that postmandate, screening digital mammography utilization would increase 4.16%, or 118,000 exams.

Utilization of digital breast tomosynthesis as an addition to screening mammography

At present there is no data or peer-reviewed literature to inform estimates of DBT utilization postmandate. Content expert input indicates with 100% benefit coverage, the availability of DBT technology will be the primary determinant of postmandate utilization for screening purposes. Based upon reports from the predominant manufacturer of DBT technology, CHBRP estimates premandate, 40% of digital mammography machines have DBT capability (Hologic, Inc., 2016). Given the relatively high cost (average price of \$430,000) of purchasing new mammography equipment with DBT capability (Rubenfire, 2015), CHBRP assumes that postmandate, the adoption rate of new systems would parallel national growth rates that followed expansion of Medicare coverage for DBT: 20 percentage points per year

(Hologic, Inc., 2016). CHBRP therefore anticipates that postmandate, approximately 60% (40% + 20%) of enrollees who utilize digital mammography would also have access to DBT technology.

Content expert input indicates that patient and provider interest in DBT is high. As noted previously, CHBRP assumes that cost sharing will not be applied to DBT when used in conjunction with screening digital mammography. In consideration of current utilization for digital mammography, a widely available technology that is covered by insurance, does not include cost sharing, and carries modest evidence for benefits, CHBRP assumes that most enrollees with access to DBT will use it, such that 93% of those who have access to the technology will receive DBT in conjunction with screening digital mammography (See Appendix C for details.).

CHBRP estimates that within one year postmandate, the percentage of screening digital mammography exams that include DBT would increase from 30% to 55.8%, for a marginal increase in screening DBT by 91%, or 784,000 exams (Table 2) (See Appendix C for details.).

Utilization of diagnostic breast imaging

As noted above, CHBRP estimates no change in coverage or cost-sharing policies for digital mammography. CHBRP assumes the main determinants of postmandate utilization of diagnostic digital mammography would be: (a) as discussed for screening, increasing adoption of digital technology to replace film equipment; and (b) changes as a result of increased utilization of DBT in conjunction with screening mammography (See Appendix C for details.).

Per the literature reviewed in the *Medical Effectiveness* analysis, CHBRP estimates that the addition of screening DBT to screening digital mammography would reduce recall for diagnostic breast imaging by 2 percentage points. Diagnostic breast imaging includes diagnostic digital mammography and breast ultrasound. Using MarketScan® data, CHBRP estimates that premandate, 7.9% of screening mammography exams would be followed by recalls for diagnostic breast imaging.

For the 55.8% of screening exams that include DBT, CHBRP estimates 5.9% would be followed by additional diagnostic imaging postmandate (See Appendix C for details.).

For the remaining 44.2% of screening mammography exams that do not include DBT, CHBRP assumes recall rates will remain unchanged from premandate, at 7.9%.

CHBRP estimates that postmandate, the net impact of shifting from film to digital and reduced recall would result in a net increase of 4.05% or 30,000 in digital diagnostic mammography exams.

CHBRP also estimates that due to reduced recall, diagnostic breast ultrasound would decrease by 0.19% or 1200 exams (Table 2)(See Appendix C for details.).

Utilization of DBT as an addition to diagnostic digital mammography

At present, there are no clinical guidelines, cost-sharing policies, or peer-reviewed literature that would inform postmandate utilization of DBT with diagnostic mammography. CHBRP assumes that clinical applications of diagnostic DBT will be similar to those for diagnostic mammography, namely (a) recall following screening mammography;(b) evaluation of patients with breast symptoms; and (c) monitoring of patients with a previous history of breast cancer.

As with other diagnostic imaging, CHBRP estimates utilization of recall diagnostic DBT for enrollees who do and do not receive screening DBT. Following the screening mammography exams that include DBT,

CHBRP estimates that only 2.5% of recall diagnostic digital mammography would include an additional DBT. DBT comprises the same exam whether utilized for screening or diagnostic purposes (in contrast, diagnostic mammography includes additional views not performed in screening mammography). Therefore, per content expert input, over 97% would not require a repeat of DBT for diagnostic imaging.

For the screening mammography exams that do not include DBT and subsequently require recall imaging, CHBRP assumes that 60% would then receive diagnostic DBT. As discussed above, CHBRP assumes that in one year postmandate, enrollees may not receive screening mammography exams due to lack of access to the technology. CHBRP assumes that among those with recalls for diagnostic imaging, the imperatives to use DBT for a potential abnormality would overcome geographic and convenience barriers (See Appendix C for details.).

For utilization of diagnostic DBT among those who receive diagnostic digital mammography for breast symptoms, or for monitoring for a previous history of breast cancer, CHBRP likewise assumes that utilization would also be conditioned by the availability, i.e., that 60% would receive diagnostic DBT.

When accounting for recall and other indications for diagnostic digital mammography, CHBRP estimates that enrollees' net use of diagnostic DBT would increase by 161,000 exams, or 52.9% (See Appendix C for detail.).

Table 2. Premandate and Postmandate Utilization of Breast Imaging Exams

Exam	Premandate	Postmandate	Net change	%Change
	Total units	Total units		
Screening exams				
Digital mammography	2,832,000	2,950,000	118,000	4.16%
DBT	862,000	1,646,000	784,000	91.0%
Film mammography	215,000	94,000	-121,000	-56.4%
Diagnostic exams				
Digital mammography	748,000	778,000	30,000	4.05%
DBT	303,000	464,000	161,000	52.9%
Breast ultrasound	654,000	652,000	-1,200	-0.19%
Film mammography	51,900	22,200	-29,700	-57.3%

Source: California Health Benefits Review Program, 2016.

Key: DBT = digital breast tomosynthesis

When accounting for both screening and diagnostic applications, CHBRP estimates that net utilization of DBT would increase by 945,000 exams or 81.1 %, in one year postmandate.

Utilization of other diagnostic and treatment services

As noted in the

Medical Effectiveness section, the evidence of the impact of DBT on biopsy rates is inconclusive. Therefore, CHRBP does not estimate a change in utilization of biopsy procedures as a result of increased utilization of DBT.

Screening DBT may increase the rate of cancers (both non-invasive and invasive) detected by approximately 1 for every 1000 screening mammography exams. Utilization of breast cancer treatment services may initially increase due to increased detection from screening or diagnostic DBT. However, as discussed in the

Medical Effectiveness section, there is insufficient evidence to assess whether this increase in cancer detection represents earlier detection that would improve outcomes, earlier detection with similar outcomes as later detection with digital mammography, or new detection and unnecessary treatment. In regards to utilization, it is therefore unknown whether the increased detection by DBT would lead to: (a) earlier detection of disease and lower intensity of treatment services; (b) earlier detection of disease that would have been detected by digital mammography later and the same intensity of treatment services; or (c) new detection of disease and increased treatment services. Therefore, CHRBP concludes there is insufficient information to estimate the net impact of DBT on utilization of cancer treatment services postmandate.

Impact on Access and Health Treatment/Service Availability

AB 2764 would increase access to DBT for enrollees whose access is currently limited due to lack of benefit coverage. As discussed above, CHRBP assumes that postmandate there would be an increase in the service availability, but due to the high cost of technology adoption, DBT would not be available for all enrollees in the first year postmandate. As a result, it is possible that some enrollees who previously utilized DBT may subsequently experience delays in access. But, given the lack of guidelines on DBT in breast cancer management, the clinical significance of such delays is not known.

Per-Unit Cost

Premandate (Baseline) and Postmandate Per-Unit Cost

CHRBP estimates the premandate unit cost of DBT is \$63.49 for screening and \$59.44 for diagnostic postmandate (see Table 1). CHRBP assumes that unit cost for DBT reflects the current rate of increase off a base cost determined by the Medicare Physician Fee Schedule (See Appendix C for detail). CHRBP estimates in one year postmandate, there would be no change in the average per-unit costs for digital mammography, breast tomosynthesis, or other breast imaging procedures (See Appendix C for detail).

Premiums and Expenditures

Premandate (Baseline) Premiums and Expenditures

Table 3 presents per member per month (PMPM) premandate estimates for premiums by market segment for DMHC-regulated plans and CDI-regulated policies.

PMPM by market segment is as follows for DMHC-regulated plans and CDI-regulated policies, respectively:

- Large group: \$553.67 and \$662.37.
- Small group: \$470.64 and \$585.28.
- Individual market: \$423.95 and \$365.22.

Prior to the mandate, enrollees incurred an estimated \$16,248,327,000 in out-of-pocket expenses for all covered benefits (deductibles, copayments, etc.) and payments for specifically for the noncovered benefits of DBT.

Total current annual expenditures for all DMHC-regulated plans and CDI-regulated policies is \$145,093,495,000.

Postmandate Expenditures

Changes in total expenditures

(AB) 2764 would increase total net annual expenditures by \$39,499,000 for enrollees with DMHC-regulated plans and CDI-regulated OPD policies. This reflects the increase in total health insurance premiums paid by employers and enrollees. Premandate, enrollees would incur an estimated \$11,698,000 in expenditures for noncovered use of DBT that would be shifted to health plans and insurers. However, enrollees would incur an additional \$911,000 in co-payments for diagnostic exam benefits.

Postmandate premium expenditures and PMPM amounts per category of payer

Increases in insurance premiums as a result of (AB) 2764 would vary by market segment. Note that the total population in Table 1 reflects the full 25,155,000 million enrollees in DMHC-regulated plans and CDI-regulated policies subject to (AB) 2764.

Overall, across plan type, CHBRP estimates a 0.04% increase in PMPM, which translates into an increase in total premium expenditures by \$50,287,000, or 0.03% (Table 4).

Total premiums for private employers purchasing group health insurance are estimated to increase by \$17,725,000, or 0.03%.

Total premiums for purchases of individual health market insurance are estimated to increase by \$12,244,000, or 0.06%. CHBRP estimates that the percentage increase for those who purchase coverage from Covered California will be 0.05% and for those outside Covered California, 0.06%.

Total employer premium expenditures for CalPERS HMOs are expected to increase by \$1,400,000, or 0.03%.

CHBRP estimates that state expenditures for Medi-Cal Managed Care Plans are estimated to increase by \$12,790,000 or 0.08%.

Average enrollee out-of-pocket expenses would decrease for all insured populations, with the exception of Medi-Cal beneficiaries, who would have no change. The estimated decrease ranges from \$0.19-\$0.20 PMPM for CDI-regulated policies to \$0.01-\$0.06 for DMHC-regulated policies and \$0.03 for CalPERS enrollees. These decreases are due to fewer expenses for DBT that were not covered previously, and the shift of DBT from diagnostic (for which cost sharing is usually applied) to screening procedures (for which CHBRP assumes no cost sharing).

Potential cost offsets or savings in the first 12 months after enactment

CHBRP estimates in the first 12 months after enactment, \$11,698,000 in out-of-pocket costs for payments of noncovered benefits for DBT would be shifted from enrollees to health insurance plans. CHBRP estimates reduced recalls for diagnostic imaging exams would result in savings, but those savings would be exceeded by the costs of overall increased utilization of DBT.

Postmandate administrative expenses and other expenses

CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and/or CDI-regulated policies would remain proportional to the increase in premiums. CHBRP assumes that if health care costs increase as a result of increased utilization or changes in unit costs, there is a corresponding proportional increase in administrative costs. CHBRP assumes that the administrative cost portion of premiums is unchanged. All health plans and insurers include a component for administration and profit in their premiums.

Related Considerations for Policymakers

Cost of exceeding essential health benefits

AB 2764 would not trigger the requirement to cover mandates that exceed EHBs, and the state would not need to defray the costs. Postmandate Changes in Uninsured and Public Program Enrollment

Changes in the number of uninsured persons²⁴

CHBRP estimates premium increases of less than 1% for each market segment; this premium increase would not have a measurable impact on the number of persons who are uninsured. CHBRP does not anticipate loss of health insurance, changes in availability of the benefit beyond those subject to the mandate, changes in offer rates of health insurance, changes in employer contribution rates, changes in take-up of health insurance by employees, or purchase of individual market policies, due to the small size of the increase in premiums after the mandate.

²⁴ See also CHBRP's *Criteria and Methods for Estimating the Impact of Mandates on the Number of Uninsured*, available at http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

Table 3. 2017 Baseline (Premandate) Per Member Per Month Premiums and Total Expenditures by Market Segment, California

	DMHC-Regulated						CDI-Regulated			Total
	Privately Funded Plans (by Market) ^(a)			Publicly Funded Plans			Privately Funded Plans (by Market) ^(a)			
	Large Group	Small Group	Individual	CalPERS HMOs ^(b)	MCMC (Under 65) ^(c)	MCMC (65+) ^(c)	Large Group	Small Group	Individual	
Enrollee counts										
Total enrollees in plans/policies subject to state mandates ^(d)	9,138,000	2,805,000	3,840,000	861,000	6,331,000	561,000	309,000	731,000	579,000	25,155,000
Total enrollees in plans/policies subject to AB 2764	9,138,000	2,805,000	3,840,000	861,000	6,331,000	561,000	309,000	731,000	579,000	25,155,000
Premium costs										
Average portion of premium paid by employer	\$444.39	\$309.74	\$0.00	\$460.33	\$180.00	\$445.00	\$523.71	\$426.22	\$0.00	\$86,263,866,000
Average portion of premium paid by employee	\$109.27	\$160.90	\$423.95	\$115.08	\$0.00	\$0.00	\$138.66	\$159.06	\$365.22	\$42,569,604,000
Total premium	\$553.67	\$470.64	\$423.95	\$575.41	\$180.00	\$445.00	\$662.37	\$585.28	\$365.22	\$128,833,470,000
Enrollee expenses										
Enrollee expenses for covered benefits (deductibles, copays, etc.)	\$44.43	\$93.55	\$112.36	\$31.43	\$0.00	\$0.00	\$111.69	\$177.13	\$108.98	\$16,248,327,000
Enrollee expenses for benefits not covered ^(e)	\$0.01	\$0.04	\$0.06	\$0.03	\$0.02	\$0.06	\$0.20	\$0.20	\$0.10	\$11,698,000
Total expenditures	\$598.11	\$564.22	\$536.37	\$606.88	\$180.02	\$445.06	\$774.25	\$762.60	\$474.39	\$145,093,495,000

Source: California Health Benefits Review Program, 2016.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance, both on Covered California and outside the exchange.

(b) As of September 2015, 57% of CalPERS HMO members were state retirees under age 65, state employees or their dependents. CHBRP assumes the same ratio for 2017.

(c) Medi-Cal Managed Care Plan expenditures for members over 65 include those who also have Medicare coverage. This population does not include enrollees in COHS.

(d) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

(e) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health Care; COHS=County Operated Health Systems; MCMC = Managed Care Medi-Cal

Table 4. 2017 Postmandate Impacts of the Mandate on Per Member Per Month Premiums and Total Expenditures by Market Segment, California

	DMHC-Regulated						CDI-Regulated			Total
	Privately Funded Plans (by Market) ^(a)			Publicly Funded Plans			Privately Funded Plans (by Market) ^(a)			
	Large Group	Small Group	Individual	CalPERS HMOs ^(b)	MCMC (Under 65) ^(c)	MCMC (65+) ^(c)	Large Group	Small Group	Individual	
Enrollee counts										
Total enrollees in plans/policies subject to state mandates ^(d)	9,138,000	2,805,000	3,840,000	861,000	6,331,000	561,000	309,000	731,000	579,000	25,155,000
Total enrollees in plans/policies subject to AB 1831	9,138,000	2,805,000	3,840,000	861,000	6,331,000	561,000	309,000	731,000	579,000	25,155,000
Premium costs										
Average portion of premium paid by employer	\$0.09	\$0.12	\$0.00	\$0.14	\$0.14	\$0.36	\$0.27	\$0.26	\$0.00	\$31,915,000
Average portion of premium paid by employee	\$0.02	\$0.06	\$0.21	\$0.03	\$0.00	\$0.00	\$0.07	\$0.10	\$0.34	\$18,372,000
Total premium	\$0.12	\$0.18	\$0.21	\$0.17	\$0.14	\$0.36	\$0.34	\$0.36	\$0.34	\$50,287,000
Enrollee expenses										
Enrollee expenses for covered benefits (deductibles, copays, etc.)	\$0.00	\$0.00	\$0.01	\$0.00	\$0.00	\$0.00	\$0.01	\$0.02	\$0.02	\$911,000
Enrollee expenses for benefits not covered ^(e)	-\$0.01	-\$0.04	-\$0.06	-\$0.03	-\$0.02	-\$0.06	-\$0.20	-\$0.20	-\$0.19	-\$11,698,000
Total expenditures	\$0.10	\$0.15	\$0.16	\$0.14	\$0.12	\$0.30	\$0.16	\$0.18	\$0.17	\$39,499,000
Postmandate percent change										
Insured premiums	0.021%	0.039%	0.050%	0.029%	0.076%	0.081%	0.052%	0.061%	0.094%	0.039%
Total expenditures	0.017%	0.026%	0.030%	0.023%	0.065%	0.068%	0.020%	0.023%	0.036%	0.027%

Source: California Health Benefits Review Program, 2016.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance, both on Covered California and outside the exchange.

(b) As of September 2015, 57% of CalPERS HMO members were state retirees under age 65, state employees or their dependents. CHBRP assumes the same ratio for 2017.

(c) Medi-Cal Managed Care Plan expenditures for members over 65 include those who also have Medicare coverage. This population does not include enrollees in COHS.

(d) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

(e) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health Care; COHS=County Operated Health Systems; MCMC = Managed Care Medi-Cal

PUBLIC HEALTH IMPACTS

As discussed previously, AB 2764 would require plans and policies to cover both digital mammography and digital breast tomosynthesis (DBT). The public health impact analysis includes estimates on mandate-relevant health outcomes, potential treatment harms, social determinants of health (including potential disparities), financial burden, premature death, and economic loss in the short and long term. This section estimates the short-term impact²⁵ of AB 2764 on health outcomes, social determinants of health and disparities, harms, and financial burden. See the *Long-Term Impact of AB 2764* section for discussion of the impact of AB 2764 on outcomes related to breast cancer detection beyond the first 12 months of the bill implementation.

As presented in the

Medical Effectiveness section, 2D digital mammography takes x-ray images of the breast and stores those images digitally. DBT is performed in conjunction with 2D digital mammography and uses a computer algorithm to reconstruct 3D images of the breast. The medical effectiveness analysis found clear and convincing evidence that digital mammography is medically effective, and leads to reduced breast cancer–related mortality compared with no screening. **Due to a lack of studies evaluating important clinical outcomes (such as breast cancer–related morbidity and mortality) attributable to the addition of DBT to digital mammography, the medical effectiveness review found insufficient evidence to determine the medical effectiveness of DBT.** However, the medical effectiveness review did review studies assessing more proximate outcomes, and found that the addition of DBT to digital mammography leads to a decrease in recall by an absolute difference of 1.6% to 2.6%, decreasing to 6.4% to 13.6% with the addition of DBT to digital mammography from 9.3% to 16.2% with digital mammography alone. and an increase of 1 cancer detected per 1,000 women or exams, from approximately 4 cancers per 1,000 to 5 cancers per 1,000.

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, an estimated 100% of enrollees have premandate coverage for digital and film mammography (both screening and diagnostic), and 61% have coverage for DBT (screening and diagnostic). CHBRP estimates that 2,051,000 enrollees would use mammography services premandate, including over 1.1 million DBT exams.

In the first year postmandate, the CHBRP estimates that 56% of screening digital mammography would be accompanied by DBT, for a postmandate net increase of 784,000 DBT screening exams. In the diagnostic setting, CHBRP estimates that among women receiving screening DBT postmandate (56% of enrollees), only 2.5% would have DBT performed as part of diagnostic mammography, but that 60% of women who are recalled but did not receive screening DBT would receive DBT as part of their diagnostic workup; furthermore, women who receive diagnostic mammography without prior screening (e.g. women with a prior history of breast cancer) would also receive DBT. This would result in an overall postmandate net increase of 161,000 diagnostic DBT exams.

Estimated Public Health Outcomes

Due to 100% premandate coverage for digital mammography, CHBRP estimates no impact on public health outcomes attributable to digital mammography resulting from AB 2764. While the *Benefit Coverage, Utilization, and Cost Impacts* section estimates an increase in utilization of DBT for both

²⁵ CHBRP defines short term impacts as changes occurring within 12 months of bill implementation.

screening and diagnostic purposes, the medical effectiveness review found insufficient evidence to determine the medical effectiveness of DBT on important clinical outcomes. The review did find a decrease in recall and increased cancer detection. Although evidence indicates that the addition of DBT to digital mammography can increase the cancer detection rate by 1 additional cancer detected per 1,000 women or exams, it is unknown whether this increase represents earlier diagnosis leading to improved outcomes, earlier diagnosis with similar outcomes to later detection by digital mammography, or overdiagnosis and unnecessary treatment.

CHBRP projects no impact on health outcomes attributable to digital mammography alone due to existing 100% premandate coverage and finds insufficient evidence of medical effectiveness to suggest that the use of DBT in addition to digital mammography as described in AB 2764 would improve clinically meaningful health outcomes (i.e., breast cancer–related morbidity and mortality). Therefore, the public health impact in the first year, postmandate, is unknown. Please note that the absence of evidence is not “evidence of no effect.” It is possible that an impact — positive or negative — could result, but current evidence is insufficient to inform an estimate.

Social Determinants of Health and Disparities

CHBRP defines social determinants of health (SDoH) as conditions in which people are born, grow, live, work, learn, and age. These social determinants of health (e.g., economic factors, social factors, education, physical environment) are shaped by the distribution of money, power, and resources and impacted by policy (adapted from CDC, 2014; Healthy People 2020, 2015). These factors generally occur prior to or outside of the health care system and are highly correlated with downstream events such as avoidable illnesses and premature death. However, the relationship between SDoH and health status/outcomes is complex and, periodically, health insurance mandates can influence SDoH.²⁶ The aforementioned social determinants of health, in conjunction with other factors (e.g., genetics, sex), may contribute to health disparities²⁷ as measured by race/ethnicity, income, gender, age, and gender identity/sexual orientation.

Research has found disparities in breast cancer outcomes exist by race/ethnicity, age, and socioeconomic status (ACS, 2014; Baquet and Commiskey, 2000; Parise and Caggiano, 2013; Sineshaw et al., 2014; Vona-Davis and Rose, 2009). A 2014 report from the American Cancer Society found that in California, non-Hispanic white women of higher socioeconomic status were more likely to be diagnosed with breast cancer (ACS, 2014), but data from the California Cancer Registry shows that non-Hispanic black women have a higher breast cancer mortality rate (CCR, 2015). A study by Parise and Caggiano (2013) examined 10 years of data from the California Cancer Registry and found that after controlling for socioeconomic status, cancer grade, and type, disparities by race and ethnicity in breast cancer mortality disappear (Parise and Caggiano, 2013). No evidence was found on the impact of DBT on racial/ethnic disparities.

²⁶ For more information about SDoH see CHBRP’s publication: *Incorporating Relevant Social Determinants of Health into CHBRP Benefit Mandate Analyses*, available at:

http://www.chbrp.org/analysis_methodology/docs/Incorporating%20Relevant%20Social%20%20Determinants%20of%20Health%20in%20CHBRP%20Analyses%20Final%2003252016.pdf.

²⁷ Several competing definitions of “health disparities” exist. CHBRP relies on the following definition:

“Health disparities are potentially avoidable differences in health (or health risks that policy can influence) between groups of people who are more or less advantaged socially; these differences systematically place socially disadvantaged groups” at risk for worse health outcomes (Braveman, 2006).

While there are socioeconomic impacts and disparities in breast cancer incidence and mortality, CHBRP finds insufficient evidence that the medical effectiveness of DBT in addition to digital mammography as described in AB 2764 would improve health outcomes. Therefore, the impact of AB 2764 on moderating the effects of SDoH on breast cancer outcomes or on reducing breast cancer disparities is unknown.

Potential Harms from DBT

When data are available, CHBRP estimates the marginal change in relevant harms associated with interventions affected by the proposed mandate. In the case of AB 2764, there is evidence to suggest that an increase in the use of DBT in addition to digital mammography could result in harm. The combined use of digital mammography with DBT may lead to overdiagnosis and can increase the radiation exposure, resulting in over twice the radiation dose and could increase the risk of radiation-induced breast cancer; however, this risk is minimal relative to the number of breast cancer deaths prevented by screening (Miglioretti et al., 2016). As discussed in the *Medical Effectiveness* section, the FDA has recently approved the use of synthetic 2D images to take the place of standard 2D, two-view digital mammography (allowing the 2D images to be reconstructed from the 3D DBT images, which would eliminate the additional radiation exposure; however, it is unknown how frequently synthetic views are currently used in clinical practice in the California

The harms outlined above must also be weighed against the harms of not screening for breast cancer, which may include later stage at diagnosis leading to increased treatment morbidity, and potentially increased risk of breast cancer-related mortality (Plecha et al., 2014).

CHBRP estimates that AB 2764 would increase the utilization of digital mammography combined with DBT in the screening and diagnostic setting (see the *Benefit Coverage, Utilization, and Cost Impacts* section). In the case of AB 2764, there is evidence to suggest that an increase in the use of digital mammography combined with DBT could result in harm. However, these harms are unknown (in the case of overdiagnosis) or very small (in the case of radiation exposure from DBT), and must be weighed against the harms of not screening, which may include later stage at diagnosis leading to increased treatment morbidity.

Financial Burden

When possible, CHBRP estimates the marginal impact of mandates on financial burden, defined as uncovered medical expenses paid by the enrollee as well as out-of-pocket expenses (e.g., deductibles, copayments, and co-insurance). AB 2764 would decrease the financial burden for those enrollees who are newly covered and use DBT under this mandate. CHBRP estimates a net increase of \$911,000 in enrollee out-of-pocket expenses for covered benefits and a decrease of \$11.7 million in enrollee expenses for previously noncovered benefits, resulting in a net reduction in enrollee financial burden associated with the use of DBT. CHBRP estimates are based on claims data and may underestimate the cost savings for enrollees due to carriers' ability to negotiate discounted rates that are unavailable to patients and their families.

CHBRP estimates that AB 2764 would modify coverage and increase the financial burden by \$911,000 in out-of-pocket expenses for covered benefits and decrease \$11.7 million in expenses for previously noncovered benefits in the first year, postmandate, for newly covered enrollees using DBT.

LONG-TERM IMPACT OF AB 2764

In this section, CHBRP estimates the long-term impact²⁸ of AB 2764, defined as impacts occurring beyond the first 12 months of implementation. These estimates are qualitative and based on the existing evidence available in the literature. CHBRP does not provide quantitative estimates of long-term impacts because of unknown improvements in clinical care, changes in prices, implementation of other complementary or conflicting policies, and other unexpected factors.

Long-Term Utilization and Cost Impacts

Utilization and Cost Impacts

In the 12 months following enactment, CHBRP estimates that AB 2764 would result in a 20% increase in utilization of DBT, and the primary constraint of utilization would be the availability of the technology. In the long term, CHBRP anticipates that AB 2764 would facilitate adoption of DBT, such that over 90% of covered enrollees utilizing screening digital mammography would simultaneously utilize DBT. CHBRP also anticipates unit costs of DBT would increase in subsequent years. As the coverage gains from AB 2764 would initially outpace the availability of DBT technology, providers may raise rates in response to increasing demand for services. CHBRP notes that the cost of DBT equipment has increased 8% in the past year (Modern Healthcare/ECRI Institute, 2016) and these costs may be passed on to payers. As noted in the

Medical Effectiveness section, the FDA approved newer software technology that produces synthetic digital mammography images from DBT; software upgrades will carry an additional cost to both existing and new DBT equipment. CHBRP anticipates use of synthetic images from DBT will increase over time. But, given the lack of evidence on effectiveness of synthetic vs. traditional digital mammography images, CHBRP is unable to project to what extent utilization and associated costs will be impacted by adoption of DBT-generated synthetic images.

CHBRP anticipates that with broad utilization of screening DBT, overall utilization of diagnostic imaging will decrease as a result of reductions in recalls. However, as recalls are estimated to occur for 5.9% of screening exams, the cost savings of reductions in recalls will be exceeded by the cost increase due to expanded DBT utilization for screening.

As discussed above, there is insufficient evidence to estimate long-term impacts on utilization and costs of breast cancer treatment services. Recent advances, such as gene expression profiling, are also being used to guide potentially less aggressive treatment for a subset of women with invasive cancers who have earlier stage disease (NCCN 2014c). Therefore, the evidence basis requires greater detail on the impacts on cancer stage, clinical information on biological markers, as well as services used and costs, in order to formulate long-term projections regarding breast cancer treatment. Thus, CHBRP does not conclude whether increased costs associated with utilization of DBT will be offset by reductions in cancer treatment costs. Note that the absence of evidence is not evidence of no effect. It is possible that an impact — positive or negative — could result, but current evidence is insufficient to inform any qualitative long-term estimate of utilization and costs.

²⁸ See also CHBRP's *Criteria and Guidelines for the Analysis of Long-Term Impacts on Healthcare Costs and Public Health*, available at http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

Long-Term Public Health Impacts

Some interventions in proposed mandates provide immediate measurable impacts (e.g., maternity service coverage or acute care treatments) while other interventions may take years to make a measurable impact (e.g., coverage for tobacco cessation or vaccinations). When possible, CHBRP estimates the long-term effects of a proposed mandate (beyond CHBRP's 12-month analytic timeframe) to capture possible impacts to the public's health that would be attributable to the mandate, including impacts on premature death and economic loss.

In the case of AB 2764, CHBRP estimates change in utilization due to AB 2764. However, as discussed in the

Medical Effectiveness and *Public Health Impacts* sections, CHBRP finds insufficient evidence of the medical effectiveness to suggest that the use of DBT in addition to digital mammography would improve health outcomes. There is also evidence to suggest that the use of DBT is associated with some harm, including increased radiation exposure. Therefore, the long-term public health impacts are unknown. Please note that the absence of evidence is not "evidence of no effect." It is possible that an impact — positive or negative — could result, but current evidence is insufficient to inform an estimate.

Potential Harms from DBT

As discussed in the *Public Health Impacts* section, there is evidence to suggest that an increase in the use of DBT in addition to digital mammography could result in harm. The combined use of digital mammography with DBT may lead to overdiagnosis and can increase the radiation exposure, resulting in over twice the radiation dose and could increase the risk of radiation-induced breast cancer; however, this risk is minimal relative to the number of breast cancer deaths prevented by screening (Miglioretti et al., 2016). As discussed in the *Medical Effectiveness* section, the FDA has recently approved the use of synthetic 2D images to take the place of standard 2D, two-view digital mammography (allowing the 2D images to be reconstructed from the 3D DBT images, which would eliminate the additional radiation exposure; however, the uptake rate of these synthetic views in clinical practice in California is unknown.

The harms outlined above must also be weighed against the harms of not screening for breast cancer, which may include later stage at diagnosis leading to increased treatment morbidity, and potentially increased risk of breast cancer-related mortality (Plecha et al., 2014).

CHBRP estimates that AB 2764 would increase the utilization of digital mammography combined with DBT in the screening and diagnostic setting (see the *Benefit Coverage, Utilization, and Cost Impacts* section). In the case of AB 2764, there is evidence to suggest that an increase in the use of digital mammography combined with DBT could result in harm. However, these harms are unknown (in the case of overdiagnosis) or very small (in the case of radiation exposure from DBT), and must be weighed against the harms of not screening, which may include later stage at diagnosis leading to increased treatment morbidity.

APPENDIX A TEXT OF BILL ANALYZED

On March 17, 2016, the California Assembly Committee on Health requested that CHBRP analyze (AB) 2764.

ASSEMBLY BILL

No. 2764

Introduced by Assembly Members Williams and Member Bonilla

February 19, 2016

An act to amend Section ~~11345 of the Business and Professions Code, relating to real estate appraisers~~; *1367.65 of the Health and Safety Code, and to amend Section 10123.81 of the Insurance Code, relating to health care coverage.*

LEGISLATIVE COUNSEL'S DIGEST

AB 2764, as amended, ~~Williams-Bonilla. Appraisal management companies: registration~~. *Health care coverage: mammography.*

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 its provisions a crime. Existing law provides for the licensure and regulation of health insurers by the Department of Insurance. Existing law requires health care service plan contracts, except specialized health care service plan contracts, and certain health insurance policies to provide coverage for mammography for screening and diagnostic purposes.

This bill would require the mammography coverage to include, but not be limited to, digital mammography and breast tomosynthesis. Because a willful violation of the bill's requirements relative to health care service plans would be a crime, the bill 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.

~~Existing law, the Real Estate Appraisers' Licensing and Certification Law, provides for the licensure and regulation of real estate appraisers and vests the duty of enforcing and administering that law in the Bureau of Real Estate Appraisers within the Department of Consumer Affairs. Existing law requires an appraisal management company, as defined, to~~

~~register with the bureau. Existing law requires the Chief of the Bureau of Real Estate Appraisers to adopt regulations governing the process and procedure of registration that require, at minimum, among other things, the business address and telephone number of the person or entity seeking registration.~~

~~This bill would additionally require that those regulations include the email address of the person or entity seeking registration.~~

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: ~~no~~-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) ~~On or after January 1, 2000, each~~ *Each* 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, *including, but not limited to, digital mammography and breast tomosynthesis*, 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.

(b) This section does not 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. This section does not authorize a plan enrollee to receive the services required to be covered by this section if those services are furnished by a nonparticipating provider, unless the plan enrollee is referred to that provider by a participating physician, nurse practitioner, or certified nurse-midwife providing care.

SEC. 2. Section 10123.81 of the Insurance Code is amended to read:

10123.81. (a) Every individual or group policy of disability insurance or self-insured employee welfare benefit plan shall ~~be deemed to~~ provide coverage for mammography, *including, but not limited to, digital mammography and breast tomosynthesis*, for

screening or diagnostic purposes upon the referral of 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.

(b) ~~Nothing in this~~ *This section shall be construed to does not* prevent the application of copayment or deductible provisions in a policy, nor shall this section be construed to require that a policy be extended to cover any other procedures under an individual or a group policy. ~~Nothing in this~~ *This section shall be construed to does not* authorize a policyholder to receive the services required to be covered by this section if those services are furnished by a nonparticipating provider, unless the policyholder is referred to that provider by a participating physician, nurse practitioner, or certified nurse-midwife providing care.

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

SEC. 3. 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.

~~SECTION 1. Section 11345 of the Business and Professions Code is amended to read:~~

~~11345. The director shall adopt regulations governing the process and procedure of applying for registration as an appraisal management company. Applications for a certificate of registration shall require, at a minimum, all of the following:~~

~~(a) The name of the person or entity seeking registration.~~

~~(b) The business address, email address, and telephone number of the person or entity seeking registration.~~

~~(c) If the applicant is not a person or entity domiciled in this state, the name and contact number of a person or entity acting as agent for service of process in this state, along with an irrevocable consent to service of process in favor of the office.~~

~~(d) The name, address, and contact information for each controlling person employed by the applicant who has operational authority to direct the management of, and establish policies for, the applicant. If the applicant employs more than 10 individuals meeting the criteria of this subdivision, the applicant may list the names, addresses, and contact information for the 10 individuals meeting the criteria who hold the greatest level of management responsibility within its organization~~

APPENDIX B LITERATURE REVIEW METHODS

Appendix B describes methods used in the medical effectiveness literature review for AB 2764. AB 2764 would require plans and policies to cover both digital mammography and digital breast tomosynthesis (DBT). The medical effectiveness review summarizes findings from the literature on the effectiveness of digital mammography alone compared to digital mammography with the addition to DBT in both screening and diagnostic settings using individual studies published after 2010.

Studies of digital mammography and DBT effectiveness were identified through searches of relevant databases of peer-reviewed literature listed below. For medical efficacy of breast cancer screening with digital mammography combined with DBT, CHBRP primarily relied on a systematic review published in 2016 (Melnikow et al., 2016), and identified additional studies published since that review. This approach is consistent with the approach CHBRP has taken in its analysis of previous topics with many different mandated benefits. Of the 481 articles identified in the literature search, 127 were reviewed as potentially relevant for inclusion in this report

While the effectiveness of digital mammography on breast cancer–related morbidity and mortality has been widely studied, CHBRP identified no studies evaluating the impact of digital mammography with DBT on these important clinical outcomes. Therefore, in most studies reviewed, test performance is the primary outcome measured to evaluate the effectiveness of DBT. In addition, any data on the risks of digital mammography and DBT are reported.

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. Further information about the criteria CHBRP uses to evaluate evidence of medical effectiveness can be found in *CHBRP’s Medical Effectiveness Analysis Research Approach*.²⁹ To grade the evidence for each outcome measured, the team uses a grading system with 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

²⁹ Available at: www.chbrp.org/analysis_methodology/docs/medeffect_methods_detail.pdf.

- Insufficient evidence.

A grade of *clear and convincing evidence* indicates that there are multiple studies of a treatment and that the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective.

A grade of *preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective. This can be further subdivided into preponderance of evidence from high-quality studies and preponderance of evidence from low-quality studies.

A grade of *ambiguous/conflicting evidence* indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

A grade of *insufficient evidence* indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

Literature Search Methods

The literature search was limited to studies published in English, females only, all age groups, all locales/countries, and all types of research design. Timeframes were as follows:
Screening studies: from September 2015 – present; Diagnostic studies: from January 2010 – present;
Cost studies: from January 2010 – present. All searches were restricted to English-language publications.

The following databases of peer-reviewed literature were searched: PubMed, Business Source Complete (EBSCO Host platform), EconLit (ProQuest platform), the Web of Science, and the Cochrane Library (which includes the Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effect, the Cochrane Register of Controlled Clinical Trials, Cochrane Methodology Register, Health Technology Assessment Database, NHS Economic Evaluation Database). See the end of the list for the “grey” literature sources searched.

Literature Search Terms

PubMed

Medical Subject Headings (MeSH)

NOTE: Terms designated as “[Majr]” are treated as major focuses of the retrieved articles. “NoExp” = does not include more specific terms indexed under the specific heading. [sh] = floating MeSH subheading

- "Asymptomatic Diseases"[Mesh]
- "Biopsy"[Mesh]
- "Breast Diseases"[Mesh]
- "Breast Diseases/ultrasonography"[Majr]
- "Breast Diseases/ultrasonography"[Mesh]
- "Breast Neoplasms/drug therapy"[Mesh]
- "Breast Neoplasms/pathology"[Mesh]
- "Breast Neoplasms/radiotherapy"[Mesh]
- "Breast Neoplasms/surgery"[Mesh]
- "Breast"[Mesh]
- "Breast/ultrasonography"[Majr]
- "Breast/ultrasonography"[Mesh]
- "Costs and Cost Analysis"[Mesh]
- "diagnosis"[sh]
- "Early Detection of Cancer"[Mesh]
- "False Positive Reactions"[Mesh]

- "Health Services Needs and Demand"[Mesh]
- "Insurance"[Mesh]
- "Mammography"[Majr:NoExp]
- "Mammography/economics"[Majr]
- "Mammography/utilization"[Mesh]
- "Mastectomy"[Mesh]
- "mortality" [sh]
- "Mortality"[Mesh]
- "Neoplasm Staging"[Mesh]
- "Predictive Value of Tests"[Mesh]
- "Tomography, X-Ray Computed/utilization"[Mesh]
- "Utilization Review"[Mesh]
- "utilization" [sh]

Keywords and Keyword Phrases

NOTE: "[ti]" = Article title field only. "[tiab]" = Article title and abstract fields only. Multiple word terms in double quotation marks are searched as exact phrases. "*" = wildcard character. Words connected with hyphens are searched as exact phrases

- "axillary dissection"
- "base-case analysis"
- "breast tomosynthesis"
- "breast tomosynthesis"[ti]
- "cancer stage"
- "cancer staging"
- "cost-effectiveness"
- "cost-utility"
- "cost offset"
- "cost savings"
- "cost sharing"
- "dbt usage"
- "dbt use"
- "dbt utilization"
- "death rate"
- demand[tiab]
- "digital breast tomosynthesis usage"
- "digital breast tomosynthesis use"
- "digital mammography"
- "digital mammography"[ti]
- "early detection"
- "expanded coverage"
- "false positive"
- "genomic test"
- "genomic testing"
- "genomic tests"
- "health care utilization"
- "health plan"[tiab]
- "health plans"[tiab]
- "hormonal therapy"
- "incremental cost"
- insured[tiab]
- "mortality rate"
- "neoplasm staging"
- "positive predictive value"
- "positive predictive value"[ti]
- "positive recall"
- "positive result"
- "positive result"[ti]
- "positive results"
- "positive results"[ti]
- positive[ti]
- "price elasticity"
- price
- "recall rate"
- "savings per member"
- "supply"[tiab]
- "symptomatic"
- "tnm staging"
- tomosynthesis
- "total mortality"
- "tumor staging"
- "unit cost"
- "use of dbt"
- "use of digital breast tomosynthesis"
- "value analysis"
- 3d-mammography
- asymptomatic
- biopsies[tiab]
- biopsy[tiab]
- breast
- breast*[tiab]
- cancer[ti]
- cancer[tiab]
- chemotherapy
- co-insurance
- coinsurance
- cost
- costs
- coverage[tiab]
- dbt
- dbt utilisation
- death[ti]
- death[tiab]
- demand[ti]
- demand[tiab]
- detection[ti]
- detection[ti]

- detection[tiab]
- diagnostic[tiab]
- digital breast tomosynthesis utilisation
- digital mammography
- economic[tiab]
- existing
- existing[ti]
- insurance[tiab]
- insured[tiab]
- lumpectomy
- mammograms*[tiab]
- mammography
- mammography[tiab]
- mastectomies[tiab]
- mastectomy[tiab]
- mortality[ti]
- mortality[tiab]
- recalls[tiab]
- reimbursed
- reimbursement
- savings[tiab]
- screening[tiab]
- supply[ti]
- supply[tiab]
- symptomatic
- symptomatic[ti]
- tomosynthesis
- tomosynthesis[ti]
- ultrasonography[ti]
- ultrasonography[tiab]
- ultrasound[ti]
- ultrasound[tiab]
- usage[ti]
- use[ti]
- utilization[ti]

Business Source Complete

Keyword

NOTE: "*" = wildcard character. Words connected with hyphens are searched as exact phrases. Multiple word terms in double quotation marks are searched as exact phrases. <word> N3 <word> = Terms occur within 3 words of each other.

- "base-case analysis"
- "cost-effective*"
- "cost-utility"
- "cost offset"
- "cost savings"
- "digital mammography"
- "price elasticity"
- "savings per member"
- "unit cost"
- "value analysis"
- 3D-mammography
- breast N3 tomosynthesis
- cost*
- demand
- economic*
- price*
- savings
- usage
- utilisation
- utilization

EconLit

NOTE: Multiple word terms in double quotation marks are searched as exact phrases.

- "digital mammography" - 1 result
- tomosynthesis - 0 results

Web of Science

NOTE: "*" = wildcard character. Words connected with hyphens are searched as exact phrases. Multiple word terms in double quotation marks are searched as exact phrases. <word> NEAR/3 <word> = Terms occur within 3 words of each other.

Terms searched as "TITLE"

- "breast cancer detection"
- "digital mammography"
- "False Positive*"
- "positive recall"
- "positive result"
- "positive results"
- "positive"
- "Recall rate"
- "symptomatic"
- biopsies
- biopsy
- cancer* NEAR/3 detect*
- cancer* NEAR/3 detection
- cost*
- death
- demand
- diagnos*

- economic*
- mammogram*
- mammography
- mortality
- price*
- radiation
- radiotherapy
- recall
- recalls
- savings
- screening
- tumor* NEAR/3 detect*
- tumor* NEAR/3 detection
- usage
- utilisation
- utilization

Terms searched as "TOPIC"

- "axillary dissection"
- "base-case analysis"
- "breast cancer detection"
- "cancer stage"
- "cancer staging"
- "cost-effective*"
- "cost-utility"
- "cost offset"
- "cost savings"
- "cost sharing"
- "death rate"
- "digital mammography"
- "genomic test*"
- "genomic testing"
- "health plan*"
- "hormonal therapy"
- "mortality rate"
- "neoplasm staging"
- "positive predictive value*"
- "positive recall"
- "positive result"
- "positive results"
- "positive"
- "price elasticity"
- "Recall rate"
- "savings per member"
- "symptomatic"
- "TNM Staging"
- "total mortality"
- "Tumor Staging"
- "unit cost"
- "value analysis"

- 3D-mammography
- asymptomatic
- breast AND tomosynthesis
- breast NEAR/3 tomosynthesis
- chemotherapy
- co-insurance
- coinsurance
- cost*
- death
- diagnos*
- economic*
- expanded NEAR/3 coverage
- insurance
- lumpectom*
- mastectom*
- mortality
- overdiagnos*
- prevention
- price*
- reimbursed
- reimbursement
- savings
- screen
- screening
- surgery
- symptomatic
- tomosynthesis
- tomosynthesis AND mammogra*
- ultrasonic*
- ultrasound
- utilisation
- utilizatio

Cochrane Library

Keywords (searched in title, abstract, and keywords)

- "breast tomosynthesis"
- "cost sharing"
- "digital mammography"
- "expanded coverage"
- "health plan"
- "health plans"
- 3D-mammography
- breast
- co-insurance
- coinsurance
- cost*
- death
- digital mammogram*
- digital mammography
- economic*
- insurance
- mammogra*
- mortality
- price*
- recall
- reimbursed
- reimbursement
- stage
- staging
- tomosynthesis
- utilisation
- utilization

Keywords (all fields)

- "base-case analysis"
- "cancer stage"
- "cancer staging"
- "cost-effective*"
- "cost-utility"
- "cost offset"
- "cost savings"
- "cost sharing"
- "expanded coverage"
- "health plan"
- "health plans"
- "neoplasm staging"
- "positive recall"
- "positive result"
- "positive results"
- "price elasticity"
- "recall rate"
- "savings per member"
- "tnm staging"
- "tumor staging"
- "unit cost"
- "value analysis"
- breast
- co-insurance
- coinsurance
- diagnos*
- diagnostic
- insurance
- mammogra*
- positive predictive value*
- prevention
- prevention
- reimbursed
- reimbursement
- screen
- screening
- symptomatic
- tomosynthesis
- usage*
- utilisation
- utilization

“Grey” Literature:

- Agency for Healthcare Research and Quality (AHRQ): <http://www.ahrq.gov/>
- Institute for Clinical Systems Improvement (ICSI): <http://www.icsi.org/>
- International Network of Agencies for Health Technology Assessment (INAHTA): <http://www.inahta.org/>
- National Guideline Clearinghouse (NGC): <http://www.guideline.gov>
- National Institute for Clinical Excellence (NICE): <http://www.nice.org.uk/>
- National Institutes of Health (NIH): <http://www.nih.gov/>
- NHS Centre for Reviews and Dissemination: <http://www.york.ac.uk/inst/crd/>

- PDQ (Physician Data Query: NCI's Comprehensive Cancer Database): <http://www.cancer.gov/publications/pdq>
- Scottish Intercollegiate Guideline Network (SIGN): <http://www.sign.ac.uk/>

Search Term: breast tomosynthesis

APPENDIX C COST IMPACT ANALYSIS: DATA SOURCES, CAVEATS, AND ASSUMPTIONS

This appendix describes data sources, estimation methodology, 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 website at: www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

The cost analysis in this report was prepared by the members of the cost team, which consists of CHBRP task force members and contributors from the University of California, Los Angeles, and the University of California, Davis, as well as contracted actuarial firms, Milliman, Inc, and Pricewaterhouse Coopers (PwC).³⁰

Data Sources

This subsection discusses the variety of data sources CHBRP uses. Key sources and data items are listed below, in

Table 5.

Table 5. Data for 2017 Projections

Data Source	Items
California Department of Health Care Services (DHCS) administrative data for the Medi-Cal program, data available as of end of December 2014	Distribution of enrollees by managed care or FFS distribution by age: 0–17; 18–64; 65+ Medi-Cal Managed Care premiums
California Department of Managed Health Care (DMHC) data from the interactive website “Health Plan Financial Summary Report,” August–October, 2015	Distribution of DMHC-regulated plans by market segment*
California Department of Insurance (CDI) Statistical Analysis Division data; data as of December 31, 2015	Distribution of CDI-regulated policies by market segment

³⁰ CHBRP’s authorizing statute, available at www.chbrp.org/docs/authorizing_statute.pdf, requires that CHBRP use a certified actuary or “other person with relevant knowledge and expertise” to determine financial impact.

Data Source	Items
California Health Benefits Review Program (CHBRP) Annual Enrollment and Premium Survey of California’s largest (by enrollment) health care service plans and health insurers; data as of September 30, 2015; responders’ data represent approximately 97% of persons not associated with CalPERS or Medi-Cal with health insurance subject to state mandates (full-service (nonspecialty) DMHC-regulated plan enrollees and of full-service (nonspecialty) CDI-regulated policy enrollees).	Enrollment by: <ul style="list-style-type: none"> • Size of firm (2–50 as small group and 51+ as large group) • DMHC vs. CDI regulated • Grandfathered vs. nongrandfathered Premiums for individual policies by: <ul style="list-style-type: none"> • DMHC vs. CDI regulated • Grandfathered vs. nongrandfathered
California Employer Health Benefits Survey, 2014 (conducted by NORC and funded by CHCF)	Enrollment by HMO/POS, PPO/indemnity self-insured, fully insured, Premiums (not self-insured) by: <ul style="list-style-type: none"> • Size of firm (3–25 as small group and 25+ as large group) • Family vs. single • HMO/POS vs. PPO/indemnity vs. HDHP employer vs. employer premium share
California Health Interview Survey (CHIS)	Uninsured, age: 65+ Medi-Cal (non-Medicare), age: 65+ Other public, age: 65+ Employer-sponsored insurance, age: 65+
California Public Employees’ Retirement System (CalPERS) data, enrollment as of October 1, 2015	CalPERS HMO and PPO enrollment <ul style="list-style-type: none"> • Age: 0–17; 18–64; 65+ • HMO premiums
California Simulation of Insurance Markets (CalSIM) (projections for 2017)	Uninsured, age: 0–17; 18–64 Medi-Cal (non-Medicare) (a), age: 0–17; 18–64 Other public (b), age: 0–64 Individual market, age: 0–17; 18–64 Small group, age: 0–17; 18–64 Large group, age: 0–17; 18–64
Centers for Medicare and Medicaid (CMS) administrative data for the Medicare program, annually (if available) as of end of September	HMO vs. FFS distribution for those 65+ (noninstitutionalized)
Milliman estimate	Medical trend influencing annual premium increases

Notes: (*) CHBRP assumes DMHC-regulated PPO group enrollees and POS enrollees are in the large-group segment.

Key: CDI=California Department of Insurance; CHCF=California HealthCare Foundation; CHIS=California Health Interview Survey; CMS=Centers for Medicare & Medicaid Services; DHCS=Department of Health Care Services; DMHC=Department of Managed Health Care; FFS=fee-for-service; HMO=health maintenance organization; NORC=National Opinion Research Center; POS=point of service; PPO=preferred provider organization.

Further discussion of external and internal data follows.

Internal data

- CHBRP's Annual Enrollment and Premium Survey collects data from the six largest providers of health insurance in California (including Aetna, Anthem Blue Cross of California, Blue Shield of California, CIGNA, Health Net, and Kaiser Foundation Health Plan) to obtain estimates of enrollment not associated with CalPERS or Medi-Cal by purchaser (i.e., large and small group and individual), state regulator (DMHC or CDI), grandfathered and nongrandfathered status, and average premiums. CalSIM and market trends were applied to project 2017 health insurance enrollment in DMHC-regulated plans and CDI-regulated policies.
- CHBRP's other surveys of the largest plans/insurers collect information on benefit coverage relevant to proposed benefit mandates CHBRP has been asked to analyze. In each report, CHBRP indicates the proportion of enrollees — statewide and by market segment — represented by responses to CHBRP's bill-specific coverage surveys. The proportions are derived from data provided by CDI and DMHC.

External sources

- California Department of Health Care Services (DHCS) data are used to estimate enrollment in Medi-Cal Managed Care (beneficiaries enrolled in Two-Plan Model, Geographic Managed Care, and County Operated Health System plans), which may be subject to state benefit mandates, as well as enrollment in Medi-Cal Fee For Service (FFS), which is not. The data are available at: www.dhcs.ca.gov/dataandstats/statistics/Pages/Monthly_Trend_Report.aspx.
- California Employer Health Benefits Survey data are used to make a number of estimates, including: premiums for employment-based enrollment in DMHC-regulated health care service plans (primarily health maintenance organizations [HMOs] and point of service [POS] plans) and premiums for employment-based enrollment in CDI-regulated health insurance policies regulated by the (primarily preferred provider organizations [PPOs]). Premiums for fee-for-service (FFS) policies are no longer available due to scarcity of these policies in California. 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. More information on the CHCF/NORC data is available at: www.chcf.org/publications/2014/01/employer-health-benefits.
- California Health Interview Survey (CHIS) data are used to estimate the number of Californians aged 65 and older, and the number of Californians dually eligible for both Medi-Cal and Medicare coverage. CHIS data are also used to determine the number of Californians with incomes below 400% of the federal poverty level. CHIS is a continuous survey that provides detailed information on demographics, health insurance coverage, health status, and access to care. More information on CHIS is available at: www.chis.ucla.edu.
- California Public Employees Retirement System (CalPERS) data are used to estimate premiums and enrollment in DMHC-regulated plans, which may be subject to state benefit mandates, as well as enrollment in CalPERS' self-insured plans, which is not. CalPERS does not currently offer enrollment in CDI-regulated policies. Data are provided for DMHC-regulated plans enrolling non-Medicare beneficiaries. In addition, CHBRP obtains information on current scope of benefits from evidence of coverage (EOC) documents publicly available at: www.calpers.ca.gov. California Simulation of Insurance Markets (CalSIM) estimates are used to project health insurance status of Californians aged 64 and under. CalSIM is a microsimulation model that projects the effects of

the Affordable Care Act on firms and individuals. More information on CalSIM is available at: <http://healthpolicy.ucla.edu/programs/health-economics/projects/CalSIM/Pages/default.aspx>.

- To estimate the premium impact of certain mandates, PwC's projections may derive from its proprietary comprehensive pricing model, which provides benchmark data and pricing capabilities for commercial health plans. The pricing model factors in health plan features such as deductibles, copays, out-of-pocket maximums, covered services, and degree of healthcare management. The pricing model uses normative data and benefit details to arrive at estimates of allowed and net benefit costs. The normative benchmarking utilization metrics within the pricing model are developed from a database of commercial (under 65) health plan experience representing approximately 20 million annual lives.
- The MarketScan databases, which reflect the health care claims experience of employees and dependents covered by the health benefit programs of large employers, are used to estimate utilization and unit cost. These claims data are collected from insurance companies, Blue Cross Blue Shield plans, and third party administrators. These data represent the medical experience of insured employees and their dependents for active employees, early retirees, individuals with COBRA continuation coverage, and Medicare-eligible retirees with employer-provided Medicare Supplemental plans. No Medicaid or Workers Compensation data are included.
- Ingenix MDR Charge Payment System, which includes information about professional fees paid for health care services, based upon claims from commercial insurance companies, HMOs, and self-insured health plans.

Projecting 2017

This subsection discusses adjustments made to CHBRP's Cost and Coverage Model to project 2017, the period when mandates proposed in 2016 would, if enacted, generally take effect. It is important to emphasize that CHBRP's analysis of specific mandate bills typically addresses the incremental effects of a mandate — specifically, how the proposed mandate would impact benefit coverage, utilization, costs, and public health, *holding all other factors constant*. CHBRP's estimates of these incremental effects are presented in the *Benefit Coverage, Utilization, and Cost Impacts* section of this report.

Baseline premium rate development methodology

The key components of the baseline model for utilization and expenditures are estimates of the per member per month (PMPM) values for each of the following:

- Insurance premiums PMPM;
- Gross claims costs PMPM;
- Member cost sharing PMPM; and
- Health care costs paid by the health plan or insurer.

For each market segment, we first obtained an estimate of the insurance premium PMPM by taking the 2015 reported premium from the abovementioned data sources and trending that value to 2017. CHBRP uses trend rates published in the Milliman HCGs to estimate the health care costs for each market segment in 2017.

The large-group market segments for each regulator (CDI and DMHC) are split into grandfathered and nongrandfathered status. For the small-group and individual markets, further splits are made to indicate

association with Covered California, the state's health insurance marketplace. Doing so allows CHBRP to separately calculate the impact of ACA and of specific mandates, both of which may apply differently among these subgroups. The premium rate data received from the CHCF/NORC California Employer Health Benefits survey did not split the premiums based on grandfathered or exchange status. However, CHBRP's Annual Enrollment and Premium (AEP) survey asked California's largest health care service plans and health insurers to provide their average premium rates separately for grandfathered and nongrandfathered plans. The ratios from the CHBRP survey data were then applied to the CHCF/NORC aggregate premium rates for large and small group, to estimate premium rates for grandfathered and nongrandfathered plans that were consistent with the NORC results. For the individual market, the premium rates received from CHBRP's AEP survey were used directly.

The remaining three values were then estimated by the following formulas:

- Health care costs paid by the health plan = insurance premiums PMPM \times (1 – profit/administration load);
- Gross claims costs PMPM = health care costs paid by the health plan \div percentage paid by health plan; and
- Member cost sharing PMPM = gross claims costs \times (1 – percentage paid by health plan).

In the above formulas, the quantity “profit/administration load” is the assumed percentage of a typical premium that is allocated to the health plan/insurer's administration and profit. These values vary by insurance category, and under the ACA, are limited by the minimum medical loss ratio requirement. CHBRP estimated these values based on actuarial expertise at Milliman, and their associated expertise in health care.

In the above formulas, the quantity “percentage paid by health plan” is the assumed percentage of gross health care costs that are paid by the health plan, as opposed to the amount paid by member cost sharing (deductibles, copays, etc.). In ACA terminology, this quantity is known as the plan's “actuarial value.” These values vary by insurance category. For each insurance category, Milliman estimated the member cost sharing for the average or typical plan in that category. Milliman then priced these plans using the Milliman Health Cost Guidelines to estimate the percentage of gross health care costs that are paid by the carrier.

General Caveats and Assumptions

This subsection discusses the general caveats and assumptions relevant to all CHBRP reports. The projected costs are estimates of 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 the premium paid by the subscriber (or employee) and the employer will be unaffected by the mandate.
- For state-sponsored programs for the uninsured, the state share will continue to be equal to the absolute dollar amount of funds dedicated to the program.
- When cost savings are estimated, they reflect savings realized for 1 year. Potential long-term cost savings or impacts are estimated if existing data and literature sources are available and provide adequate detail for estimating long-term impacts. For more information on CHBRP's criteria for estimating long-term impacts, please see: www.chbrp.org/analysis_methodology/docs/longterm_impacts08.pdf.

There are other variables that may affect costs, but which CHBRP did not consider in the estimates 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 benefits: To help offset the premium increase resulting from a mandate, deductibles or copayments may be increased. Such changes would have a direct impact on the distribution of costs between health plans/insurers and enrollees, and may also result in utilization reductions (i.e., high levels of 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, persons or employer groups who had previously foregone health insurance may elect, postmandate, to enroll in a health plan or policy because they perceive that it is now to their economic benefit to do so.
- Medical management: Health plans/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/policy types that previously had the least effective medical management (i.e., PPO plans).
- Geographic and delivery systems variation: Variation exists in existing utilization and costs, and in the impact of the mandate, by geographic area and by delivery system models. Even within the health insurance plan/policy types CHBRP modeled (HMO, including HMO and POS plans, and non-HMO, including PPO and FFS policies), there are likely variations in utilization and costs. 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/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 impacts, CHBRP typically assumes that plans and policies subject to the mandate will be in compliance with the benefit coverage requirements of the bill. Therefore, the typical postmandate coverage rates for persons enrolled in health insurance plans/policies subject to the mandate are assumed to be 100%.

Analysis Specific Caveats and Assumptions

This subsection discusses the caveats and assumptions relevant to specifically to an analysis of (AB) 2764

The following is a brief description of methodology and assumptions used to develop the estimates of cost impacts:

- *Premandate coverage.* CHBRP derived estimates of premandate coverage based upon survey responses from health insurance plans. Total enrollee coverage is then calculated based upon the proportion of each market segment represented by the respondents.
- *Postmandate coverage.* CHBRP assumes that postmandate, all enrollees will have coverage for DBT, and that health insurers/plans will not apply cost sharing for DBT when it is performed in conjunction with a screening mammogram. CHBRP notes that AB 2764 does not prevent health plans from applying cost sharing or deductibles to DBT utilization. Also, because DBT is not included USPSTF A/B guidelines, health plans are not prohibited from applying cost sharing to DBT when performed in conjunction with screening mammography. However, at baseline, the plans that do provide coverage, as well as Medicare, are not applying cost sharing for screening DBT. CHBRP anticipates that postmandate, health plans will adopt premandate cost-sharing policies for DBT in the interest of maintaining consistency with screening mammography policies. As noted in the text, CHBRP assumes that health plans will apply cost sharing to DBT when performed with diagnostic digital mammography.
- *Premandate utilization*
 - *Screening digital mammography.* Based on the MarketScan® utilization data, digital mammography comprised 84% of mammography exams in 2014 (the remaining 16% consisted of film exams). Content expert guidance and industry reports suggest that over 90% of mammography currently consists of digital exams. CHBRP estimated premandate utilization of digital mammography based upon the trend of digital mammography adoption seen in prior years of MarketScan data, which was 9 percentage points from 2013-2014.
 - *Digital breast tomosynthesis as an addition to screening digital mammography.* Content expert guidance estimated that 20-40% digital screening mammography procedures and 40-50% of diagnostic mammography exams were accompanied by DBT. In a survey conducted of members of the Society for Breast Imaging, 32.8% of respondents in the Western U.S. reported offering DBT (Hardesty et al., 2014). Using these estimates, CHBRP assumed a conservative estimate that 30% of screening and 40% of diagnostic mammography exams include DBT. Based on 2014 MarketScan® Commercial Claims and Encounters Database, of the digital mammography services performed, 2,832,000 were for screening and 748,000 were for diagnostic purposes (Table 1). CHBRP applied the estimated rates of additional DBT to estimate premandate utilization of DBT, 862,000 screening DBT (30% of 2,832,000), and 303,000 diagnostic DBT (40% of 748,000).
- *Postmandate utilization*
 - *Screening digital mammography.* Because DBT equipment has both digital mammography and DBT capabilities, CHBRP assumed that expanded coverage under AB 2764 would incentivize a marginal group of providers with film equipment to invest in

newer technology that can perform both exams. Thus CHBRP estimated a postmandate 3 percentage point increase in digital mammography as a proportion of all screening mammography. Screening digital mammography would consequently increase to 97% of all screening mammography exams postmandate. This is consistent with current FDA administrative records indicating that 97% of imaging facilities use digital (rather than film) mammography (FDA 2016).

- *Screening digital breast tomosynthesis.* Content expert input indicates with 100% benefit coverage, the availability of DBT technology would be the primary determinant of postmandate utilization for screening purposes. Based upon reports from the predominant manufacturer of DBT technology, CHBRP estimates premandate, 40% of digital mammography machines would have DBT capability (An estimated 2400/6200 of mammography systems currently have DBT. Hologic, Inc., 2016). Given the relatively high cost of purchasing new mammography equipment with DBT capability (average price \$430,000, which is on average 30% higher than a 2D digital mammography system) (Rubenfire, 2015), CHBRP assumes that within one year postmandate, the adoption rate of new systems will remain similar to existing national growth rates, i.e., the percentage of mammography machines with DBT capacity rose approximately 20 percentage points through 2015 (In 2014, approximately 1100 systems had DBT. Grady, 2014). Of note, the national growth rate for 2015 coincides with new Medicare coverage for DBT, and thus offers an estimate for market response to expanded coverage. CHBRP therefore estimates approximately 60% (40% + 20%) of enrollees who use digital mammography would also have access to DBT technology. CHBRP further assumes among those with access to the technology, a small percentage of enrollees would decline to utilize DBT due to patient and/or provider preferences. These preferences may include reluctance to order or receive a procedure with limited evidence on clinical outcomes, concerns over the increased radiation dose, or the increased time needed to perform or analyze the test (as noted in
- *Medical Effectiveness, DBT on average doubles the time needed to read a mammography).* In the absence of peer-reviewed literature, CHBRP estimated that among those with ready access to DBT technology, utilization would approximate what is observed premandate for digital mammography (93%)- a breast imaging procedure that is widely available and fully covered, but not proven to be more cost-effective than film mammography. CHBRP therefore assumes that of those 60% of enrollees who use screening digital mammography, 93% of those would also utilize DBT, such utilization of DBT would increase from 30% of screening digital exams premandate to 55.8% postmandate.
- *Diagnostic imaging procedures.* Per peer-literature review and content expert input, CHBRP assumes that increased utilization of DBT as a result of AB 2764 would reduce the amount of diagnostic imaging that is performed following screening mammography. CHBRP identified recall utilization by using the MarketScan® Commercial Claims and Encounters Database to identify all diagnostic imaging procedures performed within six months of the initial screening mammography. In 2014, 7.9% of enrollees who received screening mammography subsequently received recall diagnostic imaging. CHBRP estimates that 7.9% of screening mammography procedures that do not include breast tomosynthesis would be followed by recall and subsequent diagnostic imaging. Applying an approximate 2-percentage-point reduction indicated by the peer-reviewed literature, CHBRP estimates that for those receiving breast tomosynthesis, 5.9% (7.9% - 2 % = 5.9%) would receive recall diagnostic imaging. Thus, CHBRP estimates diagnostic

imaging utilization would be 5.9% among the estimated 55.8% of enrollees to receive screening DBT, and 7.9% for the remaining enrollees who do not receive DBT in conjunction with screening mammography. Based upon MarketScan data and content expert guidance, CHBRP included the following procedures as diagnostic breast imaging: diagnostic mammography, DBT, and breast ultrasound (Table 2). Among the literature reviewed in the Medical Effectiveness section, only one study (Lourenco et Al., 2015) reported diagnostic imaging utilization rather than general recall rates. Therefore, CHBRP concludes there is insufficient information to estimate reduction in utilization specific to each imaging modality, and thus assumed that the reduction in recall is applied equally to all diagnostic imaging procedures.

- *Digital breast tomosynthesis as an addition to diagnostic mammography.* As with diagnostic digital mammography and diagnostic ultrasound, CHBRP assumes that diagnostic DBT utilization would be impacted by changes in recall rates as a result of screening DBT. For the 55.8% of screening digital mammography exams conducted with DBT, CHBRP assumes a recall rate of 5.9%. Per content expert input, DBT exams are the same procedure whether performed for screening or diagnostic purposes- repeat imaging is rarely needed, an estimated 2.5% of the time. Therefore whereas CHBRP assumes a proportionate recall of other exams as seen in the MarketScan® data, CHBRP assumes only a small percentage of recalls would include DBT. For the remaining 44.2% of enrollees who do not receive screening DBT, CHBRP assumes that indication of an abnormality would increase both patient and provider preferences to obtain a diagnostic mammogram with DBT. This is consistent with estimated premandate trends, such that the utilization of diagnostic DBT with digital mammography (40%) parallels estimated technological capacity, at 40% of mammography equipment (Hologic Inc, 2016). Thus, CHBRP assumes postmandate utilization of diagnostic DBT would be 60% for those who did not receiving DBT with a screening mammography exam. The increase in utilization of this group of enrollees thus offsets the decrease in diagnostic DBT utilization among enrollees who received screening DBT with digital mammography.
- *Per-Unit Costs, premandate and postmandate*
 - CHBRP estimated the premandate per-unit costs for digital mammography from the MarketScan® Commercial Claims and Encounters Database. Because Current Procedural Terminology codes (reported for health insurance reimbursement) for DBT were not implemented until 2015, CHBRP was unable to estimate per-unit costs based upon MarketScan® data. CHBRP estimated per-unit costs for DBT based upon the current Medicare Physician Fee Schedule for DBT (Centers for Medicaid and Medicare, 2016), multiplied by the average additional increase paid by health insurance plans over standard Medicare Physician Fee Schedule (as determined by the MarketScan® data). Thus the DBT per-unit cost estimate reflects typical regional costs in relation to Medicare reimbursement. CHBRP assumes that one year postmandate, per-unit costs would remain consistent but does recognize that in the context of rising demand, per-unit costs may increase in subsequent years.
- *Premandate costs*
 - *Out-of-pocket costs.* CHBRP estimated enrollee out-of-pocket costs as a combination of cost sharing by covered enrollees for DBT and payments for non-covered benefits, i.e., DBT. There was no available data or literature to provide information on the insurance coverage distribution among those who utilized DBT premandate. Per content expert input and radiology survey, premandate DBT would be utilized by those with coverage

and those without coverage (as noted above, estimated 56% of enrollees have coverage premandate). CHBRP estimates that among enrollees utilizing DBT premandate, 75% are covered enrollees and 25% are enrollees without coverage.

- *Cost sharing by covered enrollees:* CHBRP estimated enrollee cost sharing by applying average cost-sharing rates by market segment per the CHBRP Annual Enrollment and Premium Survey.
 - *Costs for noncovered benefits:* Per the survey of breast imaging specialists (Hardesty et al., 2014), 26.6% of respondents reported charging an up-front fee for DBT. Thus, CHBRP assumes that among enrollees without coverage who nevertheless are utilizing DBT premandate, 26.6% are paying out of pocket for services and that the fee is equal to the unit cost of DBT.
- *Postmandate costs*
 - CHBRP estimates postmandate costs based upon increases in utilization and accompanying shifts in cost sharing for diagnostic procedures. As noted in the text, CHBRP assumes no cost sharing will be applied for screening digital mammography or DBT postmandate. Health plans that currently provide coverage for DBT, as well as Medicare, do not impose cost sharing for DBT when performed in conjunction with screening digital mammography. AB 2764 allows plans to apply cost sharing and deductibles, and CHBRP assumes that these policies will apply to diagnostic imaging procedures. CHBRP assumes enrollee costs for noncovered benefits will be shifted to health insurance plans.

Determining Public Demand for the Proposed Mandate

This subsection discusses public demand for the benefits AB 2764 would mandate. 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 therefore 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, in general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.

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 currently does not cover digital breast tomosynthesis (DBT).

To further investigate public demand, CHBRP used the bill-specific coverage survey to ask 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 limited current coverage for DBT.

REFERENCES

- American Academy of Family Physicians (AAFP). *Clinical preventive service recommendation: Breast cancer 2016*. Available at: <http://www.aafp.org/patient-care/clinical-recommendations/all/breast-cancer.html>. Accessed April 1, 2016.
- American Cancer Society (ACS). *California Cancer Facts & Figures, 2014*. 2014. Available at: http://www.ccrca.org/pdf/reports/acs_2014.pdf. Accessed March 21, 2016.
- American Cancer Society (ACS). *American Cancer Society recommendations for early breast cancer detection in women without breast symptoms*. 2015a. Available at: <http://www.cancer.org/cancer/breastcancer/moreinformation/breastcancerearlydetection/breast-cancer-early-detection-ac-recs>. Accessed April 18, 2016.
- American Cancer Society (ACS). *Frequently Asked Questions About the American Cancer Society's New Breast Cancer Screening Guideline: Why is there no recommendation for 3D mammography (tomosynthesis)?* 2015b. Available at: <http://www.cancer.org/cancer/breastcancer/moreinformation/frequently-asked-questions-about-the-american-cancer-society-new-breast-cancer-screening-guideline#3D> mammography. Accessed April 1, 2016.
- American Cancer Society (ACS). *What's the difference between a screening mammogram and a diagnostic mammogram?* 2015c. Available at: <http://www.cancer.org/treatment/understandingyourdiagnosis/examsandtestdescriptions/mammogramsandotherbreastimagingprocedures/mammograms-and-other-breast-imaging-procedures-types-of-mammograms>. Accessed April 6, 2016.
- American College of Radiology (ACR). *ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography*. 2014a. Available at: <http://www.acr.org/~/media/3484ca30845348359bad4684779d492d.pdf>. Accessed April 6, 2016.
- American College of Radiology (ACR). *ACR Statement on Breast Tomosynthesis*. 2014b. Available at: <http://www.acr.org/About-Us/Media-Center/Position-Statements/Position-Statements-Folder/20141124-ACR-Statement-on-Breast-Tomosynthesis%20>. Accessed April 1, 2016.
- American Congress of Obstetrics and Gynecology (ACOG). Practice bulletin no. 122: Breast cancer screening. *Obstetrics and gynecology*. 2011;118(2 Pt 1):372-382.
- American Congress of Obstetrics and Gynecology (ACOG). ACOG Committee Opinion no. 593: Management of women with dense breasts diagnosed by mammography. *Obstetrics and Gynecology*. 2014;123(4):910-911.
- Baquet CR, Commiskey P. Socioeconomic factors and breast carcinoma in multicultural women. *Cancer*. 2000;88(5 Suppl):1256-1264.
- Blue Cross and Blue Shield Association (BCBSA). State Legislative Health Care and Insurance Issues: 2015 Survey of Plans. Washington, DC: The Blue Cross and Blue Shield Association., Office of Policy and Representation; 2015.

- Braveman P. Health disparities and health equity: concepts and measurement. *Annual Review of Public Health*. 2006;27:167-194.
- California Cancer Registry (CCR). Age-Adjusted Cancer Mortality Rates by in California. 2015; Cancer incidence and mortality data by geographic region. Available at: <http://cancer-rates.info/ca>. Accessed April 7, 2016.
- Centers for Disease Control and Prevention. NCHHSTP Social Determinants of Health. Frequently Asked Questions. Page last reviewed: March 10, 2014. Available at: <http://www.cdc.gov/nchhstp/socialdeterminants/faq.html>. Accessed August 27, 2015.
- Centers for Medicare and Medicaid Services (CMS). *MLN Matters*, MM8874. 2015. Available at: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8874.pdf>. Accessed April 20, 2016.
- Centers for Medicare and Medicaid Services (CMS). Physician Fee Schedule 2016. HSPC Codes 77063 (screening digital breast tomosynthesis) and G0279 (diagnostic digital breast tomosynthesis).
- Ciatto S, Houssami N, Bernardi D, et al. Integration of 3D digital mammography with tomosynthesis for population breast-cancer screening (STORM): a prospective comparison study. *The Lancet Oncology*. 2013;14(7):583-589.
- Conant EF, Beaber EF, Sprague BL, et al. Breast cancer screening using tomosynthesis in combination with digital mammography compared to digital mammography alone: a cohort study within the PROSPR consortium. *Breast Cancer Research and Treatment*. 2016;156(1):109-116.
- Cornford EJ, Turnbull AE, James JJ, et al. Accuracy of GE digital breast tomosynthesis vs supplementary mammographic views for diagnosis of screen-detected soft-tissue breast lesions. *British Journal of Radiology*. 2016;89(1058):7.
- Destounis S, Arieno A, Morgan R. Initial experience with combination digital breast tomosynthesis plus full field digital mammography or full field digital mammography alone in the screening environment. *Journal of Clinical Imaging Science*. 2014;4:9.
- Durand MA, Haas BM, Yao X, et al. Early clinical experience with digital breast tomosynthesis for screening mammography. *Radiology*. 2015;274(1):85-92.
- Fornvik D, Zackrisson S, Ljungberg O, et al. Breast tomosynthesis: Accuracy of tumor measurement compared with digital mammography and ultrasonography. *Acta radiologica (Stockholm, Sweden: 1987)*. 2010;51(3):240-247.
- Friedewald SM, Rafferty EA, Rose SL, et al. Breast cancer screening using tomosynthesis in combination with digital mammography. *Jama*. 2014;311(24):2499-2507.
- GE Healthcare. *SenoClaire 3D Breast Tomosynthesis*. 2014. Available at: http://www3.gehealthcare.com/en/products/categories/mammography/senoclaire_3d. Accessed March 19, 2015.
- Gennaro G, Toledano A, di Maggio C, et al. Digital breast tomosynthesis versus digital mammography: a clinical performance study. *European Radiology*. 2010;20(7):1545-1553.

- Gilbert FJ, Tucker L, Gillan MG, et al. The TOMMY trial: a comparison of TOMosynthesis with digital MammographY in the UK NHS Breast Screening Programme--a multicentre retrospective reading study comparing the diagnostic performance of digital breast tomosynthesis and digital mammography with digital mammography alone. *Health Technology Assessment (Winchester, England)*. 2015;19(4):i-xxv, 1-136.
- Grady D. 3-D Mammography Test Appears to Improve Breast Cancer Detection Rate. *New York Times*. June 24, 2014. Available at: <http://www.nytimes.com/2014/06/25/health/breast-cancer-3d-mammography-test-x-ray.html>. Accessed May 3, 2016.
- Greenberg JS, Javitt MC, Katzen J, Michael S, Holland AE. Clinical performance metrics of 3D digital breast tomosynthesis compared with 2D digital mammography for breast cancer screening in community practice. *AJR. American Journal of Roentgenology*. 2014;203(3):687-693.
- Gur D, Zuley ML, Anello MI, et al. Dose reduction in digital breast tomosynthesis (DBT) screening using synthetically reconstructed projection images: an observer performance study. *Academic Radiology*. 2012;19(2):166-171.
- Haas BM, Kalra V, Geisel J, Raghu M, Durand M, Philpotts LE. Comparison of tomosynthesis plus digital mammography and digital mammography alone for breast cancer screening. *Radiology*. 2013;269(3):694-700.
- Hardesty LA., Kreidler SM, Glueck DH. Digital breast tomosynthesis utilization in the United States: a survey of physician members of the Society of Breast Imaging. *Journal of the American College of Radiology*. 2014;11(6): 594-9.
- Hologic, Inc. mygenius3D.com. Accessed April 20, 2016.
- Houssami N, Macaskill P, Bernardi D, et al. Breast screening using 2D-mammography or integrating digital breast tomosynthesis (3D-mammography) for single-reading or double-reading--evidence to guide future screening strategies. *European Journal of Cancer (Oxford, England: 1990)*. 2014;50(10):1799-1807.
- Iared W, Shigueoka DC, Torloni MR, et al. Comparative evaluation of digital mammography and film mammography: systematic review and meta-analysis. *Sao Paulo Medical Journal = Revista Paulista de Medicina*. 2011;129(4):250-260.
- Kerlikowske K, Hubbard RA, Miglioretti DL, et al. Comparative effectiveness of digital versus film-screen mammography in community practice in the United States: a cohort study. *Annals of Internal Medicine*. 2011;155(8):493-502.
- Lampic C, Thurfjell E, Bergh J, Sjoden PO. Short- and long-term anxiety and depression in women recalled after breast cancer screening. *European Journal of Cancer (Oxford, England: 1990)*. 2001;37(4):463-469.
- Lang K, Andersson I, Rosso A, Tingberg A, Timberg P, Zackrisson S. Performance of one-view breast tomosynthesis as a stand-alone breast cancer screening modality: results from the Malmo Breast Tomosynthesis Screening Trial, a population-based study. *European Radiology*. 2016;26(1):184-190.

- Lourenco AP, Barry-Brooks M, Baird GL, Tuttle A, Mainiero MB. Changes in recall type and patient treatment following implementation of screening digital breast tomosynthesis. *Radiology*. 2015;274(2):337-342.
- McCarthy AM, Kontos D, Synnestvedt M, et al. Screening outcomes following implementation of digital breast tomosynthesis in a general-population screening program. *Journal of the National Cancer Institute*. 2014;106(11).
- McDonald ES, McCarthy AM, Akhtar AL, Synnestvedt MB, Schnall M, Conant EF. Baseline Screening Mammography: Performance of Full-Field Digital Mammography Versus Digital Breast Tomosynthesis. *AJR. American Journal of Roentgenology*. 2015;205(5):1143-1148.
- McDonald ES, Oustimov A, Weinstein SP, Synnestvedt MB, Schnall M, Conant EF. Effectiveness of Digital Breast Tomosynthesis Compared With Digital Mammography: Outcomes Analysis From 3 Years of Breast Cancer Screening. *JAMA Oncology*. Feb 18 2016.
- Melnikow J, Fenton JJ, Miglioretti D, Whitlock EP, Weyrich MS. U.S. Preventive Services Task Force Evidence Syntheses, formerly Systematic Evidence Reviews. *Screening for Breast Cancer With Digital Breast Tomosynthesis*. Rockville (MD): Agency for Healthcare Research and Quality (US); 2016.
- Michell MJ, Iqbal A, Wasan RK, et al. A comparison of the accuracy of film-screen mammography, full-field digital mammography, and digital breast tomosynthesis. *Clinical Radiology*. 2012;67(10):976-981.
- Miglioretti DL, Lange J, van den Broek JJ, et al. Radiation-Induced Breast Cancer Incidence and Mortality From Digital Mammography Screening: A Modeling Study. *Annals of Internal Medicine*. 2016;164(4):205-214.
- Modern Healthcare/ECRI Institute Technology Price Index. January, 2015. Available at:<http://www.modernhealthcare.com/section/technology-price-index>. Accessed April 20, 2016.
- Myers ER, Moorman P, Gierisch JM, et al. Benefits and Harms of Breast Cancer Screening: A Systematic Review. *Jama*. 2015;314(15):1615-1634.
- National Cancer Institute (NCI). Mammograms: what is digital mammography? How is it different from conventional (film) mammography? 2014; <http://www.cancer.gov/types/breast/mammograms-fact-sheet#q2>. Accessed April 6, 2016.
- National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis. 2014a. Available at: http://www.nccn.org/professionals/physician_gls/f_guidelines.asp. Accessed April 1, 2016.
- National Comprehensive Cancer Network (NCCN). NCCN Guidelines for Patients: Stage 0 Breast Cancer 2014b. Available at: http://www.nccn.org/patients/guidelines/stage_0_breast/index.html#1. Accessed April 18, 2016.
- National Comprehensive Cancer Network (NCCN). NCCN Guidelines for Patients: Stage 1-2 Breast Cancer 2014c. Available at: https://www.nccn.org/patients/guidelines/stage_i_ii_breast/index.html. Accessed April 28, 2016.

- National Comprehensive Cancer Network (NCCN). *NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis*. Fort Washington, PA; 2014d.
- Nelson HD, Cantor A, Humphrey L, et al. U.S. Preventive Services Task Force Evidence Syntheses, formerly Systematic Evidence Reviews. *Screening for Breast Cancer: A Systematic Review to Update the 2009 U.S. Preventive Services Task Force Recommendation*. Rockville (MD): Agency for Healthcare Research and Quality (US); 2016.
- Noroozian M, Hadjiiski L, Rahnama-Moghadam S, et al. Digital breast tomosynthesis is comparable to mammographic spot views for mass characterization. *Radiology*. 2012;262(1):61-68.
- Oeffinger KC, Fontham ET, Etzioni R, et al. Breast Cancer Screening for Women at Average Risk: 2015 Guideline Update From the American Cancer Society. *Jama*. 2015;314(15):1599-1614.
- Office of Disease Prevention and Health Promotion. Healthy People 2020: Social Determinants of Health. Available at: Available at: www.healthypeople.gov/2020/topics-objectives/topic/socialdeterminantshealth/addressing-determinants. Accessed February 16, 2016.
- Parise CA, Caggiano V. Disparities in race/ethnicity and socioeconomic status: risk of mortality of breast cancer patients in the California Cancer Registry, 2000-2010. *BMC Cancer*. 2013;13:449.
- Peppard HR, Nicholson BE, Rochman CM, Merchant JK, Mayo RC, 3rd, Harvey JA. Digital Breast Tomosynthesis in the Diagnostic Setting: Indications and Clinical Applications. *Radiographics : a review publication of the Radiological Society of North America, Inc*. 2015;35(4):975-990.
- Pisano ED, Gatsonis C, Hendrick E, et al. Diagnostic Performance of Digital versus Film Mammography for Breast-Cancer Screening. *New England Journal of Medicine*. 2005;353(17):1773-1783.
- Pisano ED, Yaffe MJ. Digital mammography. *Radiology*. 2005;234(2):353-362.
- Plecha D, Salem N, Kremer M, et al. JOURNAL CLUB: Neglecting to Screen Women Between 40 and 49 Years Old With Mammography: What Is the Impact on Treatment Morbidity and Potential Risk Reduction? *American Journal of Roentgenology*. 2014/02/01 2014;202(2):282-288.
- Rose SL, Tidwell AL, Bujnoch LJ, Kushwaha AC, Nordmann AS, Sexton R, Jr. Implementation of breast tomosynthesis in a routine screening practice: an observational study. *AJR. American Journal of Roentgenology*. 2013;200(6):1401-1408.
- Rubenfire, A. *Demand for 3-D boosts digital mammography systems prices*. Modern Healthcare. July 6, 2015. Available at: <http://www.modernhealthcare.com/article/20150706/news/150709953>. Accessed April 20, 2016.
- Sharpe RE, Jr., Venkataraman S, Phillips J, et al. Increased Cancer Detection Rate and Variations in the Recall Rate Resulting from Implementation of 3D Digital Breast Tomosynthesis into a Population-based Screening Program. *Radiology*. 2016;278(3):698-706.
- Sineshaw HM, Gaudet M, Ward EM, et al. Association of race/ethnicity, socioeconomic status, and breast cancer subtypes in the National Cancer Data Base (2010-2011). *Breast Cancer Research and Treatment*. 2014;145(3):753-763.
- Siu AL. Screening for Breast Cancer: U.S. Preventive Services Task Force Recommendation Statement. *Annals of Internal Medicine*. 2016;164(4):279-296.

- Skaane P, Bandos AI, Gullien R, et al. Comparison of digital mammography alone and digital mammography plus tomosynthesis in a population-based screening program. *Radiology*. 2013;267(1):47-56.
- Souza FH, Wendland EM, Rosa MI, Polanczyk CA. Is full-field digital mammography more accurate than screen-film mammography in overall population screening? A systematic review and meta-analysis (Provisional abstract). *Breast (Edinburgh, Scotland)*. 2013;22(3):217-224.
- Svahn TM, Houssami N, Sechopoulos I, Mattsson S. Review of radiation dose estimates in digital breast tomosynthesis relative to those in two-view full-field digital mammography. *Breast (Edinburgh, Scotland)*. 2015;24(2):93-99.
- Tagliafico A, Astengo D, Cavagnetto F, et al. One-to-one comparison between digital spot compression view and digital breast tomosynthesis. *European Radiology*. 2012;22(3):539-544.
- Teertstra HJ, Loo CE, van den Bosch MA, et al. Breast tomosynthesis in clinical practice: initial results. *European Radiology*. 2010;20(1):16-24.
- U.S. Food and Drug Administration (FDA). SenoClaire - P130020. September 2014. Available at: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm412383.htm>. Accessed March 19, 2015.
- U.S. Food and Drug Administration (FDA). Radiation Emitting Products. Available at: <http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityScorecard/ucm113858.htm>. Accessed April 13, 2016.
- Vona-Davis L, Rose DP. The influence of socioeconomic disparities on breast cancer tumor biology and prognosis: a review. *Journal of Women's Health (2002)*. 2009;18(6):883-893.
- Waldherr C, Cerny P, Altermatt HJ, et al. Value of one-view breast tomosynthesis versus two-view mammography in diagnostic workup of women with clinical signs and symptoms and in women recalled from screening. *AJR. American Journal of Roentgenology*. 2013;200(1):226-231.
- Zuley ML, Bandos AI, Ganott MA, et al. Digital breast tomosynthesis versus supplemental diagnostic mammographic views for evaluation of noncalcified breast lesions. *Radiology*. 2013;266(1):89-95.

CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM COMMITTEES AND STAFF

A group of faculty, researchers, and staff complete the analysis that informs California Health Benefits Review Program (CHBRP) reports. The CHBRP **Faculty Task Force** comprises rotating senior faculty from University of California (UC) campuses. In addition to these representatives, there are other ongoing contributors to CHBRP from UC that conduct 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 manages all external communications, including those with the California Legislature. As required by CHBRP's authorizing legislation, UC contracts with a certified actuary, PricewaterhouseCoopers, to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit.

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 of its National Advisory Council. CHBRP assumes full responsibility for the report and the accuracy of its contents.

Faculty Task Force

Janet Coffman, MA, MPP, PhD, *Vice Chair for Medical Effectiveness*, University of California, San Francisco

Sara McMenamin, PhD, *Vice Chair for Medical Effectiveness and Public Health*, University of California, San Diego

Joy Melnikow, MD, MPH, *Vice Chair for Public Health*, University of California, Davis

Ninez Ponce, PhD, *Co-Vice Chair for Cost*, University of California, Los Angeles

Nadereh Pourat, PhD, *Co-Vice Chair for Cost*, University of California, Los Angeles

Susan L. Ettner, PhD, University of California, Los Angeles

Sheldon Greenfield, MD, University of California, Irvine

Sylvia Guendelman, PhD, LCSW, University of California, Berkeley

Marilyn Stebbins, PharmD, University of California, San Francisco

Task Force Contributors

Wade Aubry, MD, University of California, San Francisco

Diana Cassady, DrPH, University of California, Davis

Shana Charles, PhD, MPP, University of California, Los Angeles, and California State University, Fullerton

Shauna Durbin, MPH, University of California, Davis

Margaret Fix, MPH, University of California, San Francisco

Ronald Fong, MD, MPH, University of California, Davis

Brent Fulton, PhD, University of California, Berkeley

Erik Groessl, PhD, University of California, San Diego

Sarah Hiller, MA, University of California, San Diego

Jeffrey Hoch, PhD, University of California, Davis

Michelle Ko, MD, PhD, University of California, Los Angeles

Gerald Kominski, PhD, University of California, Los Angeles

Alicia LaFrance, MPH, MSW, University of California, San Francisco

Ying-Ying Meng, PhD, University of California, Los Angeles

Jack Needleman, PhD, University of California, Los Angeles
Dominique Ritley, MPH, University of California, Davis
Dylan Roby, PhD, University of California, Los Angeles, and
University of Maryland, College Park
Neil Sehgal, MPH, PhD, University of California, San Francisco
Riti Shimkhada, PhD, University of California, Los Angeles
Meghan Soulsby Weyrich, MPH, University of California, Davis
Steven Tally, PhD, University of California, San Diego
Ed Yelin, PhD, Professor Emeritus, University of California, San Francisco
Byung-Kwang (BK) Yoo, MD, MS, PhD, University of California, Davis

National Advisory Council

Lauren LeRoy, PhD, Strategic Advisor, L. LeRoy Strategies, *Chair*
Stuart H. Altman, PhD, Professor of National Health Policy, Brandeis University, Waltham, MA
Deborah Chollet, PhD, Senior Fellow, Mathematica Policy Research, Washington, DC
Joseph P. Ditré Esq., Director of Enterprise and Innovation, Families USA, Washington, DC
Allen D. Feezor, Fmr. Deputy Secretary for Health Services, North Carolina Department of Health and
Human Services, Raleigh, NC
Charles “Chip” Kahn, MPH, President and CEO, Federation of American Hospitals, Washington, DC
Jeffrey Lerner, PhD, President and CEO, ECRI Institute Headquarters, Plymouth Meeting, PA
Donald E. Metz, Executive Editor, *Health Affairs*, Bethesda, MD
Dolores Mitchell, Executive Director, Group Insurance Commission, Boston, MA
Marilyn Moon, PhD, Vice President and Director, Health Program, American Institutes for Research,
Silver Spring, MD
Carolyn Pare, President and CEO, Minnesota Health Action Group, Bloomington, MN
Michael Pollard, JD, MPH, Senior Advisor, Policy and Regulation, Pharmaceutical Care Management
Association, Washington, DC
Richard Roberts, MD, JD, Professor of Family Medicine, University of Wisconsin-Madison, Madison, WI
Prentiss Taylor, MD, Corporate Medical Director, Advocate At Work, Advocate Health Care, Chicago, IL
J. Russell Teagarden, Unaffiliated Expert in Pharmaceuticals, Danbury, CT
Alan Weil, JD, MPP, Editor-in-Chief, *Health Affairs*, Bethesda, MD

CHBRP Staff

Garen Corbett, MS, Director
John Lewis, MPA, Associate Director
Erin Shigekawa, MPH, Principal Policy Analyst
AJ Scheitler, EdD, Principal Policy Analyst
Karla Wood, Program Specialist

California Health Benefits Review Program
University of California
Office of the President
1111 Broadway, Suite 1400
Oakland, CA 94607
Tel: 510-287-3876 Fax: 510-763-4253
chbrpinfo@chbrp.org www.chbrp.org

The California Health Benefits Review Program is administered by UC Health at the University of California, Office of the President. UC Health is led by John D. Stobo, MD, Executive Vice President.

ACKNOWLEDGEMENTS

Joy Melnikow, MD, MPH, and Meghan Soulsby Weyrich, MPH, both of the University of California, Davis, prepared both the medical effectiveness analysis and the public health impact analysis. Stephen L. Clancy, MLS, AHIP, of the University of California, Irvine, conducted the literature search. Michelle Ko, MD, PhD, of the University of California, Los Angeles, prepared the cost impact analysis. Peter Davidson, FSA, MAAA, of PricewaterhouseCoopers, and supporting actuarial staff, provided actuarial analysis. Karen K. Lindfors, MD, MPH, of the University of California, Davis, provided technical assistance with the literature review and expert input on the analytic approach. John Lewis, MPA, of CHBRP staff prepared the Policy Context 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, Susan Ettner, PhD, of the University of California, Los Angeles, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

Please direct any questions concerning this document to:

California Health Benefits Review Program
University of California, Office of the President
UC Health
1111 Broadway, Suite 1400
Oakland, CA 94607
Tel: 510-287-3876
Fax: 510-763-4253
www.chbrp.org

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. 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.

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.

CHBRP is also grateful for the valuable assistance of its National Advisory Council, who provide expert reviews of draft analyses and offer general guidance on the program. CHBRP is administered by the UC Health at the University of California, Office of the President, led by John D. Stobo, MD, Executive Vice President.

CHBRP assumes full responsibility for the report and the accuracy of its contents. All CHBRP bill analyses and other publications are available at www.chbrp.org.

Garen Corbett, MS
Director