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HEALTH BENEFITS REVIEW PROGRAM

Analysis of Senate Bill 576 Health Care Coverage: Tobacco Cessation Services

A Report to the 2005-2006 California Legislature
April 16, 2005
Revised May 20, 2005
Revised August 22, 2005

CHBRP 05-07



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 though 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.

A Report to the 2005-2006 California State Legislature

Analysis of Senate Bill 576
Health Care Coverage: Tobacco Cessation Services

April 16, 2005
Revised May 20, 2005
Revised August 22, 2005

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PREFACE

This report provides an analysis of the medical, financial, and public health impacts of SB 576, a bill to mandate coverage of tobacco cessation services, as introduced on February 18, 2005 and subsequently amended and transmitted to the California Health Benefits Review Program (CHBRP) in draft form on July 21, 2005. In response to this trasmitted request from the California Senate Banking, Finance and Insurance Committee, CHBRP undertook this analysis pursuant to the provisions of Assembly Bill 1996 (2002) as chaptered in Section 127600, et seq. of the California Health and Safety Code. This analysis is similar to the Reports to the California State Legislature submitted on April 16, and May 20, 2005. The April 16, 2005 CHBRP analysis assessed the impacts of SB 576 as introduced on February 18, 2005. The May 20, 2005 CHBRP analysis assessed the impacts of the version of SB 576 as amended on May 3, 2005 and revised the cost estimates for Medi-Cal to appropriately reflect that Medi-Cal currently covers tobacco cessation treatment services. This analysis incorporates the July 21, 2005 draft amendments which would allow copayments for over-the-counter drugs for the treatment of tobacco cessation. It also revises the cost and public health estimates to correctly reflect the expected reduction of heart attacks as a result of the mandate.

Wade Aubry, MD, Patricia Franks, BA, Noelle Lee, BA, Harold S. Luft, PhD, and Edward Yelin, PhD, all of the University of California, San Francisco, prepared the medical effectiveness analysis. Min-Lin Fang, MLIS, of UCSF conducted the literature search. Sharon M. Hall, PhD*, University of California, San Francisco, provided technical assistance with the literature review and expertise for the medical effectiveness analysis. Yali Bair, PhD, Richard Kravitz, MD, Janet Keyzer, RN-C, MPA, and Christina Kuenneth, MPH, all of the University of California, Davis prepared the public health impact analysis. Gerald Kominski, PhD, and Nadereh Pourat, PhD, both of the University of California, Los Angeles, prepared the analysis of the cost impact. Robert Cosway, FSA, MAAA, and Chris Girod, FSA, MAAA, both of Milliman, provided actuarial analysis. Susan Philip, MPP, and Robert O'Reilly, BS, of CHBRP staff prepared the background section and contributed to integrating the individual sections into a single report. Other contributors include Sachin Kumar, BA, Cynthia Robinson, MPP, both 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.

Jay Ripps, FSA, MAAA of Milliman recused himself from contributing to this and all other CHBRP analyses beginning March 1, 2005. His recusal is valid through his duration as acting chief actuary at Blue Shield of California.

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

**Dr. Hall is a current member of the Society for Research on Nicotine & Tobacco (SRNT). Among other things, SRNT supports assurance that tobacco cessation treatments have been integrated into regular health care delivery systems for all patients; Dr. Hall has a current research grant funded by Pfizer on a study for a smoking cessation aid, although her role is limited to advice about treatment and data collection; Dr. Hall did not declare any proprietary interest in Pfizer.*

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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Senate Bill 576

This report provides an analysis of the medical, financial, and public health impacts of SB 576, a bill to mandate coverage of tobacco cessation services, as introduced on February 18, 2005 and subsequently amended and transmitted to the California Health Benefits Review Program (CHBRP) in draft form on July 21, 2005. In response to this trasmitted request from the California Senate Banking, Finance and Insurance Committee, CHBRP undertook this analysis pursuant to the provisions of Assembly Bill 1996 (2002) as chaptered in Section 127600, et seq. of the California Health and Safety Code. This analysis is similar to the Reports to the California State Legislature submitted on April 16, and May 20, 2005. The April 16, 2005 CHBRP analysis assessed the impacts of SB 576 as introduced on February 18, 2005. The May 20, 2005 CHBRP analysis assessed the impacts of the version of SB 576 as amended on May 3, 2005 and revised the cost estimates for Medi-Cal to appropriately reflect that Medi-Cal currently covers tobacco cessation treatment services. This analysis incorporates the July 21, 2005 draft amendments which would allow copayments for over-the-counter drugs for the treatment of tobacco cessation. It also revises the cost and public health estimates to correctly reflect the expected reduction of heart attacks as a result of the mandate.

Senate Bill (SB) 576 would require health care service plans and insurers that provide outpatient prescription drug benefits coverage to cover the following tobacco cessation services:

- Personal counseling, which may include telephone or individual counseling.
- Prescription and over-the-counter tobacco cessation medications approved by the Food and Drug Administration.
- Benefits for tobacco cessation must comply with the Public Health Service–sponsored 2000 clinical practice guideline, "A Clinical Practice Guideline for Treating Tobacco Use and Dependence" (PHS, 2000) or its successors.

Health plans and insurers would be permitted to limit the courses of treatment or how many "quit" attempts the member makes, to two per every twelve-month period.

SB 576 would allow for copayments for over-the-counter (OTC) and prescription drugs but they are not to exceed $15 copayment.[1]

SB 576 would apply to health care services plans licensed by Knox-Keene[2] and to health insurance policies regulated under the California Insurance code.

I. Medical Effectiveness

Outcomes

- Current evidence-based systematic reviews and meta-analyses all conclude that counseling interventions, brief advice from physicians and clinical staff, and Food and Drug

[1] SB 576 would add §1367.27 of the California Health and Safety Code and §10123.175 of the California Insurance Code. SB 576 excludes specialized health care service plans, such as plans that provide a specific type of service such as vision or dental.
[2] 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.

Administration (FDA)-approved pharmacotherapy are effective treatments for tobacco cessation, as measured by abstinence.

- The 2000 U.S. Public Health Service Clinical Guideline (PHS, 2000) determined that there is a strong dose-response relation between the session length of person-to-person contact and successful treatment outcomes. Evidence indicates that a minimum of four counseling sessions of at least 30 minutes each, including proactive telephone counseling and individual counseling, is effective.

- Brief advice from a physician and clinical staff is also an effective intervention for tobacco cessation. The evidence indicates that physician advice to quit tobacco use increases abstinence rates.

- Prescription and over-the-counter nicotine replacement medications increase abstinence rates, as does bupropion, a non-nicotine prescription drug. Medications can double the likelihood that a patient will cease tobacco use.

- Combinations of interventions have incremental increases in effectiveness.

- Full coverage of tobacco cessation benefits significantly increased quit rates in one trial. In a randomized controlled trial, compliance with the U.S. Public Health Service Clinical Guideline (PHS, 2000) resulted in higher abstinence rates compared with the control group.

Caveat

- The basic conclusion about the effectiveness of interventions for tobacco cessation is not likely to be altered or diminished with the publication of new studies.

II. Utilization, Cost, and Coverage Impacts

- 20,368,000 individuals are currently enrolled in health plans regulated by the Knox-Keene Act or insured by policies regulated under the California Insurance Code. Currently, 95% of this population have coverage for prescription drugs and would be affected by SB 576—this includes 12,924,000 adults ages 18 and older.

- 7,052,000 insured adults (51.6%) currently have coverage for tobacco cessation benefits, though those covered benefits generally do *not* include coverage for over-the-counter (OTC) medications except for those covered by MediCal managed care organizations. Coverage tends to include physician visits, counseling, and prescription medication.

- Total health expenditures are projected to increase by $77,098,000 (0.128%). This overall increase includes a net savings of $11,545,000 that is related to the reduced out-of-pocket expenditures for non-covered services and a savings of $3,418,000 that is related to lower health care use among additional smokers who would quit as a result of access to tobacco

cessation services under the mandate[3]. These savings represent the short-term (i.e., one-year) savings resulting from reduced use of health care services among those who quit smoking. The potential long-term savings of quitting are likely to be substantial due to reductions in the rate of smoking-related illnesses. However, calculations of such savings are considered beyond the scope of this analysis.

- The per member per month (PMPM) increases in health expenditures and premiums vary by covered population, due to variations in the current coverage levels of smoking cessation benefits and other factors. The expected increase in PMPM expenditures for large group health maintenance organizations (HMO) members is 0.120% or $ 0.31. Values for other populations are summarized in Table 10.

[3] The cost savings calculation incorporates savings associated with reduced hospitalization for acute myocardial infarction (AMI) and savings associated with fewer low-birth weight deliveries. This analysis revises the cost savings to reflect the correct reduction in expected AMIs.



Table 1. Summary of Coverage, Utilization, and Cost Effects of SB 576

Total Insured Population = 20,368,000	Before Mandate	After Mandate	Increase/Decrease	% Change After Mandate
Coverage				
Percentage of insured individuals with coverage for mandated benefit	55.1%*	95.0%	39.9%	72.4%
Number of insured individuals in California with coverage for the benefit	11,217,000*	19,341,000	8,124,000	72.4%
Percentage of insured individuals 18 years and older with coverage for mandated benefit	51.6%*	94.6%	43.0%	83.3%
Number of insured individuals 18 years and older in California with coverage for the benefit	7,052,000*	12,924,000	5,872,000	83.3%
Total Unit Cost				
Counseling	$187.50	$300.00	$112.50	60.0%
Prescription Drugs	$300.00	$300.00	—	0%
OTC Drugs	$285.00	$285.00	—	0%
Average cost of cessation treatment for those with a covered benefit	$487.50	$614.55	$127.05	26.1%
Average cost of cessation treatment for those without a covered benefit	$285.00	N/A		
Average savings in health expenditures during first year for smokers who quit	$192.14	$192.14	—	0%
Utilization				
Percentage members 18 years and older who smoke with covered benefit and who try tobacco cessation	10.0%	10.2%	0.2% point	2.0%
Percentage members 18 years and older who smoke without covered benefit and who try tobacco cessation	4%	N/A	N/A	N/A

Table 1. Summary of Coverage, Utilization, and Cost Effects of SB 576 (continued)

Total Insured Population = 20,368,000	Before Mandate	After Mandate	Increase/Decrease	% Change After Mandate
Utilization				
1-Year success rate for members 18 years and older who smoke with covered benefit and who try tobacco cessation	20%	20%	0%	0%
1-Year success rate for members 18 years and older who smoke without covered benefit and who try tobacco cessation	8%	8%	0.0%	0.0%
Annual Expenditures				
Premium expenditures by private employers for group insurance	35,360,055,000	35,412,130,000	52,075,000	0.147%
Premium expenditures by individuals with group insurance, CalPERS, or Healthy Families	10,261,105,000	10,276,255,000	15,150,000	0.148%
Premium expenditures for individually purchased insurance	3,818,726,000	3,831,714,000	12,988,000	0.340%
CalPERS employer expenditures	2,212,881,000	2,214,219,000	1,338,000	0.060%
Medi-Cal state expenditures	3,939,663,000	3,939,663,000	0	0.000%
Healthy Families state expenditures	347,858,000	347,928,000	70,000	0.020%
Member copayments	4,074,893,000	4,081,915,000	7,022,000	0.172%
Expenditures for non-covered services	11,545,000	-	11,545,000	-100.000%
Total annual expenditures	60,026,726,000	60,103,824,000	77,098,000	0.128%

Source: California Health Benefits Review Program, 2005.
*Notes:** These members have coverage for tobacco cessation benefits, though those covered benefits generally do *not* include coverage for over-the-counter (OTC) medications except for those covered by MediCal managed care organizations.
The population includes individuals and dependents in California who have private insurance (group and individual) or are enrolled in public plans subject to the Health and Safety Code, including CalPERS, Medi-Cal, or Healthy Families.
All population figures include enrollees aged 0-64 years, except the Medi-Cal population, which includes dually eligible Medicare/Medi-Cal recipients of all ages. Employees and their dependents who receive their coverage from self-insured firms are excluded because these plans are not subject to mandates.
Key: CalPERS = California Public Employees' Retirement System.

III. Public Health Impacts

- Tobacco-related disease imposes a significant cost impact on individuals, employers, and society in terms of illness, medical costs, and loss of life and productivity.

- Tobacco cessation services have been proven effective in reducing the short-term disease and cost impacts of low birth weight deliveries and acute myocardial infarction within the first year after cessation.

- Tobacco cessation services have the potential to result in long-term public health benefits and cost savings by reducing exposure to the multiple mechanisms by which smoking causes disease, disability, and death.

- During the first year after implementation, this mandate is estimated to reduce, statewide, low birth weight deliveries by approximately 58 cases and would reduce acute myocardial infarction by 12 cases.[4]

[4] This analysis revises the public health impact estimate to reflect the correct reduction in expected AMIs by basing the estimate on the corrected incidence rate of AMI which is 0.219 (as opposed to 2.19 as stated in prior CHBRP analyses of SB 576).

INTRODUCTION

Tobacco use is the leading cause of preventable death in the United States and is associated with a variety of diseases. The 2004 U.S. Surgeon General's Report concluded that tobacco cessation has immediate and long-term benefits by reducing risks for diseases caused by smoking and improving health in general (DHHS, 2004).

Senate Bill (SB) 576 would require health care service plans and insurers that provide outpatient prescription drug benefits coverage to cover the following tobacco cessation services:

- Personal counseling, which may include telephone or individual counseling.
- Prescription and over-the-counter tobacco cessation medications approved by the Food and Drug Administration.

Benefits for tobacco cessation must comply with the Public Health Service–sponsored 2000 clinical practice guideline, "A Clinical Practice Guideline for Treating Tobacco Use and Dependence" (PHS, 2000) or its successors.

Health plans and insurers would be permitted to limit the courses of treatment or how many "quit" attempts the member makes, to two per every twelve-month period.

SB 576 would allow for copayments for over-the-counter (OTC) or prescription drugs but they are not to exceed $15 copayment. The bill is silent on copayments for all other services. Therefore, this analysis assumes that the usual copayment levels for counseling and physician office visits would continue to apply.[5]

Enrollees and their providers may decide at the beginning of a tobacco cessation course what services and products they prefer in order to quit. Coverage for tobacco cessation services, including OTC drugs, would only "be available upon the order of an authorized provider."

SB 576 would apply to health care services plans licensed by Knox-Keene[6] and to health insurance policies regulated under the California Insurance code.

Currently no other state requires insurers to cover tobacco cessation programs as a health benefit. Many legislatures have considered such legislation, including New York, Maryland, Wisconsin, and Oklahoma.

Over the past several years, California has taken measures to decrease the number of smokers and prevent an increase in the number of new smokers. For example, Californians have had increased access to tobacco cessation education and services through the California Department of Health Services Tobacco Control Section. The California Tobacco Tax and Health Promotion Act of 1988 (Proposition 99) increased the state surtax on cigarettes and other tobacco-related products. Revenues from the "tobacco tax" were appropriated for tobacco-related research, tobacco cessation efforts, and health education and

[5] SB 576 would add §1367.27 of the California Health and Safety Code and §10123.175 of the California Insurance Code. SB 576 excludes specialized health care service plans, such as plans that provide a specific type of service such as vision or dental.
[6] 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.

health care for medically-indigent families. In 1995, California enacted a smoke-free workplace law in an effort to reduce the public health burden of second-hand smoke inhalation.

Tobacco settlement monies provided California with approximately $1 billion a year. However, beginning with the 2002-2003 budget, the state began to divert its share of tobacco settlement fund revenues (TFR) from health programs to debt repayment (Legislative Analyst's Office, 2002). Since 2003, the state has continued to divert all the TFR toward debt repayment.[7]

I. MEDICAL EFFECTIVENESS

This medical effectiveness analysis reviews the literature on the effectiveness of counseling, brief cessation interventions, and medications approved by the Federal Drug Administration (FDA) for the use of tobacco cessation treatment. Counseling interventions include counseling in person or via telephone and in individual or group therapy. Counseling is often provided by physicians, nurses, peer counselors, social workers, psychologists, or psychiatrists. Pharmacotherapy includes nicotine replacement therapy (NRT), which can be administered by chewing gum, nasal spray, transdermal patch, inhaler, or lozenge. Bupropion SR, which does not contain nicotine, has been FDA-approved as a tobacco cessation aid for people who smoke 10 or more cigarettes daily and are at least 18 years old. SB 576 does not specify if interventions are directed at adolescents or adults; thus, the medical effectiveness review does not exclude any population.

Extensive literature has been published on the effectiveness of various tobacco cessation interventions. Most studies reviewed employed abstinence as the primary outcome measure in evaluating the effectiveness of various interventions. Although continuous abstinence is desirable, varying definitions of relapse create difficulty in evaluating prolonged-abstinence rates in patients. However, because most relapses occur within the first three months after tobacco cessation, many systematic reviews of the literature included only those studies with follow-up of at least five months (PHS, 2000). Thus, this medical effectiveness analysis considers interventions that result in tobacco abstinence for at least five months to be effective.

The results of the review of the scientific literature relevant to SB 576 are divided into three major categories of interventions: (1) counseling, (2) brief advice given by physicians and clinical staff, and (3) pharmacotherapies. Although other interventions for tobacco cessation may exist and are effective, this review only discusses interventions proposed in the mandate.

The scope of the literature search included the following outcomes:

- Tobacco cessation (quit smoking for less than six months, quit smoking for six months to one year, quit smoking for more than one year, quit smoking for five years, quit smoking for ten years)
- Recidivism rate (smoking not resumed for the above time intervals)
- Improved pulmonary function tests (forced expiratory volume at 1 second [FEV1]/forced vital capacity [FVC])

[7] Personal communication with member of the State of California Tobacco Education and Research Oversight Committee, March 28, 2005

However, most reviews and meta-analyses considered abstinence from tobacco use for at least five months the primary outcome measure. The literature search was conducted through PubMed and the Cochrane Library for relevant research published between 2000 and 2005 and was limited to English abstracts. Internet searches were conducted and focused on several Websites, including National Commission on Quality Assurance (Health Plan Employer Data and Information Set measures), Centers for Disease Control and Prevention, U.S. Preventive Services Task Force (USPSTF), American Cancer Society, American Cancer Institute, American Lung Association, and the Task Force on Community Preventive Services. A description of methods used to conduct the medical effectiveness review, and the process used to "grade" the evidence of effectiveness 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 of Tobacco Cessation Interventions.

Evidence-Based Reviews and Meta-analyses on Tobacco Cessation Interventions

Much literature has been published on the effectiveness of various tobacco cessation interventions. Thousands of clinical trials have been published; consequently, this analysis does not review the results of individual trials, but rather reviews the recommendations and conclusions of evidence-based reviews and meta-analyses. Meta-analyses published in the Cochrane Library undergo rigorous review, and many meta-analyses were updated in 2004. (Results of these reviews are listed in Appendix B, Table B-1). In addition, the U.S. Public Health Service conducted a thorough review of articles published on the effectiveness of tobacco cessation interventions, despite the variety of interventions and the number of variables (i.e., length of counseling sessions, individual versus group therapy, etc).

In 2000, the U.S. Public Health Service released *Treating Tobacco Use and Dependence: Clinical Practice Guideline* based on the results of a systematic review and meta-analysis of the existing scientific literature (PHS, 2000). The 2000 guideline updates a previous guideline, *Smoking Cessation, Clinical Practice Guideline No. 18*, published in 1996 by the Agency for Health Care Policy and Research (now the Agency for Healthcare Research and Quality [AHRQ]), U.S. Department of Health and Human Services. The new guideline, which reviews evidence published through January 1, 1999, was written in response to new, effective clinical treatments for tobacco dependence that had been identified since the 1996 guideline was published. The following seven Federal government and nonprofit organizations sponsored the updated guideline: AHRQ, the Centers for Disease Control and Prevention (CDC), National Cancer Institute (NCI), National Heart, Lung, and Blood Institute (NHLBI), National Institute on Drug Abuse (NIDA), Robert Wood Johnson Foundation (RWJF), and University of Wisconsin Medical School's Center for Tobacco Research and Intervention (CTRI).

The key conclusions of the 2000 U.S. Public Health Service Clinical Practice Guideline (PHS, 2000), based on scientific evidence, are as follows:

1. Tobacco dependence is a chronic condition that often requires repeated intervention. However, effective treatments exist that can produce long-term or even permanent abstinence.
2. Effective tobacco dependence treatments are available.
3. Brief tobacco dependence treatment is effective.

4. There is a strong dose-response relation between the intensity of tobacco dependence counseling and its effectiveness. Treatments involving person-to-person contact (via individual, group, or proactive telephone counseling) are consistently effective, and their effectiveness increases with treatment intensity (e.g., minutes of contact).
5. Three types of counseling and behavioral therapies were found to be especially effective:
   - Provision of practical counseling (problem solving/skills training);
   - Provision of social support as part of treatment (intra-treatment social support); and
   - Help in securing social support outside of treatment (extra-treatment social support).
6. Numerous effective pharmacotherapies for tobacco cessation now exist.
   - Five first-line pharmacotherapies were identified that reliably increase long-term tobacco abstinence rates:
     - Bupropion SR
     - Nicotine gum
     - Nicotine inhaler
     - Nicotine nasal spray
     - Nicotine patch
   - Two second-line pharmacotherapies were identified as efficacious and may be considered by clinicians if first-line pharmacotherapies are not effective:
     - Clonidine
     - Nortriptyline
   - OTC nicotine patches are effective relative to placebo, and their use should be encouraged.
7. Tobacco dependence treatments are both clinically effective and cost effective relative to other medical and disease prevention interventions.

Compared with the 1996 Clinical Practice Guideline, the 2000 U.S. Public Health Service Clinical Practice Guideline (PHS, 2000) concluded that there was stronger evidence of the association between counseling intensity and successful treatment outcomes. The updated Clinical Practice Guideline disclosed evidence for additional efficacious counseling strategies and for more efficacious pharmacologic treatment strategies. The Clinical Practice Guideline indicated strong evidence that tobacco cessation benefits that cover at least four counseling sessions of at least 30 minutes each, including proactive telephone counseling and individual counseling, are effective. The report notes that person-to-person treatment delivered for four or more sessions appears especially effective in increasing abstinence rates. There is a clear trend for abstinence rates to increase with total contact time, with 31–90 minutes producing abstinence rates that were significantly higher than were rates produced by 1–3 minutes of total contact time. The estimated odds ratio was highest for total contact time ranging from 91–300 minutes. Although the U.S. Public Health Service–sponsored Clinical Practice Guideline concluded that various interventions were effective in tobacco cessation, results of the meta-analysis conducted for the guideline indicate that some interventions may be more effective than others.

Table 2. Efficacy of and Estimated Abstinence Rates for Various Types of Formats (n = 58 Studies)

Format	Number of Arms[1]	Estimated Odds Ratio
No format	20	1.0
Self-help	93	1.2
Proactive telephone counseling	26	1.2
Group counseling	52	1.3
Individual counseling	67	1.7

Source: U.S. Public Health Service, 2000.
Notes: (1) An arm can be defined as any of the treatment groups in a randomized clinical trial. Most randomized trials have two "arms," but some have three or more.

The Centers for Medicare and Medicaid Services (CMS) published *Decision Memo for Smoking and Tobacco Use Cessation Counseling* in March 2005 (CMS, 2005) and considered the recommendations of the 2000 guideline (PHS, 2000). CMS determined that "…the evidence is adequate to conclude that smoking and tobacco use cessation counseling, based on the current U.S. Public Health Service (PHS) Guideline, is reasonable and necessary for a patient with a disease or adverse health effect" that has been linked to tobacco use. CMS also had commissioned the RAND Corporation to conduct an evidence-based systematic review of which interventions are most effective for encouraging older smokers to quit (DHHS, 2000).

Major conclusions from the RAND report include:

1. Individual, telephone, and group counseling are all effective, with individual counseling being possibly the most effective.
2. There is consistent evidence from multiple analyses that greater intensity of counseling yields higher tobacco cessation rates.
3. NRT, clonidine, and bupropion are all effective as pharmacotherapy for tobacco cessation, although clonidine is not approved by the FDA for this use.
4. There is good evidence that both medical and non-medical providers are effective at delivering tobacco cessation services, but conflicting evidence about the relative degree of effectiveness between provider types exists.
5. Interventions with follow-up calls or visits are more effective than those without.

The authors of the RAND report conducted a meta-regression[8] analysis comparing an intervention with a control group to determine effectiveness by provider. The data show that many different types of providers are effective, but the trend indicates that physicians may be the most effective intervention providers.

[8] A meta-regression analysis aims to relate the size of effect to one or more characteristics of the studies involved.

Table 3. Relative Provider Effectiveness

Provider	Adjusted Odds Ratio	95% Confidence Interval
Physician	3.02	2.62-3.48
Psychiatrist/psychologist	2.68	1.79-4.00
Nurse	2.38	1.87-3.03
Counselor	1.87	1.35-2.61
Unknown	1.41	1.09-1.83
Other (self-help, etc.)	1.37	1.15-1.65

Source: DHHS (2000).

However, another meta-analysis examined 30 additional studies not included in the previous 1996 and 2000 U.S. Public Health Service clinical practice guidelines and found different results. Although psychologists, physicians, and nurses were effective in delivering tobacco cessation interventions, psychologists were most effective; the odds ratio for psychologists was 1.94, and the odds ratio for physicians was 1.87 (Mojica et al., 2004). Because there are more data on some clinician types than others, evaluating which clinician types are more effective is difficult. Consequently, CMS determined that all types of clinicians appear to be effective, with no one group more effective than another (CMS, 2005).

Key findings from the RAND report are that all forms of counseling have statistically significant effects on tobacco cessation and that nicotine replacement therapy (NRT) is more effective than the control group (usually placebo) in promoting tobacco cessation.

Effect of Insurance Coverage and Use of the U.S. Public Health Service Clinical Practice Guideline on Tobacco Cessation

In a randomized controlled trial, Schauffler et al. (2001) assigned the control group a self-help kit (video and pamphlet) and assigned the treatment group a self-help kit and fully covered benefits for OTC NRT gum and patch and participation in a group behavioral cessation program with no patient cost sharing. The quit rates after one year of follow up were 18% in the treatment group and 13% in the control group (odds ratio = 1.6). The authors concluded that the full coverage of a tobacco-dependence treatment benefit implemented in two Independent Practice Association (IPA) model health maintenance organizations (HMOs) in California was an effective strategy for significantly increasing quit rates, quit attempts, and use of nicotine gum and patch in adult smokers.

A pilot demonstration in Washington State (Ringen et al., 2002) implemented the federal Clinical Practice Guideline for tobacco cessation (PHS, 2000). In this observational study, union workers chose a one-call or a more intensive five-call tobacco cessation counseling plan provided by the Group Health Cooperative's Free and Clear program. Medications were limited to the nicotine patch, nicotine gum, and bupropion. The overall point prevalence quit rate for the population was 27.5% (one-call counseling, 25.5%; five-call counseling, 28.8%). The authors concluded that a combination of behavioral counseling

and medication therapy is most effective in treating tobacco dependency and that the addition of tobacco cessation programs to health benefit packages could provide valuable preventive benefits.

Katz et al. (2002) conducted a nonrandomized, controlled trial to determine the actual effectiveness of the guideline in primary care practice. The guideline-derived intervention included routine identification and brief counseling of smokers by nurses and medical assistants in addition to free NRT and telephone counseling of those smokers who were willing to make a quit attempt. The intervention was given at a family practice setting over a two-month period. After a two-month follow-up of 651 adults, significantly more intervention patients reported abstinence (21% versus 4%). At six months, the difference was not statistically significant (intervention, 21% versus control, 11%).

In another trial, Katz et al. (2004) performed a randomized, controlled trial of the effectiveness of the U.S. Public Health Service Clinical Practice Guideline (PHS, 2000) in 2,163 adult patients at eight community-based primary care clinics in southern Wisconsin. The intervention consisted of a tutorial for intake clinicians, group and individual performance feedback for intake clinicians, use of a modified vital signs stamp, an offer of free nicotine replacement therapy, and proactive telephone counseling. There was a significant difference in the percentage of patients who reported continuous abstinence at six months (intervention, 10.9% versus control, 3.8%, odds ratio = 3.4).

Limitations of the Analysis

Despite the abundance of literature on various tobacco cessation interventions, there may be a publication bias. Studies with significant, favorable results may be more likely to be published than studies with neutral or insignificant results. This publication bias would affect the results of evidence-based systematic reviews and meta-analyses. In addition, although the reviews considered abstinence for five months as the primary outcome, many studies did not measure relapse rates. For example, the number of patients who remain abstinent for six months, but then resume smoking two years after the conclusion of a study is not measured.

Conclusions

Evidence-based systematic reviews and meta-analyses all conclude that counseling interventions, brief advice from physicians and clinical staff, and FDA-approved pharmacotherapy are effective treatments for tobacco cessation, as measured by abstinence.

Various forms of counseling are effective. The 2000 U.S. Public Health Service Clinical Practice Guideline (PHS, 2000) determined that there is a strong dose-response relation between the session length of person-to-person contact and successful treatment outcomes. In addition, The Task Force on Community Preventive Services found strong evidence that interventions to increase cessation (a combined provider reminder *plus* provider education *with or without* patient education program; multicomponent interventions including telephone support for persons who want to stop using tobacco) are effective (CDC, 2005).

Meta-analyses have also demonstrated that brief advice from a physician and clinical staff is also an effective intervention for tobacco cessation. The 2000 U.S. Public Health Service Clinical Practice

Guideline (PHS, 2000) notes that evidence shows that physician advice to quit smoking increases abstinence rates.

Various NRTs are also effective. Prescription and OTC nicotine replacement medications increase abstinence, as does bupropion, a non-nicotine prescription drug. NRT medications include gum, dermal patches, inhalers, nasal sprays, and lozenges. For each medication, the findings of the meta-analysis conducted for the 2000 U.S. Public Health Service Clinical Practice Guideline (PHS, 2000) are similar to the effects found in more recent Cochrane reviews (see Appendix B). The 2000 Clinical Practice Guideline determined that both prescription and OTC nicotine replacement medication and bupropion are highly effective in tobacco cessation interventions. Although each intervention is effective on its own, interventions complement each other and are more effective in tobacco cessation when used together.

II. UTILIZATION, COST, AND COVERAGE IMPACTS

Introduction

According to CHBRP's estimates, there are 20,368,000 insured Californians currently enrolled in health plans regulated by the Knox-Keene Act or insured by policies regulated under the California Insurance Code. Currently, 95% of this population have coverage for prescription drugs and would be affected by SB 576—this includes 12,924,000 adults ages 18 and older.

According to CHBRP estimates, 9,151,000 insured Californians (44.9%) currently do not have coverage for tobacco cessation services. CHBRP's analysis assumes that insurance plans that currently cover tobacco cessation services use a combination of counseling, prescription medications, and physician contact (Javitz et al., 2004). Those with tobacco cessation are also likely to use OTC medications, such as transdermal patches and nicotine gum, to assist with their efforts (Javitz et al., 2004), although OTC medications are not currently covered by most health plans.

Present Baseline Cost and Coverage

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

An estimated 11,217,000 insured Californians (55.1%) currently have coverage for the mandated benefit. Smoking prevention services are particularly important in children less than 18 years of age, whereas tobacco cessation services are utilized almost exclusively by those 18 years of age and older.

CHBRP estimates that 7,052,000 insured adult Californians ages 18 and older (51.6%) currently have coverage for tobacco cessation, including:

- 1,652,000 Medi-Cal recipients in HMOs;
- 31,000 Healthy Family recipients in HMOs;
- 585,000 California Public Employees' Retirement System (CalPERS) members in HMOs;
- 528,000 persons with individually purchased coverage;
- 4,256,000 persons with employment-based coverage.

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

Current utilization
While a majority of smokers attempt to quit in California (61.5%), only a small proportion participate in a formal cessation assistance program (see Table 5). CHBRP estimates that about 1,187,000 insured adult Californians currently smoke and have coverage for tobacco cessation services, and that on average about 10% of these current smokers annually use tobacco cessation services—specifically, participating in a formal cessation program. This assumption is based on findings from Curry et al. (1998) and discussions with an expert in the field. In addition, the utilization rate of 10% is consistent with research conducted in other states by Milliman, and an analysis by Mercer prepared for the Maryland Health Care Commission[9].

Current average cost of tobacco cessation services
Currently the average cost for the package of covered tobacco cessation services—including counseling and prescription drugs—is estimates to be $487.50. This analysis assumes that advice for tobacco cessation is generally provided as part of a regular physician visit and that enrollees or members would not specifically make a doctor's office appointment solely to discuss tobacco cessation treatment, so we estimate no additional physician costs specifically for tobacco cessation.

For insured individuals without coverage for tobacco cessation coverage, those who seek to quit use OTC medications costing on average $285 (Levitz et al., 2004).

For the purposes of calculating cost impacts, CHBRP estimates, based on the review of the literature and discussion with an expert[10] in the field:

- a 20% success rate for those with covered benefits who attempt to quit.
- a 8% success rate for those without covered benefits, who attempt to quit.

Potential cost offsets or savings in the short-term
Those who quit tobacco experience measurable long-term improvements in health status. Tobacco cessation also produces long-term savings in medical expenditures. Calculations of long-term savings in medical expenditures are considered beyond the scope of CHBRP analyses. However, quitting also produces short-term savings in health expenditures related to fewer inpatient stays and ambulatory care visits related to low birth-weight deliveries, and a reduction in acute myocardial infarction (AMI), or heart attacks.

Low Birth Weight Deliveries. Based on the assumptions described in the public health section (see page 25), CHBRP estimates the mandate could result in 58 fewer low birth weight deliveries statewide[11]. The average savings per avoided low birth rate delivery is estimated to be approximately $36,000. This calculation is derived from the 1999 Lightwood study, which estimated $21 million saved (in 1995 dollars) as a result of 1,300 fewer low birth rate deliveries. This estimated savings was then was updated

[9] On page 22 of the Maryland Health Care Commission, "Annual Mandated Health Insurance Services Evaluation" December 31, 2004 report, the study estimates 10.4% of smokers will attempt to quit using smoking cessation services (52% of smokers attempt to quit, of whom 20% would use smoking cessation services).
[10] Personal communication with Sharon Hall, PhD, on March 2, 2005
[11] This is out of the total of 32,218insured pregnant women who were smokers prior to the mandate.

to 2005 terms at a rate of 8.4% per year.[12] Therefore *for each smoker who quits* as a result of the mandate, $117 is expected to be saved for avoided low birth weight deliveries.

Acute Myocardial Infarction. Based on the literature described in the public health section (see page 27) CHBRP estimates the mandate could result in 12 fewer hospitalizations due to AMI[13]. The average savings per avoided stroke and AMI hospitalization is estimated to be approximately $106,678. This calculation is derived from the 1997 Lightwood study (Lightwood and Glantz, 1997) which estimated an approximate $44 million savings (1995 dollars) in one year due to reduced numbers of AMI and strokes (based on 924 fewer hospitalizations for AMI and 538 fewer hospitalizations for strokes). Using this estimate in savings, CHBRP calculated the expected total savings (for both AMI and stroke) per avoided AMI, and then was updated to 2005 terms at a rate of 8.4% per year. Therefore *for each smoker who quits* as a result of the mandate, $75 is expected to be saved for avoided AMIs.

In total, CHBRP estimates that quitting produces an average first-year savings in health care expenditures of about $192 per smoker who quits.

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

CHBRP estimates no shift in costs among private or public payers as a result of current coverage. In the long-run, to the extent that smokers are more likely to require custodial nursing home services, reductions in smoking may produce reductions in nursing home expenditures under the Medi-Cal program.

Public demand for coverage (Section 3(j))

Based on the volume and extent of information received from outside parties, there is strong public interest in SB 576 (see Appendix E). Based on criteria specified under AB 1996 (2002), CHBRP is to report on the extent to which collective bargaining entities negotiate for and the extent to which self-insured plans currently have coverage for the benefits specified under the proposed mandate. Currently, the largest public self-insured plan, CalPERS preferred provider organization (PPO) plan explicitly excludes "drugs designed solely for or used to deter smoking." Based on conversations with the largest collective bargaining agents in California, no evidence exists 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.[14] The Pacific Business Group on Health (PBGH) Negotiating Alliance, a large-group purchasing coalition that negotiates on behalf of large employers in California, worked with the CDC to include coverage guidelines for tobacco cessation prescription drug treatment back in 1994 and then expanded that to a comprehensive tobacco cessation approach in 2000.

[12] This trend rate was based on the average annual increase in California HMO premiums from 1995 to 2004 as measured by the Milliman Intercompany HMO Rate Survey.
[13] This is out of a total of 2,299,792 insured adults who were smokers prior to the mandate.
[14] Personal communication with SEIU and California Labor Federation on February 8, 2005

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))

CHBRP estimates that the unit cost of covered tobacco cessation services will increase from $487.50 to $614.55 (26.1%), primarily due to increased use of counseling services (see Table 1).

CHBRP estimates that the average effectiveness of tobacco cessation will increase, because those with coverage are assumed to have a 20% success rate, whereas those without coverage have only an 8% success rate. We assume this differential success rate because those without coverage would primarily rely only on OTC medications and would not have coverage for other types of interventions such as counseling.

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

CHBRP estimates that the proportion of smokers currently without coverage who use tobacco cessation treatment in an attempt to quit annually will increase from 4.0% to 10.2% as a result of the mandate. Based on findings from the literature (Curry et al., 1998, Schauffler, et al., 2001, Kaper, et al, 2005), utilization is expected to increase as a result of the increased coverage for tobacco cessation treatment. In addition, among plans that already cover tobacco cessation, the proportion of smokers with coverage who attempt to quit is expected to increase as a result of the mandate, from 10.0% to 10.2%. Specifically, the mandate would limit the copayment amount for OTC products and prescription drugs to a maximum of $15.[15] All other tobacco cessation services, such as physician visits, counseling sessions are not subject to copayment limits and CHBRP assumes that the usual copayment levels for these services would continue to apply.

The expected increase in utilization following the mandate is small given that the benefits and copayments requirements are similar to current smoking cessation programs. One exception is that most programs do not currently cover OTC drugs. In addition, members would be making utilization decisions based on a mutual decision between themselves and their provider about which services would be used in any given quit attempt cycle and obtain the appropriate authorizations for those services. This is expected to dampen any potential surges in utilization for any one service, since quit cycles are limited to two per year and members would be required to obtain authorization, for services, such as prescription drugs.

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

This mandate will likely increase the administrative expenses for health plans, but this increase is expected to be in proportion to the increase in health care costs. Claims administration costs may go up slightly due to an increase in claims for smoking cessation. Health plans and insurers will have to modify

[15] The draft amended version of SB 576 requested for CHBRP analysis on July 21, 2005, is silent as to the supply of drugs to which the copayment would apply. For the purposes of analysis, CHBRP assumes the copayment would apply for a one-month supply for OTC drugs and a one-month supply for prescription drugs.

some insurance contracts and member materials to reflect the new services. In addition, health plans and insurers would need to determine how to administer the tobacco cessation benefit to comply with the mandate to cover over-the-counter tobacco cessation drugs. Health plans and insurers include a component for administration and profit in their premiums. The estimated impact of this mandate on premiums includes the assumption that plans and insurers will apply their existing administration and profit loads to the marginal increase in health care costs produced by the mandate. Therefore, although there may be administrative costs associated with the mandate, administrative costs as a proportion of the premium would not change.

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

SB 576 will increase total health care expenditures from $60,026,726,000 to $60,103,824,000 for the 20,368,000 insured individuals affected by this mandate—an increase of $77,098,000, which equals 0.128% of total expenditures for this insured population.

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

For each major category of payer, total annual expenditures would change by the following annual amounts and percentages:

- Private employer premiums: increase of $52,075,000 (0.147%)
- Employee premiums by private employees, CalPERS employees, and Healthy Families enrollees: increase of $15,150,000 (0.148%);
- Premiums for individually purchased insurance: increase of $12,988,000 (0.340%);
- CalPERS employer premiums: increase of $1,338,000 (0.060%);
- Medi-Cal state expenditures: increase of $0 (0.000%)[16];
- Healthy Families state expenditures: increase of $70,000 (0.020%);
- Member copayments: increase of $7,022,000 (0.172%) and
- Out-of-pocket payments for non-covered services: decrease of $11,545,000 (−100%).

Individuals who currently purchase tobacco cessation services, mostly OTC medications, will realize the greatest savings under the mandate, because OTC medications would be available to them under the mandate, although they will be subject to copayments, not to exceed $15.

These total expenditures for premiums take into account the total savings for those who quit smoking. The total savings are estimated to be $3,418,000.[17] Note, these savings represent the short-term (i.e., one-year) savings resulting from reduced use of ambulatory and inpatient services among those who quit smoking, and do not account for the potential long-term savings of quitting. Long-term projections are considered beyond the scope of this analysis, but are likely to be substantial due to reductions in the rate

[16] The May 20, 2005 CHBRP analysis of SB 576 corrects certain coverage assumptions related to Medi-Cal and changes the cost estimates accordingly. This analysis reflects that Medi-Cal currently covers counseling services, prescription drugs and over-the-counter nicotine replacement therapy for smoking cessation treatment. Drugs are covered provided that the beneficiary is participating in a behavioral modification smoking cessation program.

[17] The cost savings calculation incorporates savings associated with reduced hospitalization for acute myocardial infarction (AMI) and savings associated with fewer low-birth weight deliveries. This analysis revises the cost savings to reflect the correct reduction in expected AMIs.

of smoking-related illnesses associated with a long lag time between exposure to smoking and onset, for example lung cancer and emphysema.

Total annual costs of smoking cessation are likely to decline in future years, as fewer smokers remain. However, cessation costs are also likely to increase in the future due to the diminishing effectiveness of smoking cessation strategies for those who continue to smoke.

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

CHBRP estimates that the proposed mandate will have no impact on access to (i.e., the supply of) tobacco cessation services, because these services are already widely available and the mandate would not increase demand substantially. Expanded coverage of OTC medications would potentially encourage more insured individuals to use tobacco cessation services, but the availability of these services should not be limited by this increased demand.

III. PUBLIC HEALTH IMPACTS

Introduction

The first report ever issued by a United States Surgeon General, in 1964, focused on the health effects of tobacco use. Since that time, the rate of smoking in California and nationwide has decreased dramatically, but tobacco use still remains the leading preventable cause of death and disease in the United States (DHHS, 2004). Recent estimates of smoking-related morbidity and mortality in California indicate that there were 43,137 smoking-related deaths in 1999, corresponding to 12.4 years of potential life lost, and $131,741 in lost productivity per death (Max et al, 2004). According to the CDC, smoking results in approximately 440,000 deaths nationwide each year and generates costs of approximately $157 billion in annual health-related economic losses. Smoking during pregnancy was estimated to result in 560 deaths in infant boys and 410 deaths in infant girls annually.

In 2004, the current Surgeon General issued the second national report on the health effects of tobacco use (DHHS, 2004). With regard to tobacco cessation, the report states that “smokers who quit can lower their risk for smoking-caused diseases and improve their health status generally. Those who never start can avoid the predictable burden of disease and lost life expectancy that results from a lifetime of smoking. Quitting smoking has immediate as well as long term benefits, reducing risks for diseases caused by smoking and improving health in general”.

During the past 15 years, Californians have had increased access to tobacco cessation education and services through the California Department of Health Services Tobacco Control Section. The California Tobacco Tax and Health Promotion Act of 1988 (Proposition 99), increased the state surtax on cigarettes and other tobacco-related products. Revenues from the “tobacco tax” were appropriated for tobacco-related research, tobacco cessation efforts and health education, and health care for medically indigent families. In 1995, California enacted a smoke-free workplace law in an effort to reduce the public health burden of second-hand smoke inhalation. During this time period, tobacco-use rates in California decreased (22% to 17.5%) and participation in cessation activities increased (48.9% to 61.5%) (Gilpin et al., 2001; Siegel et al., 2000).

By 2003, approximately 17.9% of Californians were current smokers (Table 4). Men were more likely to be current smokers than women, and those in the 18-39 year age group were slightly more likely to smoke than those aged 40-64 years. 2001 data from the California Tobacco Survey estimates that approximately two thirds of all smokers made at least one quit attempt in the prior year (Table 5). Only about a quarter of those who made a cessation attempt maintained the cessation for over 90 days. Smokers who made quit attempts used a variety of cessation assistance techniques, including counseling (7.8%), self-help materials (15.5%), and prescription and non-prescription medication (22.9%).

Table 4. Smoking Prevalence among California Adults (%), 2003

Age (years)	*Male*	*Female*	*Total*
18-24	22.7	14.1	18.5
25-39	24.0	13.4	18.7
40-64	20.2	14.2	17.1
Total	22	13.9	17.9

Source: California Health Interview Study, 2003.

Table 5. Tobacco Cessation Attempts

Cessation Attempts	*California Smokers, %*
Quit attempts*	
Quit attempt of 1 day or longer	61.5
90 or more days of abstinence	23.7
Use of cessation assistance	
Counseling	7.8
Self-help materials	15.2
Medication	22.9

Source: *California Adult Tobacco Survey (CATS) and Behavioral Risk Factor Survey (BRFS), 1997-2001 weighted to 1990 California population. California Department of Health Services, Tobacco Control Section, 2002

Despite state-level advances in tobacco cessation, the smoking rates in California remain higher than the Healthy People 2010 target of 12% for adults, particularly for ethnic minorities and those with low socioeconomic status (Table 6). Overall, American Indians have the highest smoking rates in the state, with similar rates for men and women in this group (32%). Blacks, Whites, and those of "other" or mixed rates have similar smoking rates of approximately 20%, with women in these groups having slightly lower rates than men. Hispanics and Asians have the lowest smoking rates, with significant gender differences. Hispanic men have smoking rates that are three times higher than Hispanic women, whereas Asian men's rates are almost four times higher than those for Asian women. Socioeconomic status also appears to play a role in smoking behavior. Both men and women with incomes less than 300% of the Federal Poverty Level are more likely to smoke than those who have higher incomes.

Table 6. Racial and Economic Disparities in Smoking Prevalence (%)

Race	*Male*	*Female*	*Total*
Hispanic	21.8	7.8	15.0
Native American	32.0	32.3	32.2
Asian	23.8	6.5	14.8
Black	22.5	18.4	20.3
White	21.2	18.0	19.6
Other/2 or more races	24.2	15.8	20.1

Poverty Status	*Male*	*Female*	*Total*
0-99% FPL	28.3	14.1	20.3
100-199% FPL	26.7	16.1	21.2
200-299% FPL	25.4	15.8	20.6
300% + FPL	18.2	12.5	15.5

FPL= Federal Poverty Level
Source: California Health Interview Study, 2003.

Short-Term Health Outcomes

Our analysis of the potential public health impacts of SB 576 focuses on two primary outcome areas: low birth weight deliveries and acute myocardial infarction (AMI). These outcomes were chosen for analysis because (1) the medical literature shows that smoking has a direct causal relationship to these conditions, (2) there is evidence that tobacco cessation has an impact on these outcomes, and (3) there is evidence that these outcomes have the potential to develop within one year of smoking initiation, and conversely, the effects of these outcomes have the potential to be mitigated in the short term.

Low Birth Weight Baseline Data

A recent report from the California Department of Health Services estimated that in 1999, approximately 76.4 years of potential life were lost, per death, due to death from short gestation or low birth weight (Max et al, 2002). Low birth weight deliveries can come about either due to intrauterine growth retardation (IUGR) or pre-term birth. IUGR is a condition in which the fetus fails to grow as expected, but may be born at the appropriate time. A baby born pre-term may be growing appropriately, but be low-birth weight by virtue of the early delivery. The CDC estimates that in 1999, approximately 11.4% of pregnant women in California were smokers, and they were twice as likely as non-smokers to deliver a low birth-weight baby (12.2% vs 6.3%) (CDC, 1999). The low birthweight delivery rate as a percentage of live births in California varies by race, with Black women having significantly higher rates than women of other racial backgrounds (Table 7).

Table 7. Birth Outcomes: Low Birth Weight

Race	*Low birth weight delivery rate as a percentage of live births*
Hispanic	5.7%
White	5.9%
Black	11.7%
Native American	6.2%
Asian	7.1%
Total	*6.3%*

Source: March of Dimes, 2002.

Summary of Studies

Many studies have shown that smoking during pregnancy increases the risk for delivery of a low birth weight baby (Messecar, 2001). According to a recent CDC report, approximately 7% of all low birth weight deliveries in California are directly attributable to smoking. The cost of low birth weight deliveries can be significant due to the increased likelihood of complications during the birth, extended hospitalization for mothers and infants, and the increased need for neonatal intensive care. A 2004 report from the CDC estimates that California's 1996 neonatal expenditures attributed to maternal smoking were $567 per woman, relative to $14 per non-smoker (CDC, 2004). A recent study by Adams and colleagues showed that maternal smoking increases the risk of neonatal intensive care unit admission by 20% (Adams et al., 2002).

It appears that tobacco cessation, particularly during the first trimester of pregnancy, reduces the risk of low birth weight deliveries and infant death. Salihu and colleagues estimated that 986 infant deaths could be prevented annually in the United States, if all pregnant smokers quit (Salihu et al, 2003). A 1990 study estimated that for every $1 spent on tobacco cessation services for pregnant women, over $3 in savings were achieved in medical care of low birth weight babies, and in the reduction of perinatal mortality (Marks et al, 1990). In 1999, Lightwood and colleagues conducted an analysis of the short-term impacts of California's public health tobacco cessation programs on the incidence of and costs associated with low birth weight deliveries. This study found that an annual 1% decrease in the smoking rate (corresponding to 3%-4% of pregnant smokers quitting) would prevent 1,300 low birth weight deliveries and save $21 million in direct medical costs within the first year after cessation intervention.

Baseline population of interest

The California Tobacco Control Section reports that approximately 11.4% of pregnant women in California are smokers. According to actuarial data from the cost and utilization section of this analysis, approximately 39,893 pregnant women smokers are currently insured in California. Of these, approximately 26,122 pregnant women smokers have coverage that includes tobacco cessation benefits and 13,771 pregnant smokers are not covered for these services. After the mandate, we expect that approximately 12,236 pregnant smokers would be newly covered for tobacco cessation services, resulting in a total of 38,348 women covered for the benefit and 1,545 remaining without coverage.

Expected outcome estimates without mandate

The rate of low birth weight deliveries in California is 6.3% among non-smokers and 12.2% among smokers (CDC, 1999). In general, tobacco cessation quit rates are higher for pregnant women than for the general population of smokers. Thus, without coverage for tobacco cessation services, we would expect approximately 14% of women to quit smoking and approximately 22% of those with coverage for the benefit to quit. (Healthy People 2010 Objective 27-6), DHHS, 2004 Surgeon General's Report). Based on these assumptions, we expect that prior to the mandate, approximately 7,675 women would quit smoking during pregnancy and we would expect approximately 4,414 low birth weight deliveries.

Expected outcome estimates after mandate

Under this mandate, a total of 12,236 pregnant women smokers would be newly covered for tobacco cessation benefits. We assume that a greater percentage of women would use tobacco cessation services once they become a covered benefit. If we assume that the rate of tobacco cessation for those newly covered under the mandate would increase from 14% to 22%, we would expect a total of 8,653 women to quit smoking during pregnancy under this mandate. Applying the low birth weight rate of 12.2% to the remaining smokers and 6.3% to the non-smokers, we would expect approximately 4,356 low birth weight deliveries under the mandate. Thus, we would expect 58 fewer low birth weight deliveries statewide in the year following the enactment of SB 576.

Total insured adult pregnant smokers: 39,893
Quit rate with coverage: 22%
Quit rate without coverage: 14%
Number of smokers prior to mandate: 32,218
Number of smokers after mandate: 31,240
Low birth weight rate (smokers): 12.2%
Low birth weight rate (non-smokers): 6.3%
Baseline expected cases of low birth weight deliveries: 4,414
Expected cases of low birth weight deliveries under mandate: 4,356
Total expected reduction in low birth weight deliveries due to mandate: 58

Acute Myocardial Infarction (AMI) Baseline Data

AMI, sometimes referred to as a "heart attack," occurs when there is damage to an area of the heart due to decreased blood flow to that area. There are multiple causes of AMI, but smoking is one of the primary risk factors. Myocardial infarction is one of the leading causes of death in the United States and in California (California Center for Health Statistics). In California, the mortality rate due to AMI varies by race and gender (Table 8). For all races, men have higher AMI-related mortality than women. Black and Native American men have the highest AMI mortality rate, followed by Whites. Hispanics and Asians have the lowest mortality rates due to AMI.

Table 8. Acute Myocardial Infarction Mortality Rate* by Race, California Adults Age 18-64 Years

Race	*Men*	*Women*
Hispanic	8.1	4.7
White	19.2	7.4
Black	26.6	20.4
Native American	23.0	10.1
Asian	13.8	3.9
Total	*16.2*	*7.2*

Source: California Center for Health Statistics)
Notes: *Per 100,000 annually.

Summary of Studies

The causal association between smoking and heart disease has been well documented by over 20 years of scientific evidence (Critchley and Capewell, 2003; DHHS, 2004). According to the California Department of Health Services, in 1999, men and women between the ages of 35 and 64 years who smoked were almost twice as likely to die from heart disease as were non-smokers in this age group (Max et al., 2002). According to this report, for adults between the ages of 35 and 64 years of age in 1999, there were 24.3 years of potential life lost per death from ischemic heart disease that were attributable to smoking.

A California-specific study by Lightwood and colleagues estimated the effect of the state's public health tobacco control programs on hospitalization for AMI within the first year after cessation (Lightwood and Glantz, 1997). Lightwood estimated that an annual 1% reduction in smoking prevalence (corresponding to approximately 3%-4% of smokers quitting) would result in 924 fewer hospitalizations for AMI and 538 fewer strokes which results in approximately $44 million (1995 dollars) in savings in direct medical costs within one year. This estimate does not include deaths that occur suddenly, before transportation to a hospital can be arranged. [18]

Smoking is associated with both fatal and non-fatal AMI. According to recent systematic reviews of the literature on the association between smoking and heart disease, tobacco cessation is associated with a 36% reduction in risk of total mortality and a 32% reduction in risk of non-fatal AMI (Critchley and Capewell, 2003, 2004).

Baseline population of interest

Approximately 2,326,775 smokers are currently insured in California. Under current coverage assumptions based on actuarial data covered in the cost and utilization section of this analysis, we expect

[18] Quantifying the short-term reduction of hospitalization as it pertains to strokes is difficult due to lack of published data on this specific outcome measure. However, Lightwood and Glantz (1997) estimated that an annual 1% reduction in smoking prevalence (corresponding to approximately 3%-4% of smokers quitting) would result in 924 fewer hospitalizations for AMI and 538 fewer hospitalizations for stroke within one year. This represents a reduction of approximately 0.6 hospitalizations for stroke for every AMI hospitalization avoided. Based on this ratio, we would expect that post-mandate, there would be approximately 9 fewer stroke-related hospitalizations statewide.

that approximately 26,983 smokers would quit smoking in any given year, resulting in 2,299,792 remaining smokers.

Baseline expected outcome estimates without mandate

Lightwood's study of the effects of California's public health tobacco cessation programs on the incidence of AMI estimates the rate of AMI in the general adult population as 0.219%. Tobacco cessation reduces the risk of AMI by approximately 32% (Critchley and Capewell, 2003, 2004), bringing the rate of AMI for non-smokers to 0.149% within the first year after cessation. According to these estimates, we would expect approximately 5077 ((26,983 x 0.149%) + (2,299,792 x 0.219%)) baseline cases of AMI in the relevant population, prior to enactment of the mandate.

Expected outcome estimates after mandate

Based on actuarial data and assumptions listed in the cost and utilization section of this analysis, approximately 44,773 smokers would be expected to quit smoking after this mandate, resulting in 2,282,002 remaining smokers. According to these calculations, we would expect a total of 5,065 ((44,773 x 0.149%) + (2,282,002 x 0.219%)) cases of AMI if SB 576 were enacted. Thus, under this mandate, we would expect 12 fewer cases of AMI statewide.

Total insured adult smokers: 2,326,775
Total smokers who quit annually, prior to mandate: 26,983
Total adult smokers prior to mandate: 2,299,792
Total smokers who quit annually, after mandate: 44,773
Total adult smokers after mandate: 2,282,002
Rate of AMI among smokers 0.219%
Rate of AMI among non-smokers 0.149%
Baseline expected cases of AMI: 5,077
Expected cases of AMI under mandate: 5,065
Total expected reduction in AMI due to mandate: 12

Economic Costs of Smoking in California

Smoking has both direct and indirect costs for individuals, employers, government, and society. The Surgeon General's report (DHHS, 2004) states that young smokers have poorer health status, increased work absenteeism, and use more medical care than non-smokers (e.g., 25% more health care).

Medical care makes up the largest proportion of the direct costs of smoking. The CDC reports that men who smoke incur $15,800 (in 2002 dollars) more in lifetime medical expenses than non-smokers, and women who smoke incur $17,500 more than non-smokers (Fellows et al, 2002). According to the California Department of Health Services, in 1999, the state spent $8,564,623 in total health care costs directly attributable to smoking, including $4,016,568 in hospital care, $2,060,234 in outpatient care, and $1,133,432 for prescriptions (Max et al, 2002). A 1995 study by Wagner and colleagues estimates that tobacco cessation resulted in significant decreases in use of outpatient and inpatient health care services (Wagner et al, 1995).

Due to the multiple effects of smoking on the body, a significant proportion of the death and disease burden of smoking will not be evident until many years after smoking is initiated. Indirect costs in terms of loss of productivity, quality of life, and life years lost are difficult to estimate for outcomes that may develop over a 30-year time period. California's Department of Health Services reports that in 1999, 12.4 years of potential life were lost due to smoking-related disease, with an associated $5,175,678 in lost productivity for men and $2,019,478 in lost productivity for women (Max et al, 2002). A recent study by Mulder and colleagues estimates that smokers who successfully quit report improved quality of life relative to current smokers (Mulder et al, 2001). Another study, by Taylor and colleagues, estimates the life extension achieved by tobacco cessation. Cessation at an early age (35 years old) resulted in an additional seven to eight years of life for men and an additional six to seven years of life for women. Cessation at a later age (65 years old), although resulting in significantly fewer life years gained, one to two for men and two to three for women, illustrates the benefits of cessation at any age.

Conclusion of public health impacts

Based on the scientific evidence for the effectiveness of tobacco cessation services, the impact of tobacco cessation on both short-term and long-term outcomes, and the evidence of economic benefits from reductions in smoking-related expenses, SB 576 would likely have a positive impact on public health in the state. Short-term benefits would be limited to those associated with the reduction in morbidity and mortality associated with AMI and low birth weight deliveries. A discussion of long-term benefits of tobacco cessation is beyond the scope of this analysis. However, we might assume that the long-term effects of cessation would be likely to impact conditions that are more chronic in nature, possibly more disabling and more costly than the short-term outcomes discussed in this analysis.

Based on the baseline demographic and disease-related statistics for California, SB 576 could potentially have a disproportionate impact on men, ethnic minorities, and low-income individuals. This analysis has identified gender, income, and race-based disparities in smoking prevalence and rates of disease. A recent CDC report estimates that tobacco cessation rates have been increasing among non-Hispanic Blacks (Woollery et al, 2003). Presumably, a mandate that would make tobacco cessation services available without any associated fees would make these services more accessible to traditionally underserved populations. Thus we might expect to see increased utilization among these groups and presumably a greater reduction in morbidity and mortality, relative to groups with lower baseline smoking and disease rates.

TABLES

Table 9. Baseline (Premandate) Per Member Per Month Premium and Expenditures, California, Calendar Year 2005

	Large Group				Small Group				Individual		Public				Total Annual Expenditures
	HMO	PPO	POS	FFS	HMO	PPO	POS	FFS	HMO	PPO	CalPERS HMO	Medi-Cal HMO Over 65	Medi-Cal HMO Other	Healthy Families HMO	Total (Members)
Population currently covered	7,400,000	3,220,000	457,000	19,000	1,498,000	875,000	454,000	4,000	887,000	1,065,000	795,000	354,000	2,846,000	494,000	20,368,000
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	$235.05	$86.12	$58.68	$41,860,457,000
Average premium paid by 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	$0.00	$6.32	$14,079,831,000
Total premium	$238.42	$341.77	$286.90	$303.83	$244.64	$307.67	$275.84	$218.97	$214.23	$120.38	$276.14	$235.05	$86.12	$65.00	$55,940,289,000
Deductibles, copayments paid by members	$8.44	$46.18	$18.14	$67.04	$12.49	$45.71	$21.55	$51.02	$13.04	$28.09	$9.78	$0.00	$0.00	$1.77	$4,074,893,000
Benefits not covered	$0.04	$0.08	$0.11	$0.11	$0.05	$0.08	$0.12	$0.11	$0.05	$0.09	$0.00	$0.00	$0.00	$0.00	$11,545,000
Total Expenditures	$246.91	$388.03	$305.15	$370.98	$257.19	$353.46	$297.51	$270.09	$227.33	$148.55	$285.92	$235.05	$86.12	$66.77	$60,026,727,000

Source: California Health Benefits Review Program, 2005.
Note The population includes individuals and dependents in California who have private insurance (group and individual), or are enrolled in public plans subject to the Health and Safety Code, including CalPERS, Medi-Cal, or Healthy Families.
All population figures include enrollees aged 0-64, except the Medi-Cal population, which includes dually eligible Medicare/Medi-Cal recipients of all ages.
Employees and their dependents that receive their coverage from self-insured firms are excluded because these plans are not subject to mandates.
Key: FFS = fee for service; HMO = health maintenance organization; POS = point of service; PPO = preferred provider organization. CalPERS = California Public Employees' Retirement System.

Table 10. Postmandate Impacts on Per Member Per Month and Total Expenditures by Insurance Plan Type, California, calendar year 2005

	Large Group				Small Group				Individual		Public				Total Annual Expenditures
	HMO	PPO	POS	FFS	HMO	PPO	POS	FFS	HMO	PPO	CalPERS HMO	Medi-Cal HMO Over 65*	Medi-Cal HMO Other*	Healthy Families HMO	Total (Members)
Population currently covered	7,400,000	3,220,000	457,000	19,000	1,498,000	875,000	454,000	4,000	887,000	1,065,000	795,000	354,000	2,846,000	494,000	20,368,000
Average Portion of Premium Paid by Employer	$0.2449	$0.4064	$0.5003	$0.4687	$0.2725	$0.4109	$0.4649	$0.5421	$0.0000	$0.0000	$0.1403	$0.0000	$0.0000	$0.0117	$53,483,000
Average Portion of Premium Paid by Employee	$0.0657	$0.0828	$0.1106	$0.1232	$0.1408	$0.1284	$0.2439	$0.1105	$0.4724	$0.6228	$0.0267	$0.0000	$0.0000	$0.0013	$28,137,000
Total Premium	$0.3107	$0.4893	$0.6109	$0.5920	$0.4133	$0.5393	$0.7088	$0.6526	$0.4724	$0.6228	$0.1670	$0.0000	$0.0000	$0.0130	$81,620,000
Covered Benefits Paid by Member (Deductibles, copays, etc)	$0.0257	$0.0473	$0.0630	$0.0603	$0.0336	$0.0490	$0.0687	$0.0624	$0.0339	$0.0507	$0.0052	$0.0000	$0.0000	$0.0001	$ 7,022,000
Benefits not covered	-$0.0401	-$0.0814	-$0.1107	-$0.1060	-$0.0540	-$0.0842	-$0.1206	-$0.1097	-$0.0546	-$0.0871	$0.0000	$0.0000	$0.0000	$0.0000	$ -11,545,000
Total Expenditures	$0.2962	$0.4553	$0.5632	$0.5463	$0.3929	$0.5041	$0.6568	$0.6053	$0.4517	$0.5864	$0.1721	$0.0000	$0.0000	$0.0131	$ 77,097,000
Percentage Impact of Mandate															
Insured Premiums	0.130%	0.143%	0.213%	0.195%	0.169%	0.175%	0.257%	0.298%	0.221%	0.517%	0.060%	0.000%	0.000%	0.020%	0.146%
Total Expenditures	0.120%	0.117%	0.185%	0.147%	0.153%	0.143%	0.221%	0.224%	0.199%	0.395%	0.060%	0.000%	0.000%	0.020%	0.128%

Source: California Health Benefits Review Program, 2005.
Note The population includes individuals and dependents in California who have private insurance (group and individual), or are enrolled in public plans subject to the Health and Safety Code, including CalPERS, Medi-Cal, or Healthy Families.
All population figures include enrollees aged 0-64 years, except the Medi-Cal population, which includes dually eligible Medicare/Medi-Cal recipients of all ages.
Employees and their dependents that receive their coverage from self-insured firms are excluded because these plans are not subject to mandates.
* The May 20 CHBRP analysis of SB 576 corrects certain coverage assumptions related to Medi-Cal and changes the cost estimates accordingly. This analysis reflects that Medi-Cal currently covers counseling services, prescription drugs and over-the-counter nicotine replacement therapy for smoking cessation treatment. Drugs are covered provided that the beneficiary is participating in a behavioral modification smoking cessation program.
Key: FFS = fee for service; HMO = health maintenance organization; POS = point of service; PPO = preferred provider organization. CalPERS = California Public Employees' Retirement System.

APPENDIX A
Literature Review Methods

SB 576 is an act to add §1367.27 to the Health and Safety Code and to add §10123.175 to the Insurance Code, relating to health coverage. SB 576 mandates coverage *for tobacco cessation services that include two courses of treatment in a 12-month period including personal counseling, which may be telephone or individual, and FDA-approved medication for tobacco cessation, including prescription and over-the-counter medications. Covered treatment shall comply with the Public Health Service sponsored 2000 clinical practice guideline, "Treating Tobacco Use and Dependence," or its successors.*

Appendix A describes the literature search for studies on the medical effectiveness of tobacco cessation interventions indicated in the mandate. The search focused on the effects of counseling, brief cessation interventions by physicians and clinical staff, and prescription and OTC tobacco cessation medications approved by the FDA on abstinence, recidivism rates, and pulmonary function. This appendix also discusses the outcomes used in the analysis of the mandate.

To "grade" the evidence for all outcome measures, the CHBRP effectiveness team uses a system[19] with the following categories:

1. Favorable (statistically significant effect): Findings are uniformly favorable, and many or all are statistically significant.
2. Pattern[20] 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.

The literature search was conducted in PubMed and the Cochrane Library for relevant research published between 2000 and 2005 and was limited to English abstracts. No patient populations were excluded. Publication types included in the literature search were systematic reviews, meta-analyses, randomized controlled trials, clinical trials, multicenter studies, practice guidelines, and reviews. Internet searches were conducted and focused on several Web sites, including HEDIS, CDC, U.S. Prevention Task Force, American Cancer Society, American Cancer Institute, American Lung Association, and the Task Force on Community Preventive Services.

The *Medical Subject Headings* (MeSH) terms used by the librarian in the PubMed search were:
Smoking cessation/methods
Smoking cessation/statistics & numerical data

[19] The 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).

[20] In this instance, the word "trend" may be used synonymously with "pattern."

Smoking/adverse effects
Smoking/economics
Smoking/ mortality
Smoking/prevention & control
Smoking/ statistics & numerical data
Tobacco use cessation/methods
Tobacco use disorder/therapy
Tobacco use disorder/drug therapy
Tobacco use/prevention & control
Tobacco smoke pollution
Lung neoplasms/etiology
Lung neoplasms/mortality
Lung neoplasms/prevention & control
Esophageal neoplasm/etiology
Esophageal neoplasm/mortality
Esophageal neoplasms/prevention & control
Pancreatic neoplasms/etiology
Pancreatic neoplasms/prevention & control
Pancreatic neoplasms/mortality
Neoplasms/prevention & control
Myocardial ischemia/etiology
Myocardial ischemia/mortality
Myocardial ischemia/prevention & control
Myocardial infarction/etiology
Myocardial infarction/mortality
Myocardial infarction/prevention & control
Cerebrovascular accident/etiology
Cerebrovascular accident/mortality
Cardiovascular diseases/ economics
Cardiovascular diseases/etiology
Cardiovascular diseases/mortality
Cardiovascular diseases/ prevention & control
Coronary disease/etiology
Coronary disease/economics
Coronary disease/mortality
Coronary disease/prevention & control
Pregnancy outcome
Pregnancy complications/prevention & control
Pulmonary disease, chronic obstructive/etiology
Pulmonary disease, chronic obstructive/mortality
Pulmonary disease, chronic
Asthma/prevention & control
Forced expiratory volume/physiology
Longevity
Quality-adjusted life years
Mortality
Hospitalization
Anti-anxiety agents/ therapeutic use
Antidepressive agents/ therapeutic use

Bupropion/therapeutic use
Clonidine/therapeutic use
Dopamine uptake inhibitors/ therapeutic use
Chewing gum
Nicotine/therapeutic use
Nicotine/administration & dosage
Nicotinic agonists/ administration & dosage
Nicotinic agonists/therapeutic use
Substance withdrawal syndrome/ drug therapy
Drugs, non-prescription/therapeutic use
Drugs, non-prescrption/economics
Prescriptions, drug/therapeutic use
Prescriptions, drug/economics
Physician's role
Nurser's role
Nurse practitioners
Nursing care
Physician assistants
Patient education
Counseling
Counseling/methods
Counseling/economics
Directive counseling
Behavior therapy
Group processes
Hotline
Telephone
Cost-benefit analysis
Drug costs
Treatment outcome
Outcome and process assessment (health care)
Comparative study
Follow-up studies
Cohort studies
Intervention studies
Prospective studies
Retrospective studies
Evidence-based medicine

Additional keywords were used to find articles (* indicates truncation): cessation, pulmonary function test*, FEV2/FVC, asthma, chronic obstructive pulmonary disease, COPD, angina, myocardial infarction, stroke*, lung cancer, espophageal cancer, pancreatic cancer, cancer, second hand smok*, emergency room visit*, ED visit*, brief intervention*, individual behavioral counseling, counseling, group behavior therapy, telephone counseling, cost*, heart attack, pregnancy outcome*, nicotine replacement therapy, office-based system, benefit*, physician assistant*, nurse or nurses, nursing care, nurse practitioner*, prescription, non-prescription, over the counter, patch, nasal spray, inhaler, lozenge, bupropion SR, bupropion, clonidine, two courses, two sessions, two attempts, 30 minutes, treatment outcome*, smoking status, vital sign.

The literature search resulted in nine relevant meta-analyses described in Appendix B. The search resulted in 168 references, including journal articles and Web sites. This analysis does not review the results of each clinical trial but reviews the recommendations and conclusions of evidence-based reviews and meta-analyses. Many meta-analyses published in the Cochrane Library were updated in 2004 and contain articles published after the 2000 Public Health Service Clinical Guideline (PHS, 2000).

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. This analysis excluded over 150 articles because they represented a lower level of evidence or were already included in the systematic reviews and meta-analyses.

The literature search resulted in an extensive body of literature that addresses the effectiveness of the interventions described in SB 576. Recent meta-analyses and systematic reviews provide thorough analyses on the effectiveness of counseling, brief advice, and pharmacotherapy on tobacco cessation.

APPENDIX B
Summary of Findings on Medical Effectiveness of Tobacco Cessation Interventions

Appendix B describes the meta-analyses and evidence-based systematic reviews relevant to this analysis and summarizes their results, usually given by an odds ratio.[21] Table B-2 lists the results for each intervention, where the main outcome studied in these reviews is abstinence from smoking. Table 2-B also includes a "grade" for the effectiveness of each intervention (see Appendix A for a description).

Table B-1-a. Summary of Published Studies on Effectiveness of Tobacco Cessation Interventions (Counseling and Brief Advice)

Citation	Type of Trial	Intervention vs. Comparison Group	Population Studied	Location
Fiore et al., 2000	Meta-analysis	Counseling in person or via telephone in individual or group therapy, physician advice to quit vs. no advice	Smokers after five-months follow-up	N/A
Lancaster and Stead, 2004	Meta-analysis	Brief advice vs. no advice (or usual care)	Smokers after six-months follow-up	N/A
Stead, Lancaster, 2004	Meta-analysis	Group tobacco cessation program vs. no self-help materials or no intervention	Smokers after six-months follow-up	N/A
Lancaster, Stead, 2002	Meta-analysis	Face-to-face individual counseling from a health care worker not involved in routine clinical care vs. minimal intervention	Smokers after six-months follow-up	N/A
Rice and Stead, 2004	Meta-analysis	Advice by a nursing professional vs. no intervention	Adult smokers over 18 years after six-months follow-up	N/A
Rigotti et al., 2003	Meta-analysis	Intensive intervention (inpatient contact plus follow up for at least one month) vs. usual care	Hospital inpatients after six-months follow-up	N/A
Stead et al., 2003	Meta-analysis	Proactive telephone support vs. minimal intervention	Smokers after six-months follow-up	N/A

[21] An odds ratio can be defined as the odds of an event occurring in the intervention group divided by the odds of an event occurring in the control group. An odds ratio of 1 indicates no difference between comparison groups. For undesirable outcomes, an odd ratio of less that 1 indicates that the intervention was effective in reducing the risk of that outcome.

Citation	Type of Trial	Intervention vs. Comparison Group	Population Studied	Location
Bernstein and, Becker, 2002	Systematic review	Brief counseling (< 3 minutes counseling) vs. usual care	Emergency Department patients after six months follow-up	N/A

Table B-1-b. Summary of Published Studies on Effectiveness of Tobacco Cessation Interventions (Medications)

Citation	Type of Trial	Intervention vs. Comparison Group	Population Studied	Location
Fiore et al., 2000	Systematic review	Pharmacotherapy – buprioprion SR vs. placebo, nicotine gum vs. placebo	Smokers after five-months follow-up	N/A
Silagy et al., 2004	Meta-analysis	Different forms of Nicotine Replacement therapy vs. placebo or no treatment	Smokers after six-months follow-up	N/A
Hughes et al., 2004	Meta-analysis	Medication vs. placebo or alternative therapy	Smokers after six-months follow-up	N/A

Table B-2. Summary of Evidence of Effectiveness of Interventions on Abstinence

Various Types of Counseling, Favorable

Trial	Results	Categorization of Results (Significance, Direction)
Fiore et al., 2000 (meta-analysis)	For 4-8 person-to-person treatment sessions, odds ratio for cessation = 1.9 (23 trials) Individual counseling, odds ratio = 1.7 (67 trials) Higher intensity counseling (> 10 minutes), odds ratio = 2.3 (55 trials) 91-300 minutes (total amount of contact time), odds ratio = 3.2 (16 trials)	Sig, fav Sig, fav Sig, fav Sig, fav
Stead and Lancaster, 2004 (meta-analysis, 6 trials)	Odds ratio for cessation = 2.19	Sig, fav
Lancaster and Stead, 2002 (meta-analysis)	Individual counseling from tobacco cessation specialist vs. minimal intervention, odds ratio = 1.62 (15 trials) Intensive counseling vs. brief counseling, odds ratio = 0.98 (4 trials)	Sig, fav NS, not fav

Trial	Results	Categorization of Results (Significance, Direction)
Rigotti et al., 2003 (meta-analysis, 6 trials)	Intensive intervention, odds ratio = 1.82	Sig, fav
Stead et al., 2003 (meta-analysis, 13 trials)	Telephone counseling, odds ratio = 1.56	Sig, fav

Brief Advice to Quit, Favorable

Trial	Results	Categorization of Results (Significance, Direction)
Fiore et al., 2000 (meta-analysis, 7 trials)	Odds ratio = 1.3	Sig, fav
Lancaster and Stead, 2004 (meta-analysis, 17 trials)	Brief advice, odds ratio = 1.74 Intensive versus minimal advice, odds ratio = 1.44	Sig, fav
Rice and Stead, 2004 (meta-analysis, 20 trials)	Odds ratio = 1.47	Sig, fav
Bernstein and Becker, 2002 (systematic review, 16 trials)	Quit rates at 6-12 months = 3% (usual care), 8%-11% (brief counseling)	Sig, fav

Buproprion SR, favorable

Trial	Results	Categorization of Results (Significance, Direction)
Fiore et al., 2000 (meta-analysis, 2 trials)	Efficacy on abstinence, odds ratio = 2.1	Sig, fav
Hughes et al., 2004 (meta-analysis, 19 trials)	Efficacy on abstinence, odds ratio = 2.06	Sig, fav

Nicotine Gum, favorable

Trial	Results	Categorization of Results (Significance, Direction)
Fiore et al., 2000 (meta-analysis, 13 trials)	Efficacy on abstinence, odds ratio = 1.5	Sig, fav
Silagy et al., 2004 (meta-analysis, 52 trials)	Abstinence from smoking, odds ratio = 1.66	Sig, fav

Nicotine Nasal Spray, favorable

Trial	Results	Categorization of Results (Significance, Direction)
Fiore et al., 2000 (meta-analysis, 3 trials)	Efficacy on abstinence, odds ratio = 2.7	Sig, fav
Silagy et al., 2004 (meta-analysis, 4 trials)	Abstinence from smoking, odds ratio = 2.35	Sig, fav

Nicotine Patch, favorable

Trial	Results	Categorization of Results (Significance, Direction)
Fiore et al., 2000 (meta-analysis, 27 trials)	Efficacy on abstinence, odds ratio = 1.9	Sig, fav
Silagy et al., 2004 (meta-analysis, 37 trials)	Abstinence from smoking, odds ratio = 1.81	Sig, fav

Nicotine Inhaler, favorable

Trial	Results	Categorization of Results (Significance, Direction)
Fiore et al., 2000 (meta-analysis, 4 trials)	Efficacy on abstinence, odds ratio = 2.5	Sig, fav
Silagy et al., 2004 (meta-analysis, 4 trials)	Abstinence from smoking, odds ratio = 2.14	Sig, fav

Nicotine Lozenge, favorable

Trial	Results	Categorization of Results (Significance, Direction)
Silagy et al., 2004 (meta-analysis, 4 trials)	Abstinence from smoking, odds ratio = 2.05	Sig, fav

APPENDIX C:
Articles Not Directly Referenced Within the Analysis or Excluded from the Analysis

Appendix C lists the articles that were either not directly referenced within this analysis or excluded from this analysis. These articles represented a lower level of evidence or were already included in the systematic reviews or meta-analyses.

Influence on lifestyle measures and five-year coronary risk by a comprehensive lifestyle intervention programme in patients with coronary heart disease. (2003).. *European Journal of Cardiovascular Prevention and Rehabilitation*. 10(6):429-437.

Bupropion to aid smoking cessation. (2000). *Drug and Therapeutics Bulletin*. 38(10):73-75.

U.S. Public Health Service. (2000). A clinical practice guideline for treating tobacco use and dependence: A US public health service report. The tobacco use and dependence clinical practice guideline panel, staff, and consortium representatives. *The Journal of the American Medical Association*. 283(24):3244-54.

Task Force on Community Preventive Services (2000). Strategies for reducing exposure to environmental tobacco smoke, increasing tobacco-use cessation, and reducing initiation in communities and health-care systems. A report on recommendations of the. *MMWR Recommendations and Report*. 49(RR-12):1-11.

Ahluwalia JS, Harris KJ, Catley D, Okuyemi KS, Mayo MS. (2002). Sustained-release bupropion for smoking cessation in african americans: A randomized controlled trial. *JAMA*.. 288(4):468-474.

Ahmadi J, Ashkani H, Ahmadi M, Ahmadi N. (2003). Twenty-four week maintenance treatment of cigarette smoking with nicotine gum, clonidine and naltrexone. *Journal of Substance Abuse and Treatment*. 24(3):251-255.

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American Cancer Institute. *Prevention and Cessation of Cigarette Smoking: Control of Tobacco Use (pdq®).* http://www.cancer.gov/cancerinfo/pdq/prevention/control-of-tobacco-use/patient/

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Bolliger CT. (2000). Practical experiences in smoking reduction and cessation. *Addiction*. 95 Suppl 1:S19-24.

Bolliger CT, Zellweger JP, Danielsson T, van Biljon X, Robidou A, Westin A, Perruchoud AP, Sawe U. (2002). Influence of long-term smoking reduction on health risk markers and quality of life. *Nicotine and Tobacco Research*. 4(4):433-439.

Bolliger CT, Zellweger JP, Danielsson T, van Biljon X, Robidou A, Westin A, Perruchoud AP, Sawe U. (2000). Smoking reduction with oral nicotine inhalers: Double blind, randomised clinical trial of efficacy and safety. *British Medical Journal*. 321(7257):329-333.

Borland R, Balmford J, Segan C, Livingston P. Owen N. (2003). The effectiveness of personalized smoking cessation strategies for callers to a quitline service. *Addiction*. 98(6):837-846.

Borland R, Segan CJ, Livingston PM, Owen N. (2001). The effectiveness of callback counselling for smoking cessation: A randomized trial. *Addiction*. 96(6):881-889.

Borrelli B, Papandonatos G, Spring B, Hitsman B and Niaura R. (2004). Experimenter-defined quit dates for smoking cessation: Adherence improves outcomes for women but not for men. *Addiction*. 99(3):378-85.

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Buchanan L. (2002). Implementing a smoking cessation program for pregnant women based on current clinical practice guidelines. *Journal of the American Academy of Nurse Practitioners*. 14(6):243-250.

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APPENDIX D
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/costimpact.html.

The cost analysis in this report was prepared by Milliman and University of California, Los Angeles (UCLA), with the assistance of CHBRP staff. Per the provisions of AB 1996 (California Health and Safety Code, §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 the data were reviewed for reasonableness, they were 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 restrictive 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 E
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.

American Cancer Society
Support letter for SB 576 from James K. Knox, Vice President, Legislative Advocacy
March 2, 2005

California Tobacco Control Alliance
Information and articles submitted on March 7, 2005, including:

> Zhu SH, Anderson CM, Tedeschi GJ, Rosbrook B, Johnson CE, Byrd M, Gutierrez-Terrell E. (2002). Evidence of real-world effectiveness of a telephone quitline for smokers. *The New England Journal of Medicine*. 347(14):1087-1093.
>
> Zhu SH, Tedeschi GJ, Anderson CM, Rosbrook B, Byrd M, Johnson CE, Gutierrez-Terrell E. (2000). Telephone counseling as adjuvant treatment for nicotine replacement therapy in a real-world setting. *Preventative Medicine.* 31: 357-363
>
> Zhu SH, Stretch V, Balabanis M, Rosbrook B, Sadler G, Pierce J, (1996). Telephone counseling for smoking cessation: Effects of single-session and multiple session interventions. *Journal of Consulting and Clinical Psychology.* 64(1): 202-211.

Center for Tobacco Cessation
Support letter for SB 576 from Sara Hutchinson, Manager, Federal and State Relations
March 2, 2005

Cathy McDonald, MD, MPH
Alameda County Alcohol, Tobacco and Other Drug Treatment Provider Network
Support letter for SB 576, March 1, 2005

William V. Corr, Executive Director, National Center for Tobacco-Free Kids
Support letter for SB 576, March 2, 2005

Paul Knepprath, Vice President, American Lung Association of California
Support letter for SB 576, March 1, 2005

Chris Kotsen, Psy.D., Tobacco Dependence Treatment Specialist, Coordinator,
Tobacco Quitcenter, Behavior Health Outpatient Services, Somerset Medical Center
Hillsborough, New Jersey
Support letter for SB 576 dated March 7, 2005

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

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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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