

# **UC Office of the President**

## **Report to California Legislature**

### **Title**

Analysis of Senate Bill 255: Breast Cancer

### **Permalink**

<https://escholarship.org/uc/item/7kh2f4hx>

### **Author**

California Health Benefits Review Program

### **Publication Date**

2011-04-14



**CALIFORNIA**  
HEALTH BENEFITS REVIEW PROGRAM

---

## Analysis of Senate Bill 255: Breast Cancer

---

A Report to the 2011-2012 California Legislature  
April 14, 2011

CHBRP 11-12



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

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

# **A Report to the 2011-2012 California State Legislature**

## **Analysis of Senate Bill 255 Breast Cancer**

**April 14, 2011**

**California Health Benefits Review Program  
1111 Franklin Street, 11<sup>th</sup> Floor  
Oakland, CA 94607  
Tel: 510-287-3876  
Fax: 510-763-4253  
<http://www.chbrp.org>**

Additional free copies of this and other CHBRP bill analyses and publications may be obtained by visiting the CHBRP Web site at <http://www.chbrp.org>.

**Suggested Citation:**

California Health Benefits Review Program (CHBRP). (2011). *Analysis of Senate Bill 255: Breast Cancer*. Report to California State Legislature. Oakland, CA: CHBRP. 11-12.

## **PREFACE**

This report provides an analysis of the medical, financial, and public health impacts of Senate Bill 255. In response to a request from the California Senate Committee on Health on February 11, 2011, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the program's authorizing statute.

Janet Coffman, MPP, PhD, and Margaret Fix, MPH, of the University of California, San Francisco, prepared the medical effectiveness analysis. Penny Coppernoll-Blach, MLIS, of the University of California, San Diego, conducted the literature search. Diana Cassady, ScD, Dominique Ritley, MPH, and Meghan Soulsby, MPH, all of the University of California, Davis, prepared the public health impact analysis. Todd Gilmer, PhD, of the University of California, San Diego, and Garen Corbett, MS, of CHBRP staff, prepared the cost impact analysis. Susan Pantely, FSA, MAAA, of Milliman, provided actuarial analysis. Laura Esserman, MD, MBA, of the University of California, San Francisco, provided technical assistance with the literature review and expert input on the analytic approach. Garen Corbett, MS, of CHBRP staff, prepared the introduction and synthesized the individual sections into a single report. A subcommittee of CHBRP's National Advisory Council (see final pages of this report) and a member of the CHBRP Faculty Task Force, Sylvia Guendelman, PhD, LCSW, of the University of California, Berkeley, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

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

**California Health Benefits Review Program**  
**1111 Franklin Street, 11<sup>th</sup> Floor**  
**Oakland, CA 94607**  
**Tel: 510-287-3876**  
**Fax: 510-763-4253**  
<http://www.chbrp.org>

All CHBRP bill analyses and other publications are available on the CHBRP Web site, <http://www.chbrp.org>.

Susan Philip, MPP  
Director

## TABLE OF CONTENTS

LIST OF TABLES .....	4
EXECUTIVE SUMMARY .....	5
INTRODUCTION .....	9
Background on Breast Cancer .....	13
MEDICAL EFFECTIVENESS .....	15
Literature Review Methods.....	16
Outcomes Assessed.....	16
Study Findings .....	17
BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS.....	20
Current (Baseline) Benefit Coverage, Utilization, and Cost.....	20
Impacts of Mandated Benefit Coverage .....	22
PUBLIC HEALTH IMPACTS .....	25
Public Health Outcomes .....	25
Impact on Gender and Racial Disparities .....	26
Impacts on Premature Death and Economic Loss .....	27
APPENDICES .....	28
Appendix A: Text of Bill Analyzed.....	28
Appendix B: Literature Review Methods .....	33
Appendix C: Summary Findings on Medical Effectiveness.....	37
Appendix D: Cost Impact Analysis: Data Sources, Caveats, and Assumptions.....	44
Appendix E: Information Submitted by Outside Parties .....	53
REFERENCES .....	54

## LIST OF TABLES

<b>Table 1.</b> Incidence, Stage, and Mortality Rates for Female Breast Cancer by Race/Ethnicity in California, 2008 .....	14
<b>Table C-1a.</b> Characteristics of Published Studies Comparing Lumpectomy <i>With</i> Radiation to Mastectomy .....	37
<b>Table C-1b.</b> Characteristics of Published Studies Comparing Lumpectomy <i>With</i> Radiation to Lumpectomy <i>Without</i> Radiation .....	38
<b>Table C-2a.</b> Summary of Findings From Studies Comparing Lumpectomy <i>With</i> Radiation to Mastectomy .....	39
<b>Table C-2b.</b> Summary of Findings From Studies Comparing Lumpectomy <i>With</i> Radiation to Lumpectomy <i>Without</i> Radiation .....	41

## EXECUTIVE SUMMARY

### California Health Benefits Review Program Analysis of Senate Bill 255

The California Senate Committee on Health requested on February 11, 2011, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Senate Bill (SB) 255, a bill that would impose a health benefit mandate by revising and recasting the definition of mastectomy to include surgical treatment for breast cancer. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.<sup>1</sup>

#### Analysis of SB 255

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

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

DMHC-regulated plans and CDI-regulated policies would be subject to SB 255. Therefore, the mandate would affect the health insurance of approximately 21.9 million Californians (59%).

Currently, California law requires health plans and insurers to cover breast cancer screening and treatment. SB 255 would amend existing California law by clarifying the definition of mastectomy to specify that partial removal of the breast includes, but is not limited to, lumpectomy. Lumpectomy includes surgical removal of the tumor with clear margins. The bill would require coverage of postsurgery consultation regarding the length of any hospital stay.

The Women's Health and Cancer Rights Act of 1998 (WHCRA) is a federal law that provides protections to patients who choose to have breast reconstruction in connection with a mastectomy.

---

<sup>1</sup> CHBRP's authorizing statute is available at [http://www.chbrp.org/documents/authorizing\\_statute.pdf](http://www.chbrp.org/documents/authorizing_statute.pdf).

<sup>2</sup> CHBRP's estimates are available at [http://www.chbrp.org/documents/insur\\_source\\_est\\_2011.pdf](http://www.chbrp.org/documents/insur_source_est_2011.pdf).

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

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



Currently, 20 states mandate minimum in-patient coverage after a patient undergoes a mastectomy, including California. Lumpectomy does not routinely require an overnight stay.

### **Medical Effectiveness**

- Breast cancer is typically treated through a combination of surgery and/or radiation, chemotherapy, and hormone therapy.
- Women with early stage breast cancer (i.e., stage 0, I or, II) are often given two options for initial treatment: mastectomy or lumpectomy plus radiation.
- Factors that surgeons consider when determining whether to recommend lumpectomy plus radiation as a treatment option for women with breast cancer include size and extent of the tumor, the biology of the tumor, location of the tumor, pregnancy or another condition that would make radiation unsafe, and having a history of prior lumpectomy and/or radiation.

#### Lumpectomy With Radiation vs. Mastectomy

- There is clear and convincing evidence from multiple randomized controlled trials (RCTs) that rates of overall survival and local/regional recurrence of breast cancer are equivalent for women with stage I or II breast cancer who are treated with mastectomy or lumpectomy plus radiation.

#### Lumpectomy With Radiation vs. Lumpectomy Alone

- There is clear and convincing evidence from multiple RCTs that women with stage I or II breast cancer who receive lumpectomy with radiation have a lower rate of in-breast recurrence of breast cancer than women with stage I or II cancer who receive lumpectomy alone (i.e., without radiation). There is also a preponderance of evidence that they also have a lower rate of death from all causes.
- There is clear and convincing evidence that women with ductal carcinoma in situ (DCIS) who receive lumpectomy with radiation have lower rates of in-breast recurrence of DCIS and invasive breast cancer than women with DCIS who receive lumpectomy alone.

## **Benefit Coverage, Utilization, and Cost Impacts**

- DHMC-regulated plans and CDI-regulated policies are estimated to be currently compliant with the provision in SB 255 of medically necessary lumpectomy upon provider referral. Therefore, no measurable change in coverage for these services is expected.
- DHMC-regulated plans and CDI-regulated policies are estimated to be currently compliant with the provision in SB 255 requiring coverage of postsurgery consultation regarding the length of any hospital stay.
- Approximately 4,000 women enrolled in DMHC-regulated plans and CDI-regulated policies receive lumpectomies in California each year. The average per-unit cost of lumpectomy is \$6,958. The \$6,958 average unit cost of lumpectomy is based on the average allowed charge per case in California for a hospital stay or outpatient procedure associated with lumpectomy.
- As no measurable change in benefit coverage is expected (100% of female enrollees in DMHC-regulated plans and CDI-regulated policies are estimated to be in compliant plans), no measurable change in utilization is projected.
- As no measurable change in benefit coverage is expected, no measurable changes in total premiums and total health care expenditures are expected.
- As no measurable change in benefit coverage or cost is expected, no measurable change in the number of uninsured persons is expected.

## **Public Health Impacts**

- Although lumpectomy procedures are medically effective treatments for DCIS, stage I, and some stage II cancers, CHBRP finds that no change in enrollee coverage or utilization of this treatment would occur through SB 255. Therefore, CHBRP anticipates no public health impact on short- and long-term health outcomes, possible disparities, premature death, or economic loss related to breast cancer or its treatment through lumpectomy procedures.

## **Potential Effects of the Federal Affordable Care Act**

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

statutory and regulatory actions to be taken by California state government. The provisions that go into effect during these transitional years would affect the baseline, or current enrollment, expenditures, and premiums. It is important to note that CHBRP's analysis of specific mandate bills typically addresses the marginal effects of the mandate bill—specifically, how the proposed mandate would impact benefit coverage, utilization, costs, and public health, holding all other factors constant. CHBRP's estimates of these marginal effects are presented in this report.

### Essential health benefits offered by qualified health plans in the Exchange and potential interactions with SB 255

Essential health benefits (EHBs) are defined to include ambulatory patient services; hospitalization; and preventive and wellness services and chronic disease management. In addition, HHS when promulgating regulations on EHBs is to ensure that the EHB floor “is equal to the scope of benefits provided under a typical employer plan.” Virtually all employers provide coverage for lumpectomy services. Therefore, it is highly unlikely that there would be any impacts resulting from SB 255 in the longer term (beyond 2014).

The ACA requires, beginning 2014, for states to “make payments...to defray the cost of any additional benefits” required of QHPs sold in the Exchange.<sup>5</sup> This potential liability would depend on three factors:

- Differences in the scope of “benefits in the final EHB package and the scope of mandated benefits in SB 255;
- The number of enrollees in QHPs; and
- The methods used to define and calculate the cost of additional benefits.

Again, because lumpectomy services as defined under SB 255 are considered standard coverage for employer-based plans, and because they are likely to be considered part of EHBs, it is unlikely that there would be any additional fiscal liability to the state for qualified health plans offered in the Exchange as a result of this mandate.

---

<sup>5</sup> Affordable Care Act, 1311(d)(3)(B).

## INTRODUCTION

The California Assembly Committee on Health requested on February 11, 2011, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Senate Bill (SB) 255, a bill that would impose a health benefit mandate by revising and recasting the definition of mastectomy to include surgical treatment for breast cancer. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.<sup>6</sup>

### Analysis of SB 255

Approximately 21.9 million Californians (59%) have health insurance that may be subject to a health benefit mandate law passed at the state level.<sup>7</sup> Of the rest of the state's population, a portion is uninsured (and so has no health insurance subject to any benefit mandate), and another portion has health insurance subject to other state laws or only to federal laws.

Uniquely, California has a bifurcated system of regulation for health insurance subject to state-level benefit mandates. The California Department of Managed Health Care (DMHC)<sup>8</sup> regulates health care service plans, which offer benefit coverage to their enrollees through health plan contracts. The California Department of Insurance (CDI) regulates health insurers,<sup>9</sup> which offer benefit coverage to their enrollees through health insurance policies.

DMHC-regulated plans and/or CDI-regulated policies would be subject to SB 255. Therefore, the mandate would affect the health insurance of approximately 21.9 million Californians (59%).

### *Bill language*

The full text of SB 255 can be found in Appendix A.

Currently, California law requires health plans and insurers to cover breast cancer screening and treatment. SB 255 would amend existing California law by clarifying the definition of mastectomy to specify that partial removal of the breast includes, but is not limited to, lumpectomy. Lumpectomy is the surgical removal of the tumor with clear margins without excision of the entire breast. The bill would require coverage of postsurgery consultation regarding the length of any hospital stay.

---

<sup>6</sup> CHBRP's authorizing statute is available at: [http://www.chbrp.org/documents/authorizing\\_statute.pdf](http://www.chbrp.org/documents/authorizing_statute.pdf).

<sup>7</sup> CHBRP's estimates are available at: [http://www.chbrp.org/documents/insur\\_source\\_est\\_2011.pdf](http://www.chbrp.org/documents/insur_source_est_2011.pdf).

<sup>8</sup> DMHC was established in 2000 to enforce the Knox-Keene Health Care Service Plan of 1975; see Health and Safety Code, Section 1340.

<sup>9</sup> CDI licenses "disability insurers." Disability insurers may offer forms of insurance that are not health insurance. This report considers only the impact of the benefit mandate on health insurance policies, as defined in Insurance Code, Section 106(b) or subdivision (a) of Section 10198.6.

### *Analytic approach and key assumptions*

Due to existing law, described in the following text, CHBRP does not expect SB 255 to have any measurable cost impact.

According to the bill author, this bill is intended as a modest clarification, to help ensure that safe minimum standards are followed, and to help reduce the number of complications for women following lumpectomy procedures. The bill author noted that her office has heard about confusion from patients about coverage, and has reviewed patient education materials from DHCS that separate mastectomy and lumpectomy, raising concerns that there is confusion on this issue, among patients, and maybe even for providers and insurers. Furthermore, the bill author noted that this issue has become more important, in terms of clarifying that lumpectomy is a covered benefit, as treatment strategies around breast cancer have focused more on “breast conservation measures” when appropriate, as opposed to full mastectomy.

### *Existing California requirements*

Existing legislation addresses lumpectomy for both health care service plans regulated by DMHC and insurance policies regulated by CDI.

Health and Safety Code Section 1367.6(a) requires that full-service health plans provide coverage for treatment for breast cancer, which includes, but is not limited to, lumpectomies. Additionally, Section 1367.6(e) defines “mastectomy” to include “removal of all or part of the breast for medically necessary reasons...,” which implies coverage for lumpectomies.<sup>10</sup> Additionally, the California Insurance Code (CIC) Section 10123.8 mirrors the Health & Safety Code, by stating: “Every policy...issued, amended, delivered, or renewed on or after 1/1/2000, shall provide coverage for screening for, diagnosis of, and treatment for, breast cancer.” Partial removal of breast is required to be covered under CIC 10123.8(e), “...mastectomy means removal of all or part of the breast...” CDI currently expects lumpectomies to be covered under “treatment” requirements for breast cancer.<sup>11</sup>

Existing law also requires that both DMHC-regulated plans and CDI-regulated policies allow for coverage of prosthetic devices or reconstructive surgery, including devices or surgery to restore and achieve symmetry for the patient incident to the mastectomy. Coverage for prosthetic devices and reconstructive surgery are subject to the deductible and coinsurance conditions applicable to other benefits.

AB 7, enacted in 1998, requires every health care service plan contract and every policy of disability insurance that is issued, amended, renewed, or delivered on and after January 1, 1999, that provides coverage for mastectomies and lymph node dissections, to allow the length of a hospital stay associated with these procedures to be determined by the attending physician and surgeon in consultation with the patient and consistent with sound clinical principles and processes, to cover prosthetic devices or reconstructive surgery, and to cover all complications from a mastectomy.

---

<sup>10</sup> Personal communication, A Abu-Rahma, DMHC, February 2011.

<sup>11</sup> Personal communication J. Figueroa, CDI, March 2011.

The following is a list of complaints received by DMHC by Complaint Type for Lumpectomies. DMHC data only goes back to November 2001. There were a total of 164 complaints. The most common complaints included access and referral issues, as well as investigational treatment issues. Relatively few complaints were related to benefit coverage.<sup>12</sup> CDI reported no Independent Medical Review (IMR) requests, and no complaints to the staff's knowledge (formal tracking of complaints by CDI, by diagnosis or treatment, did not begin until 2010).<sup>13</sup>

#### *Federal requirements and requirements in other states*

The Women's Health and Cancer Rights Act of 1998 (WHCRA) is a federal law that provides protections to patients who choose to have breast reconstruction in connection with a mastectomy.

This law applies to three different types of coverage:

- Self-funded group health plans (the Centers for Medicare & Medicaid Services has jurisdiction over self-funded public sector (nonfederal governmental) plans, whereas the Department of Labor 866-444-3272 has jurisdiction over private sector self-funded group health plans);
- Fully insured group health plans; and
- Individual (nonemployment-based) health insurance policies.

Under the WHCRA, mastectomy benefits must cover:

- Reconstruction of the breast that was removed by mastectomy;
- Surgery and reconstruction of the other breast to make the breasts look symmetrical or balanced after mastectomy;
- Any external breast prostheses that are needed before or during the reconstruction; and
- Any physical complications at all stages of mastectomy, including lymphedema.

Currently, 20 states mandate minimum in-patient coverage after a patient undergoes a mastectomy, including California. Lumpectomy does not routinely require an overnight stay.

#### Potential Effects of Federal Affordable Care Act

The federal "Patient Protection and Affordable Care Act" (P.L.111-148) and the "Health Care and Education Reconciliation Act" (H.R.4872) were enacted in March 2010. These laws (together referred to as the "Affordable Care Act" [ACA]) are expected to dramatically affect the

---

<sup>12</sup> Personal communication, A. Abu-Rahma, DMHC, February 2011.

<sup>13</sup> Personal communication, J. Figueuroa, CDI, March 2011.

California health insurance market and its regulatory environment, with most changes becoming effective in 2014. How these provisions are implemented in California will largely depend on pending legal actions, funding decisions, regulations to be promulgated by federal agencies, and statutory and regulatory actions to be taken by California state government.

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

A number of ACA provisions will need regulations and further clarity. One example is the ACA's requirement for certain health insurance to cover "essential health benefits." Effective 2014, Section 1302(b) will require small-group and individual health insurance, including "qualified health plans" that will be sold in the California Exchange, to cover specified categories of benefits. These essential health benefits (EHBs) are defined as ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care. The Secretary of Health and Human Services (HHS) is charged with defining these categories through regulation, ensuring that the EHB floor "is equal to the scope of benefits provided under a typical employer plan." In addition, the ACA would allow a state to "require that a qualified health plan offered in [the Exchange] offer benefits in addition to the essential health benefits." If the state does so, the state must make payments to defray the cost of those additionally mandated benefits, either by paying the individual directly, or by paying the qualified health plan. This ACA requirement could interact with existing and proposed California benefit mandates, especially if California decided to require qualified health plans to cover California-specific mandates, and those mandates were determined to go beyond the EHB floor. Federal regulations regarding which benefits are to be covered under these broad EHB categories and other details, such as how the subsidies for purchasers of qualified health plans are structured, are forthcoming.<sup>14</sup>

*Essential health benefits offered by qualified health plans in the Exchange and potential interactions with SB 255*

As mentioned, EHBs are defined to include ambulatory patient services; hospitalization; and preventive and wellness services and chronic disease management. In addition, HHS when

---

<sup>14</sup> For further discussion on EHBs and potential interaction with state mandates, please see, *California's State Benefit Mandates and the Affordable Care Act's "Essential Health Benefits"* available at: <http://www.chbrp.org/documents/ACA-EHB-Issue-Brief-011211.pdf>.

promulgating regulations on EHBs is to ensure that the EHB floor “is equal to the scope of benefits provided under a typical employer plan.” Virtually all employers provide coverage for lumpectomy services. Therefore, it is highly unlikely that there would any impacts resulting from SB 255 in the longer term (beyond 2014).

The ACA requires, beginning 2014, for states to “make payments...to defray the cost of any additional benefits” required of QHPs sold in the Exchange.<sup>15</sup> This potential liability would depend on three factors:

- Differences in the scope of benefits in the final EHB package and the scope of mandated benefits in SB 255;
- The number of enrollees in QHPs; and
- The methods used to define and calculate the cost of additional benefits.

Again, because lumpectomy services as defined under SB 255 is considered standard coverage for employer-based plans, and because it likely to be considered part of EHBs, it is unlikely that there would be any additional fiscal liability to the state as a result of this mandate.

## **Background on Breast Cancer**

This section provides some background on breast cancer rates, but focuses on the prevalence of early stage (stage I and II) breast cancer because of SB 255’s emphasis on lumpectomy. Lumpectomy with radiation is a standard of care for early stage breast cancer (NCI, 2011). (See the *Medical Effectiveness* section for more detail.)

Breast cancer is the most commonly diagnosed cancer in California. In 2008, there were nearly 30,000 new cases of breast cancer diagnosed (including in situ cancer<sup>16</sup>) (CCR, 2011). This translates to an annual age-adjusted incidence rate of 153.1 cases of breast cancer per 100,000 women in California (CCR, 2011). An average woman’s lifetime risk of being diagnosed with breast cancer in California is one in eight (CCR, 2010). There are nearly 300,000 women currently living with breast cancer (defined as having or ever had) in California (CCR, 2010).

Breast cancer overwhelmingly affects women, although a small number of cases are diagnosed in men as well. In California, it is estimated that 0.7% of cases of breast cancer occur in men—about 165 cases and 30 deaths each year (CCR, 2010). For this analysis, CHBRP assumes that appropriate breast cancer treatment for men would not differ substantially than that for women.

In California, 71% of breast cancer is diagnosed in the early stages (see Table 1) (CCR, 2010). non-Hispanic White and Asian/Pacific Islander women have the highest incidence of early stage

---

<sup>15</sup> Affordable Care Act, 1311(d)(3)(B).

<sup>16</sup> In situ cancer refers to cancer cells that are confined to the ducts or lobules of the breast and have not invaded deeper tissues in the breast or spread to other organs. In situ breast cancer is sometimes referred to as noninvasive or pre-invasive breast cancer (ACS, 2010).



breast cancer diagnosis (72% and 73%, respectively), whereas Hispanic/Latina and African American women have the lowest (64% and 63%, respectively) (CCR, 2010).

Among California women, the 5-year relative survival rate for breast cancer is 91% (CCR, 2010). This rate varies with the stage of diagnosis, with a 99% 5-year survival rate for localized or in situ breast cancer (CCR, 2010). In 2008, there were approximately 4,200 female deaths due to breast cancer in California, equivalent to an annual mortality rate of 21.4 per 100,000 women (CCR, 2011). The mortality rates among racial and ethnic groups generally correspond to the rates of early stage diagnosis (Table 1). For example, African American women have the highest breast cancer mortality rate and the lowest percentage of early stage diagnosis of breast cancer, and the Asian/Pacific Islander women have the lowest mortality rate and the highest percentage of early stage diagnosis.

**Table 1.** Incidence, Stage, and Mortality Rates for Female Breast Cancer by Race/Ethnicity in California, 2008

Population	Incidence Rate for All Stages of Breast Cancer (per 100,000)	% Cancers Diagnosed at an Early Stage (a)	Mortality Rate for All Stages of Breast Cancer (per 100,000)
Overall	153.1	71%	21.4
Hispanic/Latina	108.9	64%	16.6
White (non-Hispanic)	174.8	72%	23.7
African American (non-Hispanic)	154.9	63%	31.9
Asian/Pacific Islander	129.2	73%	13.3

Source: California Health Benefits Review Program, 2011 (based on California Cancer Registry [CCR], 2010, 2011).

Notes: Data are age-adjusted to the 2000 U.S. Standard Million Population and reflect all breast cancer incidences, including in situ cancers.

(a) Data from *California Cancer Facts and Figures, 2011* (CCR, 2011) and reflect cases reported to the California Cancer Registry in 2008. Early stage is defined as in situ or localized, and corresponds with stage I or II.

## MEDICAL EFFECTIVENESS

Breast cancer is typically treated through a combination of surgery and/or radiation, and may include chemotherapy and hormone therapy. Initial treatment usually consists of surgery to remove the tumor from the breast, although some women receive chemotherapy prior to surgery to reduce the size of the tumor.

Women with early stage breast cancer (i.e., stage 0, I, or II) are often given two options for surgery: mastectomy or lumpectomy plus radiation.

Mastectomy is performed under general anesthesia. Most women treated with mastectomy are hospitalized for at least one night following surgery. The entire affected breast plus some lymph nodes are removed. (The lymph nodes are removed to determine whether the cancer has spread to them.) Women who have a mastectomy may choose to have breast reconstruction at the same time or at a later date (FIMDM, 2009).

Lumpectomy is performed under either local or general anesthesia and is typically provided on an outpatient basis in a hospital or outpatient surgical center. The area of the breast in which the tumor is located plus a border of healthy tissue around the tumor are removed. A second incision is often made under the arm to remove some lymph nodes.<sup>17</sup> The border of healthy tissue around the tumor is referred to as the surgical *margin*. If the surgical margin is not free of cancer, a second surgery is performed to obtain cancer-free margins.

Most women who receive lumpectomy are also treated with radiation.<sup>18</sup> Women typically begin radiation treatment 4 to 6 weeks following surgery and receive radiation 5 days per week over the course of 3 to 6 weeks (FIMDM, 2009). During these treatments, the whole breast is exposed to radiation. Researchers are currently studying partial breast radiation and targeted intraoperative radiation as alternatives to whole breast radiation. Partial breast radiation involves the use of balloons, catheters, implanted seeds, or external beams of radiation to treat only the area around where the tumor had been (Polgár et al., 2007; Sauer et al., 2005). Partial breast radiation also includes intraoperative radiation, which consists of providing a single dose of radiation targeted to the area around the tumor during lumpectomy surgery (Vaidya et al., 2010).

Breast cancer surgeons consider several major factors when determining whether to recommend lumpectomy plus radiation as a treatment option. Surgeons are most likely to recommend lumpectomy as an option to women who have small tumors in a single area of the breast. Lumpectomy is not recommended for women who have had prior radiation of the chest wall, are pregnant or have another condition that would make radiation unsafe, or who have had a prior lumpectomy in which the whole tumor plus a border of healthy tissue could not be removed, regardless of the size of the tumor (FIMDM, 2009; NCCN, 2011).

---

<sup>17</sup> Some women may have a separate procedure to remove lymph nodes prior to surgery for purposes of staging the cancer.

<sup>18</sup> Women treated with mastectomy who are at increased risk for recurrence of breast cancer (e.g., large tumor, positive lymph nodes) may also receive radiation following surgery (FIMDM, 2009).

Following mastectomy or lumpectomy plus radiation, women may be treated with chemotherapy and/or hormone therapy depending on the characteristics of their cancers, such as the grade (i.e., the degree of abnormality observed in the cancer cells), the presence or absence of cancer in the lymph nodes, whether the tumor has too much HER2/neu<sup>19</sup> protein, and whether the tumor is hormone receptor positive (FIMDM, 2009; NCCN, 2011).

The medical effectiveness review for SB 255 addresses the following questions:

- What is the evidence of the effectiveness of lumpectomy with radiation relative to mastectomy?
- What is the evidence that supplementing lumpectomy with radiation improves health outcomes?
- What is the evidence regarding the relative effectiveness of targeted versus whole breast radiation for women undergoing lumpectomy?

## **Literature Review Methods**

Studies of the effectiveness of lumpectomy were identified through searches of PubMed and the Cochrane Library. The search was limited to abstracts of meta-analyses, systematic reviews, and randomized controlled trials (RCTs) that were published in English. Abstracts for studies published from 2002 to present were retrieved, because findings from 25 years of follow-up to a large randomized controlled trial conducted in the United States that compared mastectomy to lumpectomy with and without radiation were published in that year (Fisher et al., 2002). A total of eight studies were included in the medical effectiveness review. A more thorough description of the methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure is presented in Appendix B: Literature Review Methods. Appendix C includes a table describing the studies that CHBRP reviewed (Table C-1) and a table summarizing findings from these studies (Table C-2).

## **Outcomes Assessed**

The studies included in the medical effectiveness review addressed two major outcomes of breast cancer treatment.

- Survival; and
- Recurrence of breast cancer.

---

<sup>19</sup> HER2/neu stands for "Human Epidermal growth factor Receptor 2" and is a protein giving higher aggressiveness in breast cancer.

Most studies compared the impact of mastectomy versus lumpectomy plus radiation on overall rates of survival. A few studies examined effects on disease-free survival (i.e., the length of time until breast cancer recurred).

The studies measured recurrence of breast cancer in several different ways. The most frequently used measure was the local or regional recurrence rate, which indicates the rate at which women experienced recurrence of breast cancer in the breast and/or lymph nodes near the breast. Some studies assessed the overall rate of recurrence or the rate of distant recurrence (i.e., the rate at which breast cancer recurs in another organ of the body, also known as metastatic disease).

## Study Findings

### Lumpectomy With Radiation vs. Mastectomy

Multiple RCTs comparing outcomes of lumpectomy plus radiation to outcomes of mastectomy have been conducted in countries throughout the world since the 1970s. A recent meta-analysis synthesized findings from 16 RCTs that enrolled 9,388 women with stage I or stage II breast cancer who had no evidence of metastatic disease and no prior history of cancer (Yang et al., 2008). The authors found no statistically significant differences in overall survival and rates of local or regional recurrence between women who received lumpectomy with radiation and women who received mastectomy. Findings were consistent across all lengths of follow-up assessed (3 years, 5 years, 10 years, 15 years, and 20 years).

Several of the individual studies included in Yang et al.'s (2008) meta-analysis compared the effects of mastectomy and lumpectomy plus radiation on other health outcomes. A large RCT conducted in the United States found no statistically significant difference in disease-free survival among women with stage I or II breast cancer 20 years after surgery (Poggi et al., 2003). The authors of an international RCT that enrolled women with stage I or II breast cancers of up to 5 cm in diameter who had not previously had cancer found no statistically significant difference in distant disease-free survival (van Dongen et al., 2000).

There is *clear and convincing evidence* from multiple RCTs that rates of overall survival and local regional recurrence of breast cancer are equivalent for women with stage I or II breast cancer that are treated with mastectomy or lumpectomy plus radiation.

### Lumpectomy With Radiation vs. Lumpectomy Alone

Questions have been raised regarding the necessity of providing both lumpectomy and radiation to women with early stage breast cancer. Radiation may affect cosmetic results, damage the heart and lungs, and lead women to develop new cancers. Women living in areas without radiation facilities may have to travel long distances to obtain treatment. Radiation also prolongs treatment, which may result in a loss of income (Vinh-Hung and Verschraegen, 2004).

A meta-analysis synthesized findings from RCTs that assessed the impact of supplementing lumpectomy with radiation (Vinh-Hung and Verschraegen, 2004). The authors pooled findings from 15 RCTs that enrolled a total of 9,422 women with stage I or stage II breast cancer. They found that women who were treated with lumpectomy alone had a higher relative risk of death from all causes than women treated with both lumpectomy and radiation and that the difference was statistically significant.<sup>20</sup> Women treated with lumpectomy alone had an 8.6% greater relative risk of death from all causes. The authors also found that the relative risk of in-breast recurrences of cancer was three times greater in women who received lumpectomy alone compared to women who received both lumpectomy and radiation.

Three RCTs that enrolled women with stage I or II breast cancer and were published after the RCTs included in the meta-analysis found no statistically significant differences in mortality rates 5 years after treatment (Hughes et al., 2004) (Potter et al., 2007; Tinterri et al., 2009).<sup>21</sup> Findings regarding rates of local recurrence differed between these three RCTs. Potter et al. (2007) reported that women treated with both lumpectomy and radiation had a lower rate of in-breast recurrence than women treated with lumpectomy alone, whereas Tinterri et al. (2009) found no statistically significant differences between the two groups. One possible explanation for the difference in findings concerns the age of the women enrolled. Tinterri et al. (2009) limited enrollment to women age 55 to 75 years, whereas some of the women enrolled in Potter et al.'s (2007) RCT were under age 55 years. An additional RCT by Hughes et al. (2004) reported that women over 70 years old treated with lumpectomy and tamoxifen compared to women over 70 years old treated with lumpectomy and tamoxifen plus radiation showed statistically significant better 5-year rate of local and regional recurrence but no statistically significant rates of overall survival were reported. Breast cancer grows more slowly in postmenopausal than in premenopausal women, which may dampen the impact of radiation, especially in studies with relatively short follow-up periods.

A recent meta-analysis assessed the impact of supplementing lumpectomy with radiation among women with stage 0 breast cancer, which is also known as ductal carcinoma in situ (DCIS) (Goodwin et al., 2009). The meta-analysis pooled findings from four RCTs that enrolled 3,925 women. The authors found that women treated with both lumpectomy and radiation had a lower rate of in-breast recurrence of breast cancer than women treated with radiation alone. Among women who received both lumpectomy and radiation, the rate of in-breast recurrence was 11%, whereas the rate of in-breast recurrence was 22% among women who received lumpectomy alone. Women treated with both lumpectomy and radiation had lower rates of both in-breast recurrence of DCIS and in-breast recurrence of invasive breast cancer. Adding radiation to lumpectomy reduced the relative risk of in-breast recurrence for both women under age 50 years

---

<sup>20</sup> No statistically significant differences in mortality were found in the 15 RCTs included in the meta-analysis, but the pooled effect was statistically significant (Vinh-Hung and Verschraegen, 2004).

<sup>21</sup> An article that presented final results from an RCT for which preliminary results were included in the Vinh-Hung and Verschraegen, 2004 also reported that 5 years following surgery, there was no difference in overall survival between women treated with lumpectomy, radiation, and tamoxifen and those treated with only lumpectomy and tamoxifen (Fyles et al., 2004). Final results from this RCT also indicate that women who were treated with lumpectomy, radiation, and tamoxifen had lower rates of in-breast recurrence and axillary recurrence (i.e., recurrence in the lymph nodes in the arm pit) within 5 years of surgery than women who were treated with only lumpectomy and tamoxifen.

and women over age 50 years, with a stronger effect observed among women age 50 years or older (relative risk=35% versus 67%).

There is *clear and convincing evidence* that women with ductal carcinoma in situ (DCIS), stage I, or stage II breast cancer who receive lumpectomy *with* radiation have lower rates of in-breast recurrence of cancer than women who receive lumpectomy alone. There is a preponderance of evidence that women with stage I and II breast cancer who receive lumpectomy *with* radiation also have a higher rate of survival.

## **BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS**

Senate Bill (SB) 255 would impose a health benefit mandate, by revising and recasting the definition of mastectomy to include surgical treatment for breast cancer. The bill would require the consultation regarding the length of any hospital stay to be conducted postsurgery.

This section presents the current, or baseline, costs and benefit coverage related to lumpectomy, and the estimated utilization, cost, and benefit coverage impacts if SB 255 is enacted. For further details on the underlying data sources and methods, please see Appendix D at the end of this document.

### **Current (Baseline) Benefit Coverage, Utilization, and Cost**

#### Current Coverage of the Mandated Benefit

Approximately 21,902,000 persons in California are enrolled in health plans or policies that would be subject to the mandate. Of these 21.9 million enrollees, 2,858,000 are in California Department of Insurance (CDI)-regulated plans. Current lumpectomy coverage was determined by a survey of the seven largest providers of health insurance in California.<sup>22</sup> The California Health Benefits Review Program (CHBRP) surveys the largest major health plans and insurers about coverage. Responses to this survey represented 68.2% of the CDI-regulated market and 82.4% of the California Department of Managed Health Care (DMHC)-regulated market. Combined, responses to this survey represent 79.5% of the privately funded market subject to state mandates.

Existing legislation addresses lumpectomy for both health care service plans regulated by DMHC and insurance policies regulated by CDI. On the basis of existing law, and CHBRP's survey, CHBRP estimates that 100% of female enrollees in DMHC-regulated plans and CDI-regulated policies have benefit coverage compliant with SB 255. Publicly funded plans such as the California Public Employees' Retirement System health maintenance organizations (CalPERS HMOs), Medi-Cal Managed Care Plans, Healthy Families Program (HFP), Access for Infants and Mothers (AIM), and Major Risk Medical Insurance Program (MRMIP) have lumpectomy coverage compliant with SB 255.

---

<sup>22</sup> CHBRP analysis of the share of enrollees included in CHBRP's Bill-Specific Coverage Survey of the major carriers in the state is based on "CDI Licenses with HMSR Covered Lives Greater Than 100,000" as part of the Accident and Health Covered Lives Data Call, December 31, 2009, by the California Department of Insurance, Statistical Analysis Division, data retrieved from the Department of Managed Health Care's interactive Web site "Health Plan Financial Summary Report," July-September, 2010, and CHBRP's Annual Enrollment and Premium Survey.

### Current Utilization Levels

CHBRP's Bill-Specific Coverage Survey found that 100% of enrollees in DMHC- and CDI-regulated policies have benefit coverage for lumpectomy as part of treatment for breast cancer. Baseline utilization of women receiving lumpectomies is approximately 4,000 annually. The mandate is not expected to change the number of women receiving lumpectomies nor the number of individuals with mandated coverage of lumpectomies.

### Per-Unit Cost

The cost per lumpectomy case is estimated at \$6,958, which is the average unit cost of the inpatient hospital charges or outpatient procedure costs associated with lumpectomy cases. SB 255 is not expected to affect the per-unit cost of lumpectomy or increase the utilization of lumpectomy treatment for breast cancer because an estimated 100% of enrollees have lumpectomy coverage.

### Current (Baseline) Premiums and Expenditures

Per member per month (PMPM) premiums for privately funded CDI-regulated policies are currently \$497.52 in large-group policies, \$334.45 in small-group policies, and \$199.13 in individual policies.

Per member per month (PMPM) premiums for privately funded DMHC-regulated plans are \$400.51 in large-group policies, \$350.57 in small-group policies, and \$399.69 in individual policies.

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

An estimated 100% of enrollees in DMHC-regulated plans and CDI-regulated policies are covered for lumpectomy as a treatment for breast cancer, as would be required by SB 255. Therefore, CHBRP estimates no cost shifting as a result of SB 255.

As SB 255 would have no measurable impact on benefit coverage or utilization of lumpectomy treatments.

### Public Demand for Benefit Coverage

Considering the criteria specified by CHBRP's authorizing statute, CHBRP reviews public demand for benefits relevant to a proposed mandate in two ways. CHBRP considers the bargaining history of organized labor and compares the benefits provided by self-insured health plans or policies (which are not regulated by the DMHC or CDI and thus 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 lumpectomy is a covered benefit for the members of at least one large union.<sup>23</sup>

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

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

On the basis of coverage levels of self-insured plans and responses from large unions and existing state and federal law, CHBRP concludes that there may be some public demand for lumpectomy by collective bargaining agents and by self-insured plans.

## **Impacts of Mandated Benefit Coverage**

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

#### *Impact on access and health treatment/service availability*

CHBRP does not predict changes in supply or health benefits of lumpectomies due to SB 255. No supply constraints are currently associated with lumpectomies. SB 255 is not expected to change access to lumpectomy treatment among female enrollees of CDI-regulated plans or DMHC-regulated health plans.

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

SB 255 would not be expected to change coverage of lumpectomy treatment since CHBRP estimates that 100% of enrollees in DMHC-regulated plans and CDI-regulated policies already have coverage for medically necessary lumpectomy upon a provider's referral.

#### *Impact on per-unit cost*

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

---

<sup>23</sup> Personal communication, S. Flocks, California Labor Federation, March 2011.

### How Would Utilization Change as a Result of the Mandate?

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

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

This mandate would not be expected to increase administrative expenses for health plans and insurers for lumpectomy coverage since health plans and insurers that would be subject to SB 255 already cover an estimated 100% of enrollees in a compliant fashion. SB 255 would not be likely to increase administrative costs due to postsurgery consultation after lumpectomy procedure because 100% of enrollees with benefit coverage already have coverage for medically necessary hospitalization for complications resulting from lumpectomy.

It is not expected that SB 255 would increase the share of premiums paid by employees, employers, policyholders, or public agencies that enroll their beneficiaries in DMHC-regulated plans.

### Impact of the Mandate on Total Health Care Costs

#### *Changes in total expenditures*

SB 255 would not be expected to increase total expenditures of employees with DMHC-regulated health plans or CDI-regulated health policies. Likewise, SB 255 would not be expected to increase total expenditures of employers in the small-group, large-group, or individual markets. Publicly funded plans (i.e., CalPERS HMOs, Medi-Cal Managed Care Plans, HFP, AIM, MRMIP) would be unaffected as well.

#### *Potential cost offsets or savings in the short term*

SB 255 would not be expected to change coverage of lumpectomy treatment by a measurable amount because 100% of enrollees in plans subject to the mandate are estimated to be covered. Since no changes in the coverage of lumpectomies or notifications of lumpectomy eligibility are expected no cost offsets or savings are expected in the short term.

#### *Impacts on long-term costs*

SB 255 would not change PMPM premiums or total expenditures of employers and employees with DMHC-regulated health plans or CDI-regulated health policies, including publicly purchased plans. Since no changes in the coverage of lumpectomies or notifications would be expected, no cost offsets no effects on long-term costs are expected.

## Impacts for Each Category of Payor Resulting From the Benefit Mandate

### *Changes in expenditures and PMPM amounts by payor category*

SB 255 would not be expected to increase total expenditures and PMPM premiums in the large-group, small-group, or individual markets for DMHC-regulated plans or CDI-regulated policies. Total expenditures and PMPM premiums in CalPERS HMOs, Medi-Cal Managed Care, and MRMIB plans are not expected to increase.

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

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

Since SB 255 would not be expected to lead to premium increases, CHBRP estimates no measurable loss of health insurance coverage as a result of SB 255. CHBRP's method for estimating the impact of premium increases on the number of individuals who drop their private insurance is described on CHBRP's Web site.<sup>24</sup>

### *Impact on public programs as a result of premium increases*

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

---

<sup>24</sup> CHBRP's method for estimating the effect of premium increases on the number of individuals who drop their private insurance is described on CHBRP's Web site: [http://chbrp.org/documents/uninsured\\_010109.pdf](http://chbrp.org/documents/uninsured_010109.pdf).

## PUBLIC HEALTH IMPACTS

Currently California law requires health plans and insurers to cover breast cancer screening and treatment. SB 255 would amend existing California law by clarifying the definition of mastectomy to specify that partial removal of the breast includes, but is not limited to, lumpectomy. In addition, the bill would require coverage for postsurgery consultation regarding the length of any hospital stay.

CHBRP's analysis finds that SB 255 would have no impact on public health outcomes, including gender and racial disparities, premature death, economic loss and harms associated with breast cancer and its treatment. As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, CHBRP estimates there will be no change in benefit coverage or utilization of lumpectomies as a result of SB 255; therefore, we anticipate no impact on public health.

### Public Health Outcomes

As described in the *Medical Effectiveness* section, there is clear and convincing evidence that lumpectomy with radiation is as medically effective as mastectomy for stage I and II breast cancers. The standard of care for early stage breast cancer is lumpectomy with radiation. However, SB 255 is not expected to increase the number of enrollees with benefit coverage for lumpectomy procedures nor change utilization of services (see the *Benefit Coverage, Utilization, and Cost Impacts* section). Therefore, no public health impact is expected.

SB 255 is not expected to increase the number of enrollees with benefit coverage for lumpectomy procedures nor change utilization of services. Therefore, no public health impact is expected.
--

### Potential Harms

There is evidence to suggest that the use of lumpectomy treatment is not without risk and is not without side effects. Standard practice recommends use of adjuvant radiation therapy following a lumpectomy (NCI, 2011). Two possible harms are associated with radiation therapy that accompanies lumpectomy: short-term toxicity and long-term cardiovascular disease. More recent evidence indicates that improvements in precision in delivery of radiation have recently reduced short-term toxicity by limiting exposure of normal tissue (Goodwin et al., 2009). In the longer term, those with radiation exposure to the left chest wall may increase their risk of cardiovascular disease by 20%-30% compared to women with no radiation to the left chest wall, but this risk is outweighed by the reduction in breast cancer recurrence and mortality (Clarke et al., 2005). CHBRP concludes that these risks are outweighed by the reduction in breast cancer recurrence and mortality.

Research indicates no difference or a slight improvement in quality of life measures when comparing women who have been treated with lumpectomy versus mastectomy (with and

without reconstructive surgery) (Pockaj et al., 2009). Quality of life measures include depressive symptoms, anxiety, body image, stigma, and sexual function. Researchers typically survey women before and after surgery to measure changes over time. One study found that women in all three groups adjusted well between 6-24 months postsurgery, and that measures of quality of life at 24 months were similar to measures taken before surgery (Parker et al., 2007). Another study found lumpectomy patients reported statistically significant and higher quality of life (88%) 4 years after surgery than women with mastectomy (83%). This was true for both sets of patients with and without reconstruction (Waljee et al., 2011).

## **Impact on Gender and Racial Disparities**

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

CHBRP investigated the effect that SB 255 would have on health disparities by gender, race, and ethnicity. Evaluating the impact on racial and ethnic disparities is particularly important because racial and ethnic minorities report having poorer health status and worse health indicators (KFF, 2007). One important contributor to racial and ethnic health disparities is differential rates of insurance, where minorities are more likely than Whites to be uninsured; however disparities still exist within the insured population (Kirby et al., 2006; Lillie-Blanton and Hoffman, 2005). Since SB 255 would only affect the insured population, a literature review was conducted to determine whether there are gender, racial, or ethnic disparities associated with the prevalence and treatment of breast cancer outside of disparities attributable to differences between insured and uninsured populations.

As noted in the *Introduction*, breast cancer overwhelmingly affects women, although a small number of cases are diagnosed in men as well. In California, it is estimated that 0.7% of cases of breast cancer occur in men—about 165 cases and 30 deaths each year (CCR, 2010). For the purposes of this report, CHBRP assumes treatment for men and women is equivalent.

As shown in Table 1, a smaller proportion of early stage breast cancer is detected in Hispanic/Latina and African American women compared to White and Asian women. Among women who are insured, differences in breast cancer survival rates by race persist. For instance, one study of women in the U.S. military showed that even after controlling for age and stage of breast cancer, Black women had 40% lower 5-year survival rates (Wojcik et al., 1998). Other studies show that African American women are more likely to be diagnosed with later stages of breast cancer (Li et al., 2003; Chu et al., 2003), and so may be less able to take advantage of lumpectomy surgery.

Women living in rural areas or medically underserved areas may be less likely to choose lumpectomy since it requires 3-6 weeks of daily radiation therapy. A study of more than 20,000 breast cancer patients in Virginia found that women who lived farther from radiation treatment centers were more likely to choose mastectomy, ostensibly to avoid traveling long distances for regular radiation therapy. The authors reported that 43% of women who lived within 10 miles of radiation treatment providers/centers chose a mastectomy compared to 58% who lived 50 miles or farther away (Schroen et al., 2005). This relationship remained after controlling for age, race, and stage of cancer. A smaller study in Michigan found the same relationship between distance from radiation treatment providers/centers and mastectomy providers (Meden et al., 2002).

CHBRP estimates no change in coverage or utilization of lumpectomy procedures due to SB 255; therefore, CHBRP concludes that no change in disparities among African American women, Latina/Hispanic women, and women living in rural areas would occur.

## **Impacts on Premature Death and Economic Loss**

### Premature Death

The 1990 National Institutes of Health Consensus Development Conference on the treatment of patients with early stage invasive breast cancer recommends lumpectomy with radiation therapy for women with stage I or some stage II breast cancers *or* mastectomy (NIH, 1991). This recommendation, which is now part of standard treatment options, was based on a series of randomized control trials published in the 1980s that found similar survival rates for women with early stage breast cancer who were treated with mastectomy or with lumpectomy with radiation treatment. Recent meta-analyses of randomized clinical trials confirm there is no difference in survival rates among women choosing lumpectomy with radiation or mastectomy (Poggi et al., 2003; Yang et al., 2008).

### Economic Loss

It is well documented that costs for breast cancer care, even among insured women, are high. Out-of-pocket expenditures and lost income for women undergoing breast cancer care averages \$1,455 per month, and women face a financial burden of care for the duration of treatment ranging from 26% to 98% of their monthly income, depending upon income levels (Arozullah, 2004). CHBRP found no studies that compared financial burden associated with lumpectomy versus mastectomy.

CHBRP estimates no change in coverage or utilization of lumpectomy procedures due to SB 255; therefore, CHBRP concludes that no change in enrollee financial burden for noncovered expenses of lumpectomy treatment would occur.

## APPENDICES

### Appendix A: Text of Bill Analyzed

On February 11, 2001 the Senate Committee on Health requested that CHBRP analyze SB 255.

Below is the bill language, as it was introduced on February 10, 2011.

### SENATE BILL No. 255

#### Introduced by Senator Pavley

February 10, 2011

An act to amend Section 1367.635 of the Health and Safety Code, and to amend Section 10123.86 of the Insurance Code, relating to health care coverage.

#### Legislative Counsel's Digest

SB 255, as introduced, Pavley. Health care coverage: breast cancer. 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 regulation of health insurers by the Department of Insurance. Existing law requires every health care service plan contract and health insurance policy that provides coverage for mastectomies and lymph node dissections to allow the length of any hospital stay to be determined by the attending physician and surgeon in consultation with the patient, to cover prosthetic devices or reconstructive surgery, and to cover all complications from a mastectomy. Existing law defines mastectomy for those purposes as the removal of all or part of the breast for medically necessary reasons, as determined by a licensed physician and surgeon.

This bill would revise and recast the definition of mastectomy and would specify that the partial removal of a breast includes, but is not limited to, lumpectomy, which includes surgical removal of the tumor with clear margins. The bill would require the consultation regarding the length of any hospital stay to be conducted postsurgery. Because a willful violation of these provisions by a health care service plan is 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.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: yes.

*The people of the State of California do enact as follows:*

SECTION 1. The Legislature finds and declares all of the following:

(a) The National Cancer Institute estimates that a woman born today in the United States has a one in eight chance of developing breast cancer during her lifetime.

(b) According to the American Cancer Society, excluding cancers of the skin, breast cancer is the most frequently diagnosed cancer in women.

(c) According to the American Cancer Society, an estimated 40,480 women and 450 men died from breast cancer in 2008.

(d) Nationwide, in 2008, an estimated 182,460 new cases of invasive breast cancer were diagnosed in women, and an estimated 1,990 invasive breast cancer cases were diagnosed in men. In addition, an estimated 67,770 new cases of in situ breast cancer occurred in women in 2008, and, of these, approximately 85 percent were ductal carcinoma in situ.

(e) According to the American Cancer Society, most breast cancer patients undergo some type of surgical treatment, which may involve breast-conserving surgeries, such as lumpectomy (surgical removal of the tumor with clear margins) or mastectomy (surgical removal of the breast) with removal of some of the axillary (underarm) lymph nodes.

(f) Currently, 20 states mandate minimum in-patient coverage after a patient undergoes a mastectomy, including California.

(g) Breast cancer patients have reported adverse outcomes, including infection, and inadequately controlled pain resulting from premature hospital discharge following breast cancer surgery.

SEC. 2. Section 1367.635 of the Health and Safety Code is amended to read:

**SB 255 — 2 —**

1367.635. (a) Every health care service plan contract that is issued, amended, renewed, or delivered on or after January 1, 1999, that provides coverage for surgical procedures known as mastectomies and lymph node dissections, shall do all of the following:

(1) Allow the length of a hospital stay associated with those procedures to be determined by the attending physician and surgeon in consultation with the patient, *postsurgery*, consistent with sound clinical principles and processes. No health care service plan shall



require a treating physician and surgeon to receive prior approval from the plan in determining the length of hospital stay following those procedures.

(2) Cover prosthetic devices or reconstructive surgery, including devices or surgery to restore and achieve symmetry for the patient incident to the mastectomy. Coverage for prosthetic devices and reconstructive surgery shall be subject to the deductible and coinsurance conditions applicable to other benefits.

(3) Cover all complications from a mastectomy, including lymphedema.

(b) As used in this section, all of the following definitions apply:

(1) “Coverage for prosthetic devices or reconstructive surgery” means any initial and subsequent reconstructive surgeries or prosthetic devices, and followup care deemed necessary by the attending physician and surgeon.

(2) “Prosthetic devices” means and includes the provision of initial and subsequent prosthetic devices pursuant to an order of the patient’s physician and surgeon.

(3) “Mastectomy” shall have the same meaning as in Section 1367.6 *means the removal of all or part of the breast for medically necessary reasons, as determined by a licensed physician and surgeon. Partial removal of a breast includes, but is not limited to, lumpectomy, which includes surgical removal of the tumor with clear margins.*

(4) “To restore and achieve symmetry” means that, in addition to coverage of prosthetic devices and reconstructive surgery for the diseased breast on which the mastectomy was performed, prosthetic devices and reconstructive surgery for a healthy breast is also covered if, in the opinion of the attending physician and surgeon, this surgery is necessary to achieve normal symmetrical appearance.

### — 3 — SB 255

(c) No individual, other than a licensed physician and surgeon competent to evaluate the specific clinical issues involved in the care requested, may deny requests for authorization of health care services pursuant to this section.

(d) No health care service plan shall do any of the following in providing the coverage described in subdivision (a):

(1) Reduce or limit the reimbursement of the attending provider for providing care to an individual enrollee or subscriber in accordance with the coverage requirements.

(2) Provide monetary or other incentives to an attending provider to induce the provider to provide care to an individual enrollee or subscriber in a manner inconsistent with the coverage requirements.

(3) Provide monetary payments or rebates to an individual enrollee or subscriber to encourage acceptance of less than the

coverage requirements.

(e) On or after July 1, 1999, every health care service plan shall include notice of the coverage required by this section in the plan's evidence of coverage.

(f) Nothing in this section shall be construed to limit retrospective utilization review and quality assurance activities by the plan.

SEC. 3. Section 10123.86 of the Insurance Code is amended to read:

10123.86. (a) Every policy of disability insurance covering hospital, surgical, or medical expenses that is issued, amended, renewed, or delivered on or after January 1, 1999, that provides coverage for surgical procedures known as mastectomies and lymph node dissections, shall do all of the following:

(1) Allow the length of a hospital stay associated with those procedures to be determined by the attending physician and surgeon in consultation with the patient, *postsurgery*, consistent with sound clinical principles and processes. No disability insurer shall require a treating physician and surgeon to receive prior approval in determining the length of hospital stay following those procedures.

(2) Cover prosthetic devices or reconstructive surgery, including devices or surgery to restore and achieve symmetry for the patient incident to the mastectomy. Coverage for prosthetic devices and reconstructive surgery shall be subject to the deductible and coinsurance conditions applicable to other benefits.

**SB 255 — 4 —**

(3) Cover all complications from a mastectomy, including lymphedema.

(b) As used in this section, all of the following definitions apply:

(1) "Coverage for prosthetic devices or reconstructive surgery" means any initial and subsequent reconstructive surgeries or prosthetic devices, and followup care deemed necessary by the attending physician and surgeon.

(2) "Prosthetic devices" means and includes the provision of initial and subsequent prosthetic devices pursuant to an order of the patient's physician and surgeon.

(3) "Mastectomy" shall have the same meaning as in Section 10123.8 *means the removal of all or part of the breast for medically necessary reasons, as determined by a licensed physician and surgeon. Partial removal of a breast includes, but is not limited to, lumpectomy, which includes surgical removal of the tumor with clear margins.*

(4) "To restore and achieve symmetry" means that, in addition to coverage of prosthetic devices and reconstructive surgery for the diseased breast on which the mastectomy was performed, prosthetic devices and reconstructive surgery for a healthy breast

is also covered if, in the opinion of the attending physician and surgeon, this surgery is necessary to achieve normal symmetrical appearance.

(c) No individual, other than a licensed physician and surgeon competent to evaluate the specific clinical issues involved in the care requested, may deny requests for authorization of health care services pursuant to this section.

(d) No insurer shall do any of the following in providing the coverage described in subdivision (a):

(1) Reduce or limit the reimbursement of the attending provider for providing care to an insured in accordance with the coverage requirements.

(2) Provide monetary or other incentives to an attending provider to induce the provider to provide care to an insured in a manner inconsistent with the coverage requirements.

(3) Provide monetary payments or rebates to an insured to encourage acceptance of less than the coverage requirements.

(e) On or after July 1, 1999, every insurer shall include notice of the coverage required by this section in the insurer's evidence of coverage or certificate of insurance.

**— 5 — SB 255**

(f) Nothing in this section shall be construed to limit retrospective utilization review and quality assurance activities by the insurer.

(g) This section shall only apply to health benefit plans, as defined in subdivision (a) of Section 10198.6, except that for accident only, specified disease, or hospital indemnity insurance, coverage for benefits under this section shall apply to the extent that the benefits are covered under the general terms and conditions that apply to all other benefits under the policy. Nothing in this section shall be construed as imposing a new benefit mandate on accident only, specified disease, or hospital indemnity insurance.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

## **Appendix B: Literature Review Methods**

Appendix B describes methods used in the medical effectiveness literature review conducted for SB 255. A discussion of CHBRP's system for grading evidence, as well as lists of MeSH Terms, Keywords, and Publication Types follows.

The literature search was limited to studies published in English from January 2002 to present. January 2002 was chosen as the earliest date for which abstracts would be retrieved, because the results of 25 years of follow-up to a large randomized controlled trial (RCT) conducted in the United States that compared mastectomy to lumpectomy plus radiation was published that year. The following databases of peer-reviewed literature were searched: MEDLINE (PubMed), the Cochrane Database of Systematic Reviews, and the Cochrane Register of Controlled Clinical Trials, the Cumulative Index of Nursing and Allied Health Literature, Web of Science, EconLit, and Business Source Complete.

Abstracts for 525 articles were identified. CHBRP reviewed meta-analyses and systematic reviews as well as randomized controlled trials (RCTs) published after the studies included in the meta-analyses and systematic reviews. The review was limited to these types of studies because they provide the strongest evidence regarding the effectiveness of health care services. A total of eight studies were included in the review.

Two reviewers screened the title and abstract of each citation retrieved by the literature search to determine eligibility for inclusion. The reviewers acquired the full text of articles that were deemed eligible for inclusion in the review and reapplied the initial eligibility criteria.

### Evidence Grading System

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

- Research design;
- Statistical significance;
- Direction of effect;
- Size of effect; and
- Generalizability of findings.

The grading system also contains an overall conclusion that encompasses findings in these five domains. The conclusion is a statement that captures the strength and consistency of the evidence

of an intervention's effect on an outcome. The following terms are used to characterize the body of evidence regarding an outcome:

- Clear and convincing evidence;
- Preponderance of evidence;
- Ambiguous/conflicting evidence; and
- Insufficient evidence.

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

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

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

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

## **Search Terms**

The search terms used to locate studies relevant to SB 255 Breast Cancer were as follows.

### **Medical Subject Headings (MeSH) Terms Used to Search PubMed:**

Adaptation, Physiological  
Adaptation, Psychological  
Breast Neoplasms  
Carcinoma, Ductal, Breast  
Continental Population Groups  
Costs and Cost Analysis  
Decision Making  
Ethnic Groups  
Follow-Up Studies

Insurance Benefits  
Insurance, Health, Reimbursement  
Length of Stay  
Mastectomy  
Mastectomy/Economics  
Mastectomy/Utilization  
Mastectomy, Segmental  
Outcome Assessment (Health Care)  
Survival Rate  
Treatment Outcome

**Keywords Used to Search PubMed, Business Source Complete, CINAHL, Cochrane, PsycInfo, and Econlit:**

Access  
Adjustment  
Breast Cancer  
Breast Conserving Surger?  
Cost-effectiveness  
Cost of Illness  
Costs  
Decision making  
Economic?  
Economic loss  
Financial burden  
Geograph?  
Harms  
Incidence  
Insurance  
Length of Stay  
Long-term impact  
Lumpectom?  
Mastectom?  
Morbidity  
Mortality  
Partial Mastectom?  
Patient attitudes  
Premature death  
Prevalence  
Productivity  
Quality of life  
Racial/ethnic disparit?  
Rural/urban  
Segmentectom?  
Side effects  
Stage (early, local)  
Survival

Travel distance  
Years of Potential Life

(? indicates truncation of the word stem)

**Publication Types:**

Comparative Study  
Controlled Clinical Trial  
Evaluation Studies  
Meta-Analysis  
Practice Guideline  
Randomized Controlled Trial  
Review

## Appendix C: Summary Findings on Medical Effectiveness

The medical effectiveness review for SB 255 included meta-analyses, systematic reviews, and randomized controlled trials regarding lumpectomy that made three sets of comparisons: (1) lumpectomy *with* radiation versus mastectomy, (2) lumpectomy *without* radiation versus mastectomy, and (3) lumpectomy *with* radiation versus lumpectomy *without* radiation. Tables C-1a through C-1c describes the research designs, intervention and comparison groups, populations studied, and locations for studies of the effectiveness of lumpectomy included in this review. Tables C-2a through C-2c summarizes the findings from studies of lumpectomy.

**Table C-1a.** Characteristics of Published Studies Comparing Lumpectomy *With* Radiation to Mastectomy

Citation	Research Design	Intervention and Comparison Groups	Population Studied	Location
Yang et al., 2008 (a)	Meta-analysis of 18 well-designed randomized controlled trials	Radical or modified radical mastectomy vs. lumpectomy with radiation	9,388 total women with early (stage I or II) breast cancer; 5,359 allocated to lumpectomy; and 4,039 allocated to mastectomy	Austria, China, Greece, Italy, Netherlands, South Africa South Korea Belgium, United Kingdom, United States
van Dongen et al., 2000	Level I: Well-designed randomized controlled trials	Modified radical mastectomy vs. lumpectomy with radiation	868 women under age 71 with early (stage I or II) breast cancer and tumors up to 5 cm who did not have a history of other malignancies	Belgium, Netherlands, South Africa, United Kingdom
Poggi et al., 2003	Level I: Well-designed randomized controlled trials	Mastectomy vs. lumpectomy with radiation	247 patients with clinically diagnosed stage I or stage II invasive carcinoma of the breast. Patients had a single invasive unilateral breast lesion without any other suspicious areas, no history of prior cancer or Paget disease, and no evidence of metastatic disease. Patients with in situ lesions were not eligible.	United States

Sources: Poggi et al.,2003; van Dongen et al., 2000; Yang et al., 2008.

(a) Yang et al., 2008, meta-analysis also included Poggi et al.,2003, and van Dongen et al., 2000. These two studies are cited individually because the review includes findings for some outcomes reported for these studies that were not address by Yang et al.'s meta-analysis.



**Table C-1b.** Characteristics of Published Studies Comparing Lumpectomy *With* Radiation to Lumpectomy *Without* Radiation

Citation	Research Design	Intervention and Comparison Groups	Population Studied	Location
Hughes et al., 2004	Level I: Well-designed randomized controlled trials	Lumpectomy with tamoxifen vs. lumpectomy with tamoxifen plus radiation	636 women ( 70 years or older) with clinical stage I, estrogen receptor–positive breast carcinoma treated by lumpectomy to receive tamoxifen plus radiation therapy (n=317) or tamoxifen alone (n=319)	United States
Vinh-Hung and Verschraegen, 2004	Level I: Meta-analysis of 15 randomized controlled trials	Breast conservation therapy (i.e., lumpectomy) alone vs. breast conservation therapy with radiation	15 trials with a pooled total of 9,422 patients available for analysis were identified and included in this review	Canada, Italy, Japan, Sweden, United Kingdom
Potter et al., 2007	Level I: Well-designed randomized controlled trials	Lumpectomy alone vs. lumpectomy with radiation <sup>25</sup>	831 randomly assigned postmenopausal women with early breast cancer to receive breast radiotherapy (n=414) or not (n=417) after lumpectomy	Austria
Goodwin et al., 2009	Level I: Meta-analysis of 4 randomized controlled trials	Lumpectomy alone vs. lumpectomy with radiation; One trial was a two by two factorial design comparing the use of radiation and tamoxifen	Four RCTs involving 3,925 women with ductal carcinoma in situ were identified and included in this review	Australia, Canada, New Zealand, Sweden, United Kingdom, United States
Tinterri et al., 2009	Level I: Well-designed randomized controlled trials	Lumpectomy alone vs. lumpectomy with radiation	749 postmenopausal women with early breast cancer ages 55-75 years with monofocal invasive carcinoma of the breast less than 2.5 cm in largest diameter at the histological evaluation.	Italy

Sources: Goodwin et al., 2009; Hughes et al., 2004; Potter et al., 2009; Tinterri et al., 2009; Vinh-Hung and Verschraegen, 2004.

<sup>25</sup> Women in both arms of Potter et al.'s (2007) randomized controlled trial received adjuvant hormone therapy with tamoxifen or tamoxifen followed by anastrozole for 5 years following surgery.

**Table C-2a. Summary of Findings From Studies Comparing Lumpectomy With Radiation to Mastectomy**

<b>Outcome</b>	<b>Citation</b>	<b>Research Design</b>	<b>Statistical Significance</b>	<b>Direction of Effect</b>	<b>Size of Effect</b>	<b>Conclusion</b>
Overall survival	Yang et al., 2008 <sup>b</sup>	Meta-analysis of 18 randomized controlled trials	Not statistically significant (P value: 3-year OS=0.96 5-year OS=0.37 10-year OS=0.10 15-year OS=0.21 20-year OS=0.29)	No difference	Odds ratio (95% CI):  3-year OS=1.01 (0.70-1.45)  5-year OS=0.93 (0.80-1.09)  10-year OS=1.11 (0.98-1.26)  15-year OS=0.87 (0.70-1.08)  20-year OS=1.14 (0.89-1.46)	Overall survival did not differ for women with stage 1 or II breast cancer who received mastectomy vs. lumpectomy plus radiation
Disease-free survival	Poggi et al., 2003	Level I: Well-designed randomized controlled trial	Not statistically significant (P=0.64)	No difference	Disease-free survival rate:  Mastectomy: 5 year: 81% 10 year:70% 15 year:68% 20 year:67%  Lumpectomy with radiation : 5 year:78% 10 year:73% 15 year:66% 20 year:60%	After nearly 20 years of follow-up, there was no detectable difference in disease-free survival in patients with early stage breast carcinoma who were treated with mastectomy compared with those treated with lumpectomy plus radiation

**Table C-2a.** Summary of Findings From Studies Comparing Lumpectomy *With* Radiation to Mastectomy (Cont'd)

<b>Outcome</b>	<b>Citation</b>	<b>Research Design</b>	<b>Statistical Significance</b>	<b>Direction of Effect</b>	<b>Size of Effect</b>	<b>Conclusion</b>
Distant metastasis-free survival	van Dongen et al., 2000	Level I: Well-designed randomized controlled trials	Not statistically significant (P=0.24)	No difference	Distant metastasis-free survival rates at 10 years:  Mastectomy: 66.3% (95% CI, 61.6%-70.9)  Lumpectomy plus radiation: 60.5% (95% CI, 55.8%-65.2%)	There was no difference in rates of distant metastasis-free survival between women with stage I or II breast cancer who received mastectomy vs. lumpectomy plus radiation
Local regional recurrence	Yang et al., 2008 (b)	Meta-analysis of 18 randomized controlled trials	Not statistically significant (P value: 3-year LRR=0.54 5-year LRR=0.86 10-year LRR=0.53 15-year LRR=0.15 20-year LRR=0.32)	No difference	Odds ratio (95% CI): 3-year LRR=1.50 (0.40-5.57) 5-year LRR=1.06 (0.56-2.00) 10-year LRR=1.26 (0.26-2.54) 15-year LRR=1.59 (0.84-2.98) 20-year LRR=1.79 (0.57-5.63)	There was no difference in the odds of local/regional recurrence between women with stage I or II breast cancer who received mastectomy vs. lumpectomy plus radiation

*Sources:* Poggi et al., 2003; van Dongen et al., 2000; Yang et al., 2008.

(b) The Yang et al., 2008, meta-analysis also included Poggi et al., 2003, and van Dongen et al., 2000. These two studies are cited individually because the review includes findings for some outcomes reported for these studies that were not address by Yang et al.'s meta-analysis.

*Key:* CI=confidence interval; LRR=lifetime relative risk; OS=overall survival.

**Table C-2b.** Summary of Findings From Studies Comparing Lumpectomy *With* Radiation to Lumpectomy *Without* Radiation

Outcome	Citation	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
Mortality	Vinh-Hung and Verschraegen, 2004	Meta-analysis of 15 well-designed randomized controlled trials	Statistically significant (95% CI, 1.003-1.175)	Favors adding radiation to lumpectomy	Relative risk=1.086 (95% CI, 1.003-1.175) 8.6% relative excess mortality if no radiotherapy is administered	Women with stage I or II breast cancer who received lumpectomy alone had a higher relative risk of mortality than those who received radiation in addition to lumpectomy
Overall survival	Hughes et al., 2004	Level I: Well-designed randomized controlled trials	Not statistically significant	No difference	No effect	No difference in overall survival between women who received radiation in addition to lumpectomy and tamoxifen compared to those who received lumpectomy and tamoxifen without radiation
Overall survival	Potter et al., 2007	Level I: Well-designed randomized controlled trials	Not statistically significant	No difference	No effect	No difference in overall survival between women who received radiation in addition to lumpectomy and those who received lumpectomy alone <sup>26</sup>
Overall survival	Tinterri et al., 2009	Level I: Well-designed randomized controlled trials	Not statistically significant	No difference	No effect	No difference in overall survival between women who received radiation in addition to lumpectomy and those who received lumpectomy alone
Overall relapse rate	Potter et al., 2007	Level I: Well-designed randomized controlled trials	Statistically significant (P=0.0021)	Favors adding radiation to lumpectomy	Hazard ratio=3.48 (95% CI, 1.49-8.12)	Lumpectomy <i>without</i> radiation was associated with a higher rate of overall relapse
Distant disease-free survival	Tinterri et al., 2009	Level I: Well-designed randomized controlled trials	Not statistically significant	No difference	No effect	There are no differences in terms of distant disease-free survival.

<sup>26</sup> Women in both arms of Potter et al.'s (2007) randomized controlled trial received adjuvant hormone therapy with tamoxifen or tamoxifen followed by anastrozole for 5 years following surgery.

**Table C-2b.** Summary of Findings From Studies Comparing Lumpectomy *With* Radiation to Lumpectomy *Without* Radiation (Cont'd)

Outcome	Citation	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
Local or regional recurrence	Hughes et al., 2004	Level I: Well-designed randomized controlled trials	Statistically significant at 5 years (P<0.001)	Favors adding radiation to tamoxifen after lumpectomy	Rate of local or regional recurrence at 5 years= Group given tamoxifen plus irradiation = 1% vs. the group given tamoxifen alone = 4%	Lumpectomy <i>with</i> radiation and tamoxifen was associated with a lower rate of local or regional recurrence at 5 years than lumpectomy with tamoxifen
Local relapse	Potter et al., 2007	Level I: Well-designed randomized controlled trials	Statistically significant (P=0.0001)	Favors adding radiation to lumpectomy	Hazard ratio=10.21 (95% CI, 2.38-43.84)	Lumpectomy <i>without</i> radiation was associated with a higher rate of local relapse
All ipsilateral breast tumor recurrence	Vinh-Hung and Verschraegen, 2004	Meta-analysis of 15 well-designed randomized controlled trials	Statistically significant (95% CI, 2.65-3.40)	Favors adding radiation to lumpectomy	Relative risk=3.00 (95% CI, 2.65-3.40)	Lumpectomy <i>without</i> radiation was associated with a higher relative risk of recurrence in the same breast
In-breast Recurrence	Tinterri et al., 2009	Level I: Well-designed randomized controlled trials	Not statistically significant (P=0.07)	No difference	Cumulative incidence of In-breast recurrence  Lumpectomy alone: 2.5% (95% CI, 0.7-4.4 )  Lumpectomy plus radiation: 0.7% (95% CI, 0-1.7)	Non-statistically significant difference in the percentage of women with an in-breast recurrence of cancer between women who received radiation in addition to lumpectomy and those who received lumpectomy alone
All in-breast tumor recurrence	Goodwin et al., 2009	Meta-analysis of 4 well-designed randomized controlled trials	Statistically significant (P<0.00001)	Favors adding radiation to lumpectomy	Hazard ratio (HR)=0.49 (95% CI, 0.41-0.58)	Lumpectomy <i>with</i> radiation was associated with a lower rate of in-breast recurrence of any type of tumor
In-breast invasive cancer recurrence	Goodwin et al., 2009	Meta-analysis of 4 well-designed randomized controlled trials	Statistically significant benefit (95% CI, 0.32-0.76, p=0.001)	Favors adding radiation to lumpectomy	Hazard ratio (HR)=0.50 (95% CI, 0.32-0.76)	Lumpectomy <i>with</i> radiation was associated with a lower rate of in-breast recurrence of invasive cancer

**Table C-2b.** Summary of Findings From Studies Comparing Lumpectomy *With* Radiation to Lumpectomy *Without* Radiation (Cont'd)

<b>Outcome</b>	<b>Citation</b>	<b>Research Design</b>	<b>Statistical Significance</b>	<b>Direction of Effect</b>	<b>Size of Effect</b>	<b>Conclusion</b>
Ipsilateral ductal carcinoma in situ (DCIS) recurrence	Goodwin et al., 2009	Meta-analysis of 4 well-designed randomized controlled trials	statistically significant benefit (P=0.03)	Favors adding radiation to lumpectomy	Hazard ratio (HR)=0.61 (95% CI, 0.39-0.95)	Lumpectomy <i>with</i> radiation was associated with a lower rate of in-breast recurrence of DCIS

*Sources:* Goodwin et al., 2009; Hughes et al., 2004; Potter et al., 2007; Tinterri et al., 2009; Vinh-Hung and Verschraegen, 2004.

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

This appendix describes data sources, as well as general and mandate-specific caveats and assumptions used in conducting the cost impact analysis. For additional information on the cost model and underlying methodology, please refer to the CHBRP Web site at <http://www.chbrp.org/costimpact.html>.

The cost analysis in this report was prepared by the members of cost team, which consists of CHBRP task force members and contributors from the University of California, San Diego, and the University of California, Los Angeles, as well as the contracted actuarial firm, Milliman, Inc. (Milliman). Milliman provides data and analysis support per the provisions of CHBRP's authorizing legislation.

### Data Sources

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

#### *Health insurance*

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

Health Research and Educational Trust. Information on the CHCF/NORC data is available at: <http://www.chcf.org/publications/2010/12/california-employer-health-benefits-survey>.

3. Milliman data sources are relied on to estimate the premium impact of mandates. Milliman's projections derive from the Milliman Health Cost Guidelines (HCGs). The HCGs are a health care pricing tool used by many of the major health plans in the United States. See <http://www.milliman.com/expertise/healthcare/products-tools/milliman-care-guidelines/index.php>. Most of the data sources underlying the HCGs are claims databases from commercial health insurance plans. The data are supplied by health insurance companies, Blues plans, HMOs, self-funded employers, and private data vendors. The data are mostly from loosely managed health care plans, generally those characterized as preferred provider plans, or PPOs. The HCGs currently include claims drawn from plans covering 4.6 million members. In addition to the Milliman HCGs, CHBRP's utilization and cost estimates draw on other data, including the following:
  - The MarketScan Database, which includes demographic information and claim detail data for approximately 13 million members of self-insured and insured group health plans.
  - An annual survey of HMO and PPO pricing and claim experience. The most recent survey (2010 Group Health Insurance Survey) contains data from seven major California health plans regarding their 2010 experience.
  - Ingenix MDR Charge Payment System, which includes information about professional fees paid for healthcare services, based upon approximately 800 million claims from commercial insurance companies, HMOs, and self-insured health plans.
  - These data are reviewed for applicability by an extended group of experts within Milliman but are not audited externally.
4. An annual survey by CHBRP of the seven largest providers of health insurance in California (Aetna, Anthem Blue Cross of California, Blue Shield of California, CIGNA, Health Net, Kaiser Foundation Health Plan, and PacifiCare) to obtain estimates of baseline enrollment by purchaser (i.e., large and small group and individual), type of plan (i.e., DMHC- or CDI-regulated), cost-sharing arrangements with enrollees, and average premiums. Enrollment in plans or policies offered by these seven firms represents an estimated 93.7% of the persons with health insurance subject to state mandates. This figure represents an estimated 94.4% of enrollees in full service (nonspecialty) DMHC-regulated health plans and an estimated 90.1% of enrollees in full service (nonspecialty) CDI-regulated policies.<sup>27</sup>

---

<sup>27</sup> CHBRP analysis of the share of enrollees included in CHBRP's Bill-Specific Coverage Survey of the major carriers in the state is based on "CDI Licenses with HMSR Covered Lives Greater Than 100,000" as part of the Accident and Health Covered Lives Data Call, December 31, 2009 by the California Department of Insurance, Statistical Analysis Division, data retrieved from the Department of Managed Health Care's interactive Web site



*Publicly funded insurance subject to state benefit mandates*

5. Premiums and enrollment in DMHC-regulated health plans and CDI-regulated policies by self-insured status and firm size are obtained annually from CalPERS for active state and local government public employees and their dependents who receive their benefits through CalPERS. Enrollment information is provided for DMHC-regulated health care service plans covering non-Medicare beneficiaries—about 74% of CalPERS total enrollment. CalPERS self-funded plans—approximately 26% of enrollment—are not subject to state mandates. In addition, CHBRP obtains information on current scope of benefits from evidence of coverage (EOC) documents publicly available at <http://www.calpers.ca.gov>.
6. Enrollment in Medi-Cal Managed Care (beneficiaries enrolled in Two-Plan Model, Geographic Managed Care, and County Operated Health System plans) is estimated based on CHIS and data maintained by the Department of Health Care Services (DHCS). DHCS supplies CHBRP with the statewide average premiums negotiated for the Two-Plan Model, as well as generic contracts that summarize the current scope of benefits. CHBRP assesses enrollment information online at [http://www.dhcs.ca.gov/dataandstats/statistics/Pages/RASS\\_General\\_Medi\\_Cal\\_Enrollment.aspx](http://www.dhcs.ca.gov/dataandstats/statistics/Pages/RASS_General_Medi_Cal_Enrollment.aspx).
7. Enrollment data for other public programs—Healthy Families Program (HFP), Access for Infants and Mothers (AIM), and the Major Risk Medical Insurance Program (MRMIP)—are estimated based on CHIS and data maintained by the Managed Risk Medical Insurance Board (MRMIB). The basic minimum scope of benefits offered by participating health plans under these programs must comply with all requirements for DMHC-regulated health plans, and thus these plans are affected by state-level benefit mandates. CHBRP does not include enrollment in the Post-MRMIP Guaranteed-Issue Coverage Products as these persons are already included in the enrollment for individual market health insurance offered by DMHC-regulated plans or CDI-regulated insurers. Enrollment figures for AIM and MRMIP are included with enrollment for Medi-Cal in presentation of premium impacts. Enrollment information is obtained online at <http://www.mrmib.ca.gov/>. Average statewide premium information is provided to CHBRP by MRMIB staff.

General Caveats and Assumptions

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

- Prevalence of mandated benefits before and after the mandate may be different from CHBRP assumptions.
- Utilization of mandated benefits (and, therefore, the services covered by the benefit) before and after the mandate may be different from CHBRP assumptions.

---

“Health Plan Financial Summary Report,” July-September 2010, and CHBRP's Annual Enrollment and Premium Survey.

- Random fluctuations in the utilization and cost of health care services may occur.

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

- Cost impacts are shown only for plans and policies subject to state benefit mandate laws.
- Cost impacts are only for the first year after enactment of the proposed mandate.
- Employers and employees will share proportionately (on a percentage basis) in premium rate increases resulting from the mandate. In other words, the distribution of premium paid by the subscriber (or employee) and the employer will be unaffected by the mandate.
- For state-sponsored programs for the uninsured, the state share will continue to be equal to the absolute dollar amount of funds dedicated to the program.
- When cost savings are estimated, they reflect savings realized for one year. Potential long-term cost savings or impacts are estimated if existing data and literature sources are available and provide adequate detail for estimating long-term impacts. For more information on CHBRP's criteria for estimating long-term impacts please see: [http://chbrp.org/documents/longterm\\_impacts08.pdf](http://chbrp.org/documents/longterm_impacts08.pdf).
- Several recent studies have examined the effect of private insurance premium increases on the number of uninsured (Chernew, et al., 2005; Glied and Jack, 2003; Hadley, 2006). Chernew et al. (2005) estimate that a 10% increase in private premiums results in a 0.74 to 0.92 percentage point decrease in the number of insured, while Hadley (2006) and Glied and Jack (2003) estimate that a 10% increase in private premiums produces a 0.88 and 0.84 percentage point decrease in the number of insured, respectively. The price elasticity of demand for insurance can be calculated from these studies in the following way. First, take the average percentage point decrease in the number of insured reported in these studies in response to a 1% increase in premiums (about -0.088), divided by the average percentage of insured persons (about 80%), multiplied by 100%, i.e.,  $(\{-0.088/80\} \times 100) = -0.11$ . This elasticity converts the *percentage point* decrease in the number of insured into a *percentage* decrease in the number of insured persons for every 1% increase in premiums. Because each of these studies reported results for the large-group, small-group, and individual insurance markets combined, CHBRP employs the simplifying assumption that the elasticity is the same across different types of markets. For more information on CHBRP's criteria for estimating impacts on the uninsured, please see: [http://chbrp.org/documents/uninsured\\_010109.pdf](http://chbrp.org/documents/uninsured_010109.pdf).

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

- Population shifts by type of health insurance: If a mandate increases health insurance costs, some employer groups and individuals may elect to drop their health insurance. Employers may also switch to self-funding to avoid having to comply with the mandate.

- Changes in benefit plans: To help offset the premium increase resulting from a mandate, subscribers/policyholders may elect to increase their overall plan deductibles or copayments. Such changes would have a direct impact on the distribution of costs between the health plan and policies and enrollees, and may also result in utilization reductions (i.e., high levels of patient cost sharing result in lower utilization of health care services). CHBRP did not include the effects of such potential benefit changes in its analysis.
- Adverse selection: Theoretically, individuals or employer groups who had previously foregone health insurance may now elect to enroll in a health plan or policy, postmandate, because they perceive that it is to their economic benefit to do so.
- Medical management: Health plans and insurers may react to the mandate by tightening medical management of the mandated benefit. This would tend to dampen the CHBRP cost estimates. The dampening would be more pronounced on the plan types that previously had the least effective medical management (i.e., PPO plans).
- Geographic and delivery systems variation: Variation in existing utilization and costs, and in the impact of the mandate, by geographic area and delivery system models: Even within the health insurance types CHBRP modeled (HMO—including HMO and point of service [POS] plans—and non-HMO—including PPO and fee for service [FFS] policies), there are likely variations in utilization and costs by type. Utilization also differs within California due to differences in the health status of the local population, provider practice patterns, and the level of managed care available in each community. The average cost per service would also vary due to different underlying cost levels experienced by providers throughout California and the market dynamic in negotiations between providers and health plans or insurers. Both the baseline costs prior to the mandate and the estimated cost impact of the mandate could vary within the state due to geographic and delivery system differences. For purposes of this analysis, however, CHBRP has estimated the impact on a statewide level.
- Compliance with the mandate: For estimating the postmandate coverage levels, CHBRP typically assumes that plans and policies subject to the mandate will be in compliance with the coverage requirements of the bill. Therefore, the typical postmandate coverage rates for populations subject to the mandate are assumed to be 100%.

### Potential Effects of the Federal Affordable Care Act

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

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

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

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

#### *Coverage for adult children*

PPACA Section 2714, modified by HR 4872, Section 2301, requires coverage for adult children up to age 26 as dependants to primary subscribers on all individual and group policies, effective September 23, 2010. California's recently enacted law, SB 1088 (2010) implements this provision. This could potentially affect both premiums and enrollment in 2011. According to the California Health Interview Survey (CHIS), approximately 22% of Californians aged 19-25 (1,063,000) were estimated to be uninsured at some point in 2009. As a result of the ACA, many of these young adults will likely gain access to health insurance through a parent. This dynamic may diminish the number of uninsured and may also shift some young adults from the individually purchased health insurance market into the group market. The Departments of Treasury, Labor, and Health and Human Services estimate, for 2011, the number of young adults newly covered by his/her parent's plan would be about 0.78 to 2.12 million (using high and low take-up rate assumptions, respectively). Of these young adults, about 0.2 to 1.64 million would have previously been uninsured. The corresponding incremental cost impact to group insurance policies is estimated to be a premium increase of 0.5% to 1.2%. Based on the responses to the Annual Enrollment and Premium survey, there has been an increase of 1% to 1.5% in enrollment for the 19-25 year olds, and the increase varies depending on whether the parents were enrolled in the large-group, small-group, or individual markets. Based on analysis of the estimates from the Departments of the Treasury, Labor, and Health and Human Services as well as CHIS 2009 data, approximately 25% of the increase in enrollment represents a shift from the individual market and approximately 75% were previously uninsured. CHBRP took these estimates into account and adjusted underlying population data since source data did not reflect the effects of this provision, because shift in populations were expected to be significant, and to account for potential lags in enrollment (e.g., due to awareness).

#### *Minimum medical loss ratio requirement*

PPACA Section 2718 requires health plans offering health insurance in group and individual markets to report to the Secretary of Health and Human Services the amount of premium revenue spent on clinical services, activities to improve quality, and other non-claim costs. Beginning in 2011, large-group plans that spend less than 85% of premium revenue and small-group/individual market plans that spend less than 80% of premium revenue on clinical services and quality must provide rebates to enrollees. According to the Interim Final Rule, (45 CFR Part 158) "Issuers will provide rebates to enrollees when their spending for the benefit of policyholders on reimbursement for clinical services and quality improvement activities, in

relation to the premiums charged, is less than the Medical Loss Ratio (MLR) standards established pursuant to the statute.”<sup>28</sup> The requirement to report medical loss ratio is effective for the 2010 plan year, whereas the requirement to provide rebates is effective January 1, 2011. The MLR requirement, along with the rebate payment requirement, will affect premiums for 2011, but the effects are unknown, and data are not yet available. There is potential for substantial impact on markets with higher administrative costs, including the small and individual group markets. Responses to CHBRP’s Annual Enrollment and Premiums Survey indicate that carriers intend to be in compliance with these requirements. For those that may not be in compliance, the requirement to pay rebates is intended to align the MLR retrospectively. Therefore, for modeling purposes, CHBRP has adjusted administrative and profit loads to reflect MLRs that would be in compliance with this provision.

#### *Pre-Existing Condition Insurance Plan (PCIP)*

PPACA Section 1101 establishes a temporary high-risk pool for individuals with pre-existing medical conditions, effective 90 days following enactment until January 1, 2014. In 2010, California enacted AB 1887 and SB 227, providing for the establishment of the California Pre-Existing Conditions Insurance Plan (PCIP) to be administered by the Managed Risk Medical Insurance Board (MRMIB) and federally funded per Section 1101. MRMIB has projected average enrollment of 23,100 until the end of 2013, when the program will expire. As of December 2010, there were approximately 1,100 subscribers.<sup>29</sup> The California PCIP is not subject to state benefit mandates,<sup>30</sup> and therefore, this change does not directly affect CHBRP’s Cost and Coverage Model. CHBRP has revised its annual update of *Estimates of the Sources of Health Insurance in California*<sup>31</sup> to reflect a slight increase in the number of those who are insured under other public programs that are not subject to state-level mandates.

#### *Prohibition of pre-existing condition exclusion for children*

PPACA Sections 1201& 10103(e): Prohibits pre-existing condition exclusions for children. This provision was effective upon enactment. California’s recently enacted law AB 2244 (2010) implements this provision. AB 2244 also prohibits carriers that sell individual plans or policies from refusing to sell or renew policies to children with pre-existing conditions. Carriers that do not offer new plans for children are prohibited from offering for sale new individual plans in California for 5 years.<sup>32</sup> This provision could have had significant premium effects, especially for the DMHC- and CDI-regulated individual markets. The premium information is included in the responses to CHBRP’s Annual Enrollment and Premium Survey. Thus the underlying data used in CHBRP annual model updates captured the effects of this provision.

---

<sup>28</sup> Department of Health and Human Services, *Interim Final Rule: Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act*. 45 CFR Part 158. December 1, 2010.

<sup>29</sup> Enrollment report presented at the Managed Risk Medical Insurance Board Meeting, January 19, 2010. Available at: [http://www.mrmib.ca.gov/MRMIB/Agenda\\_Minutes\\_011911/Agenda\\_Item\\_9.a\\_PCIP\\_Board\\_Report\\_for\\_Dec\\_2010\\_FINAL.pdf](http://www.mrmib.ca.gov/MRMIB/Agenda_Minutes_011911/Agenda_Item_9.a_PCIP_Board_Report_for_Dec_2010_FINAL.pdf).

<sup>30</sup> Correspondence with John Symkowitz, Legislative Coordinator, MRMIB, October 19, 2010.

<sup>31</sup> See: [http://www.chbrp.org/documents/insur\\_source\\_est\\_2010.pdf](http://www.chbrp.org/documents/insur_source_est_2010.pdf).

<sup>32</sup> See enacted language at: [http://www.leginfo.ca.gov/pub/09-10/bill/asm/ab\\_2201-2250/ab\\_2244\\_bill\\_20100930\\_chaptered.pdf](http://www.leginfo.ca.gov/pub/09-10/bill/asm/ab_2201-2250/ab_2244_bill_20100930_chaptered.pdf).

### *Prohibition of lifetime limits and annual benefit limit changes*

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

### *Medi-Cal Managed Care Enrollment: Seniors and persons with disabilities*

Although the PPACA allows states the option to expand coverage to those not currently eligible for Medicaid (Medi-Cal in California), large-scale expansions are not expected to be seen during 2011. However, as a result of the 2010-2011 California Budget Agreement, there are expected to be shifts in coverage for seniors and persons with disabilities. Specifically, “Seniors and persons with disabilities who reside in certain counties which have managed care plans, and who are not also eligible to enroll in Medicare, will be required to enroll in a managed care plan under a phased-in process.”<sup>33</sup> The Medi-Cal Managed Care enrollment in CHBRP’s 2011 Cost and Coverage Model has been adjusted to reflect this change. Baseline premium rates have also been adjusted to reflect an increase in the number of seniors and persons with disabilities in Medi-Cal Managed Care. Information from DHCS indicate these changes will go into effect July 1, 2011, and would affect approximately 427,000 Medi-Cal beneficiaries.<sup>34</sup> CHBRP used data from DHCS to adjust enrollment in Medi-Cal Managed Care, and to adjust premiums to account for the change in acuity in the underlying populations.<sup>35</sup>

### Bill Analysis-Specific Caveats and Assumptions

- Existing legislation addresses lumpectomy for both health care service plans regulated by DMHC and insurance policies regulated by CDI. Therefore, on the basis of existing law,

<sup>33</sup> Taylor M. Legislative Analyst, *The Budget Package 2010-11 California Spending Plan*. LAO: November, 2010. Available at: [http://www.lao.ca.gov/reports/2010/bud/spend\\_plan/spend\\_plan\\_110510.pdf](http://www.lao.ca.gov/reports/2010/bud/spend_plan/spend_plan_110510.pdf)

<sup>34</sup> Data from the Department of Health Care Services, Medi-Cal Managed Care Division. Received January 14, 2011.

<sup>35</sup> See the study conducted for DHCS by Mercer on this topic: Mercer, *Medi-Cal Acuity Study: Seniors and Persons with Disabilities*. September 28, 2010. Available at: [http://www.dhcs.ca.gov/provgovpart/Documents/Waiver%20Renewal/SPD\\_Study\\_092810.pdf](http://www.dhcs.ca.gov/provgovpart/Documents/Waiver%20Renewal/SPD_Study_092810.pdf).

bill-specific carrier surveys of the seven largest carriers (by market size), and confirmation from DMHC and CDI, CHBRP has assumed full coverage of lumpectomy exists premandate.

- The \$6,958 average cost of lumpectomy is based on the average allowed charge per case in the 2009 CA MedStat database for a hospital stay or outpatient procedure associated with lumpectomy. The average allowed charge for inpatient services includes all facility charges (room and board, etc.) and physician charges (surgeon, anesthesia, etc.) associated with the lumpectomy. The average allowed charge for outpatient services includes the ambulatory surgery facility charges and the physician charges. Similar to the inpatient amounts, the allowed charge is all the charges incurred that day whether facility or physician. The 2009 average cost for lumpectomy was trended to 2011 using a 10% annual trend.
- The annual utilization per 1,000 members for 2009 in the CA MedStat database is 0.20. The membership distribution of Medi-Cal has approximately 50% fewer women between the ages of 30 and 64 than that of a typical commercial population. Therefore, we used an annual utilization of 0.10 for Medi-Cal. The annual utilization per 1,000 of 0.20 (0.10 for Medi-Cal) was multiplied by the population covered to determine the estimate of annual number of lumpectomies of 4,000.

## **Appendix E: Information Submitted by Outside Parties**

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

Senator Pavley submitted a Fact Sheet on Breast Cancer Surgery/Partial Mastectomies and Lumpectomies on March 7, 2011.

Submitted information is available upon request.

For information on the processes for submitting information to CHBRP for review and consideration, please visit: <http://www.chbrp.org/requests.html>.



## REFERENCES

- Arozullah AM, Calhoun EA, Wolf M, et al. The financial burden of cancer: Estimates from a study of insured women with breast cancer. *Journal of Supportive Oncology*. 2004;2:271-278.
- Braveman P. Health disparities and health equity: Concepts and measurement. *Annual Review of Public Health*. 2006;27:167-194.
- California Cancer Registry (CCR). California cancer facts and figures, 2011. Oakland, CA: American Cancer Society, California Division, September; 2010. Available at: [http://www.ccrca.org/pdf/Reports/ACS\\_2011.pdf](http://www.ccrca.org/pdf/Reports/ACS_2011.pdf). Accessed March 2011.
- California Cancer Registry (CCR). Invasive cancer incidence rates by county in California. 2011. Available at: <http://www.cancer-rates.info/ca/index.php>. Accessed January 20, 2011.
- California Health Benefits Review Program (CHBRP). Analysis of Assembly Bill 8: Health Care Coverage: Mastectomies and Lymph Node Dissections. Report to the Calif. State Legislature. Oakland, CA: CHBRP; 2005. CHBRP-05-1. Available at: <http://www.chbrp.org/docs/index.php?action=view>. Accessed April 2011.
- California Health Interview Survey (CHIS). 2009 California Health Interview Survey: Los Angeles, CA: UCLA Center for Health Policy Research; 2009.
- Chernew M, Cutler M, Keenan PS. Increasing health insurance costs and the decline in insurance coverage. *Health Services Research*. 2005;40:1021-1039.
- Chu KC, Lamar CA, Freeman HP. Racial disparities in breast carcinoma survival rates. *Cancer*. 2003;97:2853-2860.
- Clarke M, Collins R, Darby S, et al. Effects of radiotherapy and of differences in the extent of surgery for early breast cancer on local recurrence and 15-year survival: An overview of the randomized trials. *The Lancet*. 2005;366:2087-2106.
- Foundation for Informed Medical Decision Making (FIMDM). Early-Stage Breast Cancer: Choosing Your Surgery. BCS001 v.03. Boston, MA: FIMDM; 2009.
- Fyles AW, McCready DR, Manchul LA, et al. Tamoxifen with or without breast irradiation in women 50 years of age or older with early breast cancer. *The New England Journal of Medicine*. 2004;351:963-970.
- Gabel J. California Employer Health Benefits Survey 2010. Sacramento, CA: California Health Care Foundation/National Opinion Research Center; 2010.
- Glied S, Jack K. Macroeconomic Conditions, Health Care Costs and the Distribution of Health Insurance. Cambridge, MA: National Bureau of Economic Research; 2003. Working Paper (W10029). Available at: <http://www.nber.org/papers/W10029>. Accessed August 2, 2010.
- Goodwin A, Parker S, Ghersi D, Wilcken N. Post-operative radiotherapy for ductal carcinoma in situ of the breast. *Cochrane Database of Systematic Reviews*. 2009;4:CD000563.

- Hadley J. The effects of recent employment changes and premium increases on adults' insurance coverage. *Medical Care Research and Review*. 2006;63:447-476.
- Hughes KS, Schnaper LA, Berry D, et al. (2004). Lumpectomy plus tamoxifen with or without irradiation in women 70 years of age or older with early breast cancer. *New England Journal of Medicine*. 351(10): 971-977.
- Kaiser Family Foundation (KFF). Key Facts: Race, Ethnicity and Medical Care, 2007 Update. January 2007. Available at: <http://www.kff.org/minorityhealth/upload/6069-02.pdf>. Accessed March, 2011.
- Kirby JB, Taliaferro G, Zuvekas SH. Explaining racial and ethnic disparities in health care. *Medical Care*. 2006;44(Suppl):I64-I72.
- Li CI, Malone KE, Daling JR. Differences in breast cancer stage, treatment, and survival by race and ethnicity. *Archives of Internal Medicine*. 2003;163:49-56.
- Lillie-Blanton M, Hoffman C. The role of health insurance coverage in reducing racial/ethnic disparities in health care. *Health Affairs (Millwood)*. 2005;24:398-408.
- Meden T, St. John-Larkin C, Hermes D, Sommerschild S. Relationship between travel distance and utilization of breast cancer treatment in rural northern Michigan. *Journal of the American Medical Association*. 2002;287:111.
- Milliman, USA. Milliman Health Cost Guidelines, July 2010 ed. Seattle, WA: Milliman; 2010.
- National Cancer Institute (NCI). Breast Cancer Treatment PDQ. 2011. Available at: <http://www.cancer.gov/cancertopics/pdq/treatment/breast/healthprofessional/page6>. Accessed March 22, 2011.
- National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer, Version 2. 2011. Available at: [http://www.nccn.org/professionals/physician\\_gls/f\\_guidelines.asp#site](http://www.nccn.org/professionals/physician_gls/f_guidelines.asp#site). Accessed March 2011.
- NIH Consensus Conference (NIH). Treatment of early breast cancer. *JAMA*. 1991;265:391-395.
- Parker PA, Youssef A, Walker S, et al. Short-term and long-term psychosocial adjustment and quality of life in women undergoing different surgical procedures for breast cancer. *Annals of Surgical Oncology*. 2007;14:3078-3089.
- Pockaj BA, Degnim AC, Boughey JC, et al. Quality of life after breast cancer surgery: What have we learned and where should we go next? *Journal of Surgical Oncology*. 2009;99:447-455.
- Poggi MM, Danforth DN, Sciuto LC, Smith SL, Steinberg SM, Liewehr DJ. Eighteen-year results in the treatment of early breast carcinoma with mastectomy versus breast conservation therapy: The National Cancer Institute Randomized Trial. *Cancer*. 2003. 98: 697-702.
- Polgár C, Fodor J, Major T, et al. Breast-conserving treatment with partial or whole breast radiation for low-risk invasive breast carcinoma—5-year results of a randomized trial. *International Journal of Radiation Oncology, Biology Physics*. 2007;69:694-702.

- Potter R, Gnant M, Kwasny W, et al. Lumpectomy plus tamoxifen or anastrozole with or without whole breast irradiation in women with favorable early breast cancer. *International Journal of Radiation Oncology, Biology, Physics*. 2007;68:334-340.
- Sauer G, Strnad V, Kurzeder C, Kreienberg R, Sauer R. Partial breast irradiation after breast-conserving surgery. *Strahlentherapie und Onkologie*. 2005;181:1-8.
- Schroen AT, Brenin DR, Kelly MD, Knaus WA, Slingluff CL Jr. Impact of patient distance to radiation therapy on mastectomy use in early-stage breast cancer patients. *Journal of Clinical Oncology*. 2005;23:7074-7080.
- Tinterri C, Gatzemeier W, Zanini V, et al. Conservative surgery with and without radiotherapy in elderly patients with early-stage breast cancer: A prospective randomised multicentre trial. *Breast*. 2009;18:373-377.
- Vaidya JS, Tobias JS, Bulsara M, Wenz F, Saunders C, et al. Targeted intraoperative radiotherapy versus whole breast radiotherapy for breast cancer (TARGIT-A trial): An international, prospective, randomized, non-inferiority phase 3 trial. *Lancet*. 2010;376:91-102.
- van Dongen JA, Voogd AC, Fentiman IS, et al. Long-term results of a randomized trial comparing breast-conserving therapy with mastectomy: European Organization for Research and Treatment of Cancer 10801 trial. *Journal of the National Cancer Institute*. 2000;92:1143-1150.
- Vinh-Hung V, Verschraegen C. Breast-conserving surgery with or without radiotherapy: pooled-analysis for risks of ipsilateral breast tumor recurrence and mortality. *Journal of the National Cancer Institute*. 2004;96:115-121.
- Waljee JF, Ubel PA, Atisha DM, Hu ES, Alderman AK. The choice for breast cancer surgery: can women accurately predict postoperative quality of life and disease-related stigma? *Annals of Surgical Oncology*. 2011 Feb 23.[Epub ahead of print].
- Wojcik BE, Spinks MK, Otenberg SA. Breast carcinoma survival analysis for African American and White women in an equal-access health care system. *Cancer*. 1998;82:1310-1318.
- Yang SH, Yang KH, Li YP, Zhang YC, He XD, Song AL. Breast conservation therapy for stage I or stage II breast cancer: A meta-analysis of randomized controlled trials. *Annals of Oncology*. 2008;19:1039-1044.

## California Health Benefits Review Program Committees and Staff

A group of faculty and staff undertakes most of the analysis that informs reports by the California Health Benefits Review Program (CHBRP). The CHBRP **Faculty Task Force** comprises rotating representatives from six University of California (UC) campuses and three private universities in California. In addition to these representatives, there are other ongoing contributors to CHBRP from UC. This larger group provides advice to the CHBRP staff on the overall administration of the program and conducts much of the analysis. The **CHBRP staff** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and coordinates all external communications, including those with the California Legislature. The level of involvement of members of the CHBRP Faculty Task Force and staff varies on each report, with individual participants more closely involved in the preparation of some reports and less involved in others. As required by CHBRP's authorizing legislation, UC contracts with a certified actuary, Milliman Inc., to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit. Milliman also helped with the initial development of CHBRP methods for assessing that impact. The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance and thoughtful critiques provided by the members of the National Advisory Council. However, the Council does not necessarily approve or disapprove of or endorse this report. CHBRP assumes full responsibility for the report and the accuracy of its contents.

### Faculty Task Force

**Todd Gilmer, PhD**, *Vice Chair for Cost*, University of California, San Diego  
**Joy Melnikow, MD, MPH**, *Vice Chair for Public Health*, University of California, Davis  
**Ed Yelin, PhD**, *Vice Chair for Medical Effectiveness*, University of California, San Francisco  
**Wayne S. Dysinger, MD, MPH**, Loma Linda University Medical Center  
**Susan L. Ettner, PhD**, University of California, Los Angeles  
**Theodore Ganiats, MD**, University of California, San Diego  
**Sheldon Greenfield, MD**, University of California, Irvine  
**Sylvia Guendelman, PhD, LCSW**, University of California, Berkeley  
**Kathleen Johnson, PharmD, MPH, PhD**, University of Southern California  
**Thomas MaCurdy, PhD**, Stanford University

### Task Force Contributors

**Wade Aubry, MD**, University of California, San Francisco  
**Diana Cassidy, PhD**, University of California, Davis  
**Janet Coffman, MPP, PhD**, University of California, San Francisco  
**Eric Groessl, PhD**, University of California, San Diego  
**Heather J. Hether, PhD**, University of California, Davis  
**Mi-Kyung Hong, MPH**, University of California, San Francisco  
**Matt hew Ingram, MPH, MPP**, University of California, Berkeley  
**Shana Lavarreda, PhD, MPP**, University of California, Los Angeles  
**Jennifer Lewsey, MS**, University of California, San Diego  
**Stephen McCurdy, MD, MPH**, University of California, Davis  
**Sara McMenamin, PhD**, University of California, San Diego  
**Ying-Ying Meng, DrPH**, University of California, Los Angeles  
**Ninez Ponce, PhD**, University of California, Los Angeles  
**Dominique Ritley, MPH**, University of California, Davis  
**Meghan Soulsby, MPH**, University of California, Davis  
**Chris Tonner, MPH**, University of California, San Francisco  
**Arturo Vargas Bustamante, PhD, MA, MPP**, University of California, Los Angeles

## National Advisory Council

**Lauren LeRoy, PhD**, President and CEO, Grantmakers In Health, Washington, DC, *Chair*

**Deborah Chollet, PhD**, Senior Fellow, Mathematica Policy Research, Washington, DC

**Michael Connelly, JD**, President and CEO, Catholic Healthcare Partners, Cincinnati, OH

**Susan Dentzer**, Editor-in-Chief of Health Affairs, Washington, DC

**Joseph P. Ditré Esq.**, Executive Director, Consumers for Affordable Health Care, Augusta, ME

**Allen D. Feezor**, 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

**Trudy Lieberman**, Director, Health and Medicine Reporting Program, Graduate School of Journalism, City University of New York, New York City, NY

**Marilyn Moon, PhD**, Vice President and Director, Health Program, American Institutes for Research, Silver Spring, MD

**Carolyn Pare**, CEO, Buyers Health Care Action Group, Bloomington, MN

**Michael Pollard, JD, MPH**, Senior Fellow, Institute for Health Policy Solutions, Washington, DC

**Christopher Queram**, President and CEO, Wisconsin Collaborative for Healthcare Quality, Madison, WI

**Richard Roberts, MD, JD**, Professor of Family Medicine, University of Wisconsin-Madison, Madison, WI

**Frank Samuel, LLB**, Former Science and Technology Advisor, Governor’s Office, State of Ohio, Columbus, OH

**Patricia Smith**, President and CEO, Alliance of Community Health Plans, Washington, DC

**Prentiss Taylor, MD**, Regional Center Medical Director, Advocate Health Centers, Advocate Health Care, Chicago, IL

**J. Russell Teagarden**, Vice President, Clinical Practices and Therapeutics, Medco Health Solutions, Inc, Brookfield, CT

**Alan Weil, JD, MPP**, Executive Director, National Academy for State Health Policy, Washington, DC

## CHBRP Staff

**Susan Philip, MPP**, Director

**Garen Corbett, MS**, Principal Policy Analyst

**David Guarino**, Policy Analyst

**John Lewis, MPA**, Principal Policy Analyst

**Karla Wood**, Program Specialist

**California Health Benefits Review Program**

**University of California**

**Office of the President**

**1111 Franklin Street, 11<sup>th</sup> Floor**

**Oakland, CA 94607**

**Tel: 510-287-3876 Fax: 510-763-4253**

[chbrpinfo@chbrp.org](mailto:chbrpinfo@chbrp.org)

<http://www.chbrp.org>

The California Health Benefits Review Program is administered by the Division of Health Sciences and Services at the University of California, Office of the President. The Division is led by John D. Stobo, MD, Senior Vice President.