



CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

**Analysis of Senate Bill 220:
Health Care Coverage: Tobacco
Cessation Services**

A Report to the 2009-2010 California Legislature
June 11, 2010

CHBRP 10-08



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

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

A Report to the 2009-2010 California State Legislature

Analysis of Senate Bill 220: Health Care Coverage: Tobacco Cessation Services

June 11, 2010

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PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Senate Bill 220, a bill to mandate the coverage of tobacco cessation counseling and medications (for health plans that offer outpatient prescription drug coverage) for the treatment of tobacco addiction. In response to a request from the California Assembly Committee on Health on March 12, 2010, and amended language provided on April 22, 2010, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the program's authorizing statute. Edward Yelin, PhD, Janet Coffman, MPP, PhD, and Chris Tonner, MPH, all of the University of California, San Francisco, prepared the medical effectiveness analysis. Min-Lin Fang, MLIS, of the University of California, San Francisco, conducted the literature search. Joy Melnikow, MD, MPH, Stephen McCurdy, MD, MPH, and Dominique Ritley, MPH, all of the University of California, Davis, and Matthew Ingram of the University of California, Berkeley, prepared the public health impact analysis. Shana Lavarreda, PhD, MPP, and Ying-Ying Meng, DrPH, of the University of California, Los Angeles, prepared the cost impact analysis. Robert Cosway, FSA, MAAA provided actuarial analysis. Shu-Hong Zhu, PhD, of the University of California, San Diego, and principal investigator for the statewide, state-funded California Smokers' Helpline, provided technical assistance with the literature review and expert input on the analytic approach. Garen Corbett, MS, of CHBRP staff prepared the background section and synthesized the individual sections into a single report. Sarah Ordódy provided editing services. A subcommittee of CHBRP's National Advisory Council (see final pages of this report) and a member of the CHBRP Faculty Task Force, Sheldon Greenfield, MD, of the University of California, Irvine, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

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

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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Senate Bill 220

The California Assembly Committee on Health requested on March 12, 2010, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical effectiveness and financial and public health impacts of Senate Bill (SB) 220, a bill that would impose a health benefit mandate. On April 22, 2010, the Assembly Committee on Health requested CHBRP analyze language included in further amendments to SB 220, which were made on May 26, 2010. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.

Provisions of SB 220

SB 220 requires health care service plans and health insurance policies¹ that provide outpatient prescription drug benefits to include coverage for the following smoking cessation services, to be selected by the enrollee and the provider:

- Telephone, group, or individual counseling.
- All prescription and over-the-counter (OTC) medications approved by the Food and Drug Administration (FDA) to help smokers quit, including drugs for nicotine replacement therapy (NRT) and prescription drug therapies in, but not limited to, the form of gum, dermal patch, inhaler, nasal spray, and lozenge, varenicline, and bupropion SR² or similar drugs that counter the urge to smoke or the addictive qualities of nicotine.

Conditions placed on the benefit include:

- Counseling and medications may be limited to two courses of treatment per year.
- No copayment, coinsurance, or deductible may be applied to the benefit.
- Benefits shall comply with the U.S. Public Health Service–sponsored 2008 clinical practice guidelines.
- Step therapy³ is prohibited for prescription drugs, and plans and insurers are prohibited from requiring counseling or the completion of a cessation program as part of the cessation benefit.

¹ SB 220 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*.

² Bupropion SR at strengths of 100 or 150 milligrams is the only formulation of bupropion approved by the FDA for smoking cessation. It was originally approved for sale under the brand name Zyban. Other formulations and strengths of bupropion are marketed in the U.S. but are not approved for smoking cessation.

³ *Step therapy* requires an enrollee to try a first-line medication (often a generic alternative) prior to receiving coverage for a second-line medication (often a brand-name medication).

- At least four counseling sessions must be provided for in each course of treatment, each session lasting at least 10 minutes

SB 220 aims to diminish the statewide economic and personal cost of tobacco addiction in California by expanding access to and coverage for smoking cessation services for enrollees in DMHC- and CDI-regulated plans and policies that offer outpatient prescription drugs.

Potential Effects of Health Care Reform

On March 23, 2010, the federal government enacted the federal Patient Protection and Affordable Care Act (P.L.111-148), which was further amended by the Health Care and Education Reconciliation Act (H.R.4872) that the President signed into law on March 30, 2010. These laws (referred to as “PPACA”) came into effect after CHBRP received a request for analysis for SB 220.

There are provisions in the PPACA that go into effect by 2014 and afterwards that would dramatically affect the California health insurance market and its regulatory environment. These major long-term provisions of the PPACA would require that most U.S. citizens and qualified legal residents have health insurance and that large employers offer health insurance coverage or a tax-free credit to their employees. Of particular relevance to the analysis of SB 220, the PPACA would require tobacco cessation treatments to be provided by qualified health plans providing coverage in the small-group and individual markets through the state-based insurance exchanges. Tobacco cessation will be considered part of the “essential health benefits package” to be provided, effective in 2014. Therefore, any effects of SB 220 might be diminished by the PPACA requirements following 2014.⁴ How the provisions of PPACA are implemented in California will largely depend on regulations to be promulgated by federal agencies, and statutory and regulatory actions to be undertaken by the California state government.

There are short-term provisions in the PPACA that go into effect within 6 months or less of enactment that would expand the number of Californians obtaining health insurance and their sources of health insurance. Some of these provisions include:

- Children up to the age of 26 years will be allowed to enroll in their parent’s health plan or policy (effective 6 months following enactment). This provision may decrease the number of uninsured and/or potentially shift those enrolled with individually purchased insurance to group purchased insurance.

⁴ (Subtitle D, Sec. 1302, as modified by Sec. 10104) “Requires the essential health benefits package to provide essential health benefits and limit cost-sharing. Directs the Secretary to: (1) define essential health benefits and include emergency services, hospitalization, maternity and newborn care, mental health and substance use disorder services, prescription drugs, preventive and wellness services and chronic disease management, and pediatric services, including oral and vision care; (2) ensure that the scope of the essential health benefits is equal to the scope of benefits provided under a typical employer plan; and (3) provide notice and an opportunity for public comment in defining the essential health benefits. Establishes: (1) an annual limit on cost-sharing beginning in 2014; and (2) a limitation on the deductible under a small group market health plan.” (CRS, 2010)].

- Denials to offer health insurance due to preexisting conditions will be prohibited (effective 6 months following enactment). This provision may decrease the number of uninsured, or shift enrollment in California Children Services or Healthy Families to those with privately purchased health insurance.
- A temporary high-risk pool for those with preexisting conditions will be established (effective 90 days following enactment). How California chooses to implement this provision would have implications for health insurance coverage for those high-risk individuals who are currently without health insurance and/or are on California's Major Risk Medical Insurance Plan (MRMIP). The federal government does not mandate what benefits are included in temporary high-risk pools.

These and other short-term provisions would affect CHBRP's *baseline* estimates of the number and source of health insurance for Californians in 2010. Given the uncertainty surrounding implementation of these provisions and given that Federal Health Care Reform was only recently enacted, the potential effects of these short-term provisions are not taken into account in the baseline estimates presented in this report. Further information on the provisions of Federal Health Care Reform that would alter the California health insurance market and have relevance to SB 220 is contained in this analysis.

Analytic Approach

For this analysis, CHBRP considered two factors that affect the use of smoking cessation services: benefit coverage and type of tobacco cessation use. Enrollees 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 smoking cessation medications and counseling without a deductible, copayment, or coinsurance. CHBRP uses the 2005 California Tobacco Survey data and the RAND Health Insurance Experiment's (HIE) estimated impact of cost sharing for well care to estimate pre- and post-mandate utilization.

The estimated primary impact of SB 220 is based on data and literature demonstrating increased utilization of smoking cessation treatment(s), as opposed to attempting to quit without any cessation treatment. The total number of people attempting to quit is not increasing post-mandate. In essence, the "denominator" stays the same. It's the "numerator" (utilization of cessation treatments of those attempting to quit) that changes, as more people utilize some combination of counseling and OTC and prescription medications, as opposed to trying to quit without cessation aids, or "cold turkey". While it is possible that the mandate could be the impetus that motivates more people to try to quit (the "denominator"), such an estimate is not provided in this analysis, as that data is not available. Thus, it is possible that the impact of SB 220 may be higher than CHBRP's estimates assuming that successful quit rates approach those in many of the randomized controlled trials; however, it is often the case that the effects in the "real world" may be less than in controlled trials.

Although the bill applies to all covered lives⁵, CHBRP makes the simplifying assumption to exclude adolescents aged 12 to 17 years from the analysis. This age group is typically in the initiation phase, rather than the cessation phase. Additionally, measurement of smoking prevalence in this population is difficult, due to methodological issues around telephone-based surveys of teens (frequently at home, thus potentially understating prevalence), and school-based surveys (potential overstating prevalence rate). 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 tobacco control policies, 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 effectiveness of pharmaceutical and counseling treatments for smoking cessation and the effectiveness of health insurance coverage on changing smoking cessation utilization. The standard CHBRP cost model is applied to the mandate to analyze its 1-year impact. In addition, the short-term impacts of SB 220 on three health outcomes (low-birth weight babies and acute myocardial infarction [AMI]) are analyzed, as the literature points to reductions in health care expenditures that are clearly attributable to smoking cessation. As a preventive service, smoking cessation would be expected to have long-term impacts, and the available literature is reviewed and summarized in the *Public Health Impacts* section.

Medical Effectiveness

Efficacy of Smoking Cessation Treatments

The literature on the efficacy of behavioral interventions (e.g., counseling, brief advice) and pharmaceuticals for smoking cessation is large and includes numerous meta-analyses of randomized controlled trials (RCTs), the strongest form of evidence for CHBRP analyses. These meta-analyses provide clear and convincing evidence that behavioral and pharmacological treatments and combinations of the two improve quit rates and increase the likelihood of sustained abstinence from smoking. These conclusions about the efficacy of smoking cessation interventions are 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.

Behavioral interventions

- There is clear and convincing evidence that use of multiple types of counseling increases smoking cessation.

⁵ CHBRP examines the impacts of SB 220 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.

- Individual, group, and telephone counseling by physicians and other health professionals increases smoking cessation.
- Brief counseling interventions (as little as a few minutes) are effective, and the preponderance of evidence suggests that more intensive counseling is associated with larger effects.
- Psychologists, physicians, pharmacists, and nurses are all effective in providing smoking cessation counseling.
- RCTs that enrolled smokers at high risk for adverse health outcomes (e.g., persons with coronary heart disease, pregnant women) report similar findings to RCTs that enrolled smokers who were not at increased risk relative to other smokers.

Pharmacotherapy

- 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 the following: NRT administered by gum, patch, lozenge, nasal spray, and inhaler; varenicline, a nicotine receptor partial agonist⁶; and the non-nicotine agent bupropion SR, an antidepressant useful in treating certain addiction syndromes. Second-line agents include clonidine and nortriptyline.

Among first-line agents:

- There is clear and convincing evidence that NRT administered by gum, lozenge, patch, nasal spray, and inhaler increases smoking cessation.
- There is also clear and convincing evidence that varenicline and bupropion⁷ increase smoking cessation.
- There is a preponderance of evidence that varenicline is more effective than bupropion.
- There is a preponderance of evidence that smokers who receive a combination of pharmacological agents are more likely to abstain from smoking than persons who receive a single pharmacological agent.

Among second-line agents:

- There is clear and convincing evidence that clonidine and nortriptyline also increase smoking cessation.

⁶ The nicotine receptor partial agonist simulates the effects of nicotine to reduce cravings and the pleasurable effect of smoking cigarettes.

⁷ Although bupropion SR at strengths of 100 or 150 milligrams is the only formulation of bupropion approved by the FDA for smoking cessation, meta-analyses regarding the efficacy of bupropion for smoking cessation do not indicate whether all of the RCTs they included in their analyses assessed bupropion SR. Some of the RCTs included may have evaluated other formulations of bupropion or other strengths of the medication.

- There is a preponderance of evidence that smokers who receive both counseling and pharmacological agents are more likely to abstain from smoking than smokers who only receive counseling.

Generalizability of findings

The rates of abstinence from smoking found in the RCTs summarized above may be greater than those that would be achieved if SB 220 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 treatments under SB 220. 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 Smoking Cessation Treatments

The evidence base from which conclusions can be drawn about the effects of coverage on utilization of smoking cessation treatments and abstinence from smoking is much less robust than the evidence base regarding the efficacy of these treatments.

Use of smoking cessation treatments

- The preponderance of evidence suggests that persons who have full coverage⁸ for NRT and/or bupropion are more likely to use these smoking cessation medications than are persons who do not have coverage for them.
- The evidence of the effect of full coverage for smoking cessation counseling relative to no coverage is ambiguous.
- Findings from single studies suggest that persons who have more generous coverage for NRT and/or counseling are more likely to use these smoking cessation treatments than are persons who have less generous coverage for them.

Abstinence from smoking

- The preponderance of evidence suggests that full coverage for smoking cessation counseling and pharmacotherapy is associated with improved abstinence from smoking relative to no coverage for smoking cessation treatments.
- The evidence of the effect of more generous coverage for smoking cessation counseling and pharmacotherapy relative to less generous coverage on abstinence from smoking is ambiguous.

⁸ For purposes of this report, full coverage for smoking cessation treatments is defined as coverage of 100% of costs associated with tobacco cessation medications and counseling without a deductible, copayment, or coinsurance. Partial coverage refers to coverage that requires users to pay a share of the cost of treatment (e.g., a copayment).

Benefit Coverage, Utilization, and Cost Impacts

Nearly 19.5 million Californians are currently enrolled in health care service plans regulated by the California Department of Managed Health Care (DMHC) and health insurance policies regulated by the California Department of Insurance (CDI). SB 220 mandates that all enrollees in DMHC- or CDI-regulated plans or policies with outpatient prescription drug coverage would also be offered no-cost smoking cessation services, but does not mandate that all plans or policies offer prescription drug coverage. Therefore, the coverage increase in 2011 would immediately affect the 97% of enrollees that have coverage for prescription drugs, or 18.89 million individuals (Table 1). Under SB 220, all enrollees with outpatient prescription drug coverage would also have full coverage for smoking cessation services, including counseling, NRT (either available over the counter or through a prescription), or prescription medication for smoking cessation, at no cost to the individual. In this section, we focus on the impact of SB 220 on increasing premium costs among all 19.5 million enrollees with plans or policies subject to mandate, and on the estimated increase of utilization of smoking cessation treatment among the 1.83 million adult smokers with current prescription drug coverage, since they will be the population who might attempt to quit using services covered by this newly mandated benefit coverage.

Coverage Impacts

- Currently, enrollees in all DMHC- and CDI-regulated plans and policies with drug coverage largely have some coverage for cessation interventions with cost sharing, but the rates of coverage vary by type of service.
- Eight in ten (81.7%) enrollees have full or partial coverage for smoking cessation-related counseling, 57.4% have full or partial coverage for OTC smoking cessation treatment, and 77.8% have full or partial coverage for prescription smoking cessation treatment (Table 1). If SB 220 were enacted, 100% of insured adults with drug coverage would have full coverage for smoking cessation services.
- Medi-Cal, which covers 2.6 million adults subject to the mandate (13.8%), already provides comprehensive smoking cessation benefits at no charge to enrollees.

Utilization Impacts

- CHBRP used the 2005 California Tobacco Survey data and the RAND Health Insurance Experiment's (HIE) estimated impact of cost sharing for well care to estimate pre- and post-mandate utilization. Pre-mandate, of the 1.83 million adult smokers enrolled in DMHC- or CDI-regulated plans or policies with drug coverage, 268,344 used one or more smoking cessation treatments, with 203,845 using treatments covered through their existing insurance and 64,500 enrollees using treatments for which they were uninsured.
- Post-mandate, of the 1.83 million insured adult smokers with outpatient prescription drug coverage, CHBRP estimated that the utilization of counseling services would increase by 34.3%, OTC treatments by 54.2%, and prescription treatments by 37.2% (Table 1).

- All together, the utilization of one or more smoking cessation treatments would increase by 44.2%, representing an additional 118,482 insured adult smokers getting treatment, after the mandate.

Cost Impacts

- Increases in per member per month (PMPM) premiums for the newly mandated benefit coverage vary by market segment (Table 5 in *Utilization, Cost, and Benefit Coverage Impacts*). Increases as measured by percentage changes in PMPM premiums are estimated to range from a low of 0.00% (for DMHC-regulated Medi-Cal HMO plans for ages 65+) to a high of 0.37% (for CDI-regulated individual policies) in the affected market segments. Increases as measured by PMPM premiums are estimated to range from \$0.00 to \$0.67.
- In the privately funded large-group market, the increase in premiums is estimated to range from \$0.38 PMPM among DMHC-regulated plan contracts to \$0.56 PMPM among CDI-regulated policies (Table 5 in *Utilization, Cost, and Benefit Coverage Impacts*).
- For enrollees in privately funded small-group insurance policies, health insurance premiums are estimated to increase by approximately \$0.49 PMPM for DMHC contracts to \$0.65 PMPM for CDI policies.
- In the privately funded individual market, the health insurance premiums are estimated to increase by \$0.58 PMPM and by \$0.67 PMPM in the DMHC- and CDI-regulated markets, respectively.
- In the publicly funded DMHC-regulated health plans, CHBRP estimates that premiums would remain flat for Medi-Cal HMOs, Healthy Families, and CalPERS HMOs, with the impact ranging from 0.00% to 0.07% (\$0.00 to \$0.26).
- Total net annual health expenditures are projected to increase by \$52.7 million (0.07%) (Table 1). This is due to an \$83.7 million increase in health insurance premiums partially offset by reductions in both enrollee copayments (\$10.4 million) and out-of-pocket expenditures (\$20.6 million).
- The net increase of \$52.7 million could also be reduced by a savings of \$1.04 million in health care spending, representing the potential short-term (i.e., 1-year) savings resulting from a reduction of less than ten fewer low-birth weight deliveries and hospitalizations due to AMI among those who quit smoking.
- In addition to gaining short-term savings in health expenditures, those who quit smoking may experience measurable long-term improvements in health status. Although the cost estimates presented are for one year only, 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, and individuals personally bear additional medical costs related to smoking. 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.

Public Health Impacts

SB 220 would likely have a positive impact on public health in California, based on (1) the scientific evidence of the medical effectiveness of smoking cessation treatments, (2) the likely increase in utilization of smoking cessation treatments and resultant abstinence associated with SB 220, (3) the positive impact of smoking cessation on both short- and long-term health outcomes, and (4) the cost effectiveness of smoking cessation.

- In California, the prevalence of smoking in the insured adult population is 14.2% resulting in 34,492 deaths annually (2007). The prevalence is among the lowest in the U.S., but above the *Healthy People 2010*⁹ goal of 12%.
- There is evidence to suggest that SB 220 would increase utilization of smoking cessation treatments, with approximately 118,482 insured adult smokers shifting from self-help to obtaining OTC and/or prescription medications and/or counseling services. As a result of this increase in utilization, it is estimated that an additional 8,081 smokers would successfully quit smoking annually.
- Prevalence of smoking and related health conditions differs by race, ethnicity, and gender. There are insufficient data for CHBRP to assess the extent to which SB 220 would modify gender and racial disparities for smoking and its associated health outcomes.
- During the first year of implementation, CHBRP estimates that a reduction of fewer than 10 cases of AMI and fewer than 10 low-birth weight deliveries would be attributable to SB 220 annually. These estimates are based on the insured California population and evidence-based literature.
- There is a preponderance of evidence that SB 220 would contribute to the reduction in premature death from long-term smoking-related diseases such as cancer and cardiovascular and respiratory diseases. When the estimates of increased longevity for quitters are applied to the projected 8,081 additional smokers who successfully quit each year attributable to the SB 220 mandate, approximately 56,567 to 100,204 years of potential life may be gained in the state each year.
- Smoking-related productivity loss in California in 2004 was about \$8.5 billion. Both direct costs (i.e., tobacco-related medical care) and indirect costs, (i.e., those associated with poorer quality of life among current smokers relative to quitters) are reduced by smoking cessation.

⁹ Published by the U.S. Department of Health and Human Services, *Healthy People 2010* establishes a set of health objectives for the U.S. to achieve over the first decade of the new century. States, local communities, professional organizations, and others use them to develop programs to improve health.

There is sufficient evidence to conclude that SB 220 would reduce smoking and its concomitant economic loss.

Smoking cessation treatment is cost-effective. This conclusion is supported by over two decades of health economics literature and is supported by America's Health Insurance Plans, a trade group representing health insurers, which recommends coverage of clinical treatments for smoking cessation as a cost-effective business investment. Smoking cessation compares favorably with treatment and prevention for other common health conditions with respect to cost effectiveness. For example, the cost for treating high blood pressure ranges between \$5,000 to \$45,000 per life-year gained, whereas smoking cessation treatment is estimated to cost a few hundred to a few thousand dollars per life-year gained.

Table 1. SB 220 Impacts on Benefit Coverage, Utilization, and Cost, 2010

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Benefit Coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	19,487,000	19,487,000	-	0.00%
Total enrollees with health insurance subject to SB 220	19,487,000	19,487,000	-	0.00%
Percentage of enrollees with coverage for smoking cessation counseling (b)				
No coverage	18.3%	0.0%	-18.3%	-100.00%
Coverage with cost sharing	66.9%	0.0%	-66.9%	-100.00%
Full coverage with no cost sharing	14.8%	100.0%	85.2%	576.91%
Number of enrollees with coverage for smoking cessation counseling				
No coverage	3,466,161	-	(3,466,161)	-100.00%
Coverage with cost sharing	12,635,494	-	(12,635,494)	-100.00%
Full coverage with no cost sharing	2,791,000	18,892,655	16,101,655	576.91%
Percentage of enrollees with coverage for OTC smoking cessation treatment (c)				
No coverage	42.6%	0.0%	-42.6%	-100.00%
Coverage with cost sharing	42.6%	0.0%	-42.6%	-100.00%
Full coverage with no cost sharing	14.8%	100.0%	85.2%	576.91%
Number of enrollees with coverage for OTC smoking cessation treatment				
No coverage	8,056,673	-	(8,056,673)	-100.00%
Coverage with cost sharing	8,044,982	-	(8,044,982)	-100.00%
Full coverage with no cost sharing	2,791,000	18,892,655	16,101,655	576.91%
Percentage of enrollees with coverage for prescription smoking cessation treatment (c)				
No coverage	22.2%	0.0%	-22.2%	-100.00%
Coverage with cost sharing	63.0%	0.0%	-63.0%	-100.00%
Full coverage with no cost sharing	14.8%	100.0%	85.2%	576.91%
Number of enrollees with coverage for prescription smoking cessation treatment				
No coverage	4,203,474	-	(4,203,474)	-100.00%
Coverage with cost sharing	11,898,182	-	(11,898,182)	-100.00%
Full coverage with no cost sharing	2,791,000	18,892,655	16,101,655	576.91%
Utilization and Cost				
Number of enrollees who smoke and use:				
Counseling	122,747	164,854	42,107	34.30%
OTC treatments	192,304	296,536	104,232	54.20%
Prescription drug treatments	63,419	86,984	23,565	37.16%
At least one treatment	268,344	386,826	118,482	44.15%
Average cost per course of treatment				
Counseling	\$200	\$200	\$0	0.00%
OTC treatments	\$236	\$236	\$0	0.00%
Prescription drug treatments	\$240	\$240	\$0	0.00%

Table 1. SB 220 Impacts on Benefit Coverage, Utilization, and Cost, 2010 (Cont'd)

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Expenditures				
Premium expenditures by private employers for group insurance	\$43,519,324,000	\$43,570,630,000	\$51,306,000	0.12%
Premium expenditures for individually purchased insurance	\$5,992,795,000	\$6,007,684,000	\$14,889,000	0.25%
Premium expenditures by individuals with group insurance, CalPERS HMOs, Healthy Families Program, AIM or MRMIP (d)	\$12,820,614,000	\$12,835,829,000	\$15,215,000	0.12%
CalPERS HMO employer expenditures (e)	\$3,267,842,000	\$3,270,036,000	\$2,194,000	0.07%
Medi-Cal HMOs state expenditures	\$4,015,596,000	\$4,015,596,000	\$0	0.00%
Healthy Families Program state expenditures (f)	\$910,306,000	\$910,409,000	\$103,000	0.01%
Enrollee out-of-pocket expenses for covered benefits (deductibles, copayments, etc.)	\$5,961,186,000	\$5,950,748,000	-\$10,438,000	-0.18%
Enrollee expenses for noncovered benefits (g)	\$20,615,000	\$0	(\$20,615,000)	-100.00%
Total Annual Expenditures	\$76,508,278,000	\$76,560,932,000	\$52,654,000	0.07%

Source: California Health Benefits Review Program, 2010.

Notes: (a) This population includes privately insured (group and individual) and publicly insured (e.g., CalPERS HMOs, Medi-Cal HMOs, Healthy Families Program, AIM, and MRMIP) individuals enrolled in health insurance products regulated by DMHC or CDI. Population includes enrollees aged 0-64 years and enrollees 65 years or older covered by employment-sponsored insurance.

(b) Includes telephone, individual, and group counseling.

(c) Includes all 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

(d) Premium expenditures by individuals include employee contributions to employer-sponsored health insurance and member contributions to public insurance.

(e) Of the CalPERS employer expenditures, about 58% or \$71,920 would be state expenditures for CalPERS members who are state employees.

(f) Healthy Families Program state expenditures include expenditures for 7,000 covered by the Major Risk Medical Insurance Program (MRMIP) and 7,000 covered by the Access for Infants and Mothers (AIM) program.

(g) Reflects enrollee out-of-pocket expenses for benefits that would become a covered benefit if SB 220 is enacted.

Key: AIM=Access for Infants and Mothers; CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health Care.

INTRODUCTION

The California Assembly Committee on Health requested on March 12, 2010, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical effectiveness and financial and public health impacts of Senate Bill (SB) 220, a bill that would impose a health benefit mandate. On April 22, 2010, the Assembly Committee on Health requested CHBRP to analyze language included in further amendments to SB 220, which were made on May 26, 2010. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.

Potential Effects of Health Care Reform

On March 23, 2010, the federal government enacted the federal Patient Protection and Affordable Care Act (P.L.111-148), which was further amended by the Health Care and Education Reconciliation Act (H.R.4872) that the President signed into law on March 30, 2010. These laws (referred to as the "PPACA") came into effect after CHBRP received a request for analysis for SB 220.

There are provisions in the PPACA that go into effect by 2014 and afterwards that would dramatically affect the California health insurance market and its regulatory environment. These major long-term provisions of the PPACA would require that most U.S. citizens and qualified legal residents have health insurance and that large employers offer health insurance coverage or a tax-free credit to their employees. Of particular relevance to the analysis of SB 220, the PPACA would require health plans to include tobacco cessation treatment in the small-group and individual markets through the state-based insurance exchanges. How these provisions are implemented in California will largely depend on regulations to be promulgated by federal agencies, and statutory and regulatory actions to be undertaken by the California state government.

There are short-term provisions in the PPACA that are effective within 6 months of enactment that would expand the number of Californians obtaining health insurance and their sources of health insurance. Other provisions take effect over the next several years. Some of the key provisions relevant to this analysis include:

- Children up to the age of 26 years will be allowed to enroll in their parent's health plan or policy (effective 6 months following enactment). This provision may decrease the number of uninsured and/or potentially shift those enrolled with individually purchased insurance to group purchased insurance.
- Denials to offer health insurance due to preexisting conditions will be prohibited (effective 6 months following enactment). This provision may decrease the number of uninsured, or shift enrollment in California Children Services or Healthy Families to those with privately purchased health insurance.
- A temporary high-risk pool for those with preexisting conditions will be established (effective 90 days following enactment). How California chooses to implement this provision

would have implications for health insurance coverage for those high-risk individuals who are currently without health insurance and/or are on California’s Major Risk Medical Insurance Plan (MRMIP).

- Required preventive services would include those rated “A” or “B” by the U.S. Preventive Services Task Force (USPSTF)¹⁰; Providing tobacco cessation interventions to those who use tobacco products is rated a Grade A. Combination therapy with counseling and medications is considered more effective than either component alone.
- Tobacco cessation will be considered part of the essential health benefits package to be provided by qualified health plans providing coverage in the small-group and individual markets through the state-based insurance exchanges, effective in 2014. Therefore, any effects of SB 220 might be diminished by the PPACA requirements following 2014.¹¹ The PPACA also requires plans and policies to cover preventive services with no copayments, while preventive services will be exempt from deductibles.
- For individuals enrolled in High-Deductible Health Plans (HDHPs) with Health Savings Accounts, SB 220 will interact with a change in the tax treatment of over-the-counter (OTC) medications. Starting in 2011, reimbursement of over-the-counter smoking cessation products will be treated as a taxable distribution.¹²

These and other short-term provisions would affect CHBRP’s *baseline* estimates of the number and source of health insurance for Californians in 2010. Given the uncertainty surrounding implementation of these provisions and given that Federal Health Care Reform was only recently enacted, the potential effects of these short-term provisions are not taken into account in the baseline estimates presented in this report.

Background of Disease or Condition

Tobacco use in the United States is the leading preventable cause of death. An estimated 443,000 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. Smoking cessation—that is, quitting completely—is the only safe alternative (CDC, 2009).

¹⁰ **Grade A:** The USPSTF strongly recommends that clinicians provide [the service] to eligible patients. *The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.* **Grade B:** The USPSTF recommends that clinicians provide [this service] to eligible patients. *The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.*

¹¹ (Subtitle D, Sec. 1302, as modified by Sec. 10104) “Requires the essential health benefits package to provide essential health benefits and limit cost-sharing. Directs the Secretary to: (1) define essential health benefits and include emergency services, hospitalization, maternity and newborn care, mental health and substance use disorder services, prescription drugs, preventive and wellness services and chronic disease management, and pediatric services, including oral and vision care; (2) ensure that the scope of the essential health benefits is equal to the scope of benefits provided under a typical employer plan; and (3) provide notice and an opportunity for public comment in defining the essential health benefits. Establishes: (1) an annual limit on cost-sharing beginning in 2014; and (2) a limitation on the deductible under a small group market health plan.” (CRS, 2010)].

¹² Per personal correspondence (May 21, 2010) with Kevin Knopf, Treasury Department. Mr. Knopf cites The Preventive Care Safe Harbor, which is in Notice 2004-23.

Smoking 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, 2006). Common forms of smoking cessation treatment include counseling, nicotine replacement therapy (NRT) such as gum or a patch, and the antidepressant bupropion SR (brand names = Zyban),¹³ as well as prescription cessation medications such as varenicline (brand name = Chantix). A number of public and private interests have recommended smoking cessation aids as a cost-effective treatment for tobacco-related diseases.¹⁴

Background of SB 220

Approximately 19.5 million Californians (51%) have health insurance that may be subject to a health benefit mandate law passed at the state level (CHBRP, 2010). Of the rest of the population, a portion is uninsured, and therefore is not affected by health insurance benefit mandate laws. Others have health insurance that is not subject to health insurance benefit mandate laws because those health plans or health policies are subject to other state or federal laws.

Uniquely, California has a bifurcated system of regulation for health insurance subject to state law. The California Department of Managed Health Care (DMHC)¹⁵ regulates health care service plans, which offer coverage for benefits to their enrollees through health plan contracts. The California Department of Insurance (CDI) regulates health insurers¹⁶, which offer coverage for benefits to their enrollees through health insurance policies.

SB 220 mandates that health care service plans and individual and group health insurance policies that provide outpatient prescription drug coverage shall include two courses of treatment in a 12-month period for smoking cessation. A course of treatment is defined as personal counseling, which may be telephone, group, or individual counseling, and FDA-approved medication, including prescription and OTC medications. Covered treatment shall comply with the U.S. Public Health Service–sponsored 2008 clinical practice guideline, “Treating Tobacco Use and Dependence: 2008 Update,” or its successors. This guideline recommends that health plans and health insurers provide coverage for individual, group, and telephone counseling, as well as for nicotine replacement therapy (all forms), bupropion SR, and varenicline. *Appendix G* contains a complete list of the recommendations set forth in the guideline. Additionally, SB 220

¹³ Bupropion SR in strengths of 100 or 150 milligrams is the only antidepressant that the FDA has approved for tobacco cessation, but physicians may prescribe other formulations and strengths of bupropion and other antidepressants (e.g., Prozac) off-label.

¹⁴ The U.S. Public Health Service’s *Treating Tobacco Use and Dependence* (Fiore et al., 2008) states that tobacco dependence treatments are “both clinically effective and highly 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/apps/calculator/calcintrio.aspx>.

¹⁵ The DMHC was established by the Knox-Keene Health Care Service Plan of 1975. See Health and Safety Code, Section 1340.

¹⁶ The CDI licenses “disability insurers.” Disability insurers may offer forms of insurance that are not health insurance. This report considers only the impact of the benefit mandate on health insurance policies, as defined in Insurance Code, Section 106(b) or subdivision (a) of Section 10198.6.

would prohibit applying copayments, deductibles, or coinsurance to these mandated tobacco-cessation products, and prohibit step therapy.

SB 220 seeks to diminish the statewide economic and personal cost of tobacco addiction by making cessation treatments available to all smokers¹⁷. According to the bill author, California has successfully reduced tobacco consumption in the last decade, but despite that success, tobacco use is responsible for the unnecessary deaths of 40,000 residents and remains the leading cause of preventable death in this state. Annually, tobacco addiction costs California \$8.6 billion in direct medical costs, which is approximately 12% of all health care costs. Providing smoking cessation counseling and medication is one of the most clinically effective and cost-effective health services available, second only to inoculations. SB 220 aims to diminish the statewide economic and personal cost of tobacco addiction in California by expanding coverage for smoking cessation services.

SB 220 requires health care service plans and health insurance policies¹⁸ that provide outpatient prescription drug benefits to include coverage for the following smoking cessation services, to be selected by the enrollee and the provider:

- Telephone, group, or individual counseling.
- 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).

Conditions placed on the benefit include:

- Telephone, group, or individual counseling and medications may be limited to two courses of treatment per year.
- At least four counseling sessions must be provided in each course of treatment, each session lasting at least 10 minutes.
- No copayment, coinsurance, or deductible may be applied to the benefit.
- Step therapy¹⁹ and prior authorization requirements are prohibited for smoking cessation treatments.
- Enrollees shall not be required to enter counseling in order to receive tobacco cessation medications.

¹⁷ SB 220 only applies to DMHC- and CDI-regulated plans that offer outpatient prescription drug coverage.

¹⁸ SB 220 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*.

¹⁹ *Step therapy* requires an enrollee to try a first-line medication (often a generic alternative) prior to receiving coverage for a second-line medication (often a brand name medication).

- Benefits shall comply with the U.S. Public Health Service–sponsored 2008 clinical practice guidelines.

See *Appendix A* for the full text of the analyzed provisions.²⁰

CHBRP analyzed similar language in 2005 (Ortiz, SB 576) and 2007 (Torlakson, SB 24). CHBRP analyzed an amendment to SB 24 that was not introduced. Nevertheless, the CHBRP analysis was published and it estimated that approximately 43.1% of those in DMHC- and CDI-regulated plans and policies had coverage for OTC medications (NRT), 64.5% had coverage for counseling services, and 59.4% had coverage for prescription medications for smoking cessation. As will be discussed in further detail in the *Utilization, Cost, and Benefit Coverage Impacts* section, the percentage of enrollees in DMHC- and CDI-regulated plans and policies (based on CHBRP’s surveys) with OTC medications coverage (NRT) has increased to 68.7%, coverage for smoking cessation counseling has increased to 80.9%, and today 98.9% have partial or full coverage for prescription medications for smoking cessation.

Overview of Analytic Approach

The use of smoking cessation services is affected by two factors considered by CHBRP for this analysis: benefit coverage and type 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 smoking cessation medications and counseling without a deductible, copayment, or coinsurance. Furthermore, quitting smoking is a dynamic process, involving different types of assistance (Figure 1).

The estimated primary impact of SB 220 is based on data and literature demonstrating increased utilization of smoking cessation treatment(s), as opposed to attempting to quit without any cessation treatment. The total number of people attempting to quit is not increasing post-mandate. In essence, the “denominator” stays the same. It’s the “numerator” (utilization of cessation treatments of those attempting to quit) that changes, as more people utilize some combination of counseling, OTC, and prescription medications as opposed to trying to quit smoking without smoking cessation aids or “cold turkey”. While it is possible that the mandate could be the impetus to increase the number of people attempting to quit (the “denominator”), such an estimate is not provided in this analysis, as that data is not available. Thus, it is possible that the impact of SB 220 may be higher than CHBRP’s estimates assuming that successful quit rates approach those in many of the randomized controlled trials; it is often the case that the effects in the “real world” may be less than in controlled trials.

SB 220 includes the requirement that enrollees not be required to enter counseling in order to receive smoking cessation medications. It also stipulates that plans shall not impose prior authorization or stepped-care requirements on smoking cessation treatment. These requirements would have an unknown effect, and so CHBRP assumed the effect would be nonexistent for the purposes of the cost model contained in this report.

²⁰ SB 220 contains modifications of the language in SB 24, which was analyzed by CHBRP in 2007 and can be found at http://www.chbrp.org/completed_analyses/index.php.

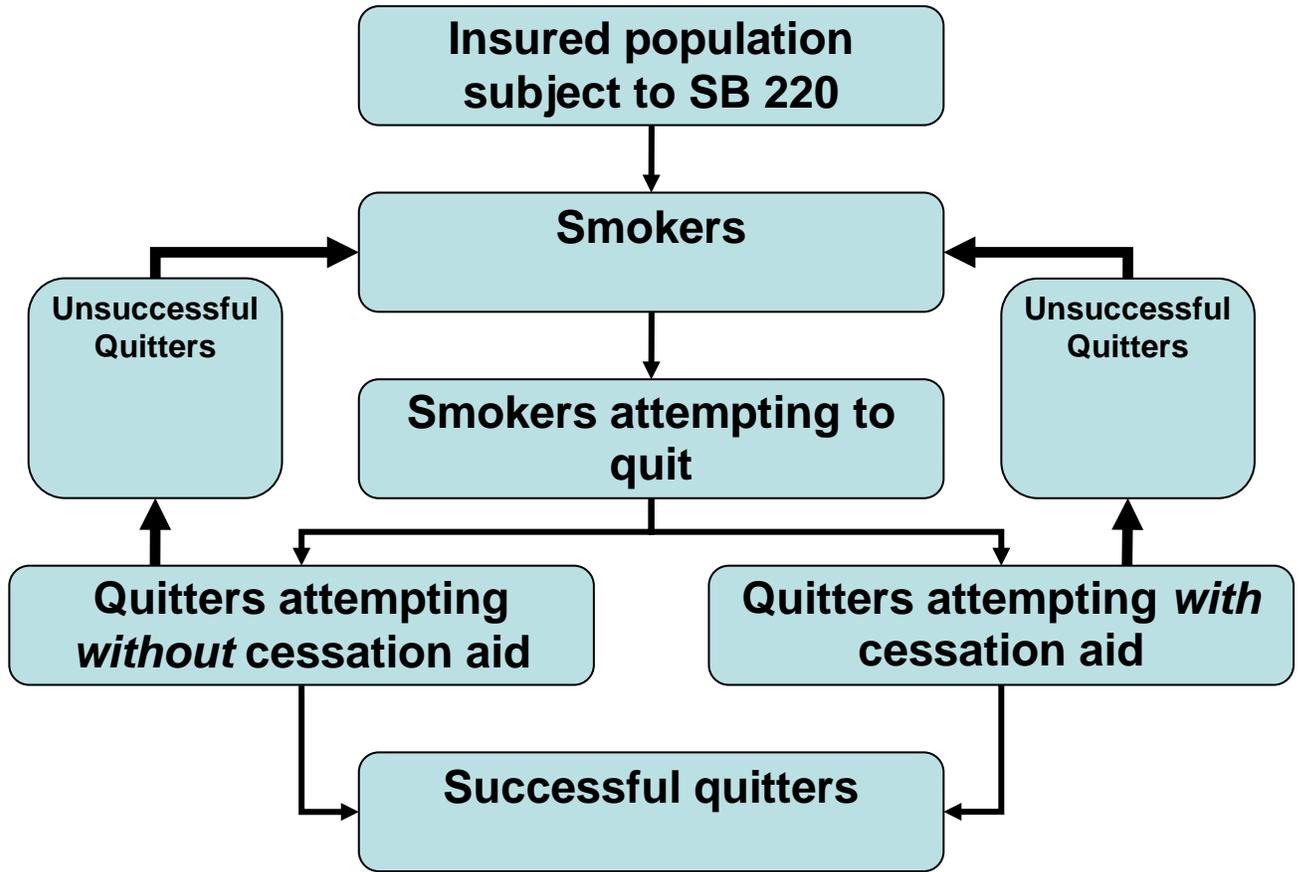
Although the bill applies to all covered lives²¹, CHBRP makes the simplifying assumption to exclude adolescents aged 12 to 17 years from the analysis. This age group is typically in the initiation phase, rather than the cessation phase. Additionally, measurement of smoking prevalence in this population is difficult, due to methodological issues around telephone-based surveys of teens (frequently at home, thus potentially understating prevalence), and school-based surveys (potential overstating prevalence rate). Moreover, public health campaigns that target youth predominantly focus on smoking prevention.

Other tobacco control policies, 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 effectiveness of pharmaceutical and counseling treatments for smoking cessation and the effectiveness of health insurance coverage on changing smoking cessation utilization. The standard CHBRP cost model is applied to the mandate to analyze its 1-year impact. In addition, the short-term impacts of SB 220 on two health outcomes (low-birth weight babies and acute myocardial infarction [AMI]) are analyzed. As a preventive service, smoking cessation would be expected to have long-term impacts, and the available literature is reviewed and summarized in the *Public Health Impacts* section.

²¹ CHBRP examines the impacts of SB 220 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 Smoking Cessation Services Benefit



Other State Activities

Currently, six states (Colorado, Maryland, New Jersey, New Mexico, Oregon, and Rhode Island) mandate coverage for smoking cessation treatment (ALA, 2009). Colorado requires health plans to cover “tobacco use screening of adults and tobacco cessation interventions by primary care providers” not subject to any deductible or coinsurance (copayment allowable) “in accordance with” U.S. Preventive Services Task Force (USPSTF) A and B recommendations.²² Maryland’s mandate requires plans that cover prescription drugs to cover two 90-day courses of NRT in a policy year (excluding OTC) with copayment or coinsurance amounts equal to comparable prescriptions.²³ New Jersey requires coverage of physician-determined treatment up to limits ranging from \$125 to \$235, based on age and gender. New Mexico requires that HMO contracts that provide maternity benefits also offer coverage for smoking cessation treatment.²⁴ The law states that such coverage may be subject to deductibles and coinsurance consistent with those imposed on other benefits of the contract, and regulation requires coverage of diagnostic services, two 90-day prescription drug courses per year (not OTC), and individual or group counseling.²⁵ Oregon requires coverage up to a lifetime limit of \$500 for smoking cessation treatment, including both “educational and medical” component following U.S. Public Health Service guidelines.²⁶ Rhode Island requires coverage of OTC and prescription cessation medications as well as 16 half-hour counseling sessions.²⁷ North Dakota requires smoking cessation coverage in its standardized plan available to small employers. Tobacco dependence treatment programs are partially covered by Medicaid programs in 37 states, and comprehensively covered²⁸ in 13 states, including California (Halpin et al., 2006).

California Activities

California is a national leader 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 (“secondhand 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). In addition, tobacco settlement monies provide 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.

²² Colorado Revised Statutes 10-16-104 (18) (b) (IX)

²³ Maryland Insurance Code Section 15-841

²⁴ New Mexico Code Section 59A-46-45

²⁵ New Mexico Administrative Code 13-10-18

²⁶ Oregon Revised Statutes 743A.170

²⁷ Rhode Island General Laws Section 27-41-70

²⁸ Defined in this survey to mean coverage for NRT, Zyban (bupropion), and individual or group counseling.

The 2008-2009 budget for the California Tobacco Control Program (CTCP) was \$54.6 million (CDPH, 2009). 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. The CTCP also provides financing for a wide variety of other anti-smoking programs. In addition to funding local health departments' efforts, the CTCP maintains a competitive grant program for nonprofit organizations engaging in work on tobacco control and smoking intervention at the local level (accounting for \$15.4 million of program spending in 2007-2008), supplementing its statewide media and advocacy work.²⁹ The CTCP also maintains the Tobacco Education Clearinghouse of California (TECC), offering a library of over 20,000 tobacco-related materials available for borrow as well as professional research assistance and other research and support services.³⁰

²⁹ <http://www.cdph.ca.gov/programs/tobacco/Pages/CTCPLocalStatewideProjects.aspx>

³⁰ <http://www.tobaccofreecatalog.org/>

MEDICAL EFFECTIVENESS

As noted in the *Introduction*, SB 220 defines smoking cessation treatments to include personal counseling and all medications approved by the FDA for smoking cessation, including all prescription and over-the-counter (OTC) medications. The medical effectiveness review summarizes findings from literature on two topics: (1) the efficacy of specific types of smoking cessation services, and (2) the effects of health insurance coverage for smoking cessation services.

Literature Review Methods

Studies of the effects of smoking cessation treatments and coverage for these treatments were identified through searches of PubMed, the Cochrane Library, the Cumulative Index of Nursing and Allied Health Literature, EconLit, PsycInfo, and SCOPUS. Web sites maintained by the following organizations that produce and/or index meta-analyses and systematic reviews were also searched: the Agency for Healthcare Research and Quality, the International Network of Agencies for Health Technology Assessment, the National Health Service Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence, and the Scottish Intercollegiate Guideline Network. The search was limited to abstracts of studies published in English. The search was limited to studies published from 2007 to present, because CHBRP had previously conducted thorough literature searches on these topics in 2005 and 2007 for SB 576, and SB 24, respectively. A total of 34 studies were included in the medical effectiveness review for SB 220, including 11 studies from the SB 576 review, 11 additional studies from the SB 24 review, and 12 new studies published since the literature review for SB 24 was completed in 2007.³¹ A more thorough description of the methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure is presented in *Appendix B: Literature Review Methods*.

The literature on behavioral and pharmacological treatments 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, CHBRP relied to the extent feasible on these meta-analyses. Where meta-analyses were not available, CHBRP drew upon individual RCTs and nonrandomized studies with comparison groups. 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*.

Outcomes Assessed

In most studies reviewed, abstinence from smoking is the primary outcome measured to evaluate the efficacy of smoking cessation interventions. Although measurement of continuous abstinence

³¹ In some cases, more current versions of meta-analyses and systematic reviews included in the SB 576 and SB 24 reports were included in the literature review for the SB 220 report. Several of the Cochrane reviews on the efficacy of smoking cessation treatments that were cited in the SB 576 and SB 24 reports were updated and re-issued following CHBRP's release of the SB 24 report in 2007. For example, Lancaster and Stead (2008) is an update of a Cochrane review that these authors initially published in 2004. In addition, the U.S. Public Health Service (PHS) issued a new version of its evidence-based guideline for treatment of tobacco dependence in 2008 (Fiore et al., 2008). The new version included meta-analyses that incorporated findings from studies published since the previous version of the PHS guideline was released in 2000.

is desirable, studies have used varying definitions of relapse, which creates difficulty in evaluating the effects of treatments on prolonged abstinence rates. However, because most relapses occur within the first 3 months after smoking cessation, many meta-analyses and systematic reviews of the literature only include those studies with follow-up of at least 5 months (Fiore, 2008). Thus, in evaluating the effectiveness of specific behavioral and pharmacological treatments, the medical effectiveness analysis includes only studies that assessed abstinence from smoking for at least 5 months. The majority of studies rely on self-reported abstinence while some use biochemically validated measures of abstinence that are likely to be more accurate.

For studies of the impact of coverage for smoking cessation services, CHBRP assessed effects on two outcomes: (1) use of smoking cessation services, and (2) abstinence from smoking. CHBRP's decision to analyze both of these outcomes reflects the causal pathway by which coverage for smoking cessation services could affect abstinence from smoking. As discussed below, CHBRP found a large body of evidence indicating that use of smoking cessation counseling and pharmacotherapy increases the likelihood that smokers will abstain from smoking. Coverage for smoking cessation services could increase the likelihood that smokers will use these services and, thus, increase the likelihood that they will abstain from smoking.

Types of Smoking Cessation Treatments

Smoking cessation treatments 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, pharmacists, peer counselors, pharmacists, 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 are medications approved by FDA for smoking cessation. Second-line agents are medications that have a greater risk of side effects than first-line agents and have not been approved by the FDA for smoking cessation but which have been found to be effective for that purpose (Fiore et al., 2008). First-line agents for smoking cessation include NRT administered by gum, patch, nasal spray, inhaler, and lozenge, varenicline (brand name = Chantix), a nicotine partial receptor agonist, and the non-nicotine agent bupropion SR (brand name = Zyban),³² an antidepressant medication used in smoking cessation. The FDA has approved the use of bupropion SR and varenicline³³ for smoking cessation among people who smoke 10 or more cigarettes daily and are at least 18 years of age. Second-line agents include clonidine and nortriptyline.

³² Bupropion SR in strengths of 100 or 150 milligrams (brand name = Zyban) is the only formulation of bupropion approved by FDA for smoking cessation. Other formulations and strengths of bupropion are approved only for treatment of depression.

³³ In May of 2008, the FDA released a Public Health Advisory about the possibility of adverse mood and behavior in patients taking varenicline, available at <http://www.fda.gov/drugs/drugsafety/publichealthadvisories/ucm051136>.

Efficacy of Smoking Cessation Treatments

CHBRP considers it highly unlikely that the conclusions this report draws about the efficacy of smoking cessation treatments will be diminished or altered with the publication of new individual studies. This is because of the magnitude of the literature, the consistently positive results with respect to specific treatments, and the quality of the research designs. CHBRP published analyses of the efficacy of smoking cessation treatments for SB 576 in 2005 and SB 24 in 2007 that reached much the same conclusion as the present analysis.

The rates of abstinence from smoking reported by the meta-analyses and systematic reviews summarized in this report may be greater than those that would be achieved in “real-world” settings if SB 220 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 220. 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

The principal behavioral intervention for smoking cessation is counseling, provided in person to individuals or groups or to individuals over the telephone. The evidence summarized in meta-analyses indicates that counseling increases smoking cessation.

Individual counseling

Fiore et al. (2008)³⁴ 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 ratio³⁵ = 1.7) when compared to no intervention. Mottillo et al. (2009) evaluated the effects of individual counseling across 23 RCTs and found a significant effect on biochemically validated cessation of at least 6 months (odds ratio = 1.5).

³⁴ The Fiore et al. (2008) report incorporates findings from meta-analysis performed for the Fiore et al. (2000) report and includes new meta-analysis performed on studies regarding new treatments for tobacco cessation (e.g., varenicline) that were published since Fiore et al. (2000) was issued.

³⁵ Odds ratios and risk ratios both compare the likelihood of an event. An odds ratio compares the relative odds of an event in each group while a risk ratio (sometimes called the relative risk) compares the probability of an event in each group.

Rice and Stead (2008) evaluated the evidence from 31 RCTs comparing individual advice by a nursing professional to no intervention. Advice from a nursing professional was found to have a favorable and statistically significant effect on smoking cessation at 6 or 12 months (odds ratio = 1.3).

Lancaster and Stead (2008) evaluated the evidence from 22 RCTs and quasi-randomized trials of face-to-face individual counseling from a health care worker not involved in routine clinical care versus minimal intervention. They reported that such counseling was associated with a favorable impact on smoking cessation at 6 months (odds ratio = 1.4).

Group counseling

Stead and Lancaster (2009) summarized the information in eight RCTs comparing group smoking 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 = 2.7). A meta-analysis by Fiore et al. (2008) found that participation in group smoking cessation counseling was associated with a modest increase in smoking cessation compared to no intervention (odds ratio = 1.3). Mottillo et al. (2009) evaluated the effects of group counseling across 12 RCTs and found significant effect on biochemically validated cessation of at least 6 months (odds ratio = 1.8).

Counseling provided over the telephone

Three meta-analyses have assessed the efficacy of telephone-based smoking cessation counseling versus minimal intervention. Telephone counseling interventions have been classified into two categories: (1) proactive counseling in which all counseling is initiated by counselors, and (2) reactive counseling in which smokers initiate counseling by calling a counseling service, usually through a toll-free telephone number (Stead et al., 2009). California and a number of other states operate quitline counseling services under which smokers initiate counseling and may choose to receive additional, proactive calls from counselors (Fiore et al., 2008; Stead et al., 2009).

Stead et al. (2009)³⁶ reviewed the results of 44 RCTs and quasi-randomized trials of proactive telephone counseling versus minimal intervention, reporting that telephone proactive counseling was associated with a favorable effect on smoking cessation at 6 months (odds ratio = 1.5).

Stead et al. (2009) also reviewed the results of nine RCTs and quasi-randomized trials of quitline telephone counseling versus minimal intervention, reporting that quitline counseling was associated with a favorable effect on smoking cessation at 6 months (odds ratio = 1.3). Fiore et al. (2008) analyzed the results of nine RCTs examining the effects of quitline telephone counseling to minimal or no intervention. At 5 months, the odds of smoking cessation were 1.6 higher for smokers in the quitline intervention group compared to the controls.

³⁶ In the Stead et al., 2009, and Stead et al., 2008a, meta-analyses, the authors reports relative risk ratios. However, in order to report outcomes in a manner consistent with the other meta-analysis, CHBRP converted the relative risk ratios to odds ratios.

Mottillo et al. (2009) evaluated the effects of telephone counseling across 10 RCTs of both proactive and reactive telephone counseling interventions. This meta-analysis found that telephone counseling had a statistically significant effect on biochemically validated cessation of at least 6 months (odds ratio = 1.6).

Brief counseling

Fiore et al. (2008) summarized seven RCTs on advice by physicians of 3 minutes or less versus no advice and reported a modest increase in the odds of smoking cessation at 5 months (odds ratio = 1.3).

Stead, Bergson, et al. (2008a) summarized 17 RCTs and quasi-randomized trials evaluating the effects of minimal³⁷ physician advice versus no advice or usual care and observed that minimal advice was associated with a favorable effect on cessation either at 6 or 12 months (odds ratio = 1.6).

Mottillo et al. (2009) summarized nine RCTs on the effects of brief advice delivered during a regular clinical visit compared to only self-help materials or no treatment. They found the odds of biochemically validated cessation to be 1.5 times higher in the counseling group at 6 months; however, this was not statistically significant.

Summary of findings regarding effects of counseling: Overall, the meta-analyses of counseling interventions provide clear and convincing evidence that individual, group, and telephone counseling increase rates of smoking cessation. The magnitude of the average increase in successful smoking cessation ranges from 2 to 13 percentage points relative to no counseling or self-help materials.³⁸

Counseling intensity

Three meta-analyses analyzed the effects of the intensity of counseling on abstinence from smoking. In the first of the meta-analyses, Fiore et al. (2008) reviewed seven studies that assessed the effects of low-intensity counseling (3-10 minutes) and higher intensity (>10 minutes) compared to no counseling. The authors reported a favorable effect of low-intensity and higher intensity when compared to no counseling (odds ratio = 1.6 and 2.3, respectively) on rates of cessation at 5 months. In a second meta-analysis, Fiore et al. (2008) compared the effect of the number of treatment sessions on abstinence from smoking across 46 trials. The number of treatment sessions was categorized into a control group, having had 0 to 1 sessions, and three treatment groups: having 2 to 4 sessions, 4 to 8 sessions, and >8 sessions. The authors report increasingly favorable effects in a step-wise fashion with increasing number of sessions (odds ratio = 1.4 for 2 to 4 sessions; 1.9 for 4 to 8 sessions; 2.3 for >8 sessions, respectively, when compared to receiving 0 to 1 session). An important limitation of Fiore et al.'s (2008) analyses of

³⁷ The amount of contact time for physician advice varied across the trials. Contact time varied from less than 5 minutes to advice lasting less than 20 minutes, while a few studies did not specify the length of contact time other than a report of "brief advice."

³⁸ The range in increase of percentage points does not include estimates from the Fiore et al. (2008) meta-analyses as the Fiore et al. (2008) report does not include the data necessary to calculate such increases in a manner consistent with other meta-analyses included in our review.

the effects of longer counseling sessions and more counseling sessions is that the authors made indirect comparisons across RCTs and did not examine any RCTs that directly compared low-intensity to high-intensity counseling.

Stead, Bergson, et al. (2008) summarized 15 RCTs and quasi-randomized trials that directly compared the impact of more intensive versus minimal advice and found a modest and statistically significant difference favoring more intensive advice (odds ratio = 1.5).

In the Lancaster and Stead (2008) meta-analysis of 5 studies that directly compared brief counseling to more intensive counseling, there was no difference in 6-month cessation rates among individuals who received brief counseling compared to individuals who received more intensive counseling.

Overall, the preponderance of evidence indicates that smokers who receive more intensive counseling are more likely to abstain from smoking than those who receive less intensive counseling.

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 smoking cessation counseling (Fiore et al., 2008; Mojica et al., 2004). The Mojica et al. (2004) meta-analysis synthesized a larger number of studies, including those included in the Fiore et al. (2008) meta-analysis. Mojica et al. (2004) concluded that psychologists, physicians, and nurses are all effective in delivering smoking cessation counseling and that none of the three types of health professionals was substantially more effective than the others. A systematic review of studies on counseling delivered by community pharmacy personnel suggest a positive effect on cessation rates; however, the strength of the evidence is limited because only two RCTs have been published on this topic (Sinclair et al., 2008).

The preponderance of evidence suggests that multiple types of health professionals can provide effective smoking cessation counseling.

Effects of Pharmacotherapy

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 are medications approved by the FDA for smoking cessation that generally have less severe side effects than second-line medications. Second-line medications are medications that are not approved by the FDA for smoking cessation but which have been found to be effective (Fiore et al., 2008). First-line agents for smoking cessation include the following: NRT administered by gum, patch, nasal spray, lozenge, and inhaler; varenicline, a nicotine receptor partial agonist³⁹; and the non-

³⁹ The nicotine receptor partial agonist simulates the effects of nicotine to reduce cravings and the pleasurable effect of smoking cigarettes.

nicotine agent bupropion SR, an antidepressant useful in treating certain addiction syndromes. Second-line agents include clonidine and nortriptyline.

First-line agents

NRT. The large majority of CHBRP findings on NRT are drawn from three meta-analyses (Eisenberg et al., 2008; Fiore et al., 2008; Stead, Perera, et al., 2008). These three meta-analyses include some of the same studies; however, the stringency of inclusion criteria differed among them. The Eisenberg et al. (2008) meta-analysis only included studies that reported biochemically validated abstinence and used a placebo for a control. The Fiore et al. (2008) analyses included studies that measured biochemically or self-report abstinence and used a placebo for a control. The Stead, Perera, et al. (2008) analyses included studies that measured biochemically or self-report abstinence and used either a placebo or no treatment for a control.

Nicotine gum. Independently, Fiore et al (2008); Stead, Perera, et al. (2008); and Eisenberg et al. (2008) synthesized the literature on the effect of nicotine gum on smoking cessation rates. Fiore et al. (2008) pooled four RCTs on the effects of using nicotine gum for more than 14 weeks, and reported that use of nicotine gum compared to placebo was associated with a favorable effect on smoking cessation rates at the end of 6 months (odds ratio = 2.2). Fiore et al. (2008) also pooled nine RCTs on shorter-term gum use (6 to 14 weeks) and reported a 1.5 increase in the odds of cessation at 6 months. Stead, Perera, et al. (2008) integrated results from 53 RCTs, again showing that using nicotine gum increases the likelihood a person will abstain from smoking (odds ratio = 1.4). Eisenberg et al. (2008) reached the same conclusions in a meta-analysis of 22 RCTs that reported biochemically verified abstinence at 6 months or more following initiation of treatment (odds ratio = 1.7)

Overall, nicotine gum has a favorable effect on smoking cessation rates. The magnitude of the average increase in successful smoking cessation ranges from 5 to 7 percentage points.

Nicotine patch. Four teams of researchers have conducted meta-analyses of the substantial literature on nicotine patches. Fiore et al. (2008) performed three separate meta-analyses. The first pooled four studies on high-dose nicotine patch use (>25 mg) and reported a 2.3 increase in odds of smoking cessation at 6 months compared to placebo. The second pooled eight studies on long-term nicotine patch use (>14 weeks) and the third meta-analysis pooled 25 studies on shorter-term (6 to 14 weeks) nicotine patch use. For both longer- and shorter-term use of the patch there was an increase of 1.9 in the odds of cessation. Stead, Perera, et al. (2008) summarized the results from 41 RCTs of the effect of the nicotine patch compared to placebo or no treatment on smoking cessation after 6 months, reporting that the patch was associated with a favorable outcome (odds ratio = 1.6). Eisenberg et al. (2008) also found the patch to be associated with greater odds of biochemically verified abstinence at or over 6 months (odds ratio = 2.1) in meta-analyses of 36 RCTs. Myung et al. (2007) reached the same conclusions when evaluating biochemically verified abstinence at 12 months in 16 RCTs (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, increasing these by approximately 5 to 6 percentage points.

Nicotine lozenge. Stead, Perera, et al. (2008) found six RCTs 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 in terms of smoking cessation rates at 6 months following treatment (odds ratio = 2.0; difference in abstinence rates = 8 percentage points). Eisenberg et al. (2008) also found a twofold increase in the odds of cessation at or over 6 months when using a nicotine tablet compared to placebo in six RCTs that reported biochemically verified abstinence.

Nicotine inhaler. Fiore et al. (2008), Stead, Perera, et al. (2008) and Eisenberg et al. (2008) pooled findings from RCTs on the effect of nicotine inhalers on smoking cessation rates. The Fiore et al. (2008) meta-analysis found six RCTs and observed that nicotine inhaler use was associated a higher rate of smoking cessation at the end of 6 months when compared to either placebo or no treatment (odds ratio = 2.1). Stead and colleagues found four RCTs meeting their inclusion criteria. They observed a favorable outcome in smoking cessation at 6 months when compared to either placebo or no treatment (odds ratio = 1.9). In a meta-analysis of four studies by Eisenberg et al. (2008), the use of an inhaler compared to placebo showed a twofold increase in the odds of cessation at or beyond 6 months, but the results were not statistically significant.

The preponderance of the limited number of RCTs on the efficacy of nicotine inhalers suggest that they have a favorable effect on smoking cessation rates, increasing these by approximately 8 percentage points.

Nicotine nasal spray. Fiore et al. (2008); Stead, Perera, et al. (2008); and Eisenberg et al. (2008) analyzed the literature on the effectiveness of nicotine nasal spray. Although there are fewer RCTs on nicotine nasal spray than on nicotine gum or nicotine patches, the results are similar. Specifically, Fiore et al. (2008) pooled four RCTs 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 6 months (odds ratio = 2.3). Stead, Perera, et al. (2008) pooled four studies, reporting a favorable outcome at the end of 6 months (odds ratio = 2.0) and Eisenberg et al. (2008) reported an increase of 2.4 in the odds of cessation at 6 months or more. Use of nicotine nasal spray is associated with a 12 percentage point increase in smoking cessation rates.

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

Summary of findings regarding effects of NRT: There is clear and convincing evidence that all forms of NRT increase abstinence from smoking when compared to a placebo or no treatment. The evidence favoring nicotine patches is especially robust. Use of NRT is associated with a 5 to 12 percentage point increase in the likelihood that a person will abstain from smoking relative to a placebo.⁴⁰

⁴⁰ The range of risk differences (i.e., percentage point differences in smoking cessation rates) does not include estimates from the Fiore et al. (2008) meta-analyses as the Fiore et al. (2008) report does not include the data necessary to calculate such increases in a manner consistent with other meta-analyses included in our review. Estimates from Eisenberg et al. (2008) are not included for nicotine lozenge, nicotine inhaler, and nicotine nasal spray because the article did not contain the data necessary to calculate risk differences.

Bupropion SR (brand name: Zyban). Meta-analyses conducted by Fiore et al. (2008), Hughes et al. (2010), and Eisenberg et al. (2008) evaluated the evidence on the effect of bupropion,⁴¹ an antidepressant agent approved for use in smoking cessation. Fiore et al. (2008) analyzed data from 24 RCTs and reported that bupropion had a favorable effect on smoking cessation rates when compared to placebo or no treatment at the end of 6 months (odds ratio = 2.0). Hughes et al. (2010) included 36 RCTs comparing bupropion to either placebo or no treatment, and reported a favorable effect on smoking cessation rates at the end of 6 months (risk ratio = 1.7). Eisenberg et al. (2008) analyzed data from 16 RCTs and found similar effects of bupropion SR on biochemically confirmed abstinence at or beyond 6 months (odds ratio = 2.1). Adverse effects of bupropion have been reported and may include an increase in the risk for seizures and suicidal thoughts or behavior (U.S. FDA, 2009; GlaxoSmithKline, 2009).

Summary of findings regarding effects of bupropion: There is clear and convincing evidence that bupropion is associated with a statistically significant increase in the likelihood of abstaining from smoking of 8 to 9 percentage points relative to a placebo.⁴²

Varenicline (brand name: Chantix). Fiore et al. (2008), Cahill et al. (2008), and Eisenberg et al. (2008) evaluated the evidence on the effect of varenicline compared to a placebo on smoking cessation. Fiore et al. (2008) reviewed four smoking cessation RCTs at 6 months; varenicline was found to have a favorable effect. A dose of 2 milligrams per day was associated with a greater effect than a dose of 1 milligram per day (odds ratios = 3.1 and 2.1, respectively). At 6-month follow-up or greater, both Cahill et al. (2008)⁴³ and Eisenberg et al. (2008) found varenicline to increase the likelihood of quitting smoking compared to placebo (Cahill: relative risk = 2.3, Eisenberg: odds ratio = 2.4). Adverse effects of varenicline may include an increase in the risk for depressed mood, agitation, changes in behavior, and suicidal thoughts or behavior (U.S. FDA, 2009).

Summary of findings regarding effects of varenicline: There is clear and convincing evidence that varenicline is associated with a statistically significant increase in the likelihood of abstaining from smoking of 11 to 18 percentage points relative to a placebo.⁴⁴

⁴¹ Bupropion SR in strengths of 100 or 150 milligrams is the only formulation of bupropion approved by the FDA for smoking cessation. Fiore et al. (2008) and Hughes et al. (2010) do not indicate whether their meta-analyses were limited to RCTs on the efficacy of bupropion SR. Some of the RCTs included in their meta-analyses may have evaluated other formulations of bupropion. Eisenberg et al. (2008) only included RCTs that examined bupropion SR.

⁴² The range of risk differences (i.e., percentage point differences in smoking cessation rates) does not include estimates from the Fiore et al. (2008) meta-analyses as the Fiore et al. (2008) report does not include the data necessary to calculate such increases in a manner consistent with other meta-analyses included in our review.

⁴³ Cahill et al. (2009) reported that all trials included in their meta-analysis on varenicline were funded and managed by Pfizer Inc., the manufacturer of varenicline.

⁴⁴ The range of risk differences (i.e., percentage point differences in smoking cessation rates) does not include estimates from the Fiore et al. (2008) meta-analyses as the Fiore et al. (2008) report does not include the data necessary to calculate such increases in a manner consistent with other meta-analyses included in our review.

The comparative effectiveness of varenicline to bupropion on smoking cessation has also been studied. Eisenberg et al. (2008) reported that varenicline has a favorable effect relative to bupropion SR (odds ratio = 2.2). Cahill et al. (2008) and Hughes et al. (2010) reached a similar conclusion.⁴⁵

Summary of findings regarding effects of first-line therapies: There is clear and convincing evidence that all forms of first-line therapy, including the multiple modes of administration of NRT, bupropion SR, and varenicline, increase smoking cessation rates. However, population surveys undertaken in California have found that NRT is less effective in facilitating long-term abstinence outside RCTs and that having a smoke-free home improves effectiveness of both NRT and bupropion SR (see page 36).

Second-line therapy

In this section, the focus of attention is on second-line pharmacological agents (i.e., agents used when initial attempts to quit are not successful)—specifically, clonidine and nortriptyline—on which meta-analyses have been published in English-language journals.

Clonidine. Fiore et al. (2008) analyzed the effects of clonidine compared to placebo on smoking cessation in three RCTs. The findings at 6 months indicate that clonidine is superior to placebo for smoking cessation (odds ratio = 2.1). Gourlay et al. (2008) performed a meta-analysis on six RCTs and found a positive effect of clonidine on 3-month cessation rates when compared to placebo (odds ratio = 1.6).

Nortriptyline. In a meta-analysis of four studies the use of nortriptyline almost doubled the likelihood of smoking cessation at 6 months compared to placebo (Fiore et al., 2008). Hughes et al. (2010) found a similar result in a meta-analysis of six studies that compared nortriptyline to either placebo or no pharmacotherapy at 6 months or greater (odds ratio = 2.0).

Summary of findings regarding effect of second-line therapies: Meta-analyses of the small number of studies on clonidine and nortriptyline provide clear and convincing evidence that they are effective in increasing smoking cessation rates relative to a placebo, increasing these approximately 10 to 11 percentage points.⁴⁶

⁴⁵ Cahill et al. (2008) and Hughes et al. (2010) do not indicate whether their meta-analyses were limited to RCTs on that assessed bupropion SR in strengths of 100 or 150 milligrams, the only formulation of bupropion approved by the FDA for smoking cessation. Some of the RCTs included may have evaluated other formulations of bupropion. Eisenberg et al. (2008) only included RCTs that examined bupropion SR.

⁴⁶ The range of risk differences (i.e., percentage point differences in smoking cessation rates) does not include estimates from the Fiore et al. (2008) meta-analyses as the Fiore et al. (2008) report does not include the data necessary to calculate such increases in a manner consistent with other meta-analyses included in our review.

Effects of Combination Therapies

CHBRP summarized the findings from meta-analyses that examined the effect of (1) adding medication to counseling, and (2) using a combination of medications for smoking cessation. Fiore et al. (2008) pooled nine studies that compared the combination of counseling and medication to counseling alone. Results showed that adding medication to counseling significantly increased the odds of cessation (odds ratio = 1.7). These authors also pooled data from three studies on the effect of using the NRT patch plus NRT gum or spray compared to placebo. Using this combination resulted in a tripling in the likelihood of cessation at 6 months. Similarly, when combining the NRT patch with bupropion⁴⁷ or with an NRT inhaler, the odds of cessation more than doubled when compared with placebo. Lastly, Shah et al. (2008) compared the effects of using the NRT patch with another first-line medication compared to a single medication. At 6 months, the odds of cessation were 1.5 times higher among those taking combined medications compared to a single medication.

Summary of findings regarding effects of combination therapies: The preponderance of evidence from studies of combination therapy suggests that they have a favorable effect on smoking cessation rates when compared to placebo or single medications, increasing these approximately 10 percentage points.⁴⁸

Generalizability of pharmacotherapy findings to Californians affected by SB 220

Two nonrandomized population studies have assessed the effectiveness of pharmacotherapy for smoking 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 RCTs, they provide important insights into its effectiveness when administered outside of RCTs, 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 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 SR (with or without NRT) were more likely to abstain from smoking than were smokers who did not use this

⁴⁷ Fiore et al. (2008) do not indicate whether their meta-analysis was limited to RCTs on the efficacy of bupropion for smoking cessation assessed bupropion SR in strengths of 100 or 150 milligrams, the only formulation of bupropion approved by the FDA for smoking cessation. Some of the RCTs included may have evaluated other formulations of bupropion.

⁴⁸ The range of risk differences (i.e., percentage point differences in smoking cessation rates) does not include estimates from the Fiore et al. (2008) meta-analyses as the Fiore et al. (2008) report does not include the data necessary to calculate such increases in a manner consistent with other meta-analyses included in our review.

drug. This study also found that bupropion SR 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 an RCT and that both NRT and bupropion SR are more likely to be effective for smokers who have smoke-free homes.

Efficacy of Treatments for Major Subpopulations

Some meta-analyses have assessed the effect of smoking cessation counseling and pharmacotherapy on smoking cessation rates among subgroups of smokers, including pregnant women, persons in inpatient settings, and persons with various medical conditions, including coronary heart disease and chronic obstructive pulmonary disease (COPD).

Pregnant women

Lumley et al. (2009) assessed the effects of smoking cessation treatments (behavioral and/or pharmacotherapy) in pregnant women. A review of 65 RCTs demonstrated a significant reduction (6%) in smoking during late pregnancy. During the postpartum period, however, the results of 14 RCTs suggest that prenatal interventions promote continued cessation up to 1 to 5 months post-delivery, but cease to be effective from 6 to 12 months post-delivery. Fiore et al. (2008) reviewed eight RCTs of smoking cessation counseling interventions in pregnant women and reported biochemically confirmed cessation rates to be higher (odds ratio= 1.8) in the intervention group when measured in late pregnancy, but found no continued effect of the intervention when measured at 5 months postpartum. The 2008 U.S. Public Health Service (PHS) guidelines did not make a recommendation regarding medication in pregnant women, as there is inconclusive evidence on the safety and effectiveness of smoking cessation medication use during pregnancy.

Inpatient and chronic conditions

Rigotti et al. (2008) analyzed the results of 17 RCTs and quasi-randomized trials to evaluate the impact of inpatient smoking cessation counseling 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 = 1.7).

Barth et al. (2008) analyzed the results of 16 RCTs in patients with coronary heart disease and found that behavioral interventions including counseling and advice increased the odds of quitting smoking (odds ratio= 1.7) after 6 to 12 months.

Strassmann et al. (2009) analyzed the effects of smoking cessation counseling in patients with chronic obstructive pulmonary disease (COPD) in six RCTs. At 6 months, the odds of cessation were not statistically different from the controls.

There is less robust literature on the effect of combining smoking cessation medications with counseling on smoking cessation rates among smokers with multiple types of medical conditions. In one meta-analysis including RCTs among hospitalized patients, using NRT or bupropion did not increase cessation beyond the effects of counseling alone (Rigotti et al., 2008). Other RCTs on medication use among patients with COPD and patients admitted to ER for chest pain were conditioned on also receiving counseling interventions (Bock et al., 2008; Strassman et al., 2009). Findings from these trials indicate that pharmacotherapy and counseling are effective in reducing smoking rates among these subgroups⁴⁹.

Summary of findings regarding effects on subpopulations: Overall, the preponderance of evidence from the meta-analyses of counseling interventions indicates that smoking cessation treatments are effective among multiple subpopulations of smokers.

Effects of Health Insurance Coverage for Smoking Cessation Treatments

CHBRP reviewed evidence of the medical effectiveness of health insurance coverage for smoking cessation treatments on two outcomes:

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

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; Bush et al., 2008; Cummings et al., 2010; Swartz et al., 2005).

⁴⁹ Nicotine gum and nicotine inhalers are not recommended for persons with cardiac conditions, because of their rapid delivery and high concentrations of nicotine. However, these persons can safely use nicotine patches, which deliver nicotine more slowly

Three nonrandomized studies were excluded from the review because they did not have comparison groups and did not present information about use of smoking cessation treatments 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 smoking cessation treatments 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 smoking cessation medications were treated by physicians who had been trained in the provision of smoking cessation treatments. In this study, the effects of coverage for smoking cessation medications cannot be separated from the effects of physician education. This study is not useful for the analysis of SB 220, because this bill only addresses coverage for smoking cessation treatments; it would not mandate physician education in smoking cessation treatment.

Use of Smoking Cessation Treatments

One meta-analysis was found that assessed the impact of coverage for smoking cessation treatments on use of these services (Kaper, Wagena, Severens, et al., 2005)⁵⁰. 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; Schaffler 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 coverage⁵¹ 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 smoking cessation treatments 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 (Schaffler 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.

⁵⁰ The content of the Kaper, Wagena, Severens, et al. (2005) was updated by Reda et al. in 2009. In the Reda et al. (2009) update, the authors defined the categories of coverage differently than in the Kaper, Wagena, Severens, et al. (2005) study. In the Reda et al. (2009) study, full coverage was defined as financial coverage for both pharmacotherapy and behavioral interventions; partial coverage was defined as financial coverage for pharmacotherapy or behavioral intervention. While financial coverage was not explicitly defined in the Kaper, Wagena, Severens, et al. study (2005), the aim and analyses examine the different levels of financial coverage, such that full coverage was a benefit covered at 100% and partial coverage a benefit for which the user paid a share of the cost (e.g., a copayment). As the Kaper, Wagena, Severens, et al. (2005) design more closely resembles the intent of the CHBRP analysis, it is cited.

⁵¹ For purposes of this report, full coverage for smoking cessation treatments is defined as coverage of 100% of costs associated with smoking cessation medications and/or counseling without a deductible, copayment, or coinsurance. Partial coverage is defined as a benefit for which the user pays a share of the cost (e.g., a copayment).

The lack of consistent findings across the two studies suggests that the evidence of the impact of full coverage for smoking 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 smoking 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.

Some health plans require persons to receive smoking cessation counseling in order to be covered for pharmacotherapy. One RCT conducted in California found that persons with coverage for counseling were more likely to receive it if coverage for smoking cessation medications was contingent on participation in counseling (Halpin 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 pooled findings from the meta-analysis indicate that full coverage was associated with a statistically significant increase in use of NRT. 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). 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., 2002). The difference between Boyle et al.'s (2002) findings and those of the other studies may reflect a difference in the amount of information subjects in the intervention groups received regarding their coverage for NRT.⁵² 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

⁵² In the RCTs conducted by Hughes et al. (1991), Kaper, Wagena, Willemsen, et al. (2005), and Schauffler et al. (2001), study personnel informed participants randomized to the intervention group orally or in writing that they had coverage for NRT and explained the procedures they needed to follow to use their coverage. The provision of such information increased awareness of coverage for NRT among smokers in the intervention group, which may have increased their likelihood of using NRT. In contrast, participants enrolled in Boyle et al.'s (2002) study did not receive information from study personnel regarding their coverage. One year after coverage for NRT became available to smokers in the intervention, only 30% of them knew that they had coverage for it (Boyle et al., 2002).

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 treatments 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 on use of bupropion. The authors concluded that persons with full coverage for bupropion were more likely to use it than were persons with no coverage, but that the difference was not statistically significant (Kaper, Wagena, Severens, et al., 2005).⁵³ 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 SR, but the increase was not statistically significant (Boyle et al., 2002).⁵⁴ 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 on use of varenicline.

⁵³ Although bupropion SR (brand name = Zyban) at strengths of 100 or 150 milligrams is the only formulation of bupropion approved by FDA for smoking cessation, one of the studies included in the meta-analysis (Kaper, Wagena, Willemsen, et al., 2005) does not state whether smokers in the intervention group received coverage for bupropion SR or another formulation of bupropion. In the other study (Boyle et al., 2002), smokers in the intervention group received coverage for bupropion SR.

⁵⁴ As discussed in the previous footnote, the difference between the findings of Kaper, Wagena, Willemsen, et al. (2005) and Boyle et al. (2002) may be due a difference in the amount of information study personnel provided to smokers in the intervention group regarding their coverage for smoking cessation services. In Kaper, Wagena, Willemsen, et al.'s (2005) study, members of the study team mailed a leaflet to smokers in the intervention group that described the types of smoking cessation services for which they could receive reimbursement (bupropion, NRT, and counseling) and the procedures for submitting claims. In contrast, participants enrolled in Boyle et al.'s (2002) study did not receive information from study personnel regarding their coverage.

Summary of findings regarding effects of coverage on use of smoking cessation treatments:

The preponderance of evidence suggests that persons who have coverage for NRT or bupropion are more likely to use these forms of pharmacotherapy for smoking 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 smoking cessation counseling are ambiguous. No studies have assessed the impact of coverage on use of varenicline.

Abstinence from Smoking

Eight studies have examined the effects of full coverage of smoking cessation treatments 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; Schaffler et al., 2001) and one conference paper that was subsequently published (Kaper, Wagena, Willemsen, et al., 2005). Three articles were published after the meta-analysis was completed (Kaper et al., 2006;⁵⁵ Land et al., 2010; Petersen et al., 2006).

The authors of the meta-analysis concluded that persons who had full coverage for smoking cessation treatments 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; Schaffler 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). In another study, the lack of a statistically significant difference in abstinence from smoking is probably due to the lack of difference in use of NRT and bupropion SR between smokers who had coverage for them and those who did not (Boyle et al., 2002).

Three articles published after the meta-analysis reported that full coverage for smoking cessation treatments was associated with statistically significant increases in abstinence from smoking relative to no coverage. A second publication from Kaper and colleagues' RCT found that persons who had full coverage were more likely to abstain from smoking for 2 years after the study was completed than were those without full coverage (Kaper et al., 2006). An article reported findings from a nonrandomized study that concluded 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 smoking cessation counseling and medication than if they lived in

⁵⁵ 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.

states in which Medicaid did not cover either of these treatments (Petersen et al., 2006). A third article presented findings from an interrupted time series analysis of the impact of implementing smoking cessation coverage for adults enrolled in Massachusetts' Medicaid program (Land et al., 2010). The authors found a statistically significant decrease in the prevalence of smoking among adult Medicaid beneficiaries following implementation of the benefit.⁵⁶

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 smoking 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 smoking cessation services increases abstinence from smoking relative to no coverage.

Three studies examined the effects of full versus partial coverage for smoking cessation treatments on abstinence from smoking. 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 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, Curry et al. (1998) examined data on all smokers who had the two types of coverage regardless of their interest in quitting and their motivation to quit. In contrast, smokers who participated in Hughes et al.'s (1991) RCT chose to participate in the study, which suggests that they were motivated to attempt to quit smoking.

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 et al., 2006). The RCT had three arms: (1) coverage for only NRT and bupropion SR (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.

⁵⁶ One important limitation of the two studies of Medicaid beneficiaries is that their authors analyzed data sources that only contained information about smoking status. They did not have access to data on use of smoking cessation counseling or pharmacotherapy and, thus, could not determine whether differences in abstinence from smoking across states or over time were due to differences in use of these treatments, which would be facilitated by coverage, versus factors unrelated to health insurance coverage, such as differences in stigma associated with smoking during pregnancy or cigarette taxes. For example, the implementation of coverage for smoking cessation services in the Massachusetts Medicaid program coincided with a \$1 per pack increase in the state's cigarette tax.

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 smoking cessation treatments 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 coverage for either pharmacotherapy or counseling but not both 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 (Petersen et al., 2006).

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

Summary of findings regarding effects of coverage on abstinence from smoking: The preponderance of evidence suggests that full coverage for smoking cessation treatments 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 Smoking Cessation Treatments

Counseling vs. No Treatment or Minimal Treatment

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Individual Counseling						
Smoking cessation rate at 5 months or more	4 meta-analyses	<ul style="list-style-type: none"> Statistically significant: 4 of 4 meta-analyses 	<ul style="list-style-type: none"> Better: 4 of 4 meta-analyses 	<ul style="list-style-type: none"> Pooled odds ratios ranged from 1.3 to 1.7 	<ul style="list-style-type: none"> Generalizable: 4 of 4 meta-analyses 	<ul style="list-style-type: none"> Clear and convincing evidence that individual counseling increases the odds of abstinence from smoking relative to no treatment or minimal intervention
Group Counseling						
Smoking cessation rate at 5 months or more	3 meta-analyses	<ul style="list-style-type: none"> Statistically significant: 3 of 3 meta-analyses 	<ul style="list-style-type: none"> Better: 3 of 3 meta-analyses 	<ul style="list-style-type: none"> Pooled odds ratios ranged from 1.3 to 2.7 	<ul style="list-style-type: none"> Generalizable: 3 of 3 meta-analyses 	<ul style="list-style-type: none"> Clear and convincing evidence that group counseling increases the odds of abstinence from smoking relative to no treatment
Counseling Provided Over the Phone						
Smoking cessation rate at 5 months or more	3 meta-analyses	<ul style="list-style-type: none"> Statistically significant: 3 of 3 meta-analyses⁵⁷ 	<ul style="list-style-type: none"> Better: 3 of 3 meta-analyses 	<ul style="list-style-type: none"> Pooled odds ratios ranged from 1.3 to 1.6 	<ul style="list-style-type: none"> Generalizable: 3 of 3 meta-analyses 	<ul style="list-style-type: none"> Clear and convincing evidence that counseling provided over the phone increases the odds of abstinence from smoking relative to no treatment or minimal intervention

⁵⁷ One meta-analysis, Stead et al. (2009), reported pooled effects from two analyses. One analysis pooled findings from RCTs on the effectiveness of proactive telephone counseling (i.e., counseling in which all calls are initiated by a counselor). The other pooled findings from RCTs on the effectiveness of quitline telephone counseling (i.e., counseling in which the initial call is made by a smoker who may choose to schedule additional, proactive calls initiated by a counselor). Both analyses found statistically significant effects that favored telephone counseling.

Counseling vs. No Treatment or Minimal Treatment (Cont'd)

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Brief Counseling						
Smoking cessation rate at 5 months or more	3 meta-analysis	<ul style="list-style-type: none"> Statistically significant: 2 of 3 meta-analyses 	<ul style="list-style-type: none"> Better: 3 of 3 meta-analyses 	<ul style="list-style-type: none"> Pooled odds ratios ranged from 1.3 to 1.6 	Generalizable: 3 of 3 meta-analyses	<ul style="list-style-type: none"> The preponderance of evidence indicates that brief counseling increases the odds of abstinence from smoking relative to no treatment or self-help materials.

Intensity of Counseling

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Smoking cessation rate at 5 months or more	3 meta-analyses	<ul style="list-style-type: none"> Statistically significant: 2 of 3 meta-analyses⁵⁸ Not statistically significant: 1 of 3 meta-analyses 	<ul style="list-style-type: none"> Better: 3 of 3 meta-analyses 	<ul style="list-style-type: none"> Pooled odds ratios ranged from 1.1 to 2.3 	<ul style="list-style-type: none"> Generalizable: 4 of 4 meta-analyses 	<ul style="list-style-type: none"> Preponderance of evidence suggests that there is a dose-response relationship, where more intensive counseling increases the odds of abstinence from smoking relative to less intensive treatment

⁵⁸ One meta-analysis, Fiore et al. (2008), reported findings from two analyses regarding the intensity of counseling. One analysis compared pooled effects of RCTs that assessed the effects of low-intensity counseling (3 to 10 minutes) and higher intensity (>10 minutes) compared to no counseling. The other analysis compared the effect of the number of treatment sessions on abstinence from smoking across 46 trials. The number of treatment sessions was categorized into a control group, having had 0 to 1 sessions, and 3 treatment groups: having 2 to 4 sessions, 4 to 8 sessions, and >8 sessions. Findings from these analyses suggest that the likelihood that a person will abstain from smoking increases as the length of counseling sessions and the number of counseling sessions increases.

Nicotine Gum vs. Placebo or No Treatment

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Smoking cessation rate at 5 months or more	3 meta-analyses	<ul style="list-style-type: none"> Statistically significant: 3 of 3 meta-analyses⁵⁹ 	<ul style="list-style-type: none"> Better: 3 of 3 meta-analyses 	<ul style="list-style-type: none"> Pooled odds ratios from meta-analyses ranged from 1.4 to 2.2 	<ul style="list-style-type: none"> Generalizable: 3 of 3 meta-analyses 	<ul style="list-style-type: none"> 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	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Smoking cessation rate at 5 months or more	4 meta-analyses	<ul style="list-style-type: none"> Statistically significant: 4 of 4 meta-analyses⁶⁰ 	<ul style="list-style-type: none"> Better: 4 of 4 meta-analyses 	<ul style="list-style-type: none"> Pooled odds ratios from meta-analyses ranged from 1.6 to 2.3 	<ul style="list-style-type: none"> Generalizable: 4 of 4 meta-analyses 	<ul style="list-style-type: none"> Clear and convincing evidence that nicotine patch increases the odds of abstinence from smoking relative to placebo or no treatment

⁵⁹ One meta-analysis, Fiore et al. (2008), reported findings from two analyses of the efficacy of nicotine gum. One analysis pooled findings from RCTs that compared use of nicotine gum for 6 to 14 weeks to a placebo. The other analysis compared use of nicotine gum for more than 14 weeks to a placebo. Both analyses found statistically significant differences favoring nicotine gum.

⁶⁰ One meta-analysis, Fiore et al. (2008), reported findings from three analyses of the efficacy of nicotine patches. The first pooled RCTs on high-dose nicotine patch use (>25 mg) compared to placebo. The second pooled RCTs on long-term nicotine patch use (>14 weeks) compared to a placebo and the third meta-analysis pooled studies on shorter-term (6 to 14 weeks) nicotine patch use compared to a placebo. All three analyses found statistically significant differences favoring nicotine patches.

Nicotine Lozenge vs. Placebo or No Treatment

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Smoking cessation rate at 5 months or more	2 meta-analyses	<ul style="list-style-type: none"> Statistically significant: 2 of 2 meta-analyses 	<ul style="list-style-type: none"> Better: 2 of 2 meta-analyses 	<ul style="list-style-type: none"> Pooled odds ratios from meta-analyses were 2.0 and 2.1 	<ul style="list-style-type: none"> Generalizable: 2 of 2 meta-analyses 	<ul style="list-style-type: none"> 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	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Smoking cessation rate at 5 months or more	3 meta-analyses	<ul style="list-style-type: none"> Statistically significant: 2 of 3 meta-analyses Not statistically significant: 1 of 3 meta-analyses 	<ul style="list-style-type: none"> Better: 3 of 3 meta-analyses 	<ul style="list-style-type: none"> Pooled odds ratios from meta-analyses were 1.9 and 2.2 	<ul style="list-style-type: none"> Generalizable: 3 of 3 meta-analyses 	<ul style="list-style-type: none"> Preponderance of evidence indicates 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	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Smoking cessation rate at 5 months or more	3 meta-analyses	<ul style="list-style-type: none"> Statistically significant: 3 of 3 meta-analyses 	<ul style="list-style-type: none"> Better: 3 of 3 meta-analyses 	<ul style="list-style-type: none"> Pooled odds ratios ranged from 2.0 to 2.4 	<ul style="list-style-type: none"> Generalizable: 3 of 3 meta-analyses 	<ul style="list-style-type: none"> Clear and convincing evidence that nicotine nasal spray increases the odds of abstinence from smoking relative to placebo or no treatment

Bupropion⁶¹ vs. Placebo or No Treatment

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Smoking cessation rate at 5 months or more	3 meta-analyses	<ul style="list-style-type: none"> Statistically significant: 3 of 3 meta-analyses 	<ul style="list-style-type: none"> Better: 3 of 3 meta-analyses 	<ul style="list-style-type: none"> Pooled odds ratios from meta-analyses range from 1.7 to 2.1 	<ul style="list-style-type: none"> Generalizable: 3 of 3 meta-analyses 	<ul style="list-style-type: none"> Clear and convincing evidence that bupropion increases the odds of abstinence from smoking relative to placebo or no treatment

Varenicline vs. Placebo

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Smoking cessation rate at 5 months or more	3 meta-analyses	<ul style="list-style-type: none"> Statistically significant: 3 of 3 meta-analyses 	<ul style="list-style-type: none"> Better: 3 of 3 meta-analyses 	<ul style="list-style-type: none"> Pooled odds ratios ranged from 2.3 to 3.1 	<ul style="list-style-type: none"> Generalizable: 3 of 3 meta-analyses 	<ul style="list-style-type: none"> Clear and convincing evidence that varenicline increases the odds of abstinence from smoking relative to placebo

Varenicline vs. Bupropion⁶²

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Smoking cessation rate at 5 months or more	3 meta-analyses	<ul style="list-style-type: none"> Statistically significant: 3 of 3 meta-analyses 	<ul style="list-style-type: none"> Better: 3 of 3 meta-analyses 	<ul style="list-style-type: none"> Pooled odds ratio ranged from 1.5 and 2.2 	<ul style="list-style-type: none"> Generalizable: 3 of 3 meta-analyses 	<ul style="list-style-type: none"> Clear and convincing evidence that varenicline increases the odds of abstinence from smoking relative to bupropion

⁶¹ Bupropion SR in strengths of 100 or 150 milligrams is the only formulation of bupropion approved by the FDA for smoking cessation. Two of the meta-analyses on the efficacy of bupropion for smoking cessation -- Fiore et al. (2008) and Hughes et al. (2010) -- do not indicate whether their meta-analyses included only RCTs that assessed the efficacy of bupropion SR. Some of the RCTs included may have evaluated other formulations of bupropion. The third meta-analysis -- Eisenberg et al. 2008 -- only included RCTs that examined bupropion SR.

⁶² Two of the meta-analyses -- Cahill et al. (2008) and Hughes et al. (2010) -- do not indicate whether their meta-analyses were limited to RCTs on that assessed bupropion SR in strengths of 100 or 150 milligrams, the only formulation of bupropion approved by the FDA for smoking cessation. Some of the RCTs included may have evaluated other formulations of bupropion. The third meta-analysis -- Eisenberg et al. 2008 -- only included RCTs that examined bupropion SR.

Clonidine vs. Placebo

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Smoking cessation rate at 3 months or more	2 meta-analyses	<ul style="list-style-type: none"> Statistically significant: 2 of 2 meta-analyses 	<ul style="list-style-type: none"> Better: 2 of 2 meta-analyses 	<ul style="list-style-type: none"> Pooled odds ratio ranged from 1.6 and 2.1 	<ul style="list-style-type: none"> Generalizable: 2 of 2 meta-analyses 	<ul style="list-style-type: none"> Clear and convincing evidence that clonidine increases the odds of abstinence from smoking compared to placebo

Nortriptyline vs. Placebo

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Smoking cessation rate at 5 months or more	2 meta-analyses	<ul style="list-style-type: none"> Statistically significant: 2 of 2 meta-analyses 	<ul style="list-style-type: none"> Better: 2 of 2 meta-analyses 	<ul style="list-style-type: none"> Pooled odds ratio ranged from 1.8 and 2.3 	<ul style="list-style-type: none"> Generalizable: 2 of 2 meta-analyses 	<ul style="list-style-type: none"> Clear and convincing evidence that nortriptyline increases the odds of abstinence from smoking compared to placebo

Combination Therapies

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Smoking cessation rate at 5 months or more	2 meta-analyses	<ul style="list-style-type: none"> Statistically significant: 2 of 2 meta-analyses 	<ul style="list-style-type: none"> Better: 2 of 2 meta-analyses 	<ul style="list-style-type: none"> Pooled odds ratio ranged from 1.5 and 3.6 	<ul style="list-style-type: none"> Generalizable: 2 of 2 meta-analyses 	<ul style="list-style-type: none"> Clear and convincing evidence that there is a dose-response relationship, where more combinations of specific therapies increases the odds of abstinence from smoking relative to placebo of a single medication

Sources: Cahill et al., 2009 Eisenberg et al., 2008; Fiore et al., 2008; Gourlay et al., 2008; Hughes et al., 2010; Lancaster and Stead, 2008; Mottillo et al., 2009; Myung et al., 2007; Rice and Stead, 2008; Shah et al., 2008; Stead and Lancaster, 2009; Stead, Bergson, et al., 2008; Stead, Perera, et al., 2008; and Stead et al., 2009.

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

Full Coverage for Smoking Cessation Treatments vs. No Coverage—Use of Cessation Treatments

Outcome	Research Design⁶³	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Use of Counseling	<ul style="list-style-type: none"> Level I: 2 studies 	<ul style="list-style-type: none"> Statistically significant: 1 of 2 studies Not statistically significant: 1 of 2 studies 	<ul style="list-style-type: none"> Better (i.e., more likely to use counseling cessation services): 1 of 2 studies No difference: 1 of 2 studies 	<ul style="list-style-type: none"> Ranged from no difference to 5 times as likely to obtain 	<ul style="list-style-type: none"> Highly generalizable = 1 of 2 studies Somewhat generalizable = 1 of 2 studies 	<ul style="list-style-type: none"> The evidence of the effect of full coverage for tobacco cessation counseling on use of counseling is ambiguous
Use of NRT	<ul style="list-style-type: none"> Level I: 3 studies Level II: 1 study Level III: 1 study 	<ul style="list-style-type: none"> Statistically significant: 3 of 5 studies Not statistically significant: 1 of 5 studies Not reported: 1 of 5 studies 	<ul style="list-style-type: none"> Better (i.e., more likely to use NRT): 4 of 5 studies No difference: 1 of 5 studies 	<ul style="list-style-type: none"> Ranged from 0.07 times less likely to use to 1.02 times more likely 	<ul style="list-style-type: none"> Highly generalizable = 1 of 5 studies Somewhat generalizable = 4 of 5 studies 	<ul style="list-style-type: none"> Preponderance of evidence suggests that full coverage for NRT increases use of NRT

⁶³ 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.

Full Coverage for Smoking Cessation Treatments vs. No Coverage—Use of Cessation Treatments (Cont'd)

Outcome	Research Design ⁶⁴	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Use of bupropion ⁶⁵ (2 studies)	<ul style="list-style-type: none"> Level I: 1 study Level III: 1 study 	<ul style="list-style-type: none"> Statistically significant: 1 of 2 studies Not statistically significant: 1 of 2 studies 	<ul style="list-style-type: none"> Better (i.e., more likely to obtain bupropion): 2 of 2 studies 	<ul style="list-style-type: none"> Ranged from 0.24 times more likely to 0.63 times more likely 	<ul style="list-style-type: none"> Somewhat generalizable = 2 of 2 studies 	<ul style="list-style-type: none"> Preponderance of the evidence suggests that full coverage for bupropion increases use of this drug for tobacco cessation

Full Coverage for Smoking Cessation Treatments vs. Partial Coverage—Use of Cessation Treatments

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Use of counseling	<ul style="list-style-type: none"> Level III: 1 study 	<ul style="list-style-type: none"> Statistically significant: 1 of 1 study 	<ul style="list-style-type: none"> Better (i.e., more likely to obtain counseling): 1 of 1 study 	<ul style="list-style-type: none"> 3 times as likely to obtain 	<ul style="list-style-type: none"> Somewhat generalizable = 1 of 1 study 	<ul style="list-style-type: none"> Single study suggests that persons who have full coverage for counseling are more likely to obtain it than persons with partial coverage
Use of NRT	<ul style="list-style-type: none"> Level II: 1 study Level III: 1 study 	<ul style="list-style-type: none"> Statistically significant: 2 of 2 studies 	<ul style="list-style-type: none"> Better (i.e., more likely to use NRT): 2 of 2 studies 	<ul style="list-style-type: none"> Ranged from 0.3 times to 2.5 times more likely to use 	<ul style="list-style-type: none"> Somewhat generalizable = 2 of 2 studies 	<ul style="list-style-type: none"> Clear and convincing evidence that persons with full coverage for NRT are more likely to use it than people with partial coverage

⁶⁴ 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.

⁶⁵ Although bupropion SR (brand name = Zyban) at strengths of 100 or 150 milligrams is the only formulation of bupropion approved by FDA for smoking cessation, one of the studies included in the meta-analysis (Kaper, Wagena, Willemsen, et al., 2005) does not state whether smokers in the intervention group received coverage for bupropion SR or another formulation of bupropion. In the other study (Boyle et al., 2002), smokers in the intervention group received coverage for bupropion SR.

Full Coverage for Smoking Cessation Treatments vs. No Coverage—Abstinence from Smoking

Outcome	Research Design ⁶⁶	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Abstinence from smoking (7 studies)	<ul style="list-style-type: none"> Level I: 3 studies Level II: 1 study Level III: 3 studies 	<ul style="list-style-type: none"> Statistically significant: 5 of 7 studies Not statistically significant: 2 of 7 studies 	<ul style="list-style-type: none"> Better (i.e., more likely to stop smoking): 5 of 7 studies No effect: 1 of 7 studies Worse: 1 of 7 studies 	<ul style="list-style-type: none"> Ranged from no difference to 1.7 times as likely to quit 	<ul style="list-style-type: none"> Highly generalizable = 1 of 7 studies Somewhat generalizable = 6 of 7 studies 	<ul style="list-style-type: none"> Preponderance of evidence suggests that coverage for tobacco cessation services increases abstinence from smoking

Full Coverage for Smoking Cessation Treatments vs. Partial Coverage—Abstinence from Smoking

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Abstinence from smoking (3 studies)	<ul style="list-style-type: none"> Level I: 1 study Level II: 1 study Level III: 1 study 	<ul style="list-style-type: none"> Not statistically significant: 3 of 3 studies 	<ul style="list-style-type: none"> Better (i.e., more likely to stop smoking): 1 of 3 studies No effect: 2 of 3 studies 	<ul style="list-style-type: none"> Ranged from no difference to twice as likely to quit 	<ul style="list-style-type: none"> Highly generalizable = 1 of 3 studies Somewhat generalizable = 2 of 3 studies 	<ul style="list-style-type: none"> The evidence of the impact of full versus partial coverage on abstinence from smoking is ambiguous

Sources: Boyle et al., 2002; Curry et al., 1998; Dey et al., 1999; Halpin et al., 2006; Hughes et al., 1991; Kaper, Wagena, Willemsen, et al., 2005; Kaper et al., 2006; Land et al., 2010; Petersen et al., 2006; and Schauffler et al., 2001.

⁶⁶ 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.

UTILIZATION, COST, AND BENEFIT COVERAGE IMPACTS

SB 220 would require DMHC-regulated health plan contracts and CDI-regulated insurance policies that provide outpatient prescription drug benefits to also provide two courses of treatment in a 12-month period for smoking cessation *without copayment or deductible*. A course of treatment is defined as coverage for counseling (including telephone, group, and individual) and FDA-approved pharmacotherapy, whether by prescription or OTC. According to CHBRP's estimates, there are 19.49 million insured Californians currently enrolled in either DMHC- or CDI-regulated health plans or policies, of which 97% have current prescription drug coverage, including 12.86 million adults aged 18 years and older.

Although SB 220 did not specify the targeted age group, CHBRP made the simplifying assumption to focus only on the adult population for the benefit coverage impact analysis. OTC and prescription smoking cessation treatments have been proven efficacious and regularly utilized by adult smokers, but for adolescents, the efficacy and usage rates for these have not been firmly established. Instead, the literature points to school-based counseling programs administered by nurses (Fritz, 2008; Joffe and McNeely, 2009). Additionally, smoking cessation in adolescents is linked to deeper psychological issues linked with peer and parental relationships (McVea et al., 2009). Thus, this report will focus only on coverage for adults who smoke.

This section will present first the current, or baseline, costs and coverage related to smoking cessation treatment for adults, and then provide the estimated utilization, cost, and benefit coverage impacts of SB 220. For further details on the underlying data sources and methods, please see *Appendix D* at the end of this document.

Present Baseline Cost and Coverage

Current Coverage of the Mandated Benefit

According to data from the 2007 California Health Interview Survey (CHIS, 2007), 14.2% of California's non-elderly adults with insurance coverage are currently smoking. About 1.9 million adults smoke who are insured with DMHC- or CDI-regulated health plans or policies, and of these, 1.83 million have current prescription drug coverage. Those without drug coverage could have coverage for smoking cessation services separately from comprehensive drug coverage, but their insurance plans or policies would not be affected by the health benefit mandate under SB 220, which mandates parity for smoking cessation treatment when existing drug coverage already exists.

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,⁶⁷ the current coverage of mandated benefits varies by types of smoking cessation services. Currently, enrollees largely have coverage for smoking cessation treatment by a physician or other clinical staff as part of a regular physician visit, which is subject to copayment (\$10 to \$15) per office visits; 77.8% have partial or full coverage for prescription

⁶⁷ The six that responded represent 94% of enrollees in DMHC-regulated health plans and 92% of enrollees covered by CDI-regulated health policies.

smoking cessation treatments (e.g., bupropion, varenicline, or inhalant forms of NRT) through outpatient prescription drug benefits with \$5 to \$75 copayment, though many plans limit it to one course of treatment per contract year; 87.1% have coverage for personal counseling through telephone or other counseling services, whereas only 67.4% have coverage for OTC treatments. In summary, privately insured, CalPERS HMO, and Healthy Families enrollees currently have only partial or no coverage for smoking cessation medications and counseling services. The partial coverage ranges from only a \$50 per enrollee per lifetime reimbursement to visits and prescriptions with up to \$15 copayments.

California's Medi-Cal Managed Care Program, which covers 13.8% (2.6 million) of adults subject to the mandate, provides comprehensive smoking cessation benefits at no charge to Medi-Cal enrollees. Contracting health plans administer smoking cessation benefits including a broad scope of pharmacological aides (including OTC medications) and coverage for smoking cessation programs that provide counseling, classes, and self-help materials.

The current per member per month (PMPM) premiums and expenditures in different market segments are detailed in Table 4. The total population in Table 4 reflects the full 19.49 million enrollees in DMHC- or CDI- regulated plans or policies that are included in the mandate under SB 220, as the premium costs are spread over all enrollees in all plans subject to SB 220, including those without drug coverage or who are non-smokers who would not utilize smoking cessation treatments.

Nearly nine in ten (87.1%) enrollees have full or partial coverage for smoking cessation-related counseling, 67.4% have full or partial coverage for OTC smoking cessation treatment, and 77.8% have full or partial coverage for prescription smoking cessation treatment. If SB 220 were enacted, 100% of insured adults with drug coverage would have full coverage for smoking cessation services.

Current Utilization Levels and Costs of the Mandated Benefit

Current utilization

According to the most recent California-specific data available, the 2005 California Tobacco Survey (CTS), 56.0% of California smokers made at least one quit attempt in a year. Among them, only a small proportion of them participated in a formal cessation assistance program (see Table 8 in *Public Health Impacts*). Typically, formal cessation assistance programs include a combination of counseling, prescription medications, and physician contact (Javitz, 2004). However, many of the quitters only used one or two of the services as a course of treatment. In summary, about 10.4% smokers who made an attempt to quit used NRT, 4.4% used counseling only, 2.0% used antidepressants, and 26.1% used one or more services. The rest (73.9%) did not use any formal assistance during a quit attempt in the year before the survey.

Though previous studies, including an RCT 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 2005 CTS data as a baseline to estimate the pre-

mandate 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 Health Insurance Experiment (HIE) estimated impact of cost sharing for well care as adjustments. HIE remains the most authoritative study on the topic of the effects of cost-sharing on health care utilization. It was a randomized controlled trial conducted in the late 1970s and early 1980s. The RAND HIE found that consumers enrolled in fee-for-service plans who paid a larger share of costs were less likely to use health care services and used smaller amounts of services than consumers who paid a smaller share of costs (Newhouse, 1993). 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 enrollees with any levels of copayments.

Pre-mandate, of the 1.83 million adult smokers enrolled in DMHC- or CDI-regulated plans or policies with outpatient prescription drug coverage, 268,344 used one or more smoking cessation treatments, with 203,845 using treatments covered through their existing insurance and 64,500 enrollees using treatments for which they were uninsured. Please see details of the calculations in *Appendix D*.

Current average cost of smoking cessation services

Currently, the average cost per course of smoking cessation treatment is an average of \$200 for counseling, \$236 for OTC, and \$240 for prescriptions. This analysis assumes that the available supply of services would meet the slightly increased demand, and that costs for the service would not increase.

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 et al., 2004). These potential savings or costs were not estimated in the current analysis, since the CHBRP cost model examines the short-term impact of the proposed benefit coverage mandate. However, CHBRP examines the relevant literature and anticipated long-term cost impact of SB 220 later in this section, under *Impact on Long-Term Costs*.

Public Demand for Coverage

A previous bill that would have mandated coverage for smoking 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.⁶⁸ Currently, CalPERS' plans vary in coverage for tobacco cessation. Some plans provide coverage for tobacco cessation counseling, others do not. All plans examined (three) provide coverage for OTC and prescription drug coverage, at varying levels of cost sharing (and requirements for enrolling in a behavioral intervention program).

Impacts of Mandated Benefit Coverage

How Would 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, CHBRP estimated that the percentage of enrollees with mandate-compliant benefit coverage would increase 85.2 percentage points, from 14.2% who currently have full coverage for smoking cessation treatment to 100% (see Table 1 in *Executive Summary*) in the CDI and DMHC-regulated markets. However, the increase is mostly among people who moved from partial coverage to full coverage. Therefore, the impact of the marginal changes in utilization and premiums (as discussed below) is less than would be implied by this large increase in mandate-compliant benefit coverage. As there is no evidence in the literature that increasing coverage for smoking cessation treatments increases the prices of those treatments, CHBRP assumes that the unit cost of covered smoking cessation services would stay the same after the mandate.

How Would Utilization Change As a Result of the Mandate?

On the basis of findings from the literature (Curry et al., 1998; Kaper, Wagena, Severens, et al., 2005; Land, et al., 2010; Schauffler et al., 2001), utilization is expected to increase as a result of the full coverage for smoking cessation treatment. CHBRP estimated the post-mandate utilization rate among smokers for smoking cessation services using the RAND HIE estimated impact of cost sharing for well care. Specifically, those without coverage would have expenditures equal to 45% of those with full coverage, whereas those with partial coverage would have expenditures equal to 80% of those with full coverage. CHBRP estimated that SB 220 would increase the utilization of all smoking cessation treatments.

Post-mandate, of the 1.83 million insured adult smokers with prescription drug coverage, CHBRP estimated that the utilization of counseling services would increase by 34.3%, OTC treatments by 54.2%, and prescription treatments by 37.2%. In summary, the utilization of one or more smoking cessation treatments would increase by 44.2%, representing an additional 118,482 insured adult smokers getting treatment, after the mandate.

⁶⁸ Personal communication with the California Labor Federation and member organizations on January 29, 2007.

Please see details of the calculations in *Appendix D*. The estimated increases of percentage points for different services are similar to the findings of two meta-analyses published recently (Gollust et al., 2008; 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 enrollees 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 may be limited to two courses of treatment per year, is also expected to dampen any potential surges in utilization for any one service.

Post-mandate, of the 1.83 million insured adult smokers with prescription drug coverage, CHBRP estimated that the utilization of counseling services would increase by 34.3%, OTC treatments by 54.2%, and prescription treatments by 37.2%. All together, the utilization of one or more smoking cessation treatments would increase by 44.2%, representing an additional 118,482 insured adult smokers getting treatment, after the mandate.

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

This mandate would 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 enrollee materials to reflect the new services. In addition, health plans and insurers would need to determine how to administer the smoking cessation benefits to comply with the mandate to cover OTC smoking cessation treatments and counseling services. Health plans and insurers include a component for administration and profit in their premiums. The estimated impact of this mandate on premiums includes the assumption that plans and insurers will apply their existing administration and profit loads to the marginal increase in health care costs produced by the mandate. Therefore, although there may be administrative costs associated with the mandate, administrative costs as a proportion of the premium would not change.

Impact of the Mandate on Total Health Care Costs

SB 220 would increase total net annual expenditures by \$52.7 million or 0.07% for this insured population (see Table 1 in *Executive Summary*). This is due to a \$83.7 million total increase in health insurance premiums, partially offset by reductions in both enrollee copayments (\$10.4 million) and out-of-pocket expenditures (\$20.6 million), because the bill requires health plans to provide complete coverage for two cycles of smoking cessation services free of charge (i.e., without a copayment or coinsurance and not subject to a deductible). The net increase of \$52.7 million would also be reduced further on a health system-level by a savings of \$1.04 million that represents the short-term (i.e., 1-year) savings resulting from a reduction in low-birth weight deliveries and in hospitalizations due to AMI among those who quit smoking (data not shown).

Potential cost offsets or savings in the short-term

The total increase in health care expenditures could be further reduced by potential short-term savings for those who quit smoking, estimated to be \$1.04 million.⁶⁹ These health-care system savings represent the 1-year savings resulting from reduced use of ambulatory and inpatient services among those who quit smoking. CHBRP applied the percentage of attempted quitters who successfully quit (from the 2005 CTS) to the estimated higher number of people using smoking cessation services, if SB 220 were to go into effect. 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, which CHBRP estimates will be fewer than ten combined. These savings can be realized within a year after quitting smoking (See Appendix D for full calculations).

Total net annual health expenditures are projected to increase by \$52.7 million (0.07%) (Table 1). This is due to an \$83.7 million increase in health insurance premiums, partially offset by reductions in both enrollee copayments (\$10.4 million) and out-of-pocket expenditures (\$20.6 million). The net increase of \$52.7 million could also be reduced by a potential savings of \$1.04 million in health care spending, representing the short-term (i.e., 1-year) savings resulting from a reduction of less than ten fewer low-birth weight deliveries and hospitalizations due to AMI among those who quit smoking.

Impact on long-term costs

Although the cost estimates presented are for one year only, tobacco use has both direct and indirect costs that affect individuals, employers, health plans, the government, and society. There are potential long-term savings of quitting, including the potential impact of total annual costs of smoking cessation possibly declining in future years, as fewer smokers remain. It is also possible that smoking cessation costs could increase in the future due to the diminishing effectiveness of smoking cessation strategies for those heavy smokers who continue to smoke despite treatments. This effect would likely be minimal, given that the treatments covered by the mandate are limited to two in a 12-month period.

But it is clear from the literature that the increase in smoking cessation would likely provide long-term savings that are not measured in the CHBRP model. Medical care contributes the largest proportion of the direct costs of smoking, and 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). Additionally, fewer low-birth weight babies can also save costs, as those children tend to use more medical care later in life (see discussion in *Public Health Impacts* section).

⁶⁹ The cost-savings calculation incorporates savings associated with reduced hospitalization for AMI and savings associated with fewer low-birth weight deliveries.

Employers may experience direct costs (e.g., medical care, higher health insurance premiums) due to smoking-related illness among their employees (Levy, 2006). Halpern et al. (2007) found that employers saved \$165 to \$457 per smoker over two years with increased use of varenicline for smoking cessation, due to decreased absenteeism and increased productivity. In addition, macro-level costs are borne by society in general. According to the California Department of Health Services (now the California Department of Public Health), in 1999, Californians spent \$8,564,623 in direct health care costs attributable to smoking (see *Public Health Impacts*). A 1995 study by Wagner and colleagues estimates that smoking cessation resulted in significant decreases in use of outpatient and inpatient health care services (Wagner et al., 1995).

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 successful quitter? Several studies have addressed this issue.

To place these costs in their proper context, cost-effectiveness studies generally report their findings in costs per quality-adjusted life-year (QALY), as recommended by the Panel on Cost Effectiveness in Health and Medicine (USPHS, 1996). For example, Warner and colleagues (2004) found that successful quitters gain on average 7.1 years of life at a net cost of \$3,417 per year of life gained, or \$24,261 per successful 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 gained, and \$1,915 per QALY (a year in perfect health is considered equal to 1.0 QALY) saved. The costs of achieving and maintaining lifetime smoking 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. More recently, Bertram et al. (2007) found that smoking cessation services ranged from a cost of \$7,900 to \$17,000 for each disability-adjusted life-year (DALY). Additionally, Bolin et al. (2009) found in their comparison study in four countries that additional 12-week treatment courses of varenicline for those who had already received treatment once improved cessation at a cost of about Euro 25,000 (or about U.S. \$30,000 at June 2010 conversion rates).

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. In addition, Kahende et al. (2009) performed a meta-analysis of the economic literature and found that in nearly every case, studies show that smoking cessation programs are either cost saving or highly cost-effective.

In addition to gaining short-term savings in health expenditures, those who quit smoking may experience measurable long-term improvements in health status. Medical care contributes the largest proportion of the direct costs of smoking, and individuals personally bear additional medical costs related to smoking. 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.

Impacts for Each Category of Payer Resulting from the Benefit Mandate

Changes in Expenditures and PMPM Amounts by Payer Category

Increases in insurance premiums vary by market segment. Note that the total population in Table 5 reflects the full 19.49 million enrollees in DMHC- or CDI- regulated plans or policies that are included in the mandate under SB 220. The premium increases are estimated to be spread among all enrollees in all plans or policies, regardless of whether they have prescription drug coverage or whether the enrollees would possibly use smoking cessation treatments.

Increases in per member per month (PMPM) premiums for the newly mandated benefit coverage vary by market segment (Table 5). Increases as measured by percentage changes in PMPM premiums are estimated to range from a low of 0.00% (for DMHC-regulated Medi-Cal HMO plans for ages 65+) to a high of 0.37% (for CDI-regulated individual policies) in the affected market segments. Increases as measured by PMPM premiums are estimated to range from \$0.00 to \$0.67.

In the privately funded large-group market, the increase in premiums is estimated to range from \$0.38 PMPM among DMHC-regulated plan contracts to \$0.56 PMPM among CDI-regulated policies (Table 5). For enrollees with privately funded small-group insurance policies, health insurance premiums are estimated to increase by approximately \$0.49 PMPM for DMHC contracts to \$0.65 PMPM for CDI policies. In the privately funded individual market, the health insurance premiums are estimated to increase by \$0.58 PMPM and by \$0.67 PMPM in the DMHC- and CDI-regulated markets, respectively.

In the publicly funded DMHC-regulated health plans, CHBRP estimates that premiums would decrease slightly or remain flat for Medi-Cal HMOs, Healthy Families and CalPERS HMOs, with the impact ranging from 0.00% to 0.07% (\$0.00 to \$0.26).

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, \$0.15 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 smoking cessation services, mostly OTC medications, would realize the greatest savings under the mandate, because full coverage for OTC medications would be available to them under the mandate.

Increases as measured by percentage changes in PMPM premiums are estimated to range from a low of 0.00% (for DMHC-regulated Medi-Cal HMO plans for ages 65+) to a high of 0.37% (for CDI-regulated individual policies) in the affected market segments. Increases as measured by PMPM premiums are estimated to range from \$0.00 to \$0.67.

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

CHBRP estimates premium increases of less than 1% for each market segment. CHBRP does not anticipate loss of health insurance, changes in availability of the benefit beyond those subject to the mandate, changes in offer rates of health insurance, changes in employer contribution rates, changes in take-up of health insurance by employees, or purchase of individual market policies, due to the small size of the increase in premiums after the mandate. This premium increase would not have a measurable impact on number of persons who are uninsured.

Impact on Access and Health Service Availability

CHBRP estimates that the proposed mandate would have no impact on the overall supply of smoking cessation treatments, because these services are already widely available and the mandate would not increase demand substantially. Expanded coverage for smoking cessation treatments would potentially encourage more insured individuals to use them and improve access for smokers who make an attempt to quit.

Table 4. Baseline (Pre-mandate) Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2010

	DMHC-Regulated							CDI-Regulated			Total Annual
	Privately Funded			CalPERS HMOs (b)	Medi-Cal HMOs		Healthy Families Program HMOs (d)	Privately Funded			
	Large Group	Small Group	Individual		65 and Over (c)	Under 65		Large Group	Small Group	Individual	
Total enrollees in plans/policies subject to state Mandates (a)	9,445,000	2,394,000	785,000	820,000	175,000	2,616,000	814,000	324,000	935,000	1,179,000	19,487,000
Total enrollees in plans/policies subject to SB 220	9,445,000	2,394,000	785,000	820,000	175,000	2,616,000	814,000	324,000	935,000	1,179,000	19,487,000
Average portion of premium paid by Employer	\$290.96	\$223.84	\$0.00	\$332.10	\$223.00	\$113.00	\$93.19	\$346.40	\$246.40	\$0.00	\$51,713,067,000
Average portion of premium paid by Employee	\$72.11	\$92.31	\$364.68	\$58.61	\$0.00	\$0.00	\$11.78	\$105.37	\$79.68	\$180.77	\$18,813,408,000
Total Premium	\$363.07	\$316.14	\$364.68	\$390.70	\$223.00	\$113.00	\$104.97	\$451.77	\$326.08	\$180.77	\$70,526,476,000
Enrollee expenses for covered benefits (Deductibles, copays, etc.)	\$19.77	\$25.74	\$64.43	\$20.15	\$0.00	\$0.00	\$1.52	\$58.78	\$116.51	\$44.19	\$5,961,186,000
Enrollee expenses for benefits not covered	\$0.09	\$0.13	\$0.13	\$0.00	\$0.00	\$0.00	\$0.00	\$0.20	\$0.21	\$0.19	\$20,615,000
Total Expenditures	\$382.93	\$342.01	\$429.24	\$410.85	\$223.00	\$113.00	\$106.50	\$510.76	\$442.80	\$225.15	\$76,508,277,000

Source: California Health Benefits Review Program, 2010.

Note: (a) This population includes persons insured with private funds (group and individual) and insured with public funds (e.g., CalPERS HMOs, Medi-Cal HMOs, Healthy Families Program, AIM, MRMIP) enrolled in health plans or policies regulated by DMHC or CDI. Population includes enrollees aged 0-64 years and enrollees 65 years or older covered by employment-sponsored insurance.

(b) Of these CalPERS HMO members, about 58% or 475,600 are state employees.

(c) Medi-Cal HMO state expenditures for members over 65 years of age include those who also have Medicare coverage.

(d) Healthy Families Program state expenditures include expenditures for the Major Risk Medical Insurance Program (MRMIP) and the Access for Infants and Mothers (AIM) program.

Table 5. Impacts of the Mandate on Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2010

	DMHC-Regulated							CDI-Regulated			Total Annual
	Privately Funded			CalPERS HMOs (b)	Medi-Cal HMOs		Healthy Families Program HMOs (d)	Privately Funded			
	Large Group	Small Group	Individual		65 and Over (c)	Under 65		Large Group	Small Group	Individual	
Total enrollees in plans/policies subject to state Mandates (a)	9,445,000	2,394,000	785,000	820,000	175,000	2,616,000	814,000	324,000	935,000	1,179,000	19,487,000
Total enrollees in plans/policies subject to SB 220	9,445,000	2,394,000	785,000	820,000	175,000	2,616,000	814,000	324,000	935,000	1,179,000	19,487,000
Average portion of premium paid by Employer	\$0.30	\$0.35	\$0.00	\$0.22	\$0.00	\$0.00	\$0.01	\$0.43	\$0.49	\$0.00	\$53,604,000.00
Average portion of premium paid by Employee	\$0.07	\$0.14	\$0.58	\$0.04	\$0.00	\$0.00	\$0.00	\$0.13	\$0.16	\$0.67	\$30,104,000
Total Premium	\$0.38	\$0.49	\$0.58	\$0.26	\$0.00	\$0.00	\$0.01	\$0.56	\$0.65	\$0.67	\$83,708,000
Enrollee expenses for covered benefits (Deductibles, copays, etc.)	-\$0.06	-\$0.05	-\$0.05	-\$0.11	\$0.00	\$0.00	\$0.00	-\$0.01	-\$0.01	-\$0.01	-\$10,437,000
Enrollee expenses for benefits not covered	-\$0.09	-\$0.13	-\$0.13	\$0.00	\$0.00	\$0.00	\$0.00	-\$0.20	-\$0.21	-\$0.19	-\$20,615,000
Total Expenditures	\$0.22	\$0.31	\$0.40	\$0.16	\$0.00	\$0.00	\$0.01	\$0.35	\$0.43	\$0.47	\$52,656,000
Percentage Impact of Mandate											
Insured Premiums	0.10%	0.16%	0.16%	0.07%	0.00%	0.00%	0.01%	0.12%	0.20%	0.37%	0.12%
Total Expenditures	0.06%	0.09%	0.09%	0.04%	0.00%	0.00%	0.01%	0.07%	0.10%	0.21%	0.07%

Source: California Health Benefits Review Program, 2010.

Note: (a) This population includes persons insured with private funds (group and individual) and insured with public funds (e.g., CalPERS HMOs, Medi-Cal HMOs, Healthy Families Program, AIM, MRMIP) enrolled in health plans or policies regulated by DMHC or CDI. This population includes enrollees aged 0-64 years and enrollees 65 years or older covered by employment-sponsored insurance.

(b) Of these CalPERS members, about 58% or 475,600 are state employees.

(c) Medi-Cal HMO state expenditures for members over 65 years of age include those who also have Medicare coverage.

(d) Healthy Families Program state expenditures include expenditures for the Major Risk Medical Insurance Program (MRMIP) and the Access for Infants and Mothers (AIM) program.

PUBLIC HEALTH IMPACTS

SB 220 mandates coverage for smoking cessation treatments for persons with outpatient prescription drug coverage through a DMHC- or CDI-regulated plan or insurance policy. Covered treatments include counseling, OTC NRT, and prescription medications. Use of these treatments individually or in combination can assist smokers with the difficult task of quitting and maintaining abstinence. In California, the prevalence of smoking in the insured adult population is 14.2% (CHIS, 2007). The average annual smoking-attributable mortality (SAM) rate was 249 per 100,000 Californians in 2004, resulting in 34,492 deaths (CDC, 2010a). During this same time period, smoking-attributable productivity losses in California were estimated to be more than \$8.5 billion (CDC, 2010a).

This section presents the estimated overall public health impact of passage of SB 220, followed by analysis examining the potential for reduction in gender and racial/ethnic disparities in health outcomes and the potential for the mandate to reduce premature death and societal economic losses as a result of smoking-related diseases.

Burden of Smoking-Related Disease

Smoking is the leading cause of preventable death and disease in the U.S. and California. The harms of smoking have been well established for many years, first receiving wide notice with the initial Surgeon General’s report on this topic in 1964. The Surgeon General’s 2004 updated report, *The Health Consequences of Smoking* (CDC, 2004), states that smoking causes multiple cardiovascular and respiratory diseases as well as cancers and estimates that one in three cancers is attributable to smoking (ACS, 2006). In California (Table 6), the most prevalent smoking-related cancers include lung, esophageal, and oral. The three most prevalent cardiovascular diseases contributing to SAM include ischemic heart disease (e.g., “heart attacks”), cerebrovascular disease (stroke), and aortic aneurysm. Respiratory diseases such as chronic airway obstruction, bronchitis/emphysema, and pneumonia/influenza account for the third largest SAM disease category (CDC, 2010a).

Table 6. California’s Average Annual Smoking-Attributable Mortality¹ by Disease, 2004

Disease	Number of Male Deaths	Number of Female Deaths	Total Deaths
Malignant neoplasms (cancer)	8,382	5,233	13,615
Cardiovascular	6,259	4,260	10,519
Respiratory	5,135	5,223	10,358
Total	19,776	14,716	34,492

Source: Centers for Disease Control and Prevention. CDC SAMMEC, Smoking-Attributable Mortality, 2010a.

¹ Among adults aged 35 years and older; does not include burn or secondhand smoke deaths.

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. Native Americans experience the highest rate of infant mortality due to Sudden Infant Death Syndrome (SIDS), which is also causally linked to smoking (Fiore, 2000).

Smoking Prevalence in California

Despite state-level advances in smoking cessation, smoking prevalence in California remains higher than the *Healthy People 2010*⁷⁰ target of 12% for adults (CHS, 2006). The 2007 California Health Interview Survey (CHIS) reported that 14.2% of insured Californians aged 18 to 64 years were current smokers (defined as smoking cigarettes every day or some days) (Table 7). Men demonstrate higher smoking prevalence than women; within each sex there is little variation by age.

Table 7. Smoking Prevalence Among Currently Insured California Adults (%), 2007

Age (years)	Male	Female	Total
18-24	18.4%	8.7%	13.4%
25-39	19.0%	10.9%	14.8%
40-64	16.7%	11.6%	14.1%
Total	17.7%	11.0%	14.2%

Source: California Health Interview Survey, 2007.

Smoking Cessation

Overcoming tobacco addiction typically involves an initial series of failed attempts (Fiore et al., 2000; Gilpin et al., 1997). The Surgeon General's 1990 report (CDC, 1990) characterized smoking 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 eventual success.

Unrestricted access to smoking cessation treatments dramatically improves the success of cessation attempts. Some studies demonstrate more than a doubling of the odds for successfully quitting among persons with full insurance benefits for smoking dependence compared to persons without such benefits (see *Medical Effectiveness* section). Utilization of cessation treatments is greatest in those populations with access to full coverage, and the greatest reductions in smoking prevalence are also found among groups with complete coverage without cost sharing (Curry, 1998).

Smoking 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 one year if all pregnant smoking women quit smoking (Ventura et al., 2003). Coronary artery disease (CAD) represents an example of both short- and long-term benefits from smoking cessation. CAD can be reversed substantially within one to two years of cessation (CDC, 1990; Lightwood and Glantz, 1997),

⁷⁰ Published by the U.S. Department of Health and Human Services, *Healthy People 2010* establishes a set of health objectives for the Nation to achieve over the first decade of the new century. States, local communities, professional organizations, and others use them to develop programs to improve health.

and after 10 to 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 reporting attempts to quit in the preceding year increased by 27% between 1990 and 2001 (CDHS/TCS, 2006). Since 1999, however, the annual quit-attempt rate has remained fairly constant at approximately 56% of current smokers. The 2005 California Tobacco Survey (CTS) showed that only one-quarter of persons attempting to quit smoking participate in a formal cessation assistance program (Table 8). Typically, such programs include a combination of counseling, prescription medications, NRT, and physician contact (Javitz, 2004). The CTS reported that NRT (alone or in combination with counseling or antidepressants) is the most frequently used treatment among persons using assistance and is used by more than 17% of persons reporting quit attempts (Al-Delaimy, 2008).

Table 8. Smoking Cessation Attempts in California, 2005

Cessation (Quit) attempts	% of California smokers
Quit Attempts (in last 12 months)	
Quit attempt of 1 day or longer	56
Successful 90+ days quit	8.6
Use by type of cessation treatment	
NRT ¹ alone	10.4
Counseling alone	4.4
Antidepressants alone	2.0
Counseling and NRT	5.1
Counseling and antidepressants	0.9
NRT and antidepressants	1.7
NRT, counseling, and antidepressants	1.6
Smokers using one or more types of treatments	26.1
No use of any cessation treatment during quit attempt	73.9

Source: California Health Benefits Review Program, 2010, based on 2005 California Tobacco Survey, Al-Delaimy, 2008.

¹The Tobacco Survey includes prescription NRT in its general term “NRT.” CHBRP uses “OTC” to describe all NRTs available over-the-counter. CHBRP defines prescription medication as inclusive of prescription NRT, other smoking cessation medications, and the antidepressant bupropion.

Impact of the Proposed Mandate on the Public’s Health

To assess the impact of a bill on the public’s health, CHBRP assesses the medical effectiveness of the intervention as well as the estimated marginal change in coverage and utilization of the intervention. In this case, the smoking cessation treatments mandated by SB 220 are considered medically effective, and coverage for these treatments demonstrably improves smoking cessation rates. (See *Medical Effectiveness* section of this report).

Impact on Health: Smoking Cessation

A precise estimate of the quantitative effect of the SB 220 mandate on smoking cessation requires detailed information about smoking habits and cessation attempts unavailable to CHBRP. However, sufficient information is available for CHBRP to estimate that **approximately 8,081 additional persons annually would successfully quit smoking attributable to passage of SB 220** (see *Appendix E* for explanation of calculation).

This estimate may undercount the number of smokers attempting to quit (and successful quits) because it assumes the denominator of smokers attempting to quit remains the same; only a shift from self-help to users of newly covered treatment(s) would occur. However, coverage for smoking cessation treatments may increase the total number of smokers attempting to quit. This effect would increase the number of successful quits. Additionally, medical literature suggests that the use of more than one treatment simultaneously improves the quit rate. This analysis presumes use of a single treatment and the estimates may be an undercount of successful quitters.

Additionally, SB 220 would reduce out-of-pocket expenses and copayments for enrollees who use smoking cessation treatments, thereby reducing enrollees' financial barriers for smoking cessation. Approximately 1.1 million enrollees who try to quit smoking with counseling and/or pharmacotherapy assistance would receive a reduction in annual copayments and out-of-pocket expenses of about \$31 million (see Table 1).

Smoking cessation treatment is typically well tolerated. However, a minority of persons may experience side effects from prescription medications (hypertension, neuropsychiatric symptoms, insomnia, increased seizure risk, etc.) or nicotine replacement therapy (nausea, irregular heartbeat, soft tissue irritation around site of administration, etc.) (FDA, 2010). Serious adverse events are rare, but may result in increased health care costs to treat the events. CHBRP estimates that, for the overall population, any cost increases would be outweighed by the benefits of smoking cessation.

CHBRP estimates that approximately 8,081 additional successful cessations would occur annually that are attributable to passage of SB 220 (see <i>Appendix E</i> for methodology).
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Impact on the Health of the Community Where Gender and Racial Disparities Exist

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

CHBRP investigated the effect that SB 220 would have on health disparities by gender, race, and ethnicity. Differential insurance rates contribute importantly to ethnic health disparities, where minorities are more likely than whites to be uninsured. However, ethnic disparities exist even within the insured population (Kirby et al., 2006; Lillie-Blanton and Hoffman, 2005). Because

SB 220 would only impact the insured population, CHBRP conducted a literature review to characterize gender, racial, or ethnic disparities associated with prevalence, treatment, and outcomes for smoking and cessation within insured populations.

Gender and Racial/Ethnic Disparities: Smoking Prevalence and Smoking Cessation

Table 10 describes ethnic and gender differences in smoking prevalence among insured California adults. The most striking finding relates to race and ethnicity: there is a 2.5-fold difference in smoking prevalence between the lowest group (Asians, 11.2%) and the highest group (American Indian/Alaska Native, 27.3%). At 12% and 11% prevalence, respectively, California’s Latino and Asian populations are closest to achieving the *Healthy People 2010* target of 12% or lower smoking prevalence. Within each racial and ethnic group there are also large differences by sex. Asian men are almost six times more likely to report smoking than are Asian women, and smoking prevalence for Latino men are twice that of Latina women. The highest smoking prevalence is among American Indian/Alaska Native men (36%), whereas the lowest is found in Asian women (3%) (CHIS, 2007).

Disparities extend to socioeconomic status as well. Both men and women with incomes less than 200% of the federal poverty level (FPL) are more likely to smoke than those who have higher incomes. The poorest individuals with incomes between 0 and 99% of FPL are almost twice as likely to report smoking as are those with incomes at or above 300% FPL.

Table 9. Racial and Economic Disparities in Smoking Prevalence Among Adults

Race (among currently insured adults)	Male	Female	Total
Latino	16.5%	8.2%	12.3%
White	16.6%	13.0%	14.8%
African American	25.2%	18.3%	21.3%
American Indian/Alaskan Native	36.4%	19.8%	27.3%
Asian	19.6%	3.4%	11.2%
Native Hawaiian/Pacific Islander	13.7%*	30.6%*	21.3%
Two Or More Races	23.7%	20.7%	22.1%
Poverty Status	Male	Female	Total
0-99% FPL	29.8%	15.3%	20.7%
100-199% FPL	19.7%	15.5%	17.4%
200-299% FPL	21.3%	12.3%	16.8%
300% + FPL	15.1%	8.7%	12.0%

Source: California Health Interview Survey, 2007

Key: FPL= Federal Poverty Level

* = Statistical issue renders this figure unreliable (variance too high or number of respondents too low)

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. Recent research recognizes that racial and socioeconomic disparities in cessation utilization exist and recommends targeted expanded cessation efforts (King, 2007). Other research indicates the

minority smokers may be less likely to use cessation aids even when available (Fu, 2008). Two research groups (Fiore et al., 2000; Lawrence et al., 2003) recommend that further investigation of targeted versus generic cessation interventions is warranted for racial and ethnic minority populations.

Gender and Racial/Ethnic Disparities: Acute myocardial infarction (AMI)

Smoking is one of the primary risk factors for AMI. For all races, men have higher AMI-related mortality than women. White men have the highest AMI mortality rate at 54.7 per 100,000 per year, whereas women of two or more races have the lowest, 4.2 per 100,000 per year (Table 11). See the section *The Extent to which the Proposed Service Reduces Premature Death and the Economic Loss Associated with Smoking: Short Term Outcomes* for more information about gender and racial differences in health outcomes related to AMI and racial differences in low-birth weight delivery outcomes due to smoking.

Smoking prevalence differs by race, ethnicity, and gender. There are insufficient data for CHBRP to assess the extent to which SB 220 would modify gender and racial disparities for smoking and its associated health outcomes.

The Extent to which the Proposed SB 220 Mandate Would Reduce Premature Death and the Economic Loss Associated with Smoking

To capture the short-term outcomes of mandated smoking cessation coverage, this analysis focuses on two health outcomes: AMI and low birth weight. CHBRP selected these short-term measures based on literature findings that (1) smoking has a direct causal link to both low birth weight and AMI, and that (2) smoking cessation has a demonstrable impact on these outcomes within 1 year of cessation (short term). Additionally, CHBRP acknowledges the role secondhand smoke plays in increased morbidity and mortality in the short- and long-term health outcomes, although we are unable to quantify it for this report. Calculated reductions in morbidity or mortality in this analysis may therefore be an underestimate because of the possible smoking cessation benefits realized by non-smokers who reside or work with smokers who quit smoking (USDHHS, 2006).

The health burden of smoking—and therefore the benefits that proceed from SB 220-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 for this report. The *Long-Term Health Outcomes: Overall Mortality* section (below) of this report will address the issue of total smoking-related mortality.

Morbidity: AMI

AMI baseline data

AMI occurs when decreased blood flow to an area of the heart muscle leads to cell damage and death. There are multiple underlying causes of AMI, but smoking is one of the primary risk factors and is related to smoking-associated damage to blood vessels, which compromises their ability to bring blood and oxygen to the brain, heart, and other body tissues.

According to the California Center for Health Statistics, AMI is one of the leading causes of death in the U.S. and in California (CHS, 2008). Mortality due to AMI in California varies by race and gender (Table 11). For all races, men have higher AMI-related mortality than women. White men have the highest AMI mortality rate (54.7 per 100,000 population), whereas women of two or more races have the lowest (4.2 per 100,000 population).

Table 10. Acute Myocardial Infarction Mortality* Rate by Race, 2008

Race	Men	Women
Asian	26.0	21.0
Black	37.8	37.3
Hispanic	12.8	11.5
White	54.7	46.3
American Indian	28.3	9.4
Pacific Islander	52.7	35.0
Two or more races	8.1	4.2
Total	33.8	29.2

Source: California Center for Health Statistics, 2008

*Deaths per 100,000 Californians in 2008.

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 (now the California Department of Public Health), 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).

Lightwood and Glantz (1997) estimated the effect of California's public health tobacco control programs on hospitalization for AMI and stroke within the first year after cessation. These investigators estimated that an annual 1% reduction in smoking prevalence across the population (corresponding to approximately 3% to 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 one 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, smoking 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). Furthermore the U.S. Surgeon General's report on exposure to tobacco smoke for nonsmokers concludes that there is sufficient evidence to infer a causal relationship between exposure to secondhand smoke and an increased risk of coronary heart disease morbidity and mortality among both men and women (USDHHS, 2006).

CHBRP estimates that passage of SB 220 would result in a reduction of fewer than 10 AMI cases annually in California (see *Appendix E* for methodology).

Morbidity: 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 12).

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

Race/Ethnicity	Low-Birth Weight Delivery As a Percentage of Live Births
Black	12.8%
Multi-race	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, analysis of the California Center for Health Statistics, *Healthy California 2010*, 2006.

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 Centers for Disease Control and Prevention (CDC) estimates that in California, 2,012 years of potential life were lost attributable to smoking-related increases in low-birth weight infants in 2004 (CDC, 2010b). Furthermore, the CDC reports an 8.1% maternal smoking prevalence in California in 2004 (most recent data available) (CDC, 2010b).

In addition to pregnant smokers contributing disproportionately to low-birth weight babies, secondhand smoke also has been causally linked with low birth weight according to the U.S. Surgeon General’s report (USDHHS, 2006). The report concludes that there is sufficient evidence to infer a causal relationship between maternal exposure to secondhand smoke during pregnancy and reduced birth weight.

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. The SAMMEC Maternal Child Health reports California’s 2003 smoking-attributable neonatal expenditures at \$11.8 million (CDC, 2010b). 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 women smokers. The prevalence of smoking among newly pregnant women was 9% in 2002, but fell to 5% by the 6th month of pregnancy (CDHS/TCS, 2006). Other researchers have found similar results. Lumley et al. (2009) reviewed 65 trials regarding the effects of smoking cessation interventions (including either behavioral and/or pharmacotherapy) in pregnant women. The trials demonstrated a significant reduction (6%) in smoking during late pregnancy. The interventions ceased to be effective from 6 to 12 months post-delivery.

Fiore et al. (2008) reviewed eight trials of smoking cessation counseling interventions in pregnant women and reported higher cessation rates in the intervention group when measured in late pregnancy. They found no continued effect of the intervention when measured at 5 months postpartum. Pickett and colleagues report that about 30% of pregnant smokers quit early in their pregnancy (Pickett et al., 2001). Colman and colleagues estimated 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, smoking 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% smoking abstention among those without coverage (Petersen et al., 2006).

Smoking 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 smoking cessation treatments 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 smoking 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.

CHBRP estimates that passage of SB 220 would result in a reduction of fewer than 10 low–birth weight deliveries annually in California (see <i>Appendix E</i> for methodology).

Long-Term Outcomes

Economists and public health experts examine premature death and economic loss associated with disease to assess the impact of a condition or disease. Premature death, often defined as death before the age of 75 (Cox, 2006), can be measured in years of potential life lost (YPLL) (Cox, 2006; Gardner and Sanborn, 1990). Economic loss associated with disease is generally estimated as the dollar value of the YPLL (i.e., valuation of years of work life lost from premature death or lost productivity due to disease or condition).

Long-Term Health Outcomes: Overall Mortality

Estimating the long-term impact of SB 220 is challenging, and CHBRP has limited capacity for modeling the long-term cost and health consequences of benefit mandates (CHBRP, 2008). However, the literature provides substantial evidence regarding reduced mortality resulting from smoking cessation. Accordingly, this report focuses 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 smoking 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 (now the California Department of Public Health) 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.

The actual years of life gained attributable to smoking cessation will vary with the age at which the smoker quit and other factors; a precise accounting for this effect would require information about the underlying population that is unavailable. Nevertheless, the following estimates are valuable for showing the approximate magnitude of benefit in years of life gained across the state attributable to the SB 220 mandate. In addition, these figures are consistent with those developed by the CDC. The CDC estimates that smokers 35 years of age and older in California annually experience 484,022 years of potential life lost attributable to smoking, or 13.2 years of life lost per death (CDC, 2010a). Using the Taylor (2002) and Max (2004) studies to estimate a range of years gained from quitting (7.0 to 12.4 years), CHBRP estimates that passage of SB 220 would produce 56,567 to 100,204 years of potential life gained annually for California smokers who successfully quit using smoking cessation treatments.

<p>When these estimates of increased longevity for successful quitters are applied to the 8,081 additional smokers who would quit each year attributable to the SB 220 mandate, between 56,567 to 100,204 years of potential life would be gained in the state each year.</p>

There is a preponderance of evidence that SB 220 would contribute to the reduction in premature death from long-term smoking-related diseases such as cancer and cardiovascular and respiratory diseases.

Economic Loss

Quantitative assessments of the disease burden imposed by smoking 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 smoking cessation treatments is beyond the scope of this report. However, according to the CDC, smoking-related productivity loss in California (2004) was \$8.5 billion (CDC, 2010a). Furthermore, there is evidence that indirect costs are reduced by smoking cessation. For example, smokers who successfully quit report improved quality of life relative to current smokers (Mulder et al., 2001).

Several studies address smoking cessation effectiveness compared to that 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 for heart disease patients (Critchley and Capewell, 2003; Suskin et al., 2001). Other studies report that the cost for treating high blood pressure ranges from \$5,000 to \$45,000 per life-year saved, whereas smoking cessation treatment is estimated to cost a few hundred to a few thousand dollars per life-year saved (Warner et al., 2004). Putting smoking cessation into a preventive treatment context demonstrates that cost effectiveness of smoking cessation is comparable or superior to other commonly used preventive services. For example, mammography screening is estimated to cost \$20,000 per life-year saved (Warner et al., 2004).

Other studies also address the cost-effectiveness of coverage for smoking cessation treatments from the employer or health insurance industry perspective (Curry, 1998; Fitch et al, 2006). Additionally, the trade association America's Health Insurance Plans (AHIP) sponsors a Web-based calculator for health insurers and employers to calculate the return on investment (ROI) for smoking cessation programs. AHIP concludes that clinical interventions for smoking cessation provide a positive ROI within 2 to 5 years of implementation (AHIP, 2010). The methodology includes time-dependent measures for smoking status, disease diagnosis, and plan disenrollment, which is of particular interest to the health insurance industry.

As presented in the *Utilization, Cost, and Benefit Coverage Impacts* section, SB 220 is expected to increase premiums by less than 1%. CHBRP does not estimate loss of coverage as a result of premium increases of less than 1%. Therefore, it is unlikely that SB 220 would result in an increase in the uninsured or contribute to the long-term health impacts of being uninsured.

Conclusion

SB 220 would likely have a positive impact on public health in California, based on (1) the scientific evidence of the medical effectiveness of smoking cessation treatments, (2) the likely increase in utilization of smoking-cessation treatments and successful smoking cessation

associated with SB 220, (3) the favorable impact of smoking cessation on both short- and long-term health outcomes, and (4) the cost effectiveness of smoking cessation. Short-term benefits include and are illustrated by reductions in morbidity and mortality associated with AMI 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 56,567 to 100,204 years gained each year under the mandate. The expected reduction in smoking prevalence and mortality attributable to SB 220 would bring California closer to achieving *Healthy People 2010* goals (CHS, 2006).

APPENDICES

Appendix A: Text of Bill Analyzed

On March 11, 2010, Senate Bill 220 was amended to include language mandating coverage for tobacco cessation services. On April 22, 2010, the Assembly Committee on Health requested CHBRP to analyze amended language (formally introduced on May 26, 2010). The following is the amended language analyzed by CHBRP.

BILL NUMBER: SB 220 AMENDED

BILL TEXT

AMENDED IN ASSEMBLY MAY 26, 2010
AMENDED IN ASSEMBLY MARCH 11, 2010
AMENDED IN ASSEMBLY JULY 16, 2009
AMENDED IN ASSEMBLY JULY 2, 2009
AMENDED IN SENATE APRIL 13, 2009

INTRODUCED BY Senator Yee

FEBRUARY 23, 2009

An act to add Section 1367.27 to the Health and Safety Code, and to add Section 10123.175 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

SB 220, as amended, Yee. Health care coverage: tobacco cessation services.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the regulation of health care service plans by the Department of Managed Health Care and makes a violation of the act a crime. Existing law provides for the regulation of health insurers by the Department of Insurance. Under existing law, a health care service plan and a health insurer are required to provide coverage for specified tests, including all generally medically accepted cancer screening tests.

This bill would require certain health care service plan contracts and health insurance policies that provide outpatient prescription drug benefits to also provide coverage for tobacco cessation services *that include specified courses of treatment and medication*, and would ~~impose limits on~~ prohibit the

imposition of copayments , coinsurance, or deductibles for the receipt of those services benefits.

Because a willful violation of the bill's provisions relative to health care service plans would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

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

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. The Legislature finds and declares the following:

(a) Providing tobacco cessation counseling and medication is one of the most clinically effective and cost-effective health services available, second only to inoculations. Tobacco cessation is 5 to 80 times more cost effective than pharmacologic interventions used to prevent heart attacks.

(b) More than 70 percent of smokers wish they could quit tobacco, and each year one of every two smokers attempts to quit. However, the unassisted successful tobacco quit rate has remained constant at less than five percent. Access to counseling and pharmaceutical benefits doubles the successful quit rate and has achieved quit rates of 25 to 30 percent. Experience in health plans indicates that access to all cessation services saves four dollars (\$4) for every dollar (\$1) invested.

(c) Each adult smoker costs employers one thousand seven hundred sixty dollars (\$1,760) in lost productivity and one thousand six hundred twenty-three dollars (\$1,623) in excess medical expenditures. Men who smoke incur fifteen thousand eight hundred dollars (\$15,800) more in lifetime medical expenses than ~~do~~ men who do not smoke. For employers, the ultimate financial return is between five dollars (\$5) and six dollars (\$6) for every dollar spent on tobacco cessation.

(d) Because of member transfers between plans, financial savings and tobacco-related disease reductions are effective only if universally available to the entire insured population. Therefore, a mandate on all plans and insurers to provide cost-effective treatment is necessary and beneficial.

(e) It is the intent of the Legislature that this act diminish the

statewide economic and personal cost of tobacco addiction by making tobacco cessation treatments available to all smokers. California has successfully reduced tobacco consumption in the last decade, but, despite that success, tobacco use is responsible for the unnecessary deaths of 40,000 residents and remains the leading cause of preventable death in this state. Annually, tobacco addiction costs California \$8.6 billion in direct medical costs, which is approximately 12 percent of all health care costs.

SEC. 2. Section 1367.27 is added to the Health and Safety Code, to read:

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, 2011, that provides outpatient prescription drug benefits, shall include coverage for tobacco cessation services that include two courses of treatment in a 12-month period including personal counseling, which may be telephone ~~or individual counseling, and FDA-approved medication for tobacco cessation, including prescription and over-the-counter medications. Covered treatment shall comply with~~ , group, or individual counseling, and all *medications approved by the FDA for the purpose of tobacco cessation, including all prescription and over-the-counter medications. Covered treatment shall follow recommendations in the Public Health Service sponsored 2008 clinical practice guideline, "Treating Tobacco Use and Dependence: 2008 Update," or its successors.*

(b) No copayment , *coinsurance*, or deductible shall be applied to ~~benefits for over-the-counter tobacco cessation medications. Copayments for each course or treatment or prescription shall not exceed fifteen dollars (\$15). the 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) 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 enrollees *at least once per year* .

(e) The coverage provided pursuant to this section shall only be available upon the order of an authorized provider. Nothing in this subdivision shall preclude a plan from allowing enrollees to access tobacco cessation services on a self-referral basis.

(f) *As used in this section, "course of treatment" shall be defined to consist of the following:*

(1) *As applied to counseling, at least four sessions of counseling, each session lasting at least 10 minutes.*

(2) *As applied to a prescription or over-the-counter medication,*

the duration of treatment approved by the FDA for that medication.

(g) Enrollees shall not be required to enter counseling in order to receive tobacco cessation medications.

(h) A health care service plan shall not impose prior authorization or stepped-care requirements on tobacco cessation treatment.

SEC. 3. 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, 2011, that provides outpatient prescription drug benefits, shall include coverage for tobacco cessation services that include two courses of treatment in a 12-month period including personal counseling, which may be telephone ~~or individual counseling,~~ and FDA-approved medication for tobacco cessation, including ~~prescription and over-the-counter medications.~~ Covered treatment shall comply with ~~, group, or individual counseling,~~ and all medications approved by the FDA for the purpose of tobacco cessation, including all prescription and over-the-counter medications. Covered treatment shall follow recommendations in the Public Health Service sponsored 2008 clinical practice guideline, "Treating Tobacco Use and Dependence: 2008 Update," or its successors.

(b) No copayment , *coinsurance*, or deductible shall be applied to ~~benefits for over-the-counter tobacco cessation medications. Copayments for each course or treatment or prescription shall not exceed fifteen dollars (\$15).~~ *the benefits under this section.*

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

(d) An insurer shall disclose the benefits under this section in its evidence of coverage and disclosure forms and communicate the availability of coverage to all insureds *at least once per year.*

(e) The coverage provided pursuant to this section shall only be available upon the order of an authorized provider. Nothing in this subdivision shall preclude an insurer from allowing insureds to access tobacco cessation services on a self-referral basis.

(f) As used in this section, "course of treatment" shall be defined to consist of the following:

(1) As applied to counseling, at least four sessions of counseling, each session lasting at least 10 minutes.

(2) As applied to a prescription or over-the-counter medication, the duration of treatment approved by the FDA for that medication.

(g) Insureds shall not be required to enter counseling in order to receive tobacco cessation medications.

(h) A health care service plan shall not impose prior authorization or stepped-care requirements on tobacco cessation treatment.

~~—(f)~~

(i) This section shall not apply to a Medicare supplement, short-term limited duration health insurance, vision-only, dental-only, or ~~Champus supplement~~ CHAMPUS-supplement insurance, or to hospital indemnity, hospital-only, accident-only, or specified disease insurance that does not pay benefits on a fixed benefit, cash payment only basis.

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

Appendix B: Literature Review Methods

Appendix B describes methods used in the medical effectiveness literature review for SB 220. This literature review updates the reviews CHBRP conducted for SB 576 in 2005 and SB 24 in 2007.

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

Studies of the effects of smoking cessation treatments and coverage for these treatments were identified through searches of PubMed, the Cochrane Library, the Cumulative Index of Nursing and Allied Health Literature, EconLit, PsycInfo, and SCOPUS. Web sites maintained by the following organizations that produce and/or index meta-analyses and systematic reviews were also searched: the Agency for Healthcare Research and Quality, the International Network of Agencies for Health Technology Assessment, the National Health Service Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence, and the Scottish Intercollegiate Guideline Network.

The search was limited to studies published in English from 2007 to present, because CHBRP had previously conducted thorough literature searches on these topics in 2005 and 2007 for SB 576, and SB 24, respectively

For the literature review for SB 220, 876 abstracts were reviewed. 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 34 studies were included in the medical effectiveness review for SB 220, including 11 studies from the SB 576 review, 11 additional studies from the SB 24 review, and 12 new studies published since the literature review for SB 24 was completed in 2007.⁷¹

The literature on behavioral and pharmacological treatments to improve smoking cessation rates and continued abstinence is extensive, including numerous meta-analyses of randomized

⁷¹ In some cases, more current versions of meta-analyses and systematic reviews included in the SB 576 and SB 24 reports were included in the literature review for the SB 220 report. Several of the Cochrane reviews on the efficacy of tobacco cessation treatments that were cited in the SB 576 and SB 24 reports were updated and re-issued following CHBRP's release of the SB 24 report in 2007. For example, Lancaster and Stead (2008) is an update of a Cochrane review that these authors initially published in 2004. In addition, the U.S. Public Health Service (PHS) issued a new version of its evidence-based guideline for treatment of tobacco dependence in 2008 (Fiore et al., 2008). The new version included meta-analyses that incorporated findings from studies published since the previous version of the PHS guideline was released in 2000.

controlled trials (RCTs), the strongest form of evidence available for CHBRP analyses. Accordingly, CHBRP relied to the extent feasible on these meta-analyses. Where meta-analyses were not available, CHBRP drew upon individual RCTs.

In contrast, less research has been completed on the impact of coverage for smoking cessation treatments on the use of these treatments and abstinence from smoking. The review on the impact of coverage included nonrandomized studies with comparison groups 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 indicates that available evidence is not sufficient to determine whether or not a health care service is effective. It is used when no research studies have been completed or when only a small number of poorly designed studies are available. It is not the same as “evidence of no effect.” A health care service for which there is insufficient evidence might or might not be found to be effective if more evidence were available.

MeSH Terms

Absenteeism
Age Distribution
Alkaloids/therapeutic use
Asthma/prevention & control
Azocines/therapeutic use
Behavior Therapy
Benzazepines/therapeutic use
Bupropion/therapeutic use
Cardiovascular Diseases/economics
Cardiovascular Diseases/etiology
Cardiovascular Diseases/mortality
Cardiovascular Diseases/prevention & control
Cerebrovascular Accident/etiology
Cerebrovascular Accident/mortality
Chewing Gum
Clonidine/therapeutic use
Cohort Studies
Coronary Disease/economics
Coronary Disease/etiology
Coronary Disease/mortality
Coronary Disease/prevention & control
Cost-Benefit Analysis
Cost Control
Cost Saving
Cost Sharing
Counseling
Counseling/economics
Counseling/methods
Cross Sectional Studies
Delivery of Health Care/economics
Dopamine Uptake Inhibitors/therapeutic use
Drug Costs
Drugs, Non-Prescription/economics
Drugs, Non-Prescription/therapeutic use
Evidence Based Medicine
Financial Management
Follow-up Studies

Group Processes
Health Benefit Plans, Employment
Health Expenditures/trends
Hospitalization
Hotline
Insurance Coverage
Insurance, Health
Intervention Studies
Longevity
Lung Neoplasms/etiology
Lung Neoplasms/mortality
Lung Neoplasms/prevention & control
Mortality
Motivation
Myocardial Infarction/etiology
Myocardial Infarction/mortality
Myocardial Infarction/prevention & control
Myocardial Ischemia/etiology
Myocardial Ischemia/mortality
Myocardial Ischemia/prevention & control
Nicotine/administration & dosage
Nicotine/adverse effects
Nicotine/therapeutic use
Nicotinic Agonists/administration & dosage
Nicotinic Agonists/therapeutic use
Nortriptyline/therapeutic use
Nurse Practitioners
Nurse's Role
Nursing Care
Outcome and Process Assessment (Health Care)
Pharmacists
Physician Assistants
Physician's Role
Pregnancy Complications/prevention & control
Pregnancy Outcome
Prescriptions, Drug/economics
Prescriptions, Drug/therapeutic use
Program Evaluation
Prospective Studies
Pulmonary Disease, Chronic Obstructive/etiology
Pulmonary Disease, Chronic Obstructive/mortality
Quality-Adjusted Life Years
Quality Assurance, Health Care/economics
Quality of Life
Quinolizines/therapeutic use
Reward

Risk
Risk Reduction Behavior
Sex Distribution
Sex Factors
Smoking/adverse effects
Smoking/economics
Smoking/mortality
Smoking/prevention & control
Smoking/statistics & numerical data
Smoking/therapy
Smoking Cessation/economics
Smoking Cessation/methods
Smoking Cessation/psychology
Smoking Cessation/statistics & numerical data
Social Supports
Substance Withdrawal Syndrome/drug therapy
Telephone
Tobacco Use/prevention & control
Tobacco Use Cessation/economics
Tobacco Use Cessation/methods
Tobacco Use Disorder/drug therapy
Tobacco Use Disorder/therapy
Treatment Outcome
Varenicline/therapeutic use
Weight Gain/drug effects

In addition to MeSH terms, Keywords were used to search SCOPUS and Web sites.

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

*indicates truncation of a keyword to search for all possible variants of it.

Publication Types

Comparative Study

Evaluation Studies

Meta-Analysis

Multicenter Study

Practice Guideline

Randomized Controlled Trial

Review

Systematic Review

Appendix C: Summary Findings on Medical Effectiveness

Appendix C describes the meta-analyses, systematic reviews, and individual studies on smoking cessation treatments 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 smoking cessation counseling. Table C-1-b lists studies of the effectiveness of over-the-counter and prescription medications for smoking cessation. Table C-1-c lists studies of the impact of coverage for smoking cessation treatments. The studies listed in these tables include studies cited in CHBRP's reports on SB 576 and SB 24, bills regarding coverage for smoking cessation treatments that were introduced in 2005 and 2007, respectively, as well as additional studies that have been published since 2007. In some cases, more recent versions of studies cited in the SB 576 and SB 24 reports are listed.⁷²

Table C-1-a. Summary of Published Studies on Effectiveness of Smoking Cessation Treatments (Counseling)

Citation	Type of Trial	Intervention vs. Comparison Group	Population Studied	Location
Barth et al., 2008	Meta-analysis	Counseling, support and advice, with or without provision of written materials vs. usual care	Patients with coronary heart disease who smoke	N/A
Bock et al., 2008	Randomized Controlled Trial	Counseling via motivational interviewing and pharmacotherapy vs. usual care	Smokers admitted to emergency room for chest pain after 6-month follow-up	Emergency department of a urban university-affiliated hospital
Fiore et al., 2008	Meta-analysis	Individual counseling vs. no intervention Group counseling vs. no intervention Quitline telephone counseling vs. minimal or no intervention Brief advice vs. no advice	Smokers after 5-month follow-up	N/A ⁷³
Lancaster and Stead, 2008	Meta-analysis	Face-to-face individual counseling from a health care worker not involved in routine clinical care vs. minimal intervention	Smokers after 6-month follow-up	N/A

⁷² Some of the Cochrane reviews that are cited in Tables C-1-a and C-1-b have been updated since CHBRP issued its report on SB 24 in 2007. For example, Lancaster and Stead (2008) is an update of a Cochrane review on individual counseling that these authors initially published in 2004. In addition, the U.S. Public Health Service (PHS) issued a new version of its evidence-based guideline for treatment of tobacco dependence in 2008 (Fiore et al., 2008). The new version included meta-analyses that incorporated findings from studies published since the previous version of the PHS guideline was released in 2000.

⁷³ Location is not reported for meta-analyses because they synthesize results from multiple studies conducted in multiple locations.

Table C-1-a. Summary of Published Studies on Effectiveness of Smoking Cessation Treatments (Counseling) (Cont'd)

Citation	Type of Trial	Intervention vs. Comparison Group	Population Studied	Location
Lumley et al., 2009	Meta-analysis	Behavioral and or pharmacotherapy vs. usual care	Pregnant women who smoke. Follow-up during late pregnancy and 1-5 months post delivery	N/A
Mojica et al., 2004	Meta-analysis	Relative effectiveness of smoking cessation counseling interventions delivered by psychologists, physicians, and nurses	Smokers after 5-month follow-up	N/A
Motillo et al., 2009	Meta-analysis	Individual counseling vs. no intervention Group counseling vs. no intervention Telephone counseling vs. no intervention Brief advice vs. no intervention	Smokers after 6-month follow-up	N/A
Rice and Stead, 2008	Meta-analysis	Advice by a nursing professional vs. no intervention	Adult smokers over 18 years, after 6-month follow-up	N/A
Rigotti et al., 2008	Meta-analysis	Intensive intervention (inpatient contact plus follow up for at least 1 month) vs. usual care	Hospital inpatients after 6-month follow-up	N/A
Sinclair et al., 2008	Meta-analysis	Smoking cessation intervention provided by community pharmacy personnel compared to usual pharmacy support or less intensive program.	Pharmacy customers who smoke and express a desire to stop smoking	N/A
Stead et al., 2009	Meta-analysis	Proactive telephone counseling vs. minimal intervention Quitline telephone counseling vs. minimal intervention	Smokers after 6-month follow-up	N/A
Stead and Lancaster, 2009	Meta-analysis	Group smoking cessation counseling vs. minimal contact or no intervention	Smokers after 6-month follow-up	N/A
Stead, Bergson, et al., 2008	Meta-analysis	Minimal advice vs. no advice or usual care	Smoker after 6 to 12 months	N/A
Strassmann et al., 2009	Meta-analysis	Counseling with and without pharmacotherapy vs. usual care	Patients with COPD after 6-month follow-up	N/A

Table C-1-b. Summary of Published Studies on Effectiveness of Smoking Cessation Treatments (Pharmacotherapy)

Citation	Type of Trial	Intervention vs. Comparison Group	Population Studied	Location
Cahill et al., 2008	Meta-analysis	Varenicline vs. placebo Varenicline vs. bupropion ⁷⁴	Smokers after 6-month follow-up	N/A
Eisenberg et al., 2008	Meta-analysis	Bupropion SR vs. placebo Nicotine replacement therapy ⁷⁵ (NRT) vs. placebo Varenicline vs. placebo Varenicline vs. bupropion SR	Smokers after 6-month follow-up	N/A
Fiore et al., 2008	Meta-analysis	Bupropion ⁷⁶ vs. placebo NRT vs. placebo Varenicline vs. placebo Varenicline vs. bupropion	Smokers after 5-month follow-up	N/A
Gourlay et al., 2008	Meta-analysis	Clonidine vs. placebo	Smokers after 3-month or greater follow-up	N/A
Hughes et al., 2010	Meta-analysis	Bupropion ⁷⁷ vs. placebo and varenicline	Smokers after 6-month follow-up	N/A
Myung et al., 2007	Meta-analysis	Nicotine patch vs. placebo	Smokers after 12-month follow-up	N/A
Shah et al., 2008	Meta-analysis	Nicotine patch plus another first-line medication vs. single medication	Smokers after 6-month follow-up	N/A
Stead, Perera, et al., 2008	Meta-analysis	NRT vs. placebo or no treatment	Smokers after 6-month follow-up	N/A

⁷⁴ Although bupropion SR at strengths of 100 or 150 milligrams is the only formulation of bupropion approved by the FDA for smoking cessation, Cahill et al., 2008 does not indicate whether all of the RCTs included in their meta-analysis received bupropion SR. Some of the RCTs may have assessed the efficacy of other formulations of bupropion.

⁷⁵ Nicotine replacement therapy (NRT) is available in five forms: gum, patch, lozenge, inhaler, and spray. Three meta-analyses assessed findings from randomized controlled trials (RCTs) of multiple types of NRT (Eisenberg et al., 2008; Fiore et al., 2008; Stead et al., 2008b).

⁷⁶ Fiore et al., 2008 does not indicate whether all of the RCTs included in their meta-analysis received bupropion SR. Some of the RCTs may have assessed the efficacy of other formulations of bupropion.

⁷⁷ Hughes et al., 2010 does not indicate whether all of the RCTs included in their meta-analysis received bupropion SR. Some of the RCTs may have assessed the efficacy of other formulations of bupropion.

Table C-1-c. Summary of Published Studies on Effects of Copayments, Coinsurance, and Deductibles on Use of Smoking Cessation Treatments 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 ⁷⁸ vs. partial and no coverage	Smokers after 6-month follow-up	N/A
Boyle et al., 2002*	Observational study—nonequivalent comparison group	Coverage for nicotine replacement therapy (NRT) and bupropion SR 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	<p>Analysis 1: Coverage for smoking 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)</p> <p>Analysis 2: Comparison based on coverage for smoking 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)</p> <p>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% coverage for behavioral intervention and 50% coverage for NRT), and (3) full plan (100% coverage for behavioral intervention and NRT)</p>	<p>Analysis 1: 10,669 adults enrolled in a group/staff model HMO</p> <p>Analysis 2: 12,386 adults enrolled in a group/staff model HMO</p> <p>Analysis 3: 345 adults enrolled in a group/staff model HMO</p>	United States—Washington State

⁷⁸ For purposes of this report, full coverage is defined as 100% coverage for smoking 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).

Table C-1-c. Summary of Published Studies on Effects of Copayments, Coinsurance, and Deductibles on Use of Smoking Cessation Treatments and on Abstinence from Smoking (Cont'd)

Citation	Type of Trial	Intervention vs. Comparison Group	Population Studied	Location
Dey et al., 1999*	Randomized controlled trial	Coverage for nicotine patches: prescription for free patches vs. prescription for patches at slight discount from retail price	General practice	United Kingdom
Halpin et al., 2006	Randomized controlled trial	Comparison of three models of coverage for smoking cessation services: (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	Coverage for NRT, bupropion, ⁷⁹ and behavioral counseling vs. no offer of coverage	Smokers insured by De Friesland Zorgverzekeraar company	The Netherlands
Kaper et al., 2006 ⁸⁰	Randomized controlled trial	Coverage for NRT, bupropion, and behavioral counseling vs. no offer of coverage	Smokers insured by De Friesland Zorgverzekeraar company	The Netherlands
Land et al., 2010	Interrupted time series	Pre-post analysis of a state law mandating Medicaid coverage for smoking cessation counseling and pharmacotherapy	Adult Medicaid recipients	United States—Massachusetts

⁷⁹ Kaper, Wagena, Severens, et al. (2005) does not indicate whether smokers in the intervention group received coverage for bupropion SR, the only formulation of bupropion approved by the FDA for smoking cessation or for other forms of bupropion.

⁸⁰ Kaper, Wagena, Severens, et al. (2005) and Kaper et al. (2006) present findings from the same RCT. Kaper, Wagena, Willemsen, et al. (2005) presents findings at six months following the completion of the intervention. Kaper et al. (2006) presents findings at two years' post-intervention.

Table C-1-c. Summary of Published Studies on Effects of Copayments, Coinsurance, and Deductibles on Use of Smoking Cessation Treatments and on Abstinence from Smoking (Cont'd)

Citation	Type of Trial	Intervention vs. Comparison Group	Population Studied	Location
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 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, as well as general and mandate-specific caveats and assumptions used in conducting the cost impact analysis. For additional information on the cost model and underlying methodology, please refer to the CHBRP Web site at http://www.chbrp.org/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 that provides data and analyses per the provisions of CHBRP's authorizing legislation.

Data Sources

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

Health Insurance

1. The latest (2007) California Health Interview Survey (CHIS), which is used to estimate health insurance for California's population and distribution by payer (i.e., employment-based, individually purchased, or publicly financed). The biannual CHIS is the largest state health survey conducted in the United States, collecting information from over approximately 53,000 households. More information on CHIS is available at www.chis.ucla.edu. The population estimates for both adults and children from 2007 were adjusted to reflect the following trends as of 2009 from the data sources listed: (1) the increase in the total non-institutionalized population in California, from the California Department of Finance; (2) the decrease in private market coverage (both group- and individual-level), from the CHBRP Annual Premium and Enrollment Survey, and (3) the increase in all types of public coverage, from enrollment data available from the Centers for Medicare & Medicaid Services, the California Medical Statistics Section, and the Managed Risk Medical Insurance Board. The residual population after accounting for these trends was assumed to be uninsured.
2. The latest (2009) California Employer Health Benefits Survey is used to estimate:
 - size of firm,
 - percentage of firms that are purchased/underwritten (versus self-insured),
 - premiums for health care service plans regulated by the Department of Managed Health Care (DMHC) (primarily health maintenance organizations [HMOs] and Point of Service Plans [POS]),
 - premiums for health insurance policies regulated by the California Department of Insurance (CDI) (primarily preferred provider organizations [PPOs] and fee-for-service plans [FFS]), and

- premiums for high deductible health plans (HDHPs) for the California population with employment-based health insurance.
 - This annual survey is currently released by the California Health Care Foundation/National Opinion Research Center (CHCF/NORC) and is similar to the national employer survey released annually by the Kaiser Family Foundation and the Health Research and Educational Trust. Information on the CHCF/NORC data is available at: <http://www.chcf.org/topics/healthinsurance/index.cfm?itemID=133543>.
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/expertise/healthcare/products-tools/milliman-care-guidelines/index.php. Most of the data sources underlying the HCGs are claims databases from commercial health insurance plans. The data are supplied by health insurance companies, Blues plans, HMOs, self-funded employers, and private data vendors. The data are mostly from loosely managed healthcare plans, generally those characterized as preferred provider plans or PPOs. The HCGs currently include claims drawn from plans covering 4.6 million members. In addition to the Milliman HCGs, CHBRP’s utilization and cost estimates draw on other data, including the following:
- The MarketScan Database, which includes demographic information and claim detail data for approximately 13 million members of self-insured and insured group health plans.
 - An annual survey of HMO and PPO pricing and claim experience. The most recent survey (2008 Group Health Insurance Survey) contains data from seven major California health plans regarding their 2007 experience.
 - Ingenix MDR Charge Payment System, which includes information about professional fees paid for healthcare services, based upon approximately 800 million claims from commercial insurance companies, HMOs, and self-insured health plans.
 - These data are reviewed for applicability by an extended group of experts within Milliman but are not audited externally.
4. An annual survey by CHBRP of the seven largest providers of health insurance in California (Aetna, Anthem Blue Cross of California, Blue Shield of California, CIGNA, Health Net, Kaiser Foundation Health Plan, and PacifiCare) to obtain estimates of baseline enrollment by purchaser (i.e., large and small group and individual), type of plan (i.e., DMHC or CDI-regulated), cost-sharing arrangements with enrollees, and average premiums. Enrollment in plans or policies offered by these seven firms represents 95.9% of the persons with health insurance subject to state mandates. This figure represents 98.0% of enrollees in full service (non-specialty) DMHC-regulated health plans and 85.3% of enrollees in full service (non-specialty) CDI-regulated policies.

Publicly funded insurance subject to state benefit mandates

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

General Caveats and Assumptions

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

- Prevalence of mandated benefits before and after the mandate may be different from CHBRP assumptions.
- Utilization of mandated benefits (and, therefore, the services covered by the benefit) before and after the mandate may be different from CHBRP assumptions.
- Random fluctuations in the utilization and cost of health care services may occur.

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

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

- Population shifts by type of health insurance: If a mandate increases health insurance costs, some employer groups and individuals may elect to drop their health insurance. Employers may also switch to self-funding to avoid having to comply with the mandate.
- Changes in benefit plans: To help offset the premium increase resulting from a mandate, subscribers/policyholders may elect to increase their overall plan deductibles or copayments. Such changes would have a direct impact on the distribution of costs between the health plan and policies and enrollees, and may also result in utilization reductions (i.e., high levels of patient cost sharing result in lower utilization of health care

services). CHBRP did not include the effects of such potential benefit changes in its analysis.

- Adverse selection: Theoretically, individuals or employer groups who had previously foregone health insurance may now elect to enroll in a health plan or policy, post-mandate, because they perceive that it is to their economic benefit to do so.
- 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.
- Geographic and delivery systems variation: Variation in existing utilization and costs, and in the impact of the mandate, by geographic area and delivery system models: Even within the health insurance types CHBRP modeled (HMO—including HMO and point of service [POS] plans—and non-HMO—including PPO and fee for service [FFS] policies), there are likely variations in utilization and costs by type. Utilization also differs within California due to differences in the health status of the local population, provider practice patterns, and the level of managed care available in each community. The average cost per service would also vary due to different underlying cost levels experienced by providers throughout California and the market dynamic in negotiations between providers and health plans or insurers. Both the baseline costs prior to the mandate and the estimated cost impact of the mandate could vary within the state due to geographic and delivery system differences. For purposes of this analysis, however, CHBRP has estimated the impact on a statewide level.
- Compliance with the mandate: For estimating the post-mandate coverage levels, CHBRP typically assumes that plans and policies subject to the mandate will be in compliance with the coverage requirements of the bill. Therefore, the typical post-mandate coverage rates for populations subject to the mandate are assumed to be 100%.

Bill Analysis-Specific Caveats and Assumptions

CHBRP assumes that high-deductible health plans (HDHP) would cover smoking cessation treatments as “preventive services,” and thus would not be required to include co-payments or deductibles for smoking cessation as part of their charter under Sec. 223 of the federal regulatory code for keeping their HDHP status. In this arrangement, any out-of-pocket expenses for smoking cessation treatment could possibly be reimbursed by the health savings account (HSA), and if so, that would be considered taxable income for the enrollee. CHBRP assumes that this income would have been taxable for an enrollee with an HSA regardless, and therefore it does not change the marginal impact of the costs for insured enrollees under SB 220.

CHBRP used the 2005 California Tobacco Survey data and the RAND Health Insurance Experiment’s (HIE) estimated impact of cost sharing for well care to estimate pre- and post-mandate utilization among smokers who make an attempt to quit. An illustration of CHBRP’s calculations to develop pre- and post-mandate utilization by coverage status for NRT is as follows:

Pre-mandate (Baseline)

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

$$10.5\% = 18.8\% \times 56.0\%$$

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)

$$82.4\% = (45\% \text{ relative utilization under no coverage}) \times (1.2\% \text{ enrollees with no coverage}) \\ + (80\% \text{ relative utilization under partial coverage}) \times (84.4\% \text{ with partial coverage}) \\ + (100\% \text{ relative utilization under full coverage}) \times (14.3\% \text{ with full coverage}).$$

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)

$$12.8\% = 10.5\% / 82.4\% \times 100\%$$

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)

$$10.2\% = 10.5\% / 82.4\% \times 80\%$$

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)

$$5.8\% = 10.5\% / 82.4\% \times 45\%$$

Post-mandate

Post-mandate, those enrollees 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.

Short-Term Cost Impact of Reduction in LBW Deliveries and Hospitalizations Due to AMI

Low-Birth Weight Deliveries. CHBRP estimated the mandate could result in one fewer low-birth weight deliveries statewide during 2011, using the application of the lower rate of low-birth weight babies to former smokers as compared to smokers for the larger population who would be successful quitters based on the increased number of pregnant women who would use smoking cessation treatment covered by SB 220.⁸¹ The average savings per avoided low-birth

⁸¹ This is out of the total of 27,000 insured pregnant women who were smokers prior to the mandate.

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 et al., 1999). This estimated savings was then updated to 2010 dollars at a rate of 8.4% per year.⁸² Therefore, as a result of the mandate, quitting produces an average first-year savings in health care expenditures of about \$57,000 from avoided low-birth weight deliveries.

AMI. CHBRP estimated the mandate could result in six fewer hospitalizations due to AMI during 2011, based on the reduction in AMI risk due to smoking cessation applied to the larger population using smoking cessation services covered by SB 220 (Critchley and Capewell, 2003; Critchley and Capewell, 2004).⁸³ The average savings per avoided 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 (based on 924 fewer hospitalizations). Using this estimate in savings, CHBRP calculated the expected total savings per avoided AMI, and then updated this number to 2010 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 \$980,000 from avoided AMIs.

⁸² 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.

⁸³ This is out of a total of 1.83 million insured adults who were smokers with drug coverage prior to the mandate.

Appendix E: Public Health Impact Calculations

Due to the number of assumptions that must be made to estimate the impacts of SB 220 on smoking cessation utilization for the insured population, CHBRP chooses to round its conclusions to avoid misrepresentation of bill impact. The methods and calculations below explain the logic behind this report's estimates, but the outcomes will change if assumptions are varied.

Public Health Calculations: Successful Quitters

The pre-mandate number of quitters sums two elements: number of people who successfully quit while using a smoking cessation treatment and the number of people who successfully quit without using a smoking cessation treatment. The medical literature suggests that “attempters” using smoking cessation treatment experience twice the success rate of smokers attempting to quit with no use of treatment. The formula is summarized as: Overall success rate = (% of people who used a treatment × success rate for using a treatment) + (% of people who use no treatment × success rate for no treatment). The *2005 California Tobacco Survey* reports that 8.6% of smokers attempting to quit are successful at 90 days after quitting. This overall 8.6% success rate represents a mix of persons who used no cessation treatment, who therefore experienced a low success rate, and persons who used a cessation treatment, who therefore experienced a higher success rate. The equation for determining the success rates for these two groups is:

$$(0.261 \times 2r) + (0.739 \times r) = 0.086$$

Where r is the success rate among the 73.4% of attempters using no cessation treatment, and $2r$ is the success rate among the 26.1% of persons who used a cessation treatment.

Solving the equation algebraically yields 6.8% as the success rate for those who use no treatment and 13.6% as the success rate for those who use a treatment.

Using data submitted to CHBRP by the insurers, CHBRP estimates the number of people who used at least one treatment for their quit attempt pre-mandate: 268,344 (Table 1). Therefore, $268,344 \text{ (from Table 1)} \times 13.64\% = 36,602$ people who successfully quit while using a treatment. To calculate the number of smokers who attempt to quit with no assistance, CHBRP uses the total number of smokers (Table 1) multiplied by the probability that they try to quit (56%) and then subtracts the group of smokers who attempted to quit using a treatment. This subset was multiplied by the probability of quitting with no use of a treatment. The equation is: $[(1,891,582 \times 56\%) - 268,344] \times 6.82\% = 53,942$ people who successfully quit without using a treatment.

The post-mandate calculation uses the same process, except the number of people using at least one treatment increases from 268,344 to 386,826 due to new coverage (Table 1). The pre-mandate successful quitters are subtracted from the post-mandate successful quitters to find the incremental increase in successful quitters attributable to SB 220. Using figures available from the *Utilization, Cost, and Coverage* model, CHBRP estimates that approximately 8,081 persons will succeed in quitting attributable to passage of SB 220.

Public Health Calculations for AMI*

Baseline Population of Interest

Approximately 1,826,596 smokers are currently insured in California. Under current coverage assumptions based on actuarial data used in a cost model for the *Utilization, Cost, and Coverage* section of this analysis, we expect that approximately 36,602 smokers would successfully quit smoking in any given year, resulting in 1,789,994 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

$(36,602 \times 0.149\%) + (1,789,994 \times 0.219\%) = 3,937^*$ 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 52,763 smokers would be expected to successfully quit smoking with this mandate, resulting in 1,776,456 remaining smokers. According to these calculations, we would expect a total of

$(52,763 \times 0.149\%) + (1,773,833 \times 0.219\%) = 3,932^*$ cases of AMI if SB 220 were enacted. Subtracting the expected AMI cases (with mandate) from baseline cases (without mandate) equals total expected reduction in AMI cases due to SB 220 as $(3,937 - 3,932 = 5)$:

Total estimated reduction in cases of AMI due to mandate: 5.

*Results are rounded.

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 27,199 pregnant women smokers are currently insured in California. Of these, approximately 26,318 pregnant smokers have coverage that includes tobacco cessation benefits, and 882 pregnant smokers are not covered for these services. After the mandate, we expect that approximately 176* pregnant smokers would be newly covered for tobacco cessation services, resulting in a total of 26,493* 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, smoking 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 13,766* women in the covered population would quit smoking during pregnancy, and there would be approximately 2,604* low birth-weight deliveries.

Expected Outcome Estimates With Mandate:

Under this mandate, a total of 176* pregnant smokers would be newly covered for smoking cessation benefits. We assume that a greater percentage of women would use smoking cessation services once they become a covered benefit. If it is assumed that the rate of smoking cessation for those newly covered under the mandate would increase from 39% to 51%, it would be expected that a total of 13,787* women would quit during their pregnancy under this mandate. Applying the low-birth weight rate of 7.3% to the nonsmokers and 11.9% to the remaining smokers, it is expected that approximately 2,603* low birth-weight deliveries in the covered population would result under the mandate.

Total estimated reduction in low-birth weight deliveries due to mandate: 1.

*Results are rounded.

Appendix F: Information Submitted by Outside Parties

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

The American Lung Association submitted information on April 20, 2010.

The submissions include (with brief summary or highlighted data):

- 1) American Lung Association (ALA) Report (2009)
 - a. Recommendations on coverage of smoking cessation (including insurance coverage)
 - b. Cites effectiveness of smoking cessation
 - c. Data on states with Medicaid coverage, state mandate laws, etc.
- 2) Study conducted by Milliman in conjunction with The American Legacy Foundation
 - a. Milliman provides current estimates of smoking's short-term cost impact on employer-sponsored health and life insurance benefit programs. It also provides cost estimates for smoking cessation programs. The report finds that:
 - Smoking cessation programs are low cost. A comprehensive and effective smoking cessation program will usually cost less than \$0.50 per member per month (PMPM).
 - Each employee or dependent who quits smoking reduces annual medical and life insurance costs by at least \$210 almost immediately.
- 3) Summary/press release of 2008 CDC Report
 - a. Evidence of the direct relationship between increased funding for state tobacco prevention and cessation programs and declines in adult smoking.
- 4) Tobacco Cessation Benefit Report, produced by the Pacific Business Group on Health (PBGH) (2008)
 - a. Tobacco use results in huge costs to the nation as a whole, to California, and to employers, in particular. In 2004, the estimated costs to the health care system for treating smoking-related illness were \$96 billion for the United States and \$9 billion for California. Smokers consume more health care resources, experience greater absenteeism and tend to be less productive while at work. Over a lifetime, women who smoke incur \$21,500 more in medical expenses and men who smoke incur \$19,400 more than do nonsmokers. Evidence also supports investment in smoking cessation as a public health priority given quality of life improvements, savings in medical costs, and other critical factors.
 - b. PBGH utilizes several tools. One is the standardized annual eValue8 Health Plan Request for Information (RFI), which is used to assess the services that plans offer to their enrollees and to drive improvements in evidence-based benefit design. EValue8 enables PBGH member companies to obtain comparable information on health plan quality performance and programs such as smoking cessation services. The most recent California eValue8 results are used here to inform the extent and nature of smoking cessation services

available through California health plans and offered by PBGH member companies.

- 5) ALA Mandate Coverage Talking Points and Links
- 6) The Land Study on the Massachusetts Medicaid Program. Also, the ALA provided a summary of the Mass Medicaid Report on its Web site, at: <http://www.lungusa.org/about-us/our-impact/top-stories/alert-to-congress-medicaid.html>
- 7) Costs of Smoking Cessation Report, Feb. 2010—Word file with GAO and other estimates
- 8) <http://www.businesscaseroi.org/roi/apps/execsum.aspx> (AHIP RESOURCE, including ROI calculator).

This information is available upon request.

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

Appendix G: Ten Key Recommendations of the U.S. Public Health Service Guideline: Treating Tobacco Use and Dependence: 2008 Update

1. Tobacco dependence is a chronic disease that often requires repeated intervention and multiple attempts to quit. Effective treatments exist, however, that can significantly increase rates of long-term abstinence.
2. It is essential that clinicians and health care delivery systems consistently identify and document tobacco use status and treat every tobacco user seen in a health care setting.
3. Tobacco dependence treatments are effective across a broad range of populations. Clinicians should encourage every patient willing to make a quit attempt to use the counseling treatments and medications recommended in this Guideline.
4. Brief tobacco dependence treatment is effective. Clinicians should offer every patient who uses tobacco at least the brief treatments shown to be effective in this Guideline.
5. Individual, group, and telephone counseling are effective, and their effectiveness increases with treatment intensity. Two components of counseling are especially effective, and clinicians should use these when counseling patients making a quit attempt: Practical counseling (problem solving/skills training), and social support delivered as part of treatment.
6. Numerous effective medications are available for tobacco dependence, and clinicians should encourage their use by all patients attempting to quit smoking—except when medically contraindicated or with specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers, and adolescents).
 - Seven first-line medications (5 nicotine and 2 non-nicotine) reliably increase long-term smoking abstinence rates:
 - Bupropion SR
 - Nicotine gum
 - Nicotine inhaler
 - Nicotine lozenge
 - Nicotine nasal spray
 - Nicotine patch
 - Varenicline
 - Clinicians also should consider the use of certain combinations of medications identified as effective in this Guideline.
7. Counseling and medication are effective when used by themselves for treating tobacco dependence. The combination of counseling and medication, however, is more effective than either alone. Thus, clinicians should encourage all individuals making a quit attempt to use both counseling and medication.

8. Telephone quitline counseling is effective with diverse populations and has broad reach. Therefore, both clinicians and health care delivery systems should ensure patient access to quitlines and promote quitline use.
9. If a tobacco user currently is unwilling to make a quit attempt, clinicians should use the motivational treatments shown in this Guideline to be effective in increasing future quit attempts.
10. Tobacco dependence treatments are both clinically effective and highly cost-effective relative to interventions for other clinical disorders. Providing coverage for these treatments increases quit rates. Insurers and purchasers should ensure that all insurance plans include the counseling and medication identified as effective in this Guideline as covered benefits.

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A group of faculty and staff undertakes most of the analysis that informs reports by the California Health Benefits Review Program (CHBRP). The CHBRP **Faculty Task Force** comprises rotating representatives from six University of California (UC) campuses and three private universities in California. In addition to these representatives, there are other ongoing contributors to CHBRP from UC. This larger group provides advice to the CHBRP staff on the overall administration of the program and conducts much of the analysis. The **CHBRP staff** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and coordinates all external communications, including those with the California Legislature. The level of involvement of members of the CHBRP Faculty Task Force and staff varies on each report, with individual participants more closely involved in the preparation of some reports and less involved in others. As required by CHBRP's authorizing legislation, UC contracts with a certified actuary, Milliman Inc., to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit. . Milliman also helped with the initial development of CHBRP methods for assessing that impact.

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

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