CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

# Analysis of Senate Bill 24: Tobacco Cessation

A Report to the 2007–2008 California Legislature
April 20, 2007

CHBRP 07-04


The California Health Benefits Review Program (CHBRP) responds to requests from the State Legislature to provide independent analyses of the medical, financial, and public health impacts of proposed health insurance benefit mandates and proposed repeals of health insurance benefit mandates. CHBRP was established in 2002, to implement the provisions of Assembly Bill 1996 (*California Health and Safety Code*, Section 127660, et seq.) and was reauthorized by Senate Bill 1704 in 2006 (Chapter 684, Statutes of 2006). The statute defines a health insurance benefit mandate as a requirement that a health insurer or managed care health plan (1) permit covered individuals to obtain health care treatment or services from a particular type of health care provider; (2) offer or provide coverage for the screening, diagnosis, or treatment of a particular disease or condition; or (3) offer or provide coverage of a particular type of health care treatment or service, or of medical equipment, medical supplies, or drugs used in connection with a health care treatment or service.

A small analytic staff in the University of California's Office of the President supports a task force of faculty 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, drawn from experts from outside the state of California and designed to provide balanced representation among groups with an interest in health insurance benefit mandates, reviews draft studies to ensure their quality before they are transmitted to the Legislature. Each report summarizes scientific evidence relevant to the proposed mandate, or proposed mandate repeal, but does not make recommendations, deferring policy decision making to the Legislature. The State funds this work through a small annual assessment of health plans and insurers in California. All CHBRP reports and information about current requests from the California Legislature are available at the CHBRP Web site, www.chbrp.org.

**A Report to the 2007–2008 California State Legislature**

# Analysis of Senate Bill 24: Tobacco Cessation

**April 20, 2007**

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## PREFACE

The California Health Benefits Review Program (CHBRP) conducts evidence-based assessments of the medical, financial, and public health impacts of health benefit mandate and repeal bills, at the request of the California Legislature. In response to a request from the California Senate Health Committee on February 22, 2007, CHBRP undertook this analysis of Senate Bill 24 (Tobacco Cessation) pursuant to the provisions of Senate Bill 1704 (Chapter 684, Statutes of 2006) as chaptered in Section 127600, et seq. of the *California Health and Safety Code*. This report analyzes draft language (Appendix A) that was modified from SB 576, which CHBRP analyzed in 2005.

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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:

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## EXECUTIVE SUMMARY

### California Health Benefits Review Program Analysis of Senate Bill 24: Tobacco Cessation

The California Legislature asked the California Health Benefits Review Program (CHBRP) to conduct an evidence-based assessment of the medical, financial, and public health impacts of Senate Bill (SB) 24. In response to a request from the California Senate Health Committee on February 22, 2007, CHBRP undertook this analysis pursuant to the provisions of Senate Bill 1704 (Chapter 684, Statutes of 2006) as chaptered in Section 127600, et seq. of the *California Health and Safety Code*.

SB 24 would amend Section 1367.27 of the *Health and Safety Code* and Section 10123.175 of the *Insurance Code* to require health care service plans and health insurance policies[1] that provide outpatient prescription drug benefits to include coverage for tobacco cessation services.

- These tobacco cessation services, chosen by the enrollee and provider, shall include:
  - telephone counseling,
  - brief cessation intervention by a physician, and
  - all prescription and over-the-counter medications approved by the Food and Drug Administration to help smokers quit.
- Conditions that apply to the benefit include:
  - telephone counseling and medications may be limited to two courses of treatment per year,
  - compliance with Public Health Service-sponsored 2000 clinical practice guidelines,
  - no copayment or deductible may be applied to the benefit, and
  - coverage for interventions shall include reimbursement for physician advice, charting, and referral.
- In addition, SB 24 includes medical recordkeeping and policy disclosure requirements, and provisions for contracting with qualified local, state, and national providers.

SB 24 contains modifications of the language in SB 576, which was analyzed by CHBRP in 2005.

[1] Health care service plans, commonly referred to as health maintenance organizations, are regulated and licensed by the California Department of Managed Health Care (DMHC), as provided in the Knox-Keene Health Care Services Plan Act of 1975. The Knox-Keene Health Care Services Plan Act is codified in the California Health and Safety Code. Health insurance policies are regulated by the California Department of Insurance and are subject to the California Insurance Code.

**Medical Effectiveness**

Effectiveness of Tobacco Cessation Services

The literature on the efficacy of behavioral interventions (e.g., counseling, brief advice) and pharmaceuticals to improve smoking cessation rates and continued abstinence once cessation occurs is large, including numerous meta-analyses of randomized controlled trials (RCTs), the strongest form of evidence for CHBRP analyses. The literature indicates that behavioral and pharmacological interventions and combinations of the two improve quit rates and continued abstinence.

- Various types of counseling administered to individuals and groups increase smoking cessation.
    - Brief counseling by physicians and other health professionals, often as little as a few minutes, increases smoking cessation.
    - Telephone counseling is an efficacious mode in smoking cessation.
    - Psychologists, physicians, and nurses are all effective in providing tobacco cessation counseling.
- Pharmacological agents for smoking cessation are commonly divided into those used in initial attempts to quit smoking ("first-line agents"), followed by those used when initial attempts to quit have not been successful ("second-line agents"). First-line agents for smoking cessation include nicotine replacement therapy (NRT), administered by gum, patch, nasal sprays, and inhalers, and the non-nicotine agent bupropion, an antidepressant useful in treating certain addiction syndromes. Second-line agents include clonidine, nortriptyline, and varenicline, a newly approved drug that is a form of cytisine.
    - Among first-line agents:
        - NRT administered by gum, lozenges, patches, nasal sprays, and inhalers increase smoking cessation.
        - Bupropion also increases smoking cessation.
    - Among second-line agents:
        - Varenicline and other forms of cytisine increase smoking cessation.
        - Clonidine and nortriptyline also increase smoking cessation.
- This conclusion about the efficacy of smoking cessation interventions is not likely to be diminished or altered with the publication of new studies, because of the large quantity of literature summarized in the meta-analyses.

The rates of abstinence from smoking found in RCTs summarized above may be greater than those that would be achieved if SB 24 were enacted. Most of these RCTs used strict inclusion/exclusion criteria to maximize their ability to determine whether counseling or pharmacotherapy increases smoking cessation. These studies may have excluded some smokers

who would have coverage for these services under SB 24. In addition, smokers who take the initiative to enroll in RCTs are probably more highly motivated to quit than the average smoker. Clinician researchers may also work harder than other clinicians to ensure that smokers use recommended amounts of counseling and/or pharmacotherapy.

Effects of Coverage for Tobacco Cessation Services

The literature on the impact of coverage for tobacco cessation services is much less extensive than the literature on the efficacy of these services. Therefore, the evidence base from which conclusions can be drawn about the effects of coverage on utilization of tobacco cessation services and abstinence from smoking is much less robust than the evidence base regarding the efficacy of these services.

*Use of tobacco cessation services*

- Persons who have full coverage[2] for NRT and/or bupropion are more likely to use these tobacco cessation medications than are persons who do not have coverage for tobacco cessation services.

- The evidence of the effect of full coverage for tobacco cessation counseling relative to no coverage on obtaining counseling is ambiguous.

- Persons who have full coverage for NRT and/or counseling are more likely to use these tobacco cessation services than are persons who have partial coverage for them.

*Abstinence from smoking*

- Full coverage for tobacco cessation counseling and pharmacotherapy is associated with improved abstinence from smoking relative to no coverage for tobacco cessation services.

- The evidence of the effect of full coverage for tobacco cessation counseling and pharmacotherapy relative to partial coverage on abstinence from smoking is ambiguous.

**Utilization, Cost, and Coverage Impacts**

About 20.69 million Californians 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 24—this includes 12.89 million adults ages 18 years and older.

- Currently, members largely have coverage for brief cessation interventions by a physician or other clinical staff as part of a regular physician visit, 59.4% have partial or full coverage for

[2] For purposes of this report, full coverage for tobacco cessation services is defined as coverage of 100% of costs associated with tobacco cessation medications and counseling without a deductible, copayment, or coinsurance.

prescription smoking cessation medications, 64.5% have coverage for personal counseling through telephone or other counseling services, whereas only 43.1% have coverage for NRT. Privately insured, California Public Employees' Retirement System (CalPERS), and Healthy Families members have only partial or no coverage for smoking cessation medications and counseling services. Medi-Cal, which covers 8% (1.03 million) of adults subject to the mandate, provides comprehensive tobacco cessation benefits at no charge to members.

- CHBRP used the 2002 California Tobacco Survey data and the RAND Health Insurance Experiment's (HIE) estimated impact of cost sharing for well care to estimate pre- and postmandate utilization. CHPRP estimated that premandate, among members with *partial or full* coverage, about 13.2% adult members who smoke used NRT, 8.4% used counseling, 4.2% used an antidepressant, and 18.1% used one or more services. Among members with *no* coverage, about 7.4% adult members who smoke used NRT, 4.8% used counseling, 2.4% used antidepressant, and 10.2% used one or more services. CHBRP estimated that the utilization of NRT would increase to 16.5%, counseling to 10.6%, an antidepressant to 5.3%, and one or more services to 22.6% after the mandate.

- Total net annual health expenditures are projected to increase by $70.05 million (0.10%), due to a $113.35 million increase in health insurance premiums ($94.38 million paid by employers and people who purchase individual insurance and $18.97 million paid by employees), partially offset by a net reduction in member copayments of $9.82 million and out-of-pocket expenditures of $33.49 million. The net increase of $70.05 million also includes a net savings of $4.28 million that represent the short-term (i.e., 1-year) savings resulting from a reduction in low birth-weight deliveries and in hospitalizations due to acute myocardial infarction (AMI), or stroke among those who quit smoking.

- Increases in insurance per member per month (PMPM) premiums vary by market segment (Table 5). Increases as measured by percentage changes in PMPM premiums are estimated to range from 0.01% to 0.54% in the affected market segments. Increases as measured by PMPM premiums are estimated to range from $0.01 to $0.81.

- In the large-group market, the increase in premiums is estimated to range from $0.47 to $0.74 PMPM (Table 5). For members with small-group insurance policies, health insurance premiums are estimated to increase by approximately $0.62 to $0.82 PMPM. In the individual market, the health insurance premiums are estimated to increase by $0.73 PMPM in Department of Managed Health Care (DMHC)-regulated market and by $0.81 PMPM in California Department of Insurance (CDI)-regulated market.

- In addition to gaining short-term savings in health expenditures, those who quit smoking may experience measurable long-term improvements in health status. A number of studies have examined the long-term cost consequences of reductions in tobacco use, and all generally find that smoking cessation is cost effective. For example, Warner et al. (2004) found that quitters gain on average 7.1 years of life at a net cost of $3,417 per year of life saved, or $24,261 per quitter.

**Table 1.** Summary of Coverage, Utilization, and Cost Effects of SB 24

| | Before Mandate | After Mandate | Increase/ Decrease | Change After Mandate |
|---|---|---|---|---|
| **Coverage** | | | | |
| Percentage of insured individuals with partial/full coverage for mandated benefit | | | | |
| NRT | 43.1% | 100.0% | 56.9% | 132.0% |
| Counseling | 64.5% | 100.0% | 35.5% | 55.1% |
| Antidepressant | 59.4% | 100.0% | 40.6% | 68.3% |
| | | | | |
| Number of insured individuals in California with coverage for the benefit (a) | | | | |
| NRT | 8,430,000 | 19,557,000 | 11,127,000 | 132.0% |
| Counseling | 12,607,000 | 19,557,000 | 6,950,000 | 55.1% |
| Antidepressant | 11,623,000 | 19,557,000 | 7,934,000 | 68.3% |
| | | | | |
| **Utilization** | | | | |
| Percentage of members 18 yrs and older who smoke *with* partial/full covered benefit and who use: | | | | |
| NRT | 13.2% | 16.5% | 3.3% | 25.0% |
| Counseling | 8.4% | 10.6% | 2.1% | 25.0% |
| Antidepressant | 4.2% | 5.3% | 1.1% | 25.0% |
| Total (one or more services used) (b) | 18.1% | 22.6% | 4.5% | 25.0% |
| | | | | |
| Percentage of members 18 and older who smoke *without* covered benefit and who use: | | | | |
| NRT | 7.4% | 16.5% | 9.1% | 122.2% |
| Counseling | 4.8% | 10.6% | 5.8% | 122.2% |
| Antidepressant | 2.4% | 5.3% | 2.9% | 122.2% |
| Total (one or more services used) (b) | 10.2% | 22.6% | 12.5% | 122.2% |
| | | | | |
| **Average cost** | | | | |
| NRT | $285 | $285 | $0 | 0.0% |
| Counseling | $185 | $185 | $0 | 0.0% |
| Antidepressant | $300 | $300 | $0 | 0.0% |
| | | | | |
| **Expenditures** | | | | |
| Premium expenditures by private employers for group insurance | $43,944,936,000 | $44,018,063,000 | $73,127,000 | 0.17% |
| Premium expenditures for individually purchased insurance | $5,515,939,000 | $5,534,790,000 | $18,851,000 | 0.34% |
| CalPERS employer expenditures | $2,631,085,000 | $2,633,428,000 | $2,343,000 | 0.09% |
| Medi-Cal state expenditures (c) | $4,015,964,000 | $4,015,964,000 | $0 | 0.00% |
| Healthy Families state expenditures | $627,766,000 | $627,824,000 | $58,000 | 0.01% |
| Premium expenditures by employees with group insurance or CalPERS, and by individuals with Healthy Families | $11,515,939,000 | $11,534,912,000 | $18,973,000 | 0.16% |
| Member copayments | $5,261,095,000 | $5,251,275,000 | –$9,820,000 | –0.19% |
| Expenditures for noncovered services | $33,485,000 | $0 | –$33,485,000 | –100.00% |
| **Total annual expenditures** | $73,546,209,000 | $73,616,256,000 | $70,047,000 | 0.10% |

**Table 1 (Continued)**
(a) Of 20,694,000 members in plans subject to mandate, only the 19,557,000 members with prescription drug coverage are directly affected by the mandate.
(b) A member can use more than one of the treatment methods listed above.
(c) Medi-Cal state expenditures for members under 65 years of age include expenditures for Major Risk Medical Insurance Program (MRMIP) and Access for Infants and Mothers (AIM) program.

*Source:* California Health Benefits Review Program, 2007.
*Notes:* The population includes individuals and dependents covered by employer-sponsored insurance (including CalPERS), individually purchased insurance, or public health insurance provided by a health plan subject to the requirements of the Knox-Keene Health Care Service Plan Act of 1975. All population figures include enrollees aged 0–64 years and enrollees 65 years or older covered by employment-sponsored insurance. Member contributions to premiums include employee contributions to employer-sponsored health insurance and member contributions to public health insurance. Expenditures for adults insured through the Managed Risk Medical Insurance Board are included in Medi-Cal premiums.
*Key:* CalPERS = California Public Employees' Retirement System. NRT = nicotine replacement therapy

## Public Health Impacts

SB 24 would likely have a positive impact on public health, based on scientific evidence of the medical effectiveness of tobacco cessation services, the impact of tobacco cessation on both short-term and long-term health outcomes, and the evidence of tobacco cessation cost-effectiveness.

- Approximately 15% of California adults are smokers, which is above the *Healthy People 2010* goal of 12%. Smoking prevalence varies markedly by gender (17.2% men versus 12.1% women), socioeconomic status (increased smoking among low-income groups), and racial and ethnic groups with Native Americans experiencing the highest smoking prevalence (32%), and Latinos/Hispanics experiencing the lowest (13%).

- Tobacco use is the leading cause of preventable death and disease in the California. Latest figures (2001) show that smoking caused 37,324 deaths in California, resulting in a lost-productivity cost of more than $8 billion.

- Tobacco cessation is proven to lower the risk for adverse health outcomes in the short term, (such as low birth-weight deliveries and AMIs and stroke) as well as in the long term for cardiovascular and respiratory diseases and cancer.

- During the first year after implementation, this mandate is estimated to result in 22 fewer cases of AMI or stroke and 35 fewer low birth-weight deliveries each year.

- We estimate that 31,716 smokers will quit, attributable to the mandate each year. Each of these will experience between 7.0 and 12.4 years of life gained due to prevention of premature death from smoking-related illnesses. This adds up to a total of 222,012 to 393,278 years of potential life gained across the state each year.

## INTRODUCTION

Tobacco use in the United States is the leading preventable cause of death. An estimated 438,000 deaths per year are attributable to tobacco use, or one in five deaths annually. Smoking leads to lung cancer, coronary heart disease, chronic lung disease, stroke, and other cancers. Tobacco cessation, that is, quitting completely, is the only safe alternative (CDC, 2007a,b).

Tobacco cessation, however, is a complex process: there are typically multiple quit attempts, degrees of "quitting" (i.e., cutting down consumption), high rates of relapse, and increasing choices of cessation aids (CDHS/TCS 2003). Common forms of tobacco cessation treatment include counseling, nicotine replacement therapy (NRT) such as gum or a patch, and the antidepressant, bupropion (common brand names are Zyban and Wellbutrin).[3] A number of public and private interests have recommended tobacco cessation aids as a cost effective treatment for tobacco related diseases.[4]

### Bill Description

Senate Bill (SB) 24 aims to avoid the health consequences of smoking in California through prevention by expanding coverage for tobacco cessation services.

SB 24 requires health care service plans and health insurance policies[5] that provide outpatient prescription drug benefits to include coverage for the following tobacco cessation services, to be selected by the enrollee and the provider:

- telephone counseling,
- brief cessation intervention by a physician, and
- all prescription and over-the-counter (OTC) medications approved by the Food and Drug Administration (FDA) to help smokers quit (including drugs for NRT and prescription drug therapies in, but not limited to, the form of gum, dermal patch, inhaler, nasal spray and lozenge, and bupropion SR or similar drugs that counter the urge to smoke or the addictive qualities of nicotine).

[3] Bupropion is the only antidepressant that the FDA has approved for tobacco cessation, but physicians may prescribe other antidepressants (e.g., Prozac) off-label.

[4] The Public Health Service's *Treating Tobacco Use and* Dependence (Fiore et al., 2000) states that tobacco dependence treatments are "cost-effective relative to other medical and disease prevention interventions." America's Health Insurance Plans (AHIP) provides an interactive model for estimating return on investment (ROI) at http://www.businesscaseroi.org/roi/default.aspx.

[5] SB 24 would amend Section 1367.27 of the *Health and Safety Code* and Section 10123.175 of the *Insurance Code.* Health care service plans, commonly referred to as health maintenance organizations, are regulated and licensed by the California Department of Managed Health Care (DMHC), as provided in the Knox-Keene Health Care Services Plan Act of 1975. The Knox-Keene Health Care Services Plan Act is codified in the *California Health and Safety Code*. Health insurance policies are regulated by the California Department of Insurance and are subject to the *California Insurance Code.*

Several other conditions are placed on the benefit including:

- telephone counseling and medications may be limited to two courses of treatment per year,
- no copayment or deductible may be applied to the benefit,
- coverage for interventions shall include reimbursement for physician advice, charting, and referral, and
- benefits shall comply with the Public Health Service–sponsored 2000 clinical practice guidelines.

In addition, SB 24 includes medical recordkeeping and policy disclosure requirements, and provisions for contracting with qualified local, state, and national providers. See Appendix A for the full text of the analyzed provisions.[6]

**State Activities**

California Activities

California has taken measures to decrease the number of smokers and prevent an increase in the number of new smokers. 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. In addition, 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 from health programs to debt repayment (California Legislative Analyst's Office, 2002). Since 2003, the state has continued to divert all the revenue toward debt repayment.

The 2005–2006 budget for the California Tobacco Control Program (CTCP) was $80.8 million (CDHS/TCS, 2006a). One recipient of funds is the California Smokers' Helpline, which is a free telephone counseling service created in 1992. It provides counseling in five languages, including English, Spanish, Korean, Vietnamese, and Chinese (Mandarin and Cantonese), and specialized services for teens, pregnant women, and tobacco chewers.

Other State Activities

As of October 2005, Maryland has a mandated health benefit for smoking cessation that covers FDA-approved prescription drugs and two 90-day courses of NRT in a policy year, with copayment and deductible amounts to be the same as comparable prescriptions. Many legislatures have considered such legislation, including New York,[7] Wisconsin, Oklahoma, and New Jersey.

[6] SB 24 contains modifications of the language in SB 576, which was analyzed by CHBRP in 2005 and can be found at http://www.chbrp.org/completed_analyses/index.php.
[7] The New York State Department of Health (2006) has published a recent report on its smoking cessation efforts.

Tobacco dependence treatment programs are partially covered by Medicaid programs in 37 states, and comprehensively covered[8] in 13 states, including California (Halpin, Bellows, et al., 2006).

## Overview of Analytic Approach

The use of tobacco cessation services is affected by two factors considered by CHBRP for this analysis: benefit coverage and phase of tobacco use. A beneficiary can have varying degrees of coverage ranging from no coverage to full coverage, which is defined in this report as coverage of 100% of costs associated with tobacco cessation medications and counseling without a deductible, copayment, or coinsurance. Furthermore, quitting tobacco usage is a dynamic process, involving varying degrees of assistance (Figure 1).

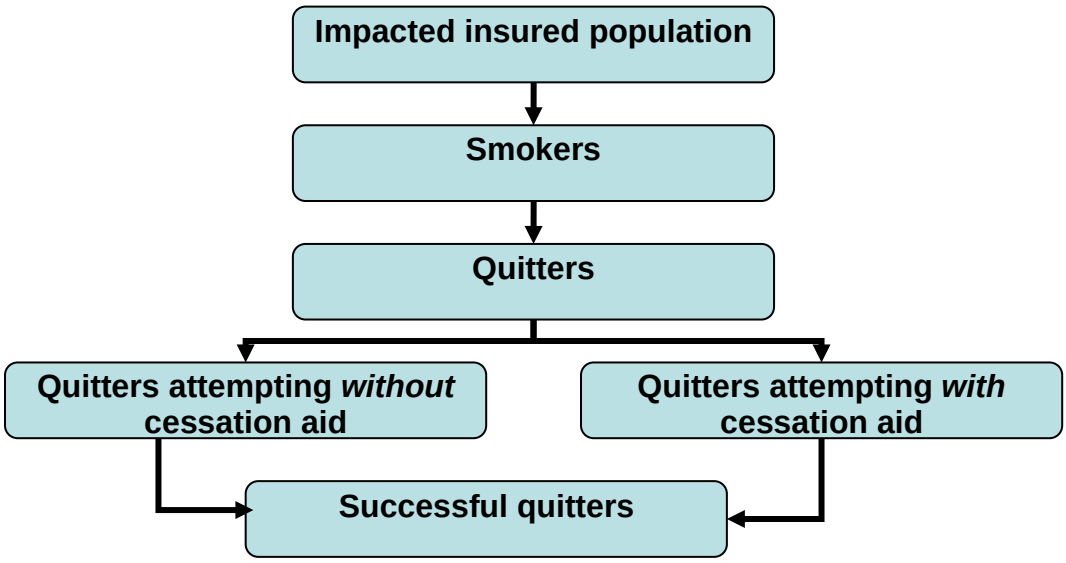
Other factors affecting tobacco cessation are handled with certain simplifying assumptions. Although the bill applies to all covered lives[9], CHBRP makes the simplifying assumption to exclude adolescents aged 12–17 years from the analysis. This age group is typically in the initiation phase, rather than quitting and cessation phase. Moreover, public health campaigns that target youth predominantly focus on smoking prevention. Individual consumption of tobacco is one other factor in cessation (e.g., light, moderate, and heavy smokers); however, because of lack of overall data, CHBRP does not attempt to disaggregate the available data by consumption.

Other factors that affect smoking cessation, such as media campaigns, tobacco taxes, and smoking bans, are not considered here because this analysis considers the impact of only the proposed health benefit mandate.

The medical effectiveness review examines two topics: the effects of specific kinds of tobacco cessation services and the effects of health insurance coverage for tobacco cessation services. The standard CHBRP cost model is applied to the mandate to analyze its 1-year impact. In addition, two health outcomes (low birth-weight babies, and acute myocardial infarction (AMI) and stroke) were used to analyze the short-term impacts. As a preventive service, tobacco cessation would be expected to have long-term impacts, and the available literature is reviewed and summarized by CHBRP.

[8] Defined in this survey to mean coverage for NRT, Zyban (bupropion), and individual or group counseling.
[9] CHBRP examines the impacts of SB 24 on those plans and policies that are subject to the benefit mandates. This excludes populations enrolled in self-insured plans and those with Medicare as a primary payer. See http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php for more information regarding the population typically subject to benefit mandates.

**Figure 1**. Subpopulations Affected by Tobacco Cessation Services Benefit



## MEDICAL EFFECTIVENESS

### Effects of Specific Types of Tobacco Cessation Services

Tobacco cessation services include pharmacotherapy and behavioral interventions, such as counseling and brief advice. Counseling may occur in person or via telephone, and may be provided either in individual or group sessions. Counseling may be provided by physicians, nurses, peer counselors, social workers, psychologists, or psychiatrists.

Pharmacological agents for smoking cessation are commonly divided into those most frequently used in initial attempts to quit smoking ("first-line agents") and those most frequently used when initial attempts to quit smoking have not been successful ("second-line agents"). First-line agents for smoking cessation include nicotine replacement therapies (NRT), administered by gum, patch, nasal sprays, inhalers, and lozenges, and the non-nicotine agent, bupropion, an antidepressant medication used in smoking cessation. The FDA has approved the use of bupropion for smoking cessation among people who smoke 10 or more cigarettes daily and are at least 18 years of age. Second-line agents approved by the FDA include clonidine, nortriptyline, and a newly approved drug, varenicline (a form of cytisine).[10]

The literature on behavioral and pharmacological interventions to improve smoking cessation rates and continued abstinence is extensive, including numerous meta-analyses of randomized controlled trials (RCTs), the strongest form of evidence for CHBRP analyses. Accordingly, we rely to the extent feasible on these meta-analyses, supplemented by individual RCTs published since the literature reviews for the meta-analyses were conducted. Findings from the meta-analyses are summarized in Tables 2 and 3, which appear at the end of the Medical Effectiveness section. Descriptive information about the meta-analyses is presented in Appendix C

In most studies reviewed, abstinence from smoking is the primary outcome measured to evaluate the efficacy of tobacco cessation interventions. Although continuous abstinence is desirable, studies have used varying definitions of relapse, which creates difficulty in evaluating prolonged abstinence rates in patients. However, because most relapses occur within the first 3 months after tobacco cessation, many meta-analyses and systematic reviews of the literature only include those studies with follow-up of at least 5 months (Fiore, 2000). Thus, in evaluating the effectiveness of specific behavioral and pharmacological interventions, the medical effectiveness analysis includes only studies that assessed abstinence from smoking for at least 5 months.

CHBRP considers it highly unlikely that the conclusions this report draws about the efficacy of smoking cessation therapies will be diminished or altered with the publication of new individual studies, because of the magnitude of the literature, the consistently positive results with respect to specific therapies, and the quality of the research designs. (CHBRP published an analysis of smoking cessation services for SB 576 in 2005 that reached much the same conclusion as the present analysis).

[10] A press release announcing the drug's approval can be found at www.fda.gov/bbs/topics/NEWS/2006/NEW01370.html.

The rates of abstinence from smoking reported by the meta-analyses, systematic reviews, and RCTs summarized in this report may be greater than those that would be achieved if SB 24 were enacted. Most of the meta-analyses and systematic reviews synthesized findings from RCTs. Most of these RCTs used strict inclusion/exclusion criteria to maximize their ability to determine whether counseling or pharmacotherapy increases smoking cessation. They may exclude some smokers who would have coverage for these services under SB 24. In addition, smokers who take the initiative to enroll in RCTs are probably more highly motivated to quit than the average smoker. Their motivation may enhance their success in abstaining from smoking. Clinician researchers may also work harder than other clinicians to ensure that smokers use recommended amounts of counseling and/or pharmacotherapy. As discussed below, nonrandomized studies conducted in California found that NRT is less effective than the findings that RCTs suggest, especially for light smokers (Pierce and Gilpin, 2002).

## Effects of Counseling and Brief Advice

The principal behavioral interventions for smoking cessation are professional and peer counseling, either extensive or brief. The evidence summarized in several meta-analyses of both forms of counseling, indicates that counseling increases smoking cessation.

### *Counseling*

Fiore et al. (2000) reviewed the effect of individual counseling versus no intervention on smoking cessation rates at 5 months. Of note, of the 58 studies incorporated into the meta-analyses, all provided evidence at Level I (well-implemented RCTs or cluster randomized trials) or II (randomized trials or cluster randomized trials with major weaknesses in design). Fiore et al. concluded that individual counseling was associated with a statistically significant effect on smoking cessation of at least 5 months' duration (odds ratio = 1.7) when compared to no intervention.

Stead et al. (2006) reviewed the results of eight randomized and quasi-randomized trials of proactive telephone support versus minimal intervention, reporting that telephone support was associated with a favorable effect on smoking cessation at 6 months (odds ratio = 1.4).

Stead and Lancaster (2005) summarized the information in seven randomized trials comparing group tobacco cessation programs to self-help materials or no intervention, finding that group programs have a favorable effect on smoking cessation at 6 months (odds ratio = 2.2).

Lancaster and Stead (2005) evaluated the evidence from 17 trials of face-to-face individual counseling from a health care worker not involved in routine clinical care versus a minimal intervention. They reported that such counseling was associated with a favorable impact on smoking cessation at 6 months (odds ratio = 1.56). Three studies that compared intensive to brief forms of counseling reported no difference between the forms.

Rigotti et al. (2002) analyzed the results of six randomized and quasi-randomized trials to evaluate the impact of inpatient contact plus follow-up post-hospitalization of at least 1 month versus usual care, reporting that the inpatient contact plus follow-up had a favorable effect on smoking cessation rates (odds ratio = 1.8).

Sussman et al. (2006) analyzed data from 48 controlled trials of cessation programs aimed at teens versus usual care for this age group. Such programs were associated with a favorable impact on smoking cessation rates, with a 46% increase in the likelihood of quitting.

Finally, Grimshaw and Stanton (2006) analyzed studies using a transtheoretical model of change in adolescent behavior versus standard care or dietary advice among persons 20 years of age or younger. They report a favorable effect on smoking cessation at 12 months in studies using this model of change (odds ratio = 1.7). In contrast, when the authors' evaluated studies that used the "Not on Tobacco" program, which is based on social cognitive theory, versus brief interventions, they found a marginally significant effect on smoking cessation from the pooled results, but not from the individual studies.

Overall, the evidence from the meta-analyses of counseling interventions indicates that counseling increases rates of smoking cessation.

*Brief advice*

Three meta-analyses and a systematic review analyze the effect of brief advice to quit smoking. In the first of the meta-analyses, Fiore et al. (2000) reviewed seven studies with Level I or II evidence that assessed the effect of 5 minutes or less of physician advice to quit smoking versus no advice. The authors reported a favorable effect of such a brief intervention on rates of cessation at 5 months (odds ratio = 1.3).

Similarly, Lancaster and Stead (2004) summarized 17 trials, presenting two kinds of evidence. In the first, they evaluated the effect of brief advice versus none, and observed that brief advice was associated with a favorable effect on cessation either at 6 or 12 months (odds ratio = 1.7). In the second, they evaluated the impact of intensive versus minimal advice, reporting a "small advantage for intensive advice" (odds ratio = 1.4).

The meta-analysis of Rice and Stead (2004) evaluated the evidence from 20 trials comparing advice by a nursing professional to no intervention. Advice from a nursing professional was found to have a favorable effect on smoking cessation at 6 or 12 months (odds ratio = 1.5).

Bernstein and Becker (2002) undertook a systematic review of the evidence of the effect of brief inventions (some as brief as 3 minutes) in emergency departments on smoking cessation rates when compared to usual care. The authors found that a brief intervention in an emergency department is associated with an increase in cessation rates at 6 to 12 months from 3% to between 8% and 11%.

Overall, the evidence indicates that brief counseling interventions increase smoking cessation rates.

*Relative effectiveness of different types of health professionals in providing counseling*

Two meta-analyses have examined whether different types of health professionals are more or less effective in providing tobacco cessation counseling (Fiore et al., 2000; Mojica et al., 2004). The more recent of the two meta-analyses synthesized a larger number of studies, including

those included in the previous meta-analysis. The authors of the former meta-analysis concluded that psychologists, physicians, and nurses are all effective in delivering tobacco cessation counseling and that none of the three types of health professionals was substantially more effective than the others (Mojica et al, 2004).

Effects of Pharmacotherapy

*First-line therapy*

**NRT:**

**Nicotine gum**. Two meta-analyses have synthesized the literature on the effect of nicotine gum on smoking cessation rates. Fiore et al. (2000) pooled 13 randomized trials, and reported that nicotine gum, compared to either placebo or no treatment, was associated with a favorable effect on smoking cessation rates at the end of 5 months (odds ratio = 1.5). Silagy et al. (2004) integrated results from 52 trials, again showing that using nicotine gum increases the likelihood a person will abstain from smoking (odds ratio = 1.7).

Overall, nicotine gum has a favorable effect on smoking cessation rates.

**Nicotine patch**. Fiore et al. (2000) and Silagy et al. (2004) also analyzed the substantial literature on nicotine patches. Fiore et al. (2000) found 27 randomized trials meeting their study criteria. These investigators found that nicotine patches were associated with a higher rate of smoking cessation 5 months after treatment (odds ratio = 1.9). Similarly, Silagy et al. (2004) summarized the results from 37 randomized trials of the effect of the nicotine patch on smoking cessation after 6 months, reporting that the patch was associated with a favorable outcome (odds ratio = 1.8).

Overall, on the basis of a large literature, the nicotine patch has been found to have a favorable effect on smoking cessation rates.

**Nicotine lozenge.** Silagy et al. (2004) found four randomized trials to summarize on the effect of nicotine lozenges on cessation in comparison to placebo or no treatment. This mode of administration of NRT was associated with a favorable outcome over 6 months in terms of smoking cessation rates (odds ratio = 2.0).

**Nicotine inhaler.** Again, Fiore et al. (2000) and Silagy et al. (2004) pooled the literature on the effect of nicotine inhalers on smoking cessation rates. The authors of the former meta-analysis found four studies meeting their study criteria, and observed that nicotine inhalers were associated a higher rate of smoking cessation at the end of 5 months when compared either to placebo or no treatment (odds ratio = 2.5). The authors of the latter meta-analysis also found four studies meeting their study criteria. They observed a favorable outcome in smoking cessation at 6 months when compared to either placebo or no treatment (odds ratio = 2.1).

The small number of studies of nicotine inhalers suggest that they have a favorable effect on smoking cessation rates.

**Nicotine nasal spray**. Fiore et al. (2000) and Silagy et al. (2004) also synthesized the literature on the effectiveness of nicotine nasal spray. Although there are fewer studies on nicotine nasal spray than on nicotine gum, the results are similar. Specifically, Fiore et al. (2000) pooled three studies comparing nicotine nasal spray to placebo or no treatment, and indicated that this mode of administration of NRT is associated with a favorable outcome with respect to smoking cessation at the end of 5 months (odds ratio = 2.7). Silagy et al. (2004) pooled four studies, reporting a favorable outcome at the end of 6 months (odds ratio = 2.4).

Thus, although the literature is not that voluminous, it appears that nicotine nasal spray has a favorable effect on smoking cessation rates.

**Summary of effects of nicotine replacement therapy.** All forms of nicotine replacement therapy increase smoking cessation when compared to placebo or no treatment.

**Bupropion.** Fiore et al. (2000), Hughes et al. (2007), and Wu et al. (2006) evaluated the evidence on the effect of bupropion, an antidepressant agent approved for use in smoking cessation efforts. When Fiore et al. searched the literature, they found two studies meeting their inclusion criteria; they reported that bupropion had a favorable effect on smoking cessation rates when compared to placebo or no treatment at the end of 5 months (odds ratio = 2.1). Hughes et al. (2007) found 31 randomized trials comparing bupropion to either placebo or no treatment, and reported a favorable effect in smoking cessation rates at the end of 6 months when compared to placebo or no treatment (odds ratio = 1.9). The latter set of authors also found three studies comparing bupropion to the nicotine patch, but they observed no difference in smoking cessation rates over the 6-month period between persons who used bupropion and those who used the nicotine patch. Wu et al. (2006) reached similar conclusions.

Overall, bupropion was found to have a favorable effect on smoking cessation rates.

Two nonrandomized population studies have assessed the effectiveness of pharmacotherapy for tobacco cessation in California (Gilpin et al., 2006; Pierce and Gilpin, 2002). Although population studies do not provide as strong evidence of the efficacy of pharmacotherapy as do RCTs, they do provide important insights into its effectiveness when administered outside of clinical trials, which typically enroll motivated, compliant participants. These two studies are of particular interest to CHBRP because they analyzed data from the California Tobacco Survey (CTS), a survey of a large, representative sample of Californians. The first study found that after NRT became an over-the-counter (OTC) drug, it continued to improve short-term rates of abstinence from smoking among moderate-to-heavy smokers (≥15 cigarettes/day) relative to no use of pharmacotherapy, but no longer produced the long-term gains that had been observed when NRT was only available by prescription. The long-term gains may have disappeared because many smokers used NRT for a shorter period of time than recommended (Pierce and Gilpin, 2002). The authors also found that OTC NRT was not effective for light smokers (<15 cigarettes/day).

The second study reported that moderate-to-heavy smokers who used bupropion (with or without NRT) were more likely to abstain from smoking than were smokers who did not use this drug. This study also found that bupropion and NRT were especially effective when used by smokers

who had smoke-free homes and had no other smokers in their households (Gilpin et al., 2006). The findings from these two studies suggest that NRT may be less effective when used OTC outside of a clinical trial and that both NRT and bupropion are more likely to be effective for smokers who have smoke-free homes.

**Summary of effects of first-line therapies.** All forms of first-line therapy, including the multiple modes of administration of NRT and bupropion, increase smoking cessation rates. Results of clinical trials suggest that these two forms of pharmacotherapy are equally efficacious. However, population surveys undertaken in California have found that NRT is less effective in facilitating long-term abstinence outside clinical trials and that having a smoke-free home improves effectiveness of both NRT and bupropion.

*Second-line therapy*

CHBRP reviewed the effect of extant second-line therapies, including clonidine and nortriptyline, on smoking cessation as part of the analysis of SB 576 (CHBRP, 2005), concluding that both are effective. In this section, the focus of attention is on second-line therapies on which meta-analyses have only recently been published in English language journals, specifically cytisine and varenicline (a subcategory of the cytisine class of agents approved by the FDA in 2006 for use as a tobacco cessation aid).

**Cytisine.** Cahill et al. (2007) and Etter (2006) reviewed the effect of cytisine on smoking cessation rates. The study by Cahill and colleagues compared cytisine to placebo in terms of smoking cessation rates at 24 months, finding that cytisine has a favorable effect (odds ratio = 1.8). Etter (2006) summarized two studies evaluating the effect of cytisine compared to placebo on smoking cessation at 3 to 6 months. Cytisine had a favorable effect (odds ratio = 1.8).

Overall, cytisine has a favorable effect on smoking cessation rates.

**Varenicline.** Cahill et al. (2007) reviewed four randomized trials comparing varenicline to placebo for smoking cessation at 12 months; varenicline was found to have a favorable effect (odds ratio = 3.2). These authors also reviewed three randomized trials comparing the effect of varenicline to bupropion on smoking cessation rates at the same point, reporting that varenicline has a favorable effect relative to bupropion (odds ratio = 1.7). Wu et al. (2006) reviewed the same studies and reached the same conclusions.

Overall, it would be appear that varenicline has a favorable impact on smoking cessation rates, although the literature on this relatively new agent is still sparse.

**Summary of effect of second-line therapies.** On the basis of the review in the prior CHBRP analysis of clonidine and nortriptyline (CHBRP, 2005) and the review of cytisine agents, including varenicline presented above, several second-line therapies would appear to be efficacious in improving cessation rates.

Effects of Tobacco Cessation Services on Major Subpopulations

CHBRP evaluated the effect of various smoking cessation modalities on smoking cessation rates among subgroups of smokers, including women versus men; racial and ethnic minorities;

younger versus older smokers; pregnant women; persons with various medical conditions, including cardiovascular disease and chronic obstructive pulmonary disease (COPD); and, in terms of smoking status, light versus heavy smokers. The preponderance of evidence indicates that effectiveness does not vary among the subgroups assessed (Dorenelas et al., 2006; Evans et al., 2006; Fiore et al., 2000; Froelicher et al., 2004; Rigotti et al., 2006; Scharf,and Shiffman, 2004; Shiffman, 2005; Singleton et al., 2005; Tonnesen et al., 2006). One exception is that among pregnant smokers, smoking cessation modalities would appear to be more effective in light than heavy smokers (Rigotti et al., 2006).

Nicotine gum and nicotine inhalers are not recommended for persons with cardiac conditions, because of their rapid delivery and high concentrations of nicotine. However, they can safely use nicotine patches, which deliver nicotine more slowly, Similarly, the 2000 U.S. Public Health Service (PHS) guidelines recommend that clinicians and pregnant smokers consider both the risks of pharmacotherapy and the benefits of quitting smoking when deciding whether a pregnant smoker should use pharmacotherapy as well as behavioral interventions (Fiore et al., 2000).

**Summary of effects on subpopulations.** The preponderance of evidence indicates that efficacy of behavioral interventions and pharmacotherapy for tobacco cessation does not vary among the subgroups that have been assessed.

### Effects of Health Insurance Coverage for Tobacco Cessation Services

CHBRP reviewed evidence of the medical effectiveness of coverage for tobacco cessation services on two outcomes:

- use of tobacco cessation services, including NRT, bupropion, and counseling, and
- abstinence from smoking.

Ten studies of the impact of health insurance coverage for tobacco cessation services were reviewed. These studies included a meta-analysis, RCTs, and nonrandomized studies that had comparison groups. Studies of the provision of free counseling and medications by state telephone counseling programs were excluded because these programs are available to all persons in states that operate them regardless of whether they have health insurance (Bauer et al., 2006, Swartz et al., 2005).

An additional three studies were excluded from the review because they did not have comparison groups and did not present information about use of tobacco cessation services by the study population prior to coverage (Burns et al., 2005, 2007; Ringen et al., 2002). It is not possible to determine whether the rates of use of tobacco cessation services reported in such studies are different from rates of use in the study population prior to coverage or from rates observed among persons who do not have coverage.

One RCT (Twardella and Brenner, 2007) was excluded from the review because persons enrolled in the two arms of the trial in which participants received coverage for tobacco cessation medications were treated by physicians who had been trained in the provision of tobacco

cessation services. In this study, the effects of coverage for tobacco cessation medications cannot be separated from the effects of physician education. This study is not useful for the analysis of SB 24, because this bill only addresses coverage for tobacco cessation services; it would not mandate physician education in tobacco cessation treatment.

Use of Tobacco Cessation Services

One meta-analysis was found that assessed the impact of coverage for tobacco cessation services on use of these services (Kaper, Wagena, Severens, et al., 2005). This meta-analysis synthesized the results of six studies. Five of these studies had been published in peer review journals (Boyle et al., 2002; Curry et al., 1998; Dey et al., 1999; Hughes et al., 1991; Schauffler et al., 2001), and one was a conference paper that was subsequently published (Kaper, Wagena, Willemsen, et al., 2005). The authors reported separate estimates for counseling, NRT, and bupropion. They compared the effects of full coverage[11] to no coverage, and full coverage to partial coverage.

**Counseling.** The meta-analysis pooled the results of two RCTs that assessed the effect of full coverage for tobacco cessation services versus no coverage on receipt of counseling. In the pooled analysis, the authors found no statistically significant difference in the percentage of persons obtaining counseling (Kaper, Wagena, Severens, et al., 2005). One of the studies included in the meta-analysis reported that full coverage was associated with a statistically significant increase in use of counseling (Kaper, Wagena, Willemsen, et al., 2005), and the other study found no difference (Schauffler et al., 2001). In both studies, few persons with full coverage obtained counseling. One study reported that 5% of persons with full coverage received counseling, and the other reported that 1% used it.

The lack of consistent findings across the two studies suggests that the evidence of the impact of full coverage for tobacco cessation counseling relative to no coverage is ambiguous.

One nonrandomized study included in the meta-analysis compared the effects of full and partial coverage for tobacco cessation counseling on receipt of counseling (Curry et al., 1998). The authors found that persons who had coverage for 100% of the costs of counseling were more likely to obtain it than were persons who had coverage for only 50% of the costs. An RCT published after the meta-analysis reported that persons with coverage for counseling were more likely to receive it if coverage for tobacco cessation medications was contingent on participation in counseling (Halpin, McMenamin, et al., 2006).

**NRT.** The meta-analysis included five studies of the effects of full coverage versus no coverage on use of NRT (Kaper, Wagena, Severens, et al., 2005). The authors found that full coverage was associated with a statistically significant increase in use of NRT. Three RCTs included in the meta-analysis also reported statistically significant increases in use of NRT (Hughes et al., 1991; Kaper, Wagena, Willemsen, et al., 2005; Schauffler et al., 2001). One study that did not report results of tests of statistical significance nevertheless reported a large increase in use (Dey et al., 1999). One nonrandomized study reported no statistically significant difference (Boyle et al.,

[11] For purposes of this report, full coverage for tobacco cessation services is defined as coverage of 100% of costs associated with tobacco cessation medications and/or counseling without a deductible, copayment, or coinsurance.

2002). The authors of the meta-analysis estimated that 18% of persons who had full coverage for NRT used it versus 13% of persons who did not have coverage (Kaper, Wagena, Willemsen, et al., 2005). Estimates of use from the five studies included in the meta-analysis ranged from 4% (Kaper, Wagena, Willemsen, et al., 2005) to 97% (Dey et al., 1999). One study examined persons enrolled in two California health maintenance organizations (HMOs) and reported that 25% of persons in the full-coverage group used NRT versus 14% of persons in the no-coverage group (Schauffler et al., 2001).

Overall, the preponderance of the evidence suggests that persons who have full coverage for NRT are more likely to use it than are persons who do not have coverage.

Two studies included in the meta-analysis compared full and partial coverage for NRT. One study found that persons who had coverage for 100% of the costs of NRT were over three times as likely to obtain it as persons who had coverage for only 50% of the costs (7% vs. 2%) (Curry et al., 1998). Another study found that 75% of persons who had full coverage for nicotine gum obtained at least one box of gum versus 58% of persons who had only partial coverage (Hughes et al., 1991). Thus, there is consistent evidence that persons with full coverage for nicotine gum are more likely to use it than are persons with partial coverage. The latter study, may have found that a much higher percentage of persons used NRT because it was an RCT, whereas the former study was an observational study. Smokers who enroll in RCTs may be more highly motivated to use NRT and other smoking cessation services than the average smoker regardless of their level of coverage for NRT.

One study compared partial coverage for nicotine gum to no coverage (Hughes et al., 1991). The authors found that persons who had partial coverage were more likely to use the gum than were persons who did not have coverage (58% vs. 47%).

**Bupropion.** The meta-analysis synthesized the results of two studies that investigated the impact of full versus no coverage for tobacco cessation services on use of bupropion. The authors concluded that persons with full coverage for bupropion were more likely to use the drug than were persons with no coverage, but that the difference was not statistically significant (Kaper, Wagena, Severens, et al., 2005). One of the studies included in the meta-analysis reported a statistically significant difference in use of bupropion that favored full coverage (Kaper, Wagena, Willemsen, et al., 2005). The other study also found an increase in the use of bupropion, but the increase was not statistically significant (Boyle et al., 2002). The rates of use among persons with full coverage ranged from 4% (Kaper, Wagena, Willemsen, et al., 2005) to 24% (Boyle et al., 2002). No studies compared the effects of full versus partial coverage for bupropion or the effects of partial versus no coverage.

In summary, the preponderance of evidence suggests that persons who have full coverage for bupropion are more likely to use this drug than persons who do not have coverage.

**Varenicline.** No studies examined the impact of coverage for varenicline, a medication sold under the brand name Chantix, which the FDA approved in May 2006. The lack of studies probably reflects the short length of time that this drug has been on the market.

**Summary of Effects of Coverage on Use of Tobacco Cessation Services.** The preponderance of evidence suggests that persons who have coverage for NRT or bupropion are more likely to use these forms of pharmacotherapy for tobacco cessation than persons who do not have coverage. There is also evidence that persons who have partial coverage for NRT are more likely to use it than persons who have no coverage. Findings regarding the effect of coverage on use of tobacco cessation counseling are ambiguous. No studies assess the impact of coverage on use of varenicline.

Abstinence from Smoking

Seven studies have examined the effects of full coverage of tobacco cessation services versus no coverage on abstinence from smoking. The results of five of these studies were synthesized in the meta-analysis (Kaper, Wagena, Severens, et al., 2005), including four studies published in peer review journals (Boyle et al., 2002; Dey et al., 1999; Hughes et al., 1991; Schauffler et al., 2001) and one conference paper that was subsequently published (Kaper, Wagena, Willemsen, et al., 2005). Two studies were published after the meta-analysis was completed (Kaper et al., 2006;[12] Petersen et al., 2006).

The authors of the meta-analysis concluded that persons who had full coverage for tobacco cessations services were more likely to have quit smoking at 6 months post-treatment than were persons who had no coverage and that the difference was statistically significant (Kaper, Wagena, Severens, et al., 2005). They estimated that 5% of persons who had full coverage had quit smoking versus 4% of persons with no coverage. Two RCTs included in the meta-analysis reported that that full coverage was associated with a statistically significant increase in the percentages of persons who had abstained from smoking (Kaper, Wagena, Willemsen, et al., 2005; Schauffler et al., 2001). Three studies, two RCTs (Dey et al., 1999; Hughes et al., 1991) and one nonrandomized study (Boyle et al., 2002) found no statistically significant difference in abstinence from smoking. In one of these studies, persons with full coverage were more likely to abstain from smoking, but the small sample size limited the authors' ability to detect statistically significant differences (Hughes et al., 1991).

Two studies published after the meta-analysis found that full coverage for tobacco cessation services was associated with statistically significant increases in abstinence from smoking relative to no coverage. One study found that persons who had full coverage were more likely to abstain from smoking for 2 years after the tobacco cessation intervention was completed than were those without full coverage (Kaper et al., 2006). The other study reported that women enrolled in Medicaid were more likely to abstain from smoking during and after pregnancy if they resided in states in which Medicaid covered both tobacco cessation counseling and medication than if they lived in states in which Medicaid did not cover either of these services (Petersen et al., 2006).

[12] Kaper et al., 2006, reports findings from the same study as Kaper, Wagena, Willemsen, et al., 2005. The difference between the two studies is that Kaper, Wagena, Willemsen, et al., 2005, presents findings for use of tobacco cessation services and abstinence from smoking at 6 months after intervention, whereas Kaper et al., 2006, presents additional findings regarding abstinence from smoking at 2 years after intervention.

Among studies of full versus no coverage that enrolled men and women with a wide range of ages and incomes, rates of abstinence from smoking ranged from 4% (Boyle et al., 2002) to 44% (Hughes et al., 1991). One study examined persons enrolled in two California HMOs and reported that 18% of persons in the full-coverage group abstained from smoking versus 13% of persons in the no-coverage group (Schauffler et al., 2001). The study of women enrolled in Medicaid found that 51% of those who resided in states in which Medicaid covered tobacco cessation counseling and medications quit smoking during pregnancy and that 48% of these women (24% of all women in the study) abstained from smoking 4 months after delivery.

Overall, the preponderance of evidence suggests that full coverage for tobacco cessation services increases abstinence from smoking relative to no coverage.

Three studies examined the effects of full versus partial coverage for tobacco cessation services. One study found that persons with full coverage for NRT were three times more likely to abstain from smoking than persons with partial coverage, but the difference was not statistically significant (Hughes et al., 1991). Another study found no difference in rates of abstinence from smoking between persons who had 100% coverage for NRT and counseling, and persons who had 50% coverage (Curry et al., 1998). Hughes et al. (1991) may have found that a higher rate of abstinence from smoking than Curry et al. (1998) because it was an RCT. Smokers who enroll in RCTs may be more highly motivated to quit smoking than many smokers included in observational studies. For example, the second study above examined data on all smokers who had the two types of coverage regardless of their interest in quitting and their motivation to quit.

A third study reported the results of an RCT in which the subjects were enrolled in individual preferred provider organization (PPO) plans in California (Halpin, McMenamin et al., 2006). The RCT had three arms: (1) coverage for only NRT and bupropion (no coverage for counseling), (2) coverage for pharmacotherapy and counseling, and (3) coverage for pharmacotherapy if persons also obtained counseling. The authors found no statistically significant differences in rates of abstinence from smoking across the three groups. The rates of abstinence were 19% for coverage of pharmacotherapy only, 13% coverage of pharmacotherapy drugs and counseling, and 18% for coverage of pharmacotherapy if counseling was used.

The lack of consistent findings across these three studies suggests that evidence of the impact of full versus partial coverage on abstinence from smoking is ambiguous.

Two studies compared persons with partial coverage for tobacco cessation services with persons who had no coverage. One study of men and women of various ages with various levels of income reported that persons with partial coverage for NRT were no more likely to abstain from smoking than persons with no coverage (Hughes et al., 1991). The study of women enrolled in Medicaid found that women who lived in states in which Medicaid provided partial coverage for tobacco cessation services (pharmacotherapy or counseling) were more likely to quit smoking during pregnancy than women in states in which Medicaid did not cover either of these services, but found no difference in the likelihood of abstaining from smoking after delivery.

Thus, the evidence of the effects of partial versus no coverage on abstinence from smoking is ambiguous.

**Summary of Effects of Coverage on Abstinence from Smoking.** The preponderance of evidence suggests that full coverage for tobacco cessation services increases abstinence from smoking relative to no coverage. The evidence of the effects of full versus partial coverage on abstinence from smoking is ambiguous, as is the evidence of the effects of partial versus no coverage.

**Table 2.** Summary of Findings from Studies of the Effectiveness of Tobacco Cessation Services

**Counseling vs. Brief Advice or No Treatment**

| Outcome | Research Design[13] | Statistical Significance | Direction of Effect | Size of Effect | Generalizability | Conclusion |
|---|---|---|---|---|---|---|
| Smoking cessation rate at 5 months or more (7 meta-analyses) | 7 meta-analyses | • Statistically significant: 7 of 7 meta-analyses | • Better: 7 of 7 meta-analyses | • Pooled odds ratios ranged from 1.4 to 2.2 | • Somewhat generalizable: 7 of 7 meta-analyses | • Clear and convincing evidence that counseling increases the odds of abstinence from smoking relative to no treatment |

**Counseling vs. Brief Advice**

| Outcome | Research Design[13] | Statistical Significance | Direction of Effect | Size of Effect | Generalizability | Conclusion |
|---|---|---|---|---|---|---|
| Smoking cessation rate at 5 months or more (2 meta-analyses) | 2 meta-analyses | • Statistically significant: 1 of 2 meta-analyses<br>• Not statistically significant: 1 of 2 meta-analyses | • Better: 1 of 2 meta-analyses<br>• No difference: 1 of 2 meta-analyses | • For the meta-analysis with favorable findings, the pooled odds ratio was 1.9<br>• No effect: 1 of 2 meta-analyses | • Somewhat generalizable: 2 of 2 meta-analyses | • The evidence of the effect of counseling relative to brief advice on odds of abstinence from smoking is ambiguous |

[13] Level I = Well-implemented RCTs and cluster RCTs; Level II = RCTs and cluster RCTs with major weaknesses; Level III = Nonrandomized studies that include an intervention group and one or more comparison groups and time series analyses; Level IV = Case series and case reports; and Level V = Clinical/practice guidelines based on consensus or opinion.

**Brief Advice vs. No Treatment**

| Outcome | Research Design[13] | Statistical Significance | Direction of Effect | Size of Effect | Generalizability | Conclusion |
|---|---|---|---|---|---|---|
| Smoking cessation rate at 5 months or more (4 meta-analyses) | 3 meta-analyses and 1 systematic review | • Statistically significant: 4 of 4 meta-analyses and systematic reviews | • Better: 4 of 4 meta-analyses and systematic reviews | • Pooled odds ratios ranged from 1.3 to 1.7 | • Somewhat generalizable: 4 of 4 meta-analyses and systematic reviews | • Clear and convincing evidence that brief advice increases the odds of abstinence from smoking relative to no treatment |

**Nicotine Gum vs. Placebo or No Treatment**

| Outcome | Research Design[13] | Statistical Significance | Direction of Effect | Size of Effect | Generalizability | Conclusion |
|---|---|---|---|---|---|---|
| Smoking cessation rate at 5 months or more (3 meta-analyses and systematic reviews) | 2 meta-analyses and 1 systematic review | • Statistically significant: 3 of 3 meta-analyses and systematic reviews | • Better: 3 of 3 meta-analyses and systematic reviews | • Pooled odds ratios from meta-analyses were 1.5 and 1.7 | • Somewhat generalizable: 3 of 3 meta-analyses and systematic reviews | • Clear and convincing evidence that nicotine gum increases the odds of abstinence from smoking relative to placebo or no treatment |

**Nicotine Patch vs. Placebo or No Treatment**

| Outcome | Research Design[13] | Statistical Significance | Direction of Effect | Size of Effect | Generalizability | Conclusion |
|---|---|---|---|---|---|---|
| Smoking cessation rate at 5 months or more (2 meta-analyses and systematic reviews) | 2 meta-analyses and 1 systematic review | • Statistically significant: 3 of 3 meta-analyses and systematic reviews | • Better: 3 of 3 meta-analyses and systematic reviews | • Pooled odds ratios from meta-analyses were 1.8 and 1.9 | • Somewhat generalizable: 3 of 3 meta-analyses and systematic reviews | • Clear and convincing evidence that nicotine patch increases the odds of abstinence from smoking relative to placebo or no treatment |

**Nicotine Lozenge vs. Placebo or No Treatment**

| Outcome | Research Design[13] | Statistical Significance | Direction of Effect | Size of Effect | Generalizability | Conclusion |
|---|---|---|---|---|---|---|
| Smoking cessation rate at 5 months or more (1 meta-analysis) | 1 meta-analysis | • Statistically significant: 1 of 1 meta-analysis | • Better: 1 of 1 meta-analysis | • Pooled odds ratio = 2.0 | • Somewhat generalizable: 1 of 1 meta-analysis | • Clear and convincing evidence that nicotine lozenge increases the odds of abstinence from smoking relative to placebo or no treatment |

**Nicotine Inhaler vs. Placebo or No Treatment**

| Outcome | Research Design[13] | Statistical Significance | Direction of Effect | Size of Effect | Generalizability | Conclusion |
|---|---|---|---|---|---|---|
| Smoking cessation rate at 5 months or more (2 meta-analyses and 1 systematic review) | 2 meta-analyses and 1 systematic review | • Statistically significant: 3 of 3 meta-analyses and systematic reviews | • Better: 3 of 3 meta-analyses and systematic reviews | • Pooled odds ratios from meta-analyses were 2.1 and 2.5 | • Somewhat generalizable: 3 of 3 meta-analyses | • Clear and convincing evidence that nicotine inhaler increases the odds of abstinence from smoking relative to placebo or no treatment |

**Nicotine Nasal Spray vs. Placebo or No Treatment**

| Outcome | Research Design[13] | Statistical Significance | Direction of Effect | Size of Effect | Generalizability | Conclusion |
|---|---|---|---|---|---|---|
| Smoking cessation rate at 5 months or more (2 meta-analyses) | 2 meta-analyses | • Statistically significant: 2 of 2 meta-analyses | • Better: 2 of 2 meta-analyses | • Pooled odds ratios were 2.4 and 2.7 | • Somewhat generalizable: 2 of 2 meta-analyses | • Clear and convincing evidence that nicotine nasal spray increases the odds of abstinence from smoking relative to placebo or no treatment |

**Bupropion vs. Placebo or No Treatment**

| Outcome | Research Design[13] | Statistical Significance | Direction of Effect | Size of Effect | Generalizability | Conclusion |
|---|---|---|---|---|---|---|
| Smoking cessation rate at 5 months or more (3 meta-analyses and systematic reviews) | 2 meta-analyses and 1 systematic review | • Statistically significant: 3 of 3 meta-analyses and systematic reviews | • Better: 3 of 3 meta-analyses and systematic reviews | • Pooled odds ratios from meta-analyses range from 1.9 to 2.1 | • Somewhat generalizable: 3 of 3 meta-analyses and systematic reviews | • Clear and convincing evidence that bupropion increases the odds of abstinence from smoking relative to placebo or no treatment |

**Bupropion vs. Nicotine Patch**

| Outcome | Research Design[13] | Statistical Significance | Direction of Effect | Size of Effect | Generalizability | Conclusion |
|---|---|---|---|---|---|---|
| Smoking cessation rate at 5 months or more | 1 meta-analysis | • Not statistically significant: 1 of 1 meta-analysis | • No effect: 1 of 1 meta-analysis | • Pooled odds ratio = 1.3 | • Somewhat generalizable: 1 of 1 meta-analysis | • Clear and convincing evidence that bupropion does not increase the odds of abstinence from smoking relative to the nicotine patch (because the odds ratio was not statistically significant) |

**Varenicline and Other Forms of Cytisine vs. Placebo**

| Outcome | Research Design[13] | Statistical Significance | Direction of Effect | Size of Effect | Generalizability | Conclusion |
|---|---|---|---|---|---|---|
| Smoking cessation rate at 5 months or more (3 meta-analyses) | 3 meta-analyses | • Statistically significant: 3 of 3 meta-analyses | • Better: 3 of 3 meta-analyses | • Pooled odds ratios ranged from 1.8 and 3.2 | • Somewhat generalizable: 3 of 3 meta-analyses | • Clear and convincing evidence that varenicline increases the odds of abstinence from smoking relative to placebo |

**Varenicline vs. Bupropion**

| Outcome | Research Design[13] | Statistical Significance | Direction of Effect | Size of Effect | Generalizability | Conclusion |
|---|---|---|---|---|---|---|
| Smoking cessation rate at 12 months | 1 meta-analysis | • Statistically significant: 1 of 1 meta-analysis | • Better: 1 of 1 meta-analysis | • Pooled odds ratio = 1.7 | • Somewhat generalizable: 1 of 1 meta-analysis | • Clear and convincing evidence that varenicline increases the odds of abstinence from smoking relative to bupropion |

**Table 3.** Summary of Findings from Studies of the Effects of Coverage for Tobacco Cessation Services on Use of Services and Abstinence from Smoking

**Full Coverage for Tobacco Cessation Services vs. No Coverage—Use of Cessation Services**

| Outcome | Research Design[14] | Statistical Significance | Direction of Effect | Size of Effect | Generalizability | Conclusion |
|---|---|---|---|---|---|---|
| Use of pharmaco-therapy and/or counseling (1 study) | • Level I: 1 study | • Statistically significant: 1 of 1 study | • Better (i.e., more likely to use either or both types of cessation services): 1 of 1 study | • 1.75 times as likely to use | • Somewhat generalizable = 1 of 1 study | • Single study suggests that full coverage for pharmaco-therapy and counseling increases use of these tobacco cessation services |
| Use of counseling (2 studies) | • Level I: 2 studies | • Statistically significant: 1 of 2 studies<br>• Not statistically significant: 1 of 2 studies | • Better (i.e., more likely to obtain counseling): 1 of 1 study<br>• No effect: 1 of 2 studies | • Ranged from no difference to 4 times as likely to obtain | • Highly generalizable = 1 of 2 studies<br>• Somewhat generalizable = 1 of 2 studies | • The evidence of the effect of full coverage for tobacco cessation counseling on use of counseling is ambiguous |

[14] Level I = Well-implemented RCTs and cluster RCTs; Level II = RCTs and cluster RCTs with major weaknesses; Level III = Nonrandomized studies that include an intervention group and one or more comparison groups and time series analyses; Level IV = Case series and case reports; and Level V = Clinical/practice guidelines based on consensus or opinion.

| Outcome | Research Design[14] | Statistical Significance | Direction of Effect | Size of Effect | Generalizability | Conclusion |
|---|---|---|---|---|---|---|
| Use of NRT (5 studies) | • Level I: 3 studies<br>• Level II: 1 study<br>• Level III: 1 study | • Statistically significant: 3 of 5 studies<br>• Not statistically significant: 1 of 5 studies<br>• Not reported: 1 of 5 studies | • Better (i.e., more likely to use NRT): 4 of 5 studies<br>• Worse: 1 of 5 studies | • Ranged from 0.07 times less likely to use to 1.02 times more likely | • Highly generalizable = 1 of 5 studies<br>• Somewhat generalizable = 4 of 5 studies | • Preponderance of evidence suggests that full coverage for NRT increases use of NRT |
| Use of bupropion (2 studies) | • Level I: 1 study<br>• Level III: 1 study | • Statistically significant: 1 of 2 studies<br>• Not statistically significant: 1 of 2 studies | • Better (i.e., more likely to obtain bupropion): 2 of 2 studies | • Ranged from 0.24 times more likely to 0.63 times more likely | • Somewhat generalizable = 2 of 2 studies | • Preponderance of the evidence suggests that full coverage for bupropion increases use of this drug for tobacco cessation |

**Full Coverage for Tobacco Cessation Services vs. Partial Coverage—Use of Cessation Services**

| Outcome | Research Design[14] | Statistical Significance | Direction of Effect | Size of Effect | Generalizability | Conclusion |
|---|---|---|---|---|---|---|
| Use of nicotine replacement therapy (2 studies) | • Level II: 1 study<br>• Level III: 1 study | • Statistically significant: 2 of 2 studies | • Better (i.e., more likely to use NRT): 2 of 2 studies | • Ranged from 0.3 times to 2.5 times more likely to use | • Somewhat generalizable = 2 of 2 studies | • Clear and convincing evidence that persons with full coverage for NRT are more likely to use it than people with partial coverage |
| Use of counseling (1 study) | • Level III: 1 study | • Statistically significant: 1 study | • Better (i.e., more likely to obtain counseling): 1 of 1 study | • 3 times as likely to obtain | • Somewhat generalizable = 1 of 1 study | • Single study suggests that persons who have full coverage for counseling are more likely to obtain it than persons with partial coverage |

**Full Coverage for Tobacco Cessation Services vs. No Coverage—Abstinence from Smoking**

| Outcome | Research Design[14] | Statistical Significance | Direction of Effect | Size of Effect | Generalizability | Conclusion |
|---|---|---|---|---|---|---|
| Abstinence from smoking (7 studies) | • Level I: 4 studies<br>• Level II: 1 study<br>• Level III: 2 studies | • Statistically significant: 4 of 7 studies<br>• Not statistically significant: 3 of 7 studies | • Better (i.e., more likely to stop smoking): 5 of 7 studies<br>• No effect: 1 of 7 studies<br>• Worse: 1 of 7 studies | • Ranged from no difference to 1.7 times as likely to quit | • Highly generalizable = 1 of 7 studies<br>• Somewhat generalizable = 6 of 7 studies | • Preponderance of evidence suggests that coverage for tobacco cessation services increases abstinence from smoking |

**Full Coverage for Tobacco Cessation Services vs. Partial Coverage—Abstinence from Smoking**

| Outcome | Research Design[14] | Statistical Significance | Direction of Effect | Size of Effect | Generalizability | Conclusion |
|---|---|---|---|---|---|---|
| Abstinence from smoking (3 studies) | • Level I: 1 study<br>• Level II: 1 study<br>• Level III: 1 study | • Not statistically significant: 3 of 3 studies | • Better (i.e., more likely to stop smoking): 1 of 3 studies<br>• No effect: 2 of 3 studies | • Ranged from no difference to twice as likely to quit | • Highly generalizable = 1 of 3 studies<br>• Somewhat generalizable = 2 of 3 studies | • The evidence of the impact of full versus partial coverage on abstinence from smoking is ambiguous |

## UTILIZATION, COST, AND COVERAGE IMPACTS

SB 24 would require Knox-Keene licensed health care service plan contracts and insurance policies sold in the group and individual market that provide outpatient prescription drug benefits to provide tobacco cessation treatment coverage for two courses of treatment per contract year *without copayment or deductible*. A course of treatment is defined as coverage for telephone counseling and medications, whether by prescription or over-the-counter (OTC). According to CHBRP's estimates, there are 20.69 million insured Californians currently enrolled in health plans regulated under the Knox-Keene Act or insured by policies regulated under the California Insurance Code; this includes 12.89 million adults aged 18 years and older. Although SB 24 did not specify the targeted age group, CHBRP made the simplifying assumption to focus only on the adult population for the coverage impact analysis because smoking *cessation* services are utilized mostly by those 18 years of age and older, whereas, smoking *prevention* services are particularly important in children under 18 years of age. This section will present the current, or baseline, costs and coverage related to smoking cessation for adults, and then will detail the estimated utilization, cost, and coverage impacts of SB 24.

For further details on the underlying data sources and methods, please see Appendix D at the end of this document. A discussion of the current or baseline levels precedes presentation of the impact estimates for SB 24.

### Present Baseline Cost and Coverage

Current Coverage of the Mandated Benefit

According to data from the 2005 California Health Interview Survey (CHIS, 2005), 14.6% of California's non-elderly adults with insurance coverage are currently smoking. As a result, about 1.88 million California adult smokers, excluding members (5%) who do not have coverage for outpatient prescription drug benefits, would benefit from this mandate. Current coverage of smoking cessation services was determined by a survey of the seven largest providers of health insurance in California. On the basis of the responses of six health plans and insurers in California,[15] the current coverage of mandated benefits varies by types of smoking cessation services. Currently, members largely have coverage for brief cessation interventions by a physician or other clinical staff as part of a regular physician visit, which is subject to copayment ($10–$15) per office visits; 59.4% have partial or full coverage for prescription smoking cessation medications (e.g. antidepressants, such as bupropion or similar drugs) through outpatient prescription drug benefits with $10–$35 copayment, though many plans limit it to one course of treatment per contract year; 64.5% have coverage for personal counseling through telephone or other counseling services, whereas only 43.1% have coverage for NRT (three OTC forms—gum, lozenge and patch; and two prescription forms—inhaler and nasal spray). In summary, privately insured, CalPERS, and Healthy Families members currently have only partial or no coverage for smoking cessation medications and counseling services. The partial

[15] The six that responded represent 75% of enrollees in full-service health plans regulated by DMHC and 78% of the lives covered by comprehensive health insurance products regulated by CDI.

coverage ranges from only a $10 copayment by members per prescription or office visit to maximum coverage up to $50 per member per lifetime.

California's Medi-Cal Managed Care Program, which covers 8.0% (1.03 million) of adults subject to the mandate, provides comprehensive tobacco cessation benefits at no charge to Medi-Cal members. Contracting health plans administer tobacco cessation benefits including a broad scope of pharmacological aides (including OTC medications) and coverage for tobacco cessation programs that provide counseling, classes, and self-help materials. The premandate per member per month (PMPM) premiums and expenditures in different market segments are detailed in Table 4.

## Current Utilization Levels and Costs of the Mandated Benefit

### *Current utilization*

According to the 2002 California Tobacco Survey, 58.9% California smokers made at least one quit attempt in a year.[16] Among them, only a small proportion of them participated in a formal cessation assistance program (see Table 9). Typically, formal cessation assistance programs include a combination of counseling, prescription medications, and physician contact (Javitz, 2004). However, many Californians smoking quitters only used one or two of the services as a course of treatment. In summary, about 17.9% smokers who made an attempt to quit used NRT, 12% used counseling, 5.8% used antidepressant, and 25.4% used one or more services. The rest (74.6%) do not use any formal assistance during a quit attempt in the year before the survey.

Though previous studies, including RCTs in California HMOs, showed utilization rates of smoking cessation services among those with or without coverage (see details in the Medical Effectiveness section), CHBRP decided to use CTS data as a baseline to estimate the premandate utilization because these data were weighted to represent a complete utilization pattern of all Californians. Because CTS data did not provide utilization information by insurance coverage, CHBRP decided to use the RAND HIE's estimated impact of cost sharing for well care as adjustments. The Rand HIE tested the effects of cost sharing on the use of medical services and developed utilization rates for no copays, or 25%, 50%, or 95% coinsurance (Newhouse, 1993). The Rand HIE indicates that an increase from zero copay to 25% coinsurance reduces utilization rates by about 25%. CHBRP used an average of 20% reduction to estimate current utilization levels based on the proportion of members with any levels of copayments. Among members with *partial or full* coverage, about 13.2% adult members who smoke used NRT, 8.4% used counseling, 4.2% used antidepressant, and 18.1% used one or more services. Among members with *no* coverage, about 7.4% adult members who smoke used NRT, 4.8% used counseling, 2.4% used antidepressant, and 10.2% used one or more services. Please see details of the calculations in Appendix D.

[16] The 2002 California Tobacco Survey data presented here is revised data presented in CDHS/CTS (2003) based on personal communication with John Pierce.

*Current average cost of tobacco cessation services*

Currently, the average cost per course of treatment is $185 for the counseling services, $285 for OTC NRT, and an average of $300 for antidepressant ($400 for brand name antidepressant and $200 for generic antidepressant) (Halpin, McMenamin, et al., 2006; Marlow and Stoller, 2003). This analysis assumes that advice for tobacco cessation is generally provided as part of a regular physician visit, and, therefore, CHBRP estimated no additional physician costs specifically for tobacco cessation services, except a cost offset for current copayment for office visits.

The Extent to Which Costs Resulting from Lack of Coverage Are Shifted to Other Payers, Including Both Public and Private Entities

CHBRP estimated no shift in costs among private or public payers as a result of current coverage. In the long term, 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. In contrast, because quitters will live longer, they incur health care expenditures including custodial care during more years of life (Warner, 2004). These potential savings or costs, however, were not estimated in the current analysis.

Public Demand for Coverage

A previous bill that would have mandated coverage for tobacco cessation (SB 576) had 18 formal supporters, indicative of public interest for this benefit.

In addition, under criteria specified by 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. On the basis of conversations with the largest collective bargaining agents in California, CHBRP determined that no evidence exists that unions currently include such detailed provisions (specific to smoking cessation) during the negotiations of their health insurance policies. In general, unions tend to negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and coinsurance levels. In order to determine whether any local unions engage in negotiations in such detail, they would need to be surveyed individually.[17] Currently, the largest public self-insured plan, CalPERS PPO plan members are covered for up to $100 a year for counseling (and the $100 is exempt from the calendar year deductible and calendar year maximum copay), and members have no prescription drug benefit or OTC medication benefit for tobacco cessation.

[17] Personal communication with the California Labor Federation and member organizations on January 29, 2007.

**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?

On the basis of the responses of six health plans and insurers in California,[18] CHBRP estimated that coverage would increase by 35.5% for counseling, 40.6% for antidepressant, and 56.9% for NRT. CHBRP estimates that the unit cost of covered tobacco cessation services would stay the same after the mandate because CHBRP does not anticipate a price increase in the overall market due to an increase in the utilization (see Table 1).

How Will Utilization Change as a Result of the Mandate?

On the based of findings from the literature (Curry et al., 1998; Kaper, Wagena, Severens, et al., 2005; Schauffler et al., 2001), utilization is expected to increase as a result of the full coverage for tobacco cessation treatment. CHBRP estimated the postmandate utilization rate among smokers for smoking cessation services using the RAND HIE estimated impact of cost sharing for well care. Specifically, those without coverage will have expenditures equal to 45% of those with full coverage, whereas those with partial coverage will have expenditures equal to 80% of those with full coverage. CHBRP estimated that SB 24 would increase the utilization of all tobacco cessation modalities. Specifically, CHBRP estimated that the utilization of NRT would increase to 16.5%, counseling to 10.6%, antidepressant 5.3%, and one or more services to 22.6% after the mandate. Please see details of the calculations in Appendix D. The estimated increases of percentage points for different services are similar to the findings of a meta-analysis published recently (Kaper et al., 2006) and other studies (Curry et al., 1998; Schauffler et al. 2001).

The expected increase in utilization following the mandate is modest given that 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. The coverage, which is limited to two courses of treatment per year, is also expected to dampen any potential surges in utilization for any one service.

To What Extent Does the Mandate Affect Administrative and Other Expenses?

This mandate will likely increase the administrative expenses for health plans, especially in the first few years, 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 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 OTC tobacco cessation drugs and non-clinical smoking counselors. 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

[18] The six that responded represent 75% of enrollees in full-service health plans regulated by DMHC and 78% of the lives covered by comprehensive health insurance products regulated by CDI.

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

SB 24 will increase total net annual expenditures by $70.05 million or 0.10% for this insured population. The mandate will increase premiums by $113.35 million ($73.13 million for the portion of group insurance premiums paid by private employers, $18.85 million for individually purchased insurance, $2.34 million by CalPERS employer, and $18.97 million for the portion of group insurance, CalPERS, and Healthy Families premiums paid by enrollees). At the same time, there is a net reduction in member copayments of $9.82 million and *out-of-pocket* expenditures of $33.49 million, because the bill requires health plans to provide complete coverage for two cycles of tobacco cessation services free of charge (i.e., without a copayment or coinsurance and not subject to a deductible).

Costs or Savings for Each Category of Insurer Resulting from the Benefit Mandate

Increases in insurance premiums vary by market segment. Increases as measured by percentage changes in PMPM premiums are estimated to range from 0.01% to 0.54% in the affected market segments (Table 5). Increases as measured by PMPM premiums are estimated to range from $0.01 to $0.81. The greatest impact on premiums would be on the small-group and individual markets. A substantial portion of the increase in insurance premiums would be due to insurance absorbing a portion of the benefit's cost previously paid for by the insured. This transfer effect is discussed below.

In the large-group market, the increase in premiums is estimated to range from $0.47 to $0.74 PMPM. For members with small-group insurance policies, health insurance premiums are estimated to increase by approximately $0.62 to $0.82 PMPM. In the individual market, the health insurance premiums are estimated to increase by $0.73 PMPM in the DMHC-regulated market and by $0.81 PMPM in the CDI-regulated market.

Medi-Cal currently covers smoking cessation program without copayment, so it would incur no cost as a result of the mandate. No cost shifting is expected to occur from the public programs to the privately insured market. The largest portion of the shift in benefit expenditures would be from privately insured individuals' out-of-pocket expenses to third parties, and in turn to the employers and employees who pay premiums to the third parties. For example, in the large-group HMO market, $0.19 of the out-of-pocket expenses (measured as PMPM costs) would be expected to shift to the health plan or insurer. Individuals who currently purchase tobacco cessation services, mostly OTC medications, will realize the greatest savings under the mandate, because full coverage for OTC medications would be available to them under the mandate.

These total expenditures for premiums take into account the total savings for those who quit smoking. The total savings are estimated to be $4.28 million.[19] These savings represent the

[19] The cost-savings calculation incorporates savings associated with reduced hospitalization for acute myocardial infarction (AMI) and savings associated with fewer low birth-weight deliveries.

short-term (i.e., 1-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 (details are in the following section). Additionally, 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. Long-term costs and savings are not included in the projections presented here because it is difficult to quantify those affects on premiums and expenditure changes for a given year. (See section below on the long-term cost effectiveness of cessation services.)

*Potential cost offsets or savings in the short term*

Smoking cessation produces short-term savings in health expenditures as a result of fewer inpatient stays and ambulatory care visits related to low birth-weight deliveries, and a reduction in hospitalization due to AMI or stroke. These savings can be realized within a year after quitting smoking.

**Low Birth-Weight Deliveries.** On the basis of the assumptions described in the Public Health Impacts section (see page 49), CHBRP estimated the mandate could result in 35 fewer low birth-weight deliveries statewide.[20] The average savings per avoided low birth-weight delivery is estimated to be approximately $42,523. This number is derived from the 1999 Lightwood study, which estimated $21 million saved (in 1995 dollars) as a result of 1,300 fewer low birth-weight deliveries (Lightwood and Phibbs, 1999). This estimated savings was then was updated to 2006 dollars at a rate of 8.4% per year.[21] Therefore, as a result of the mandate, quitting produces an average first-year savings in health care expenditures of about $1.49 million from avoided low birth-weight deliveries.

**AMI and Stroke.** On the basis of the literature described in the public health section (see page 48), CHBRP estimated the mandate could result in 22 fewer hospitalizations due to AMI or stroke.[22] The average savings per avoided stroke and AMI hospitalization is estimated to be approximately $125,352. This calculation is derived from the 1997 Lightwood study (Lightwood and Glantz, 1997), which estimated an approximate $44 million savings (1995 dollars) in 1 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/stroke, and then updated this number to 2006 terms at a rate of 8.4% per year. In total, CHBRP estimated that quitting produces an average first-year savings in health care expenditures of about $2.79 million from avoided AMIs and strokes.

*Long-term cost effectiveness of smoking cessation*

In addition to gaining those short-term savings in health expenditures, those who quit smoking experience measurable long-term improvements in health status. The reductions in smoking

[20] This is out of the total of 27,060 insured pregnant women who were smokers prior to the mandate.
[21] This trend rate was based on the average annual increase in California HMO premiums from 1995 to 2006 as measured by the Milliman Intercompany HMO Rate Survey.
[22] This is out of a total of 1,882,219 insured adults who were smokers prior to the mandate.

produce many health benefits, including reduced rates of lung and other types of cancer (CDC, 1990), coronary heart disease (CDC, 2001b), and respiratory symptoms (CDC, 1990). A number of studies have examined the long-term cost consequences of reductions in tobacco use, and all generally find that smoking cessation is cost effective instead of cost saving, because the savings associated with reductions in disease are offset by the aggregate costs of smoking cessation programs.

In California, Max and colleagues (2004) estimate that the annual economic burden of smoking is $3,331 per smoker, including $1,810 in medical costs and $1,521 in productivity costs. These figures provide a basis for understanding the potential annual savings associated with each individual who quits smoking. However, an important question for evaluating the long-term *net costs* of smoking cessation is: how much does it cost to produce a lifetime quitter? Several studies have addressed this issue. For example, Warner and colleagues (2004) found that quitters gain on average 7.1 years of life at a net cost of $3,417 per year of life saved, or $24,261 per quitter. Cromwell and colleagues (1997) found that implementation of smoking cessation guidelines would have a net cost of $3,779 per quitter, $2,587 per life-year saved, and $1,915 per quality-adjusted life-year (QALY, a year in perfect health is considered equal to 1.0 QALY) saved. The costs of achieving and maintaining lifetime tobacco cessation are generally greater than the long-term savings related to disease reduction. This is true in part because most of the savings occur years after cessation, so those costs are discounted heavily when converted into present value dollars. In addition, the costs per lifetime quitter are high because smoking cessation is not 100% effective, so costs are incurred by individuals who are not successful in quitting, and because most quitters require multiple attempts before they quit. However, to place these costs in their proper context, cost-effectiveness studies generally report their findings in costs per QALY, as recommended by the Panel on Cost Effectiveness in Health and Medicine (USPHS, 1996). It is generally accepted that interventions that cost less than $50,000 per QALY, such as mammography, are viewed by society as cost effective (Fiore, 1998). According to these standards, smoking cessation programs are highly cost effective in the long term, producing significant reductions in mortality and morbidity at a net cost that is well below the $50,000/QALY threshold.

Impact on Access and Health Service Availability

CHBRP estimates that the proposed mandate will have no impact on availability of (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 for smoking cessation services would potentially encourage more insured individuals to use tobacco cessation services and improve the access to those services, such as non-clinical counseling and OTC medications for smokers who make an attempt to quit.

**Table 4**. Baseline (Premandate) Per Member Per Month Premium and Expenditures by Insurance and Health Plan Type, California, 2007

| | Large Group | | Small Group | | Individual | | Total Annual |
|---|---|---|---|---|---|---|---|
| | **DMHC Regulated** | **CDI Regulated** | **DMHC Regulated** | **CDI Regulated** | **DMHC Regulated** | **CDI Regulated** | |
| **Population currently covered** | 10,354,000 | 363,000 | 3,086,000 | 679,000 | 1,268,000 | 794,000 | 16,544,000 |
| | | | | | | | |
| Average portion of premium paid by employer | $249.51 | $323.69 | $249.52 | $281.52 | $0.00 | $0.00 | $43,944,936,000 |
| Average portion of premium paid by employee | $53.66 | $74.60 | $94.73 | $61.82 | $269.42 | $148.66 | $16,520,318,000 |
| **Total premium** | $303.17 | $398.28 | $344.26 | $343.34 | $269.42 | $148.66 | $60,465,254,000 |
| | | | | | | | |
| Covered benefits paid by member (deductibles, copays, etc.) | $16.69 | $41.50 | $25.59 | $102.13 | $45.45 | $35.38 | $5,062,894,000 |
| Benefits not covered | $0.14 | $0.30 | $0.19 | $0.30 | $0.19 | $0.25 | $33,485,000 |
| | | | | | | | |
| **Total expenditures** | $320.00 | $440.09 | $370.04 | $445.77 | $315.06 | $184.30 | $65,561,634,000 |
| | | | | | | | |

| | CalPERS and Public Insurance | | | | Total Public Annual | | Grand Total Annual |
|---|---|---|---|---|---|---|---|
| | **CalPERS** | **MediCal DMHC-Regulated** | **MediCal DMHC-Regulated** | **Healthy Families** | | | |
| | **HMO** | **65 yrs and Over** | **Under 65 yrs** | | | | |
| **Population currently covered** | 791,000 | 165,000 | 2,513,000 | 681,000 | 4,150,000 | | 20,694,000 |
| | | | | | | | |
| Average portion of premium paid by employer | $277.19 | $181.00 | $120.43 | $76.82 | $7,249,068,000 | | $51,194,004,000 |
| Average portion of premium paid by employee | $48.92 | $0.00 | $0.85 | $5.78 | $537,307,000 | | $17,057,625,000 |
| **Total premium** | $326.11 | $181.00 | $121.29 | $82.60 | $7,786,375,000 | | $68,251,629,000 |
| | | | | | | | |
| Covered benefits paid by member (deductibles, copays, etc) | $17.17 | $0.00 | $0.56 | $2.25 | $198,201,000 | | $5,261,095,000 |
| Benefits not covered | $0.00 | $0.00 | $0.00 | $0.00 | $0 | | $33,485,000 |
| | | | | | | | |
| **Total expenditures** | $343.27 | $181.00 | $121.85 | $84.85 | $7,984,576,000 | | $73,546,210,000 |

*Source*: California Health Benefits Review Program, 2007.

*Note*: The population includes individuals and dependents in California who have private insurance (group and individual) or public insurance (e.g, CalPERS, Medi-Cal, Healthy Families, AIM, MRMIP) under health plans or policies regulated by DMHC or CDI., All population figures include enrollees aged 0–64 years and enrollees 65 years or older covered by employment-based coverage.

*Key:* CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; HMO = health maintenance organization and point of service plans.

**Table 5.** Postmandate Changes in Utilization Rates per 1,000 Insured and Per Member Per Month Costs, California, 2007

| | Large Group | | Small Group | | Individual | | CalPERS | Medi-Cal | | Healthy Families | Total Annual |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | DMHC Regulated | CDI Regulated | DMHC Regulated | CDI Regulated | DMHC Regulated | CDI Regulated | HMO | Managed Care 65 yrs and Over | Managed Care Under 65 yrs | Managed Care | |
| **Population currently covered** | 10,354,000 | 363,000 | 3,086,000 | 679,000 | 1,268,000 | 794,000 | 791,000 | 165,000 | 2,513,000 | 681,000 | 20,694,000 |
| Average portion of premium paid by employer | $0.39 | $0.60 | $0.45 | $0.67 | $0.00 | $0.00 | $0.25 | $0.00 | $0.00 | $0.01 | $75,528,000 |
| Average portion of premium paid by employee | $0.08 | $0.14 | $0.17 | $0.15 | $0.73 | $0.81 | $0.04 | $0.00 | $0.00 | $0.00 | $37,824,000 |
| **Total premium** | $0.47 | $0.74 | $0.62 | $0.82 | $0.73 | $0.81 | $0.29 | $0.00 | $0.00 | $0.01 | $113,351,000 |
| Covered benefits paid by member (deductibles, copayments, etc.) | -$0.05 | $0.00 | -$0.04 | -$0.01 | -$0.04 | $0.00 | -$0.11 | $0.00 | $0.00 | $0.00 | -$9,821,000 |
| Member expenses for benefits not covered | -$0.14 | -$0.30 | -$0.19 | -$0.30 | -$0.19 | -$0.25 | $0.00 | $0.00 | $0.00 | $0.00 | -$33,485,000 |
| **Total expenditures** | $0.28 | $0.44 | $0.39 | $0.52 | $0.50 | $0.55 | $0.18 | $0.00 | $0.00 | $0.01 | $70,045,000 |
| **Percentage impact of mandate** | | | | | | | | | | | |
| Insured premiums | 0.16% | 0.19% | 0.18% | 0.24% | 0.27% | 0.54% | 0.09% | 0.00% | 0.00% | 0.01% | 0.17% |
| Total expenditures | 0.09% | 0.10% | 0.11% | 0.12% | 0.16% | 0.30% | 0.05% | 0.00% | 0.00% | 0.01% | 0.10% |

*Source*: California Health Benefits Review Program, 2007.
*Note*: The population includes individuals and dependents in California who have private insurance (group and individual) or public insurance (e.g, CalPERS, Medi-Cal, Healthy Families, AIM, MRMIP) under health plans or policies regulated by DMHC or CDI. All population figures include enrollees aged 0–64 years and enrollees 65 years or older covered by employment-based coverage. Number may not match Table 1 exactly due to rounding.
*Key:* CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; HMO = health maintenance organization and point of service plans.

## PUBLIC HEALTH IMPACTS

### Introduction

Tobacco use is well known as the leading cause of preventable death and disease in the U.S. and California. Since the Surgeon General's 1964 seminal report on the health effects of tobacco use, smoking prevalence in California and the U.S. has decreased dramatically over the last 40 years. Nevertheless, smoking accounts for approximately 440,000 deaths nationwide each year and generates costs of approximately $157 billion in annual health-related economic losses (CDC, 2007b). In California, the smoking-attributable mortality (SAM) rate in 2001 was 245 per 100,000 Californians, resulting in 37,324 deaths, or 16% of total deaths. During this same time period, smoking-attributable productivity losses in California were estimated at more than $8 billion. (CDC, 2001a).

California leads the nation in tobacco control policy. The 1988 California Tobacco Tax and Health Promotion Act (Proposition 99) increased the state surtax on cigarettes and other tobacco-related products, resulting in additional revenues that were appropriated for tobacco-related research, health care for medically indigent families, and tobacco cessation education and services (administered through the California DHS Tobacco Control Section). In 1995, California enacted a smoke-free workplace law in an effort to reduce the public health burden of environmental tobacco smoke ("second-hand smoke"). Since 1989, smoking prevalence in California decreased 38% (from 22.0% to 14.6%); and attempts to quit smoking (i.e., the percentage of smokers reporting a quit attempt in the preceding 12 months) increased from 49% to 59% between 1990 and 2002 (CDHS/TCS, 2005).

#### Health Outcomes Related to Tobacco Use

The Surgeon General's 2004 report (CDC, 2004) states that smoking causes multiple cardiovascular and respiratory diseases as well as cancers, and it is estimated that one in three cancers is attributable to tobacco (ACS, 2006). In California (Table 6), the most prevalent smoking-associated cancers include lung, esophageal, and oral. The three most prevalent cardiovascular diseases contributing to SAM include ischemic heart disease, cerebrovascular disease, and aortic aneurysm. Respiratory diseases, such as chronic airway obstruction, bronchitis/emphysema, and pneumonia/influenza, account for the third largest SAM disease category (CDC, 2001a).

**Table 6.** California's Smoking-Attributable Mortality by Disease, 2001

| Disease | Number of Male Deaths | Number of Female Deaths | Total Deaths (a) |
|---|---|---|---|
| Malignant neoplasms (cancer) | 8,964 | 5,445 | 14,409 |
| Cardiovascular | 7,137 | 4,800 | 11,937 |
| Respiratory | 5,464 | 5,514 | 10,978 |
| **Total** | **21,565** | **15,759** | **37,324** |

(a) Includes adults 35 years and older, and does not include burn or second-hand smoke deaths.
*Source:* Centers for Disease Control and Prevention (CDC) SAMMEC, 2001a.

Ethnic and racial disparities within disease categories are well documented. For example, African Americans experience a higher incidence of cardiovascular disease, cancer, and infant death, all of which are smoking-related diseases. Native Americans experience the highest rate of infant mortality due to Sudden Infant Death Syndrome (SIDS), which is also causally linked to tobacco use (Fiore, 2000).

Smoking Prevalence in California

Despite state-level advances in tobacco cessation, smoking prevalence in California remains higher than the *Healthy People 2010* target of 12% for adults (CHS, 2006). The 2005 California Health Interview Survey (CHIS) reported that 14.6% of Californians were current smokers (Table 7). While all age categories experienced similar smoking prevalence, men were more likely to be current smokers than women.

**Table 7.** Smoking Prevalence Among California Adults (%), 2005

| Age (years) | Male | Female | Total |
|---|---|---|---|
| 18–24 | 15.4 | 11.9 | 13.5 |
| 25–39 | 18.1 | 11.6 | 14.8 |
| 40–64 | 17.1 | 12.6 | 14.8 |
| Total | 17.2 | 12.1 | 14.6 |

Data shown is for the insured population aged 18–64 years.
*Source:* California Health Interview Survey, 2005.

*Community Health Disparities*

Racial and ethnic disparities in smoking prevalence are also apparent in California (Table 8). According to the 2005 CHIS, the highest smoking prevalences are seen among Native Americans (32%) and those of "other" or mixed races (22%). African Americans and Whites closely follow with a smoking prevalence of 20% and 18%, respectively. At 13% prevalence each, California's Latino and Asian populations are close to achieving the *Healthy People 2010* target.

Gender differences remain significant for the Asian and Latino populations. Asian men are five times more likely to smoke than Asian women, and smoking prevalence for Latino men is twice that of Latina women. The "other/2 or more races" population also demonstrates a gender difference: men are two times more likely to smoke than women. The highest smoking prevalence is among Native American men (38%), whereas the lowest is found in Asian women (5%) (CHIS, 2005).

Disparities extend to socioeconomic status as well. Both men and women with incomes less than 200% of the federal poverty level are more likely to smoke than those who have higher incomes.

**Table 8**. Racial and Economic Disparities in Smoking Prevalence (%)

| Race | Male | Female | Total |
|---|---|---|---|
| Latino/Hispanic | 16.6 | 6.9 | 12.6 |
| Native American | 37.8 | 25.8 | 31.8 |
| Asian | 21.1 | 4.7 | 12.9 |
| Black | 22.0 | 17.7 | 19.9 |
| White | 19.3 | 16.9 | 18.1 |
| Other/2 or more races | 29.9 | 13.4 | 21.7 |

| Poverty Status | Male | Female | Total |
|---|---|---|---|
| 0%–99% FPL | 25.1 | 14.7 | 19.9 |
| 100%–199% FPL | 26.5 | 13.3 | 19.9 |
| 200%–299% FPL | 21.6 | 13.9 | 17.8 |
| 300% + FPL | 16.5 | 11.5 | 14.0 |

FPL= Federal poverty level.
*Source:* California Health Interview Study, 2005.

The extent to which SB 24 will modify these disparities is unknown. Evidence is inconclusive regarding the efficacy of "generic" cessation treatments (i.e., programs meant for all ethnic groups and not designed for a specific group) in minority populations. Two research groups (Fiore et al., 2000, and Lawrence et al., 2003) recommend that further investigation of targeted versus generic cessation interventions is warranted for racial and ethnic minority populations.

Tobacco Cessation

Tobacco cessation usually requires many attempts before success is achieved (Fiore et al., 2000; Gilpin et al., 1997). The Surgeon General's 1990 report (CDC, 1990) characterized tobacco cessation as a "dynamic process." The tenacity of tobacco addiction is recognized by the medical community, which characterizes it as a chronic disease and recommends repeated courses of treatment as needed to achieve smoking cessation.

Tobacco cessation lowers the risk for many diseases over the short term and for premature death over the long term. For example, the proportion of low birth-weight infants, expressed as a percentage of all live births, would drop by an estimated 10.4% in 1 year if all pregnant smoking women quit smoking (Ventura et al., 2003). Another short-term impact example is coronary artery disease. This disease can be reversed substantially within 1 to 2 years of cessation (CDC, 1990; Lightwood and Glantz, 1997). Long-term benefits are also attainable from cessation. After 10–15 years of cessation, risk of all-cause mortality returns to close to that of a "never" smoker (CDC, 1990).

The percentage of California smokers attempting to quit in the preceding year increased by 27% between 1990 and 2001 (CDHS/TCS, 2006a). Since 1999, however, the annual quit-attempt rate has remained fairly constant. The 2002 California Tobacco Survey (CTS)[23] found that, although a majority of smokers attempt to quit in California (58.9%) in a year, only a quarter participate in

[23] The 2002 California Tobacco Survey data presented here is revised data presented in CDHS/CTS (2003) based on personal communication with John Pierce.

a formal cessation assistance program (Table 9). Typically, formal cessation assistance programs include a combination of counseling, prescription medications, and physician contact (Javitz, 2004). Data from the 2002 CTS shows that 10% of California adult smokers who attempted to quit used NRT, 4.5% used counseling, 2.0% used antidepressants, 5.0% used both counseling and NRT, 0.9% used both counseling and antidepressants, 1.3% used both NRT and antidepressants, and 1.6% used a combination of NRT, antidepressants, and counseling.

**Table 9.** Tobacco Cessation Attempts in California, 2002

| Cessation (Quit) Attempts | California Smokers % |
|---|---|
| Quit attempts (in last 12 months) | |
| Quit attempt of 1 day or longer | 58.9 |
| Successful 90+ days quit | 8.9 |
| Use of cessation assistance | |
| NRT | 10.0 |
| Counseling | 4.5 |
| Antidepressants | 2.0 |
| Counseling and NRT | 5.0 |
| Counseling and antidepressants | 0.9 |
| NRT and antidepressants | 1.3 |
| NRT, antidepressants and counseling | 1.6 |

*Source:* 2002 California Tobacco Survey.

## Measurable Public Health Outcomes of Tobacco Cessation

To capture the short-term outcomes of mandated tobacco cessation coverage, this analysis focuses on several health outcomes: acute myocardial infarction (AMI) and stroke, and low birth weight (LBW). The selected short-term measures are based on literature findings that (1) smoking has a direct causal link to both LBW and AMI/stroke, and that (2) tobacco cessation has a demonstrable impact on these outcomes within 1 year of cessation (short term).

The health burden of tobacco—and therefore the benefits that proceed from SB 24-related smoking cessation—extend significantly beyond these selected conditions. However, characterizing the health burdens and benefits associated with each of the numerous other relevant conditions is not feasible within the time available for this report. (The Long-Term Health Outcomes: Overall Mortality section (below) of this report will address the issue of total smoking-related mortality.)

### Short-Term Health Outcomes: AMI and Stroke

*AMI and Stroke baseline data*

Stroke occurs when the blood flow to the brain is interrupted by a blockage or rupture of an artery to the brain thereby preventing the flow of oxygen. AMI, sometimes referred to as a "heart attack," occurs when there is damage to an area of the heart due to decreased local blood flow. There are multiple causes of AMI and stroke, but smoking is one of the primary risk factors. Smoking increases the risk of stroke in men by 40% and increases the risk by 60% in women (Kamigaki, et al., 2002). According to the California Center for Health Statistics, approximately

11,000 deaths due to stroke occurred in 2004. Myocardial infarction is one of the leading causes of death in the U.S. and in California (CHS, 2004). Mortality due to AMI in California varies by race and gender (Table 10). For all races, men have higher AMI-related mortality than women. African American men have the highest AMI mortality rate (26.6/100,000), whereas Asian women have the lowest rate (3.9/100,000).

**Table 10.** Acute Myocardial Infarction Mortality Incidence by Race (California Adults Aged 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** |

Data shown is for new cases per 100,000 Californians annually.
*Source:* California Center for Health Statistics, 2004

The causal association between smoking and heart disease has been well documented by several decades of scientific evidence (Critchley and Capewell, 2003; CDC, 2004). According to the California DHS, in 1999, adults between the ages of 35 and 64 years who smoked were almost twice as likely to die from heart disease as were nonsmokers in this age group. Furthermore, for adults in the same cohort, there were 24.3 years of potential life lost per death from ischemic heart disease attributable to smoking (Max et al., 2002).

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

Smoking is associated with both fatal and nonfatal AMI. According to 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 nonfatal AMI (Critchley and Capewell, 2003, 2004).

On the basis of calculations and assumptions shown in Appendix E, 22 fewer cases of AMI and stroke in California are expected in 1 year attributable to the SB 24 mandate (Table 12).

Short-Term Health Outcomes: Low Birth Weight

*Low birth-weight baseline data*

California's Center for Health Statistics reports that 37,653 low birth-weight infants were delivered in 2005, representing 6.9% of all live births (CHS, 2006). This total low birth-weight proportion is higher than the *Healthy People 2010* goal of 5.0%. The likelihood of low birth weight deliveries in California varies by race, with African American women having significantly higher rates than women of other racial backgrounds (Table 11).

**Table 11.** Birth Outcomes: Low Birth Weight by Race/Ethnicity

| **Race/Ethnicity** | **Low Birth-Weight Delivery Rate as a Percentage of Live Births** |
|---|---|
| Black | 12.8% |
| Multirace | 7.8% |
| Asian | 7.4% |
| Hawaiian/other Pacific Islander | 7.2% |
| American Indian/Alaska Native | 6.6% |
| White | 6.5% |
| Hispanic | 6.3% |
| **Total** | **6.9%** |

*Source:* California Health Benefits Review Program, 2007 analysis of the California Center for Health Statistics, *Healthy California 2010*, 2006.

Specific to smoking-related low birth-weight deliveries, the Centers for Disease Control and Prevention (CDC) show that in California, 2,307 years of potential life were lost due to pregnant smokers delivering low birth-weight infants in 2001 (CDC, 2001a). The California DHS, Tobacco Control Section reports that in 2002, 9.0% of pregnant women were smokers (CDHS/CTS, 2006b).

Several sources report similar findings that pregnant women who smoke are about twice as likely as nonsmoking pregnant women to deliver a low birth-weight infant. A National Vital Statistics Report showed that the likelihood of delivering a low birth-weight infant was 11.9% for smoking women compared to 7.3% for nonsmoking women (Martin et al., 2002). The CDC reported that, in 1999, pregnant smokers were twice as likely as pregnant nonsmokers to deliver a low birth-weight baby (12.2% vs. 6.3%). Ventura and colleagues found a similar pattern: the likelihood of delivering a low birth-weight infant was 10.4% among smokers compared to 5.6% among nonsmokers (Ventura et al., 2003). For purposes of this analysis, CHBRP used the National Vital Statistics prevalence rates because they are the most recent rates available.

The cost of low birth-weight deliveries can be significant due to increased complications during the birth, extended hospitalization for mothers and infants, and 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 pregnant woman, compared to $14 per nonsmoking pregnant woman (CDC, 2004). A study by Adams and colleagues showed that

maternal smoking increases the risk of neonatal intensive care unit admission by 20% (Adams et al., 2002).

Pregnant women who smoke have a higher cessation rate than nonpregnant female smokers. The prevalence of smoking among newly pregnant women was 9% in 2002, but fell to 5% by the sixth month of pregnancy (CDHS/TCS, 2006b). Other researchers have found similar results. Pickett and colleagues report that about 30% of pregnant smokers quit early in their pregnancy (Pickett et al., 2001). Colman and colleagues estimate that 46% of pre-pregnancy smokers quit during pregnancy in 1999, but of those quitters, half relapsed within 6 months postpartum (Colman et al., 2002). Petersen and colleagues found that, in general, tobacco cessation rates are higher for pregnant smokers than for the general population of smokers. Peterson and colleagues studied the effect of insurance coverage on quit rates for pregnant smoking women. They found that 51% of pregnant smokers with full coverage abstained from smoking during pregnancy versus 39% of those without coverage who abstained (Petersen et al., 2006).

Tobacco cessation, particularly during the first trimester of pregnancy, reduces 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 reduced need for medical care of low birth-weight babies and in reduced 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 and costs associated with low birth-weight deliveries. This study found that an annual 1% decrease in the smoking prevalence among pregnant women in California (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.

On the basis of calculations and assumptions described in Appendix E, 35 fewer cases of low birth-weight deliveries in California are expected in 1 year attributable to the SB 24 mandate (Table 12).

Long-Term Health Outcomes: Overall Mortality

Estimating the long-term impact of SB 24 is challenging. Due to limitations of medical literature and time constraints, it is not feasible for CHBRP to develop models projecting the long-term benefits associated with individual conditions such as cancer, cardiovascular disease, and others in a comprehensive manner. However, the literature provides information regarding reduced mortality resulting from smoking cessation. Accordingly, we chose to focus on additional years of life gained by smoking cessation, which represents a summary measure of the increased longevity due to prevention of premature death from the numerous health conditions associated with smoking.

Taylor and colleagues estimate the life extension achieved by tobacco cessation (Taylor et al., 2002). Cessation at an early age (35 years old) results in a predicted additional 7 to 8 years of life for men and a predicted additional 6 to 7 years of life for women. Cessation at a later age (65 years old), although resulting in significantly fewer predicted life years gained (1 to 2 years for

men and 2 to 3 years for women) illustrates the benefits of cessation at any age. California's Department of Health Services reported that in 1999, on average, 12.4 years of potential life were lost per smoker due to smoking-related disease, with an associated $5.5 billion in lost productivity for men and almost $3 billion in lost productivity for women (Max et al., 2004). Should some smokers quit, a corresponding increase in productivity would result.

We note that the actual years of life gained will vary with the age at which the smoker quit. However, accounting for this effect would require assumptions about the underlying population for which we have little data. Nevertheless, these estimates are valuable for showing the approximate magnitude of benefit in years of life gained across the state attributable to the SB 24 mandate. In addition, these figures are consistent with those developed by the CDC, which estimates that smokers 35 years of age and older in California in 2001 suffered a total of 498,279 years of potential life lost attributable to smoking (CDC, 2001a). Productivity loss associated with the smoking-related premature deaths in 2001 was $8.4 billion (CDC, 2001a).

**Table 12.** Estimated Annual Impact of Selected Short- and Long-Term Health Outcomes Attributable to SB 24

| Health Outcome | Annual Number of Cases Prevented Attributable to Mandate (a) | Years of Potential Life Lost for Each Case | Sum of Years of Potential Life Saved Each Year Attributable to Mandate (b) |
|---|---|---|---|
| **Short term** | | | |
| Acute myocardial infarction | 22 | 24.3 (c) | 923 |
| Low birth weight | 35 | 76.4 (d) | 2,674 |
| | | | |
| **Long term** | | | |
| Years of potential life gained | 31,716 smokers who quit (e) | 7.0–12.4 (f) | 222,012–393,278 |

(a) Based on CHBRP calculations of the impact SB 24 has on smoking cessation, Appendix E.
(b) The sum of years of potential life saved each year attributable to the mandate is the number of annual cases prevented attributable to the mandate multiplied by the years of potential life lost for each case.
(c) Max et al., 2002.
(d) Centers for Disease Control and Prevention, MCH SAMMEC, 2001a.
(e) Quitters were calculated by subtracting the number of smokers quitting without mandate benefit from the smokers who quit with mandate benefit (85,223–53,507=31,716).
(f) Range reflects conclusions by Taylor et al., 2002, and Max et al., 2004.
*Source*: California Health Benefits Review Program, 2007

When these estimates of increased longevity for quitters are applied to the 31,716 smokers who quit each year attributable to the SB 24 mandate, this adds up to between 222,012 to 393,278 years of potential life gained in the state each year (Table 12).

## Public Health and Economic Impacts

Tobacco use has both direct and indirect costs that affect individuals, employers, health plans, the government, and society. Medical care contributes the largest proportion of the direct costs of smoking. Individuals personally bear additional medical costs related to smoking. The CDC reports that, on average, men who smoke incur $15,800 (in 2002 dollars) more in lifetime medical expenses than nonsmokers, and women who smoke incur $17,500 more than nonsmokers (CDC, 2002).

Employers may experience direct costs (e.g., medical care, higher health insurance premiums) due to smoking-related illness among their employees (Levy, 2006). According to the California Department of Health Services, in 1999, Californians spent $8,564,623 in direct health care costs attributable to smoking (Table 13). 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).

**Table 13.** California State Smoking-Attributable Expenditures, 1999

| Health Care Service | Millions |
|---|---|
| Hospital care | $4,016,568 |
| Outpatient care | $2,060,234 |
| Nursing home care | $1,267,232 |
| Prescription drugs | $1,133,432 |
| Home health care | $87,157 |
| **Total** | **$8,564,623** |

*Source:* California Health Benefits Review Program (Max et al., 2004)

Quantitative assessments of the disease burden imposed by tobacco use can be an important complement to the epidemiologic data presented. In-depth modeling of indirect costs (e.g., effects on quality of life, years of life gained, and loss of productivity) by full insurance coverage of tobacco cessation treatments is beyond the scope of this report. However, there is evidence that indirect costs are reduced by tobacco cessation. For example, smokers who successfully quit report improved quality of life relative to current smokers (Mulder et al., 2001).

Several studies address tobacco cessation effectiveness in relation to effectiveness of other medical treatments for smoking-attributable diseases. Two separate studies concluded that quitting results in a similar reduction in morbidity and mortality that would be achieved through pharmaceutical interventions commonly prescribed to heart disease patients (Critchley and Capewell, 2003; Suskin et al., 2001). Other studies report that the cost for treating high blood pressure ranges between $5,000 to $45,000 per life-year saved, whereas tobacco cessation treatment is estimated to cost a few hundred to a few thousand dollars per life-year saved (Warner et al., 2004). Putting tobacco cessation into a preventive treatment context demonstrates that this type of service costs the same or less than other commonly used preventive services. For example, mammography screening is estimated to cost $20,000 per life-year saved (Warner et al., 2004).

**Conclusion of Public Health Impacts**

California is a national leader in reducing the health and economic burden of tobacco use. Primarily through policy measures affecting social norms over the last 20 years, the state has experienced a significant reduction in smoking prevalence and a resulting decrease in tobacco-related diseases such as cancer, stroke, and heart disease (including those diseases acquired through second-hand smoke exposure) (CDC, 2007a).

SB 24 would likely have a positive impact on public health in California, based on the scientific evidence of the medical effectiveness of tobacco cessation services, the impact of tobacco cessation on both short-term and long-term health outcomes, and the evidence of tobacco cessation cost effectiveness. Short-term benefits include and are illustrated by reductions in morbidity and mortality associated with AMI/stroke and low birth-weight deliveries. Overall smoking-attributable mortality would also be reduced, with between 7 and 12.4 years of life gained for each quitter attributable to the mandate, totaling between 222,012 to 393,278 years gained each year under the mandate. The expected reduction in smoking prevalence and mortality attributable to SB 24 would bring California closer to achieving *Healthy People 2010* goals (CHS, 2006).

## APPENDICES

### Appendix A: Text of Bill Analyzed

*SB 24 was introduced on December 4, 2006 by Senator Tom Torlakson. CHBRP analyzed the draft language below with the understanding that it would appear in an amended version of the bill.*

1367.27. (a) A health care service plan contract, except a specialized health care service plan contract, that is issued, amended, delivered, or renewed on or after July 1, 2008, that provides outpatient prescription drug benefits, shall include coverage for the following tobacco cessation services:

(1) Personal counseling via telephone by qualified tobacco counselors.

(2) Brief cessation intervention by a physician of record or clinical staff to establish and record tobacco use status, to advise patients regarding the potential benefits of cessation, and to recommend sources of cessation services.

(3) All prescription and over-the-counter tobacco cessation medications approved by the food and drug Administration to help smokers quit. These drugs include drugs for nicotine replacement therapy and prescription drug therapies in, but not limited to, the form of gum, dermal patch, inhaler, nasal spray and lozenge, and Bupropion SR or similar drugs that counter the urge to smoke or the addictive qualities of nicotine.

(4) Enrollees, beneficiaries, and their providers may select a course of treatment and those services and products that they prefer. Coverage for telephone counseling and medications, whether by prescription or over-the-counter, may be limited to two courses of treatment per year. Referrals for tobacco cessation services, the outcome of the referrals, and the smoking status of referred beneficiaries shall be entered into the patient's medical record.

(b) No copayment or deductible shall be applied to benefits under this section.

(c) A health care service plan may contract with qualified local, statewide, or national providers, whether for profit or nonprofit, for the provision of services under this section.

(d) Coverage for interventions shall include reimbursement for physician advice, charting, and referral.

(e) A health care service plan shall disclose the benefits under this section in its evidence of coverage and disclosure forms and communicate the availability of coverage to all group subscribers.

(f) For the purposes of this section, benefits for tobacco cessation shall comply with the Public Health Service sponsored 2000 clinical practice guideline, "Treating Tobacco Use and Dependence" or its successors.

Sec 2. Section 10123.175 is added to the Insurance Code, to read:

10123.175. (a) Every individual or group health insurance policy that is issued, amended, delivered, or renewed on or after July 1, 2008, that provides outpatient prescription drug benefits, shall include coverage for the following tobacco cessation services:

(1) Personal counseling via telephone by qualified tobacco counselors.

(2) Brief cessation intervention by a physician of record or clinical staff to establish and record tobacco use status, to advise patients regarding the potential benefits of cessation, and to recommend sources of cessation services.

(3) All prescription and over-the-counter tobacco cessation medications approved by the Food and drug Administration to help smokers quit. These drugs include drugs for nicotine replacement therapy and pr4escription drug therapies in, but not limited to, the form of gum, dermal patch, inhaler, nasal spray and lozenge, and Bupropion SR or similar drugs that counter the urge to smoke or the addictive qualities of nicotine.

(4) Enrollees, beneficiaries, and their providers may select a course of treatment and those services and products that they prefer. Coverage for telephone counseling and medications, whether by prescription or over-the-counter, may be limited to two courses of treatment per year. Referrals for tobacco cessation services, the outcome of the referrals, and the smoking status of referred beneficiaries shall be entered into the patient's medical record.

(b) No copayment or deductible shall be applied to benefits under this section.

(c) A health care insurer may contract with qualified local, statewide, or national providers, whether for profit or nonprofit, for the provision of services under this section.

(d) Coverage for interventions shall include reimbursement for physician advice, charting, and referral.

(e) A health insurance policy shall disclose the benefits under this section in its evidence of coverage and disclosure forms and communicate the availability of coverage to all group subscribers.

(f) For the purposes of this section, benefits for tobacco cessation shall comply with the Public Health Service sponsored 2000 clinical practice guideline, "Treating Tobacco Use and Dependence" or its successors.

Sec 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

## Appendix B: Literature Review Methods

Appendix B describes methods used in the medical effectiveness literature review for SB 24. This literature review updates the review CHBRP staff conducted for SB 576 in 2005. Some articles included in this literature review were also included in the literature review for AB 2281, a bill introduced in 2006 that addressed coverage for tobacco cessation services and other preventive services by high-deductible health plans.

The literature search for SB 24 included meta-analyses, systematic reviews, randomized controlled trials, controlled clinical trials, and observational studies. PubMed and the Cochrane library were searched. Web sites of government agencies and other organizations engaged in tobacco cessation activities and research were also searched.

The search was conducted to retrieve literature on four major topics: (1) the effectiveness of tobacco cessation services (including counseling, brief advice, and pharmacotherapy); (2) the impact of coverage for tobacco cessation services on use of services and abstinence from smoking; (3) the cost-effectiveness of tobacco cessation; and (4) the public health effects of tobacco cessation. The medical effectiveness review addressed the first two topics, and the cost and public health reviews addressed the third and fourth topics, respectively.

The medical effectiveness literature search focused on articles published since the literature review for SB 576 was conducted in 2005. The search for literature on the cost effectiveness and public health effects of tobacco cessation encompassed literature published from 1997 to present, because the literature on these topics was not reviewed for the SB 576 report. For all topics, the literature review was limited to articles published in English.

Seven hundred abstracts were reviewed for the literature review for SB 24. 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.

A total of 40 studies were included in the medical effectiveness review, consisting of 10 studies from the SB 576 review, 4 studies from the AB 2281 review, and 26 additional studies.

The review of the effectiveness of tobacco cessation services synthesized findings from meta-analyses and systematic reviews of randomized controlled trials (RCTs), as well as individual RCTs that were not included in the meta-analyses and systematic reviews. Such studies provide the strongest evidence of effectiveness. CHBRP was able to focus its review on such studies because a large number of RCTs have been conducted on the effectiveness of tobacco cessation services.

In contrast, relatively little research has been completed on the impact of coverage for tobacco cessation services on the use of these services and abstinence from smoking. Only 10 studies on these topics were located. Thus, the review on the impact of coverage included several studies with nonrandomized designs as well as RCTs and a meta-analysis.

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

- research design,
- statistical significance,
- direction of effect,
- size of effect, and
- generalizability of findings.

The grading system also contains an overall conclusion that encompasses findings in these five domains. The conclusion is a statement that captures the strength and consistency of the evidence of an intervention's effect on an outcome. The following terms are used to characterize the body of evidence regarding an outcome:

- clear and convincing evidence,
- preponderance of evidence,
- ambiguous/conflicting evidence, and
- insufficient evidence.

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

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

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

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

The search terms used to locate studies relevant to the SB 24 were as follows:

**MeSH Terms**

Smoking Cessation/economics
Smoking Cessation/methods
Smoking Cessation/statistics & numerical data
Smoking/adverse effects
Smoking/economics
Smoking/mortality
Smoking/prevention & control
Smoking/statistics & numerical data
Tobacco Use Cessation/economics
Tobacco Use Cessation/methods
Tobacco Use Disorder/drug therapy
Tobacco Use Disorder/therapy
Tobacco Use/prevention & control
Lung Neoplasms/etiology
Lung Neoplasms/mortality
Lung Neoplasms/prevention & control
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/economics
Coronary Disease/etiology
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
Quality of Life

Mortality
Motivation
Hospitalization
Bupropion/therapeutic use
Clonidine/therapeutic use
Dopamine Uptake Inhibitors/therapeutic use
Nortriptyline/therapeutic use
Varenicline/therapeutic use
Chewing Gum
Nicotine/adverse effects
Nicotine/therapeutic use
Nicotine/administration & dosage
Nicotinic Agonists/administration & dosage
Nicotinic Agonists/therapeutic use
Substance Withdrawal Syndrome/drug therapy
Drugs, Non-Prescription/economics
Drugs, Non-Prescription/therapeutic use
Prescriptions, Drug/economics
Prescriptions, Drug/therapeutic use
Physician's Role
Nurse's Role
Nurse Practitioners
Nursing Care
Physician Assistants
Age Distribution
Sex Distribution
Sex Factors
Insurance, Health
Insurance Coverage
Health Benefit Plans, Employment
Counseling
Counseling/economics
Counseling/methods
Directive Counseling
Behavior Therapy
Group Processes
Hotline
Telephone
Social Supports
Absenteeism
Cost-Benefit Analysis
Cost Control
Cost Sharing
Cost Saving
Financial Management
Drug Costs

Treatment Outcome
Risk
Risk Reduction Behavior
Reward
Survival analysis
Health Expenditures/trends
Outcome and Process Assessment (Health Care)
Quality Assurance, Health Care/economics
Comparative Study
Follow-up Studies
Cohort Studies
Intervention Studies
Prospective Studies
Retrospective Studies
Evidence Based Medicine
Program Evaluation
Cross Sectional Studies
Multicenter Study

**Publication Types**

Evaluation Studies
Meta-Analysis
Multicenter Studies
Practice Guideline
Randomized Controlled Trial
Review
Systematic Review

**Keywords**

smoking cessation, pulmonary function test*, FEV2/FVC, asthma, chronic obstructive pulmonary disease, COPD, angina, myocardial infarction, stroke*, lung cancer, cancer, second hand smok* emergency room visit*, ER visit*, brief intervention*, individual behavioral counseling, counseling, group behavior therapy, telephone counseling, hotlines, cost*, heart attack, decrease, reduction, pregnancy outcome*, nicotine replacement therapy, benefit*, physician assistant*, nurse or nurses, nursing care, nurse practitioner*, prescription, non-prescription, over the counter, patch, nasal spray, nicotine inhaler, chewing gum, nicotine lozenge, bupropion SR, bupropion, clonidine, varenicline, nortriptyline, lighter smoker*, reimbursement, copayment, insurance coverage, health insurance, treatment outcome*, smoking status, vital sign, financial management, quit rate, age, gender, school intervention, effective*, efficiency, effect*, impact, abstinence, recidivism, cost sharing, cost saving, health care cost*, cost control, airway function improve*, cigarette, nicotine dependence, level of smoking, sex, financial incentive*, reimbursement

* indicates truncation

## Appendix C: Description of Studies on Medical Effectiveness of Tobacco Cessation Interventions

Appendix C describes the meta-analyses, systematic reviews, and individual studies on tobacco cessations services that were analyzed by the medical effectiveness team. Tables C-1-a through C-1-c present information regarding the citation, type of study, intervention and comparison groups, population studied, and the location at which a study was conducted. Table C-1-a lists studies that assessed the effects of tobacco cessation counseling and brief advice. Table C-1-b lists studies of the effectiveness of tobacco cessation medications. Table C-1-c lists studies of the impact of cover

**Table C-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 | Individual counseling vs. no intervention | Smokers after 5-months follow-up | N/A[24] |
| Grimshaw and Stanton, 2006 | Meta-analysis | 1. Transtheoretical Model of Change intervention vs. control[25]<br>2. "Not on Tobacco" behavioral intervention vs. control | Smokers aged 20 yrs or less | N/A |
| Lancaster and Stead, 2004 | Meta-analysis | Brief advice vs. no advice (or usual care) | Smokers after 6-months follow-up | N/A |
| Lancaster and Stead, 2005 | Meta-analysis | Face-to-face individual counseling from a health care worker not involved in routine clinical care vs. minimal intervention | Smokers after 6-months follow-up | N/A |
| Rice and Stead, 2004 | Meta-analysis | Advice by a nursing professional vs. no intervention | Adult smokers over 18 yrs, after 6-months follow-up | N/A |
| Rigotti et al., 2002 | Meta-analysis | Intensive intervention (inpatient contact plus follow up for at least one month) vs. usual care | Hospital inpatients after 6-months follow-up | N/A |
| Stead et al., 2006 | Meta-analysis | Proactive telephone support vs. minimal intervention | Smokers after 6-months follow-up | N/A |
| Stead and Lancaster, | Meta-analysis | Group tobacco cessation program vs. minimal contact or no intervention | Smokers after 6-months follow-up | N/A |

[24] Location is not reported for meta-analyses because they synthesize results from multiple studies conducted in multiple locations.
[25] Interventions in the control arm may include: no intervention, delayed intervention, information on stopping smoking, or general tobacco education given to all participants.

| Citation | Type of Trial | Intervention vs. Comparison Group | Population Studied | Location |
|---|---|---|---|---|
| 2005 | | | | |
| Sussman et al., 2006 | Meta-analysis | Cessation programs (including counseling, medical, and environmental interventions) vs. control conditions | 12 to 19 years of age | N/A |
| Bernstein and Becker, 2002 | Systematic review | Brief counseling (<3 minutes counseling) vs. usual care | Emergency department patients, after 6 months follow-up | N/A |
| Lancaster et al., 2006 | Systematic review | Relapse prevention skills training vs. cessation intervention alone or no intervention | People who quit on their own, underwent enforced abstinence, or were in cessation programs | N/A |

**Table C-1-b.** Summary of Published Studies on Effectiveness of Tobacco Cessation Interventions (Pharmacotherapy)

| Citation | Type of Trial | Intervention vs. Comparison Group | Population Studied | Location |
|---|---|---|---|---|
| Silagy et al., 2004 | Meta-analysis | Different forms of NRT vs. placebo or no treatment | Smokers after 6-months follow-up | N/A |
| Fiore et al., 2000 | Meta-analysis | Pharmacotherapy: bupropion SR vs. placebo, nicotine gum vs. placebo | Smokers after 5-months follow-up | N/A |
| Hughes et al., 2007 | Meta-analysis | Pharmacotherapy:<br>1. bupropion vs. placebo<br>2. bupropion and NRT vs. NRT | Smokers after 6-months follow-up | N/A |
| Wu et al., 2006 | Meta-analysis | Pharmacotherapy:<br>1. NRT vs. control<br>2. bupropion vs. placebo<br>3. varenicline vs. placebo<br>4. NRT vs. bupropion<br>5. bupropion vs. varenicline | Smokers after 12-months follow-up | N/A |
| Ludvig et al., 2005 | Systematic review | Pharmacotherapy: bupropion vs. placebo | Smokers after 6-months follow-up | N/A |
| Cahill et al., 2007 | Meta-analysis | Pharmacotherapy: varenicline vs. placebo and bupropion | Smokers after 12-month follow-up | N/A |
| Etter, 2006 | Meta-analysis | Pharmacotherapy: cytisine vs. control | Smokers after various follow-up times | N/A |

**Table C-1-c.** Summary of Published Studies on Effects of Copayments, Coinsurance, and Deductibles on Use of Tobacco Cessation Services and on Abstinence from Smoking

| Citation | Type of Trial | Intervention vs. Comparison Group | Population Studied | Location |
|---|---|---|---|---|
| Kaper, Wagena, Severens, et al., 2005 | Meta-analysis | Comparison of full[26] vs. partial and no coverage | Smokers after 6 month follow-up | N/A |
| Boyle et al., 2002* | Observational study—nonequivalent comparison group | Coverage for tobacco cessation medications vs. no coverage | 2,327 persons who received employer-sponsored health insurance coverage through a group/staff model HMO or a network-based insurer. | United States—Minnesota |
| Curry et al., 1998* | Observational study—two analyses: (1) 3-group pre/post design, (2) 2-group post design | Analysis 1: Coverage for tobacco cessation services in 3 groups: (1) standard plan (50% coverage for behavioral intervention and 100% coverage for nicotine replacement therapy) verses, (2) full plan (100% coverage for behavioral intervention and NRT), and (3) flipped plan (100% coverage for behavioral intervention and 50% coverage for NRT)<br><br>Analysis 2: Comparison based on coverage for tobacco cessation: (1) standard plan (50% coverage for behavioral intervention and 100% coverage for NRT), and (2) reduced plan (50% coverage for behavioral intervention and 50% coverage for NRT)<br><br>Analysis 3: Comparison of standard plan (50% coverage for behavioral intervention and 100% coverage for NRT) to (1) flipped plan (100% coverage for behavioral intervention and 50% coverage for NRT), (2) reduced plan (50% | Analysis 1: 10,669 adults enrolled in a group/staff model HMO<br><br>Analysis 2: 12,386 adults enrolled in a group/staff model HMO<br><br>Analysis 3: 345 adults enrolled in a group/staff model HMO | United States—Washington State |

[26] For purposes of this report, full coverage is defined as 100% coverage for tobacco cessation services (i.e., health plan pays entire cost and does not charge a copayment or coinsurance and does not require an enrollee to meet a deductible before receiving coverage).

| Citation | Type of Trial | Intervention vs. Comparison Group | Population Studied | Location |
|---|---|---|---|---|
| | | coverage for behavioral intervention and 50% coverage for NRT), and (3) full plan (100% coverage for behavioral intervention and NRT) | | |
| Dey et al., 1999* | Randomized controlled trial | Comparison based on coverage for nicotine patches: prescription for free patches vs. prescription for patches at slight discount from retail price | General practice | United Kingdom |
| Halpin, McMenamin, et al., 2006 | Randomized controlled trial | Comparison based on coverage for tobacco cessation: (1) pharmacotherapy only, (2) pharmacotherapy and/or counseling, and (3) pharmacotherapy conditional on participation in counseling | 388 smokers enrolled in a group/staff model HMO | United States—California |
| Hughes et al., 1991* | Randomized controlled trial | Comparisons based on cost-sharing for nicotine gum: (1) free, (2) $6 per box, and (3) $20 per box | 106 adults recruited from rural family practices | United States—rural Vermont |
| Kaper, Wagena, Willemsen, et al., 2005 | Randomized controlled trial | Comparison based on an offer of coverage for NRT, bupropion, and behavioral counseling: Received offer of coverage vs. no offer of coverage | Smokers insured by De Friesland Zorgverzekeraar company | The Netherlands |
| Kaper et al., 2006 | Randomized controlled trial | Comparison based on an offer of coverage for NRT, bupropion, and behavioral counseling: Received offer of coverage vs. no offer of coverage | Smokers insured by De Friesland Zorgverzekeraar company | The Netherlands |
| Petersen et al., 2006 | Observational study—survey data | 15 US states are categorized into three levels of coverage for smoking cessation interventions and compared: (1) extensive (pharmacotherapies and counseling), (2) some (pharmacotherapies or counseling), and (3) none | Analysis 1: 7,513 women enrolled in Medicaid who smoked 3 months before pregnancy<br><br>Analysis 2: 2,898 women enrolled in Medicaid who smoked 3 months before pregnancy and quit smoking during pregnancy | United States—15 States |
| Schauffler et al., 2001* | Randomized controlled trial | Coverage for group behavioral counseling, OTC nicotine replacement therapy, and self-help kit vs. self-help kit alone | 1,204 persons enrolled in two large, independent practice association model HMOs | United States—California |

* Included in the meta-analysis (Kaper, Wagena, Severens, et al., 2005)

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

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

The cost analysis in this report was prepared by the Cost Team which consists of CHBRP task force members and staff, specifically from the University of California, Los Angeles, and Milliman Inc. (Milliman). Milliman is an actuarial firm, and provides data and analyses per the provisions of CHBRP authorizing legislation.

Data Sources

In preparing cost estimates, the Cost Team relies on a variety of data sources as described below.

*Private Health Insurance*

1. The latest (2005) California Health Interview Survey (CHIS, 2005), which is utilized to estimate insurance coverage for California's population and distribution by payer (i.e., employment-based, privately purchased, or publicly financed). The biannual CHIS is the largest state health survey conducted in the United States, collecting information from over 40,000 households. More information on CHIS is available at www.chis.ucla.edu/
2. The latest (2006) California Employer Health Benefits Survey is utilized to estimate:
    - size of firm,
    - percentage of firms that are purchased/underwritten (versus self-insured),
    - premiums for plans regulated by the Department of Managed Health Care (DMHC) (primarily HMOs),
    - premiums for policies regulated by the California Department of Insurance (CDI) (primarily PPOs), and
    - premiums for high deductible health plans (HDHP) for the California population covered under employment-based health insurance.

This annual survey is released by the California Health Care Foundation/Center for Studying Health System Change (CHCF/HSC) and is similar to the national employer survey released annually by the Kaiser Family Foundation and the Center for Studying Health System Change. More information on the CHCF/HSC is available at: www.chcf.org/topics/healthinsurance/index.cfm?itemID=127480

3. Milliman data sources are relied on to estimate the premium impact of mandates. Milliman's projections derive from the Milliman Health Cost Guidelines (HCGs). The HCGs are a health care pricing tool used by many of the major health plans in the United States (see www.milliman.com/tools_products/healthcare/Health_Cost_Guidelines.php). Most of the data sources underlying the HCGs are claims databases from commercial health insurance plans. The data are supplied by health insurance companies, Blues plans,

HMOs, self-funded employers, and private data vendors. The data are mostly from loosely managed health care plans, generally those characterized as preferred provider plans or PPOs. The HCGs currently include claims drawn from plans covering 4.6 million members. In addition to the Milliman HCGs, CHBRP's utilization and cost estimates draw on other data, including the following.

- The MEDSTAT MarketScan Database, which includes demographic information and claim detail data for approximately 13 million members of self-insured and insured group health plans.
- An annual survey of HMO and PPO pricing and claim experience, the most recent survey (2006 Group Health Insurance Survey) contains data from six major California health plans regarding their 2005 experience.
- Ingenix MDR Charge Payment System, which includes information about professional fees paid for health care services, based upon approximately 800 million claims from commercial insurance companies HMOs and self-insured health plans.

These data are reviewed for generalizability by an extended group of experts within Milliman, but are not audited externally

4. An annual survey by CHBRP of the seven largest providers of health insurance in California (Aetna, Blue Cross of California, Blue Shield of California, CIGNA, Health Net, Kaiser Foundation Health Plan, and PacifiCare) to obtain estimates of baseline enrollment by purchaser (i.e., large and small group and individual) type of plan (i.e., DMHC- or CDI-regulated), cost-sharing arrangements with enrollees, and average premiums. Enrollment in these seven firms represents 85% of enrollees in full-service health plans regulated by DMHC and 82% of lives covered by comprehensive health insurance products regulated by CDI.

*Public Health Insurance*

5. Premiums and enrollment in DMHC- and CDI-regulated plans by self-insured status and firm size are obtained annually from CalPERS for active state and local government public employees and their family members who receive their benefits through CalPERS. Enrollment information is provided for fully funded, Knox-Keene licensed health care service plans—which is about 75% of CalPERS' total enrollment. CalPERS self-funded plans—approximately 25% of enrollment—are not subject to state mandates. In addition, CHBRP obtains information on current scope of benefits from health plans' evidence of coverage (EOCs), which is publicly available at www.calpers.ca.gov.
6. Enrollment in Medi-Cal Managed Care (Knox-Keene licensed plans regulated by DMHC) is estimated based on CHIS and data maintained by the Department of Health Services (DHS). DHS supplies CHBRP with the statewide average premiums negotiated for the Two-Plan Model, as well as generic contracts that summarize the current scope of benefits. CHBRP assesses enrollment information online at www.dhs.ca.gov/admin/ffdmb/mcss/RequestedData/Beneficiary%20files.htm.
7. Enrollment data for other public programs: Healthy Families, Access for Infants and Mothers (AIM), and the Major Risk Medical Insurance Program (MRMIP) are estimated based on CHIS and data maintained by the Major Risk Medical Insurance Board

(MRMIB). The basic minimum scope of benefits offered by participating plans under these programs must comply with all requirements of the Knox-Keene Act, and thus these plans are affected by changes in coverage for Knox-Keene licensed plans. CHBRP does not include enrollment in the Post-MRMIB Guaranteed-Issue Coverage Products, because these individuals are already included in the enrollment for individual health insurance products offered by private carriers. Enrollment figures for AIM and MRMIP are included with enrollment for Medi-Cal in presentation of premium impacts. The enrollment information is obtained online at www.mrmib.ca.gov/. Average statewide premium information is provided to CHBRP by MRMIB staff.

General Caveats and Assumptions

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

- prevalence of mandated benefits before and after the mandate may be different from CHBRP assumptions,
- utilization of mandated services before and after the mandate may be different from CHBRP assumptions, and
- random fluctuations in the utilization and cost of health care services may occur.

Additional assumptions that underlie the cost estimates presented in this report are as follows.

- Cost impacts are shown only for people with insurance.
- The projections do not include people covered under self-insured employer plans because those 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.
- For state-sponsored programs for the uninsured, the state share will continue to be equal to absolute dollar amount of funds dedicated to the program.
- When cost savings are estimated, they reflect savings realized for 1 year. Potential long-term cost savings or impacts are estimated if existing data and literature sources are available and provide adequate detail for estimating long-term impacts. For more information on CHBRP's criteria for estimating long-term impacts, please see: http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

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

- Population shifts by type of health insurance coverage. If a mandate increases health insurance costs, then some employer groups or individuals may elect to drop their

coverage. Employers may also switch to self-funding to avoid having to comply with the mandate.

- Changes in benefit plans. To help offset the premium increase resulting from a mandate, members or insured may elect to increase their overall plan deductibles or copayments. Such changes 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). CHBRP did not include the effects of such potential benefit changes in its analysis.
- Adverse selection. Theoretically, individuals or employer groups who had previously foregone 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 the CHBRP cost estimates. The dampening would be more pronounced on the plan types that previously had the least effective medical management (i.e., PPO plans).
- 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 CHBRP modeled (HMO—including HMO and point of service (POS) plans—and non-HMO—including PPO and fee for service (FFS) policies), there are likely variations in utilization and costs by these plan types. Utilization also 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, CHBRP has estimated the impact on a statewide level.

<u>Mandate-Specific Assumptions</u>

CHBRP used the 2002 California Tobacco Survey data and the RAND Health Insurance Experiment's (HIE) estimated impact of cost sharing for well care to estimate pre- and postmandate utilization among smokers who make an attempt to quit. An illustration of our calculations to develop pre- and postmandate utilization by coverage status for NRT is as follows:

*Premandate(Baseline)*

Step 1. (% use of NRT among smokers using CTS data) = (% usage among smokers who attempt to quit ) x (% attempting to quit among smokers )

10.5% = 17.9% x 58.9%

Step 2. (weighted average % relative utilization under various coverage) = ( sum-product of % relative utilization from HIE and % distribution of coverage from CHBRP health plan survey)

63.5% = (45% relative utilization under no coverage) x (51.7% members with no coverage) + (80% relative utilization under partial coverage) x (40.3% with partial coverage) + (100% relative utilization under full coverage) x (8.0% with full coverage).

Step 3a. (% usage among smokers with *full* coverage) = (% usage among smokers) / (weighted average % relative utilization under various coverage) x (100% NRT use under full coverage)

16.5% = 10.5% / 63.5% x 100%

Step 3b. (% usage among smokers with *partial* coverage) = (% usage among smokers ) / (weighted average % relative utilization under various coverage) x (80% NRT use under partial coverage)

13.2% = 10.5% / 63.5% x 80%

Step 3c. (% usage among smokers with *no* coverage) = (% usage among smokers) / (weighted average % relative utilization under various coverage) x (45% NRT use under no coverage)

7.4% = 10.5% / 63.5% x 45%

*Postmandate*

Postmandate, those members currently with partial or no coverage will have full coverage. So, 100% of the weight is given to full coverage. In other words, the utilization among those with full coverage is applied to everybody.

## Appendix E: Public Health Impact Calculations

### Public Health Calculations for AMI and Stroke

*Baseline Population of Interest*
Approximately 1,882,219 smokers are currently insured in California. Under current coverage assumptions based on actuarial data covered in the Utilization, Cost, and Coverage section of this analysis, we expect that approximately 53,507 smokers would quit smoking in any given year, resulting in 1,828,712 remaining smokers.

*Baseline Expected Outcome Estimates Without Mandate*
Lightwood's 1997 study of the effects of California's public health tobacco cessation programs in the incidence of AMI estimates the rate of AMI in the general adult population as 0.219%. Tobacco cessation reduces the incidence of risk of AMI by approximately 32% (Critchley and Capewell, 2003, 2004), bringing the rate of AMI for nonsmokers to 0.149% within the first year after cessation. According to these estimates, we would expect approximately 4,084 ((53,507 × 0.149%) + (1,828,712 × 0.219%)) baseline cases of AMI in the relevant population, without a mandate.

*Expected Outcome Estimates After Mandate*
Based on actuarial data and assumptions listed in the Utilization, Cost, and Coverage section of this analysis, approximately 85,223 smokers would be expected to quit smoking with this mandate, resulting in 1,797,068 remaining smokers. According to these calculations, we would expect a total of 4,062 ((85,223 × 0.149%) + (1,797,068 × 0.219%)) cases of AMI/stroke if SB 24 were enacted. Subtracting the expected AMI/stroke cases (with mandate) from baseline cases (without mandate) equals total expected reduction in AMI/stroke cases due to SB 24 (4,084 – 4,062=22)

Total insured adult smokers: 1,882,219
Total adult smokers who quit annually without mandate: 53,507
Total adult smokers remaining without mandate: 1,828,712

Total adult smokers who quit annually with mandate: 85,223
Total adult smokers after mandate*: 1,797,068
(* derived by subtracting total adult smokers who quit annually with mandate from total insured adult smokers: 1,882,291 – 85,223=1,797,068)

Adult smokers who quit attributable to the mandate*: 31,716
(*derived from smokers who quit without mandate subtracted from smokers who quit with mandate: 85,223 – 53,507=31,716)

Rate of AMI among adult smokers: 0.219%
Rate of AMI among adult nonsmokers: 0.149%
Baseline expected cases of AMI/stroke without mandate: 4,084
Expected cases of AMI/stroke with mandate: 4,062
**Total expected reduction in cases of AMI and stroke due to mandate: 22.**

**Public Health Calculations for Low Birth-Weight Deliveries**

*Baseline Population of Interest*
The California Tobacco Control Section reports that approximately 9% of pregnant women in California are smokers. According to actuarial data from the Utilization, Cost, and Coverage section of this analysis, approximately 28,410 pregnant women smokers are currently insured in California. Of these, approximately 20,727 pregnant smokers have coverage that includes tobacco cessation benefits, and 7,684 pregnant smokers are not covered for these services. After the mandate, we expect that approximately 6,333 smokers would be newly covered for tobacco cessation services, resulting in a total of 27,060 pregnant smokers covered for the benefit.

*Baseline Expected Outcome Estimates Without Mandate: LBW*
The rate of low birth-weight deliveries in California is 7.3% among nonsmokers and 11.9% among smokers (Martin et al., 2002). In general, tobacco cessation quit rates are higher for pregnant smokers than for the general population of smokers. Peterson and colleagues found that 51% of pregnant smokers with full coverage abstained from smoking during pregnancy versus 39% of those without coverage who abstained (Petersen et al., 2006). On the basis of these assumptions, we expect that prior to the mandate, approximately 13,567 women would quit smoking during pregnancy, and we would expect approximately 2,757 low birth-weight deliveries.

*Expected Outcome Estimates With Mandate: LBW*
Under this mandate, a total of 6,333 pregnant 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 it is assumed that the rate of tobacco cessation for those newly covered under the mandate would increase from 39% to 51%, it would be expected that a total of 14,327 women would quit during their pregnancy under this mandate. Applying the low birth-weight rate of 7.3% nonsmokers and 11.9% to the remaining smokers, it is expected that approximately 2,722 low birth-weight deliveries would result under the mandate. **Thus, 35 fewer low birth-weight deliveries statewide are expected in the year following the enactment of SB 24**.

Total insured adult pregnant smokers: 28,410
Quit rate with coverage: 51%
Quit rate without coverage: 39%
Number of pregnant smokers without mandate: 20,727
Number of pregnant smokers with mandate: 27,060
Number of pregnant smokers quitting attributable to mandate: 6,333
Low birth weight rate for smokers: 11.9%
Low birth weight rate for nonsmokers: 7.3%
Baseline expected cases of low birth-weight deliveries: 2,757
Expected cases of low birth-weight deliveries under mandate: 2,722
**Total expected reduction in low birth-weight deliveries due to mandate: 35.**

## Appendix F: Information Submitted by Outside Parties

In accordance with CHBRP policy to analyze information submitted by outside parties during the first 2 weeks of the CHBRP review, the following parties chose to submit information.

**Senator Tom Torlakson,** March 8, 2007

- "Making the Business Case for Smoking Cessation Programs" available at www.businesscaseroi.org.
- "The Business Case for Quality: Case Studies and An Analysis" by Leatherman S, Berwick D, Iles D, et al. *Health Affairs*. Vol. 22, No. 2, pp. 17–30. 2003.
- Agency for Healthcare Research and Quality. "Tobacco Use: Prevention, Cessation, and Control." Available at: www.ahrq.gov/clinic/tp/tobusetp.htm.
- National Institutes of Health State-of-the-Science conference statement: "Tobacco Use: Prevention, Cessation, and Control." *Annals of Internal Medicine*. Vol. 145, No. 11, pp. 839–844. 2006.
- "LA Health." *LA Public Health Letter*. November 2006.
- Additional Internet resources: Tobacco-Free Coalition of Oregon, www.tobaccofreeoregon.org; PACT: Professional Assisted Cessation Therapy, www.endsmoking.org; Tobacco Cessation Leadership Network, www.tcln.org/index.html; and www.cdc.gov/tobacco.

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

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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 the CHBRP Faculty Task Force and staff varies on each report, with individual participants more closely involved in the preparation of some reports and less involved in others.

As required by the CHBRP authorizing legislation, UC contracts with a certified actuary, Milliman Inc. (Milliman), to assist in assessing the financial impact of each benefit mandate bill. Milliman also helped with the initial development of CHBRP methods for assessing that impact.

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

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*Helen Halpin, Nicole Bellows, and Sara McMenamin recused themselves from participation in this review.

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