



CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Analysis of Senate Bill 136: Tobacco Cessation

A Report to the 2011-2012 California Legislature
April 7, 2011

CHBRP 11-08



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 2011-2012 California State Legislature

Analysis of Senate Bill 136: Health Care Coverage: Tobacco Cessation

April 7, 2011

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PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Senate Bill 136. In response to a request from the California Senate Committee on Health on February 4, 2011, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the program's authorizing statute.

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

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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Senate Bill 136

The California Senate Committee on Health requested on February 4, 2011, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Senate Bill (SB) 136, a bill that would require coverage of tobacco cessation benefits. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.¹

Analysis of SB 136

Approximately 21.9 million Californians (59%) have health insurance that may be subject to a health benefit mandate law passed at the state level.² Of the rest of the state's population, a portion is uninsured (and so has no health insurance subject to any benefit mandate) and another portion has health insurance subject to other state law or only to federal laws.

Uniquely, California has a bifurcated system of regulation for health insurance subject to state-level benefit mandates. The California Department of Managed Health Care (DMHC)³ regulates health care service plans, which offer benefit coverage to their enrollees through health plan contracts. The California Department of Insurance (CDI) regulates health insurers⁴, which offer benefit coverage to their enrollees through health insurance policies.

DMHC-regulated plans and CDI-regulated policies would be subject to SB 136. Therefore, the mandate would affect the health insurance of approximately 21.9 Californians (59%).

SB 136 would require health care service plans and health insurance policies⁵ to include coverage for smoking cessation services, to be selected by the enrollee and the provider. These services would include:

- 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,

¹ CHBRP's authorizing statute is available at http://www.chbrp.org/documents/authorizing_statute.pdf.

² CHBRP's estimates are available at http://www.chbrp.org/other_publications/index.php.

³ The DMHC was established in 2000 to enforce the Knox-Keene Health Care Service Plan Act of 1975; see Health and Safety Code, Section 1340.

⁴ 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.

⁵ SB 136 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*.

dermal patch, inhaler, nasal spray, and lozenge, varenicline, and bupropion SR⁶ 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.
- Step therapy⁷ 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 after the first treatment.
- At least four counseling sessions must be provided in each course of treatment, each session lasting at least 10 minutes.

SB 136 would become inoperative on the date that the state determines that, taking into account any state savings identified,⁸ SB 136 would result in the state assuming additional costs pursuant to subparagraph (B) of paragraph (3) of subsection (d) of Section 1311 of the federal Patient Protection and Affordable Care Act (ACA). The ACA establishes that under health benefit Exchanges, qualified health plans are required to offer essential health benefits (to be established federally). This provision requires that states assume the costs of any additional benefits they require in addition to the essential health benefits specified under section 1302(b).

Currently, six states (Colorado, Maryland, New Jersey, New Mexico, Oregon, and Rhode Island) mandate coverage for smoking cessation treatment (ALA, 2009). North Dakota provides a \$150 lifetime smoking cessation benefit for specific group plans.

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.

⁶ 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 United States but are not approved for smoking cessation.

⁷ *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).

⁸ Section C of SB 136 would request that CHBRP prepare a report by December 31, 2014, evaluating the requirements of this section and determining any state savings as a result of those requirements.

- 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 agonist⁹; 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 bupropion¹⁰ 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 relative to placebo.

⁹ The nicotine receptor partial agonist simulates the effects of nicotine to reduce cravings and the pleasurable effect of smoking cigarettes.

¹⁰ 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 136 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 136. In addition, smokers who take the initiative to enroll in RCTs are probably more highly motivated to quit than the average smoker. Greater motivation may lead to higher rates of abstinence from smoking among persons enrolled in both the intervention and control groups of RCTs than would occur in the “real world.” 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 coverage¹¹ 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 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.

¹¹ For purposes of this report, full coverage for smoking cessation treatments is defined as coverage of all three modalities of smoking cessation.

Benefit Coverage, Utilization, and Cost Impacts

In this section, CHBRP presents the cost impact of SB 136 on all plans or policies subject to mandate, which includes enrollment of 21.9 million Californians. The estimated increase of utilization of smoking cessation treatment is among the 1.93 million (estimated) adult smokers with DMHC- or CDI-regulated plans or policies, since they will be the population who might attempt to quit using services covered by this newly mandated benefit coverage. Unlike previous versions of smoking cessation treatment benefit mandates (see CHBRP report on SB 220 from 2010); SB 136 does not require that cost sharing be eliminated in order for coverage to be mandate compliant. CHBRP assumes that if SB 136 was enacted, all DMHC-regulated plans and CDI-regulated policies would then include mandate-compliant coverage for smoking cessation treatments that includes enrollee cost sharing.

Table 1 summarizes the expected benefit coverage, cost, and utilization impacts for SB 136.

Benefit Coverage Impacts

- Of the population subject to the mandate, 82.5% of enrollees have mandate-compliant coverage for smoking cessation-related counseling and 98.8% have mandate-compliant coverage for prescription smoking cessation treatment, but a lower percentage (62.0%) have mandate-compliant coverage for over-the-counter (OTC) smoking cessation treatment (Table 1). If SB 136 were enacted, 100% of this population would have mandate-compliant coverage for smoking cessation treatments.
- Medi-Cal Managed Care Plans (MMCPs), which cover 1.68 million adults subject to the mandate (11.7%), generally already provides mandate-compliant smoking cessation treatment benefits. If SB 136 were enacted, the mandate would eliminate the prior authorization requirements that currently exist in some MMCPs. Some individual Medi-Cal Managed Care Plans may need to be amended to comply with specific provisions of the bill, such as prior authorization restrictions beyond the first treatment. CHBRP did not have sufficient evidence to estimate the impact of any needed administrative changes on the utilization of smoking cessation services.
- CHBRP estimates no measurable impact of the mandate on the number of uninsured due to premium increases.

Utilization Impacts

- CHBRP used the 2008 and 2005 California Tobacco Survey data and the RAND Health Insurance Experiment's (HIE) estimated impact of cost sharing for "well care" to estimate premandate and postmandate utilization. Premandate, of the 1.93 million adult smokers enrolled in DMHC- or CDI-regulated plans or policies, 308,604 used one or more smoking cessation treatments, with 252,226 using treatments covered through their existing insurance and 56,378 enrollees using treatments for which they were not covered.

- Postmandate, of the 1.93 million insured adult smokers, CHBRP estimates that the utilization of counseling services would increase by 9.2%, OTC treatments by 19.8%, and prescription treatments by 0.6% (Table 1).
- In total, the utilization of one or more smoking cessation treatments would increase by 11.2%, representing an additional 34,660 insured adult smokers receiving treatment postmandate.

Cost Impacts

- Increases in per member per month (PMPM) premiums for the newly mandated benefit coverage vary by market segment. Increases as measured by percentage changes in PMPM premiums are estimated to range from an average increase of 0.00% (for DMHC-regulated MMCPs) to an average increase of 0.17% (for CDI-regulated individual policies) in the affected market segments. Increases as measured by PMPM premiums are estimated to range from \$0.00 to \$0.33.
- In the privately funded large-group market, the increase in premiums is estimated to range from an average increase of \$0.06 PMPM among DMHC-regulated plan contracts to an average increase of \$0.23 PMPM among CDI-regulated policies.
- For enrollees in privately funded small-group insurance policies, health insurance premiums are estimated to increase by an average increase of \$0.11 PMPM for DMHC contracts to an average increase of \$0.28 PMPM for CDI policies.
- In the privately funded individual market, the health insurance premiums are estimated to range by an average increase of \$0.08 PMPM to an average increase of \$0.33 PMPM in the DMHC- and CDI-regulated markets, respectively.
- Among publicly funded DMHC-regulated health plans, CHBRP estimates that premium increases for Medi-Cal Managed Care Plans, MRMIB plans, and CalPERS HMOs would range from averages of 0.00% to 0.05% (\$0.00 to \$0.20).
- Total net health expenditures are projected to increase by \$16.4 million (0.017%) (Table 1). This is due to a \$32.9 million increase in health insurance premiums and enrollee expenses for newly covered benefits, partially offset by a reduction in enrollee out-of-pocket expenditures for previously noncovered benefits (\$16.5 million).

Public Health Impacts

- CHBRP estimates that due to clear and convincing evidence of effectiveness of smoking cessation treatments and increased enrollee coverage, SB 136 would produce a positive public health impact by increasing the number of successful quitters by 2,364 enrollees annually. This would translate into real, improved health outcomes for these new quitters in

the long term. Furthermore, literature indicates that the additional quitters enabled by SB 136 would reduce harms from secondhand smoke postmandate.

- CHRBP estimates that, for the overall population, any cost increase or physical harms from rare serious adverse events from pharmacotherapy would be outweighed by the benefits of smoking cessation.
- Due to lack of data, CHRBP cannot quantify the impact of SB 136 on reducing existing gender disparities in smoking prevalence nor on the relevant health outcomes in the insured population. Therefore, the impact of SB 136 on reducing gender disparities is unknown.
- Due to lack of data, CHRBP cannot quantify the impact of SB 136 on reducing racial/ethnic disparities in smoking prevalence nor on the relevant health outcomes in the insured population. Therefore, the impact of SB 136 on reducing racial/ethnic disparities is unknown.
- There is clear and convincing evidence that SB 136 would contribute to the reduction in premature death from smoking-related conditions such as cancer, low birth weight infants, and cardiovascular and respiratory diseases. However, CHRBP cannot estimate the precise magnitude.
- CHRBP estimates that SB 136 would increase utilization of smoking cessation treatments and increase quit rates postmandate. This increase would contribute to a reduction in economic loss due to reductions in lost productivity from smoking-related illness and premature death, but the magnitude cannot be estimated.
- CHRBP finds clear and convincing evidence that smoking cessation is a cost-effective preventive treatment that results in improvements in long-term in multiple health outcomes and reduces both direct medical costs and indirect costs associated with smoking. CHRBP estimates between 16,548 to 29,314 life years would be gained annually under the new mandate. The expected reduction in smoking prevalence and mortality attributable to SB 136 would bring California closer to achieving *Healthy People 2020* goals.

Potential Effects of the Federal Affordable Care Act

The federal “Patient Protection and Affordable Care Act” (P.L.111-148) and the “Health Care and Education Reconciliation Act” (H.R.4872) were enacted in March 2010. These laws (together referred to as the “Affordable Care Act [ACA]”) are expected to dramatically affect the California health insurance market and its regulatory environment, with most changes becoming effective in 2014. How these provisions are implemented in California will largely depend on pending legal actions, funding decisions, regulations to be promulgated by federal agencies, and statutory and regulatory actions to be taken by California state government.

Essential health benefits offered by qualified health plans in the Exchange and potential interactions with SB 136

The ACA requires beginning 2014 that states “make payments...to defray the cost of any additional benefits” required of qualified health plans (QHPs) sold in the Exchange.¹² SB 136 would make the requirements of the bill inoperative if the state determines that the requirements would “result in the state assuming additional costs pursuant to subparagraph (B) of paragraph (3) of subsection (d) of Section 1311 of the federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by subsection (e) of Section 10104 of Title X of that act.” Therefore, the marginal impact as presented in this report would no longer apply after 2014 if the requirements of SB 136 were deemed to add fiscal costs for qualified health plans to be offered in the Exchange.

When promulgating regulations on essential health benefits (EHBs), the U.S. Department of Health and Human Services is to ensure that the EHB floor “is equal to the scope of benefits provided under a typical employer plan.” CHBRP found some variation in coverage based on carrier surveys (such as the types of counseling services provided, and inclusion of OTC smoking cessation items). Assuming this is true nationally, there is likely variation in employer coverage for services mandated under SB 136. Therefore, it is uncertain whether federal regulations and guidance would deem all the services mandated under SB 136 as being included under EHBs. In order for the state to determine whether any additional fiscal liability for the state would be incurred under SB 136, the following factors would need to be examined:

- Differences in the scope of benefits in the final EHB package and the scope of mandated benefits in SB 136;
- The number of enrollees in QHPs; and,
- The methods used to define and calculate the cost of additional benefits.

All of these factors are unknown at this time, and are dependent upon the details of pending federal regulations, state legislative and regulatory actions, and enrollment into QHPs after the Exchange is implemented.

Preventive benefits as required under the ACA and SB 136

“New plans” (i.e., those not covered under the ACA’s “grandfather” provisions) were required to cover certain preventive services at zero cost sharing beginning September 23, 2010. Tobacco use counseling and interventions are preventive services (US Preventive Services Task Force, 2010) that fall under USPSTF “A and B” benefits and thus under the ACA’s requirement to cover those benefits at zero cost sharing. These services include:

- Tobacco use counseling for pregnant women: The USPSTF recommends that clinicians ask all pregnant women about tobacco use and provide augmented, pregnancy-tailored counseling to those who smoke. Grade A, April 2009.¹³

¹² Affordable Care Act, 1311(d)(3)(B).

¹³ *USPSTF A and B Recommendations*. August 2010. U.S. Preventive Services Task Force. <http://www.uspreventiveservicestaskforce.org/uspstf/uspsabrecs.htm>

- Tobacco use counseling and interventions for nonpregnant adults. The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products. Grade A, April 2009.¹⁴

¹⁴ *USPSTF A and B Recommendations*. August 2010. U.S. Preventive Services Task Force. <http://www.uspreventiveservicestaskforce.org/uspstf/uspsabrecs.htm> ¹⁵ CHBRP's authorizing statute is available at: http://www.chbrp.org/documents/authorizing_statute.pdf.

Table 1. SB 136 Impacts on Benefit Coverage, Utilization, and Cost, 2011

| | Before Mandate | After Mandate | Increase/ Decrease | Change After Mandate |
|---|---------------------------|----------------------|-------------------------------|-------------------------------------|
| Benefit Coverage | | | | |
| Total enrollees with health insurance subject to state-level benefit mandates (a) | 21,902,000 | 21,902,000 | 0 | 0% |
| Total enrollees with health insurance subject to SB 136 | 21,902,000 | 21,902,000 | 0 | 0% |
| Number of enrollees with coverage for counseling | | | | |
| No coverage | 3,843,297 | 0 | -3,843,297 | -100% |
| Mandate-compliant coverage with cost sharing | 12,514,703 | 16,358,000 | 3,843,297 | 30.7% |
| Mandate-compliant coverage, no cost sharing | 5,544,000 | 5,544,000 | 0 | 0.0% |
| Percentage of enrollees with coverage for counseling | | | | |
| No coverage | 17.5% | 0.0% | -17.5% | -100% |
| Mandate-compliant coverage with cost sharing | 57.1% | 74.7% | 17.5% | 30.7% |
| Mandate-compliant coverage, no cost sharing | 25.3% | 25.3% | 0.0% | 0.0% |
| Number of enrollees with coverage for over-the-counter (OTC) treatments | | | | |
| No coverage | 8,329,710 | 0 | -8,329,710 | -100% |
| Mandate-compliant coverage with cost sharing | 9,748,290 | 18,078,000 | 8,329,710 | 85.4% |
| Mandate-compliant coverage, no cost sharing | 3,824,000 | 3,824,000 | 0 | 0.0 |
| Percentage of enrollees with coverage for OTC treatments | | | | |
| No coverage | 38.0% | 0.0% | -38.0% | -100% |
| Mandate-compliant coverage with cost sharing | 44.5% | 82.5% | 38.0% | 85% |
| Mandate-compliant coverage | 17.5% | 17.5% | 0.0% | 0% |
| Number of enrollees with coverage for prescription smoking cessation treatments | | | | |
| No Coverage | 279,441 | 0 | -279,441 | 100.0% |
| Mandate-compliant coverage with cost sharing | 17,798,559 | 18,078,000 | 279,441 | 1.6% |
| Mandate-compliant coverage, no cost sharing | 3,824,000 | 3,824,000 | 0 | 0.0% |
| Percentage of enrollees with coverage for prescription smoking cessation treatments | | | | |
| No coverage | 1.3% | 0.0% | -1.3% | -100% |
| Mandate-compliant coverage with cost sharing | 81.3% | 82.5% | 1.3% | 1.6% |
| Mandate-compliant coverage, no cost sharing | 17.5% | 17.5% | 0.0% | 0.0% |

Table 1. SB 136 Impacts on Benefit Coverage, Utilization, and Cost, 2011 (Cont'd)

| | Before Mandate | After Mandate | Increase/ Decrease | Change After Mandate |
|--|---------------------------|-------------------------|-------------------------------|-------------------------------------|
| Utilization and Cost | | | | |
| Number of enrollees who smoke and use: | | | | |
| Counseling | 139,510 | 152,341 | 12,831 | 9.2% |
| OTC treatments | 218,566 | 261,739 | 43,173 | 19.8% |
| Prescription smoking cessation | 72,080 | 72,540 | 459 | 0.6% |
| Total (at least one or more services) | 308,604 | 343,265 | 34,660 | 11.2% |
| Average cost per course of treatment: | | | | |
| Counseling | \$200 | \$200 | \$0 | 0% |
| OTC treatments | \$236 | \$236 | \$0 | 0% |
| Prescription smoking cessation | \$240 | \$240 | \$0 | 0% |
| Expenditures | | | | |
| Premium expenditures by private employers for group insurance | \$52,713,266,000 | \$52,725,172,000 | \$11,906,000 | 0.0226% |
| Premium expenditures for individually purchased insurance | \$6,724,851,000 | \$6,730,843,000 | \$5,992,000 | 0.0891% |
| Premium expenditures by persons with group insurance, CalPERS HMOs, Healthy Families Program, AIM or MRMIP (b) | \$15,173,472,000 | \$15,177,073,000 | \$3,601,000 | 0.0237% |
| CalPERS HMO employer expenditures (c) | \$3,465,785,000 | \$3,467,377,000 | \$1,592,000 | 0.0459% |
| Medi-Cal Managed Care Plan expenditures | \$8,657,688,000 | \$8,657,688,000 | \$0 | 0.000% |
| MRMIB Plan expenditures (d) | \$1,050,631,000 | \$1,050,784,000 | \$153,000 | 0.0146% |
| Enrollee out-of-pocket expenses for covered benefits (deductibles, copayments, etc.) | \$7,548,415,000 | \$7,558,116,000 | \$9,701,000 | 0.1285% |
| Enrollee expenses for noncovered benefits (e) | \$16,548,000 | \$0 | -\$16,548,000 | -100% |
| Total Expenditures | \$95,350,656,000 | \$95,367,053,000 | \$16,397,000 | 0.0172% |

Source: California Health Benefits Review Program, 2011.

Notes: (a) This population includes persons with privately funded and publicly funded (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans, Healthy Families Program, AIM, MRMIP) health insurance products regulated by the DMHC or CDI. Population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employment-sponsored insurance.

(b) Premium expenditures by enrollees include employee contributions to employer-sponsored health insurance and enrollee contributions for publicly purchased insurance.

(c) Of the increase in CalPERS employer expenditures, about 58% or \$923,000 would be state expenditures for CalPERS members who are state employees or their dependents.

(d) MRMIB Plan expenditures include expenditures for 874,000 enrollees of the Healthy Families Program, 8,000 enrollees of MRMIP, and 7,000 enrollees of the AIM program.

(e) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

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; MRMIB=Managed Risk Medical Insurance Board; MRMIP=Major Risk Medical Insurance Program.

INTRODUCTION

The California Senate Committee on Health requested on February 4, 2011, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Senate Bill (SB) 136, a bill that would impose a health benefit mandate for smoking cessation services. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.¹⁵

Analysis of SB 136

Approximately 21.9 million Californians (59%) have health insurance that may be subject to a health benefit mandate law passed at the state level.¹⁶ Of the rest of the state's population, a portion is uninsured (and so has no health insurance subject to any benefit mandate) and another portion has health insurance subject to other state law or only to federal laws.

Uniquely, California has a bifurcated system of regulation for health insurance subject to state-level benefit mandates. The California Department of Managed Health Care (DMHC)¹⁷ regulates health care service plans, which offer benefit coverage to their enrollees through health plan contracts. The California Department of Insurance (CDI) regulates health insurers¹⁸, which offer benefit coverage to their enrollees through health insurance policies.

DMHC-regulated plans and/or CDI-regulated policies, with the exception of Medicare supplement plan contracts and specialized health care service plan contracts, would be subject to SB 136. Therefore, the mandate would affect the health insurance of approximately 21.9 million Californians (59%).

Bill language

See Appendix A for the full text of the analyzed provisions.¹⁹

CHBRP analyzed bills with similar language in 2010 (Yee, SB 220) and 2007 (Torlakson, SB 24). CHBRP analyzed an amendment to SB 24 that was not introduced. Additionally, CHBRP analyzed a tobacco cessation bill in 2005 (Ortiz, SB 576). The CHBRP analysis of SB 220 in 2010 estimated that approximately 68.7% of those in DMHC- and CDI-regulated plans and policies had coverage for over-the-counter nicotine replacement therapy (OTC NRT)

¹⁵ CHBRP's authorizing statute is available at: http://www.chbrp.org/documents/authorizing_statute.pdf.

¹⁶ CHBRP's estimates are available at: http://www.chbrp.org/other_publications/index.php.

¹⁷ DMHC was established in 2000 to enforce the Knox-Keene Health Care Service Plan of 1975; see Health and Safety Code, Section 1340.

¹⁸ 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.

¹⁹ SB 136 contains modifications of the language in SB 220, which was analyzed by CHBRP in 2010 and can be found at http://www.chbrp.org/completed_analyses/index.php.

medications, 80.9% had coverage for counseling services, and 98.9% had coverage for prescription medications for smoking cessation. Current figures will be discussed in the *Benefit Coverage, Utilization, and Cost Impacts* section.

Overview of Analytic Approach

SB 136 requires health care service plans and health insurance policies²⁰ 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 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, varenicline, and bupropion SR²¹ 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.
- Step therapy²² 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 after the first treatment.
- At least four counseling sessions must be provided for in each course of treatment (at least two courses of treatment each year); each counseling session lasting at least 10 minutes.
- SB 136 would become inoperative on the date that the state determines that, taking into account any state savings identified,²³ SB 136 would result in the state assuming additional costs pursuant to subparagraph (B) of paragraph (3) of subsection (d) of Section 1311 of the federal Patient Protection and Affordable Care Act.

According to the bill author, SB 136 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. The bill author noted that smoking cessation has been categorized as being as

²⁰ SB 136 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*.

²¹ 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 United States but are not approved for smoking cessation.

²² *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).

²³ Section C of SB 136 would request that CHBRP prepare a report by December 31, 2014, evaluating the requirements of this section and determining any state savings as a result of those requirements.

cost effective as inoculations, in terms of the preventive services rankings (Maciosek, 2010), and that smoking cessation is one of the most clinically and cost-effective treatments that exists, according to the National Commission on Prevention Priorities. Finally, the bill author noted that, in light of uncertainty about what the federal government will do in light of the ACA, that it is important that California have the strongest smoking cessation benefits, even in absence of the federal government.

Analytic approach and key assumptions

For this analysis, CHBRP considered two factors that affect the use of smoking cessation services: benefit coverage and type of smoking cessation modality 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 the three categories of smoking cessation treatment (medications, OTC NRTs, and counseling). CHBRP uses the 2008 California Tobacco Survey data and the RAND Health Insurance Experiment's (HIE) estimated impact of cost sharing for well care to estimate premandate and postmandate utilization, and the CHIS 2009 survey to estimate present number of smokers.

The estimated primary impact of SB 136 is based on data and literature demonstrating increased utilization of smoking cessation treatment(s), as opposed to attempting to quit without any cessation treatment. CHBRP assumes the total number of persons attempting to quit would not change postmandate; however, a shift would occur from persons using newly covered cessation treatments from no treatment use. Literature indicates that persons using cessation treatments experience a higher quit rate than those going "cold turkey" (no treatment use). Therefore, under SB 136, CHBRP assumes an increased utilization of treatments and a higher quit rate postmandate. 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 those data are not available. Thus, it is possible that the impact of SB 136 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 136 includes the requirement that enrollees not be required to enter counseling in order to receive smoking cessation medications after the first treatment. It also stipulates that plans shall not impose prior authorization or stepped-care requirements on smoking cessation treatment after the first treatment. This would constitute a change in utilization requirements for certain managed care plans (including Medi-Cal Managed Care). CHBRP is unable to quantify the effects of this change on projected utilization and costs.

Although the bill applies to all enrollees²⁴, CHBRP does not address the potential impacts on adolescents aged 12-17 years. This is because 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

²⁴ CHBRP examines the impacts of SB 136 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 www.chbrp.org/analysis_methodology/cost_impact_analysis.php for more information regarding the population typically subject to benefit mandates.

(frequently at home, thus potentially understating prevalence), and school-based surveys (potential overstating prevalence rate).

Individual consumption of tobacco is one other factor in cessation (e.g., light, moderate, and heavy smokers); however, because of lack of overall data on the intensity of consumption, CHBRP does not attempt to disaggregate the available data by extent of cigarette consumption.

The 2009 American Recovery and Reinvestment Act (ARRA) allocates millions of dollars in funding to prevention and wellness programs, including tobacco prevention and cessation. These funds have been distributed to national, state, and local public health departments and organizations to enact programs to reduce tobacco use, including comprehensive smokefree laws, higher tobacco prices, and media campaigns. These, and other existing 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 insurance 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. 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.

The use of smoking cessation services is affected by two factors considered by CHBRP for this analysis: benefit coverage and estimates of the type of smoking cessation treatment(s) used. A beneficiary can have varying degrees of coverage ranging from no coverage to full coverage, which is defined in this report as coverage of all three modalities of smoking cessation: counseling, prescription medications, and OTC coverage of NRTs, etc. Furthermore, quitting smoking is a dynamic process, involving different types of assistance, and in many cases, multiple quit attempts (Figure 1).

Existing California requirements

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”). From 1989 to 2008, smoking prevalence in California decreased 40% (from 22.7% to 13.3%) (CDPH/TCP, 2010b); 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.

The Fiscal 2011-2012 year budget for the California Tobacco Control Program (CTCP) was \$49.9 million (CDPH, 2010b). One recipient of funds is the California Smokers' Helpline, which is a free telephone counseling service created in 1992²⁵. It provides counseling in six languages, including English, Spanish, Korean, Vietnamese, Mandarin, and Cantonese)²⁶, 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, supplementing its statewide media and advocacy work.²⁷ 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.²⁸

Requirements in other states

Currently, six states (Colorado, Maryland, New Jersey, New Mexico, Oregon and Rhode Island) mandate coverage for smoking cessation treatment (ALA, 2009) and North Dakota provides a \$150 lifetime smoking cessation benefit for specific group plans (ALA, 2009). Beginning in January 2010, 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 ("reasonable" copayments are allowable) "in accordance with" U.S. Preventive Services Task Force A and B recommendations.²⁹ 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.³⁰ Some of these state requirements are being supplanted by requirements contained in the Federal Affordable Care Act (ACA).

Additionally, 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 all private health insurance plans that provide maternity benefits also offer coverage for smoking cessation treatment to pregnant women.³¹ The law in New Mexico 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.³² 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.³³ Rhode Island requires

²⁵ The California Smokers' Helpline does not provide in-person individual or group counseling or pharmacotherapy.

²⁶ California Smokers' Helpline website,

<http://www.californiasmokershelpline.org/Language%20Services%20Available.shtml>. Accessed March 20, 2011.

²⁷ Available at: <http://www.cdph.ca.gov/programs/tobacco/Pages/CTCPLocalStatewideProjects.aspx>.

²⁸ Available at: <http://www.tobaccofreecatalog.org/>.

²⁹ Colorado Revised Statutes 10-16-104 (18) (b) (IX)

³⁰ Maryland Insurance Code Section 15-841

³¹ New Mexico Code Section 59A-46-45

³² New Mexico Administrative Code 13-10-18

³³ Oregon Revised Statutes 743A.170

coverage of both OTC and prescription cessation medications as well as 16 half-hour counseling sessions.³⁴

Tobacco dependence treatment programs are partially covered by Medicaid programs in 37 states, and comprehensively covered³⁵ in 13 states, including California (Halpin, et al., 2006). Six states—Indiana, Massachusetts, Minnesota, Nevada, Oregon and Pennsylvania—offer comprehensive cessation benefits to tobacco users on Medicaid. Additionally, as of October 1, 2010, all state Medicaid programs are required to offer comprehensive tobacco cessation benefits to pregnant women, per ACA requirements (more details follow in the ACA discussion).

One state that provides comprehensive smoking cessation benefits in its Medicaid program, is Massachusetts. An ongoing evaluation of the impacts has been undertaken. In July 2006, the Massachusetts health care reform law mandated tobacco cessation coverage for the Massachusetts Medicaid population. The law mandated coverage for two types of tobacco cessation treatment: behavioral counseling and all FDA-approved medications (including OTCs for smoking cessation). Prior to 2006, MassHealth (the Massachusetts Medicaid program) did not provide tobacco cessation benefits. The new benefit included behavioral counseling and all medications approved for tobacco cessation treatment by the U.S. Food and Drug Administration (FDA). Between July 1, 2006, and December 31, 2008, a total of 70,140 unique Massachusetts Medicaid subscribers used the newly available benefit, which is approximately 37% of all Massachusetts Medicaid smokers. The crude smoking rate decreased by 26%. (Land et al., 2010)

Potential Effects of Federal Affordable Care Act

The federal “Patient Protection and Affordable Care Act” (P.L.111-148) and the “Health Care and Education Reconciliation Act” (H.R.4872) were enacted in March 2010. These laws (together referred to as the “Affordable Care Act [ACA]”) are expected to dramatically affect the California health insurance market and its regulatory environment, with most changes becoming effective in 2014. How these provisions are implemented in California will largely depend on pending legal actions, funding decisions, regulations to be promulgated by federal agencies, and statutory and regulatory actions to be taken by California state government.

The provisions that go into effect during the transitional years (2011-2013) would affect the baseline, or current enrollment, expenditures, and premiums. It is important to note that CHBRP’s analysis of specific mandate bills typically address the marginal effects of the mandate bill—specifically, how the proposed mandate would impact benefit coverage, utilization, costs, and public health, holding all other factors constant. CHBRP’s estimates of these marginal effects are presented in this report. Each of the provisions that have gone into effect by January 2011 has been considered to determine whether they may affect CHBRP’s 2011 Cost and Coverage Model. There are still a number of provisions that have gone into effect for which data are not yet available. Where data allows, CHBRP has made adjustments to the Cost and Coverage model to reflect changes in enrollment and/or baseline premiums. These adjustments are discussed in further detail in Appendix D.

³⁴ Rhode Island General Laws Section 27-41-70

³⁵ Defined in this survey to mean coverage for NRT, Zyban (bupropion), and individual or group counseling.

A number of ACA provisions will need regulations and further clarity. One example is the ACA's requirement for certain health insurance to cover "essential health benefits" (EHBs). Effective 2014, Section 1302(b) will require small group and individual health insurance, including "qualified health plans" (QHPs) that will be sold in the California Exchange, to cover specified categories of benefits. These EHBs are defined as ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care. The Secretary of Health and Human Services (HHS) is charged with defining these categories through regulation, ensuring that the EHB floor "is equal to the scope of benefits provided under a typical employer plan." In addition, the ACA would allow a state to "require that a qualified health plan offered in [the Exchange] offer benefits in addition to the essential health benefits." If the state does so, the state must make payments to defray the cost of those additionally mandated benefits, either by paying the individual directly, or by paying the qualified health plan. This ACA requirement could interact with existing and proposed California benefit mandates, especially if California decided to require qualified health plans to cover California-specific mandates, and those mandates were determined to go beyond the EHB floor. Federal regulations regarding which benefits are to be covered under these broad EHB categories and other details, such as how the subsidies for purchasers of qualified health plans are structured, are forthcoming.³⁶

Essential health benefits and potential interactions with SB 136

The ACA requires beginning 2014 that states "make payments...to defray the cost of any additional benefits" required of QHPs sold in the Exchange.³⁷ SB 136 would make the requirements of the bill inoperative if the state determines that the requirements would "result in the state assuming additional costs pursuant to subparagraph (B) of paragraph (3) of subsection (d) of Section 1311 of the federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by subsection (e) of Section 10104 of Title X of that act." Therefore, the marginal impact as presented in this report would no longer apply after 2014 if the requirements of SB 136 were deemed to add fiscal costs for QHPs to be offered in the California Exchange.

EHBs are defined to include prescription drugs; mental health and substance use disorder services, including behavioral health treatment; and preventive and wellness services and chronic disease management. These EHBs may be considered to include certain benefits and services mandated by SB 136. For example, smoking cessation prescription drugs may be considered covered under the prescription drug EHB; counseling may be considered covered under "behavioral health treatment;" and any benefit or service included in SB 136 may be considered covered under "substance use disorder" services, since nicotine dependence is considered a substance use disorder per the DSM-IV.

³⁶ For further discussion on EHBs and potential interaction with state mandates, please see, *California's State Benefit Mandates and the Affordable Care Act's "Essential Health Benefits"* available here:

http://www.chbrp.org/other_publications/index.php.

³⁷ Affordable Care Act, 1311(d)(3)(B).

When promulgating regulations on EHBs, HHS is to ensure that the EHB floor “is equal to the scope of benefits provided under a typical employer plan.” CHBRP found some variation in coverage based on carrier surveys, such as the types of counseling services provided, and inclusion of OTC smoking cessation items. Assuming this is true nationally, there is likely variation in employer coverage for services mandated under SB 136. Therefore it is uncertain whether federal regulations and guidance would deem all the services mandated under SB 136 as being included under EHBs. In order for the state to determine whether any additional fiscal liability for the state would be incurred under SB 136, the following factors would need to be examined.

- Differences in the scope of benefits in the final EHB package and the scope of mandated benefits in SB 136;
- The number of enrollees in QHPs; and,
- The methods used to define and calculate the cost of additional benefits.

All of these factors are unknown at this time, and are dependent upon the details of pending federal regulations, state legislative and regulatory actions, and enrollment into QHPs after the Exchange is implemented.

Preventive benefits as required under the ACA and SB 136

“New plans” (i.e., those not covered under the ACA’s “grandfather” provisions) were required to cover certain preventive services at zero cost sharing beginning September 23, 2010. Tobacco use counseling and interventions are preventive services (U.S. Preventive Services Task Force, 2010) that fall under USPSTF “A and B” benefits and thus under the ACA’s requirement to cover those benefits at zero cost sharing. These services include:

- Tobacco use counseling for pregnant women: The USPSTF recommends that clinicians ask all pregnant women about tobacco use and provide augmented, pregnancy-tailored counseling to those who smoke. Grade A, April 2009 (USPSTF, 2010).
- Tobacco use counseling and interventions for nonpregnant adults. The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products. Grade A, April 2009 (USPSTF, 2010).
- Section 4107 of the ACA mandates coverage of comprehensive tobacco cessation services for pregnant women in Medicaid. States are required to provide Medicaid coverage for counseling and pharmacotherapy for tobacco cessation by pregnant women, and the ACA prohibits cost sharing for these services. Beginning October 1, 2010, all states were required to extend comprehensive cessation services to all pregnant women enrolled in Medicaid programs (ALA, 2011b).

Background on Condition

Tobacco use is the leading preventable cause of death in the United States and California. 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). 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 more choices of cessation treatments (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,³⁸ as well as prescription cessation medications such as varenicline. A number of public and private interests have recommended smoking cessation aids as a cost-effective strategy to prevent tobacco-related diseases.³⁹

The harms of smoking have been well established for decades, 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), stated that smoking causes multiple cardiovascular and respiratory diseases as well as cancers and estimated that one in three cases of cancer is attributable to smoking (ACS, 2011). The Surgeon General also reported a causal relationship between smoking and low birth weight infants, Sudden Infant Death Syndrome (SIDS), and preterm births.

Smoking Prevalence in California

Despite state-level advances in smoking cessation, smoking prevalence in California remains higher than the *Healthy People 2020*⁴⁰ target of 12% for adults (USDHHS, 2010). The 2009 California Health Interview Survey (CHIS, 2011) reported that 13.4% of insured Californians aged 18 to 64 years were current smokers (defined as smoking cigarettes every day or some days) (Table 2). Men demonstrate higher smoking prevalence than women; within each sex there is little variation by age.

³⁸ 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.

³⁹ 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) (AHIP, 2011). The National Council on Prevention Policies which ranked tobacco-screening and brief intervention (including offer of pharmacotherapy) as one of the three most clinically and cost-effective preventive services (Maciosek et al., 2006).

⁴⁰ Published by the U.S. Department of Health and Human Services, *Healthy People 2020* 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.

Table 2. Smoking Prevalence Among Currently Insured California Adults (%), 2009

| | Male | Female | Total |
|----------------------------------|-------|--------|-------|
| Overall | 16.8 | 10.1 | 13.4% |
| Age (years) | | | |
| 28-24 | 17.1 | 8.7 | 13.4 |
| 25-64 | 20.2 | 10.2 | 15.1 |
| 40-64 | 14.8 | 10.5 | 12.5 |
| Race/Ethnicity | | | |
| Latino | 18.4 | 6.1 | 12.2 |
| White | 15.7 | 12.7 | 14.1 |
| African American | 18.1 | 15.7 | 16.8 |
| American Indian/Alaskan Native | 31.7 | 28.8 | 29.9 |
| Asian | 15.6 | 5.5 | 10.1 |
| Native Hawaiian/Pacific Islander | 22.1* | 26.2* | 24.6* |
| Two or More Races | 21.9 | 18.1 | 20.0 |
| Poverty Status | | | |
| 0-99% FPL | 27.1 | 14.8 | 20.0 |
| 100-199% FPL | 21.9 | 12.1 | 16.9 |
| 200-299% FPL | 17.4 | 10.6 | 13.7 |
| 300% + FPL | 13.7 | 8.5 | 11.1 |

Source: California Health Benefits Review Program, 2011. (Based on 2009 California Health Interview Survey)

Note: Adults ages 18-64 who are currently insured.

*Statistical issues render this figure unreliable (variance too high or number of respondents too low).

Key: FPL = Federal Poverty Level

The smoking prevalence by race and ethnicity varies; there is nearly a 3-fold difference in smoking prevalence between the lowest group (Asians, 10.1%) and the highest group (American Indian/Alaska Native, 29.9%) (Table 2). California's Latino and Asian populations achieve the *Healthy People 2020* target for smoking prevalence at 12.2% and 10.1%, respectively. Within each racial and ethnic group there are also large differences by sex. Asian men are almost three times more likely to report smoking than Asian women, and smoking prevalence for Latino men is three times that of Latina women. The highest smoking prevalence is among American Indian/Alaska Native men (31.7%), whereas the lowest is found in Asian women (5.5%) (CHIS, 2011).

Disparities extend to socioeconomic status as well (Table 2). Both men and women with income less than 200% of the federal poverty level⁴¹ (FPL) are more likely to smoke than those who have higher incomes. The poorest individuals with incomes between 0 and 99% of the FPL are almost twice as likely to report smoking as are those with incomes at or above 300% of the FPL (CHIS, 2011).

⁴¹ The federal poverty level is an income-based criteria used to determine benefit levels for many low-income assistance programs. In 2011, for a family of three, 100% of FPL is equivalent to annual gross income of \$18,530; 200% = \$37,060; and 300% = \$55,590 (FHCE, 2011).

Burden of Smoking-Related Disease

In California (Table 3), 19% of heart disease mortality is attributed to smoking, followed by cancer (trachea, bronchus, and lung), chronic obstructive pulmonary disease and stroke, at 6%, 5%, and 5% respectively (CDPH, 2010a).

The health burden of smoking—and therefore the benefits that proceed from AB 136-related smoking cessation—extends significantly beyond these selected conditions. Characterizing the health burdens and benefits associated with each of the numerous relevant conditions is not feasible; however, certain examples will be given when relevant. The *Impacts on Premature Death and Economic Loss* section of this report will address further the issue of total smoking-related mortality.

Table 3. Leading Causes of Tobacco-related Deaths in California, 2005

| Tobacco-related Causes of Death | Number (%) | Age-adjusted rate/100,000 |
|---|-------------------|----------------------------------|
| Ischemic heart disease | 45,059 (19%) | 176.0 |
| Cancer of trachea, lung, bronchus | 13,350(6%) | 52.7 |
| Chronic obstructive pulmonary diseases (COPD) | 12,562(5%) | 49.8 |
| Stroke | 11,680(5%) | 46.0 |
| Diabetes | 7,689(3%) | 26.8 |
| Other tobacco-related neoplasms | 1,210 (1%) | 5.0 |
| Total | | |

Source: CDPH/TCP, 2010a.

Gender and racial/ethnic disparities continue beyond smoking prevalence and extend to smoking-related morbidity and mortality. Despite a lower rate of smoking than men, women experience higher incidence rates of smoking-related disease, including lung cancer and cervical cancer and, according to one study, a 30-fold increase in myocardial infarction risk. In contrast, there was a three-fold higher smoking-related death rate for California men than women 2000-2004 (CDPH, 2010). Ethnic and racial disparities are also well documented. For example, African Americans experience a higher incidence of cardiovascular disease, cancer, and infant mortality, all of which are smoking-related. Native Americans experience the highest rate of infant mortality due to SIDS, which is also causally linked to smoking (Fiore, 2000; Piper et al., 2001). In another example, among cigarette smokers, African American and Native Hawaiian men had the highest incidence of lung cancer (Haimen et al., 2006).

In addition to compromising the health of the smoker, literature indicates secondhand smoke impacts the health of others. The Surgeon General's office has declared that secondhand smoke is associated with an increased risk of lung cancer, heart disease, stroke, asthma and other respiratory problems and estimates that nearly 60% of children aged 3 to 11 years and more than 40% of nonsmoking adults are exposed to secondhand smoke (USDHHS, 2006). In its seminal report, *The Health Consequences of Involuntary Exposure to Tobacco Smoke*, the Surgeon

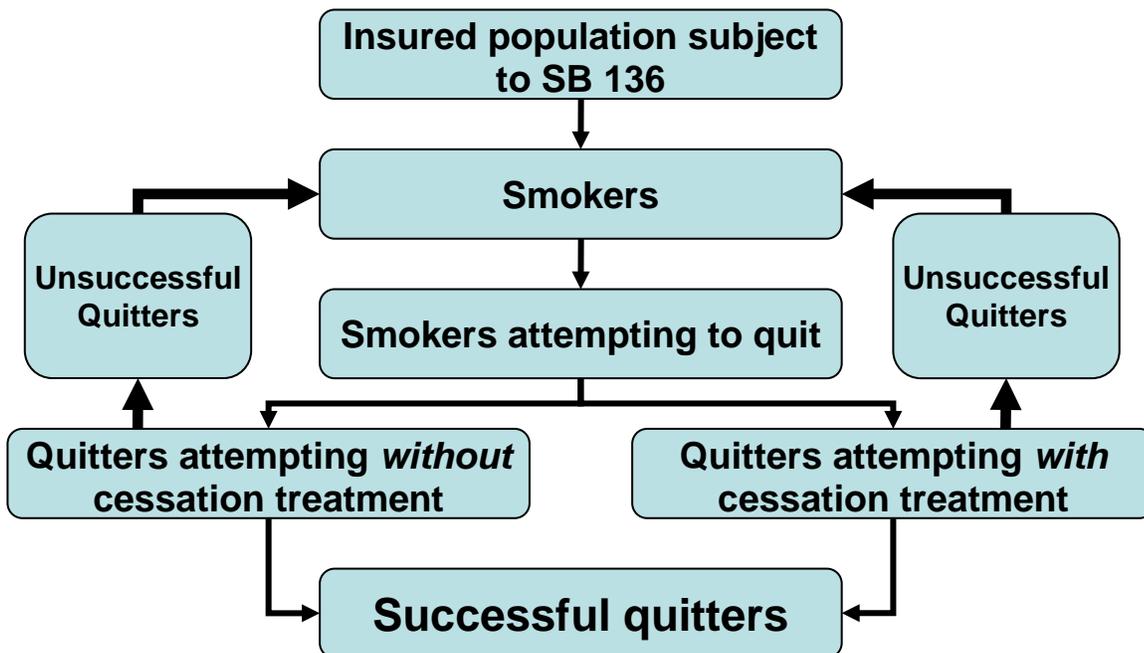
General reported a 20%-30% increase in the lung cancer risk, as well as a 25%-30% increase in the risk of coronary heart disease, due to secondhand smoke exposure (USDHHS, 2006). Exposure to secondhand smoke is particularly harmful for children, and is associated with a higher risk of SIDS, ear infections, and lower respiratory infections such as pneumonia and bronchitis, and is causally linked with low birth weight (USDHHS, 2006). The American Lung Association estimates that 50,000 deaths each year are attributable to secondhand smoke (ALA, 2011a).

In California, nonsmokers are exposed to smoke primarily at home and in cars, since the majority of workplaces and many public places are smoke-free. In 2006, the California Environmental Protection Agency (EPA) declared secondhand smoke to be a "toxic air contaminant" and estimated that secondhand smoke is responsible for 21 cases of SIDS, 1,600 cases of low birth weight infants, 4,700 pre-term deliveries, 31,000 episodes of asthma in children, 400 cases of lung cancer, and 3,600 cardiac deaths each year in the state (EPA, 2006).

The process of quitting smoking

Smoking cessation is a complex process typically requiring multiple quit attempts, degrees of quitting (i.e., cutting down consumption), and high rates of relapse (see Figure 1) (Fiore et al., 2000; Gilpin et al., 1997; CDHS/TCS, 2006). The Surgeon General’s 1990 report characterized smoking cessation as a “dynamic process” (CDC, 1990). The tenacity of smoking 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.

Figure 1. Process of quitting smoking with and without treatment assistance



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, although the most recent California Tobacco Survey (2008) reported 60% of smokers attempting to quit (Al-Delaimy et al., 2010). 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 4). 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 et al., 2008).

Gender disparities in smoking cessation attempts and quit rates exist and literature identifies numerous potential barriers to successful smoking cessation for women. For example, women are twice as likely as men to be concerned over post-cessation weight gain, and these concerns appear associated with lower smoking abstinence rates among those attempting to quit (Clark et al., 2006; Schnoll et al., 2007).

Table 4. Smoking Cessation Attempts in California, 2005 and 2008

| Cessation (Quit) attempts | % of California smokers |
|--|--------------------------------|
| Quit Attempts (in last 12 months) | |
| Quit attempt of 1 day or longer | 60.2 |
| Successful 90+ days quit | 8.6 |
| Use by type of cessation treatment | |
| NRT alone ^a | 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 and 2008 California Tobacco Surveys; Al-Delaimy, 2008, 2010).

Note: This table combines data available from the 2008 California Tobacco Survey (CTS) Summary Report, which states that 60% of smokers attempted to quit in 2008, and retains “Use by Type of Cessation Treatment” data from the 2005 CTS, which is not statistically different from the 2008 CTS.

^aThe CTS 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.

MEDICAL EFFECTIVENESS

As noted in the *Introduction*, SB 136 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 2010 to present because CHBRP had previously conducted thorough literature searches on these topics in 2005, 2007, and 2010 for SB 576, SB 24, and SB 220 respectively. A total of 34 studies were included in the medical effectiveness review for SB 136, including 10 studies from the SB 576 review, 11 additional studies from the SB 24 review, 13 studies from the SB 220 review, and 1 new study published since the literature review for SB 220 was completed in 2010.⁴² 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.

⁴² In some cases, more current versions of meta-analyses and systematic reviews included in the SB 576, SB 24, and SB 220 reports were included in the literature review for the SB 136 report. For example, Cahill et al. (2011) is an update of a Cochrane review that these authors previously published in 2008. 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.

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 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),⁴³ an antidepressant medication used in smoking cessation. The FDA has approved the use of bupropion SR and varenicline⁴⁴ 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.

⁴³ 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.

⁴⁴ 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, SB 24 in 2007, and SB 220 in 2010 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 136 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 136. In addition, smokers who take the initiative to enroll in RCTs are probably more highly motivated to quit than the average smoker. Greater motivation may lead to higher rates of abstinence from smoking among persons enrolled in both the intervention and control groups of RCTs than would occur in the “real world.” 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)⁴⁵ 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 ratio⁴⁶ = 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).

⁴⁵ 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.

⁴⁶ 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)⁴⁷ 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.

⁴⁷ In the Stead et al., 2009, and Stead, Bergson et al., 2008, 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. (2008) summarized 17 RCTs and quasi-randomized trials evaluating the effects of minimal⁴⁸ 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.⁴⁹

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

⁴⁸ 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."

⁴⁹ 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.

compared to receiving 0 to 1 session). An important limitation of Fiore et al.'s (2008) analyses of 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 agonist⁵⁰; and the non-

⁵⁰ 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.⁵¹

⁵¹ 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,⁵² 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.⁵³

Varenicline (brand name: Chantix). Fiore et al. (2008), Cahill et al. (2011), 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. (2011)⁵⁴ 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.⁵⁵

⁵² 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.

⁵³ 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.

⁵⁴ Cahill et al. (2011) reported that trials included in their meta-analysis on varenicline were funded and managed by Pfizer Inc., the manufacturer of varenicline.

⁵⁵ 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. (2011) and Hughes et al. (2010) reached a similar conclusion.⁵⁶

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 (an antihypertensive medication) and nortriptyline (an antidepressant medication)—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.⁵⁷

⁵⁶ 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.

⁵⁷ 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 bupropion⁵⁸ 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.⁵⁹

Generalizability of pharmacotherapy findings to Californians affected by SB 136

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 drug. This study also found that bupropion SR and NRT were especially effective when used by

⁵⁸ 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.

⁵⁹ 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.

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). Finding from these trials indicate that pharmacotherapy and counseling are effective in reducing smoking rates among these subgroups⁶⁰.

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).

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 136, 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)⁶¹. This meta-analysis

⁶⁰ 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

⁶¹ 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

synthesized the results of six studies. Five of these studies had been published in peer review journals (Boyle et al., 2002; Curry et al., 1998; Dey et al., 1999; Hughes et al., 1991; Schauffler et al., 2001), and one was a conference paper that was subsequently published (Kaper, Wagena, Willemsen, et al., 2005). The authors reported separate estimates for counseling, NRT, and bupropion. They compared the effects of full coverage⁶² 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 (Schauffler et al., 2001). In both studies, few persons with full coverage obtained counseling. One study reported that 5% of persons with full coverage received counseling, and the other reported that 1% used it.

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

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.

⁶² 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).

(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.⁶³ One study examined persons enrolled in two California health maintenance organizations (HMOs) and reported that 25% of persons in the full-coverage group used NRT versus 14% of persons in the no-coverage group (Schauffler et al., 2001).

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

Two studies included in the meta-analysis compared full and partial coverage for NRT. One study found that persons who had coverage for 100% of the costs of NRT were over three times as likely to obtain it as persons who had coverage for only 50% of the costs (7% vs. 2%) (Curry et al., 1998). Another study found that 75% of persons who had full coverage for nicotine gum obtained at least one box of gum versus 58% of persons who had only partial coverage (Hughes et al., 1991). Thus, there is consistent evidence that persons with full coverage for nicotine gum are more likely to use it than are persons with partial coverage. The latter study may have found that a much higher percentage of persons used NRT because it was an RCT, whereas the former study was an observational study. Smokers who enroll in RCTs may be more highly motivated to use NRT and other smoking cessation 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).⁶⁴ One of the

⁶³ 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).

⁶⁴ 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.

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). A nonrandomized study also found an increase in the use of bupropion SR, but the increase was not statistically significant (Boyle et al., 2002). The rates of use among persons with full coverage ranged from 4% (Kaper, Wagena, Willemsen, et al., 2005) to 24% (Boyle et al., 2002).⁶⁵ 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.

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 reviewed journals (Boyle et al., 2002; Dey et al., 1999; Hughes et al., 1991; Schauffler et al., 2001) and one conference paper that was subsequently published (Kaper, Wagena, Willemsen, et al., 2005). Three articles were published after the meta-analysis was completed (Kaper et al., 2006;⁶⁶ 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

⁶⁵ 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.

⁶⁶ 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.

quit smoking versus 4% of persons with no coverage. Two RCTs included in the meta-analysis reported that full coverage was associated with a statistically significant increase in the percentages of persons who had abstained from smoking (Kaper, Wagena, Willemsen, et al., 2005; Schauffler et al., 2001). Three studies, two RCTs (Dey et al., 1999; Hughes et al., 1991) and one nonrandomized study (Boyle et al., 2002) found no statistically significant difference in abstinence from smoking. In one of these studies, persons with full coverage were more likely to abstain from smoking, but the small sample size limited the authors' ability to detect statistically significant differences (Hughes et al., 1991). 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 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.⁶⁷

Among studies of full coverage versus no coverage that enrolled men and women with a wide range of ages and incomes, rates of abstinence from smoking ranged from 4% to 19% among the full coverage group versus 4% to 8% in the no coverage groups (Boyle et al., 2002; 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 who resided in states in which Medicaid covered smoking cessation counseling and medications found that 51% quit smoking during pregnancy versus 39% of women who resided in states with no Medicaid coverage for such smoking cessation treatments (Petersen et al., 2006).

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

⁶⁷ 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.

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% for coverage of pharmacotherapy drugs and counseling, and 18% for coverage of pharmacotherapy if counseling was used.

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

Two studies compared persons with partial coverage for 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 5. 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-analyses⁶⁸ | <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 |
| 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 | <ul style="list-style-type: none"> 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 |

⁶⁸ 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.

Table 5. Summary of Findings from Studies of the Effectiveness of Smoking Cessation Treatments (Cont'd)

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-analyses⁶⁹ 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 |

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-analyses⁷⁰ | <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 |

⁶⁹ 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.

⁷⁰ 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.

Table 5. Summary of Findings from Studies of the Effectiveness of Smoking Cessation Treatments (Cont'd)

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-analyses⁷¹ | <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 |

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 |

⁷¹ 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.

Table 5. Summary of Findings from Studies of the Effectiveness of Smoking Cessation Treatments (Cont'd)

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 |

Bupropion⁷² 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 |

⁷² 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.

Table 5. Summary of Findings from Studies of the Effectiveness of Smoking Cessation Treatments (Cont'd)

Varenicline vs. Bupropion⁷³

| 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 |

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 |

⁷³ Two of the meta-analyses—Cahill et al. (2011) 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.

Table 5. Summary of Findings from Studies of the Effectiveness of Smoking Cessation Treatments (Cont'd)

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., 2011; 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 6. 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 Design ⁷⁴ | 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 |

⁷⁴ 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.

Table 6. Summary of Findings from Studies of the Effects of Coverage for Smoking Cessation Treatments on Use of Treatments and Abstinence from Smoking (Cont'd)

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

| Outcome | Research Design ⁷⁵ | Statistical Significance | Direction of Effect | Size of Effect | Generalizability | Conclusion |
|---|--|--|--|--|---|--|
| Use of bupropion ⁷⁶ (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 |

⁷⁵ 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.

⁷⁶ 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.

Table 6. Summary of Findings from Studies of the Effects of Coverage for Smoking Cessation Treatments on Use of Treatments and Abstinence from Smoking (Cont'd)

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 |

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

| Outcome | Research Design ⁷⁷ | 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 |

⁷⁷ 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.

Table 6. Summary of Findings from Studies of the Effects of Coverage for Smoking Cessation Treatments on Use of Treatments and Abstinence from Smoking (Cont'd)

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.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

SB 136 would require all DMHC-regulated health plan contracts and CDI-regulated insurance policies to also provide coverage for smoking cessation treatments. 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 21.9 million insured Californians currently enrolled in either DMHC- or CDI-regulated health plans or policies, including 14.41 million enrollees aged 18 years and older.

Although SB 136 did not specify a 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, the utilization analysis in this report will focus only smoking cessation treatments for adults who smoke.

Unlike previous versions of smoking cessation treatment benefit mandates (see CHBRP report on SB 220 from 2010), SB 136 does not specify whether cost sharing would be eliminated in order for coverage to be mandate compliant. CHBRP assumes that if SB 136 were enacted, all DMHC-regulated plans and CDI-regulated policies would then include mandate-compliant coverage for smoking cessation treatments that includes enrollee cost sharing, as there is no incentive for expanding coverage to include no cost sharing. This assumption affects our postmandate utilization estimates. For a full description on the derivation of the postmandate utilization estimates, see Appendix D at the end of this document.

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 136. For further details on the underlying data sources and methods, please see Appendix D.

Current (Baseline) Benefit Coverage, Utilization, and Cost

Current Coverage of the Mandated Benefit

Current coverage of smoking cessation services was determined by a survey of the seven largest providers of health insurance in California. CHBRP surveys the largest major health plans and insurers regarding coverage. Responses to this survey represented 26.0% of the privately funded, CDI-regulated market and 67.2% of the privately funded, DMHC-regulated market. Combined, responses to this survey represent 58.6% of the privately funded market subject to state mandates.

Currently, enrollees in DMHC- or CDI-regulated plans or policies may 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. Additionally, 98.8% have mandate-compliant coverage for prescription smoking cessation treatments (e.g., bupropion, varenicline, or inhalant forms of nicotine replacement therapy) through outpatient prescription drug benefits with \$5 to \$75 copayment, though many plans limit it to one course of treatment per contract year. While 82.5% have coverage for personal counseling through telephone or other counseling services, a smaller number (62.0%) have mandate-compliant coverage for OTC treatments. The partial coverage ranges from 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 11.7% (1.68 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.

Nearly nine in ten (82.5%) enrollees have mandate-compliant coverage for smoking cessation-related counseling, and 98.8% have mandate-compliant coverage for prescription smoking cessation treatment, but 62.0% have mandate-compliant coverage for OTC smoking cessation treatment. If SB 136 were enacted, 100% of insured adults would have mandate-compliant coverage for smoking cessation services.

Current Utilization Levels

Current utilization

According to the most recent California-specific data available, the 2008 California Tobacco Survey (CTS), 60.2% 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. Detailed data from the 2008 CTS was unavailable, but the California Department of Public Health reported that percentages of those using a smoking cessation method had remained constant from the prior survey in 2005 (Al-Delaimy et al., 2010). CHBRP used the 2005 CTS data and found that 10.4% smokers who made an attempt to quit used NRT, 4.4% used counseling only, 2.0% used a pharmaceutical smoking cessation method, 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 the 2008 and 2005 CTS data as a baseline to estimate the premandate utilization because these data were weighted to represent a complete utilization pattern of all Californians. Because CTS data did not provide utilization information by insurance coverage, CHBRP decided to use the RAND 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.

Premandate, of the 1.93 million adult smokers enrolled in DMHC- or CDI-regulated plans or policies with outpatient prescription drug coverage, 308,604 used one or more smoking cessation treatments, with 252,226 using treatments covered through their existing insurance and 56,378 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. The average costs for counseling assume four sessions in either group or individual settings, each a minimum of ten minutes. Use of the free statewide quit telephone helpline is not included in this estimate, as it does not affect costs and utilization is not measurable. This analysis assumes that the available supply of services would meet the slightly increased demand, and that costs for the service would not increase.

Current (Baseline) Premiums and Expenditures

Table 7 (at the end of this section) presents per member per month (PMPM) premandate estimates for premiums and expenditures by market segment.

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

CHBRP estimated no shift in costs among private or public payors 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 136 for private payors later in this section, under *Impact on Long-Term Costs*, and for enrollees in the *Public Health Impacts* section.

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.

As a way to determine whether public demand exists for the proposed mandate (based on criteria specified by CHBRP's authorizing statute), 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.⁷⁸ Currently, CalPERS' plans vary in coverage for tobacco cessation. Some plans provide coverage for tobacco cessation counseling, others do not. Based on responses from health plans, all plans 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 Benefit Coverage Related to the Mandate Affect the Availability of the Newly Covered Treatment/Service, the Health Benefit of the Newly Covered Treatment/Service and the Per-Unit Cost?

On the basis of the responses of three health plans and insurers in California, CHBRP estimated that the percentage of enrollees with mandate-compliant benefit coverage would increase 38 percentage points, from 62.0% who currently have any coverage for all smoking cessation treatment types 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 no coverage to partial coverage of counseling and/or OTC smoking cessation treatments, since SB 136 does not contain a requirement that the coverage include no cost sharing. Therefore, the impact of the marginal changes in utilization and premiums (as discussed below) is less than might be expected were the smoking cessation benefits mandated without cost sharing.

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.

Impact on per-unit cost

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.

⁷⁸ Personal communication with the California Labor Federation and member organizations on January 29, 2007.

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 postmandate utilization rate among smokers for smoking cessation services using the RAND HIE estimated impact of cost sharing for well care. Specifically, those without coverage 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 136 would increase the utilization of all smoking cessation treatments. If SB 136 were enacted, the mandate would eliminate the prior authorization requirements (beyond the first treatment) that currently exist in some managed care plans. This may have a slight impact on utilization, but these cannot be measured.

Postmandate, of the 1.93 million insured adult smokers, CHBRP estimated that the utilization of counseling services would increase by 9.2%, OTC treatments by 19.8%, and prescription treatments by 0.6%. In summary, the utilization of one or more smoking cessation treatments would increase by 11.2%, representing an additional 34,660 insured adult smokers attempting to quit smoking through the use of a smoking cessation treatment, after the mandate.

Please see details of the calculations in Appendix D. The estimated increases of percentage points for different services are similar to the findings of two published meta-analyses (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 will include cost sharing, is also expected to dampen any potential surges in utilization for any one service.

Postmandate, of the 1.93 million insured adult smokers, CHBRP estimated that the utilization of counseling services would increase by 9.2%, OTC treatments by 19.8%, and prescription treatments by 0.6%. In summary, the utilization of one or more smoking cessation treatments would increase by 11.2%, representing an additional 34,660 insured adult smokers attempting to quit smoking through the use of a smoking cessation treatment, after the mandate.

To What Extent Would 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 would 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. If SB 136 were enacted, the mandate would eliminate the prior authorization requirements that currently exist in some managed care plans (beyond the first treatment). 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 136 would increase total net annual expenditures by \$16.4 million or 0.017% for this insured population (see Table 1 in *Executive Summary*). This is due to a \$32.9 million total increase in health insurance premiums and enrollee expenses for newly covered benefits, partially offset by a reduction in enrollee expenditures for previously noncovered benefits (\$16.5 million).

Potential cost offsets or savings in the short-term

The net increase of \$16.4 million could possibly also be reduced further on a health system-level by savings from a reduction in low birth weight deliveries and in hospitalizations due to AMI among those who quit smoking, but that number is close to zero for short-term (i.e., one-year) timeframe of the CHBRP cost model.

Total net annual health expenditures are projected to increase by \$16.4 million or 0.017% for this insured population (Table 1). This is due to a \$32.9 million total increase in health insurance premiums and enrollee expenses for newly covered benefits, partially offset by a reduction in enrollee out-of-pocket expenditures for previously noncovered benefits (\$16.5 million).

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.

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. Most recently, a meta-analysis by Leeks et al. (2010) found that worksite tobacco-reduction programs were associated with positive economic returns on the employer's initial investment. These

figures provide a basis for understanding the potential annual savings associated with encouraging smoking cessation programs.

Impacts for Each Category of Payor Resulting from the Benefit Mandate

Changes in expenditures and PMPM amounts by payor category

Increases in insurance premiums vary by market segment. 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 an average increase of 0.00% (for DMHC-regulated Medi-Cal Managed Care Plans) to an average increase of 0.17% (for CDI-regulated individual policies) in the affected market segments. Increases as measured by PMPM premiums are estimated to range from \$0.00 to \$0.33.

In the privately funded large-group market, the increase in premiums is estimated to range from an average increase of \$0.06 PMPM among DMHC-regulated plan contracts to an average increase of \$0.23 PMPM among CDI-regulated policies (Table 5). For enrollees with privately funded small-group insurance policies, health insurance premiums are estimated to range from an average increase of \$0.11 PMPM for DMHC contracts to an average increase of \$0.28 PMPM for CDI policies. In the privately funded individual market, the health insurance premiums are estimated to range from an average increase of \$0.08 PMPM to an average increase of \$0.33 PMPM in the DMHC- and CDI-regulated markets, respectively.

Among publicly funded DMHC-regulated health plans, CHBRP estimates that premium increases for Medi-Cal Managed Care Plans, MRMIB plans and CalPERS HMOs would range from average increases of 0.00% to 0.05% (\$0.00 to \$0.20).

The largest portion of the shift in expenditures would be from privately insured enrollees' expenses for noncovered benefits to premiums. For example, in the individual CDI-regulated policy market, an average of \$0.22 of the enrollee expenses for noncovered benefits (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 higher rates of partial coverage for OTC medications would be available to them under the mandate.

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| Increases as measured by percentage changes in PMPM premiums are estimated to range from an average increase of 0.00% (for DMHC-regulated Medi-Cal Managed Care Plans) to an average increase of 0.17% (for CDI-regulated individual policies) in the affected market segments. Increases as measured by PMPM premiums are estimated to range from \$0.00 to \$0.33. |
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Impacts on the Uninsured and Public Programs As a Result of the Cost Impacts of the Mandate

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 public programs as a result of premium increases

CHBRP estimates that the mandate would produce no measurable impact on enrollment in publicly funded insurance programs or on utilization of covered benefits in the publicly funded insurance market.

Table 7. Baseline (Premandate) Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2011

| | DMHC-Regulated | | | | | | | CDI-Regulated | | | Total |
|--|---------------------------------------|-----------------|-----------------|---------------------|--------------------------------|-----------------|--------------------|--|-----------------|-----------------|-------------------------|
| | Privately Funded Plans (by market) | | | CalPERS HMOs (b) | Medi-Cal Managed Care Plans | | MRMIB Plans (d) | Privately Funded Policies (by market) | | | |
| | 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) | 10,526,000 | 2,241,000 | 733,000 | 831,000 | 285,000 | 3,539,000 | 889,000 | 397,000 | 1,118,000 | 1,343,000 | 21,902,000 |
| Total enrollees in plans/policies subject to SB 136 | 10,526,000 | 2,241,000 | 733,000 | 831,000 | 285,000 | 3,539,000 | 889,000 | 397,000 | 1,118,000 | 1,343,000 | 21,902,000 |
| Average portion of premium paid by Employer | \$317.59 | \$267.09 | \$0.00 | \$347.55 | \$346.00 | \$176.00 | \$98.48 | \$375.44 | \$270.30 | \$0.00 | \$65,887,370,000 |
| Average portion of premium paid by Employee | \$82.91 | \$83.47 | \$399.69 | \$86.89 | \$0.00 | \$0.00 | \$13.79 | \$122.08 | \$64.15 | \$199.13 | \$21,898,323,000 |
| Total Premium | \$400.51 | \$350.57 | \$399.69 | \$434.44 | \$346.00 | \$176.00 | \$112.27 | \$497.52 | \$334.45 | \$199.13 | \$87,785,693,000 |
| Enrollee expenses for covered benefits (Deductibles, copays, etc.) | \$21.82 | \$32.63 | \$84.77 | \$22.41 | \$0.00 | \$0.00 | \$4.68 | \$63.15 | \$123.11 | \$58.53 | \$7,548,415,000 |
| Enrollee expenses for benefits not covered (e) | \$0.04 | \$0.07 | \$0.05 | \$0.15 | \$0.00 | \$0.00 | \$0.01 | \$0.17 | \$0.19 | \$0.22 | \$16,548,000 |
| Total Expenditures | \$422.37 | \$383.27 | \$484.51 | \$456.99 | \$346.00 | \$176.00 | \$116.97 | \$560.84 | \$457.75 | \$257.88 | \$95,350,656,000 |

Source: California Health Benefits Review Program, 2011.

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

(b) Of these CalPERS HMO members, about 58% or 482,000 are state employees or their dependents.

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

(d) MRMIB Plan expenditures include expenditures for 874,000 enrollees of the Healthy Families Program, 8,000 enrollees of MRMIB, and 7,000 enrollees of the AIM program.

(e) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Table 8. Impacts of the Mandate on Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2011

| | DMHC-Regulated | | | | | | | CDI-Regulated | | | Total |
|--|------------------------------------|-------------|------------|------------------|-----------------------------|-----------|-----------------|---------------------------------------|-------------|------------|--------------|
| | Privately Funded Plans (by market) | | | CalPERS HMOs (b) | Medi-Cal Managed Care Plans | | MRMIB Plans (d) | Privately Funded Policies (by market) | | | |
| | 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) | 10,526,000 | 2,241,000 | 733,000 | 831,000 | 285,000 | 3,539,000 | 889,000 | 397,000 | 1,118,000 | 1,343,000 | 21,902,000 |
| Total enrollees in plans/policies subject to SB 136 | 10,526,000 | 2,241,000 | 733,000 | 831,000 | 285,000 | 3,539,000 | 889,000 | 397,000 | 1,118,000 | 1,343,000 | 21,902,000 |
| Average portion of premium paid by Employer | \$0.0460 | \$0.0823 | \$0.0000 | \$0.1596 | \$0.0000 | \$0.000 | \$0.0143 | \$0.1715 | \$0.2289 | \$0.0000 | \$13,651,000 |
| Average portion of premium paid by Employee | \$0.0120 | \$0.0252 | \$0.0766 | \$0.0399 | \$0.0000 | \$0.0000 | \$0.0020 | \$0.0558 | \$0.0538 | \$0.3300 | \$9,592,000 |
| Total Premium | \$0.0580 | \$0.1075 | \$0.0766 | \$0.1995 | \$0.0000 | \$0.0000 | \$0.0163 | \$0.2272 | \$0.2827 | \$0.3300 | \$23,243,000 |
| Enrollee expenses for covered benefits (Deductibles, copays, etc.) | \$0.0259 | \$0.0433 | \$0.0294 | \$0.0876 | \$0.0000 | \$0.0000 | \$0.0074 | \$0.0979 | \$0.1119 | \$0.1295 | \$9,701,000 |
| Enrollee expenses for benefits not covered (e) | -\$0.0438 | -\$0.0741 | -\$0.0516 | -\$0.1455 | \$0.0000 | \$0.0000 | -\$0.0123 | -\$0.1652 | -\$0.1925 | -\$0.2241 | \$16,548,000 |
| Total Expenditures | \$0.0400 | \$0.0768 | \$0.0543 | \$0.1417 | \$0.0000 | \$0.000 | \$0.0114 | \$0.1599 | \$0.2021 | \$0.2354 | \$16,397,000 |
| Percentage Impact of Mandate | | | | | | | | | | | |
| Insured Premiums | 0.0145% | 0.0307% | 0.0192% | 0.0459% | 0.0000% | 0.000% | 0.0145% | 0.0457% | 0.0845% | 0.1657% | 0.0265% |
| Total Expenditures | 0.0095% | 0.0200% | 0.0112% | 0.0310% | 0.0000% | 0.000% | 0.0098% | 0.0285% | 0.0441% | 0.0913% | 0.0172% |

Source: California Health Benefits Review Program, 2011.

- Note:* (a) This population includes persons insured with private funds (group and individual) and insured with public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans, Healthy Families Program, AIM, MRMIB) enrolled in health plans or policies regulated by the DMHC or CDI. This population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employment-sponsored insurance.
- (b) Of these CalPERS members, about 58% or 482,000 are state employees or their dependents.
- (c) Medi-Cal Managed Care Plan expenditures for members over 65 years of age include those who also have Medicare coverage.
- (d) MRMIB Plan expenditures include expenditures for 874,000 enrollees of the Healthy Families Program, 8,000 enrollees of MRMIB, and 7,000 enrollees of the AIM program.
- (e) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

PUBLIC HEALTH IMPACTS

SB 136 would require DMHC-regulated plans and CDI-insurance policies to cover smoking cessation treatments as rated A or B by the United States Preventive Sciences Task Force (USPSTF) and permit cost sharing between the enrollee and the plan or policy for such treatments (unless the plans/policies have grandfathered status). Covered treatments include counseling, over-the-counter nicotine replacement therapy (OTC NRT), and prescription medications. Use of these treatments individually or in combination can assist smokers with the difficult task of quitting smoking, maintaining abstinence, and positively impacting California's 13.4% smoking prevalence rate in the insured adult population (CHIS, 2011).

The literature on harms of smoking and subsequent health improvements from cessation are well documented through decades of research. The evidence presented in this report about the efficacy and improved outcomes from sustained abstinence from smoking are unlikely to be diminished or altered with the publication of new studies. This section presents the estimated marginal public health impact of SB 136, including the additional enrollees attempting to quit, successful quitters, potential for reduction in gender and racial/ethnic disparities in health outcomes, premature death, societal economic losses, and long term outcomes of smoking-related diseases.

Public Health Outcomes

Improving the quit rate of smokers improves shorter term health outcomes, for example, smoking cessation will reduce rates of low birth weight babies and acute myocardial infarction (AMI). However, the all the benefits to heart disease and AMI are not fully realized in the immediate 12 months postmandate that CHBRP commonly models. In the short-term, 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). Additionally, a Cochrane review reported similar conclusions for pregnant women who quit smoking during pregnancy (Table 9) (Lumley et al., 2009).

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, and after 10 to 15 years of cessation, risk of all-cause mortality returns to close to that of a never smoker (CDC, 1990; Lightwood and Glantz, 1997). Similarly, a recent study on the Massachusetts Medicaid program found a decline in hospitalizations for acute myocardial infarction and other acute coronary heart disease diagnoses 2.5 years after a comprehensive smoking cessation benefit was implemented (Table 9) (Land et al., 2010). The authors also estimated the smoking prevalence among subscribers decreased by 10% in this time period (Land et al., 2010).

Table 9. Improved Perinatal and Adult Health Outcomes Due to Smoking Cessation

| Improved Health Outcomes Due to Smoking Cessation | |
|---|---------------------------------|
| Perinatal Outcomes from Lumley et al., Study | Birth Outcomes |
| Low birth weight | RR = 0.94 (CI = 0.93 – 0.96) |
| Preterm birth | RR=0.86 (CI = 0.74 – 0.98) |
| Mean birth weight (grams) | 59.9g (CI = 10.44g – 95.4g) |
| Adult Outcomes from Land et al., Study | % Decline in Hospitalizations |
| Acute myocardial infarction | 46% (CI = 2% - 70%) |
| Acute coronary heart disease | 49% (CI = 6% - 72%) |

Source: California Health Benefits Review Program, 2011. (Based on Lumley et al., 2009, and Land et al., 2010.)

Note: RR = risk ratio or relative risk. A risk ratio or relative risk < 1.0 means a decreased risk of disease attributable to smoking cessation. CI = confidence interval

As presented in the *Medical Effectiveness* section, there is clear and convincing evidence that the smoking cessation treatments mandated by SB 136 are medically effective, and coverage for these treatments demonstrably improves smoking cessation rates. The preponderance of evidence shows that full coverage for smoking cessation treatment improves rates of smoking cessation. Some studies demonstrate an approximate doubling of the odds for successfully quitting among persons with full or partial (e.g., co-pays) insurance benefits for smoking cessation compared to persons without such benefits (see *Medical Effectiveness* section). Utilization of nicotine replacement therapies or bupropion treatments is greatest in those populations with access to full coverage compared to partial coverage (e.g., co-pays) and no treatment, and the greatest reductions in smoking prevalence are also found among groups with complete coverage without cost sharing (Curry, 1998).

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, CHBRP estimates SB 136 would increase enrollee coverage for smoking cessation treatments, which would result in about a 11% increase in utilization (of one or more treatments). As a result of this increased utilization, it is estimated that SB 136 would provide an additional 34,660 enrollees who attempt to quit annually, of which 2,364⁷⁹ enrollees would successfully quit.

Additionally, postmandate, a reduction in harms from secondhand smoke would be realized in both the short term and long term. For example, reductions in maternal exposure to secondhand smoke would result in decreased incidence of sudden infant death syndrome (SIDS) and low birth weight deliveries, and reductions in exposure to parental smoking would result in decreases in lower respiratory illnesses, middle ear infections, “wheeze” illnesses, and asthma in infants,

⁷⁹ Estimated premandate total number of people who quit: 100,335; postmandate total number of people who quit: 102,699. CHBRP calculated the estimated number of additional quitters due to SB 136 by subtracting the premandate total number of people who quit from the postmandate total number of people who quit: 102,699 - 100,335 = 2,364.

children and adolescents (USDHHS, 2006). In addition, a reduction in exposure to secondhand smoke as an adult would decrease the risk of developing lung cancer and coronary heart disease.

CHBRP estimates that due to clear and convincing evidence of effectiveness of smoking cessation treatments and increased enrollee coverage, SB 136 would produce a positive public health impact by increasing the number of successful quitters by 2,364 enrollees annually. This would suggest real improved health outcomes for these new quitters in the long term. Although CHBRP cannot quantify the reduction in harms from secondhand smoke due to lack of data, literature indicates that the additional quitters enabled by SB 136 would reduce harms from secondhand smoke postmandate.

Potential harms from smoking cessation treatment

While smoking cessation treatment is typically well tolerated, there is evidence to suggest that an increase in the use of smoking cessation treatment is not without risk and there is the potential for increased harm. A small proportion of individuals may experience side effects from prescription medications (hypertension, neuropsychotic symptoms, insomnia, increased seizure risk, etc.) or nicotine replacement therapy (nausea, irregular heartbeat, soft tissue irritation around site of administration, etc.) (Hays and Ebbert, 2010; FDA, 2010). Serious adverse events are rare, but may result in increased health costs to treat the events.

CHBRP estimates that, for the overall population, any cost increase or physical harms from rare serious adverse events from pharmacotherapy would be outweighed by the benefits of smoking cessation.

Impact on Gender and Racial Disparities

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 great health risks than more advantaged groups* (Braveman, 2006).

CHBRP investigated the effect that SB 136 would have on health disparities by gender, race, and ethnicity. Evaluating the impact on racial and ethnic disparities is particularly important because racial and ethnic minorities report having poorer health status and worse health indicators (KFF, 2007). One important contributor to racial and ethnic health disparities is differential rates of insurance, where minorities are more likely than whites to be uninsured; however disparities still exist within the insured population (Kirby et al, 2006; Lille-Blanton and Hoffman, 2005). Since SB 136 would only affect the insured population, a literature review was conducted to determine whether there are gender, racial, or ethnic disparities associated with the prevalence, treatment, and outcomes for smoking and cessation outside of disparities attributable to differences between insured and uninsured populations.

Impact on Gender Disparities

Gender disparities in the prevalence of smoking exist in California. As presented in Table 2 of the *Introduction*, 16.8% of insured men smoke and 10.1% of insured women smoke (CHIS, 2011). The California Tobacco Survey found that a higher percentage of men than women made a quit attempt in 2008 (63% and 56% respectively) (Al-Delaimy et al., 2010). CHBRP found no studies that reported insurance status, type of cessation method used, and quit rates by gender, which are all necessary components to calculating the public health impact of SB 136.

Due to lack of data, CHBRP cannot quantify the impact of SB 136 on reducing existing gender disparities in smoking prevalence nor on the relevant health outcomes in the insured population. Therefore, the impact of SB 136 on reducing gender disparities is unknown.

Impact on Racial/Ethnic Disparities

Racial and ethnic disparities in the prevalence of smoking exist in California. As presented in Table 2 of the *Introduction*, there is nearly a 3-fold difference in smoking prevalence between the lowest group (Asians, 10.1%) and the highest group (American Indian/Alaska Native, 29.9%) (CHIS, 2011).

There is evidence that cessation utilization and quit rates among racial and ethnic groups are disparate. For example, one study states that African American smokers are more likely to attempt to quit, but are less likely to use a cessation treatment (Piper et al., 2010). Related to these conclusions is California-specific data from the 2008 CTS that indicated that non-Hispanic Whites are less likely to make a quit attempt (54%) than African Americans (72%) and Hispanics (68%) (Al Delaimy et al., 2010). Others reported that minority smokers may be less likely to use cessation aides when available (Fu, 2008; King, 2007) and two other studies recommended that further investigation of targeted-versus generic-cessation interventions is warranted for racial and ethnic minority populations (Fiore et al., 2000; Lawrence et al., 2003). More recent research found that minority groups are less likely than Whites to be prescribed or use NRT to quit smoking (Trinidad et al., 2011). CHBRP found no studies that reported insurance status, type of cessation method used, and quit rates by race/ethnicity, which are all necessary components to calculating the public health impact of SB 136.

Due to lack of data, CHBRP cannot quantify the impact of SB 136 on reducing racial/ethnic disparities in smoking prevalence nor on the relevant health outcomes in the insured population. Therefore, the impact of SB 136 on reducing racial/ethnic disparities is unknown.

Impacts on Premature Death and Economic Loss

Premature death is often defined as death before the age of 75 (Cox, 2006). The overall impact of premature death due to a particular disease can be measured in years of potential life lost prior to age 75 and summed for the population (generally referred to as “YPLL”) (Cox, 2006; Gardner and Sanborn, 1990). In California, it is estimated that there are nearly 102,000 premature deaths each year accounting for more than two million YPLL (Cox, 2006). In order to measure the impact of premature mortality across the population impacted by a proposed mandate, CHBRP

first collects baseline mortality rates. Next, the medical effectiveness literature is examined to determine if the proposed mandated benefit impacts mortality. In cases where a reduction in mortality is projected, a literature review is conducted to determine if the YPLL has been established for the given condition. Some diseases and conditions do not result in death and therefore a mortality outcome is not relevant.

Economic loss associated with disease is generally presented in the literature as an estimation of the value of the YPLL in dollar amount (i.e., valuation of a population's lost years of work over a lifetime). For CHBRP analyses, a literature review is conducted to determine if lost productivity has been established in the literature. In addition, morbidity associated with the disease or condition of interest can also result in lost productivity; either by causing the worker to miss days of work due to their illness or due to their role as a caregiver for someone else who is ill.

Premature death

The literature provides substantial evidence regarding reduced mortality resulting from smoking cessation. 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.

Several studies found that smoking cessation is as effective as 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).

California-specific data show the societal effects of premature death and morbidity attributable to smoking. The CDC estimated that in 2004 in California, 2,012 years of potential life were lost to maternal smoking-related low birth weight infants who died (CDC, 2010b), and the average annual smoking-attributable mortality rate was 249 per 100,000, resulting in 34,492 deaths (CDC, 2010a).

Taylor and colleagues (2002) estimated the life extension achieved by smoking cessation. Cessation at 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. In contrast, cessation at 65 years old results in significantly fewer predicted life years gained (1 to 2 years for men and 2 to 3 years for women), but nevertheless 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 (Max et al., 2004).

The actual years of life gained due to smoking cessation will vary with the age at which the smoker quit and other factors; a precise accounting of 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 136 mandate. In addition, these figures are consistent with those developed

by the CDC. The CDC estimates that smokers aged 35 years and older in California annually experience 484,022 years of potential life lost due to smoking, or 13.2 years of life lost per death (CDC, 2010b). 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 the passage of SB 136 would produce 16,548 to 29,314 years of potential life gained annually⁸⁰ for California smokers who successfully quit using smoking cessation treatments.*

There is clear and convincing evidence that SB 136 would contribute to the reduction in premature death from smoking-related conditions such as cancer, low birth weight infants who died, and cardiovascular and respiratory diseases, however the precise magnitude of this reduction could not be estimated by CHBRP.

In California, it is estimated that secondhand smoke is responsible for 21 cases of SIDS, 1,600 cases of low birth weight infants, 4,700 pre-term deliveries, 31,000 episodes of asthma in children, 400 cases of lung cancer, and 3,600 cardiac deaths each year in the state (EPA, 2006). To the extent that smokers quit, a corresponding improvement in health outcomes for nonsmokers exposed to secondhand smoke would likely result.

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 of quality of life, years of life gained, loss of productivity) by full insurance coverage of smoking cessation treatments is beyond the scope of this report. However, according to the California Department of Public Health, \$8.5 billion (47%) of smoking-related health care costs in California were due to lost productivity from smoking-attributed early death or illness (not including burn or secondhand smoke deaths) (CDPH, 2010a). Furthermore, there is evidence that other 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).

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 and Child Health reports California's 2003 smoking-attributable neonatal expenditures at \$11.8 million (CDC, 2010b) and a study by Adams and colleagues showed that maternal smoking increases the risk of neonatal intensive care unit admissions by 20% (Adams et al., 2002).

Other studies report that the cost for treating high blood pressure, associated with heart disease, 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). Placing smoking cessation into a preventative 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

⁸⁰ Total additional quitters (2,364) * 7 years = 16,548 years. Total additional quitters (2,364) * 12.4 years = 29,314 years.

(Warner et al., 2004). Should some smokers quit, a corresponding increase in productivity would likely result.

CHBRP estimates that SB 136 would increase utilization of smoking cessation treatments and increase quit rates postmandate. This increase would contribute to a reduction in economic loss due to reductions in lost productivity from smoking-related illness and premature death, but the magnitude cannot be estimated. Additionally, CHBRP estimates that enrollee expenses for previously noncovered smoking cessation treatments would be reduced by about \$16.5 million. However, this savings would be partially offset by a \$9.7 million increase in cost-sharing for the newly covered benefits.

On an annual basis, secondhand smoke costs the United States nearly \$5 billion in medical costs associated with diseases related to tobacco exposure (lung cancer, asthma, coronary artery disease, etc.), as well as an additional \$4.6 billion in lost wages (Behan et al., 2005). One study found that exposure to parental smoking is associated with 5.4 million excess cases of disease (including low birth weight, ear infections, asthma and burns) resulting in a total cost of \$4.6 billion per year for direct medical expenditures. Loss of life costs associated with exposure to parental smoking is estimated to result in cost in excess of \$8 billion (Aligne et al., 1997).

Long-Term Public Health Impacts

CHBRP's modeling focuses on cost and utilization estimates for the immediate 12 months postmandate. However, many health outcomes resulting from various interventions are not immediately apparent; and smoking cessation is a classic public health example that results in a diverse set of long-term benefits. Estimating the long-term impact of SB 136 is challenging, precisely because smoking (and treatment cessation) have far reaching effects on direct and indirect costs and the large number of health outcomes 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 and improved health outcomes 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 infants can also save costs, as those children tend to use more medical care later in life.

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.

Depending on the parameters used, the costs of achieving and maintaining lifetime smoking cessation can be 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. Many of these studies also include general medical costs accrued from increased life expectancy, which can reduce the perceived cost effectiveness of smoking cessation. To address the latter issue, Solberg et al. (2006) modeled the cost-effectiveness of multiple cessation counseling sessions over multiple years and included cost savings from smoking-attributable illnesses, but not medical costs unrelated to smoking. Using these variables, they estimated 2.47 million QALYs were saved at a cost savings of \$500 per smoker receiving the intervention. If no financial savings from tobacco-attributable illnesses are factored, the cessation treatment is still found to be cost-effective at \$1,100/QALY saved. If financial savings from averted smoking related illnesses are included, the authors reported a cost savings of \$65/smoker (Solberg et al., 2006).

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. Additionally, Bolin et al. (2009) performed a cost-utility analysis of an additional 12-week treatment course of varenicline for those who had already received one treatment as compared with those receiving only one 12-week course of treatment. The authors concluded that the incremental cost per quality-adjusted life-year gained (QALY) for the additional treatment (including indirect costs of productivity and increased consumption related to survival) was about Euro 25,000 (or about U.S. \$35,550 at March 2011 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.

Other long-term impacts of SB 136 relate to whether increases in premiums postmandate would increase the uninsured population by pricing people out of the market. As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, SB 136 is expected to increase premiums by less than 1%, therefore, it is unlikely that SB 136 would result in an increase in the uninsured or contribute to the long-term health impacts of being uninsured.

CHBRP finds clear and convincing evidence that smoking cessation is a cost-effective preventive treatment that results in improvements in multiple long-term health outcomes and reduces both direct medical costs and indirect costs associated with smoking.

Conclusion

SB 136 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 136, (3) the favorable impact of smoking cessation on both short- and long-term health outcomes, and (4) the cost effectiveness of smoking cessation. 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 16,548 to 29,314 life years gained annually under the new mandate. The expected reduction in smoking prevalence and mortality attributable to SB 136 would bring California closer to achieving *Healthy People 2020* goals (USDHHS, 2010).

APPENDICES

Appendix A: Text of Bill Analyzed

On February 4, 2011 the Senate Committee on Health requested that CHBRP analyze SB 136.

Below is the bill language, as it was introduced on January 31, 2011.

SENATE BILL No. 136

Introduced by Senator Yee

January 31, 2011

An act to add Section 1367.667 to the Health and Safety Code, and to add Section 10123.25 to the Insurance Code, relating to health care coverage.

Legislative Counsel's Digest

SB 136, as introduced, Yee. Health care coverage: tobacco cessation. 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. Existing law requests the University of California to establish the California Health Benefit Review Program to assess legislation proposing to mandate a benefit or service and legislation proposing to repeal a mandated benefit or service, as specified.

This bill would require certain health care service plan contracts and health insurance policies issued, amended, renewed, or delivered on or after January 1, 2012, to provide coverage for tobacco cessation treatment that includes specified courses of treatment and medication. The bill would request the University of California, as part of the California Health Benefit Review Program, to prepare a report regarding any state savings as a result of this coverage requirement. The bill would make the coverage requirement inoperative upon a determination that it will result in the state assuming additional costs, as specified. 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 hereby finds and declares the following:

(a) 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.

(b) Cigarette smoking and other uses of tobacco remain the leading cause of preventable death in California, as well as the cause of many other serious health problems, including heart disease, emphysema, and other chronic illnesses.

(c) The treatment of tobacco-related diseases continues to impose a significant burden on California's health care system, including local and state-funded health care systems. Tobacco use costs Californians billions of dollars a year in medical expenses and lost productivity.

(d) Providing tobacco cessation counseling and medication is one of the most clinically effective and cost-effective health services available, second only to inoculations.

(e) Reducing the smoking rate in California by one percentage point will result in approximately \$91 million saved over five years from fewer smoking-caused heart attacks and strokes.

(f) The United States Public Health Service Clinical Practice Guideline entitled Treating Tobacco Use and Dependence has identified the medications and counseling that are scientifically proven to be effective in helping smokers quit.

SEC. 2. Section 1367.667 is added to the Health and Safety Code, to read:

1367.667. (a) (1) A health care service plan contract issued, amended, renewed, or delivered on or after January 1, 2012, shall cover a minimum of two courses of treatment in a 12-month period for all smoking cessation treatments rated "A" or "B" by the United States Preventive Services Task Force, which shall include counseling and over-the-counter medication and prescription pharmacotherapy approved by the federal Food and Drug Administration.

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

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

- (A) As applied to counseling, at least four sessions of counseling, which may be telephone, group, or individual counseling with each session lasting at least 10 minutes.
- (B) As applied to a prescription or over-the-counter medication, the duration of treatment approved by the federal Food and Drug Administration for that medication.
- (4) Enrollees shall not be required to enter counseling in order to receive tobacco cessation medications after the patient's first course of treatment.
- (5) A health care service plan may not impose prior authorization or stepped-care requirements on tobacco cessation treatments after the patient's first course of treatment.
- (b) This section shall not apply to Medicare supplement plan contracts or to specialized health care service plan contracts.
- (c) The Legislature hereby requests that the University of California, as part of the California Health Benefit Review Program established under Section 127660, prepare a report by December 31, 2014, evaluating the requirements of this section and determining any state savings as a result of those requirements. The Legislature requests that this report be made available to the Legislature, the Department of Insurance, and the Department of Managed Health Care.
- (d) This section shall become inoperative on the date that the state determines that, taking into account any state savings identified under subdivision (c), the requirements of this section will result in the state assuming additional costs pursuant to subparagraph (B) of paragraph (3) of subsection (d) of Section 1311 of the federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by subsection (e) of Section 10104 of Title X of that act.

SEC. 3. Section 10123.25 is added to the Insurance Code, to read:

10123.25. (a) (1) A health insurance policy issued, amended, renewed, or delivered on or after January 1, 2012, shall cover a minimum of two courses of treatment in a 12-month period for all smoking cessation treatments rated "A" or "B" by the United States Preventive Services Task Force, which shall include counseling and over-the-counter medication and prescription pharmacotherapy approved by the federal Food and Drug Administration.

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

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

(A) As applied to counseling, at least four sessions of

counseling, which may be telephone, group, or individual counseling with each session lasting at least 10 minutes.

(B) As applied to a prescription or over-the-counter medication, the duration of treatment approved by the federal Food and Drug Administration for that medication.

(4) Insureds shall not be required to enter counseling in order to receive tobacco cessation medications after the patient's first course of treatment.

(5) A health insurer shall not impose prior authorization or stepped-care requirements on tobacco cessation treatments after the patient's first course of treatment.

(b) This section shall not apply to Medicare supplement policies or to specialized health insurance policies.

(c) The Legislature hereby requests that the University of California, as part of the California Health Benefit Review Program established under Section 127660 of the Health and Safety Code, prepare a report by December 31, 2014, evaluating the requirements of this section and determining any state savings as a result of those requirements. The Legislature requests that this report be made available to the Legislature, the Department of Insurance, and the Department of Managed Health Care.

(d) This section shall become inoperative on the date that the state determines that, taking into account any state savings identified under subdivision (c), the requirements of this section will result in the state assuming additional costs pursuant to subparagraph (B) of paragraph (3) of subsection (d) of Section 1311 of the federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by subsection (e) of Section 10104 of Title X of that act.

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 136. This literature review updates the reviews CHBRP conducted for SB 576 in 2005, SB 24 in 2007, and SB 220 in 2010.

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.

Studies of the effects of smoking cessation treatments were identified through searches of the Cochrane Library and web site maintained by the USPSTF and the FDA. CHBRP limited the search for literature on the effects of smoking cessation treatments because it is 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, SB 24 in 2007, and SB 220 in 2010 that reached much the same conclusion as the present analysis.

Studies of the effects of coverage for these treatments were identified through search of PubMed, the Cochrane Library, the Cumulative Index of Nursing and Allied Health Literature, and EconLit. 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 Employee Benefits Research Institute, and the National Compensation Survey.

The search was limited to studies published in English from 2010 to present, because CHBRP had previously conducted thorough literature searches on these topics in 2005, 2007, and 2010 for SB 576, SB 24, and SB 220 respectively.

For the literature review for SB 136, over 300 abstracts were reviewed. The title and abstract of each citation returned by the literature search were reviewed 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 136, including 10 studies from the SB 576 review, 11 studies from the SB 24 review, 12 studies from the SB 220

review, and 1 new study published since the literature review for SB 220 was completed in 2010.⁸¹

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 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.

⁸¹ In some cases, more current versions of meta-analyses and systematic reviews included in the SB 576, SB 24, and SB 220 reports were included in the literature review for the SB 136 report. For example, Cahill et al. (2011) is an update of a Cochrane review that these authors previously published in 2008. 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.

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

- *Health Education
- *Health Promotion/og [Organization & Administration]
- *Health Status Disparities
- *Intention to Treat Analysis/mt [Methods]
- *Internet
- *Medication Adherence
- *Smoking Cessation
- *Smoking Cessation/mt [Methods]
- *Smoking/ae [Adverse Effects]
- *Smoking/ep [Epidemiology]
- *Smoking/px [Psychology]
- *Tobacco Use Cessation/mt [Methods]
- *Tobacco Use Disorder/dt [Drug Therapy]
- Antidepressive Agents, Second-Generation/
Antidepressive Agents
- Attitude to Health
- Behavior Therapy/
Behavior, Addictive
- Bupropion
- California/epidemiology
- Choice Behavior
- Chronic Disease/ epidemiology
- Cost control
- Cost effectiveness
- Cost of Illness

Cost Savings
Cost-Benefit Analysis
Counseling/
Directive Counseling
Dopamine Uptake Inhibitors/
Guideline Adherence
Health Care Costs
Health Education
Health Knowledge, Attitudes, Practice
Health Promotion
Health Status
Health Status Disparities
Health Status Indicators
Health Surveys
Healthcare Disparities
Hotlines
Incidence
Insurance Coverage
Life expectancy
Medication Adherence
Morbidity/trends
Mortality
Mortality -- United States
Neoplasms/ etiology/prevention & control
Neoplasms/ psychology
Neoplasms/chemically induced
Nicotine
Nicotinic agonists
Outcome and Process Assessment (Health Care)
Outcome Assessment (Health Care)
Patient Acceptance of Health Care
Patient Compliance
Patient Discharge/
Patient Dropouts/
Patient Education as Topic
Patients/
Physician-Patient Relations
Physician's Practice Patterns/ statistics & numerical data
Population Surveillance
Prevalence
Preventive Health Services
Primary Health Care
Program Development
Program Evaluation
Public Health
Public Health Practice

Public Policy
Quinolizines
Smoking
Smoking Cessation
Substance Abuse
Substance Withdrawal Syndrome
Tobacco Use Cessation
Tobacco Use Disorder
Tobacco, Smokeless
Treatment Failure
Treatment Outcome
Treatment Refusal
United States

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

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-1a through C-1c 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-1a lists studies that assessed the effects of smoking cessation counseling. Table C-1b lists studies of the effectiveness of over-the-counter and prescription medications for smoking cessation. Table C-1c 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, SB 24, and SB 220 regarding coverage for smoking cessation treatments that were introduced in 2005, 2007, and 2010, respectively, as well as one additional study that has been published since 2010. In some cases, more recent versions of studies cited in the SB 576, SB 24, and SB 220 reports are listed.⁸²

Table C-1a. 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 ⁸³ |
| 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 |

⁸² In some cases, more current versions of meta-analyses and systematic reviews included in the SB 576, SB 24, and SB 220 reports were included in the literature review for the SB 136 report. For example, Cahill et al. (2011) is an update of a Cochrane review that these authors previously published in 2008. 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.

⁸³ Location is not reported for meta-analyses because they synthesize results from multiple studies conducted in multiple locations.

Table C-1a. 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-1b. 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., 2011 | Meta-analysis | Varenicline vs. placebo Varenicline vs. bupropion | Smokers after 6-month follow-up | N/A |
| Eisenberg et al., 2008 | Meta-analysis | Bupropion SR vs. placebo Nicotine replacement therapy ⁸⁴ (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 ⁸⁵ 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 ⁸⁶ 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 |

⁸⁴ 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).

⁸⁵ 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.

⁸⁶ 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-1c. 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 ⁸⁷ 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 |

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

⁸⁷ 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-1c. 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, ⁸⁸ and behavioral counseling vs. no offer of coverage | Smokers insured by De Friesland Zorgverzekeraar company | The Netherlands |
| Kaper et al., 2006 ⁸⁹ | 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 |

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

⁸⁸ 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.

⁸⁹ 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-1c. 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 www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

The cost analysis in this report was prepared by the members of cost team, which consists of CHBRP task force members and contributors from the University of California, San Diego, and the University of California, Los Angeles, as well as the contracted actuarial firm, Milliman, Inc. (Milliman). Milliman 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 (2009) California Health Interview Survey (CHIS), which is used to estimate health insurance for California's population and distribution by payor (i.e., employment-based, individually purchased, or publicly financed). The biennial CHIS is the largest state health survey conducted in the United States, collecting information from approximately 50,000 households. More information on CHIS is available at <http://www.chis.ucla.edu>.
2. The latest (2010) 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/publications/2010/12/california-employer-health-benefits-survey>.

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 <http://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 (2010 Group Health Insurance Survey) contains data from seven major California health plans regarding their 2010 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 an estimated 93.7% of the persons with health insurance subject to state mandates. This figure represents an estimated 94.4% of enrollees in full service (non-specialty) DMHC-regulated health plans and an estimated 90.1% of enrollees in full service (non-specialty) CDI-regulated policies.⁹⁰

⁹⁰ CHBRP analysis of the share of enrollees included in CHBRP’s Bill-Specific Coverage Survey of the major carriers in the state is based on “CDI Licenses with HMSR Covered Lives Greater than 100,000” as part of the Accident and Health Covered Lives Data Call, December 31, 2009, by the California Department of Insurance, Statistical Analysis Division, data retrieved from the Department of Managed Health Care’s interactive Web site “Health Plan Financial Summary Report,” July-September 2010, and CHBRP’s Annual Enrollment and Premium Survey.

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 <http://www.calpers.ca.gov>.
6. Enrollment in Medi-Cal Managed Care (which are 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/RASS_General_Medi_Cal_Enrollment.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 (MRMIB)—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-MRMIB 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 MRMIB are included with enrollment for Medi-Cal in presentation of premium impacts. Enrollment information is obtained online at <http://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: 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: 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, postmandate, because they perceive that it is to their economic benefit to do so.
- Medical management: Health plans and insurers may react to the mandate by tightening medical management of the mandated benefit. This would tend to dampen the CHBRP cost estimates. The dampening would be more pronounced on the plan types that previously had the least effective medical management (i.e., PPO plans).
- 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 postmandate 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 postmandate coverage rates for populations subject to the mandate are assumed to be 100%.

Potential Effects of the Federal Affordable Care Act

As discussed in the *Introduction*, there are a number of the ACA provisions that have already gone into or will go into effect over the next three years. Some of these provisions affect the baseline or current enrollment, expenditures, and premiums. This subsection discusses adjustments made to the 2011 Cost and Coverage Model to account for the potential impacts of the ACA that have gone into effect by January 2011. It is important to emphasize that CHBRP's analysis of specific mandate bills typically address the marginal effects of the mandate bill—specifically, how the proposed mandate would impact benefit coverage, utilization, costs, and public health, holding all other factors constant. CHBRP's estimates of these marginal effects are presented in the *Benefit Coverage, Utilization, and Cost Impacts* section of this report.

CHBRP reviewed the ACA provisions and determined whether and how these provisions might affect:

1. The number of covered lives in California, and specifically the makeup of the population with health insurance subject to state mandates
2. Baseline premiums and expenditures for health insurance subject to state mandates, and
3. Benefits required to be covered in various health insurance plans subject to state mandates

There are still a number of provisions that have gone into effect for which data are not yet available. Where data allows, CHBRP has made adjustments to the 2011 Cost and Coverage model to reflect changes in enrollment and/or baseline premiums and these are discussed here.

Coverage for adult children

PPACA Section 2714, modified by HR 4872, Section 2301, requires coverage for adult children up to age 26 as dependants to primary subscribers on all individual and group policies, effective September 23, 2010. California's recently enacted law, SB 1088 (2010) implements this provision. This could potentially affect both premiums and enrollment in 2011. According to the California Health Interview Survey (CHIS) approximately 22% of Californians aged 19-25 (1,063,000) were estimated to be uninsured at some point in 2009. As a result of the ACA, many of these young adults will likely gain access to health insurance through a parent. This dynamic may diminish the number of uninsured and may also shift some young adults from the individually purchased health insurance market into the group market. The Departments of Treasury, Labor, and Health and Human Services estimate, for 2011, the number of young adults newly covered by his/her parent's plan would be about 0.78 to 2.12 million (using high and low take-up rate assumptions respectively). Of these young adults, about 0.2 to 1.64 million would have previously been uninsured. The corresponding incremental cost impact to group insurance policies is estimated to be a premium increase of 0.5% to 1.2%. Based on the responses to the Annual Enrollment and Premium survey, there has been an increase of 1% to 1.5% in enrollment for the 19-25 year olds and the increase varies depending on whether the parents were enrolled in the large group, small group, or individual markets. Based on analysis of the estimates from the Departments of Treasury, Labor and Health and Human Services as well as CHIS 2009 data, approximately 25% of the increase in enrollment represents a shift from the individual market and approximately 75% were previously uninsured. CHBRP took these estimates into account and adjusted underlying population data since source data did not reflect the effects of this provision, because shift in populations were expected to be significant, and to account for potential lags in enrollment (e.g., due to awareness).

Minimum Medical Loss Ratio requirement

PPACA Section 2718 requires health plans offering health insurance in group and individual markets to report to the Secretary of Health and Human Services the amount of premium revenue spent on clinical services, activities to improve quality, and other non-claim costs. Beginning in 2011, large group plans that spend less than 85% of premium revenue and small group/individual market plans that spend less than 80% of premium revenue on clinical services and quality must provide rebates to enrollees. According to the Interim Final Rule (45 CFR Part 158), "Issuers will provide rebates to enrollees when their spending for the benefit of policyholders on reimbursement for clinical services and quality improvement activities, in relation to the premiums charged, is less than the MLR standards established pursuant to the statute."⁹¹ The requirement to report medical loss ratio is effective for the 2010 plan year, while the requirement to provide rebates is effective January 1, 2011. The MLR requirement, along with the rebate payment requirement, will affect premiums for 2011, but the effects are unknown and data are

⁹¹ Department of Health and Human Services, *Interim Final Rule: Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act*. 45 CFR Part 158. December 1, 2010.

not yet available. There is potential for substantial impact on markets with higher administrative costs, including the small and individual group markets. Responses to CHBRP's Annual Enrollment and Premiums Survey indicate that carriers intend to be in compliance with these requirements. For those that may not be in compliance, the requirement to pay rebates is intended to align the MLR retrospectively. Therefore for modeling purposes, CHBRP has adjusted administrative and profit loads to reflect MLRs that would be in compliance with this provision.

Pre-Existing Condition Insurance Plan (PCIP)

PPACA Section 1101 establishes a temporary high-risk pool for individuals with pre-existing medical conditions, effective 90 days following enactment until January 1, 2014. In 2010, California enacted AB 1887 and SB 227, providing for the establishment of the California Pre-Existing Condition Insurance Plan (PCIP) to be administered by the Managed Risk Medical Insurance Board (MRMIB) and federally funded per Section 1101. MRMIB has projected average enrollment of 23,100 until the end of 2013, when the program will expire. As of December 2010, there were approximately 1,100 subscribers.⁹² The California PCIP is not subject to state benefit mandates,⁹³ and therefore this change does not directly affect CHBRP's Cost and Coverage Model. CHBRP has revised its annual update of *Estimates of the Sources of Health Insurance in California*.⁹⁴ to reflect that a slight increase in the number of those who are insured under other public programs that are not subject to state level mandates.

Prohibition of pre-existing condition exclusion for children

PPACA Sections 1201& 10103(e): Prohibits pre-existing condition exclusions for children. This provision was effective upon enactment). California's recently enacted law, AB 2244 (2010) implements this provision. AB 2244 also prohibits carriers that sell individual plans or policies from refusing to sell or renew policies to children with pre-existing conditions. Carriers that do not offer new plans for children are prohibited from offering for sale new individual plans in California for five years.⁹⁵ This provision could have had significant premium effects, especially for the DMHC- and CDI-regulated individual markets. The premium information is included in the responses to CHBRP's Annual Enrollment and Premium Survey. Thus the underlying data used in CHBRP annual model updates captured the effects of this provision.

Prohibition of lifetime limits and annual benefit limit changes

PPACA Section 2711 prohibits individual and group health plans from placing lifetime limits on the dollar value of coverage, effective September 23, 2010. Plans may only impose annual limits on coverage and these annual limits may be no less than \$750,000 for "essential health benefits." The minimum annual limit will increase to \$1.25 million on Sept. 23, 2011, and to \$2 million Sept. 23, 2012. Earlier in 2010, CHBRP conducted an analysis of SB 890 which sought to prohibit lifetime and annual limits for "basic health care services" covered by CDI-regulated

⁹² Enrollment report presented at the Managed Risk Medical Insurance Board Meeting, January 19, 2010. Available at: http://www.mrmib.ca.gov/MRMIB/Agenda_Minutes_011911/Agenda_Item_9.a_PCIP_Board_Report_for_Dec_2010_FINAL.pdf

⁹³ Correspondence with John Symkowitz, Legislative Coordinator, MRMIB, October 19, 2010.

⁹⁴ See: http://www.chbrp.org/other_publications/index.php.

⁹⁵ See enacted language at: http://www.leginfo.ca.gov/pub/09-10/bill/asm/ab_2201-2250/ab_2244_bill_20100930_chaptered.pdf

policies. CHBRP's indicated that DMHC-regulated plans were generally prohibited from having annual or lifetime limits. The analysis also indicated that less than 1% of CDI-regulated policies in the state had annual benefit limits and of those, the average annual benefit limit was approximately \$70,000 for the group market and \$100,000 for the individual market. Almost all CDI-regulated policies had lifetime limits in place and the average lifetime limits was \$5 million. After the effective date of the PPACA Section 2711, removal of these limits may have had an effect on premiums. As mentioned, premium information is included in the responses to CHBRP's Annual Enrollment and Premium Survey. Thus the underlying data used in CHBRP annual model updates captured the effects of this provision to remove lifetime limits and to increase annual limits for those limited number of policies that had annual limits that fell below \$750,000.

Medi-Cal Managed Care Enrollment: Seniors and Persons with Disabilities

While the PPACA allows states the option to expand coverage to those not currently eligible for Medicaid (Medi-Cal in California), large scale expansions are not expected to be seen during 2011. However, as a result of the 2010-2011 California Budget Agreement, there are expected to be shifts in coverage for seniors and persons with disabilities. Specifically, "Seniors and persons with disabilities who reside in certain counties which have managed care plans, and who are not also eligible to enroll in Medicare, will be required to enroll in a managed care plan under a phased-in process."⁹⁶ The Medi-Cal Managed Care enrollment in CHBRP's 2011 Cost and Coverage Model has been adjusted to reflect this change. Baseline premium rates have also been adjusted to reflect an increase in the number of seniors and persons with disabilities in Medi-Cal Managed Care. Information from DHCS indicates these changes will go into effect July 1, 2011, and would affect approximately 427,000 Medi-Cal beneficiaries.⁹⁷ CHBRP used data from DHCS to adjust enrollment in Medi-Cal Managed Care, and to adjust premiums to account for the change in acuity in the underlying populations.⁹⁸

Bill Analysis-Specific Caveats and Assumptions

Calculations related to utilization rates

CHBRP used the 2008 and 2005 California Tobacco Survey data and the RAND Health Insurance Experiment's (HIE) estimated impact of cost sharing for well care to estimate premandate and postmandate utilization among smokers who make an attempt to quit. An illustration of CHBRP's calculations to develop premandate and postmandate utilization by coverage status for counseling is as follows:

⁹⁶ Taylor, M. Legislative Analyst, *The Budget Package 2010-11 California Spending Plan*. LAO: November, 2010. Available at:

http://www.lao.ca.gov/reports/2010/bud/spend_plan/spend_plan_110510.pdf

⁹⁷ Data from the Department of Health Care Services, Medi-Cal Managed Care Division. Received January 14, 2011.

⁹⁸ See the study conducted for DHCS by Mercer on this topic: Mercer, *Medi-Cal Acuity Study: Seniors and Persons with Disabilities*. September 28, 2010. Available at

http://www.dhcs.ca.gov/provgovpart/Documents/Waiver%20Renewal/SPD_Study_092810.pdf

Premandate (baseline)

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

$$7.2\% = 12.0\% \times 60.2\%$$

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)

$$79.9\% = (45\% \text{ relative utilization under no coverage}) \times (10.7\% \text{ enrollees with no coverage}) \\ + (80\% \text{ relative utilization under partial coverage}) \times (88.9\% \text{ with partial coverage}) \\ + (100\% \text{ relative utilization under full coverage}) \times (0.4\% \text{ with full coverage}).$$

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)

$$9.0\% = 7.2\% / 79.9\% \times 100\%$$

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)

$$7.2\% = 7.2\% / 79.9\% \times 80\%$$

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)

$$4.1\% = 7.2\% / 79.9\% \times 45\%$$

Postmandate

Postmandate, those enrollees who currently have no coverage are assumed to have mandate compliant partial coverage for smoking cessation treatments. The utilization rate for partial coverage (as derived above) is then applied to the total postmandate population with partial coverage, to estimate the total utilization of smoking cessation treatments among those with partial coverage. The utilization among those with partial coverage is then added to the utilization of those who maintained full coverage (assumed to be 100%, as per the RAND HIE estimates), to estimate the final postmandate utilization of smoking cessation treatments among those with any kind of mandate compliant coverage.

Appendix E: 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.

No information was submitted by interested parties for this analysis.

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

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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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