



CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Analysis of Assembly Bill 8
Health Care Coverage: Mastectomies
and Lymph Node Dissections

A Report to the 2005-2006 California Legislature
March 7, 2005

CHBRP 05-01



Established in 2002 to implement the provisions of Assembly Bill 1996 (*California Health and Safety Code*, Section 127660, et seq.), the California Health Benefits Review Program (CHBRP) responds to requests from the State Legislature to provide independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit mandates. The statute defines a health insurance benefit mandate as a requirement that a health insurer and/or managed care health plan (1) permit covered individuals to receive 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 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 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, made up of experts from outside the state of California and designed to provide balanced representation among groups with an interest in health insurance benefit mandates, reviews draft studies to ensure their quality before they are transmitted to the Legislature. Each report summarizes sound scientific evidence relevant to the proposed mandate but does not make recommendations, deferring policy decision making to the Legislature. The State funds this work through a small annual assessment of health plans and insurers in California. All CHBRP reports and information about current requests from the California Legislature are available at CHBRP's Web site, www.chbrp.org.

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Analysis of Assembly Bill 8 Health Care Coverage: Mastectomies and Lymph Node Dissections

March 7, 2005

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PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill 8, a bill to mandate that health care service plans and insurance policies regulated and licensed by the California Department of Managed Care or the California Department of Insurance provide coverage for a minimum of 48 hours of inpatient care for a mastectomy and 24 hours of inpatient care for a lymph node dissection for the treatment of breast cancer. The bill would also require coverage to be provided for a follow-up visit with a licensed health care professional within 48 hours of the patient's discharge from inpatient care. In response to a request from the California Assembly Committee on Health on January 6, 2005, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the provisions of Assembly Bill 1996 (2002) as chaptered in Section 127660, et seq., of the *California Health and Safety Code*.

Wade Aubry, MD, Patricia Franks, BA, Harold S. Luft, PhD, Karen Rappaport, MD, PhD, and Edward Yelin, PhD, all of the University of California, San Francisco, prepared the medical effectiveness analysis. Patricia Ganz, MD, of the University of California, Los Angeles, provided technical assistance with the literature review and clinical expertise for the medical effectiveness analysis. Helen Halpin, PhD, Sara McMenamin, PhD, and Nicole Bellows, MHSA, all of the University of California, Berkeley, prepared the public health impact analysis. Miriam Laugesen, PhD of the University of California, Los Angeles prepared the cost of illness section in the public health impact analysis. Gerald Kominski, PhD, Miriam Laugesen, PhD, and Nadereh Pourat, PhD, all of the University of California, Los Angeles, prepared the analysis of the cost impact. Robert Cosway, FSA, MAAA, of Milliman, provided actuarial analysis. Susan Philip, MPP, of CHBRP staff prepared the background section and contributed to preparing the individual sections into a single report. Other contributors include Sachin Kumar, BA, of CHBRP staff, and Cherie Wilkerson, who provided editing services. In addition, a subcommittee of CHBRP's National Advisory Council (see final pages of this report) reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

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

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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Assembly Bill 8 Health Care Coverage: Mastectomies and Lymph Node Dissections

The California Legislature has asked the California Health Benefits Review Program to conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 8.

AB 8 would mandate coverage for “not less than 48 hours of inpatient care for a woman undergoing a mastectomy and not less than 24 hours of inpatient care for a woman undergoing a lymph node dissection for treatment for breast cancer.” Mastectomy and axillary lymph node dissection are surgical procedures to treat breast cancer and may be carried out either on an outpatient or inpatient basis. In addition, the bill would mandate coverage for a “follow-up visit with a licensed health care professional, in the health care professional’s office, or at the patient’s home, within 48 hours of discharge from inpatient care for either surgical procedure.”

AB 8 would apply to health care services plans licensed by Knox-Keene¹ and to health insurance policies regulated under the California Insurance code.²

I. Medical Effectiveness

- There are no published studies relevant to the proposed mandate that provide evidence of a difference in patient health outcomes for mastectomy or axillary lymph node dissection based on length of hospital stay (less than 24 hours versus 24 hours or greater, or specific lengths of stay, such as 24 or 48 hours, for specific procedures).
- No published studies or clinical guidelines were found related to the provision of follow-up visits with a licensed health care professional in his or her office or at the patient’s home within 48 hours of discharge for patients undergoing mastectomy and/or axillary lymph node dissection either as outpatient or inpatient procedures.
- No randomized controlled trial studies of outcomes of mastectomy and axillary lymph node dissection in terms of medical complications, management of symptoms, and recovery were found with respect to inpatient versus outpatient stays. Results from observational studies are summarized later.
- Key findings from available observational studies related to medical complications include:
 - Postoperative infection: Patients who underwent mastectomy and/or axillary lymph node dissection on an outpatient basis were no more likely to have postoperative wound infections than were patients who underwent these procedures on an inpatient basis.
 - Postoperative drain care: Two studies of how outpatients’ care for the drains inserted during surgery in the home setting concluded that patients manage successfully, particularly with the assistance of caregivers, but there were no inpatient comparison groups in these studies.

¹ Health maintenance organizations in California are licensed under the Knox-Keene Health Care Services Plan Act, which is part of the California Health and Safety Code.

² AB 8 amends Section 1367.635 of the Health and Safety Code and Section 10123.86 of the Insurance Code relating to health coverage. AB 8 would not apply to specialized health care service plans, such as vision or dental plans.

- Hospital readmission: The evidence comparing hospital readmission rates for outpatients and inpatients after mastectomy and/or axillary node dissection is unfavorable, with higher readmission rates for outpatients.
- Key findings from available observational studies related to management of symptoms include:
 - Pain control: One study comparing outpatients and inpatients on the adequacy of pain control found that outpatients were at least as likely as inpatients to report that pain control is adequate.
 - Emotional adjustment: The preponderance of evidence in one study, using various measures of emotional adjustment to assess both outpatients and inpatients, indicated outcomes at least as good for outpatients as inpatients, but the results were not statistically significant in many cases.
- A key finding from the one available observational study related to recovery concerned the time taken to return to usual activities. This study indicates that there was significantly faster recovery from surgery and faster return to usual activities for outpatients than for inpatients. However, the authors did not consider potentially important differences between the two groups of patients that might explain this finding.

II. Utilization, Cost, and Coverage Impacts

Baseline

Coverage

- A total of 20.2 million insured Californians will be affected by this legislation, including 5.3 million women aged 30-64 years who are potentially eligible for breast cancer treatment.
- Current law requires coverage of inpatient stay following a mastectomy or lymph node dissection. Current law does not specify a minimum inpatient length of stay except that the length of stay is as determined by the attending physician and surgeon in consultation with the patient.
- Since there is an existing law requiring coverage, 100% of the population affected has coverage for inpatient treatment of breast cancer.
- None of the health plans or insurers surveyed by CHBRP limit the length of stay for breast cancer treatment.

Baseline Cost and Utilization

- The average cost of an inpatient stay for mastectomy and lymph node dissection is approximately \$4,464.
- The average outpatient charge is approximately \$3,000.
- The average length of stay for mastectomy or lymph node dissection is 1.89 days.
- There are 0.40 hospital days utilized for mastectomy or lymph node dissection for every 1,000 insured members in California.
- There are 0.69 outpatient utilizations per 1,000 members.
- There 0.21 hospital admissions for mastectomy and lymph node dissection for every 1,000 members insured in California.

Public Demand and Effects of Lack of Coverage

- There is no evidence to suggest that there is a shift in cost from private to public payers in the absence of the mandate.
- Collective bargaining agents do not typically negotiate for health insurance benefits in such detail, (e.g., for specific length of stays for treatment interventions.) Therefore there is no evidence to

indicate that demand among collective bargaining agents exists or not. The largest public self-insured plans currently cover inpatient care after a mastectomy or lymph node dissection with no coverage limitations.

Impact of AB 8

Benefit of the Service and the Unit Cost

- The legislation is not projected to limit the supply of hospital or outpatient care for breast cancer.
- The per day price of hospital treatment and the price per case of outpatient treatment are not estimated to increase.
- However, the average cost per inpatient stay is likely to increase because of the increase in the average length of stay—from \$4,464 to \$4,484, a difference of \$20
- Increases in the average length of stay will not increase or decrease the clinical benefit of the service.

Impact of Mandate on Utilization

- Overall utilization rates of breast cancer surgery are projected to remain the same.
- The average inpatient hospital length of stay for mastectomies and lymph node dissection is estimated to increase from 1.89 to 1.90 days, an increase of 0.53%.
- Hospital admissions are estimated to increase from 0.21 to 0.23 per 1,000 members, an increase of 9.5%.
- The combined utilization rate for outpatient mastectomy and lymph node dissection is expected to decline from 0.69 to 0.67 cases per 1,000 members, a change of –3.0%. Public awareness of the legislation is expected to have an impact on utilization. Awareness of the legislation may influence patient and provider decisions about whether surgery should be performed on an inpatient or outpatient basis. Ten percent of patients who would otherwise undergo outpatient treatment are expected to undergo hospital-based mastectomies and lymph node dissection after the mandate.
- The number of hospital days utilized for mastectomies and lymph node dissection is projected to increase from 0.40 days to 0.44 days per 1,000 members—an increase of 0.04 days, or 10%.

Impact on Administrative and Other Expenses

- Administrative costs are projected to remain the same when expressed as a percentage of total premium revenue.
- Out-of-pocket costs will not be affected.

Impact on Total Health Care Costs

- Total annual expenditure for the population affected by this legislation (20.2 million Californians) is estimated to increase from \$57,633,360,000 to \$57,634,200,000—an increase of 0.002%.
- Annual premium expenditure is estimated to increase from \$54,326,280,000 to \$54,327,120,000, an increase of 0.002% for private employers, employees, individual purchasers, and public sector purchasers affected by the mandate.
- Public sector insurers whose members are enrolled in managed care plans and state programs (California Public Employees' Retirement System [CalPERS], Medi-Cal, and Healthy Families) will pay an additional \$120,000 per year for those with health maintenance organization (HMO) coverage, an increase of 0.002%.
- Annual CalPERS expenditures are expected to increase by \$38,000—an increase of 0.001%. Annual total expenditure by Medi-Cal is estimated to increase by \$91,100, an increase of 0.003%. Healthy Families' expenditures will remain the same.

Table 1. Summary of Cost Effects of Mandate

Effect On	Before Mandate	Change After Mandate	Change After Mandate
Plans and insurers	Health and Safety and Insurance Codes require coverage of hospital treatment but does not specify minimum length of stay	Health and Safety and Insurance Codes require coverage of hospital treatment with specific minimum length of stays	
Private health insurance coverage of service	100% of insured individuals have coverage for mandated benefit	100% of insured individuals will have coverage for mandated benefit	0.0%
Number of people* in California with coverage for the benefit.	20,201,000	20,201,000	0.0%
People* in California directly affected by the mandate	5,300,860 women aged 30-64 yrs.	5,300,860 women aged 30-64 yrs.	0.0%
Total cost per service	For 1.89 days (average) length of stay in hospital: \$4,464 Outpatient surgery: \$3,000	For 1.90 days (average) length of stay in hospital: \$4,484 Outpatient surgery: \$3,000	Inpatient surgery: 4.79%** Outpatient surgery: no change
Utilization: annual number of services per 1,000 members.	0.21 mastectomy and lymph node dissection inpatient admissions per 1,000 members	0.23 mastectomy and lymph node dissection inpatient admissions per 1,000 members	9.5% increase in inpatient admissions for mastectomy and lymph node dissection
	Total outpatient surgeries per 1,000 members: 0.69	Total outpatient surgeries per 1,000 members: 0.67	-3.0% decrease in outpatient surgery for mastectomy and lymph node dissection
	Total inpatient days for these procedures per 1,000 members: 0.40	Total inpatient days per 1,000 members: 0.44	10% increase in inpatient days for mastectomy and lymph node dissection
Total premium expenditures per year (employee plus employer)	\$54,326,280,000	\$54,327,120,000	0.002%
Total out-of-pocket expenditures per year for service	\$3,307,080,000	\$3,307,080,000	0.000%
Total expenditures per year	\$57,633,360,000	\$57,634,200,000	0.002%

Source: California Health Benefits Review Program analysis, 2005

*Population younger than 65 years currently covered (excluding self-insured firms) with private insurance (group and individual), including those enrolled in managed care plans subject to the Health and Safety Code or those insured by health insurance policies subject to the Insurance Code. This includes people enrolled through CalPERS, Medi-Cal, or Healthy Families.

**The cost per inpatient day or cost per surgical procedure is not expected to increase. However the cost per inpatient surgery is expected to increase due to the expected increase in length of stay.

III. Public Health Impacts

- Approximately 1.8% of women ages 18-64 years with private health insurance in California report that they have at some point been diagnosed with breast cancer. In 2005, there are expected to be 21,800 new cases in California and 4,230 expected deaths due to breast cancer.
- Based on the available observational studies, the evidence does not support a judgment that outcomes would be substantially different under the mandate—specifically for any of the five potential health outcomes: infection after surgery, adequate pain control, emotional and physical adjustment, readmission following surgery, and recovery from surgery or return to usual activities.
- Analysis of new breast cancer cases and breast cancer deaths in California in 2000 by race/ethnicity indicates an underlying difference in disease patterns, whereby non-Hispanic Whites have the highest incidence rates compared with Blacks, Asian/Pacific Islanders, and Hispanics. Analysis of utilization data also indicates that length of stay differs across racial groups, with Blacks having higher average length of stays. However, there is no evidence that differences in length of stay will have an impact on the population's health. As such, there is no evidence that AB 8 will have an impact on racial and ethnic disparities in the treatment of breast cancer or in health outcomes.
- Studies on the outcomes measures (infection after surgery, adequate pain control, emotional and physical adjustment, and recovery from surgery or return to usual activities) do not include evidence related to the impact of differential length of stay or treatment setting on premature death for patients with breast cancer. There is no evidence indicating that AB 8 will have an impact on premature death associated with breast cancer.
- There is no evidence that AB 8 will affect the number of people diagnosed and treated for breast cancer or the health outcomes of those treated; therefore there is no evidence that this mandate will have an impact on the reduction of economic loss associated with breast cancer.

INTRODUCTION

Assembly Bill (AB) 8 would mandate coverage for a minimum length of stay “not less than 48-hours of inpatient care for a woman undergoing a mastectomy and not less than 24 hours of inpatient care for a woman undergoing a lymph node dissection for treatment for breast cancer.” AB 8 would allow for any greater length of stay to be covered if determined appropriate by the patient’s attending physician and surgeon in consultation with the patient. The bill permits stays shorter than the mandated level if the attending physician, surgeon, and patient determine that is appropriate. Current law requires coverage of inpatient stay after a mastectomy or lymph node dissection, as determined by the attending physician and surgeon in consultation with the patient, consistent with sound clinical principles and processes.

In addition, AB 8 would mandate coverage for a “follow-up visit with a licensed health care professional, in the health care professional’s office, or at the patient’s home, within 48-hours of discharge from inpatient care for either surgical procedure.”

The current version of AB 8 would not explicitly prohibit coverage for patients who have undergone a mastectomy or lymph node dissection in an outpatient setting from choosing to have an inpatient stay after the surgical procedure. This analysis, therefore, assumes the coverage requirements for a minimum length of inpatient stay apply, regardless of the setting of the surgery.

AB 8 would apply to health care services plans licensed by Knox-Keene and to health insurance policies regulated under the California Insurance code.³

Currently, twenty states⁴ (including California) have an existing mandate requiring health insurers to cover inpatient stay after a mastectomy or lymph node dissection as “determined by the attending physician.” Eleven of these states include a specified time period of inpatient stay, usually 48 hours, after surgery.

Similar federal legislation has been proposed both in the House and Senate during the last (108th) Congress. Two of the these bills (one in each chamber), known in both houses as the Breast Cancer Patient Protection Act of 2003, included coverage requirements for specified lengths of stay for inpatients after mastectomy. These bills never passed out of their respective chambers, and similar legislation has not been introduced in the current congressional session as of the writing of this report.

I. MEDICAL EFFECTIVENESS

The proposed mandate, AB 8, defines mastectomy as “removal of all or part of the breast for medically necessary reasons.”⁵ This broad definition includes limited breast-conserving procedures, such as a *lumpectomy*, or removal of a small tumor with normal tissue margins, as well as *simple* or *total mastectomy*, or removal of the entire breast, and *radical mastectomy*, which involves removing both the breast and lymph nodes. In clinical practice, *mastectomy* usually refers to removal of breast tissue for the treatment of breast cancer or for the prevention of breast cancer in high-risk individuals, and not the

³ AB 8 amends Section 1367.635 of the Health and Safety Code and Section 10123.86 of the Insurance Code relating to health coverage. AB 8 would not apply to specialized health care service plans, such as vision-only or dental-only plans.

⁴ Arkansas, California, Connecticut, Florida, Georgia, Illinois, Maine, Montana, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Texas, Virginia, West Virginia. (<http://www.statehealthfacts.org>)

⁵ Section 1367.6 of the California Health and Safety Code and Section 10123.8 of the Insurance Code

removal of breast tissue for diagnostic purposes. *Axillary lymph node dissection*, also sometimes called *axillary lymphadenectomy*, is a surgical procedure to detect, stage, and treat metastatic breast cancer involving removal of one or more of the three different levels of lymph nodes under the arm in the axilla. *Mastectomy* and/or *axillary lymph node dissection*, which are surgical procedures to treat breast cancer, may be carried out on an outpatient or inpatient basis.

There are no published studies relevant to the proposed mandate that provide evidence, based on randomized controlled studies, of a difference in patient health outcomes for mastectomy or axillary lymph node dissection with respect to length of hospital stay (less than 24 hours versus 24 hours or greater, or specific lengths of stay, such as 24 hours, 48 hours, or 72 hours for specific procedures).

The only studies of some relevance to the mandate in the medical literature were observational (i.e., non-experimental) studies of patients undergoing mastectomies and/or axillary lymph node dissections as an outpatient procedure (involving a hospital or surgical center stay of less than 24 hours) or an inpatient procedure (involving a stay of 24 hours or greater) and did not include patients undergoing immediate breast reconstruction surgery, which, most surgeons agree, necessitates a hospital stay (Burke et al., 1997).

In an observational study, the patients undergoing inpatient surgery might differ in important respects from the outpatient group, such as the patient's other health problems, expected extent of surgery, and likely surgical risk, rendering comparisons between the groups difficult. Indeed, it is quite possible that women undergoing outpatient mastectomy may be at lower risk of poor outcomes than those undergoing inpatient procedures. In observational studies, the possibility that these types of differences, rather than the true effect of an outpatient versus an inpatient procedure, accounts for differences in outcomes cannot be ruled out. For example, healthier women may elect outpatient surgery and sicker women may elect inpatient stays. Therefore, it is not possible to conclude that any effects experienced in one group versus the other were due to whether the surgery was performed on an outpatient or inpatient basis, rather than to initial health status.

For example, in some of the observational studies, outpatients were less likely than inpatients to undergo axillary lymph node dissection, a procedure that may contribute to considerable morbidity postoperatively. Some of the observational studies in this analysis used either historical or concurrent comparison groups, whereas other studies did not include any comparison groups. Some were surveys measuring patient satisfaction and emotional health issues. There were no studies available that looked exclusively at outcomes for lymph node dissections without mastectomy. For some outcomes of interest, there either were no relevant studies or the studies lacked a comparison group of patients undergoing inpatient surgery.

No randomized controlled trial studies of inpatient versus outpatient mastectomy or lymph node dissection were found in the search of the peer-reviewed scientific literature. Randomized clinical trials involve a study of a treatment group that receives a particular intervention as well as a control group that is essentially the same (e.g., age, gender, health status, health problems) but receives either no intervention, or an alternative treatment. In a randomized clinical trial, participants have an equal chance of being assigned to either group, and the outcomes in the intervention and control (or alternative treatment) group can be compared. Such trials are the most credible and reliable method of answering questions about the effectiveness of medical interventions, but they are not always feasible, for practical or ethical reasons.

The results of the review of the scientific literature relevant to AB 8 are divided into three major categories of effects: medical complications, management of symptoms during the early postoperative period, and recovery in the late postoperative period.

The scope of the literature search included the following outcomes:

- Medical complications
 - Postoperative infection
 - Postoperative drain care
 - Hospital readmission
 - Postoperative bleeding
 - Incidence of seroma (accumulation of fluids at the surgical site)
 - Reoperation
 - Incidence of pulmonary embolism
- Management of symptoms
 - Pain control
 - Emotional adjustment
- Recovery
 - Time to return to usual activities
 - Patient satisfaction
 - Problems associated with range of motion in the arm(s)

The search was conducted through PubMed and the Cochrane Library for relevant research published over the last twenty years. A description of methods used to conduct the medical effectiveness review, and the process used to “grade” the evidence can be found in Appendix A: Literature Review Methods. Summary tables with detailed findings from the literature can be found in Appendix B, Summary of Findings on Medical Effectiveness Related to Mastectomy and Axillary Node Dissection.

Medical Complications

Postoperative infection

In an analysis of the first 86 mastectomy patients treated after implementation of an outpatient surgery program, Dooley (2002) found one case of postoperative infection (1%). In contrast, 6% of inpatient mastectomy patients (number of inpatients not available) from the previous year had developed postoperative infections. Burke et al. (1997) found no evidence of postoperative infection in 52 patients undergoing mastectomies as outpatients. In a study of 100 consecutive women undergoing breast cancer surgery, Tan and Guenther (1997) found that none of the 50 women who underwent surgery as outpatients and none of the 44 women who were hospitalized as inpatients for one night developed postoperative wound infection. One of the six patients hospitalized for more than one night, a woman with multiple sclerosis, developed an infection of the breast and axilla postoperatively secondary to her dependence on crutches. Seltzer (1995) found 2 of 133 outpatient mastectomy patients and 2 of 45 inpatient mastectomy patients with postoperative wound infection. Similarly, McManus et al. (1994) and Goodman and Mendez (1993) found a zero incidence of postoperative infection in 118 and 221 patients undergoing outpatient breast cancer surgery.

The evidence suggests that the postoperative infection rate among otherwise healthy patients undergoing outpatient mastectomies is very small and is possibly lower than that among mastectomy patients who

remain in the hospital. There was a pattern toward a favorable outcome in terms of postoperative infections in studies including outpatients, but the results did not reach statistical significance.

Postoperative drain care

Whether patients are treated as outpatients in an ambulatory care center or undergo surgery in a hospital where they remain for no more than two nights, most are discharged with incisional drains that serve as conduits for the removal of excess fluid, blood, and debris from the surgical site. Numerous studies in different countries have demonstrated the safety of discharging patients with drains (Chadha et al., 2004; Davis et al., 2000; Deo et al., 1997; Wells et al., 2004). Burke et al. (1997) surveyed 52 patients between 24 and 72 hours after surgery in an outpatient surgical center that admitted patients for less than 23 hours and found that eight patients (16%)⁶ had problems with their drains that were solved either with the assistance of a caregiver or by a health care professional on an outpatient basis. Interviews seven to ten days post surgery showed that six patients (13%) had problems maintaining drain suction, three patients (6%) had difficulty manipulating the drain tubing, two patients (4%) had difficulty emptying the drainage, and two (4%) had difficulty recording the amount of drainage. McManus et al. (1994) reported that none of their 118 outpatients reported difficulties with their drains.

However, the studies that analyzed the difficulties faced by patients undergoing outpatient mastectomies in caring for drains or the incision did not utilize comparison groups of inpatients.

Therefore, the evidence is insufficient to suggest that outpatients have more or fewer problems caring for drains than those patients who stay in the hospital for one or more nights.

Hospital readmission

Of 86 outpatient mastectomy patients (one of the original 87 patients opted to remain in the hospital overnight), Dooley (2002) found that no patients had been admitted as inpatients shortly after discharge from the ambulatory care setting.

However, other studies show contradictory findings. Ferrante et al. (2000) and Warren et al. (1998) both noted that women who have had outpatient mastectomies are significantly more likely to be readmitted to the hospital as inpatients in the short term. Using state discharge abstracts from Florida and the state's tumor registry data, Ferrante et al. (2000) found readmission rates of 1.3% for outpatients (14 of 1,089) and 0.6% for inpatients (24 of 4,329). Outpatients were also more likely than were inpatients to experience an urgent readmission to the hospital, but the findings were of borderline significance ($p = 0.057$). Using Medicare data, Warren et al. (1998) found that the odds of rehospitalization were significantly greater for outpatients than for one-day-stay simple mastectomy patients: 84% higher (OR = 1.84) within 7 days and 43% higher (OR = 1.43) within 30 days. Similarly, the odds of rehospitalization were significantly greater for outpatients than for one-day-stay modified radical mastectomy patients: 72% higher within 7 days (OR = 1.72) and 28% higher within 30 days (OR = 1.28). The women at greatest risk of rehospitalization for reasons related to surgery were those women who had been hospitalized for three days or more, suggesting that they may have had more advanced cancers or poorer health status. Of note, it cannot be determined with certainty from the articles if patients who receive their mastectomies as outpatients and are discharged directly to an inpatient service for management of complications are counted as "readmissions. Furthermore, even if there is no difference in health outcomes, if complications arise within a few hours of surgery, these may be dealt with during the usual inpatient stay, but require an unanticipated admission if the procedure was originally performed on an outpatient basis (see Appendix E)."

⁶ Not all patients answered every question.

Similar to Dooley (2002), Tan and Guenther (1997) found no readmissions among the 50 patients who underwent outpatient surgery or among the 44 patients who remained in the hospital overnight. Seltzer (1995) also did not find any readmissions among 133 outpatients, but he did not provide comparison information for inpatients. However, these studies were very small.

Overall, the evidence concerning differences in hospital readmission rates (possibly for reasons related to surgery) after surgery for breast cancer is mixed. However, all studies show low readmission rates of no more than approximately 3% for either inpatients or outpatients.

Postoperative bleeding

McManus et al. (1994) reported that the bandages of 1 of 118 patients undergoing mastectomy as outpatients were soaked with blood immediately prior to discharge. Instead of being discharged to home, this patient was admitted overnight for observation. Goodman and Mendez (1993) reported that none of the 221 patients undergoing mastectomy as outpatients experienced substantial postoperative bleeding. However, neither study employed a comparison group of inpatients.

Therefore, the evidence is insufficient to suggest that outpatients had more or fewer problems with postoperative bleeding than did inpatients.

Incidence of seromas

The possibility that different rates of seroma formation (localized fluid collection in the surgical site) might be found between outpatients and inpatients undergoing mastectomy was considered. Seromas are thought to be a consequence of inadequate drainage of wounds after surgery (Yii et al., 1995). Removing drains early may reduce the risk of infection by removing a portal of entry for microorganisms. However, patients often have to undergo aspiration of seromas if drains are removed too soon. Seltzer (1995) found that three of 133 outpatients, but none of the 45 inpatients, developed seromas. McManus et al. (1994), who provided limited information on their inpatient comparison group, reported “several” seromas managed by aspiration. and Goodman and Mendez (1993), who did not have an inpatient comparison group, reported a 15% incidence of seroma formation.

Several studies from England, where outpatient mastectomy surgery is not as common as in the US, and patients are often hospitalized until the removal of the drains four or five days after surgery, evaluate short stays of 48 hours versus longer stays for mastectomy patients. Yii et al. (1995) from the United Kingdom examine seroma formation and conclude that use of suction drains allows for removal of drains after a 48-hour hospitalization. In their study, 10% of patients treated with suction drains for 48 hours or less developed seromas, none of which had to be aspirated more than twice.

Overall, there was insufficient evidence to conclude that outpatients had more or fewer seromas than did inpatients.

Reoperation

No studies were found.

Incidence of pulmonary embolism

No studies were found.

Management of Symptoms

Pain control

Margolese and Lasry (2000) used a 5-point scale (0 = no pain, 2 = discomforting, 3 = distressing, 4 = horrible, 5 = excruciating) to measure pain and found that inpatients reported significantly more pain on the first day (mean, 1.76 on the 5-point scale) and during the first week (mean, 2.27 on the scale) than did outpatients (mean, 1.59 and 2.07, respectively on the scale). Of 100 patients in a study by Tan and Guenther (1997), only three patients required immediate admission to the hospital for control of pain after surgery. In the study by McManus et al. (1994), 100% of outpatients were satisfied with pain control.

The findings suggest that pain control for outpatients is at least as good as, if not superior to, pain control for inpatients. On the other hand, patients undergoing surgery as inpatients may be more likely to require more extensive surgical procedures, necessitating more pain control. Outpatients may appear to have superior pain control when they just require less of it due to the nature of their surgical procedures.

Emotional and physical adjustment

Margolese and Lasry (2000) analyzed various measures of adjustment in outpatient mastectomy patients and obtained results that compared favorably with measures obtained from inpatients. Outpatients had a significantly higher score than did inpatients on a 5-point scale of emotional adjustment with 5 indicating the best adjustment (mean, 3.89 versus mean, 3.46, respectively ($p < 0.05$)). (The authors did not include the scale in the published article.) Again using a 5-point scale, Margolese and Lasry found that outpatients also had better scores on a quality of life index (mean, 3.70 for outpatients versus mean, 3.56 for inpatients), but the results were not significant. (This scale was not included in the published article.) The authors used a 15-item distress symptom scale. (Details of the scale were not provided in the article, except that it can be inferred from the text of the article that higher scores indicate more distress.) On this scale, outpatients fared better psychologically than did inpatients (mean, 8.6 for outpatients versus mean, 11.7 for inpatients), but the findings were not significant ($p < .09$). Outpatients were significantly more likely than were inpatients to be completely asymptomatic on mental and physical indices ($p < 0.02$). In contrast, outpatients needed slightly more days to recover from the stress of surgery (127.8 days for outpatients versus 119.1 days for inpatients), but the results were not significant.

Overall, on most measures of emotional and physical adjustment, mastectomy patients undergoing outpatient surgery experienced outcomes at least as good as those of inpatients, but these results in many cases were not significant and may have been influenced by factors other than the setting of the procedure. It would not be surprising that patients undergoing less extensive surgeries for smaller cancers would have better emotional and physical adjustments than patients who have undergone more extensive surgeries and have a worse prognosis.

Recovery

Time to return to usual activities

Margolese and Lasry (2000) reported that outpatients needed significantly fewer days to recover from surgery than did inpatients (17.4 versus 26.8 days). Outpatients also returned to usual activities faster than did inpatients (35.1 versus 46.4 days).

Overall, the results of two measures in the Margolese and Lasry (2000) study suggest a favorable outcome for outpatients with respect to return to usual activities as compared with inpatients, however the same caveat applies. The inpatient and outpatient populations may not be comparable since patients who

undergo surgery as an outpatient may have fewer risk factors and comorbidities and may be undergoing less extensive surgery than patients who undergo surgery as an inpatient.

Patient satisfaction

Seltzer (1995) did not survey patients to determine the level of satisfaction with outpatient surgery. However, 2 of 133 women undergoing outpatient breast cancer surgery expressed dissatisfaction retrospectively about not having been hospitalized overnight. Burke et al. (1997) surveyed 52 outpatients and found that 41 of the 52 outpatients (85%) felt prepared to leave the hospital after surgery, whereas 7 (15%) did not. Of the 52 women in the study, 11 indicated retrospectively that a hospital stay of 2-3 days would have improved the experience.

Overall, because neither study had a comparison group, there is insufficient evidence to conclude that outpatients had more or less satisfaction than inpatients with their surgeries.

Range of motion in the arm(s)

McManus et al. (1994) did not find that outpatients suffered postoperatively from range of motion problems in their arms on the side in which a mastectomy was performed. However, the study did not include a comparison group of inpatients.

Limitations of the Analysis

All of the studies found during the literature search were observational studies; none were randomized controlled trials in which patients are randomly assigned to inpatient and outpatient treatment groups for the purpose of undertaking an unbiased analysis. Most of the studies reviewed had higher proportions of women undergoing simple mastectomies without axillary lymph node dissections in the outpatient group and higher proportions of women undergoing modified radical mastectomies with axillary lymph node dissections in the inpatient group. The differences between patients undergoing outpatient and inpatient mastectomies as well as more extensive preoperative educational programs for outpatients and their caregivers might also explain the more frequent reporting of good outcomes among outpatients.

Summary

There are no published studies relevant to the proposed mandate that provide evidence of a difference in patient health outcomes for mastectomy or axillary lymph node dissection based on length of hospital stay (less than 24 hours versus 24 hours or greater, or specific lengths of stay, such as 24 hours or 48 hours, for specific procedures).

No randomized controlled studies comparing outcomes (i.e., medical complications, management of symptoms, and recovery) for those undergoing mastectomy and/or axillary lymph node dissection as outpatient and inpatient procedures were found. No evidence was found from the available observational studies that outpatient mastectomy procedures increase the risk of infections, are associated with an increase in problems with drain or incision care, or lead to substantially more rehospitalizations during the postoperative period. In addition, no evidence was found that pain control is less adequate among outpatients than among inpatients or that outpatients have poorer psychological adjustment and slower return to usual activities than do inpatients.

Overall, the evidence suggests that outpatient mastectomy and axillary lymph node dissection are not less safe than inpatient surgery, especially if the attending surgeon has the discretion to admit high-risk patients after surgery. However, the contribution of preoperative education programs for patients and caregivers to the evidence in support of outpatient mastectomy is not known. No evidence was found,

favorable or unfavorable, concerning the effect of a follow-up visit for patients who had undergone mastectomy and/or axillary lymph node dissection within 48 hours after surgery.

II. UTILIZATION, COST, AND COVERAGE IMPACTS

Baseline Cost and Coverage

Current coverage of the mandated benefit (3(i))

Coverage data were collected in January 2005 by CHBRP from six of the seven major California health insurance and managed care organizations. All six organizations currently provide coverage for mastectomy and lymph node dissection for the treatment of breast cancer. According to this survey of health plans and insurers, the services mandated by AB 8 are available to 100% of enrollees.

Approximately 20.201 million people with private insurance or coverage through state program HMOs (CalPERS, Medi-Cal Managed Care, or Healthy Families) are presently covered for these benefits. Of this group, 5,300,860 women are aged 30-64 years and would be directly affected by the mandate, as shown in Table 3.

None of the health plans and insurers that responded to the survey placed coverage restrictions on the length of stay. Two of the six organizations required pre-authorization for inpatient stays. Generally, the patient's physician determines the length of stay in consultation with patients. Only one organization responded stating that they use published utilization management guidelines to evaluate the length of stay for breast cancer surgery.

All health plans and insurers provide coverage for surgery in outpatient and inpatient settings. All health plans and insurers cover follow-up visits by physicians.

Health plans and insurers vary in their coverage of home health care or house calls by physicians. Two of the organizations surveyed cover home visits by the attending surgeon and other professionals, one with limited restrictions and one without restrictions. Two health plans and insurers provide home health services only with authorization, and one only provides home health care when the member is confined to their home.

All state health insurance programs already include coverage of the services included in the mandate.

Unit costs

The average total cost per stay in hospital for a mastectomy or lymph node dissection is \$4,464. The average cost per case for outpatient treatment is \$3,000. These costs are based on Milliman's estimate of average health plan/hospital payment rates in California for uncomplicated medical/surgical days. Cost estimates include all the fees related to the hospital cost, but exclude the physician cost, which is billed separately and is assumed to stay the same regardless of the setting of the surgery or the length of stay.

Inpatient utilization

The average length of stay for mastectomy and lymph node dissection is 1.89 days. Table 6 shows that 56% of admissions for breast cancer were for one day or less, and 24% stayed two days. One-fifth (20%) of patients were in the hospital for three days or more.

Table 7 shows 0.21 hospital admissions for mastectomy and lymph node dissection for every 1,000 members insured in California. For every 1,000 members, there are 0.40 inpatient hospital days utilized.⁷

For every 1,000 members insured in California, there are 0.17 cases of outpatient total mastectomies, 0.07 outpatient lymph node dissections, and 0.45 outpatient “other”⁸ mastectomies (Table 7).

Physician visits

AB 8 requires coverage of a follow-up visit with a licensed health care professional within 48 hours of a patient’s discharge from inpatient care. Discussions with health care professionals revealed that follow-up visits are already standard practice for physicians, although the visits may not always occur within 48 hours of discharge. Because follow-up visits by the surgeon are covered by the surgery fee and not billed separately, accurate counts on the number and timing of follow-up visits are not available.

The extent to which costs resulting from lack of coverage are shifted to other payers, including both public and private entities. (Section 3(f))

There is no evidence that the absence of the mandated length of stay proposed in AB 8 presently results in cost-shifting to other payers, public or private, because the services mandated by AB 8 are already covered.

Public demand for coverage (Section 3(j))

Based on conversations with the largest collective bargaining agents in California, there is no evidence that unions currently include such detailed provisions during the negotiations of their health insurance policies. In order to determine whether any local unions engage in negotiations at such detail, they would need to be surveyed individually.⁹

Currently, the largest public self-insured plans, CalPERS preferred provider organization (PPO) plans cover a minimum inpatient length of stay of 96 hours for enrollees who have undergone a mastectomy or lymph node dissection. In addition, there are no benefit limitations on inpatient coverage for breast cancer treatment.

Impacts of Mandated Coverage

How will changes in coverage related to the mandate affect the benefit of the newly covered service and the per-unit cost? (Section 3(a))

Supply of services, effectiveness, and unit costs

As discussed below, AB 8 is likely to increase in the length of stay, from 1.89 days to 1.90 days. Utilization changes are unlikely to increase or decrease the supply of services available to patients. Therefore, there should be no supply constraints on services that influence the effectiveness or unit costs of the mandated service.

The unit costs of outpatient and inpatient hospital treatment for mastectomy and lymph node dissection varies widely in California. Costs vary due to geography, the contracts between the health plan and the

⁷ The insured population mentioned here refers only to people who are in plans regulated by Knox Keene or the Insurance Code.

⁸ “Other” mastectomies are partial mastectomies including, mastectomy for gynecomastia, partial mastectomy with axillary lymphadenectomy.

⁹ Conversations with SEIU and California Labor Federation on February 8, 2005

hospital, and the severity of the case. For our analysis we needed to estimate two types of unit costs:

- First, the cost for additional days for existing inpatient admissions whose lengths of stay might increase due to this mandate. We estimated the cost of each additional inpatient day to be \$2,362. This was based on Milliman's estimate of average health plan/hospital payment rates in California for uncomplicated medical/surgical days.
- Second, we needed to estimate the difference in unit costs for cases that are currently performed on an outpatient basis, but that might be performed on an inpatient basis after the mandate. For this purpose, we estimate the average cost of an outpatient mastectomy and lymphadenectomy case to be \$3,000, and the average cost if this same case was performed inpatient to be \$3,543 (\$2,362 per day and an average 1.5 day stay).

All of these estimates include all the fees related to the hospital cost, but exclude the physician cost which is billed separately and is assumed to not vary based on the setting of the surgery or the length of stay.

Changes in the average benefit of surgery

CHBRP's effectiveness analysis suggests that there is no additional health benefit, on average, from longer hospital stays.

How will utilization change as a result of the mandate? (Section 3(b))

Overall utilization

The utilization rates of *breast cancer surgery*, including both mastectomies and lymph node dissection, are unlikely to increase. The demand for surgery, which is driven by underlying prevalence of breast cancer, will not be influenced by the mandate.

There are two kinds of anticipated effects: (1) for cases that are already being performed as inpatient, an increase in the length of stay for mastectomies and lymph node dissection, due to some cases that currently stay only one night staying an extra night in the hospital; and (2) a transfer of cases that are currently performed outpatient to an inpatient setting.

The estimates of changes in length of stay were made by actuaries familiar with the California market and knowledgeable about industry practices. Actuaries modeled the utilization changes based on the assumption that health plans are not pressuring women to leave the hospital. Instead, the utilization analysis assumes that practice patterns reflect current law—that physicians determine the length of stay in consultation with patients.

For cases already being performed as inpatient: The change after the mandate is unlikely to cause *all* one-day stays to become two-day stays. This was confirmed by looking at data from another state, Texas, that has a similar mandate currently in place. The estimated change in length of stay is based on the assumption that 10% of cases would shift from one-day to two-day cases. On average, this would mean the percentage of one-day stays for existing inpatient cases would decline from 56% to 50%. For these cases, the average length of stay is projected to increase after the mandate from approximately 1.89 days to approximately 1.94 days, a change of 2.65%. We also assume that only 10% of the one-days stays in California would shift to two-day stays after the mandate because physicians are likely to continue to recommend that their patients return home as soon as possible after surgery, particularly in light of the lack of evidence regarding clinical benefit of two-day inpatient stays relative to one-day inpatient stays.

Hospital stays beyond two days would not be affected because these are already longer than the mandated time.

For cases being performed as an outpatient: New cases that would move from outpatient to inpatient are assumed to only have a 1.50 days length of stay. These estimates assume that after the mandate, 10% of outpatient total mastectomies and lymph node dissection currently performed in an outpatient setting would have an inpatient stay in the hospital. This assumption is based on the expectation that most doctors will continue to recommend outpatient surgery for patients, but increased awareness of the mandate, after AB 8 is passed, may encourage more women to seek surgery on an inpatient basis.

Resulting changes in utilization: Based on these two anticipated effects, the average length of stay is projected to increase after the mandate from approximately 1.89 days to approximately 1.90 days, a change of 0.53%.

The total inpatient hospital days utilized for mastectomy and lymph node dissection are projected to increase from approximately 0.40 days per 1,000 members to 0.44 days per members, an increase of 0.04 days per 1,000 members.

As a result of the increase in the number of women treated as inpatients, there would be a corresponding reduction in outpatient cases treated. Outpatient cases of mastectomies and lymph node dissection are projected to fall from approximately 0.69 to approximately 0.67 per 1,000 members. Total inpatient cases admitted to hospital are projected to increase from approximately 0.21 cases per 1,000 to approximately 0.23 cases per 1,000 members.

Complementary, alternative, and substitution effects

There is no evidence that complementary service utilization will be affected by this mandate.

The main alternative to inpatient surgery is outpatient surgery, and as discussed earlier, around 10% of women would be expected to have inpatient surgery instead of outpatient surgery as a result of the mandate.

Outpatient surgery

Outpatient surgery is presently also a covered benefit, so costs will not be shifted from one payer to another.

As discussed in Section 3b, 10% of women who currently undergo outpatient surgery may elect inpatient care. As a result, there could be some small changes in the population that will choose hospital inpatient treatment of breast cancer under AB 8. The patients who need inpatient stays are assumed to be receiving medically necessary care prior to the mandate, and this would be unchanged. According to CHBRP estimates, women who would have selected outpatient care prior to AB 8 but who would now select inpatient care would have shorter hospital stays on average relative to other inpatients (1.50 days versus 1.90 days). This estimate of a shorter length of stay for this particular group of patients only is not based on research specific to breast cancer treatment, but represent patterns of utilization observed for other health care services. The group of women who would otherwise be eligible for outpatient treatment but select inpatient over outpatient treatment would tend to be healthier or have less advanced breast cancer, and are likely to have fewer co-existing health conditions, compared with the patients who would not be suitable candidates for outpatient surgery. There are no changes expected in the utilization of pharmaceutical, physician, or other health care services as a result of this mandate.

To what extent does the mandate affect administrative and other expenses? (Section 3(c))

Responses to a CHBRP survey of health plans and insurers suggested that these organizations believe they will incur limited additional administrative charges if this mandate is adopted. Health plans and insurers will need to send notices of the new requirements to the members and physicians, and update and

file the evidence of coverage and certificates. However, provided the legislation takes effect July 2006, plans will have time to include it in the material given to new members on January 1, which coincides with the start of new enrollment for the majority of the insured population and when plans and insurers typically notify their members about changes to benefits. Notification on these changes would be included along with other annual notice of changes to members' benefits. Thus no disproportionate increase in administrative costs is expected. Accordingly, we retain the standard model used by CHBRP, which assumes administrative costs to be a fixed proportion of benefit costs.

The average cost of a hospital stay for a mastectomy or lymph node dissection is expected to increase from \$4,464 to \$4,484 as a result of increased length of stay from 1.89 to 1.90 days. We estimated the cost of each additional inpatient day to be \$2,362. This was based on Milliman's estimate of average health plan/hospital payment rates in California for uncomplicated medical/surgical days. Outpatient stay costs remain the same.

The \$20 increase in average costs is also influenced by cases transferring from outpatient to inpatient treatment after the mandate. The average cost of an outpatient mastectomy or lymph node dissection case is \$3,000. The average cost of inpatient treatment for women eligible for outpatient treatment would be \$3,543 (\$2,362 per day and an average 1.5-day stay). This is lower than the post-mandate average cost of \$4,484 because women who are eligible for outpatient treatment, but choose inpatient care, are on average healthier than women who would not be suitable for outpatient care and therefore their stay would be assumed to be shorter.

Impact of the mandate on total health care costs (Section 3(d))

There will be no off-setting savings as a result of the mandate.

Total health care expenditures, all payers

Total annual health care expenditures are expected to increase from \$57,633,360,000 to \$57,634,200,000, an increase of 0.002% spread across 20.2 million insured persons.

Total expenditures, by payer

Private employers' total costs will increase by \$480,000 per year, an increase of 0.002%. Employees' premiums will increase by \$120,000 per year. Individual purchasers of insurance will pay an additional \$120,000 per year, an increase of 0.003%.

Public sector insurers whose members are enrolled in managed care plans and state programs (CalPERS, Medi-Cal, and Healthy Families), will pay an additional \$120,000 per year for enrollees with HMO coverage, an increase of 0.002%. CalPERS expenditures are expected to increase by \$38,000, an increase of 0.001%. Annual total expenditure by Medi-Cal is estimated to increase by \$91,100, an increase of 0.003%. Healthy Families' expenditures will remain the same.

Total premium expenditures, all payers

All payers' total combined premium expenditure is projected to increase by \$840,000 per year.

Out-of-Pocket Expenditures

Out-of-pocket expenditures are not expected to increase, as shown in Table 1.

Costs or savings for each category of insurer resulting from the benefit mandate (Section 3(e))

Estimates of the impact for different payers are shown in Table 2 (with details of the baseline and postmandate levels summarized in Tables 4 and 5 respectively). The differences across payers are less than 0.1%.

The impact of AB 8 varies among different-sized employers, retirement systems such as CalPERS and local retirement systems, individually purchased policies, and publicly funded health insurance programs such as Medi-Cal and Healthy Families. Impacts may vary because the proportion of female policy holders is different among some plans, and because practice patterns vary across health plans and insurers. For example, HMOs and point of service (POS) plans may have shorter lengths of stay at present, so the effect of a shift to a mandated length of stay may be more noticeable for these plans.

An additional 0.002% increase in premiums is not likely to change the willingness of employers to offer insurance, or pay higher premiums on behalf of their employees. Likewise, the take-up of employer-sponsored insurance by employees will not change as a result of AB 8. Copayments and coinsurance are unlikely to change as a result of the mandate. Individuals' decisions to purchase insurance are unlikely to change as a result of the mandate.

Impact on access and health service availability (Section 3(g))

There will be minimal impacts on the access and availability of the services required by AB 8. This is because access and availability to these services is already high, and because the change in utilization and costs are not substantial. Follow-up visits are presently widely utilized after surgery, and coverage of this benefit is already high. As noted in section 3(e), effects of AB 8 may vary across purchasers, but the magnitude of these effects is estimated to be negligible.

III. PUBLIC HEALTH IMPACTS

Present Baseline Health Outcomes

Approximately 1.8% of women ages 18-64 years with private health insurance in California report that they have at some point been diagnosed with breast cancer (CHIS, 2001). As presented in Table 8, it is expected that 21,800 new cases of breast cancer will be diagnosed in California in 2005 with 4,230 deaths due to breast cancer (ACS, 2004). An analysis of new breast cancer cases and breast cancer deaths in California in 2000 by race/ethnicity indicates an underlying difference in disease patterns (Table 9). For example, non-Hispanic Whites have the highest incidence rates of breast cancer in California (82.6 cases per 100,000 population) compared with Blacks (69.2), Asian/Pacific Islanders (47.2), or Hispanics (44.8). Although Blacks have a lower incidence rate compared with non-Hispanic Whites, they have a higher mortality rate (20.5 versus 15.3 deaths per 100,000 population).

The treatment options for breast cancer depend primarily on stage of diagnosis (Morris and Kwong, 2004). Table 10 presents the overall distribution of stage of diagnosis in California from 1988 to 1999: 13% of breast cancers are diagnosed in situ, 36% are diagnosed at Stage I (tumor less than 2 cm in greatest dimension with no spread to axillary lymph nodes), 34% are diagnosed at Stage II (tumor less than 5 cm, lymph nodes involved, but movable or tumor more than 2 cm with no spread to axillary lymph nodes), 5% are diagnosed at Stage III (tumor more than 5 cm, lymph nodes involved, but movable or tumor of any size, lymph nodes involved and fixed to each other or other structures), and 4% are diagnosed at Stage IV (spread to other organs).

Rates of breast-conserving surgeries are highest for breast cancers found in earlier stages, whereas rates of mastectomies rise as the stage of diagnosis progresses. The exception is in breast cancers found in Stage IV, where only half undergo treatment in the form of breast-conserving surgery or mastectomy. Currently, the rate at which women, ages 0-64 years enrolled in private employer-based health plans or policies,

undergo partial mastectomies is 85 per 100,000; the rate for mastectomies is 72 per 100,000, and the rate of lymph node dissection is 13 per 100,000 (Milliman, 2003). Of those who are hospitalized to undergo surgery for breast cancer, 56% stay in the hospital for one day, 24% are hospitalized for two days, and 20% are hospitalized for three or more days (Table 11).

Within the three main categories of health outcomes (medical complications, management of symptoms, and recovery), there are five specific outcomes identified in the review of the medical effectiveness literature with sufficient evidence to examine their impact on length of stay for mastectomy and lymph node dissections. These outcomes are infection after surgery, adequate pain control, emotional and physical adjustment, readmission following surgery, and recovery from surgery or return to usual activities. There are no baseline data available on the rates of these outcomes in the population of women undergoing these surgical treatments in California.

Impact of the Proposed Mandate on Public Health

Impact on Community Health (Section 1A)

Based on the observational studies found in the medical effectiveness literature review, the available evidence does not support a judgment that outcomes would be substantially different under the mandate—specifically for any of the five potential health outcomes: infection after surgery, adequate pain control, emotional and physical adjustment, readmission following surgery, and recovery from surgery or return to usual activities. Therefore we are unable to determine what effect, if any, AB8 would have on the health of the community.

Impact on Community Health where Gender and Racial Disparities Exist (Section 1B)

A substantial amount of research has focused on racial disparities among women with breast cancer. Much of the public health literature focuses on differences between Black women and White women. Black women have lower overall incidence rates of breast cancer compared with White women (Clarke et al., 2003). In spite of the lower incidence, however, Black women tend to be diagnosed at a younger age (Clarke et al., 2003; Porter et al., 2004), at a later stage of the disease (Clarke et al., 2003; Ghafoor et al., 2003; Mancino et al., 2001; Porter et al., 2004), and have poorer survival rates (Campbell, 2002; Chu et al., 2003; Jatoi et al., 2003; Newman et al., 2002; Roetzheim et al., 2000).

The literature review found some discussion of different treatment patterns between Black and White women. Shavers and Brown (2002) conducted a literature review of 23 studies on breast cancer treatment and found mixed results, where 12 studies found racial variations in treatment, 6 of which were statistically significant. Subsequent studies also found racial disparities in the provision of treatment (Bradley et al., 2002; Mandelblatt et al., 2002; Shavers et al., 2003). The most consistent finding in the treatment disparities literature is that Black women receive less radiation therapy after breast-conserving surgery (Mandelblatt et al., 2002; Shavers and Brown. 2002; Shavers et al., 2003).

An analysis of utilization data shows differences in length of hospital stay after surgery to treat breast cancer across racial groups (Table 11). An analysis of utilization data shows no differences in length of hospital stay after surgery to treat breast cancer across racial groups (Table 11). Similarly, as shown in Tables 12 and 13, there are no differences seen in the rates of breast-conserving surgery versus mastectomy across racial/ethnic groups or by age. As such, there is no evidence that AB 8 will have an effect on racial and ethnic disparities in the treatment of breast cancer or in health outcomes. In addition, as shown in Tables 12 and 13, there are no differences seen in the rates of breast-conserving surgery versus mastectomy across racial/ethnic groups or by age.

Reduction of Premature Death and the Economic Loss Associated with Disease (Section 1C)

The four specific health outcomes examined in this report included infection after surgery for breast cancer, adequate pain control, emotional and physical adjustment, and recovery from surgery/return to usual activities. For the most part, these outcomes represent measures of quality of life and are not measures of premature death related to the mandate. It is possible that infection after surgery could lead to premature death, but no literature was identified to support that this occurs. Therefore we conclude that there is no evidence indicating that AB 8 will have an impact on premature death associated with breast cancer.

A literature review was conducted to address the potential impact of the mandate on economic loss associated with breast cancer. The economic impact of mortality and morbidity from breast cancer is estimated by calculating the direct and indirect cost to society. Direct costs include the costs of treating breast cancer. Indirect costs refer to the productivity losses to society due to premature death and disability. This review found that national direct costs were estimated to be \$6.38 billion in 1996, (Brown et al., 2001), equivalent to \$8.67 billion dollars in 2005. Estimates of the indirect costs of breast cancer, and cancer in general, are lacking (Brown et al., 2001; National Cancer Institute 2005). However, some preliminary data from a study in California (Max 2005) are reported here.

The total cost of breast cancer in California during the years 2000-2001 was approximately \$1.4 billion dollars. This figure is comprised of direct and indirect costs, as reported in Table 14. Table 14 shows that the total direct cost of inpatient and outpatient treatment of breast cancer from all payers in California was \$284 million dollars in 2000. The cost of inpatient treatment of breast cancer was approximately \$108 million dollars, and the cost of outpatient treatment was approximately \$176 million. Outpatient treatment includes physician services, medications, nursing home care, home health care, and emergency department visits. The indirect cost of breast cancer in California, shown in Table 14 was approximately \$1.1 billion dollars in 2001. This figure includes the value of years of life lost (Max 2005). Since there is no evidence that AB 8 will affect the number of people diagnosed and treated for breast cancer or the health outcomes of those treated, there is no evidence that this mandate will have an impact on the reduction of economic loss associated with breast cancer.

Table 2. Premium and Total Expenditures Before and After Mandate Per Month and Per Year, 2005

Population = 20,163,000*	Per Month	Per Year
Premandate		
Average covered benefit dollars that already include the mandated provisions (%)	100%	100%
Premiums paid:		
Premium paid by employers	\$3,332,700,000	\$39,992,400,000
Premium contribution from employee	\$1,194,490,000	\$14,333,880,000
A. Total premiums	\$4,527,190,000	\$54,326,280,000
B. Total expenditures by all members on covered benefits (deductibles, copayments, etc.)	\$275,590,000	\$3,307,080,000
C. Total expenditures by all members on benefits not covered by insurance	\$0	\$0
D. Total expenditures (A+B+C=D)	\$4,802,780,000	\$57,633,360,000
Postmandate		
Average covered benefit dollars that include the mandated provisions (%)	100%	100%
Additional premium paid by all employers and public insurers	\$50,000	\$600,000
Additional premium contribution paid by all employees and individual purchasers.	\$20,000	\$240,000
A. Additional total premiums from employers, public insurers, employees, and individuals	\$70,000	\$840,000
B. Additional total expenditures by individuals on covered benefits (deductibles, copayments, etc.)	\$0	\$0
C. Additional total expenditures by individuals on benefits not covered by insurance	\$0	\$0
D. Additional total expenditures (A+B+C=D)**	\$80,000	\$960,000
Impact of Mandate		
A. Premiums, % change from premandate premium	0.002%	0.002%
E. Expenditure % change from premandate expenditures	0.002%	0.002%

Source: California Health Benefits Review Program analysis, 2005

*Population younger than 65 years currently covered (excluding self-insured firms) with private insurance (group and individual), including those enrolled in managed care plans subject to the Health and Safety Code or those insured by health insurance policies subject to the Insurance Code. This includes people enrolled through CalPERS, Medi-Cal, or Healthy Families. **Amount is more than \$70,000 because of rounding.

Table 3. Women Aged 30-64 Years by Type of Insurance

	Large Group				Small Group				Individual	Public			Healthy Families
	HMO	PPO	POS	FFS	HMO	PPO	POS	FFS	HMO	PPO	CalPERS	Medi-Cal	
Number Affected by Mandate	2,199,960	398,160	430,920	5,320	546,840	130,200	239,400	1,120	266,100	319,500	222,600	540,740	-

Source: California Health Benefits Review Program analysis, 2005

Key: FFS = fee for service; HMO = health maintenance organization; POS = point of service; PPO = preferred provider organization

Table 4. Baseline (Premandate) Per Member Per Month Premium and Other Expenditures, California, Calendar Year 2005

	Employer coverage, large group market				Employer coverage, small group market				Individually purchased		Public		Healthy Families	Total Per Month, All
	HMO	PPO	POS	FFS	HMO	PPO	POS	FFS	HMO	PPO	CalPERS	Medi-Cal		
Population*	7,857,000	1,422,000	1,539,000	19,000	1,953,000	465,000	855,000	4,000	887,000	1,065,000	795,000	2,846,000	494,000	20,201,000
Average covered benefit dollars that already include the mandated provisions (%)	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	
Average premiums														
Average premium paid by employer	\$187.97	\$283.90	\$234.95	\$240.59	\$161.28	\$234.40	\$180.93	\$181.88	\$0.00	\$0.00	\$231.96	\$103	\$58.68	\$3,332,700,000
Average contribution from employee	\$50.45	\$57.87	\$51.96	\$63.25	\$83.36	\$73.27	\$94.91	\$37.09	\$214.23	\$120.38	\$44.18	\$0.00	\$6.32	\$1,194,490,000
A. Total average premium paid	\$238.42	\$341.77	\$286.90	\$303.83	\$244.64	\$307.67	\$275.84	\$218.97	\$214.23	\$120.38	\$276.14	\$103	\$65.00	\$4,527,190,000
B. Average expenditures per member per month on covered benefits excluding premium (deductibles, copays, etc.)	\$8.44	\$46.18	\$18.14	\$67.04	\$12.49	\$45.71	\$21.55	\$51.02	\$13.04	\$28.09	\$9.78	\$0.00	\$1.71	\$275,590,000
C. Average expenditures per member per month on benefits not covered by insurance	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
E. Average total expenditures per member per month (A+B+C=D)	\$246.87	\$387.95	\$305.04	\$370.87	\$257.13	\$353.38	\$297.39	\$269.98	\$227.27	\$148.47	\$285.92	\$103	\$66.71	\$4,802,780,000

Source: California Health Benefits Review Program analysis, 2005

Note: "Per Member Per Month" is the total expenditures within each category divided by the number of people in that market.

*Population younger than 65 years currently covered (excluding self-insured firms) with private insurance (group and individual), including those enrolled in managed care plans subject to the Health and Safety Code or those insured by health insurance policies subject to the Insurance Code. This includes people enrolled through CalPERS, Medi-Cal, or Healthy Families. **Total amounts may differ due to rounding.

Key: FFS = fee for service; HMO = health maintenance organization; POS = point of service; PPO = preferred provider organization

Table 5. Postmandate Impacts on Per Member Per Month and Total Expenditures, California, Calendar Year 2005, by Insurance Type

Per Member Per Month \$ Impact of Mandate	Employer Coverage, Large Group Market				Employer Coverage, Small Group Market				Individually Purchased		Public		Total	
	HMO	PPO	POS	FFS	HMO	PPO	POS	FFS	HMO	PPO	CalPERS	Medi-Cal	Healthy Families	Per Month, All
Population*	7,857,000	1,422,000	1,539,000	19,000	1,953,000	465,000	855,000	4,000	887,000	1,065,000	795,000	2,846,000	494,000	20,201,000
A. Average additional total premium paid by employers and employees, of which:	\$0.0038	\$0.0035	\$0.0037	\$0.0032	\$0.0039	\$0.0036	\$0.0038	\$0.0033	\$0.0047	\$0.0038	\$0.0038	\$0.0027	\$0.0000	\$70,000
Average portion of premium paid by employer	\$0.0030	\$0.0029	\$0.0030	\$0.0025	\$0.0026	\$0.0027	\$0.0025	\$0.0027	\$0.0000	\$0.0000	\$0.0032	\$0.0027	\$0.0000	\$50,000
Average portion of premium paid by employee	\$0.0008	\$0.0006	\$0.0007	\$0.0007	\$0.0013	\$0.0009	\$0.0013	\$0.0006	\$0.0047	\$0.0038	\$0.0006	\$0.0000	\$0.0000	\$20,000
B. Average additional expenditures per member per month on covered benefits excluding premium (deductibles, copays, etc.) after mandate	\$0.0001	\$0.0005	\$0.0002	\$0.0007	\$0.0002	\$0.0005	\$0.0003	\$0.0008	\$0.0003	\$0.0009	\$0.0001	\$0.0000	\$0.0000	\$0
C. Average additional expenditures per member per month on benefits not covered by insurance after mandate	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0
D. Average additional total expenditures per member per month (A+ B+C=D)** after mandate	\$0.0039	\$0.0039	\$0.0039	\$0.0039	\$0.0041	\$0.0041	\$0.0041	\$0.0041	\$0.0050	\$0.0047	\$0.0039	\$0.0027	\$0.0000	\$80,000
Change (%) in premiums	0.002%	0.001%	0.001%	0.001%	0.002%	0.001%	0.001%	0.002%	0.002%	0.003%	0.003%	0.002%	0.000%	0.002%
Change (%) in total expenditures per member per month	0.002%	0.001%	0.001%	0.001%	0.002%	0.001%	0.001%	0.002%	0.002%	0.003%	0.003%	0.002%	0.000%	0.002%

Source: California Health Benefits Review Program analysis, 2005

Note: "Per Member Per Month" is the total expenditures within each category divided by the number of people in that market.

*Population younger than 65 years currently covered (excluding self-insured firms) with private insurance (group and individual), including those enrolled in managed care plans subject to the Health and Safety Code or those insured by health insurance policies subject to the Insurance Code. This includes people enrolled through CalPERS, Medi-Cal, or Healthy Families. **Total amount is more than \$70,000 because of rounding.

Key: FFS = fee for service; HMO = health maintenance organization; POS = point of service; PPO = preferred provider organization

Table 6. Proportion of Hospital Admissions for Mastectomy and Lymph Node Dissection by Days in Hospital and Average Length of Stay, California

Length of Stay	Baseline	Postmandate
Average	1.89 days	1.90 days
1 day	56%	50%
2 days	24%	30%
3 days or more	20%	20%
Total	100%	100%

Source: California Health Benefits Review Program analysis, 2005

Table 7. Summary of Mastectomy and Lymph Node Dissection, Inpatient and Outpatient Cases in California

Mastectomy and Lymph Node Dissection	Baseline	Postmandate
<i>Inpatient Cases and Days</i>		
Hospital admissions per 1,000 members for mastectomy and lymph node dissection	0.21	0.23
Total inpatient hospital days per 1,000 members	0.40	0.44
<i>Outpatient Cases</i>		
Outpatient cases per 1,000 members of mastectomy (total), mastectomy (other), and lymph node dissection	0.69	0.67

Source: California Health Benefits Review Program analysis, 2005

Note: Breast-conserving surgery includes partial or segmental mastectomy, quadrantectomy, tylectomy, wedge resection, nipple resection, lumpectomy, or excisional biopsy, with or without dissection of axillary lymph nodes. The category "Other" includes surgery not specified, no cancer surgery, and unknown treatment.

Table 8. Expected New Cancer Cases and Deaths in California, 2005

Site = Breast	Total	Males	Females
New cases	21,800	150	21,620
Deaths	4,230	35	4,195

Source: American Cancer Society (ACS), California Division and Public Health Institute, California Cancer Registry (2004). *California Cancer Facts and Figures, 2005*. Oakland, CA: American Cancer Society, California Division.

Note: Male and female cases and deaths may not sum up to the total because of rounding numbers. AB 8 would only apply to females.

Table 9. Cancer Incidence, Mortality, and Age-Adjusted Rates per 100,000 Population by Gender and Race/Ethnicity, California, 2000

Race/Ethnicity	Incidence (No.)	Incidence (Rate)	Mortality (No.)	Mortality (Rate)
All Races	21,664	71.9	4,263	13.9
Asian/Pacific Islander	1,701	47.2	260	7.6
Black	1,259	69.2	362	20.5
Hispanic	2,509	44.8	497	8.8
Non-Hispanic White	15,974	82.6	3,134	15.3

Source: Kwong and Wright, 2003..

Table 10. Overall Distribution of Stage at Diagnosis and Stage at Diagnosis by Surgical Procedure, California, 1988-1999.

	Overall	Breast-Conserving Surgery	Mastectomy	Other	Total
In situ	12.9%	62%	36%	2%	100%
Stage I	36.3%	57%	43%	<1%	100%
Stage II	34.2%	33%	66%	1%	100%
Stage III	5.2%	10%	81%	9%	100%
Stage IV	3.7%	20%	29%	51%	100%
Unknown	7.7%	30%	46%	23%	100%

Source: Morris and Kwong, 2004..

Note: Breast-conserving surgery includes partial or segmental mastectomy, quadrantectomy, tylectomy, wedge resection, nipple resection, lumpectomy, or excisional biopsy, with or without dissection of axillary lymph nodes. The category "Other" includes surgery not specified, no cancer surgery, and unknown treatment.

Table 11. Distribution of Length of Stay (Days) by Race, California, 2002

	1 Day	2 Days	3+ Days	Total
All Races	56%	24%	20%	100%
Asian	56%	26%	18%	100%
White	58%	24%	18%	100%
Black	56%	25%	19%	100%

Source: California Inpatient Hospital Discharge Data, Office of Statewide Health Planning and Development 2002

Table 12. Type of Surgery in Women with Early Stage Breast Cancer by Race/Ethnicity, California, 1995-1999.

	Breast-Conserving Surgery		Mastectomy		Total
	Number	% of total	Number	% of total	Number
All Races	44,902	63%	26,939	37%	71,841
Asian/Pacific Islander	2,932	52%	2,709	48%	5,641
Black	2,218	63%	1,323	37%	3,541
Hispanic	4,429	59%	3,120	41%	7,549
White	34,626	64%	19,584	36%	54,210

Note: Early stage breast cancer is defined as the following stages at diagnosis: Stage 0 (*in situ* tumor), Stage I (tumor less than 2 cm in greatest dimension with no spread to axillary lymph nodes), Stage IIa (tumor less than 2 cm, lymph nodes involved, but movable or tumor 2 to 5 cm with no spread to axillary lymph nodes). Breast-conserving surgery includes partial or segmental mastectomy, quadrantectomy, tylectomy, wedge resection, nipple resection, lumpectomy, or excisional biopsy, with or without dissection of axillary lymph nodes. The category All-Races includes data for persons of other and unknown race/ethnicity.

Source: Morris and Kwong, 2004.

Table 13. Type of Surgery for Women with Early Stage Breast Cancer by Age at Diagnosis, California, 1995-1999.

	Breast-Conserving Surgery		Mastectomy		Total
	Number	% of total	Number	% of total	Number
All ages	44,902	63%	26,919	37%	71,821
0-39 years	2,041	57%	1,548	43%	3,589
40-49 years	9,317	62%	5,602	38%	14,919
50-64 years	14,504	65%	7,942	35%	22,446
65-74 years	10,598	62%	6,383	38%	16,981
75+ years	8,442	61%	5,444	39%	13,886

Source: Morris and Kwong, 2004.

Note: Early stage breast cancer is defined as the following stages at diagnosis: Stage 0 (*in situ* tumor), Stage I (tumor less than 2 cm in greatest dimension with no spread to axillary lymph nodes), Stage IIa (tumor less than 2 cm, lymph nodes involved, but movable or tumor 2 to 5 cm with no spread to axillary lymph nodes). Breast-conserving surgery includes partial or segmental mastectomy, quadrantectomy, tylectomy, wedge resection, nipple resection, lumpectomy, or excisional biopsy, with or without dissection of axillary lymph nodes.

Table 14. The Cost of Breast Cancer in California, 2000-2001

Direct Costs, 2000	
Inpatient	\$108,000,000
Outpatient	\$176,000,000
Total direct costs	\$284,000,000
Indirect Costs, 2001	
Total lost productivity	\$1,100,000,000
Total costs, indirect and direct	\$1,384,000,000

Source: All data from Max, 2005.

Note: Outpatient costs include physician services, medications, nursing home care, home health care, and emergency department visits. Direct costs of treatment are expenditures paid by all payers (individual, public, and private).

APPENDIX A

Literature Review Methods

AB 8 is 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 coverage. AB 8 mandates coverage for *not less than 48-hours of inpatient care for a woman undergoing a mastectomy and not less than 24 hours of inpatient care for a woman undergoing a lymph node dissection for treatment for breast cancer*. The bill also mandates coverage for a *follow-up visit with a licensed health care professional, in the health care professional's office, or at the patient's home, within 48 hours of discharge from inpatient care for either surgical procedure*.

Appendix A describes the literature search for studies on the medical effectiveness of inpatient surgery (surgery in the hospital followed by hospitalization for one or more nights) in comparison with outpatient surgery (surgery in an outpatient surgical unit followed by a stay of less than 24 hours in an outpatient recovery area) as well as for studies on postoperative visits with a licensed health care provider within 48 hours of discharge after mastectomy or axillary lymph node dissection. This appendix also discusses the outcomes used in analysis of the mandate.

To “grade” the evidence for all outcome measures, the CHBRP effectiveness team uses a system¹⁰ with the following categories:

1. Favorable (statistically significant effect): Findings are uniformly favorable, and many or all are statistically significant.
2. Pattern¹¹ toward favorable (but not statistically significant): Findings are generally favorable, but there may be none that are statistically significant.
3. Ambiguous/mixed evidence: Some findings are significantly favorable, and some findings with sufficient statistical power show no effect.
4. Pattern toward no effect/weak evidence: Studies generally find no effect, but this may be due to a lack of statistical power.
5. No effect: There is statistical evidence of no clinical effect in the literature with sufficient statistical power to make this assessment.
6. Unfavorable: No findings show a statistically significant benefit, and some show significant harms.
7. Insufficient evidence to make a “call”: There are very few relevant findings, so that it is difficult to discern a pattern.

Studies of length of stay after mastectomy surgery were identified from PubMed (January 1985-January 2005) and Cochrane databases. The initial search terms were infection rate, pulmonary embolism, return

¹⁰The foregoing system was adapted from the system used by the U.S. Preventive Services Task Force, available at <http://www.ahcpr.gov/clinic/3rduspstf/ratings.htm>. The medical effectiveness team also considered guidelines from the Centers for Medicare & Medicaid Services, (available at <http://www.cms.hhs.gov/mcac/8b1-i9.asp>) and guidelines from the Blue Cross and Blue Shield Association (available at <http://www.bcbs.com/tec/teccriteria.html>).

¹¹ In this instance, the word “trend” may be used synonymously with “pattern.”

to usual activities, patient satisfaction, psychological distress, pain, fear, disability days, lymphedema, sentinel node biopsy, and costs.

The *Medical Subject Headings (MeSH)* terms used by the librarian in the PubMed search were:

mastectomy with subheadings:

adverse effects, economics, psychology, statistics and
numerical data, trends, utilization

breast neoplasms with subheading surgery, radiotherapy

length of stay

length of stay with subheadings:

economics, psychology, standards, statistics and numerical data, trends

ambulatory surgical procedures

patient discharge

patient discharge with subheadings:

economics, standard, statistics and numerical data, trends

postoperative complications

surgical wound infection

treatment outcome

activities of daily living

pulmonary embolism with subheading epidemiology

patient readmission

patient satisfaction

stress, psychological

adaptation, psychological

pain

anxiety

fear

arm

lymphedema

lymphedema with subheadings:

drug therapy, economics, epidemiology, psychology, therapy

lymph node excision

sentinel lymph node biopsy

costs and cost analysis

cost-benefit analysis

cost control

cost savings

cost of illness

health care costs

direct service costs

drug costs

Additional key words were used to identify recent articles that had not yet been assigned MeSH terms:

mastectomy, breast neoplasms surgery, breast cancer surgery, length of stay,

early discharge, short stay, patient discharge, outpatient mastectomy, ambulatory

mastectomy, ambulatory surgical procedures, lymphedema, sentinel lymph node biopsy,

lymph node dissection, cost, patient satisfaction, quality of life, arm edema, prevalence, incidence, disability, readmission, infection, complication, outcome, pulmonary embolism, return to work, return to usual activities, re-operation rate, pain, fear, anxiety, psychological, and psychosocial.

The only pertinent studies that were found were observational studies. No meta-analyses were found. Some of the observational studies included comparison groups of outpatients and patients hospitalized as inpatients for one or more nights after surgery. Most of the articles included patients undergoing modified radical mastectomy, simple mastectomy, and lumpectomy with or without axillary lymph node dissection. None of the articles focused exclusively on patients undergoing axillary lymph node dissection as an isolated procedure.

The scope of the literature search included effects of outpatient and inpatient mastectomy on these outcomes: postoperative infection rate, postoperative drain care, hospital readmission rate, postoperative bleeding, incidence of seroma (accumulation of fluids at the surgical site), re-operation rate, incidence of pulmonary embolism, pain control, emotional adjustment, time to return to usual activities, patient satisfaction, and problems associated with range of motion in the arm(s)

Search results included 95 English and non-English language articles, but non-English language articles were not used. The articles on lymphedema and sentinel lymph node biopsy were outside the scope of the mandate.

At least two reviewers screened the title and abstract of each citation returned by the literature search to determine eligibility for inclusion. Full-text articles were obtained and reviewers reapplied the initial eligibility criteria.

In Europe, Asia, and Australia, hospitalizations after mastectomy tend to be longer than in the United States. Most of the foreign literature (and the older American literature) concerning length of stay after a mastectomy focuses on the question of whether remaining in the hospital for only 48 hours and discharging patients with drains is just as effective as remaining in the hospital several more days until drains are removed. This is no longer a concern in the United States, where discharging patients with drains has been accepted medical practice for more than a decade.

The following 10 articles were excluded from the Appendix B Tables B-1 and B-2 summarizing study findings and evidence, because the authors' definitions of "early discharge" and "late discharge" were different from current practice in the United States and were considerably longer. However, four of the articles (Wells et al., Davis et al, Deo et al., and Yii et al.) are cited in the text because they provided important information.

Boman L, Bjorvell, H, Cedermark, B, Theve, N, Wilking, N, (1993). Effects of early discharge from hospital after surgery for primary breast cancer. *European Journal of Surgery*. 159(2):67-73.

Chapman D, Purushotham AD. (2001). Acceptability of early discharge with drain in situ after breast surgery. *British Journal of Nursing*. 10(22):1447-1450.

Davis C, Williams P, Redman S. (2000). Early discharge following breast surgery: assessing care, support, and informational needs of women with early breast cancer in Australia. *Australian and New Zealand Journal of Surgery*. 70(8):569-572.

Deo SV, Shukla NK, Goel AK, Kishore J. (1997). Short stay surgery for breast cancer: an audit of an experience in a regional cancer centre in northern India. *European Journal of Surgical Oncology*. 23(4):335-338.

Holcombe C, West N, Mansel RE, Horgan K. (1995). The satisfaction and savings of early discharge with drain in situ following axillary lymphadenectomy in the treatment of breast cancer. *European Journal of Surgical Oncology*. 21(6):604-606.

Kopelman D, Klemm O, Bahous H, Klein R, Krausz M, Hashmonai M. (1999). Postoperative suction drainage of the axilla: for how long? Prospective randomised trial. *European Journal of Surgery*. 165(2):117-120.

Litvak S, Borrero E, Katz R, Munoz E, Wise L, Santoso U, Iau PT, (1987). Early discharge of the postmastectomy patient: unbundling of hospital services to improve profitability under DRGs. *American Surgeon*. 53(10):577-579.

Murphy A, Holcombe C. (2001). Effects of early discharge following breast surgery. *Professional Nurse*, 16(5):1087-1090.

Wells M, Harrow A, Donnan P, Donnan P, Davey P, Devereux S, Little G, McKenna E, Wood R. (2004). Patient, carer and health service outcomes of nurse-led early discharge after breast cancer surgery: a randomised controlled trial. *British Journal of Cancer*. 91(4):651-658.

Yii M, Murphy C, Orr N. (1995) Early removal of drains and discharge of breast cancer surgery patients: a controlled prospective clinical trial. *Annals of the Royal College of Surgeons of England*. 77(5):377-379.

One recent study from England, (Chadha NK, Cumming S, O'Connor R, Burke M. (2004) Is discharge home with drains after breast surgery producing satisfactory outcomes? *Annals of the Royal College of Surgeons of England*. 85(5):353-357), was excluded because the authors failed to define "early discharge."

The focus of the analysis was to determine if there were evidence from studies of hospitalization for 48 hours after surgery that inpatient procedures and stays of a specific length produce better outcomes than outpatient procedures and stays of a specific length. The articles that were included in the analysis were those that provided information on the safety of current practice (outpatient mastectomy) that the mandate seeks to modify. Some of the studies also included data on patients hospitalized for one or more nights after surgery.

None of the studies found in the peer-reviewed medical literature specifically addressed the benefit of 48 hours of hospitalization after a mastectomy. The search identified nine observational studies in English that were relevant to the mandate. All of the studies were conducted in the United States.

Results from each study were organized into a table specific to each outcome (see Appendix B). The outcomes tables were organized into three categories: medical complications (which included such outcomes as postoperative infection rate, hospital readmission rate, and postoperative drain care), management of symptoms (which included pain control and emotional adjustment), and recovery (which included outcomes such as patient satisfaction and return to usual activities).

Due to the absence of randomized controlled trials, the effectiveness of hospitalization for 48 hours after mastectomy or for 24 hours for axillary lymph node dissection could not be determined with certainty because (1) the researchers conducting each of the observational studies employed different programs to educate patients to care for themselves, to help them adjust post-surgery, and to follow patients; and (2) there were significant differences between the patients undergoing outpatient and inpatient mastectomies. Inpatients were more likely to have other health problems and were more likely to be undergoing more radical surgery. In addition, for some studies, a comparison group was not provided.

No studies addressed the benefit of 24 hours of hospitalization after axillary lymph node dissection.

No articles were found in the peer-reviewed medical literature that examined the benefit of an outpatient follow-up visit 48 hours after discharge either from the hospital or from an outpatient clinic. Most of the authors of the observational studies of the effectiveness of outpatient surgeries maintain that education and care must be provided both preoperatively and postoperatively to compensate for the lack of inpatient care but did not examine the benefit of providing it.

APPENDIX B

Summary of Findings on Effectiveness Related to Mastectomy and Axillary Node Dissection

Table B-1. Summary of Published Studies on Effects of Mastectomy and Axillary Lymph Node Dissection as Outpatient (<24 hours) and Inpatient (<48 hours and >48 hours) Procedures

Citation	Type of Study	Intervention vs. Comparison Group	Population Studied	Location
Dooley, 2002	Observational study	87 outpatient breast cancer patients [†] v. inpatient breast cancer patients who underwent surgery the year before (number of inpatients not provided).	Lumpectomy with ALND/sampling, mastectomy (total, MRM, or Halstead radical)	Free-standing for-profit ambulatory surgicenter, OK
Ferrante et al., 2000	Observational study using state discharge abstracts	1,089 (20.1%) outpatient vs. 4,329 (79.9%) inpatient mastectomies	Breast cancer patients treated with mastectomies: 4,888 (90.2%) MRM and 530 (9.8%) SM	FL
Margolese and Lasry, 2000	Observational study (telephone survey) of two groups of unselected, consecutively treated patients	Outpatient (55 women) vs. inpatient (45 women) (immediately prior to move to standard outpatient surgeries) groups	Women undergoing ALND (80% had concurrent breast surgery)	Montreal, Canada
Warren et al., 1998	Observational study	13,212 patients undergoing simple mastectomy (20.3% or 2,682 as outpatients) and 104,770 undergoing MRM (5.6% or 5,857 as outpatients)	Medicare database—all SM and MRM reported to Medicare	US
Burke et al., 1997	Evaluation—telephone survey (concurrent, descriptive, exploratory)	52 women undergoing breast cancer surgery with 23-hour short stay (no comparison group)	Women undergoing definitive breast procedures (but not segmental mastectomy without ALND)	Comprehensive cancer center ,TX
Tan and Guenther, 1997	Observational study (retrospective)	100 consecutive women: 50 discharged to home same day, 44 admitted overnight, 6 remained in hospital 2-3 days	Women undergoing ALND, SM, or MRM	Kaiser Permanente, Los Angeles, CA

Citation	Type of Study	Intervention vs. Comparison Group	Population Studied	Location
Seltzer, 1995	Observational study	133 women undergoing breast cancer surgery as outpatients versus 45 inpatients (one or more nights) undergoing same operative procedure	Women undergoing partial mastectomy and limited axillary dissection	Academic medical center, NJ
McManus et al., 1994	Observational study	118 consecutive patients (115 discharged to home same day) v 55 inpatient surgery patients (limited info for latter group)	MRM, lumpectomy with ALND, ALND, SM/partial mastectomy	Academic medical center, NJ
Goodman and Mendez, 1993	Retrospective review (self-selected patients)	221 patients undergoing 223 procedures for breast cancer on an outpatient basis (no comparison group)	Patients undergoing MRM, partial mastectomies with ALND, total mastectomies, partial mastectomies, and radical ALND. Patients with co-morbidities requiring inpatient monitoring excluded. One patient American Society of Anesthesiology Risk Status (ASA) Class III. Remainder, class I or II)	FL

[‡] Includes one patient who chose to remain overnight, but not two with co-morbidities who were identified as high outpatient risks prior to surgery)

Key: ALND= axillary lymph node dissection; MRM= modified radical mastectomy; SM= simple mastectomy

Outpatient stay = <24 hours

Inpatient stay = <48 hours and >48 hours

Short stay per AB 8 for mastectomy for both outpatients and inpatients = <48 hours

Short stay per AB 8 for axillary node dissection for both outpatients and inpatients = <24 hours

Table B-2. Summary of Evidence of Effectiveness by Outcome for Mastectomy and Axillary Lymph Node Dissection as Outpatient (<24 hours) and Inpatient (<48 hours and >48 hours) Procedures
Medical Complications

Postoperative Infection, Pattern toward Favorable		
Citation	Results	Categorization of Results (Significance, Direction)
Dooley, 2002 [§]	1/86 outpatients (1%) 6% inpatients (number of patients not provided)	NS Favorable for outpatients
Burke et al., 1997 [§]	0/52 outpatients	NS Favorable for outpatients
Tan and Guenther, 1997 [*]	0/50 outpatients 1/50 inpatients	NS Favorable for outpatients
Seltzer, 1995	2/133 outpatients 2/45 inpatients	NS Favorable for outpatients
McManus et al., 1994 [§]	0/118 outpatients	No comparison group
Goodman and Mendez, 1993 [§]	0/221 outpatients	No comparison group

Postoperative Drain Care, Insufficient Evidence		
Citation	Results	Categorization of Results Significance and Direction
Burke et al., 1997 [§]	First interview of outpatients at 24-72 hours post surgery: 8 patients (16 % of responders)- had problems resolved by caregiver on an outpatient basis Second interview of outpatients at 7-10 days post-surgery: 6 patients (13 %), problems maintaining suction; 3 patients (6%), problems stripping tubing; 3 patients (6%), problems measuring drainage; 2 patients (4%), problems emptying drainage; and 2 patients (4%), problems recording drainage. Most patients reported that caregiver assisted them.	No comparison group
McManus et al., 1994 [§]	0/118 outpatients	No comparison group

Hospital Readmission, Apparently Unfavorable for Outpatients (See Appendix E)

Citation	Results	Categorization of Results (Significance, Direction)
Dooley et al., 2002 ^s	0/86 for outpatients 2% historical (inpatient) controls for infection or wound complications	NS Favorable for outpatients
Ferrante et al., 2000	RR for readmission for outpatients vs. inpatients: 2.32, 95% CI 1.20-4.48, p = 0.009 RR for urgent readmission: 2.27, 95% CI 0.96-5.41, p = 0.057 Overall: readmission rates were 1.3 % for outpatients (14 of 1,089) and .6% for inpatients (24 of 4,329)	Sig Unfavorable for outpatients NS Unfavorable for outpatients
Warren et al., 1998	Odds re-hospitalization Sig greater for outpatients v. 1-day-stay SM patients: 84% higher (OR = 1.84) within 7 days and 43% higher (OR = 1.43) within 30 days. Odds re-hospitalization Sig greater for outpatients v. 1-day stay MRM patients: 72 % higher within 7 days (OR = 1.72) and 28% higher within 30 days (OR = 1.28)	Sig Unfavorable for outpatients Sig Unfavorable for outpatients
Tan and Guenther, 1997 [*]	0/50 outpatients 1/50 inpatients	NS Favorable for outpatients
Seltzer, 1995	0/133 outpatients No information on inpatients	No comparison group

Postoperative Bleeding, Insufficient Evidence

Citation	Results	Categorization of Results (Significance, Direction))
Goodman and Mendez, 1993 [§]	0/221 outpatients	No comparison group
McManus et al., 1994 [§]	1/118 outpatients- blood soaked dressing (patient admitted overnight)	No comparison group

Incidence of Seromas, Insufficient Evidence

Citation	Results	Categorization of Results (Significance, Direction))
Seltzer, 1995	3/133 outpatients 0/45 inpatients	NS Unfavorable for outpatients
Goodman and Mendez, 1993 [§]	15% of 221 outpatients	No comparison group
McManus et al., 1994 [§]	“Several” outpatients (managed by aspiration)	No comparison group

Management of Symptoms

Pain Control, Pattern toward Favorable

Citation	Results	Categorization of Results (Significance, Direction))
Margolese and Lasry., 2000	Measured pain using scale of 0 = no pain, 2 = discomforting, 3 = distressing, 4 = horrible, 5 = excruciating. Outpatients pain on first day = 1.59 and during first week = 2.07, Inpatients pain on first day = 1.76 and during first week = 2.27	NS Favorable for outpatients
Burke, et al., 1997 [§]	50 patients (95% of responders)—pain control satisfactory on first interview 49 (96% of responders)—pain control satisfactory on second interview	No comparison group

Tan and Geunther 1997*	97/100 (3 required admission immediately postsurgery for control of pain)	No comparison group
McManus et al., 1994 [§]	0/118 (oral pain meds adequate for all outpatients)	No comparison group

Emotional and Physical Adjustment: Emotional adjustment index, favorable Quality of life index, pattern toward favorable Distress symptom scale, pattern toward favorable Completely asymptomatic, favorable Days to recover from stress of surgery, pattern toward unfavorable		
Citation	Results	Categorization of Results (Significance, Direction)
Margolese and Lasry, 2000	Emotional adjustment index (scale from 1-5, with better scores = higher scores): Outpatient = 3.89, Inpatient = 3.46 (p < 0.05) with better adjustment among outpatients Quality of life index: Outpatient = 3.70, Inpatient = 3.56 Distress symptom scale: Outpatient = 8.6, Inpatient = 11.7 (p < 0.09) with outpatient expressing somewhat less psychological distress Completely asymptomatic for mental and physical health indices: outpatients more likely to be asymptomatic Days to recover from stress of surgery: 127.8 (outpatients) vs. 119.1 (inpatients)	Sig Favorable for outpatients NS Favorable for outpatients NS Favorable for outpatients Sig Favorable for outpatients NS Unfavorable for outpatients

Recovery

Recovery from Surgery/ Return to Usual Activities, Favorable

Citation	Results	Categorization of Results (Significance, Direction)
Margolese and Lasry, 2000	Days to recover from surgery Outpatients: 17.4 days Inpatients: 26.8 days ($p < 0.05$)	Sig Favorable for outpatients
	Days to return to usual activities Outpatients: 35.1 days Inpatients: 46.4 days ($p < 0.02$)	Sig Favorable for outpatients

Patient satisfaction, Insufficient evidence

Citation	Results	Categorization of Results (Significance, Direction)
Seltzer, 1995	2/133 outpatients expressed dissatisfaction with lack of hospitalization (anecdotal- survey not performed)	No comparison group queried
Burke et al., 1997	41 (85%) outpatients felt prepared to leave hospital after surgery. 7 (15%) outpatients did not feel prepared to leave hospital 11 (total number responding to question or percentage responding not provided) wished they had stayed in hospital for 2-3 days	No comparison group

Range of Motion, Insufficient Evidence

Citation	Results	Categorization of Results (Significance, Direction)
McManus et al., 1994 [§]	No range of motion problems for outpatients	No comparison group

*Results of tests of significance presented in original paper only to show differences between outpatient and inpatient groups in terms of patient characteristics. In comparison with inpatients, outpatients were significantly more likely to have undergone axillary lymph node dissection (as an isolated procedure) or a simply mastectomy, and were less likely to have undergone modified radical mastectomy. [§]Results of tests of significance not presented in these studies. Key OR=Odds ratio

APPENDIX C

Cost Impact Analysis: General Caveats and Assumptions

This appendix describes general 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, http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php

The cost analysis in this report was prepared by Milliman and University of California, Los Angeles, with the assistance of CHBRP staff. Per the provisions of AB 1996 (California Health and Safety Code, Section 127660, et seq.), the analysis includes input and data from an independent actuarial firm, Milliman. In preparing cost estimates, Milliman and UCLA relied on a variety of external data sources. The *Milliman Health Cost Guidelines* (HCG) were used to augment the specific data gathered for this mandate. The HCGs are updated annually and are widely used in the health insurance industry to estimate the impact of plan changes on health care costs. Although this data was reviewed for reasonableness, it was used without independent audit.

The expected costs in this report are not predictions of future costs. Instead, they 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 different from our assumptions.
- Utilization of mandated services before and after the mandate different from our assumptions.
- Random fluctuations in the utilization and cost of health care services.

Additional assumptions that underlie the cost estimates presented here are:

- Cost impacts are only shown for people with insurance.
- The projections do not include people covered under self-insurance employer plans because those employee benefit plans are not subject to state-mandated minimum benefit requirements.
- 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.

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

- Population shifts by type of health insurance coverage. If a mandate increases health insurance costs, then some employer groups or individuals may elect to drop their coverage. Employers may also switch to self-funding to avoid having to comply with the mandate.
- Changes in benefit plans. To help offset the premium increase resulting from a mandate, members or insured may elect to increase their overall plan deductibles or copayments. Such changes would have a direct impact on the distribution of costs between the health plan and the insured person, and may also result in utilization reductions (i.e., high levels of patient cost sharing result in lower utilization of health care services). Milliman did not include the effects of such potential benefit changes in its analysis.

- Adverse Selection. Theoretically, individuals or employer groups who had previously foregone insurance may now elect to enroll in an insurance plan postmandate because they perceive that it is to their economic benefit to do so.
- Health plans may react to the mandate by tightening their medical management of the mandated benefit. This would tend to dampen our cost estimates. The dampening would be more pronounced on the plan types that previously had the least effective medical management (i.e., FFS and PPO plans).
- Variation in existing utilization and costs, and in the impact of the mandate, by geographic area and delivery system models: Even within the plan types we modeled (HMO, PPO, POS, and FFS), there are variations in utilization and costs within California. One source of difference is geographic. Utilization differs within California due to differences in the health status of the local commercial population, provider practice patterns, and the level of managed care available in each community. The average cost per service would also vary due to different underlying cost levels experienced by providers throughout California and the market dynamic in negotiations between health plans and providers.

Both the baseline costs prior to the mandate and the estimated cost impact of the mandate could vary within the state due to geographic and delivery system differences. For purposes of this analysis, however, we have estimated the impact on a statewide level.

APPENDIX D
Information Submitted by Outside Parties for Consideration for CHBRP Analysis

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.

Kaiser Foundation Health Plan, Inc.

Information about the clinical rationales and standards of care for mastectomies and lymph node dissections for the treatment of breast cancer.

Conference call on February 2, 2005, and letter dated February 11, 2005.

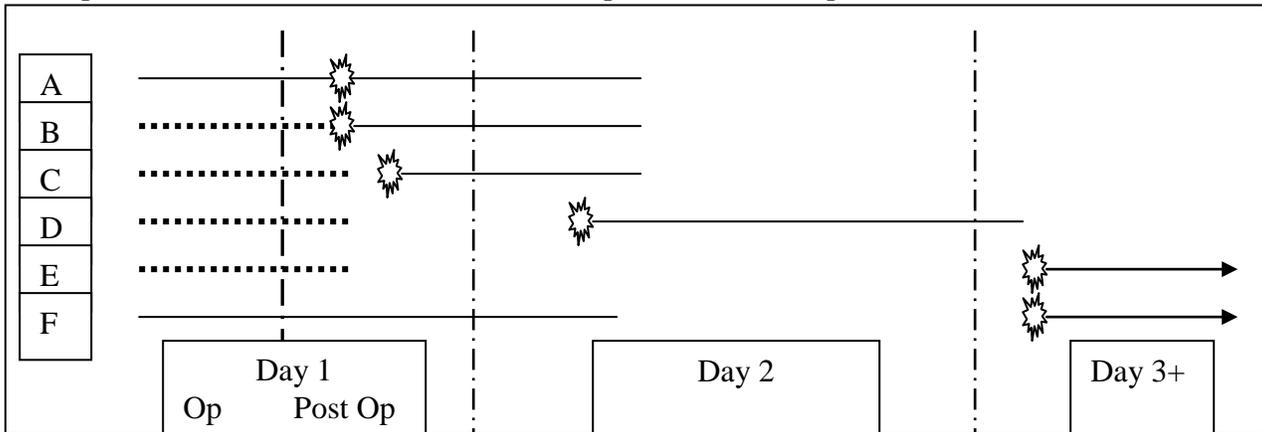
For information on the processes for submitting information to CHBRP for review and consideration please visit: http://www.chbrp.org/recent_requests/index.php

APPENDIX E

Clarification of “Readmission” after Inpatient versus Outpatient Surgery

The interpretation of a “readmission” after inpatient vs. outpatient surgery is sometimes complex, especially if (re)admission is considered as an indicator of an unfavorable outcome. Technically, the goal is to capture (1) the first admission after completion (discharge) from an outpatient procedure, and (2) a readmission after an initial inpatient admission. The problem arises in the interpretation of what the “first admission” or “readmission” indicates.

Consider five women who have a mastectomy procedure. Patients A and F have their surgery as inpatients, while B, C, D, and E have their procedures as outpatients.



The clinical course for patients A, B, and C is identical; each has a problem post-operatively, such as significant nausea that resolves within 12 hours.

With patient A, this problem occurs while she is in the hospital and she is discharged early on the second day as planned with a one-day stay.

Patient B’s nausea occurs while she is in the post-op recovery room and, instead of being discharged home, she is admitted to the hospital for overnight observation. This could be a formal separate admission to the hospital. It might, however, be part of an “outpatient stay” of less than 24 hours, in which case it might not be coded as either an admission or readmission to the inpatient setting.

Patient C actually goes home, but then is admitted to the hospital a few hours later to address her continuing nausea.

It might be argued that the care for patients A and B is essentially identical, except for the intention to have the patient B discharged after just outpatient surgery.

It also might be argued that patient C was sent home prematurely, but with no long-term consequences.

The cases of patients D, E, and F are substantially different. Patient D’s problem occurs on the second day. Had she been an inpatient, the problem might not have occurred, and thus inferring that this admission implies a bad outcome is warranted. Even if the problem had occurred during her scheduled

one-day stay, the stay would probably have been extended, and that could have shown up in a longer than average stay. The complications experienced by both patients E and F occurred a good bit after the peri-operative period and probably are not sensitive to the different definitions and “windows” used for inpatient and outpatient episodes.

It appears, but is not certain, that the Warren, et al., study would recode Patient B as an inpatient, but the fact that the window for readmissions includes “0-days” means that patient C would be considered a “readmission” in contrast to her colleagues A and B. On the other hand, it appears, but is not certain, that the Ferrante et al. study would have considered patient B as a readmission. (The lack of clarity arises both from a careful reading of the papers, as well as personal communications (March 7, 2005) with the authors, who no longer have ready access to the specific coding algorithms used.)

Overall, it is clear that both studies show statistically significantly higher rates of readmission for women with outpatient procedures, but it is unclear exactly what the clinical significance is of those higher rates and the extent to which they are artifacts of the ways in that readmissions are coded or how the patients are coded or recorded (i.e., as inpatients or outpatients). An additional factor, related to evaluating the data on effectiveness for the proposed mandate for a minimum of 48 hours of inpatient care for a mastectomy, is that some “inpatients” represent stays of greater than 24 hours and less than 48 hours, further confounding a comparison of short stay (less than 24 hours) versus longer stay (48 hours or greater). Thus, some inpatients with stays of less than 48 hours would be considered “inpatients” rather than “short stay” admissions.

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California Health Benefits Review Program Committees and Staff

A group of faculty and staff undertakes most of the analysis that informs reports by the California Health Benefits Review Program (CHBRP). The CHBRP **Faculty Task Force** comprises rotating representatives from six University of California (UC) campuses and three private universities in California. In addition to these representatives, there are other ongoing contributors to CHBRP from UC. This larger group provides advice to the CHBRP staff on the overall administration of the program and conducts much of the analysis. The CHBRP **staff** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and coordinates all external communications, including those with the California Legislature. The level of involvement of members of CHBRP's 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, to assist in assessing the financial impact of each benefit mandate bill. Milliman also helped with the initial development of CHBRP's methods for assessing that impact.

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

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