CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Analysis of Assembly Bill 547
Ovarian Cancer Screening

A Report to the 2003-2004 California Legislature
February 9, 2004
Revised October 8, 2004

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, University of Southern California, and Stanford University to complete each analysis within 60 days, 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 though an annual assessment on health plans and insurers in California. All CHBRP reports and information about current requests from the California Legislature are available on CHBRP's Web site, www.chbrp.org.

A REPORT TO THE 2003-2004 CALIFORNIA STATE LEGISLATURE

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PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill 547, a bill to require every individual or group health care service plan contract, except for a specialized health care service plan contract, to provide coverage for the screening and diagnosis of ovarian cancer, including, but not limited to, the appropriate blood tests, a transvaginal sonogram, and a rectovaginal pelvic examination, when medically necessary and consistent with good professional practice. In response to a request from the California Assembly Committee on Health on May 19, 2003, 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*.

Theodore Ganiats, MD, Kristin David, MPH, and Cheryl Saenz, MD, all of the University of California, San Diego, coordinated the preparation of this report and prepared the medical effectiveness section. Alberto Manetta, MD, of the University of California, Irvine, provided technical assistance with the literature review and clinical expertise for the medical effectiveness section. Gerald Kominski, PhD, Miriam Laugesen, PhD, and Nadereh Pourat, PhD, all of the University of California, Los Angeles, prepared the cost impact section. Helen Halpin, PhD, and Sara McMenamin, PhD, both of the University of California, Berkeley, prepared the public health impact section. Robert Cosway, FSA, MAAA, and Jay Ripps, FSA, MAAA, both of Milliman USA, provided actuarial analysis. Other contributors include Michael E. Gluck, PhD, of CHBRP staff. Catherine Nancarrow of the University of California Office of the President provided editorial guidance on early drafts of this report, and Katrina Mather, freelance editor, served as copy editor. In addition, a balanced 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 these contributions but assumes full responsibility for all of the report and its contents. Please direct any questions concerning this report to CHBRP:

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Michael E. Gluck, PhD
Director

Revision:
October 8, 2004: Added a standard preface and appendix to appear in all CHBRP reports, identifying individual contributions to the analysis.

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EXECUTIVE SUMMARY

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Assembly Bill (AB 547) proposes to require every individual or group health care service plan contract, except for a specialized health care service plan contract, to provide coverage for the screening and diagnosis of ovarian cancer, including, but not limited to, the appropriate blood tests, a transvaginal sonogram, and a rectovaginal pelvic examination, when medically necessary and consistent with good professional practice. The number of women potentially affected by this legislation is large, because the bill specifies no age range. For the purposes of this analysis, all women aged 18 to 64 years are included.

The California Health Benefits Review Program has been asked by the California Legislature to conduct an evidence-based scientific review of the medical, financial, and public health impacts of this legislation. Because all insurance plans currently cover the diagnosis of ovarian cancer, the analysis is limited to screening for this disease. Major report findings follow.

I. Medical Effectiveness

- Ovarian cancer is a significant source of cancer mortality, especially in postmenopausal women. Ovarian cancer has the highest mortality of all cancers of the female reproductive system and often is a rapidly fatal disease (National Cancer Institute, 1996, 2003b). This has led to a search for appropriate screening methods for this cancer.
- Currently, several technologies allow early detection of ovarian cancer. These include the blood test (CA-125), sonogram (transvaginal sonogram), and physical examination (rectovaginal examination) mentioned in AB 547. Although several screening tests are available, the best screening approach (e.g., blood test, blood test followed by sonogram, sonogram followed by blood test) has not been determined. A positive screening test (blood, sonogram, or a combination) requires a complete diagnostic work-up and an exploratory laparoscopy and/or laparotomy, depending on the specifics for each individual. Both surgical procedures carry the potential for complications.
- At this time there is insufficient evidence that early diagnosis improves cancer outcomes. There is insufficient evidence to know if ovarian cancer screening prolongs life or reduces mortality. Based on this lack of evidence, no major medical organization recommends screening (routine testing of all women) for ovarian cancer, and such screening does not reflect the current standard of care. The clinical benefits of screening are currently unknown: there is insufficient evidence to support screening's benefit, and insufficient evidence to support there is no benefit. Conversely, all interventions, whether they are medications or surgical treatments, have known risks. It is not generally considered good medical practice to subject a patient to the potential of harm (treatment side effects) unless the possibility of benefit is known or can be reasonably expected to outweigh the harm. At this time, there are two large, ongoing clinical trials that seek to further evaluate the potential of

ovarian screening to improve outcomes. These studies may provide data useful in evaluating the medical effectiveness of ovarian cancer screening.

II. Utilization, Costs, and Coverage Impacts

The analysis indicates that the proposed mandate for ovarian cancer screening will have the following impacts:

- The number of women obtaining such screening will increase. Up to approximately 6% of women aged 18 to 64 years currently receive tests that can screen for ovarian cancer (according to commercial data provided by Milliman USA). An estimated 20% of women aged 18 to 49 years and 30% of women aged 50 to 64 years would be screened annually after the mandate.
- Approximately 5,890,000 women, 18 to 64 years of age, with private insurance would be eligible for the mandated benefit (excluding those in firms that self-insure). Essentially no policy currently covers routine screening for ovarian cancer. Given reasonable assumptions of the costs of each procedure and one standard protocol for screening (currently used in one of the randomized trials), the average cost per screening (in 2004 dollars) will be $73 for women aged 50 to 64 years and $92 for women aged 18 to 49 years, with an overall average of $87 for women in both age groups. Additional unspecified costs would result from complications related to the work-up of false-positive tests.
- Total expenditures (including total premiums and out-of-pocket expenditures) will increase by 0.18% on average for privately insured individuals (excluding those in firms that self-insure), with increases ranging from 0.11% to 0.23% for different categories of insurance. The estimated increase in expenditures may produce no net medical benefit and may be associated with a net harm, because screening for ovarian cancer has not been shown to be effective in improving ovarian cancer survival rates.

III. Public Health Impacts

- There is an uncertain effect of ovarian cancer screening on mortality. The major outcome of public health interest in relation to ovarian cancer screening is mortality. In 1999, there were 1,417 deaths (8.6 deaths per 100,000 women) due to ovarian cancer in California; 34% of these women were 18 to 64 years of age. Ovarian cancer mortality rates vary by race and ethnicity. Non-Hispanic white women have the highest mortality rates (9.6 deaths per 100,000 women) compared with blacks (8.1 per 100,000), Hispanics (6.5 per 100,000), or Asian/Pacific Islanders (5.8 per 100,000). However, without evidence supporting screening's beneficial impact on mortality, it is uncertain whether the mandate will offer a benefit.
- There are two harms that would occur as a result of mass screening of asymptomatic women for ovarian cancer. Of an estimated 1.1 million women who would be newly screened for ovarian cancer, approximately 184,000 healthy women will be subject to psychological distress (e.g., anxiety, stress, and depression) over a false-positive test result. In addition, there is the discomfort and inconvenience as well as the potential risk of surgical complications and resulting physical injury for more than 10,000

women with a false-positive test result who go on to have a confirmatory laparoscopy or laparotomy. Thus widespread screening would provide for care that has known medical harms and uncertain benefits.

INTRODUCTION

Assembly Bill (AB 547) proposes a mandate for ovarian cancer screening:

> …Every individual or group health care service plan contract, except for a specialized health care service plan contract, that is issued, amended, delivered, or renewed on or after January 1, 2004, shall be deemed to provide coverage for the screening and diagnosis of ovarian cancer, including, but not limited to, the appropriate blood tests, a transvaginal sonogram, and a rectovaginal pelvic examination when medically necessary and consistent with good professional practice….

The bill as written raises two significant issues with interpretation and analysis. First, the phrase "…when medically necessary and consistent with good professional practice…" does not apply to the practice of ovarian cancer screening (routine testing of all women): No major group currently recommends ovarian cancer screening because such screening has yet to be shown to be beneficial. The literature review, focusing first on meta-analyses and clinical practice guidelines from the Cochrane Collaboration and the National Guideline Clearinghouse, confirmed the lack of definitive studies. (Because all insurance plans currently cover tests for ovarian cancer *diagnosis*, this part of the bill has no effect on coverage.) Second, the bill does not state a lower age limit, which affects impact estimations. The incidence of ovarian cancer in women in older age groups is up to 60 cases per 100,000 women per year; the incidence of ovarian cancer in 20-year-old women is 3 cases per 100,000 women per year. The proposed legislation takes into account no such distinction. (In comparison, age-adjusted breast cancer rates are almost 10 times higher.) (Centers for Disease Control and Prevention, 2000.)
There is a relatively low disease incidence and a lack of a documented benefit from ovarian cancer screening. Insurance currently covers diagnostic tests. The medical effectiveness and financial and public health impacts of this legislation are detailed below.

I. MEDICAL EFFECTIVENESS

The discussion of the medical effectiveness of ovarian cancer screening is limited by a few factors. First, there is insufficient evidence to know if ovarian cancer screening prolongs life or reduces mortality. Because of this, no major medical organization recommends screening (routine testing of all women) for ovarian cancer, and such screening does not currently reflect the standard of care.[1] Second, the incidence of ovarian cancer varies widely by age (it is more common after menopause). Third, "rectovaginal pelvic examination" (as highlighted in the bill) is part of a routine physical examination and therefore is not a separate, billable item. Finally,

[1] For example, the American Cancer Society states, "In preliminary studies of women at average risk of ovarian cancer, these screening tests did not lower the number of deaths caused by ovarian cancer. For this reason, transvaginal sonography and the CA-125 blood test are not recommended for ovarian cancer screening of women without known strong risk factors. Ways to improve ovarian cancer screening tests are being researched. It is hoped that further improvements will make these tests effective enough to lower the ovarian cancer death rate. (Revised 6-23-03; http://www.cancer.org/docroot/CRI/content /CRI_2_4_3X_Can_ovarian_cancer_be_found_early_33.asp?sitearea=)

screening of the asymptomatic population does not fit the definition of "medically necessary and consistent with good professional practice," because screening is not treatment.

The effectiveness of ovarian cancer screening remains an ongoing research question; it is not known if ovarian cancer screening prolongs life or reduces mortality. The clinical benefits of screening are thus unknown: There is insufficient evidence to support screening's benefit, but there is also insufficient evidence to support that there is no benefit. On the other hand, all interventions, whether they are medications or surgical treatments, have known risks. For this reason, it is not generally considered good medical practice to subject a patient to the potential of harm (treatment side effects) unless the possibility of benefit is known to outweigh the harm. Thus, the question is not answered completely, and there are two large, ongoing clinical trials to further evaluate the potential of this screening.

Often, screening detects cancers early. The problem with ovarian cancer screening is mixed findings regarding the ability of screening to provide a favorable stage shift in the cancer (finding more cancers at an earlier stage) at diagnosis. The larger randomized trial showed no such stage shift (Jacobs et al., 1999). As is common, data from some non-randomized trials showed a shift. Survival and stage-shift data from non-randomized studies, however, must be viewed cautiously because they are subject to several types of bias. For example, cancers found by screening tend to be less aggressive than cancers not detected by screening. Thus, cancers found by screening have a better prognosis than other cancers (lead-time bias) (Patz et al, 2000). Another problem is that screening finds a cancer early, so that a person may live longer *with the knowledge* she has cancer but not actually live longer with the cancer (length-time bias) (Patz et al, 2000).

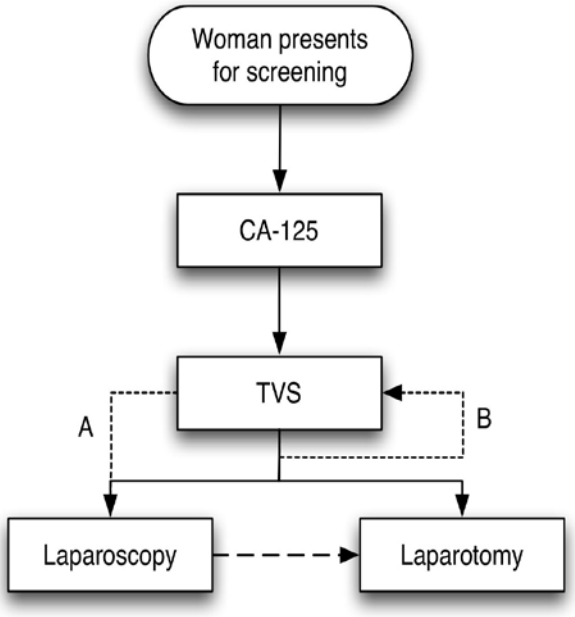
These biases are eliminated in a randomized trial. Until recently, there were three international randomized trials addressing the question of ovarian cancer screening effectiveness. The Prostate, Lung, Colorectal, and Ovarian Cancer (PLCO) Screening Trial, sponsored by the National Cancer Institute, is examining transvaginal sonogram (TVS; an ultrasound study) and CA-125 (a blood test) screening (National Cancer Institute, 2003a). The study involves nearly 74,000 women older than 60 years at medical facilities in 10 geographic areas across the United States. The PLCO Screening Trial is collecting and analyzing data from participants for up to 16 years from the time they enrolled (between 1992 and 2001). This trial will have 80% power to detect a 30% reduction in mortality. The United Kingdom Collaborative Trial of Ovarian Cancer Screening started recruitment in 2001 (National Health Service, 2003). In this trial, which will span more than 10 years, TVS and multimodal screening are compared with a control group. The European Multicentre Study was planned as a trial of 120,000 postmenopausal women randomized to a control group or to one of two study groups (TVS every 1.5 or 3 years), but the study was stopped prematurely owing to funding difficulties and complications (see below) (K. Law, personal communication, December 2003).

Because these major clinical trials are still in progress, clinical trial evidence to support screening is lacking. Consequently, this report relies on estimates of process and outcomes for screening in postmenopausal women based on a pilot study by Jacobs et al. (1999), supplemented as needed by expert opinion from Dr. Alberto Manetta (University of California at Irvine Cancer Center) and Dr. Cheryl Saenz (University of California at San Diego Cancer

Center). Because no data on process or outcomes for screening in premenopausal women are available, experts' opinions for these data are used.

Importantly, the randomized controlled trial described by Jacobs et al. showed a grade-shift benefit of screening, but the authors note it was a pilot study and its results only reinforce the need for a larger trial. (The article by Jacobs et al. provided the pilot data for the United Kingdom trial noted above.)

Age is an important factor in any analysis of the effects of ovarian cancer screening. The incidence of ovarian cancer screening varies by age (it is rare in younger women). In addition, prior to menopause, many conditions other than ovarian cancer can be associated with a positive CA-125 (e.g., endometriosis, pelvic infection, uterine fibroids, pregnancy) and a positive TVS (e.g., ovarian cyst). Thus, in premenopausal women, the number of false-positive screening results increases while the incidence of the disease is lower compared with the postmenopausal woman. For these reasons, screening in younger women carries more adverse effects and greater costs while finding fewer cancers than when screening older women.



The process of ovarian cancer screening can be quite varied (as frequently occurs when there is no strong evidence supporting a single approach). In this report, the methods highlighted in the article by Jacobs et al. are accepted and outlined in Figure 1 (see also Table 1 for more details and definition of terms) (Jacobs et al., 1999). The solid line describes women who are screened with a CA-125 blood test. Those whose test results are positive receive a TVS.

Figure 1. Approach to Ovarian Cancer Screening
Source: Jacobs et al., 1999

By themselves, both tests offer minimal risk. However, everyone with a positive TVS will undergo surgical evaluation of the pelvis: either laparoscopy (if the mass is small) or laparotomy (if the mass is larger or otherwise suspicious). Many women who undergo laparoscopy will go on to laparotomy if the biopsy shows a cancer (dashed line). At laparotomy, most of these women will have a total hysterectomy.

The dotted lines in Figure 1 relate to some important exceptions to the pathway. The line labeled A refers to women who are quite anxious after the positive CA-125 and undergo laparoscopy despite a normal TVS. The line labeled B refers to some premenopausal women who, given the high false-positive rate of screening in their age group, opt for a 'watchful waiting' approach

instead of laparoscopy. These women receive a repeat TVS after a few months. If that TVS is normal, the woman is reassured and no further testing is performed. If the TVS is positive, the woman undergoes laparoscopy. Laparotomy is unusual in the premenopausal woman because most of the causes of a positive result of screening can be handled laparoscopically.

The results of screening premenopausal women, postmenopausal women, and no screening are listed in Tables 2A, 2B, and 2C. For every 10,000 postmenopausal women screened, there will be about 100 laparoscopies and laparotomies with about 24 hysterectomies and 6 oophorectomies. For every 10,000 premenopausal women screened there will be 88 laparoscopies. All of these numbers are likely *underestimates* because, in practice, many women go on to laparoscopy even if the TVS is negative (see Figure 1, line A). The diagnostic work-up that follows a positive finding on screening tests is significant not only because its benefit has yet to be demonstrated, but also there can be significant harm. For example, one reason the European Multicentre Study mentioned above was stopped was two deaths that occurred in Denmark to women undergoing the evaluation of a positive screening test.

In conclusion, there is no conclusive evidence on the effectiveness of ovarian cancer screening by CA-125, TVS, or in combination; these questions are the subject of ongoing clinical trials. Although it is possible that such screening is effective at reducing ovarian cancer mortality, this has not yet been shown. What is known is that a significant number of women will have to undergo invasive procedures in order to detect about 1 cancer for every 3,300 postmenopausal women screened and 1 cancer for every 10,000 premenopausal woman screened.

II. UTILIZATION, COST, AND COVERAGE IMPACTS

PRESENT BASELINE COST AND COVERAGE

1. Current utilization levels and costs of the mandated benefit (Section 3(h))

Up to an estimated 6% of women aged 18 to 64 years currently receive screening for ovarian cancer. This rate, which reflects the total number of ultrasound tests done in this age group, is an upper-bound estimate, because the analysis of this mandate assumes that no women in this age range are currently covered for this benefit, and that those who are currently "screened" do so because of medical indications or doctors ordered the test despite it not being a covered benefit. An estimated 5,890,000 women aged 18 to 64 years with private insurance would be eligible for the mandated benefit in California.

Based on data provided to the California Health Benefits Review Program from commercial databases at Milliman USA (Table 3), the average cost per screening (in 2004 dollars) will be $73 for women aged 50 to 64 years and $92 for women aged 18 to 49 years. Screening costs are slightly higher in the younger age group because screening is more likely to find abnormalities requiring additional diagnostic work-up. The overall average cost of screening for women aged 18 to 64 years is $87. This cost per screening assumes the following:

- 100% of women screened first receive a CA-125 test at a cost of $45 per test
- 20% of women aged 18 to 49 years and 10% of women aged 50 to 64 years screened with CA-125 have a positive result and then receive a TVS at $200 per test
- 6% of women aged 50 to 64 years screened with TVS have a positive result and will get a follow-up CA-125. 10% of women aged 18 to 49 years will have a positive TVS, 75% of whom will have a repeat TVS
- 50% of women aged 50 to 64 years with a positive TVS result (0.3% of those originally screened) undergo laparoscopy at $800 per procedure, whereas 25% of women aged 18 to 49 undergo immediate laparoscopy, and 25% of the women who have repeat TVS receive a delayed laparoscopy (for a total 0.88% of those originally screened)
- 50% of women aged 50 to 64 years with a positive TVS result (0.3% of those originally screened) undergo laparotomy at $1,757 per procedure
- 5% of women aged 50 to 64 years receiving either a laparotomy or laparoscopy are confirmed ovarian cancer patients (0.03% of those originally screened), whereas 1% of women aged 18 to 49 years who undergo laparoscopy are confirmed ovarian cancer patients (0.01% of those originally screened).
-

In sum, ovarian cancer is detected in 3 of 10,000 screened cases for women aged 50 to 64 years, and 1 of 10,000 screened cases for women aged 18 to 49 years.

2. Current coverage of the mandated benefit (Section 3(i))

A survey of several large health plans indicates that women are generally not covered for this benefit.

3. Public demand for health care coverage (Section 3(j))

The analysis found no evidence of public demand for the proposed mandate.

IMPACTS OF MANDATED COVERAGE

4. 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))

There is no evidence that the mandate would affect the per-unit cost of screening. There is no evidence of medical benefit from screening for ovarian cancer. Although increased screening may slightly improve the detection of ovarian cancer (see previous section for details), this will not result in improved mortality. Screening does, however, subject women to false-positive diagnoses and subsequent interventions that are otherwise medically unnecessary. The follow-up evaluation and treatment of women with a pelvic mass is the same whether the mass is detected by screening or after the presentation of symptoms. However, screening increases the number of procedures through the evaluation of all true and false-positive tests. The number of screening-induced surgical interventions to rule out ovarian cancer is estimated to increase two-fold for laparotomies and three-fold for laparoscopies, without improving outcomes from ovarian cancer. Therefore, the average "benefit" of screening will be negative, because there will be no benefits

but more women will undergo procedures (i.e., laparotomies and laparoscopies) for cancer they do not have, and a small percentage will have complications related to those surgical treatments.

This analysis equates the baseline (i.e., pre-mandate) per-unit cost of screening to the post-mandate per-unit cost and suggests that the mandate would only affect the percentage of women who would be screened and are more likely to request such screening.

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

Utilization estimates show a possible increase from the current rate of about 6% of women aged 18 to 64 years who undergo ovarian cancer screening to a rate of 20% for younger women (aged 18 to 49 years) and 30% for older women (aged 50 to 64 years) (Tables 3 and 4). The demand for screening is likely to increase, even though screening has not been proven effective, because patients are likely to assume that newly covered benefits are effective. Physicians are likely to increase screening by a greater percentage among women aged 50 to 64 years because those women are at higher risk for ovarian cancer.

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

The mandate is estimated to have no measurable effect on administrative expenses (see Appendix A).

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

The mandate will have a small impact on privately insured individuals. Total expenditures (including total premiums and out-of-pocket expenditures) are estimated to increase by 0.18% on average for privately insured individuals (excluding those in firms that self-insure) (Table 5). These estimates include the costs of CA-125 and TVS screening, as well as the increased use of surgical procedures (i.e., laparoscopies and laparotomies) to rule out ovarian cancer for women who have positive findings on screening tests.

Based on the best available medical evidence, however, the estimated increase in expenditures would produce no net medical benefit (in fact, it would be associated with a net harm), because screening for ovarian cancer has not been shown to be effective in improving ovarian cancer survival rates. Furthermore, the increased use of screening is likely to increase the number of complications associated with increased use of laparoscopies and laparotomies. The additional costs of these complications are not included in the cost estimates provided above. Thus, included cost estimates understate the additional expenditures that would be directed toward medically ineffective services.

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

As shown in Table 5, the impact of the mandate is estimated to range from 0.11% to 0.23% for different categories of employment-based insurance. Public insurers are exempt from the

mandate and thus are not affected, and California Public Employees' Retirement System members are included primarily in the large-group HMO insurance category. In the absence of detailed information about current utilization levels for each category of private insurance, estimates use the same rate of current utilization among women aged 18 to 64 years and the same increase in utilization after the mandate.

9. Current costs borne by payers (both public and private entities) in the absence of the mandated benefit (Section 3(f))

In the absence of the mandate, the costs of diagnosing and treating suspected ovarian cancers is borne by both public and private insurers. Broad screening for ovarian cancer is not done because the two most common screening procedures, CA-125 and TVS, have not been proven effective in increasing the ovarian cancer survival rate. To the extent that women currently choose to be screened in the absence of symptoms, those costs are estimated to be borne by the patients themselves, because they are receiving a diagnostic test that is neither medically necessary nor consistent with good professional practice and therefore not covered by relevant insurance plans.

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

The mandate would increase the availability of CA-125 and TVS screening. The CA-125 is a blood test, and coverage would increase the number of tests being evaluated and the number of laboratories performing the test. The TVS involves the use of diagnostic equipment that can be located in the physician's office, although currently the test is usually performed in a designated radiology facility. By providing coverage and thus payment for these screening services, physicians would have an incentive to make these services readily available, even in the absence of definitive evidence regarding the benefits of screening for ovarian cancer.

III. PUBLIC HEALTH IMPACTS

PRESENT BASELINE HEALTH OUTCOMES

Incidence

In California in 1999, 2,533 women were diagnosed with ovarian cancer, at a rate of 1.55 diagnosed cases per 10,000 women (Table 6). Of these 2,533 women, 1,417 (56%)[2] were aged 18 to 64 years (i.e., the target population for this proposed legislation), with a median age of diagnosis of 62 years (California Department of Health Services, 2001a). Incidence of ovarian cancer varies greatly by race and ethnicity. Non-Hispanic white women have the highest rates of diagnosis (1.73 cases per 10,000 women) compared with Hispanics (1.19 cases per 10,000 women), blacks, and Asian/Pacific Islanders (1.17 cases per 10,000 women).

[2] The incidence and mortality data broken down by age were pooled for years 1995-1999. The percentage of the population aged 18-64 years with ovarian cancer was taken from this pooled data and applied to the incidence and mortality numbers in 1999.

Mortality

The major outcome of public health interest in relation to ovarian cancer screening is mortality (Table 7). In California in 1999, there were 1,417 deaths due to ovarian cancer (a rate of 8.6 deaths per 100,000 women). Of these 1,417 deaths, 486 (34%) were of women aged 18 to 64 years. Death from ovarian cancer represents 3% of all cancer deaths annually (American Cancer Society, 2003). Ovarian cancer mortality rates also vary by race and ethnicity. Non-Hispanic white women have the highest mortality rates (9.6 deaths per 100,000 women) compared with blacks (8.1 per 100,000), Hispanics (6.5 per 100,000), or Asian/Pacific Islanders (5.8 per 100,000).

The survival rate of ovarian cancer varies by the stage in which the disease was diagnosed (Table 8). Overall, 52% of women diagnosed with ovarian cancer survive 5 years after diagnosis. A breakout by stage of disease shows a 95% survival rate 5 years out for localized cancers, 81% survival rate 5 years out for regional cancers, and 29% survival rate 5 years out for those with distant metastases. As mentioned above, by itself these data do not prove screening is effective; data from randomized trials are needed.

IMPACT OF THE PROPOSED MANDATE ON PUBLIC HEALTH

The current state of medical knowledge is that ovarian cancer screening is associated with uncertain benefits and known harms (e.g., anxiety of false-positive results, costs of screening and evaluations, risks of complications from surgical evaluations).

Benefits

As presented in Section II of this report, there is evidence that ovarian cancer screening can detect cancer at an earlier stage. However, showing that cancer can be detected early does not prove its benefit. Evidence must show that the early detection makes a difference in measureable outcomes, and there is currently no evidence that ovarian cancer screening and early intervention decreases mortality rates. Therefore, the potential benefit of this mandate on public health is unknown and awaits the completion of several ongoing randomized controlled trials. Specifically, there is no evidence available to suggest that this mandate will impact the health of the community through the benefits of ovarian cancer screening. There is no evidence that indicate that the proposed mandate would result in any improvements in health outcomes such as mortality rates, where racial and ethnic disparities are known to exist, or reduce overall ovarian cancer mortality rates among women. Finally, there is no evidence available to suggest that ovarian cancer screening changes five-year survival rates.

Harms

Two harms could occur as a result of mass screening of asymptomatic women for ovarian cancer (Table 9). The first is the psychological distress that could result from a false-positive screening test result. The rates of a positive CA-125 test for ovarian cancer are 20% for premenopausal women (aged 18 to 49 years) and 10% for postmenopausal women (aged 50 to 64 years). The rates of both a positive CA-125 test result followed by a positive TVS are 10% for

premenopausal women and 6% for postmenopausal women. Among the 1.1 million women who are newly screened for ovarian cancer as a result of the mandate, an estimated 184,000 healthy women will be subject to psychological distress (e.g., anxiety, stress, and depression) over a false-positive test result.

Additional harms associated with screening are the discomfort and inconvenience and the potential risk of physical injury as a result of complications from surgery for more than 10,000 women with a false-positive test, who go on to have a confirmatory laparoscopy.

Table 1. Immediate Outcomes from Ovarian Cancer Screening

Outcome	Screened Group		Unscreened Group		Comment
	Premenopause	Postmenopause	Premenopause	Postmenopause	
Patient-oriented Getting test ("hassle" of test, time off work, etc. The TVS involves a condom-covered dildo-shaped instrument (an ultrasound transducer being placed in the vagina.)	20% of women will get CA-125. 20% of those will be positive and then get a TVS	30% of women will get CA-125. 10% of those will be positive and then get a TVS	0%	0%	Unclear what actual rate will be. Unlike mammography, for example, where the rate is higher than 50%, no group recommends this screening and it is not standard of care to screen. Doctors may say screening leaves them open to litigation should harm occur. On the other hand, many women fear ovarian cancer and may request the test.
Women experiencing anxiety of a positive screening	20%	10%	0%	0%	Some anxiety accompanies every positive test. At times, the anxiety is significant.
Women experiencing reassurance from a negative screening	80%	90%	0%	0%	Some reassurance accompanies every negative test. At times, the reassurance is significant.
Laparoscopy with or without biospy (a surgery where a doctor looks inside the abdomen through a small tube)	44% of those with a positive TVS (see comment)	50% of those with a positive TVS	Very small, given the low incidence of the disease	Very small, given the low incidence of the disease; probably 10% the number in those who are screened	25% of women with positive TVS will undergo laparoscopy immediately, the rest will get a repeat TVS. 25% of those with a repeat TVS will ultimately get a laparoscopy

Table 1. Immediate Outcomes from Ovarian Cancer Screening (Cont'd)

Outcome	**Screened group**		**Unscreened group**		**Comment**
Patient-oriented	Premenopause	Postmenopause	Premenopause	Postmenopause	
Laparotomy with or without biospy (a surgery where a regular incision is made, providing the surgeon better access to the abominal cavity)	Unusual (see comment)	50% of those with a positive TVS	Very small	50% of those who have laparoscopy	Laparotomy will be unusual in the premenopausal patient because the causes of a positive test can usually be handled by laparoscopy.
Oophorectomy (removal of the ovary)	Small	80% of those with laparotomy or laparoscopy	Small	80% of those with laparotomy or laparoscopy	
Transabdominal hysterectomy and bilateral salpingoophorectomy (TAH-BSO; removal of the uterus and ovaries.)	Unusual	80% of those with Oophorectomy	Very small	80% of those with Oophorectomy	
Cancer treatment	NA	NA	NA	NA	Estimated to be the same in both groups

Source: California Health Benefits Review Program, 2003 (based on a pilot study by Jacobs et al., 1999 and expert opinion from Dr. Alberto Manetta, University of California at Irvine Cancer Center, and Dr. Cheryl Saenz, University of California at San Diego Cancer Center).
Note: Includes work-up of positive screening. Does not include treatment of cancer or complications of the work-up.
Does not include repeat tests (see Tables 2A and 2B).

Table 2A. Sample Numbers for Hypothetical Cohort of 10,000 Postmenopausal* Women Screened Using Clinical Expert Judgment

Population	%	Number
Group screened	100	10,000
Positive CA-125	10	1,000
Positive TVS	6	60
Surgical evaluation	100	60
Laparoscopy	Up to 50	30
Laparotomy	Up to 50	30
Oophorectomy	20	6
TAH-BSO**	80	24
Cancers found		3

Table 2B. Sample Numbers for Hypothetical Cohort of 10,000 Premenopausal* Women Screened Using Clinical Expert Judgment

Population	%	Number
Group screened	100	10,000
Positive CA-125	20	2,000
Positive TVS	10	200
Immediate laparoscopy	25	50
Follow-up TVS	75	150
Delayed laparoscopy	25	38
Cancers found		1

Table 2C. Sample Numbers for Hypothetical Cohort of 10,000 Women Older Than Age 45 Screened Using Data from Jacobs et al.

Population	%	Number
Group screened	100	10,000
Positive CA-125	3	325
Positive TVS	5	15
Surgical evaluation	100	15
Cancers found	20	3

Source: California Health Benefits Review Program,2003 (based on a pilot study by Jacobs et al., 1999 and expert opinion from Dr. Alberto Manetta, University of California at Irvine Cancer Center, and Dr. Cheryl Saenz, University of California at San Diego Cancer Center).

*The overall cancer incidence for women older than age 50 is approximately 6 per 10,000 per year, so if the test were perfect, an estimated six cases a year would be found. Finding three cases per year implies a "real world" sensitivity of 50%. The Jacobs et al. numbers are in a clinical trial and are likely not representative of the real world. The University of California specialists estimate approximately 100 of the 10,000 women will undergo a surgical procedure in order to find three to six cancers, at no known benefit to the woman.

**TAH-BSO indicates transabdominal hysterectomy and bilateral salpingoophorectomy; TVS, transvaginal sonogram

Table 3. Assumptions Used in Analysis of Assembly Bill 547

	Large Group				Small Group				
	HMO	PPO	POS	FFS	HMO	PPO	POS	FFS	Individual
% of Women Receiving Insurer-Paid Screening (Pre-mandate)*									
Aged 18-49 years	6%	6%	6%	6%	6%	6%	6%	6%	6%
Aged 50-64 years	6%	6%	6%	6%	6%	6%	6%	6%	6%
Composite for women 18-64 years	6%	6%	6%	6%	6%	6%	6%	6%	6%
% of Women Receiving Insurer-Paid Screening (Post-mandate)**									
Aged 18-49 years	20%	20%	20%	20%	20%	20%	20%	20%	20%
Aged 50-64 years	30%	30%	30%	30%	30%	30%	30%	30%	30%
Composite for women 18-64 years	22%	22%	22%	22%	22%	22%	22%	22%	22%
Cost Per Screening if Paid by Carrier***									
Aged 18-49 years	$92	$92	$92	$92	$92	$92	$92	$92	$92
Aged 50-64 years	$73	$73	$73	$73	$73	$73	$73	$73	$73
Composite for women 18-64 years (pre-mandate)	$87	$87	$87	$87	$87	$87	$87	$87	$87
Composite for women 18-64 years (post-mandate)	$86	$86	$86	$86	$86	$86	$86	$86	$86
Aged 18-49 years	25.4%	25.4%	25.4%	25.4%	25.4%	25.4%	25.4%	25.4%	25.4%
Aged 50-64 years	8.40%	8.40%	8.40%	8.40%	8.40%	8.40%	8.40%	8.40%	8.40%
Additional Cost of Ovarian Cancer Treatment†	$0	$0	$0	$0	$0	$0	$0	$0	$0

Sources: California Health Benefits Review Program, 2003 (see Appendix A for details about data sources).

*Baseline level of screening procedures is estimated to be due to coverage of ultrasound for suspected diagnoses. Use of screening among women without risk factors in the 18-64 age group is estimated to be small.

**** 30% for women aged 50-64 years is less than the percentage of women at these ages that receive annual exams. Assumption is that doctors will not perform these tests as routinely as other well-visit tests because of inconclusive medical evidence as to their effectiveness. Lower value is assumed for 18- to 49-year-old women because evidence is even less clear for premenopausal women.

***Cost per screening changes slightly due to mandate, because a higher proportion of women aged 50-64 years are estimated to get the screen, and their screens cost less.

†Analysis assumes that the cancers detected through screening would have been detected shortly thereafter, so there would be no material change in the cost of ovarian cancer treatment.

Table 4. Assumed Utilization and Per Member Per Month Costs of Mandated Service, Calendar Year 2004

	Large Group				Small Group				
	HMO	PPO	POS	FFS	HMO	PPO	POS	FFS	Individual
Existing Coverage (Pre-mandate)									
Frequency of screening									
% of women aged 18-64 years who receive plan-paid screening	6%	6%	6%	6%	6%	6%	6%	6%	6%
Average cost per screening	$87.00	$87.00	$87.00	$87.00	$87.00	$87.00	$87.00	$87.00	$87.00
Current PMPM cost of screening per woman aged 18-64 years*	$0.44	$0.44	$0.44	$0.44	$0.44	$0.44	$0.44	$0.44	$0.44
Coverage After Mandate									
Frequency of screening									
% of women aged 18-64 years that get plan-paid screening	22%	22%	22%	22%	22%	22%	22%	22%	22%
Average cost per screening	$86.00	$86.00	$86.00	$86.00	$86.00	$86.00	$86.00	$86.00	$86.00
PMPM cost of screening per woman aged 18-64 years	$1.58	$1.58	$1.58	$1.58	$1.58	$1.58	$1.58	$1.58	$1.58
Marginal Impact of Mandate									
Increase in % of women aged 18-64 years that get screening	16%	16%	16%	16%	16%	16%	16%	16%	16%
Additional annual cost per newly diagnosed ovarian cancer patient due to early detection (in addition to screening cost)	$0	$0	$0	$0	$0	$0	$0	$0	$0
Increase in PMPM health care costs due to mandate (per female aged 18-64 years)									
Screening	$1.14	$1.14	$1.14	$1.14	$1.14	$1.14	$1.14	$1.14	$1.14
Additional cost of treatment for women diagnosed w/ovarian cancer	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Total	$1.14	$1.14	$1.14	$1.14	$1.14	$1.14	$1.14	$1.14	$1.14
Assumed % of members who are women aged 18-64 years	33.80%	33.80%	33.80%	33.80%	33.80%	33.80%	33.80%	33.80%	33.80%
Increase in PMPM healthcare costs due to mandate (all members)									
Screening	$0.39	$0.39	$0.39	$0.39	$0.39	$0.39	$0.39	$0.39	$0.39
Additional cost of treatment for women diagnosed w/ovarian cancer	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Total	$0.39	$0.39	$0.39	$0.39	$0.39	$0.39	$0.39	$0.39	$0.39

Source: California Health Benefits Review Program, 2003 (see Appendix A for details about data sources).
*Costs related to the current incidence of ovarian cancer screening and treatment are assumed to be included in the baseline costs.

Table 5. Per Member Per Month Cost and Utilization Summary Table, Calendar Year 2004

	HMO	PPO	POS	FFS	HMO	PPO	POS	FFS	Individual	Total
Population Under Age 65 (excluding self-insured firms)	5,692,000	1,538,000	1,433,000	54,000	2,325,000	1,103,000	775,000	40,000	1,602,000	14,562,000
Baseline PMPM Costs										
A. Insured Premiums										
Total Premium	$218.00	$314.73	$251.73	$319.70	$225.89	$317.75	$246.57	$331.59	$188.19	$3,484,310,000
Average Portion of Premium Paid by Employer	$169.13	$256.17	$185.92	$276.33	$168.18	$269.65	$194.56	$276.96	$0.00	$2,488,310,000
Average Portion of Premium Paid by Employee	$48.87	$58.56	$65.80	$43.37	$57.71	$48.11	$52.01	$54.63	$188.19	$996,060,000
Total Premium	$218.00	$314.73	$251.73	$319.70	$225.89	$317.75	$246.57	$331.59	$188.19	$3,484,310,000
B. Covered Benefits Paid by Member (Deductibles, Copays, etc.)	$7.72	$42.52	$15.92	$70.54	$11.53	$47.21	$19.26	$77.26	$32.93	$285,630,000
C. Total Cost of Covered Benefits	$225.72	$357.25	$267.64	$390.24	$237.42	$364.96	$265.83	$408.85	$221.12	$3,770,010,000
D. Benefits Not Covered	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0
E. Total Expenditures	$225.72	$357.25	$267.64	$390.24	$237.42	$364.96	$265.83	$408.85	$221.12	$3,770,010,000
PMPM $ Impact of Mandate										
A. Insured Premiums										
Total Premium	$0.44	$0.40	$0.43	$0.37	$0.45	$0.42	$0.44	$0.38	$0.44	$6,310,000
Average Portion of Premium Paid by Employer	$0.34	$0.33	$0.32	$0.32	$0.34	$0.35	$0.35	$0.32	$0.00	$4,350,000
Average Portion of Premium Paid by Employee	$0.10	$0.07	$0.11	$0.05	$0.12	$0.06	$0.09	$0.06	$0.44	$1,950,000
Total Premium	$0.44	$0.40	$0.43	$0.37	$0.45	$0.42	$0.44	$0.38	$0.44	$6,310,000
B. Covered Benefits Paid by Member (Deductibles, Copays, etc.)	$0.02	$0.05	$0.03	$0.08	$0.02	$0.06	$0.03	$0.09	$0.08	$490,000
C. Total Cost of Covered Benefits	$0.45	$0.45	$0.45	$0.45	$0.48	$0.48	$0.48	$0.47	$0.52	$6,800,000
D. Benefits Not Covered	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0
E. Total Expenditures	$0.45	$0.45	$0.45	$0.45	$0.48	$0.48	$0.48	$0.47	$0.52	$6,800,000
Percentage Impact of Mandate										
A. Insured Premiums	0.20%	0.13%	0.17%	0.11%	0.20%	0.13%	0.18%	0.11%	0.23%	0.18%
E. Total Expenditures	0.20%	0.13%	0.17%	0.11%	0.20%	0.13%	0.18%	0.11%	0.23%	0.18%

Source: California Health Benefits Review Program, 2003 (see Appendix A for details about data sources).

Table 6. Ovarian Cancer: Incidence in California, per 10,000 (1999)

	Total	White	Hispanic	Black	Asian/Pacific Islander
Annual Rate	1.55	1.73	1.19	1.17	1.17
New Cases (#)	2,533	1,811	372	117	214
New Cases (0-64)	1,417	914	259	74	158

Source: California Department of Health Services. *Cancer in California: 1988-1999*, 2001.
Notes: The race/ethnic categories do not sum to the total due to cases in which race/ethnicity was unknown. The annual rate is presented as the number of ovarian cancer new cases/deaths per 10,000 women. The incidence data broken down by age was pooled for years 1995-1999. The percentage of the population aged 18-64 years with ovarian cancer was taken from this pooled data and applied to the incidence numbers in 1999.

Table 7. Ovarian Cancer: Mortality in California per 100,000 (1999)

	Total	White	Hispanic	Black	Asian/Pacific Islander
Annual Rate	8.6	9.6	6.5	8.1	5.8
Deaths (#)	1,417	1,072	169	76	98
Deaths (18-64)	486	323	81	35	54

Source: California Department of Health Services. *Cancer in California: 1988-1999*, 2001.
Notes: The race/ethnic categories do not sum to the total due to cases in which race/ethnicity was unknown. The annual rate is presented as the number of ovarian cancer new cases/deaths per 100,000 women. The mortality data broken down by age was pooled for years 1995-1999. The percentage of the population aged 18-64 years with ovarian cancer deaths was taken from this pooled data and applied to the mortality numbers in 1999.

Table 8. Percent of Women Surviving Five Years After Diagnosis with Ovarian Cancer, by Stage of Disease (1999)

	All Stages	Localized	Regional	Distant
Survival*	52%	95%	81%	29%
% Tumors found at this stage	100%	26%	10%	59%

Source: California Department of Health Services. *Ovarian Cancer in California*. 2001.
*There is no evidence available to conclude that screening changes survival rates among women screened compared with women not screened.

Table 9. Public Health Impact of Ovarian Cancer Screening Mandate in Women Aged 18-64 Years, California

Ovarian Cancer Screening	Total Women (18-64 years)	Premenopausal Women (18-49 years)	Postmenopausal Women (50-64 years)
Total women eligible for screening under mandate	4,893,504	3,699,256	1,194,248
Newly covered women (100%)	4,893,504	3,699,256	1,194,248
Newly screened women*	1,098,126	739,851	358,274
Experience anxiety of a false-positive screen**	**183,798**	**147,970**	**35,827**
Potential harm from laparoscopy complications	**10,093**	**6,511**	**3,583**
Cancers detected***	182	74	108
Deaths prevented as a result of screening	**0**	**0**	**0**

Source: California Health Benefits Review Program, 2003.

**Assume that 20% of women aged 18-49 years will be screened; 30% of women aged 50-64 years will be screened.

**The rate of positive CA-125 blood test followed by positive transvaginal sonogram is 6% of screened women aged 18-49 years, and 10% of screened women aged 50-64 years, minus the number of cancers detected, yields number of false-positives.

***Assumes average rate of ovarian cancer detected in women aged 50-64 years is 3 per 10,000 screened and 1 per 10,000 in women aged 18-49 years.

APPENDIX A

Cost Analysis and Estimates Used in This Report

COST ESTIMATION APPROACH – GENERAL ASSUMPTIONS

The process of estimating the cost impact of a mandate involves developing assumptions regarding the current levels of health care coverage in place and then simulating the impact of the mandate on costs, premium levels, and benefit coverage. Four different "model" plans were selected: health maintenance organization (HMO), preferred provider organization (PPO), point-of-service (POS), and fee-for-service (FFS), along with three insured types (large group, small group, and individual) to represent typical insured plan benefits in California.

Coverage of mandated benefits in each model plan was estimated by surveying the seven largest California health insurers. Although this information is reflected in the modeling, each of these carriers offers a range of plan options, and it is impractical to summarize actual current coverage levels overall. Based on general knowledge of today's health insurance marketplace and information received from California insurers, the model plans are designed to be a reasonable representation of the average plans offered in California today.

The model plans used in the analysis are as follows:

- Large-Group HMO
- Large-Group PPO
- Large-Group POS
- Large-Group FFS
- Small-Group HMO
- Small-Group PPO
- Small-Group POS
- Small-Group FFS
- Individual (HMO and PPO)

The commercial market was divided into large-group (51 or more employees), small-group (2 to 50 employees), and individual coverage. Each of these markets is subject to different regulations and market forces.

Four model plans were selected, representing the four general plan types that are commonly available in today's market. These plan types vary in terms of the benefit structure, the limitations on choice of providers (i.e., physicians and hospitals), and the level of managed care restrictions imposed by the health insurer. Standard descriptions of these plan types are as follows:

- **HMO** – A health maintenance organization is a "closed-panel" plan that limits coverage to those providers in a designated panel (other than in emergency situations). The plan member is typically required to select one of the panel's primary care physicians, who

serves as the referral point to specialty care. The primary care physician, by agreeing to participate in the HMO's network, agrees to abide by the utilization management requirements and the fee schedules or other reimbursement approaches specified by the HMO.

The HMO coverage is broader than fee-for-service coverage, meaning it has lower member cost sharing and includes certain preventive care services that are not generally covered under an FFS or PPO plan. The model HMO plan used in this analysis is assumed to be moderately managed in terms of the degree of managed care, meaning that the plan uses some management protocols and standards, with moderate conformity to such standards.

- **PPO** – A preferred provider organization uses a fee-for-service approach to paying providers. The plan designates a preferred network of providers; members must use providers in the network in order to receive the highest level of benefit coverage. If a member chooses to use a non-network provider, the services are covered but the member must pay a substantially greater level of cost sharing. The model PPO plan used in this analysis is assumed to be loosely managed with respect to all services.

- **POS** – A point-of-service plan has a closed panel that is similar to an HMO plan, but it also allows members to go outside the panel, subject to paying a significantly higher level of cost sharing. The level of coverage for "in-network" benefits, meaning services within the closed panel, is similar to HMO coverage and has the same primary care physician role. The model POS plan used for this analysis is assumed to be moderately managed with respect to in-network coverage and loosely managed for out-of-network coverage.

- **Fee-for-Service (FFS)** – The fee-for-service plan is a traditional indemnity plan with minimal focus on managed care (referred to as "loosely managed"). Members can seek care from the providers of their choice.

The following information was estimated for each of the model plans:

Population Younger Than Age 65 Currently Covered

The data for these analyses were obtained from multiple sources. The California Health Interview Survey (CHIS), 2001 was used to identify the demographic characteristics and estimate the insurance coverage of the population in the state. CHIS is a random telephone survey of more than 55,000 households that is conducted in multiple languages by the University of California at Los Angeles Center for Health Policy Research. CHIS is the first state-level survey of its kind to provide detailed information on demographics and health insurance coverage as well as health status and access to care, including representative samples of non–English-speaking populations. CHIS insurance coverage estimates were cross-validated with administrative or other data sources.

To obtain estimates of the percentage of employees by size of firm and type of health plan, this analysis used the 2001 Health Research and Educational Trust (HRET) survey of California employers. Conducted annually for the Kaiser Family Foundation (KFF) of representative

samples of small and large employers, these data provide estimates of numbers of employees working in such firms and their types of coverage. Coverage categories include conventional FFS, PPOs, POS, and HMOs. Furthermore, the HRET/KFF survey also provides information on whether each health plan is self-insured or underwritten. The latter two data points were used to complement CHIS data, because CHIS does not provide details on PPO and POS or self-insured coverage. The HRET/KFF survey also contains data on health insurance premium costs of individual and family plans as well as the proportion of premiums that are paid by the employee and the firm for each type of health plan.

The percentages of workers with employment-based coverage obtained from CHIS data were inflated to reflect children and non-working individuals with this type of coverage. The final numbers of individuals with each type of coverage used in the analysis included only those covered under insured policies.

Baseline PMPM Costs – Insured Premiums

For large and small groups, the single and family premium rates from the HRET/KFF data were converted to per member per month (PMPM) rates by assuming 44% of covered employees had single coverage and 56% had family coverage. Employees with family coverage were assumed to have 2.21 dependents on average. These demographic assumptions were based on Milliman USA research.

For individual coverage, PMPM premium information was obtained through a survey of the largest insurers and HMOs in California.

The historical PMPM premium information discussed above was inflated by a rate of 12% per year to estimate premiums for calendar year 2004.

An actuarial cost model was constructed for each plan type, breaking down the observed premiums into administration costs and detailed health care service categories. The current utilization and average cost per service were estimated for each service category. The starting point for cost estimates in the analysis was the *Milliman Health Cost Guidelines* (HCGs), July 2003 edition. The HCGs are Milliman USA's proprietary information base that show how the components of per capita medical claim costs vary with benefit design, demographic composition, location, provider reimbursement arrangements, degree of managed care delivery, and other factors. In most instances, HCG cost assumptions are based on an evaluation of several data sources and are not specifically attributable to a single data source. The HCGs are used by Milliman USA client insurance companies, HMOs, and other organizations, primarily for pricing and evaluating health insurance products.

Adjustment factors from the HCGs were used to modify utilization and unit cost assumptions specifically for the state of California. The resulting cost estimates were then compared with the average premium rate information for the State of California from Milliman USA's *2003 HMO Intercompany Rate Survey* and to the premium rate survey discussed above to ensure the reasonableness of the estimates of the overall health care cost and premium levels.

Baseline PMPM Costs – Average Portion of Insured Premium Paid by Employer/Employee

Most employers require employees to pay a portion of the health premium through monthly contributions. The calendar year 2002 data from HRET/KFF 2002 included the average single and family monthly employee contribution rates. The residual between the total premium and the employee contribution rates was assumed to be the portion of the premium paid by the employer. Note that the employee costs in this value are just the monthly contribution rates; member cost sharing at the point of service is calculated separately.

Covered Benefits Paid by Member

This value varies by the plan type. Using the actuarial cost models described above, an estimate was made for the PMPM value of the deductibles and copays paid by plan members/insured as a percentage of total PMPM health care costs for each plan type:

	Member Cost Sharing As a Percent of Total Health Care Costs
Large-Group HMO	4%
Large-Group PPO	14%
Large-Group POS	7%
Large-Group FFS	21%
Small-Group HMO	6%
Small-Group PPO	16%
Small-Group POS	9%
Small-Group FFS	23%
Individual	20%

Benefits Not Covered

For each mandate, an estimate was made for the cost of services that are now being paid for directly by patients, exclusive of deductible and cost sharing for benefits that would be covered by insurance under the mandate.

Administrative/Profit Component of Premiums

Estimates are expressed as the percent change in premiums. These same percent changes would also apply separately to the benefit costs and the administrative expenses of health insurers. It was estimated that insurers' administrative expenses would change proportionately to the underlying change in benefit costs, reflecting the expected impact on claims-processing costs, utilization management costs, and other administrative functions.

The following table contains the assumed administrative/profit component of premium, expressed as a percentage of total premiums. These assumptions are general, and may not reflect the assumptions used by any particular insured plan in California.

	Administrative/Profit Expenses as a Percent of Total Insured Premiums
Large-Group HMO	15%
Large-Group PPO	17%
Large-Group POS	16%
Large-Group FFS	17%
Small-Group HMO	20%
Small-Group PPO	22%
Small-Group POS	21%
Small-Group FFS	22%
Individual	30%

COST ESTIMATION APPROACH – MANDATE IMPACT METHODOLOGY

Once the current baseline PMPM health care costs and premiums are determined, the next step is to estimate the increase in these PMPM costs and premiums due to the mandate.

Step 1: Estimate the change in health care costs covered by insurance

For services that are newly required by the mandate, the PMPM health care cost of these services that are already covered and being paid for under insurance plans was determined first. Note that these are the total costs for insured benefits, including the amounts paid by the insurer and amounts paid by the member through cost sharing. For a given plan type, this is calculated as follows:

(Percentage of members currently covered for the service), X
(Percentage of currently covered members expected to use the service in a year), X
(The cost per person who uses the service)

These costs are assumed to be included in the baseline costs estimated above.

Next is determined the cost of these mandated services covered under insurance plans after the mandate. For a given plan type, this is calculated as follows:

(Percentage of members covered for the service (assumed to be 100%)), X
(Percentage of current and newly covered members expected to use the service in a year), X
(The cost per person who uses the service)

The difference between the PMPM insured health care costs of newly mandated services before and after the mandate is the change in the *direct* health care costs covered by insurance.

In some cases, the increase in cost due to the newly covered services is offset by a decrease in the cost for other health care services.

The total change in health care costs covered by insurance is equal to the change in the *direct* health care costs covered by insurance less the value of the offset due to decreases in other health care costs.

Step 2: Allocate the change in health care costs covered by insurance between amounts paid by member cost sharing and amounts paid by the insurer

The portion of new health care costs that is paid by member cost sharing, "Covered Benefits Paid by Member," is estimated based on the above table, "Member Cost Sharing as a Percent of Total Health Care Costs." This is modified if the impact of the mandate is to modify the cost-sharing provisions as opposed to adding new covered benefits.

The portion of new health care costs not paid by member cost sharing is defined as the increase in the health care component of insured premiums.

Step 3: Estimate the change in insured premiums

The change in insured premiums is equal to the increase in the health care component of insured premiums, from Step 2, plus the increase in the administration and profit expense of the insurer. The administration and profit portion of the increase in insured premiums is based on the above table, "Administrative/Profit Expenses as a Percent of Total Insured Premiums."

The total of the increase in the health care and administrative/profit components of premium is added to the baseline PMPM premiums to estimate the PMPM premiums after the mandate.

Step 4: Allocate the change in health care premiums between amounts paid by the employer and amounts paid by the employee

The PMPM premium after the mandate is allocated between the portions paid by the employer and employee by assuming employers will continue to pay the same percentage of health care costs as before the mandate.

Step 5: Estimate the health care costs for newly mandated services that are currently paid by individuals due to lack of insurance coverage

For services that are newly required by the mandate, the PMPM health care cost of these services that are not currently covered but are being paid out of pocket by individuals is determined. For a given plan type, this is calculated as follows:

(Percentage of members currently not covered for the service), X
(Percentage of currently not-covered members expected to use the service in a year), X
(The cost per person who uses the service)

Step 6: Estimate the health care costs for newly mandated services that will be paid by individuals due to lack of insurance coverage after the mandate

This value is assumed to be zero.

Step 6: Estimate the impact on total expenditures for the insured population

The impact on total expenditures is equal to the total change in insured premiums, plus the change in the Covered Benefits Paid by Member, plus the change in the Benefits not Covered. Note that this amount is typically less than the impact on Insured Premiums, because some of the increase in Insured Premiums is offset by decreases in the Covered Benefits Paid by Member and Benefits not Covered. Also, the analysis assumes the estimated net change in actuarial costs translates fully into expenditure changes.

General Caveats and Assumptions

The California Health Benefit Review Program conducted the cost analysis presented in this report. 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, U.S.A.

A variety of external data sources was used in preparing the cost estimates for this report. Although this data was reviewed for reasonableness, it was used without independent audit. The *Milliman Health Cost Guidelines* were used extensively 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.

Unless otherwise noted in the report, the estimated net changes in actuarial costs are not the same as economic costs associated with the mandate because actuaries and economists define "costs" differently. While actuarial costs are net expenditures as just described, estimates of economic costs would typically include the value of the alternative uses of resources associated with the mandate.

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 already covered different from analysis assumptions
- Utilization of mandated services before and after the mandate different from analysis assumptions
- Assumptions used by health plans to price the mandated benefits different from analysis assumptions
- Random fluctuations in the utilization and cost of health care services

Additional assumptions that underlie the cost estimates presented here are as follows:

- Cost impacts are shown only for people with insurance.

- The projections do not include people covered under self-insurance employer plans, as 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 by unaffected by the mandate.

There are other variables that may affect costs but were not considered in the cost projections presented in this report. Such variables include, but are not limited to, the following:

- 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 will 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). The effects of such potential benefit changes in its analysis were not included.

- Adverse Selection. Theoretically, individuals or employer groups who had previously foregone insurance may now elect to enroll in an insurance plan because they perceive that it is to their economic benefit to do so.

- Medical Management. Health plans may react to the mandate by tightening their medical management of the mandated benefit. This would tend to dampen cost estimates in the analysis. 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 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 provider practice patterns, the level of managed care, and possibly the underlying health status of the local commercial population. The average cost per service varies due to different underlying cost levels experienced by providers 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, the impact has been estimated on a statewide level.

Cost Estimation Approach - Mandate Impact Assumptions

The following assumption underlie discussions in the Utilization, Cost, and Coverage Impact section of this report, specifically as it related to:

- Current coverage of ovarian cancer screening
- Current utilization rate for ovarian cancer screening procedures
- Post-mandate utilization rate for ovarian cancer screening procedures
- Average Cost for initial and follow-up screening procedures, per newly screened member.

No reductions in other health care costs were assumed to result from the increase in utilization of ovarian cancer screening procedures.

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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 USA, to assist in assessing the financial impact of each benefit mandate bill. Milliman USA 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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