



CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Analysis of Assembly Bill 2064: Immunizations for Children

A Report to the 2011-2012 California Legislature
April 23, 2012



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 Assembly Bill 2064 Immunizations for Children

April 23, 2012

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PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill 2064. In response to a request from the California Assembly Committee on Health on February 28, 2012, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the program's authorizing statute.

Theodore Ganiats, MD, and Sara McMenamain, PhD, of the University of California, San Diego, prepared the medical effectiveness analysis. Stephen L. Clancy, MLS, AHIP, of the University of California, Irvine, conducted the literature search. Diana Cassidy, DrPH, and Dominique Ritley, MPH, of the University of California, Davis, prepared the public health impact analysis. Shana Lavarreda, PhD, MPP, prepared the cost impact analysis. Susan Pantely, FSA, MAAA, of Milliman, provided actuarial analysis. Byung-Kwang Yoo, MD, MSc, PhD, of the University of California, Davis, provided technical assistance with the literature review and expert input on the analytic approach. John Lewis, MPA, of CHBRP staff prepared the introduction and synthesized the individual sections into a single report. A subcommittee of CHBRP's National Advisory Council (see final pages of this report) and a member of the CHBRP Faculty Task Force, Sylvia Guendelman, PhD, LCSW, of the University of California, Berkeley, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

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

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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Assembly Bill 2064

The California Assembly Committee on Health requested on February 28, 2012, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 2064 (Perez), Immunizations for Children, a bill that would impose a health benefit mandate. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.¹

Only one of the several requirements in AB 2064—the requirement to be placed as Health and Safety Code Section 1367.36(g) and as Insurance Code Section 10123.56 (b)—is a health insurance benefit mandate. Therefore, this report analyzes *only the impact of the benefit mandate*.

Approximately 21.882 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 that provide coverage for childhood and adolescent immunizations would be subject to AB 2064. Coverage for “immunizations” includes coverage for both the vaccine itself (which is a prescription drug) and coverage for related procedures (including administration of the vaccine during a provider visit). CHBRP estimates that nearly all enrollees with health insurance subject to state-level benefit mandates have coverage for immunizations, so the mandate would affect the health insurance of approximately 21.873 of the 21.882 million Californians.

For DMHC-regulated plans and CDI-regulated policies that provide coverage for childhood and adolescent immunizations, the benefit mandate in AB 2064 would prohibit cost sharing (defined as including deductibles, copayments, and coinsurance, and “other cost-sharing mechanisms”)

¹ 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 DMHC was established in 2000 to enforce the Knox-Keene Health Care Service Plan of 1975; see Health and Safety Code Section 1340.

⁴ 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.

for administration of a childhood or adolescent immunization or for procedures related to administration. The mandate would also prohibit dollar-limit provisions for childhood or adolescent immunization-related procedures. Dollar-limit provisions establish a limit (either an annual or a lifetime limit) beyond which benefit coverage is no longer provided.

AB 2064 references existing mandates⁵ that require coverage for immunizations listed in the most current version of the “Recommended Childhood Immunization Schedule/United States, jointly adopted by the American Academy of Pediatrics, the Advisory Committee on Immunization Practices, and the American Academy of Family Physicians.” Therefore, CHBRP has assumed for this analysis that AB 2064 would prohibit cost sharing for immunization-related procedures for all of the childhood and adolescent immunizations listed in the most currently recommended Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) immunization schedule, hereafter referred to as “ACIP recommendations.”

Background on Immunization and Vaccine-Preventable Diseases

Evidence indicates that childhood and adolescent immunization are cost-effective (and, in many cases, cost-saving) medical procedures that prevent, reduce, or eliminate the incidence of numerous vaccine-preventable diseases and their associated morbidity, mortality, and health care costs. When a disease is transmitted from person to person or when humans are the reservoir for a disease, immunizations *directly* protect those who are immunized and *indirectly* protect unimmunized persons by reducing their risk of exposure to the disease. This indirect protection, or “herd immunity,” is relevant to most of the immunizations discussed in this report, including immunizations to prevent measles, pertussis, influenza, hepatitis A and B, polio, rubella, mumps, and diphtheria.

California implemented several school-based laws to promote immunization against 10 diseases: diphtheria, hepatitis b, *haemophilus influenzae* type b, measles, mumps, rubella, pertussis, polio, tetanus, and varicella⁶. These laws require a complete dose of these immunizations in children (aged 0-18 years) prior to admission into schools (public and private) or licensed childcare facilities (although exemptions for medical reasons or personal beliefs are permitted). These laws also require schools and licensed childcare facilities to collect and report immunization rates of their enrollees to the California Department of Public Health (CDPH).

Currently, about 71% of children in California, by age 35 months, receive the vaccine series 4:3:1:3:1:4⁷, with rates for immunizations against particular diseases ranging between 53% and 91% for children and adolescents. California appears to be meeting national targets for about half of the national ACIP-recommended immunizations (by age 35 months). The rates for the immunizations required for California daycare or school entrance are consistently close to the national targets with the exception of the pertussis (whooping cough) immunization.

⁵ Health and Safety Code Sections 1367.35, 1367.002 and Insurance Code Sections 10123.5, 10112.2

⁶ California Code of Regulations Title 17, Div. 1, Chap. 4, Subchap. 8 Sections 6000-6075 and Health and Safety Code: Div. 105, Part 2, Chap. 1, Sections 120325-120380

⁷ 4:3:1:3:1:4= the abbreviation for a grouping of individual vaccines per the CDC’s National Immunization Survey: ≥4DTaP; ≥3 polio; ≥1 MMR; ≥3 Hep B; ≥1 varicella (chickenpox); ≥4 PCV vaccines.

Other Requirements

CHBRP is aware of several requirements that could overlap or interact with AB 2064.

California State Benefit Mandates:

- Comprehensive preventive care for children aged 16 years or younger⁸
- Comprehensive preventive care for children aged 17 or 18 years⁹
- Preventive services coverage without cost sharing¹⁰

The first state mandate requires coverage for immunization. The second requires that benefit coverage be offered. The third state mandate requires compliance with an existing federal mandate. The federal mandate is discussed below, under the heading “Effects of the Affordable Care Act.”

DMHC-regulated plans are also required to cover “basic health care services,” including a range of preventive care services. Regulations further specify that health plans are to cover preventive services, including recommended immunizations for children.¹¹ Laws and regulations related to CDI-regulated policies do not have a similar set of broad “basic health care services” requirements.

Although CHBRP is aware of well-child care coverage mandates in 35 states (BCBSA, 2011), CHBRP is unaware of benefit mandates in other states that prohibit cost sharing for immunization-related procedures.

Medical Effectiveness

It is not feasible for CHBRP to review the large volume of literature on the medical effectiveness of the administration and efficacy of each of the ACIP-recommended vaccines and their immunization-related procedures within the 60-day time frame allotted for this analysis. Therefore, the medical effectiveness review utilized the information compiled by ACIP on immunization-related procedures and vaccine efficacy.

- ACIP has 38 current vaccine-specific recommendations, plus one report summarizing general recommendations on immunization. Of the 39 current recommendations, 14 were excluded because they were not relevant (i.e., not for pediatric population, not a routine immunization, etc.). The 25 remaining recommendations were retrieved and reviewed.

⁸ Health and Safety Code Section 1367.35 and Insurance Code Section 10123.5

⁹ Health and Safety Code Section 1367.3 and Insurance Code Section 10123.55

¹⁰ Health and Safety Code Section 1367.002 and Insurance Code Section 10112.2

¹¹ Personal communication, C. Hamilton, DMHC, April 2012.

- To ensure proper and safe administration of vaccines, ACIP issues recommendations regarding immunization-related procedures such as infection control, sterile immunization techniques, and the proper administration, storage, and handling of vaccines. Deviation from the recommended administration could lead to a reduction in the effectiveness of the vaccine or an increase in adverse reactions.

There are 12 vaccines recommended by ACIP for routine use in children and adolescents (aged 0-18 years):

- Diphtheria, tetanus, acellular pertussis (DTaP/Tdap);
 - *Haemophilus influenzae* type b (Hib);
 - Hepatitis A (HepA);
 - Hepatitis B (HepB);
 - Human papillomavirus (HPV);
 - Influenza;
 - Measles, mumps, rubella (MMR);
 - Meningococcal conjugate;
 - Pneumococcal conjugate (PCV);
 - Inactivated poliovirus (IPV);
 - Rotavirus; and
 - Varicella.
- Due to the rigor and thoroughness of the ACIP systematic review on the efficacy and safety of vaccines, for the purposes of this report, CHBRP concludes that any vaccine that has been recommended as part of the routine immunization schedule has *clear and convincing evidence* that it is effective in preventing disease.

Benefit Coverage, Utilization, and Cost Impacts

AB 2064 has many requirements including but not limited to a health insurance benefit mandate. This report analyzes only the health benefit mandate contained in AB 2064, and makes no comment on the potential impacts of other requirements.

Table 1 and the following bullets summarize the expected benefit coverage, cost, and utilization impacts *only for the health benefit mandate* included in AB 2064.

Benefit Coverage Impacts

- Of the population with health insurance subject to the mandate, nearly all (98.3%) enrollees have mandate-compliant benefit coverage for immunization-related procedures with no cost sharing. The remaining 1.7% of enrollees (381,000) has benefit coverage not compliant with

the mandate (Table 1). If AB 2064 were enacted, 100% of enrollees would have compliant benefit coverage for immunization-related procedures.

- DMHC-regulated Medi-Cal managed care plans already provide mandate-compliant coverage for immunization-related procedures with no cost sharing for enrollees. Therefore, CHBRP estimates that AB 2064 would have no impact on this subpopulation.
- DMHC-regulated CalPERS HMOs already provide mandate-compliant coverage for immunization-related procedures with no cost sharing for enrollees. Therefore, CHBRP estimates that AB 2064 would have no impact on this subpopulation.
- DMHC-regulated MRMIB plans (which enroll beneficiaries of the Healthy Families program, the Aid to Infants and Mothers (AIM) program, and the Major Risk Medical Insurance Program (MRMIP)) already provide mandate-compliant coverage for immunization-related procedures with no cost sharing. Therefore, CHBRP estimates that AB 2064 would have no impact on this subpopulation.
- CHBRP estimates no measurable impact of the mandate on the number of uninsured due to the estimated premium increases of less than 1%.

Utilization Impacts

- Premandate, CHBRP estimates that the 1.46 million enrollees aged 0 to 4 years would obtain an average of 2.94 immunizations each (including both immunization-related procedures and vaccines) within a 12-month period, for a total of 4.285 million immunization-related procedures (Table 1). The 1.12 million enrolled children aged 5 to 7 would obtain an average of 0.64 immunizations each, for a total of 719,000 immunization-related procedures. Finally, the 5.19 million enrollee children aged 8 to 18 would obtain an average of 0.45 immunizations each, for a total of 2.33 million immunization-related procedures.
- Postmandate, CHBRP estimates that there will be some increase in utilization due to the change in cost sharing, but that the total increase in the number of immunizations will be less than 100 for all age groups (Table 1). However, approximately 89,000 immunization-related procedures would no longer be subject to cost-sharing.

Cost Impacts

- Increases in per member per month (PMPM) premiums due to the prohibition on cost sharing for immunization-related procedures vary by regulator. There would be no impact on DMHC-regulated plans if AB 2064 were enacted, but there would be some impact for CDI-regulated policies.
- Increases as measured by percentage changes in PMPM premiums among CDI-regulated policies are estimated to range from a low of 0.0030% (for the large-group market segment) to a high of 0.0101% (for the individual policies market segment). Increases as measured by PMPM premiums are estimated to be \$0.02 for CDI-regulated policies.

- Total net health expenditures are projected to increase by \$155,000 (0.0001%) (Table 1). This is due to a \$648,000 increase in health insurance premiums partially offset by reductions in enrollee out-of-pocket expenditures for covered benefits (\$493,000).

Public Health Impacts

- CHBRP estimates that the health insurance benefit mandate in AB 2064 would result in fewer than 100 additional immunizations administered. Therefore, CHBRP estimates that AB 2064 would have no impact on California's rates of immunizations and vaccine-preventable diseases and their related mortality.
- Evidence shows that decreased cost sharing is associated with increased immunization rates, thus CHBRP projects that AB 2064 would remove the cost-sharing barrier. CHBRP estimates that approximately 89,000 immunization-related procedures would be no longer subject to cost-sharing postmandate. This would result in a savings of about \$493,000 in out-of-pocket expenses (coinsurance and deductibles) for those enrollees with newly compliant coverage who use immunizations. Those children whose parents abstained from or delayed immunization due to cost-sharing requirements for immunization-related procedures may benefit from AB 2064, as this cost barrier to completing recommended immunizations in a timely manner would be eliminated.
- CHBRP estimates that, to the extent that racial and ethnic disparities may exist in rates of immunization, vaccine-preventable disease incidence and related mortality, AB 2064 would have no statistically significant impact on those disparities due to the use of fewer than 100 additional immunizations postmandate. Furthermore, CHBRP found no evidence of gender disparities in rates of immunization, and vaccine-preventable disease incidence and related mortality. CHBRP estimates no statistically significant changes in these rates due to AB 2064.
- CHBRP expects AB 2064 would produce no statistically significant change in California's premature death rates for vaccine-preventable diseases because CHBRP estimates that the bill would increase utilization by fewer than 100 immunizations postmandate.
- Although vaccine-preventable diseases are known to cause economic loss, CHBRP expects AB 2064 would produce no statistically significant change in years of life saved or reductions in lost productivity due to less than an estimated 100 additional childhood and adolescent immunizations administered postmandate.
- CHBRP estimates that beyond 12 months postmandate, AB 2064 would have no statistically significant impact on California's rates of immunizations and vaccine-preventable diseases and mortality due to an estimated increase of less than 100 additional immunizations administered; however, those persons who abstained from or delayed immunization due to cost-sharing requirements for immunization-related procedures may benefit from AB 2064 by helping them complete their recommended immunization schedule.

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. Together, these laws are referred to as the “Affordable Care Act (ACA).

Although AB 2064’s interaction with the essential health benefits (EHB) categories lists in the ACA is unclear, it seems likely that AB 2064’s prohibition on cost sharing for child and adolescent immunization-related procedures would be “within” EHBs due to use of a nongrandfathered¹² plan or policy (subject to the federal preventive services benefit mandate¹³) as the benchmark plan options to define EHBs. So it seems likely that passage of the benefit mandate contained in AB 2064 would not require the state to defray costs related to EHBs exceeding the selected benchmark in 2014 and 2015.

Potential interactions of the benefit mandate included in AB 2064 and the ACA are further discussed in the *Introduction* of this report, under the heading “Effects of the Affordable Care Act.”

¹² A grandfathered health plan is defined as “a group health plan that was created—or an individual health insurance policy that was purchased—on or before March 23, 2010. Grandfathered plans are exempted from many changes required under the Affordable Care Act. Plans or policies may lose their ‘grandfathered’ status if they make certain significant changes that reduce benefits or increase costs to consumers” (<http://www.healthcare.gov/glossary/g/grandfathered-health.html>).

¹³ Affordable Care Act of 2010 Section 1001, modifying Section 2713 of the Public Health Services Act

Table 1. AB 2064 (Benefit Mandate Only) Impacts on Benefit Coverage, Utilization, and Cost, 2012

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Benefit coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	21,882,000	21,882,000	0	0%
Total enrollees with health insurance subject to AB 2064	21,873,000	21,873,000	0	0%
Percentage of enrollees with coverage for immunization-related procedures				
Coverage not subject to cost sharing (b)	98.3%	100.0%	1.7%	2%
Coverage subject to cost sharing	1.7%	0.0%	-1.7%	-100%
Number of enrollees with coverage for immunization-related procedures				
Coverage not subject to cost sharing	21,492,000 (c)	21,873,000	381,000	2%
Coverage subject to cost sharing	381,000 (c)	0	-381,000	-100%
Utilization and cost				
Number of immunization-related procedures: Ages 0-4	4,285,000	4,285,000 (d)	0 (d)	0% (d)
Number of immunization-related procedures: Ages 5-7	719,000	719,000 (d)	0 (d)	0% (d)
Number of immunization-related procedures: Ages 8-18	2,335,000	2,335,000 (d)	0 (d)	0% (d)
Average per-unit cost of immunization-related procedures only	\$25	\$25	0	0%
Expenditures				
Premium expenditures by private employers for group insurance	\$60,279,820,000	\$60,280,020,000	\$200,000	0.0003%
Premium expenditures for individually purchased insurance	\$7,543,951,000	\$7,544,340,000	\$389,000	0.0052%
Premium expenditures by persons with group insurance, CalPERS HMOs, Healthy Families Program, AIM, or MRMIP (e)	\$14,706,245,000	\$14,706,304,000	\$59,000	0.0004%
CalPERS HMO employer expenditures (f)	\$3,651,121,000	\$3,651,121,000	\$0	0.0000%
Medi-Cal Managed Care Plan expenditures	\$7,637,700,000	\$7,637,700,000	\$0	0.0000%
MRMIB Plan expenditures (g)	\$1,046,243,000	\$1,046,243,000	\$0	0.0000%
Enrollee out-of-pocket expenses for covered benefits (deductibles, copayments, etc.)	\$8,521,470,000	\$8,520,977,000	-\$493,000	-0.0058%
Enrollee expenses for noncovered benefits that would be covered postmandate (h)	\$0	\$0	\$0	0.000%
Total expenditures	\$103,386,550,000	\$103,386,705,000	\$155,000	0.0001%

Source: California Health Benefits Review Program, 2012.

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 DMHC or CDI. Population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employment-sponsored insurance.

- (b) “Cost sharing” includes copayments, coinsurance, deductibles, and dollar-limit provisions.
 - (c) Populations are calculated from unrounded numbers, and may not match precisely if percentages are multiplied by rounded population totals.
 - (d) CHBRP estimates that utilization will increase by less than 100 across all age groups. While this number is greater than 0, in this table it is included in the rounding.
 - (e) Premium expenditures by enrollees include employee contributions to employer-sponsored health insurance and enrollee contributions for publicly purchased insurance.
 - (f) Of the increase in CalPERS employer expenditures, about 58%, or \$0 would be state expenditures for CalPERS members who are state employees or their dependents.
 - (g) MRMIB Plan expenditures include expenditures for 874,000 enrollees of the Healthy Families Program, 7,000 enrollees of MRMIP, and 7,000 enrollees of the AIM program.
 - (h) Includes only those expenses that enrollees pay directly to providers for uncovered services related to the mandated benefit *and* 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 Assembly Committee on Health requested on February 28, 2012, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 2064 (Perez), Immunizations for Children, a bill that would impose a health benefit mandate. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program’s authorizing statute.¹⁴

Only one of the several requirements in AB 2064—the requirement to be placed as Health and Safety Code Section 1367.36(g) and as Insurance Code Section 10123.56 (b)—is a health insurance benefit mandate. Therefore, this report analyzes only the impact of this single requirement.

Approximately 21.882 million Californians (59%) have health insurance that may be subject to a health benefit mandate law passed at the state level.¹⁵ 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)¹⁶ regulates health care service plans, which offer benefit coverage to their enrollees through health plan contracts. The California Department of Insurance (CDI) regulates health insurers¹⁷, which offer benefit coverage to their enrollees through health insurance policies.

DMHC-regulated plans and CDI-regulated policies that provide coverage for childhood and adolescent immunizations would be subject to AB 2064. Coverage for “immunizations” includes coverage for both the vaccine itself (which is a prescription drug) and coverage for related procedures (including administration of the vaccine during a provider visit). CHBRP estimates that nearly all enrollees with health insurance subject to state-level benefit mandates have coverage for immunizations, so the mandate would affect the health insurance of approximately 21.873 of the 21.882 million Californians.

Bill Language

The full text of AB 2064 can be found in Appendix A.

¹⁴ Available at: http://www.chbrp.org/documents/authorizing_statute.pdf

¹⁵ CHBRP’s estimates are available at: http://www.chbrp.org/other_publications/index.php.

¹⁶ DMHC was established in 2000 to enforce the Knox-Keene Health Care Service Plan of 1975; see Health and Safety Code Section 1340.

¹⁷ 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.

For DMHC-regulated plans and CDI-regulated policies that provide coverage for childhood and adolescent immunizations, the benefit mandate would prohibit cost sharing (defined as including deductibles, copayments, and coinsurance, and “other cost-sharing mechanisms”) for administration of a childhood or adolescent immunization or for procedures related to administration. The mandate would also prohibit dollar-limit provisions for childhood or adolescent immunization-related procedures. Dollar-limit provisions establish a limit (either an annual or a lifetime limit) beyond which benefit coverage is no longer provided.

Analytic Approach and Key Assumptions

In clinical terms, immunization is the process by which a person’s immune system becomes fortified against a foreign (non-self) agent (an immunogen). The word “immunization” is frequently used as a synonym for “vaccination.” Vaccination is an active means of accomplishing immunization against microorganisms that can cause disease through the administration (by injection or other means) of a vaccine. For this analysis, CHBRP has assumed that immunization and vaccination are synonyms and has primarily used the word “immunization” in order to be consistent with the language of AB 2064.

An enrollee’s benefit coverage for the two components of immunization (the vaccine and the immunization-related procedures) may not be identical. Depending on the terms of an enrollee’s health services plan contract or health insurance policy, an enrollee may be subject to cost sharing for only one, for both, or for neither. Because the language of the benefit mandate in AB 2064 addresses only cost sharing for immunization-related procedures, AB 2064 would not affect cost sharing for vaccines.¹⁸

AB 2064 references existing mandates¹⁹ that require coverage for immunizations listed in the most current version of the “Recommended Childhood Immunization Schedule/United States, jointly adopted by the American Academy of Pediatrics, the Advisory Committee on Immunization Practices, and the American Academy of Family Physicians.” Therefore, CHBRP has assumed for this analysis that AB 2064 would prohibit cost sharing for immunization-related procedures for all of the childhood and adolescent immunizations listed in the most currently recommended Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) immunization schedule, hereafter referred to as “ACIP recommendations.”

The terms “childhood” and “adolescent” are not defined in the language of AB 2064. However, the childhood and adolescent immunizations recommended in the current ACIP schedule are for persons 18 years or less. For this analysis, CHBRP has assumed that the mandate is relevant only to immunizations of persons 18 years or less—and not to any “late” immunization of a person over age 18 with vaccines recommended by ACIP for children and adolescents.

Existing requirements

CHBRP is aware of several requirements that could overlap or interact with AB 2064.

¹⁸ Personal communication, A. Abu-Rahma, DMHC, March 2012.

¹⁹ Health and Safety Code Sections 1367.35, 1367.002 and Insurance Code Sections 10123.5, 10112.2

California State Benefit Mandates:

- Comprehensive preventive care for children aged 16 years or younger²⁰
- Comprehensive preventive care for children aged 17 or 18 years²¹
- Preventive services coverage without cost sharing²²

The first state mandate requires coverage for immunization. The second requires that benefit coverage be offered. The third state mandate requires compliance with an existing federal mandate. The federal mandate is discussed below, under the heading “Effects of the Affordable Care Act.”

DMHC-regulated plans are also required to cover “basic health care services,” including a range of preventive care services. Regulations further specify that health plans are to cover preventive services, including recommended immunizations for children.²³ Laws and regulations related to CDI-regulated policies do not have a similar set of broad “basic health care services” requirements.

Requirements in other states

Although CHBRP is aware of well-child care coverage mandates in 35 states (BCBSA, 2011), CHBRP is unaware of benefit mandates in other states that prohibit cost sharing for immunization-related procedures.

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 the 2014 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.

Current effects

Provisions of the ACA that go into effect during the transitional years (2010-2013) affect current (or baseline) 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

²⁰ Health and Safety Code Section 1367.35 and Insurance Code Section 10123.5

²¹ Health and Safety Code Section 1367.3 and Insurance Code Section 10123.55

²² Health and Safety Code Section 1367.002 and Insurance Code Section 10112.2

²³ Personal communication, C. Hamilton, DMHC, April 2012.

presented in this report. Each of the provisions that have gone into effect by January 2012 has been considered. Where data allow, CHBRP has made adjustments to reflect changes in enrollment and/or baseline premiums. These adjustments are discussed in further detail in Appendix D.

Some of the provisions of the ACA enacted federal health insurance benefit mandates.²⁴ The mandate relevant to AB 2064 is discussed below.

Effective 2010: preventive services

The ACA requires that nongrandfathered²⁵ health plans and policies cover certain preventive services with no cost sharing beginning September 23, 2010, including ACIP-recommended immunizations.²⁶ The federal mandate prohibits cost sharing for immunization-related procedures. Although grandfathered plans and policies are not subject to the federal mandate's prohibition, plans and policies regulated by DMHC or CDI would be subject to the benefit mandate contained in AB 2064. Therefore, AB 2064 would broaden the mandated prohibition against cost sharing for immunization-related procedures. It is not clear how many DMHC-regulated plans and CDI-regulated policies are grandfathered and therefore not subject to the mandate. The U.S. Departments of Labor and Treasury estimate that by 2013, between 39% and 69% of all employer group plans will have relinquished their grandfathered status.²⁷

Effective in 2014: essential health benefits

The ACA requires nongrandfathered small-group and individual health insurance, including but not limited to qualified health plans (QHPs) sold through the California Exchange, to cover specified categories of benefits called essential health benefits (EHBs)²⁸ beginning January 1, 2014. The ACA defines EHBs as including these categories: (1) ambulatory patient services; (2) emergency services; (3) hospitalization; (4) maternity and newborn care; (5) mental health and substance use disorder services, including behavioral health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventive and wellness services and chronic disease management; and (10) pediatric services, including oral and vision care. The Secretary of Health and Human Services (HHS) is charged with defining

²⁴ The benefit mandates enacted by the ACA and other federal benefit mandates appear in a list updated regularly by CHBRP. See *Current Mandates: Health Insurance Benefit Mandates in California State Law*, available at http://www.chbrp.org/other_publications/index.php.

²⁵ A grandfathered health plan is defined as “a group health plan that was created—or an individual health insurance policy that was purchased—on or before March 23, 2010. Grandfathered plans are exempted from many changes required under the Affordable Care Act. Plans or policies may lose their ‘grandfathered’ status if they make certain significant changes that reduce benefits or increase costs to consumers” (<http://www.healthcare.gov/glossary/g/grandfathered-health.html>).

²⁶ Affordable Care Act of 2010 Section 1001, modifying Section 2713 of the Public Health Services Act

²⁷ For small employers (3 to 99 employees), the estimated percentage relinquishing grandfathered status is between 49% and 80%; for large employers (more than 100 employees), the estimate is 34% to 64%. U.S. Department of Labor and Department of Treasury, *Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act*, (June 17, 2010), available at <https://www.federalregister.gov/articles/2010/06/17/2010-14488/interim-final-rules-for-group-health-plans-and-health-insurance-coverage-relating-to-status-as-a>

²⁸ Affordable Care Act of 2010 Section 1302(b)

these categories through regulation and ensuring that the EHB floor “is equal to the scope of benefits provided under a typical employer plan.”

The ACA allows a state to require QHPs sold through an exchange to provide benefits that are “in addition to” EHBs. However, if the state does so, the state must defray the cost of those additionally mandated benefits that exceed EHBs, either by paying the purchaser directly, or by paying the QHP.

HHS has proposed²⁹ that each state define its own EHBs for 2014 and 2015 by selecting one of a set of specified benchmark plan options. The choice of benchmark plan is expected to dictate which state benefit mandates, if any, will be included in the state’s EHBs.

Any state-mandated benefit enacted after December 31, 2011, may not be part of the EHBs for 2014 and 2015.³⁰ If passed, AB 2064 would be effective January 1, 2013. Therefore, if any proposed benefit coverage mandates included in AB 2064 exceed EHBs, as defined in 2014 and 2015, California may be required to defray the cost for QHPs sold through an Exchange.

HHS has not released final guidance on defining the EHBs or final guidance on how states will defray the costs of state benefit mandates that require QHPs to exceed EHBs. However, it seems likely that states would be required to defray the marginal cost impact associated with the state benefit mandates’ exceeding EHBs. Such a marginal cost may be calculated in a fashion similar to the manner in which CHBRP estimates marginal cost impacts when assessing benefit mandate bills on behalf of the California Legislature. For further discussion on how state benefit mandates may interact with the EHBs and the benchmark plan regulatory approach, please see CHBRP issue brief *Interaction between California’s State Benefit Mandates and the Affordable Care Act’s “Essential Health Benefits.”*³¹

Effects beginning in 2014: interactions between essential health benefits and AB 2064

Because of the potential fiscal responsibility for the state, CHBRP is providing the following consideration of how the benefit mandate in AB 2064 might interact with EHBs.

As mentioned, the 10 EHB categories in the ACA explicitly include prevention and wellness services. Although definitions of the EHB categories are not yet available, it seems likely that childhood and adolescent immunizations recommended by ACIP will be included in the final definition of “prevention services.” However, it is unclear whether AB 2064’s prohibition on cost sharing for immunization-related procedures for ACIP-recommended childhood and adolescent immunizations would be part of the final definition to be issued by HHS.

Also as mentioned, HHS has suggested that states will begin defining EHBs for 2014 and 2015 by selecting a benchmark plan option. Older mandates may effectively become part of the

²⁹ CCIIO, *Essential Health Benefits Bulletin* (December 2011). Available at: http://cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf.

³⁰ CCIIO, *Frequently Asked Questions on Essential Health Benefit Bulletin*, (February 2012)). Available at: <http://cciio.cms.gov/resources/files/Files2/02172012/ehb-faq-508.pdf>.

³¹ Available at: http://www.chbrp.org/other_publications/index.php.

definition of EHBs because the plan or policy selected as the benchmark plan option is already compliant with them. Because AB 2064 would not be in effect until after a benchmark plan option is selected, it seems unlikely that the benefit mandate in AB 2064 would become part of the EHBs for 2014 and 2015. However, many of the benchmark plan options may already be compliant with AB 2064 (applying no cost sharing for immunization-related procedures). Furthermore, of the possible benchmark plan options, few would be grandfathered plans or policies, so it seems likely that selected benchmark plan option would be subject to the previously discussed federal preventive services health insurance benefit mandate, which prohibits cost sharing for immunization-related procedures when associated with ACIP-recommended childhood and adolescent immunizations.

Although interaction with the EHB categories listed in the ACA is unclear, it seems likely that AB 2064’s prohibition on cost sharing for child and adolescent immunization-related procedures would be “within” EHBs due to use of a nongrandfathered plan or policy as the benchmark plan option to define EHBs (see Table 2). So it seems likely that passage of the benefit mandate contained in AB 2064 would not require the state to defray costs related to EHBs exceeding the selected benchmark in 2014 and 2015.

Table 2. Potential Interaction of Essential Health Benefits (EHBs) in 2014-2015 with the Benefit Mandate Included in AB 2064

Affordable Care Act (ACA) Essential Health Benefits (EHBs)	AB 2064’s Prohibition on Cost Sharing for Immunization-Related Procedures for ACIP-Recommended Childhood and Adolescent Immunizations
10 ACA EHB categories	Unclear
Proposed approach for defining EHBs in 2014-2015	
Benchmark plan option 1: small group insurance product*	Within
Benchmark plan option 2: state employee health benefits plan—CalPERS HMO*	Within
Benchmark plan option 2: state employee health benefits plan—CalPERS self-insured PPO*	Within
Benchmark plan option 3: Federal Employees Health Benefits Program (FEHBP)*	Within
Benchmark plan option 4: largest commercial HMO*	Within

Source: CHBRP, 2012.

Notes: (*) Assumes a nongrandfathered plan or policy (therefore subject to the federal preventive services health benefit mandate)³²

Key: ACIP=Centers for Disease Control and Prevention Advisory Committee on Immunization Practices CalPERS HMO=California Public Employees’ Retirement System Health Maintenance Organization; CalPERS HMO=California Public Employees’ Retirement System Preferred Provider Organization.

³² Affordable Care Act of 2010 Section 1001, modifying Section 2713 of the Public Health Services Act

Background on Immunization and Vaccine-Preventable Diseases

Evidence indicates that childhood and adolescent immunizations are cost-effective (and cost-saving in many cases) in preventing, reducing, or eliminating the incidence of numerous infectious diseases and their associated morbidity, mortality, and health care costs (NVAC, 2009; Shortridge et al., 2011). When an infectious disease is transmitted from person to person or when humans are the reservoir for a disease, immunizations *directly* protect those who are immunized and *indirectly* protect unimmunized persons by reducing their risk of exposure to the disease (Smith et al., 2010). This indirect protection, or “herd immunity,” is relevant to most of the immunizations discussed in this report, including immunizations to prevent measles, pertussis, influenza, polio, rubella, mumps, and diphtheria (Fine, 1993). Tetanus is an exception because it is not passed from person to person, nor are humans a reservoir for this disease. The proportion of the population required to be immunized in order to achieve herd immunity varies by disease, but generally is at or above 80% of the population immunized (Fine, 1993).

Infectious diseases including diphtheria, polio, and measles were common sources of illness and death in the United States before the 1960s. For instance, the Centers for Disease Control and Prevention estimated there were approximately 16,000 cases of polio each year in the 20th century before the advent of the vaccine in 1955 and improvements in the vaccine in 1961 (CDC, 2011c). Table 3 shows the impact of immunization in nearly eliminating cases of diphtheria, measles, polio, and rubella.

Table 3. Comparison of U.S. Annual Morbidity (All Ages), 20th Century Pre-Vaccine Era and 2010

Disease	20th Century Pre-Vaccine Era: Annual Number of Cases	Vaccine’s Year of First U.S. Licensure	2010: Number of Cases	Reduction
Diphtheria	21,053	1940 ^a	0	100%
Hepatitis A	117,333	1995	8,493	93%
Hepatitis B, acute	66,232	1981	9,419	86%
<i>Haemophilus influenzae</i> type b in children aged <5 yrs.	20,000	1987	240	99%
Measles	530,217	1963	63	>99%
Mumps	162,344	1967	2,612	98%
Pertussis	200,752	1970 ^a	27,538	86%
Pneumococcus, invasive <5 yrs	63,607	2000	44,000	30%
Polio (poliomyelitis, paralytic)	16,316	1955	0	100%
Rotavirus, hospitalizations	62,500	2006	28,125	55%
Rubella	47,745	1969	5	>99%
Tetanus	580	1943 ^a	26	96%
Varicella	4,085,120	1995	408,572	90%

Source: California Health Benefits Review Program, 2012. Based on Hinman et al., 2011.

^a The combined diphtheria-tetanus-pertussis vaccine was first licensed in 1970. Individual vaccines were first licensed starting in the 1940s.

In California, efforts to immunize children and adolescents have resulted in similar declines in vaccine-preventable diseases (CDPH, 2009). For example, the annual number of *haemophilus influenzae* type b (Hib) cases reported in California declined from 332 (1990) to a total of 25 cases between 2002 and 2007. Of the 25 cases, two deaths were reported. Prior to the measles vaccine introduction, California experienced 39,201 cases of measles (1961), which dropped to a total of 30 cases between 2002 and 2007 after immunization became routine. Of the 30 measles cases, 10 occurred in children under age 19 (four had personal belief exemptions, two had undocumented immunization history, and one completed one of two required doses). The number of child/adolescent rubella cases reported between 2002 and 2007 (a total of 8 cases with an average age of 37 years) declined significantly from 8,000 cases reported in the early 1970s (CDPH, 2009).

Immunization Efforts

Public and private immunization efforts at the federal, state, and local levels over a 60-year period are credited with a reduction in the incidence of vaccine-preventable diseases. As shown in Table 3, immunizations have virtually eliminated diphtheria and polio, and hepatitis A and hepatitis B cases have been reduced by 93% and 86% respectively (CDC, 2011c).

In addition to the health insurance benefit mandates already discussed, California has implemented several laws affecting school and childcare facility enrollment to promote immunization against 10 diseases: diphtheria, hepatitis B, *haemophilus influenzae* type b, measles, mumps, rubella, pertussis, polio, tetanus, and varicella³³. These laws require a complete dose of these immunizations for children (aged 0-18 years) prior to admission into schools (public and private) or licensed childcare facilities (although exemptions for medical reasons or personal beliefs are permitted). These laws also require schools and licensed childcare facilities to collect and report immunization rates of their enrollees to the California Department of Public Health (CDPH). Evidence indicates that following enactment of California's school laws (between 1979 and 1986), immunization rates of California's children aged 5 to 6 years increased 15 percentage points to 90% (Briss et al., 2000).

The federal government uses financial subsidies, goal setting strategies, and federal law to promote immunization nationally. Uninsured and underinsured children and adolescents are eligible for free immunizations through two federally financed programs that are managed through the states. The Vaccines for Children³⁴ (VFC) and "Section 317"³⁵ finance vaccine acquisition and administration for about 50% of a given birth cohort that qualifies for services based on low income (NVAC, 2009). Furthermore, the U.S. Department of Health and Human Services (HHS) seeks to promote childhood and adolescent immunization by establishing a national target of 80% of U.S. children fully immunized against six key diseases by 2020.

³³ California Code of Regulations (Title 17, Div. 1, Chap. 4, Subchap. 8) Sections 6000-6075 and Health and Safety Code: Div. 105, Part 2, Chap. 1, Sections 120325-120380

³⁴ VFC is an entitlement program for Medicaid-eligible children through age 18 as well as the uninsured, underinsured, Alaskan natives, and American Indians. Uninsured children/adolescents must obtain VFC immunizations from federally qualified health centers and rural health clinics.

³⁵ "Section 317" is a Public Health Service (federal) discretionary grant program with appropriations that provided 35% of funds for vaccine purchase in FY 2000 and 10% in FY 2007.

National targets for immunizations vary from 60% to 90%, depending on the disease being addressed and the age of the child (DHHS, 2010). In addition, as previously discussed, the federal government requires many forms of health insurance to provide coverage for ACIP recommendations for childhood and adolescent vaccines and their administration without cost sharing.³⁶

Private sector initiatives promoting immunization include voluntary “first dollar” benefit coverage (no cost sharing by enrollees) provided by many forms of health insurance and voluntary public reporting of immunization rates through the Healthcare Effectiveness Data and Information Set (HEDIS) (NCQA, 2012, NVAC, 2009).

California Immunization Rates

Currently, about 71% of children in California, by age 35 months, receive the vaccine series 4:3:1:3:1:4³⁷ (CDC, 2011a), compared to the *Healthy People 2020* target of 80% (DHHS, 2010). Rates for immunizations against particular diseases range between 53% and 91% for children and adolescents (CDC, 2011a; CDC, 2011b). ACIP recommends the following immunizations for children (aged 0-6 years) and adolescents (aged 7-18 years) (CDC, 2011c):

- diphtheria, tetanus, acellular pertussis (collectively referred to as DTaP or Tdap);
- Inactivated poliovirus (IPV) polio;
- measles, mumps, rubella (collectively referred to as MMR);
- *Haemophilus influenzae* type b (Hib);
- hepatitis B (Hep B);
- hepatitis A (Hep A);
- rotavirus;
- varicella;
- pneumococcal conjugate (PCV); and
- influenza;
- and meningococcal conjugate, DTaP booster, and HPV for adolescents.

For children up to age 35 months, California appears to be meeting national targets for about half of the ACIP recommendations (Table 4) and the rates for the immunizations required for California childcare facility or school entrance are consistently close to the national targets with the exception of the pertussis (whooping cough) immunization. This lower rate likely contributed to the 2010 pertussis outbreak in California (CDPH, 2011c).

³⁶ Affordable Care Act of 2010 Section 1001, modifying Section 2713 of the Public Health Services Act

³⁷ 4:3:1:3:1:4= the abbreviation for a grouping of individual vaccines per the CDC’s National Immunization Survey: ≥4DTaP; ≥3 polio; ≥1 MMR; ≥3 Hep B; ≥1 varicella (chickenpox); ≥4 PCV vaccines.

Table 4. Crosswalk of Immunization Recommendations, Requirements, Rates, and Goals

ACIP-Recommended Immunizations (a)	California School and Licensed Childcare Requirements ³⁸	California Immunization Rates (at age 35 mos.), 2010 (b)	Healthy People 2020 National Targets (c)
0-6 years			
Hepatitis B (HepB)	Required	90.1%	90%
Diphtheria, tetanus, acellular pertussis (DTaP/Tdap)	Required	79.7%	90%
<i>Haemophilus influenzae</i> type b (Hib)	Required	89.3%	90%
Inactivated poliovirus (IPV)	Required	91.0%	90%
Measles, Mumps, Rubella (MMR)	Required	91.4%	90%
Varicella	Required	88.9%	90%
Hepatitis A (HepA)	Not required	53.4%	60%
Pneumococcal conjugate (PCV-13)	Not required	83.5%	90%
Rotavirus	Not required	58.9%	80%
Influenza	Not required	Not reported	90%
7-18 years			
Human papillomavirus (HPV)	Not required	61.0% ^d	80%
Meningococcal conjugate (MCV-4)	Not required	66.7%	80%
Tetanus, diphtheria, acellular pertussis (Tdap) booster (after age 10)	Required in future (e)	71.2%	80%

Source: California Health Benefits Review Program, 2012. Adapted from CDC 2011a, CDC 2011b, and DHHS, 2010.

Notes: General: For nonimmunized children aged 7 to 18 years, ACIP recommends catch-up immunizations for the 0 to 6 year cohort in addition to HPV and meningococcal immunizations and a Tdap booster; (a) ACIP-recommended immunization schedule. (b) California immunization rates are from the CDC's 2010 National Immunization Study: http://www.cdc.gov/vaccines/stats-surv/nis/data/tables_2010.htm#overall ; (c) *Healthy People 2020* Immunization and Infectious Disease Objectives: <http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=23>; (d) Percentage among females only. HPV immunization includes both quadrivalent and bivalent vaccines. (e) DTaP boosters will be required for admission into 7th grade as of July 1, 2012.

Approximately 94% of California's kindergartners (aged 5 years) enrolled in spring 2011 met state immunization requirements for enrollment; 3% were conditional entrants; 0.08% submitted permanent medical exemptions, and 2.5% registered personal belief exemptions (CDPH, 2011a). This rate is significantly higher than the CDC-reported rate of 71% because of the different age groups included in each data set. California appears to meet the national immunization goals, but not until age 5; thus children with delayed immunizations are at higher risk of contracting a vaccine-preventable disease during that delay.

³⁸ California Code of Regulations (Title 17, Div. 1, Chap. 4, Subchap. 8) Sections 6000-6075 and Health and Safety Codes Div. 105, Part 2, Chap. 1, Sections 120325-120380

Baseline Differences in Immunization Rates by Gender and Race/Ethnicity

CHBRP found no reports of gender disparities in the ACIP recommendations for the 4:3:1:3:3:1³⁹ vaccine series (CDC, 2011a, b). A gender disparity in the administration of the HPV vaccine (recommended in adolescence) currently exists as fewer males are immunized. But this disparity is likely due to the later (2009) approval by the U.S. Food and Drug Administration (FDA) of the quadrivalent vaccine’s use in males. The gap in uptake may close in the near future due to the more recent ACIP recommendation (2011) for routine use of that vaccine in males aged 11 to 12 years.

In 2008, at a national level, most racial and ethnic disparities are no longer statistically significant (Zhao and Luman, 2010). The CDPH Immunization Branch’s most recent report on immunization coverage confirms that disparities in immunization rates in California are similar to the national pattern (CDPH, 2011b). The report raises the question as to whether a disparity exists for Blacks who appear to have the lowest rate (61.2%) for completing the 4:3:1:3:1 series of childhood immunizations by the recommended age of 24 months. However, in this relatively small study, CDPH reported that the difference was not statistically significant (Table 5). The report indicates that there are no disparities by race/ethnicity for the individual vaccines listed below except for DTaP, where the rate for Blacks is 68.1%. This rate is lower than the statewide rate and the rates for Hispanics, Asians, and whites.

Table 5. Immunization Rates Among California’s Kindergarten Students at 24 months of Age, by Race/Ethnicity

	n	DTaP (4+ doses)	Polio (3+ doses)	MMR (1+ dose)	Hep B (3+ doses)	Var (1+ dose)	4:3:1:3:1
ALL	2,872	79.9%	92.3%	92.7%	91.3%	88.1%	71.0%
White	666	80.2%	90.2%	90.3%	90.1%	83.2%	68.6%
Hispanic	1,342	80.2%	93.6%	94.9%	92.8%	91.1%	72.7%
Black	318	68.1%	84.5%	88.3%	85.8%	84.8%	61.2%
Asian	273	81.7%	94.3%	92.2%	92.5%	88.8%	72.0%
Other	125	81.1%	93.4%	89.2%	87.1%	84.9%	72.0%
Unknown	148	84.5%	93.4%	92.3%	90.8%	88.0%	74.2%

Source: California Health Benefits Review Program, 2012. Adapted from CDPH, 2011b.

Key: DTaP=diphtheria, tetanus, pertussis; MMR=measles, mumps, rubella; Hep B=hepatitis B; Var=varicella; 4:3:1:3:1=DTaP, MMR, Polio, Hep B, varicella

Vaccine-Preventable Diseases

Immunization, nationally and in California, is credited with an 80% to 100% decline in most vaccine-preventable diseases recorded over the last 50 years (CDPH, 2009). CDPH reports that “the number of reported cases is at or near record lows” for children and adolescents (CDPH, 2009). For example, as shown in Table 6, California’s 2010 incidence rates are less than or equal to 1 case each/1 million persons for the following reportable vaccine-preventable diseases: *Haemophilus influenzae* type b, measles, mumps, rubella, tetanus, and varicella. Incidence of meningococcal disease in California is about 3 cases/1 million persons and cases of hepatitis A

³⁹ 4:3:1:3:3:1= the abbreviation for a common grouping of individual vaccines: ≥4DTaP4 DTaP; ≥3 polio; ≥1 MMR; ≥3Hib3 Hib; ≥3 Hep B; ≥1 varicella (chickenpox) vaccines.

and acute hepatitis B are about 6 cases/1 million persons. An outbreak of pertussis occurred in California in 2009 and peaked in 2010 with 9,156 cases and 10 deaths (all infants).⁴⁰ Incidence is now declining (2,937 cases in 2011 with no deaths), a decline that is credited to DTaP booster administered to adolescents, children, and caretakers of young children (CDPH, 2011c).

Table 6. Number and Incidence of Reportable Vaccine-Preventable Diseases (All Ages), California, 2010

Diseases	Number of Cases (all ages) 2010	Rate per 1,000,000 (all ages) 2010	Reported Deaths (0-18 years) 2002-20 07
Pertussis	9,156	233.96	27 (b)
Hepatitis B (Acute)	252	6.44	0
Hepatitis A	238	6.08	0
Meningococcal	121	3.09	NR
Varicella	42	1.07	3
Mumps	29	0.74	0
Measles	27	0.69	0
Rubella	1	0.03	0
<i>Haemophilus influenzae</i> type b (Hib)	0	0.00	2
Tetanus	0	0.00	0
Diphtheria (a)	0	0.00	0
Polio (a)	0	0.00	0
Human papillomavirus (HPV) (c)	NR	NR	NR

Source: California Health Benefits Review Program, 2012, adapted from CDPH, 2010a, CDPH, 2009

Notes: (a) No cases reported for many years: The last case of indigenously acquired poliovirus in the United States was reported in 1979 and no cases of diphtheria were reported in California between 2001-2010; (b) Reported deaths occurred 2001-2007; (c) Not reported by CDPH.

Key: NR=Not reported

Similarly, premature death attributable to childhood infectious disease has declined substantially. Table 6 shows that, from 2002 to 2007, the following were reported: no pediatric deaths for 8 reportable vaccine-preventable diseases; two pediatric deaths from *Haemophilus influenzae* type b; and three pediatric deaths from varicella (CDPH, 2009).

⁴⁰ This figure reports a rate for 2010 only, where table 6 reports an aggregate rate for the years 2002-2007. Therefore, the figures are different.

MEDICAL EFFECTIVENESS

For DMHC-regulated plans and CDI-regulated policies that provide coverage for childhood and adolescent immunizations, the benefit mandate in AB 2064 would prohibit cost sharing (defined as including deductibles, copayments, and coinsurance, and “other cost-sharing mechanisms”) for administration of a childhood or adolescent immunization or for procedures related to administration. The mandate would also prohibit dollar-limit provisions for childhood or adolescent immunization-related procedures. Dollar-limit provisions establish a limit (either an annual or a lifetime limit) beyond which benefit coverage is no longer provided.

The *Medical Effectiveness* section will review ACIP recommendations on childhood and adolescent immunizations published to date.

ACIP Recommendations

ACIP was established by the U.S. Surgeon General in 1964 to help with prevention and control of infectious diseases (Smith, 2009). ACIP holds three regularly scheduled meetings each year, while 14 designated work groups meet on a monthly basis (Smith, 2009). The members of these workgroups—each experts in vaccinology, immunology, pediatrics, internal medicine, infectious disease, preventive medicine, or public health—are responsible for conducting in-depth reviews of vaccine-related data and publications (Smith, 2009). The official recommendations made by ACIP are published in the CDC’s Morbidity and Mortality Weekly Report (MMWR).

There are 12 vaccines recommended for use in children and adolescents (aged 0-18) by ACIP: diphtheria, tetanus, acellular pertussis (DTaP/Tdap); *haemophilus influenzae* type b (Hib); hepatitis A; hepatitis B; human papillomavirus (HPV); influenza; measles, mumps, rubella (MMR); meningococcal conjugate; pneumococcal conjugate; inactivated poliovirus (IPV); rotavirus; and varicella. It is not feasible for CHBRP to review the large volume of literature on the medical effectiveness of each of these vaccines and their associated form of immunization-related procedures within the 60-day time frame allotted for this analysis.

Due to the rigor and thoroughness of the ACIP systematic review on the efficacy and safety of vaccines, for the purposes of this report, CHBRP concludes that any vaccine that has been recommended as part of the routine immunization schedule has **clear and convincing evidence** that it is effective in preventing disease.

This review does not address the following vaccines because they are not recommended by ACIP for routine use among children and adolescents who reside in the United States: anthrax, tuberculosis, Japanese encephalitis, rabies, smallpox, and typhoid.

The recommendations released by ACIP were reviewed for information on immunization-related procedures and information specific to the 12 vaccines recommended for routine use among children and adolescents in the United States. ACIP has 38 current vaccine-specific recommendations, along with one report summarizing general recommendations on

immunization. Of the 39 current recommendations, 14 were excluded because they were not relevant (i.e., not for pediatric population, not a routine immunization, etc.). The 25 remaining recommendations were retrieved and reviewed. The findings from this review are summarized below. A summary of ACIP-recommended immunization-related procedures is given followed by a brief summary of each of the 12 ACIP-recommended vaccines, including background of the disease, administration route and schedule, and efficacy of the vaccine. These findings are also presented in Table 7. While most CHBRP reviews present data on medical effectiveness, this report will provide information on the efficacy of immunizations. Efficacy refers to the prevention of illness among immunized persons in controlled trials while effectiveness refers to the prevention of illness among immunized persons in the population. ACIP recommendations report on the efficacy seen in clinical trials and rarely report on the effectiveness in the population.

Immunization-Related Procedures

To ensure proper and safe administration of vaccines, ACIP issues recommendations regarding immunization-related procedures such as infection control, sterile immunization techniques, and the proper administration, storage, and handling of vaccines (CDC, 2011c). Health care personnel are recommended to wash their hands with soap and water or use an alcohol-based antiseptic before preparing the vaccine and between each patient contact (CDC, 2011c). Gloves are not required when administering vaccines, but if worn, they should be changed between patients (CDC, 2011c). The needles and syringes used for immunizations must be sterile and disposable and a separate needle should be used for each injection (CDC, 2011c). ACIP does not recommend the prefilling of syringes due to the potential for administration errors and wastage (CDC, 2011c).

There are four routes of administration used for routine childhood immunizations: oral, intranasal, intramuscular injection, and subcutaneous injection. As presented in Table 7 the rotavirus vaccine is the only routine childhood vaccine administered orally, while the live attenuated influenza vaccine is the only vaccine administered intranasally (CDC, 2011c). The remaining vaccines are administered through injection—either intramuscularly or subcutaneously. Intramuscular injections are delivered at a 90-degree angle to the skin to either the thigh or deltoid muscle (CDC, 2011c). The majority of routine childhood immunizations are delivered intramuscularly. Subcutaneous injections are administered at a 45-degree angle usually in the thigh, for infants, or the upper-outer triceps area, for older children. The varicella and MMR vaccines are administered subcutaneously, while the polio vaccine can be administered through either intramuscular or subcutaneous injection. ACIP recommends administration of vaccines consistent with the route recommended by the vaccine manufacturer. Deviation from the recommended route of administration could lead to a reduction in the effectiveness of the vaccine or an increase in adverse reactions (CDC, 2011c).

Proper storage and handling of vaccines is essential to maintaining the integrity of the vaccine. Vaccines are either recommended to be stored in a refrigerator at 35 to 46 degrees Fahrenheit or frozen at temperatures less than or equal to 5 degrees Fahrenheit. It is recommended that vaccines are stored in a dedicated vaccine refrigerator or freezer with enough space to hold a year's supply of vaccine placed away from the walls of the storage unit (CDC, 2011c). Monitoring of vaccine temperature during storage should be conducted routinely. ACIP

recommends that one staff member should be assigned the responsibility of maintaining and reviewing a temperature log. The temperature should be monitored and recorded in the temperature log twice a day, and an additional staff person should review the temperature log each week (CDC, 2011c). Each facility should have a plan in place for what to do in the event of an out-of-range temperature reading. ACIP recommends storage and handling of vaccines in accordance with the vaccine manufacturer's instructions in order to maintain their potency (CDC, 2011c).

Vaccine-Specific Findings

Diphtheria, Tetanus, Acellular Pertussis (DTaP/Tdap)

Diphtheria, tetanus, and pertussis are serious diseases caused by bacterial infections (CDC, 2007a). Diphtheria infections are caused by the bacteria *Corynebacterium diphtheriae* and lead to a thick covering in the back of the throat (CDC, 2007a). This can lead to serious complications such as breathing problems, heart failure, paralysis, and death (CDC, 2007a).

The bacteria *Clostridium tetani* causes tetanus disease, otherwise known as lockjaw. Tetanus causes painful tightening of muscles all over the body (CDC, 2007a). This can lead to the inability to open the mouth or swallow and leads to death in 20% of cases (CDC, 2007a). Whereas diphtheria and pertussis are generally transmitted from person to person, tetanus generally enters the body through cuts or wounds (CDC, 2007a).

Pertussis, known as whooping cough, is caused by the bacteria *Bordetella pertussis*. Pertussis disease is characterized by coughing spells that can be so severe in infants that they are unable to eat, drink, or breathe (CDC, 2007a). This can lead to severe consequences such as pneumonia, seizures, brain damage, and death (CDC, 2007a).

Simultaneous administration of vaccines for diphtheria, tetanus, and pertussis has been a routine practice in the United States since the 1940s (CDC, 2006a). The first combined vaccine targeting diphtheria, tetanus, and pertussis (DTP) used a whole-cell pertussis (CDC, 1997). The efficacy of four doses of whole-cell DTP vaccine is between 70% and 90% (CDC, 1997). In 1997, ACIP released recommendations for DTaP, using acellular pertussis in place of whole-cell pertussis (CDC, 1997).

The following preparations are currently available in the United States: DTaP, DT, Td, Tdap. Routine immunization using DTaP is recommended by ACIP in five doses given intramuscularly at 2 months, 4 months, 6 months, 15 to 18 months, and 4 to 6 years (CDC, 2000a). DT is available for children who cannot tolerate the pertussis vaccine. Both DTaP and DT are licensed for use in children under 7 years of age (CDC, 2000a). Tdap is the version of the DTaP that is used in anyone 7 years or older. ACIP recommends that one-dose Tdap is administered to children between 11 and 18 years with 11 to 12 being the preferred age to immunize (CDC, 2000a). Td is the version of DT used in children and adults aged 7 and older and immunization every 10 years is recommended with Td after administration of the Tdap vaccine (CDC, 2000a). The efficacy of four doses of DTaP has been reported between 73% and 85% and the efficacy of the five-dose series has not been reported (CDC, 1997).

Haemophilus influenzae type b (Hib)

Hib is the leading cause of invasive bacterial disease among children in the United States (CDC, 1991). Sixty percent of children infected with Hib develop meningitis, which can lead to hearing loss, mental retardation, and death (CDC, 1991).

The first Hib vaccine was FDA-licensed for use in the United States in 1985. The Hib vaccine comes in several formulations, including both single Hib vaccine as well as Hib in combination with other vaccines such as tetanus and diphtheria (CDC, 1993). The number of doses recommended will depend on which formulation is used, but the ACIP recommendation is intramuscular injection at 2 months and 4 months (also 6 months for some formulations) with a booster between 12 and 15 months. Studies of Hib vaccine efficacy performed in the United States among children aged 15 to 60 months ranged from 74% to 96% (CDC, 1993).

Hepatitis A

Infection with Hepatitis A virus leads to liver disease that causes symptoms such as fever, malaise, loss of appetite, nausea, abdominal discomfort, dark urine, and jaundice (CDC, 2006b). In children younger than 6 years old, infections are typically asymptomatic and are only discovered after transmission to an adult occurs. In older children and adults, symptoms may be more severe and can lead to liver failure and death.

Between 1995 and 1996, the FDA licensed the inactivated Hepatitis A vaccine and in 1999 ACIP began recommending routine Hepatitis A immunization in children. The recommended vaccine administration and schedule is intramuscular administration in two doses spaced 6 to 18 months apart to all children starting at one year of age (CDC, 2006b).

The efficacy of the vaccine, as measured in two large double-blind, controlled, randomized clinical trials was 94% and 100% (CDC, 2006b). An analysis of the trends in hepatitis A incidence in 17 states with pre-1999 higher-than-average incidence rates shows an 88% decline in incidence since routine immunization of children was established (CDC, 2006b).

Hepatitis B

Hepatitis B virus also causes an infection in the liver that can lead to liver disease (CDC, 2012a). Although children are often asymptomatic, hepatitis B infection can result in fever, nausea, abdominal discomfort, and jaundice (CDC, 2012a). Persons infected as infants or children are more likely to develop chronic liver disease compared to persons infected later in life which can lead to death (CDC, 2005a).

Although hepatitis B immunization was recommended for some children and adults starting in 1982, it was not until 1990 that routine immunization was recommended by ACIP for all children (CDC, 2012a). The vaccine is administered via intramuscular injection at birth, 1 to 2 months, and 6 to 18 months (CDC, 2005a). In 2002, the FDA licensed a vaccine combining

DTaP, inactivated poliovirus, and hepatitis B vaccines (Pediarix). If immunizing with a combination vaccine, the recommended schedule to administer is birth, 2 months, 4 months and either 6 months or 12 to 15 months, depending on the vaccine. This will result in the child receiving a total of four doses of the hepatitis B vaccine. Efficacy data was not reported in the ACIP recommendations, but among children and adolescents from 1990 to 2004, as administration of the hepatitis B vaccine increased, rates of hepatitis B disease decreased by 94% (CDC, 2005a).

Influenza

Influenza, also known as the flu, is caused by the influenza virus. There are many different strains of this virus, but the most common symptoms of infection include fever, cough, sore throat, chills, and runny or stuffy nose. In young children, influenza can have more serious complications such as high fever, pneumonia, diarrhea, seizures, and death (CDC, 2011d).

There are two different types of influenza vaccines. Inactivated influenza vaccine is an inactivated (killed) strain of the flu that is injected into the muscle. Live attenuated (weakened) influenza vaccine is a weakened strain of the flu that is sprayed into the nostrils. Each vaccine contains three strains of influenza virus (two strains of influenza A and one strain of influenza B). The FDA recently approved a quadrivalent influenza vaccine that will include two influenza B strains (FDA, 2012).

Each year scientists attempt to predict which influenza strains will be the dominant cause of influenza and include these strains in the vaccine (CDC, 2011d). For this reason, annual single immunization is recommended for all children aged 6 months through 18 years, with two doses spaced four weeks apart recommended for children aged 6 months through 8 years who are getting their first ever dose of influenza vaccine (CDC, 2011e). Vaccine recommendation statements on influenza vaccines are published by ACIP on an annual basis. Efficacy and effectiveness data on annual influenza vaccines vary from year to year and depend on factors such as age and health status of the patient as well as the degree to which the vaccine produced in any given year corresponds to the dominant strains of influenza in the population (CDC, 2010b).

Measles, Mumps, Rubella (MMR)

The MMR vaccine targets three separate diseases (measles, mumps, and rubella) in one combination vaccine. The measles virus causes fever, rash, cough, and runny nose, and in severe cases can lead to pneumonia, brain damage, and death (CDC, 2008a). In 1963, a vaccine was first licensed for measles, but before then, it was estimated that nearly all children acquired measles during their childhood (CDC, 2008a). In 1989, ACIP issued recommendations for routine measles immunization with all children receiving two doses of measles-containing vaccine (CDC, 1998).

Mumps is a virus that can lead to fever, headache, orchitis, and swollen glands, and in severe cases, can lead to encephalitis, meningitis, and rarely, death. It can lead to long-term deafness and impaired fertility (CDC, 2008a). In 1950, a mumps vaccine was licensed for use in the United States. This vaccine relied on a killed version of the mumps virus, but it was determined

that this vaccine did not provide lasting immunity. When a live mumps virus was licensed for use in 1967, it slowly started to replace the killed virus vaccine. In 1978, the killed virus vaccine was withdrawn from the market (CDC, 1998).

Rubella, also known as German measles, is a virus that causes a rash, mild fever, and arthritis. In pregnant women, rubella can have serious health consequences such as miscarriage and birth defects (CDC, 2008a). Before a rubella vaccine was licensed in 1969, rubella was a common childhood disease (CDC, 1998).

In 1989, ACIP released recommendations that emphasized the use of the combined MMR vaccine for routine immunization with the first dose given at age 12 to 15 months and the second dose given at age 4 to 6 years (CDC, 1998). The ACIP recommendations did not contain information on the efficacy of the MMR combination vaccine. In 2010, ACIP issued recommendations that for the first dose, either the MMR or the MMR plus varicella (MMRV) vaccine could be used, but the separate MMR and varicella vaccines are preferred. For the second dose, MMRV is preferred (CDC, 2010c).

Pneumococcal Conjugate

Invasive pneumococcal disease is caused by an infection with *streptococcus pneumoniae* bacteria, which can cause blood infections, pneumonia, and meningitis (CDC, 2010d). In rare instances, pneumococcal meningitis can lead to deafness, brain damage, and death (CDC, 2010d).

In 2000, the FDA licensed pneumococcal conjugate vaccine (PCV)-7 for the prevention of invasive pneumococcal disease. This vaccine targeted seven different pneumococcal strains. In 2010, the FDA licensed PCV-13, a vaccine that includes 6 additional pneumococcal strains. In 2010, ACIP revised recommendations to replace PCV-7 with PCV-13 for routine immunization of infants. The vaccine is given via an intramuscular injection with a recommended schedule of four doses at 2 months, 4 months, 6 months, and 12 to 15 months (CDC, 2010e). An additional dose of pneumococcal polysaccharide (PPSV) is recommended for children with underlying medical conditions after completion of the four-dose PCV-13 series (CDC, 2010e).

The FDA licensure of PCV-13 was based on immunogenicity studies alone and did not include any efficacy data (CDC, 2010e). The only available efficacy data is based on the previously recommended vaccine, PCV-7, which had a clinical efficacy of 97% (CDC, 2010e). The effectiveness of the PCV-7 vaccine has been decreasing over time as new strains of *Streptococcus pneumoniae* bacteria are associated with documented invasive pneumococcal disease. It is anticipated that the PCV-13, covering 6 additional strains, will increase the vaccine's overall effectiveness against invasive pneumococcal disease (CDC, 2010e).

Polio

The poliomyelitis virus, known as polio, is a highly infectious disease of the nervous system that is spread by person-to-person contact. More than 99% of infected persons will have no symptoms or will have minor symptoms such as fever, headache, nausea, and mild leg pain (CDC, 2011f). Fewer than 1% of infected persons have severe complications such as permanent

paralysis of the limbs or paralysis of the respiratory muscles, which may result in death (CDC, 2011f).

There are two types of polio vaccines: inactivated poliovirus vaccine (IPV) introduced in the 1950s and the attenuated live oral poliovirus vaccine (OPV) introduced in the 1960s. In 2000, IPV became the exclusively recommended vaccine for routine immunization in the United States due to the rare chance that the OPV could lead to vaccine-associated paralytic polio (AAP, 2011; CDC, 2000b). The last reported case of polio caused by wild poliovirus in the United States was reported in 1979 (CDC, 2000b).

Poliovirus still exists in other parts of the world; therefore routine immunization of U.S. children is recommended to prevent a potential outbreak of poliovirus imported into the United States. (AAP, 2011). The ACIP-recommended schedule for routine immunization is four doses of IPV at 2 months, 4 months, 6 to 18 months, and 4 to 6 years (CDC, 2000b). The ACIP recommendation for routine immunization is based on efficacy data that shows that 90% to 100% of children develop protective antibodies after two doses of IPV and 99% to 100% develop antibodies after three doses (CDC, 2000b).

Rotavirus

Rotavirus is a virus that causes diarrhea, often in combination with fever and vomiting leading to dehydration (CDC, 2010f). It is seen most frequently in babies and young children. Before the rotavirus vaccine was developed, it was estimated that nearly all children had been exposed to the virus by the time they were five years old (CDC, 2010f).

In 2006, the first rotavirus vaccine (RV5) was approved by the FDA and recommended for routine immunization in three doses among infants in the United States (CDC, 2009b). In 2008, a second rotavirus vaccine (RV1) was FDA approved and ACIP-recommended routine immunization in a two-dose series (CDC, 2009b). The vaccine is given orally at 2 months and 4 months, and again at 6 months if using the RV5 vaccine. ACIP does not express a preference for one vaccine over the other (CDC, 2009b). The efficacy of the RV5 rotavirus vaccine has been estimated at 74% for rotavirus of any severity and 85% to 98% against severe rotavirus gastroenteritis (CDC, 2009b). Efficacy data of RV1 in the United States was not reported (CDC, 2009b).

Varicella

Varicella, also known as chickenpox, is a highly contagious disease caused by the varicella-zoster virus. Common symptoms include rash, itching, and fever. More severe cases can lead to pneumonia, severe skin infections, brain damage, or death (CDC, 2008b).

There are two live varicella vaccines available in the United States. One is a single-antigen varicella vaccine while the other is a combination with measles, mumps, and rubella vaccines (MMRV) (CDC, 2007b). The 2007 ACIP recommendations call for two doses of vaccine administered subcutaneously, with the first dose at age 12 to 15 months and the second dose at age 4 to 6 years (CDC, 2007b). Subsequent recommendations regarding the combination

varicella and MMR vaccine (MMRV) indicate that separate varicella and MMR vaccinations should be administered for the first dose and the combination MMRV is preferred for the second dose (CDC, 2010c).

Efficacy studies of the varicella vaccine have shown that the 10-year efficacy among children immunized with one dose of varicella vaccine ranged from 90% to 94% and 96% to 98% for children receiving two doses (CDC, 2007b).

Immunizations Recommended for Adolescents

Human papillomavirus (HPV)

HPV is the most commonly sexually transmitted infection in the United States (CDC, 2007c). It is estimated that 80% of people will be infected with HPV at some point in their lifetime. The majority of infections do not present any clinical symptoms, and resolve on their own. Clinical manifestations of HPV infections include genital warts. Persistent infection is the cause of cervical cancer in women and other anogenital cancers (CDC, 2007c).

In 2006, the FDA licensed the quadrivalent HPV vaccine (strains 6, 11, 16, 18) and shortly thereafter ACIP released a recommendation for routine immunization of females (CDC, 2007c). The bivalent HPV vaccine (strains 16, 18) was FDA-approved and ACIP-recommended routine immunization in 2009. The recommendations for both HPV vaccines call for a three-dose series given intramuscularly at age 11 to 12 years, a second dose 1 to 2 months later, with the final dose 6 months from the first (CDC, 2010g). In October 2011, ACIP released recommendations for the routine immunization of males on the same schedule as previously released for females (CDC, 2011g).

Efficacy data on the bivalent HPV vaccine in females was taken from clinical trials and ranges from 86.7% to 92.9% in prevention of precancerous lesions and disease (CDC, 2010g). The quadrivalent vaccine had efficacy ranges of 98.2% to 100% in preventing precancerous lesions and disease and 99% efficacy in preventing genital warts among females (CDC, 2010g). A phase III clinical trial on the use of the quadrivalent vaccine in males found that efficacy of the prevention of genital warts was 89.3% (CDC, 2011g). The efficacy data does not include health outcomes attributable to strains of HPV outside of those targeted by the vaccines.

Meningococcal

Meningococcal disease is a bacterial infection that is the leading cause of bacterial meningitis in children aged 2 to 18 years in the United States (CDC, 2011h). Approximately 10% to 15% of people who get meningococcal disease die, while another 11% to 19% lose a limb, become deaf or mentally retarded, or suffer seizures (CDC, 2011h). Children less than one year of age as well as those aged 16 to 21 years are at greatest risk (CDC, 2011h).

There are two types of meningococcal vaccines: meningococcal conjugate (MCV4) and meningococcal polysaccharide (MPSV4). MCV4 is used in populations aged 55 or younger whereas MPSV4 is used in populations 55 and older (CDC, 2011i). Both types of vaccines cover four strains of meningococcal disease. In 2010, ACIP approved new recommendations regarding

routine immunization of adolescents. ACIP recommends MCV4 given intramuscularly at age 11 to 12 and a booster dose at age 16 (CDC, 2011i). One study on the overall vaccine effectiveness reported in adolescents has been conducted. This overall vaccine effectiveness of persons immunized 0 to 5 years earlier was 78% (CDC, 2011i).

Adverse Reactions

Although routine immunization during childhood has led to a great reduction in childhood infectious diseases, adverse reactions to immunizations are reported each year (CDC, 2011c). Mild adverse reactions are the most common and include fever, headache, vomiting, nausea, diarrhea, abdominal pain, fussiness, tiredness, hoarseness, itchy eyes, runny nose, nasal congestion, cough, and muscle or joint pain (CDC, 2012b). Other common mild reactions include pain, redness, swelling, warmth, soreness, or tenderness where the shot was given. Moderate reactions are uncommon and include seizure and high fever (105 degrees Fahrenheit or more) (CDC, 2012b). Severe reactions are very rare (occurring in less than one in a million children) but can include pneumonia, seizures, coma, deafness, permanent brain damage, and life-threatening allergic reactions (CDC, 2012b).

Table 7. Summary of the Advisory Committee on Immunization Practices (ACIP) Recommendations for Children (Aged 0-18 Years)

Vaccine	Vaccine-Preventable Disease	Preventable Health Outcomes	Schedule and Route of Administration	Storage and Handling	Efficacy Rate
Diphtheria, tetanus, acellular pertussis (DTaP/Tdap) (a)	Diphtheria, tetanus (lockjaw), pertussis (whooping cough)	Breathing problems, muscle pain, heart failure, coughing, pneumonia, brain damage, paralysis, death	5 doses DTaP given intramuscularly at 2m, 4m, 6m, 15-18m, 4-6yrs; 1 dose Tdap at 11-18 yrs	Refrigerate at 35-46 °F; do not freeze	Efficacy of 4-dose series is 73%-85%; 5-dose series not reported
Hib (b)	<i>Haemophilus influenzae</i> type b	Bacterial meningitis, hearing impairments, neurological disorders, death	Intramuscular injection (2-3 doses) at 2m, 4m (6m) + booster at 12-15m	Refrigerate at 35-46 °F	74%-96% efficacy
HepA (c)	Hepatitis A	Liver disease causes illness such as fever, nausea, jaundice, and death	Intramuscular injection (2 doses) 6m to 18m apart starting at 1yr	Refrigerate at 35-46 °F; do not freeze	94%-100% efficacy
HepB (d)	Hepatitis B	Liver disease causes illness such as fever, nausea, abdominal discomfort, jaundice, and death	Intramuscular injection (3 doses) at birth, 1-2m, and 6-18m; may have 4 doses if using combo vaccines	Refrigerate at 35-46 °F; do not freeze	Not reported
HPV (e)	Human papillomavirus infection	Genital warts, cervical cancer, anogenital cancers	Intramuscular injection (3 doses) at 11-12yrs, 1-2m from first dose, 6m from first dose	Refrigerate at 35-46 °F; do not freeze; protect from light	87%-93% efficacy in preventing precancerous lesions & disease in females
Influenza (f)	Influenza (flu)	Fever, cough, runny or stuffy nose, pneumonia, death.	Annual intramuscular injection/ intranasally (1 dose) for children aged 6m-18yrs	Refrigerate at 35-46 °F; protect from light	Variable from year to year
MMR (g)	Measles, mumps, and rubella (German measles)	Fever, rash, cough, pneumonia, brain damage, meningitis, death. Rubella in pregnant women can lead to miscarriage and birth defects.	Subcutaneous injection (2 doses) at 12-15m and 4-6yrs; MMRV preferred for dose 2	Refrigerate at 35-46 °F; protect from light	Not reported
Meningococcal conjugate (MCV4) (h)	Meningococcal disease	Amputation of limb, deafness, mental retardation, seizures, death	Given intramuscularly at 11-12yrs with a booster dose at 16yrs	Refrigerate at 35-46 °F; protect from light	78% effectiveness 0-5 years post-immunization

Table 7. Summary of the Advisory Committee on Immunization Practices (ACIP) Recommendations for Children (Aged 0-18 Years) (Cont'd)

Pneumococcal conjugate (PCV-13) (i)	Pneumococcal disease	Blood infections, pneumonia, meningitis, and death.	Intramuscular injection (4 doses) at 2m, 4m, 6m, 12-15m	Refrigerate at 35-46 °F	PCV-13, not available; PCV-7, 97% efficacy
Polio (IPV) (j)	Polio	Fever, nausea, leg pain, limb paralysis and death.	Subcutaneous or intramuscular injection (4 doses) at 2m, 4m, 6-18m, 4-6yrs	Refrigerate at 35-46 °F	99%-100% efficacy after 3 doses
Rotavirus (k)	Rotavirus	Diarrhea, fever, vomiting, dehydration.	Given orally (2 or 3 doses) at 2m and 4m (+ 6m for RV5)	Refrigerate at 35-46 °F; protect from light	85%-98% efficacy against severe disease
Varicella (l)	Varicella (chickenpox)	Rash, itching, fever, brain damage, pneumonia, death.	Subcutaneous (2 doses) at 12-15m and 4-6yrs; MMRV preferred for dose 2	Freeze at ≤5 °F; discard after 72 hrs out of freezer; protect from light	96%-98% for 2 doses

Source: California Health Benefits Review Program, 2012. Adapted from multiple sources, as indicated in *Notes*.

Notes: (a) CDC, 1997; CDC, 2000a; (b) CDC, 1991; CDC, 1993; (c) CDC, 2006b; (d) CDC, 2005a; (e) CDC, 2007c; (f) CDC, 2011e; (g) CDC, 1998; CDC, 2010g; (h) CDC, 2011i; (i) CDC, 2010e; (j) CDC, 2000b; (k) CDC, 2009b; (l) CDC, 2007b; CDC, 2010c.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

AB 2064 has many requirements including but not limited to a health insurance benefit mandate.

This report addresses only the benefit mandate and makes no comment on the potential impacts of other requirements contained in AB 2064.

For DMHC-regulated plans and CDI-regulated policies that provide coverage for childhood and adolescent immunizations, the benefit mandate in AB 2064 would prohibit cost sharing (defined as including deductibles, copayments, and coinsurance, and “other cost-sharing mechanisms”) for administration of a childhood or adolescent immunization or for procedures related to administration. The mandate would also prohibit dollar-limit provisions for childhood or adolescent immunization-related procedures. Dollar-limit provisions establish a limit (either an annual or a lifetime limit) beyond which benefit coverage is no longer provided.

This report does not examine elimination of cost sharing for vaccines that are administered through immunization-related procedures. These would still be allowable if AB 2064 were enacted.

The population most affected by AB 2064 would be those who would move from having benefit coverage that is currently not compliant with AB 2064 for immunization-related procedures because of cost sharing to compliant benefit coverage, or 1.7% of enrollees. This report focuses on immunizations among children and adolescents, aged 0 to 18 years. The terms “childhood” and “adolescent” are not defined in the language of AB 2064. For this analysis, CHBRP assumes the phrase indicates persons aged 18 years or less because AB 2064 references existing mandates⁴¹ that require coverage for immunizations listed in the most current Advisory Committee on Immunization Practices (ACIP) recommendations. Therefore, CHBRP has assumed for this analysis that AB 2064 would prohibit cost sharing for immunization-related procedures for ACIP-recommended immunizations.

This section will present the current (baseline) costs and benefit coverage for immunization-related procedures, and then provide the estimated utilization, cost, and benefit coverage impacts of AB 2064. For further details on the underlying data sources and methods, please see Appendix D at the end of this document.

Current (Baseline) Benefit Coverage, Utilization, and Cost

Current Coverage of the Mandated Benefit

CHBRP conducted a Bill-Specific Coverage Survey of California’s largest health plans and insurers. Responses to this survey represented approximately 68% of the privately funded CDI-regulated market and 82% of the privately funded DMHC-regulated market. Combined, responses to this survey represent 79% of the privately funded market subject to state mandates.

⁴¹ Health and Safety Code Sections 1367.35, 1367.002 and Insurance Code Sections 10123.5, 10112.2

Premandate, enrollees may have coverage for immunizations that could be subject to multiple types of cost sharing. There could be copayments associated with a well-child visit in which the immunization is administered, the vaccine itself (which is administered as part of the immunization), and the immunization-related procedures. Coinsurance may also apply, which would include all costs except services that have been specifically excluded. Finally, enrollees may also have an applicable deductible, if the plan or policy includes one. In this analysis, CHBRP focuses on the cost sharing for immunization-related procedures only, as only cost sharing for immunization-related procedures would be prohibited by the benefit mandate portion of AB 2064. “Cost sharing” includes copayments, coinsurance, exclusion from deductibles, and dollar limits. CHBRP assumes that existing cost sharing for the well-child visit or the vaccine itself would not be reduced if AB 2064 were enacted. If immunization-related procedures are not charged separately from the well-child visit or vaccine copayment, then the copayment is assumed to remain the same postmandate.

Premandate, nearly all (98.3%) enrollees with health insurance that would be subject to AB 2064 have benefit coverage for immunization-related procedures without cost sharing. If AB 2064 were enacted, 100% of enrollees would have mandate-compliant coverage for immunization-related procedures with no cost sharing (see Table 1 in *Executive Summary*).

DMHC-regulated Medi-Cal managed care plans already provide mandate-compliant coverage for immunization-related procedures with no cost sharing for enrollees. DMHC-regulated CalPERS HMOs also already provide mandate-compliant coverage, as do DMHC-regulated MRMIB plans (which enroll beneficiaries of the Healthy Families program, the Aid to Infants and Mothers (AIM) program, and the Major Risk Medical Insurance Program (MRMIP)), Therefore, CHBRP estimates that AB 2064 would have no impact on these populations.

Current Utilization Levels

Premandate, CHBRP estimates that the 1.46 million enrollees aged 0 to 4 years would obtain an average of 2.94 immunizations each (including both immunization-related procedures and vaccines) within a 12-month period, for a total of 4.285 million immunization-related procedures (Table 1). The 1.12 million enrolled children aged 5 to 7 would obtain an average of 0.64 immunization each, for a total of 719,000 immunization-related procedures. Finally, the 5.19 million enrollee children aged 8 to 19 would obtain an average of 0.45 immunizations each, for a total of 2.33 million immunization-related procedures.

Current Average Cost of Immunizations

The cost of an immunization is the total of the cost of the vaccine plus the cost of the immunization-related procedures. Currently, the average price for a vaccine ranges from \$7.50 for a flu vaccine to \$180 for a MMRV vaccine. The average price for immunization-related procedures is \$14.50 to \$27, with most costing between \$23 and \$27.

Current (Baseline) Premiums and Expenditures

Table 8 (at the end of this section) presents per member per month (PMPM) premandate estimates for premiums and expenditures by market segment. Prior to the mandate, total expenditures PMPM are \$464 in DMHC-regulated privately funded large-group plans, \$426 in small-group plans, and \$530 in individual plans. Total expenditures PMPM for CDI-regulated policies are \$569 in the large-group market, \$562 in the small-group market, and \$288 in the individual market. In publicly funded plans, the expenditures PMPM are \$468 for CalPERS HMOs, \$279 for Medi-Cal managed care for those over 65, \$164 for Medi-Cal managed care for those under 65, and \$118 for MRMIB plans.

The Extent to Which Costs Resulting From Lack of Benefit Coverage Would Be Shifted to Other Payers, Including Both Public and Private Entities

CHBRP estimated no shift in costs among private or public payers as a result of current benefit coverage of cost sharing for immunization-related procedures, as the rate of benefit coverage is nearly 100%, and there is little room for a lack of coverage to cause a shift.

Public Demand for Benefit Coverage

Considering the criteria specified by CHBRP's authorizing statute, CHBRP reviews public demand for benefits relevant to a proposed mandate in two ways. CHBRP:

- considers the bargaining history of organized labor
- compares the benefits provided by self-insured health plans or policies (which are not regulated by the DMHC or CDI and so not subject to state-level mandates) with the benefits that are provided by plans or policies that would be subject to the mandate

On the basis of conversations with the largest collective bargaining agents in California, CHBRP concluded that unions currently do not include cost-sharing arrangements for immunization-related procedures in their health insurance negotiations. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.⁴²

Among publicly funded self-insured health insurance policies, the preferred provider organization (PPO) plans offered by CalPERS currently have the largest number of enrollees. The CalPERS PPOs provide benefit coverage similar to what is available through group health insurance plans and policies that would be subject to the mandate.

To further investigate public demand, CHBRP used the bill-specific coverage survey to ask carriers who act as third-party administrators for (non-CalPERS) self-insured group health insurance programs whether the relevant benefit coverage differed from what is offered in group market plans or policies that would be subject to the mandate. The responses indicated that there were no substantive differences.

Given the lack of specificity in labor-negotiated benefits and the general match between health insurance that would be subject to the mandate and self-insured health insurance (not subject to

⁴² Personal communication, S Flocks, California Labor Federation, March 2012.

state-level mandates), CHBRP concludes that public demand for coverage is essentially satisfied by the current state of the market.

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?

Impact on access and health treatment/service availability

The total estimated increase in the number of immunizations is less than 100, which would have no impact on the market supply of the vaccines or the supply of providers available to administer vaccines. Therefore, CHBRP estimates that AB 2064 will have no impact on the access to immunizations, or in the availability of immunizations.

Impact on the health benefit of the treatment/service newly available under compliant coverage

The existing body of academic literature provides strong evidence of an association between decreasing cost sharing for immunizations (combining out-of-pocket costs for both vaccines and immunization-related procedures) and increasing rates of immunizations among children and adolescents (Briss et al., 2000; EAPO, 2007; Molinari et al., 2007; Rodewald et al., 1997). A meta-analysis performed by Briss et al. was performed on studies from 1980 to 1997. In their article, Briss and co-authors summarized the findings of the analysis along with their recommendation as the federal Task Force on Community Preventive Services. One of their key conclusions was that reducing enrollee cost sharing was effective in increasing the rates of immunization, overall (Briss et al., 2000). The median increase in the immunization rate was 10 percentage points when reduction of cost sharing was the only intervention performed. An updated meta-analysis that included studies from 1997 to 2007 remains unpublished (EAPO, 2007). The summary page of the Task Force's website, housed in the Epidemiology Branch Program Office of the Centers for Disease Control (CDC), indicates that the unpublished update resulted in similar conclusions, and found an even larger impact of reducing cost sharing on increasing immunization rates (a median increase of 22 percentage points).

Molinari et al. (2007) used claims data from both public and private insurers in Georgia to estimate a measured elasticity of demand for enrollee copayment and coinsurance expenditures for childhood immunizations (up to age 5) that were included in the ACIP-recommended series. They found that a 1% decrease in out-of-pocket costs was associated with a 0.07% increase in immunization rates. CHBRP found no literature pertaining to whether parents who face cost sharing for immunizations delay getting their children immunized.

While the populations in these studies were not directly applicable to the population with health insurance that would be subject to AB 2064 (and therefore not used to calculate either baseline or changes in utilization rates), they indicate a body of academic literature that has come to the conclusion that reductions in cost sharing for enrollees is linked to increases in immunization rates. The improved health outcomes associated with ACIP-recommended immunizations (see *Medical Effectiveness* section) are also universally accepted within the scientific community. It is

strongly indicated that decreasing consumer cost sharing will lead to more children achieving these desirable long-term health outcomes, as will be discussed in further detail in the *Public Health Impacts* section of this report.

Impact on per-unit cost

CHBRP is aware of no evidence in the literature indicating that prohibiting cost sharing for immunization-related procedures or vaccines increases their prices. Additionally, the increase in utilization is estimated to be less than 100 units for the total child and adolescent population subject to AB 2064. Therefore, CHBRP does not expect that the unit cost of immunizations (including both procedures and vaccines) would change, postmandate.

How Would Utilization Change As a Result of the Mandate?

Postmandate, CHBRP estimates that there will be some increase in utilization due to the change in cost sharing, but that the total increase in the number of immunizations will be less than 100 for all age groups combined. However, approximately 89,000 immunization-related procedures would no longer be subject to cost-sharing.

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

CHBRP assumes that if health care costs increase as a result of increased utilization or changes in unit costs, there is a corresponding proportional increase in administrative costs. CHBRP assumes that the administrative cost proportion of premiums is unchanged. All health plans and insurers include a component for administration and profit in their premiums. CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and/or CDI-regulated policies will remain proportional to the increase in premiums.

Impact of the Mandate on Total Health Care Costs

Changes in total expenditures

CHBRP estimates that AB 2064 would increase total net annual expenditures by \$155,000 or 0.0001% for the insured population (see Table 1 in *Executive Summary*). This is due to a \$648,000 increase in health insurance premiums partially offset by reductions in enrollee out-of-pocket expenditures for covered benefits, including copayments, coinsurance, and deductible exclusions (\$493,000).

Potential cost offsets or savings in the short term

In some cases, an increase in total expenditures due to an expansion in benefit coverage is accompanied by a decrease in the expenditures for other health care services, known as a “cost offset.” As the change in utilization is expected to be less than 100 additional immunizations, CHBRP does not estimate a cost offset in the first year following implementation.

Impact on long-term costs

CHBRP estimates there would be some long-term decrease in costs due to the mandate, in addition to the 1-year impacts presented early in this section, but that these are too small to quantify with an estimated increased utilization of less than 100 units. While future vaccine approvals may increase costs if those immunizations prove to be much more expensive than their aggregate savings, this has not been the case with the existing ACIP-approved immunizations.

Impacts for Each Category of Payer Resulting from the Benefit Mandate

Changes in expenditures and PMPM amounts by payer category

Increases in per member per month (PMPM) premiums due to the prohibition on cost sharing for immunization-related procedures vary by regulator, as all DMHC-regulated plans would have no impact if AB 2064 were enacted, but there would be some impact for CDI-regulated policies (Table 9).

Increases as measured by percentage changes in PMPM premiums among CDI-regulated policies are estimated to range from a low of 0.0030% (for large-group market policies) to a high of 0.0101% (for individual market policies). Increases as measured by PMPM premiums are estimated to be \$0.02 for CDI-regulated policies.

The largest shift in expenditures would be from out-of-pocket expenses from enrollees in CDI-regulated individual policies to premiums. In this market, \$0.02 of the current out-of-pocket expenses (measured as PMPM costs) would be expected to shift to the health plan or insurer, who would then pass this increase along to all enrollees as increase premiums.

Increases as measured by percentage changes in PMPM premiums are estimated to range from a low of 0.00% (for all DMHC-regulated plans) to a high of 0.0101% (for CDI-regulated individual policies) in the affected market segments. Increases in premiums as measured per member per month (PMPM) are estimated to range from \$0.00 to \$0.02.

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.

CHBRP's method for estimating the impact of premium increases on the number of individuals who drop their private insurance is described on CHBRP's website.⁴³

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.

⁴³ See: http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

Table 8. Baseline (Premandate) Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2012

	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)	10,538,000	2,231,000	695,000	854,000	201,000	3,539,000	888,000	389,000	1,108,000	1,439,000	21,882,000
Total enrollees in plans/policies subject to AB 2064	10,538,000	2,231,000	695,000	854,000	201,000	3,539,000	888,000	389,000	1,108,000	1,430,000	21,873,000
Average portion of premium paid by employer	\$367.66	\$292.19	\$0.00	\$356.28	\$279.00	\$164.00	\$98.18	\$390.79	\$311.39	\$0.00	\$72,614,883,000
Average portion of premium paid by employee	\$72.69	\$95.87	\$442.61	\$89.07	\$0.00	\$0.00	\$15.00	\$110.30	\$102.25	\$223.11	\$22,250,196,000
Total premium	\$440.36	\$388.06	\$442.61	\$445.35	\$279.00	\$164.00	\$113.19	\$501.09	\$413.64	\$223.11	\$94,865,079,000
Enrollee expenses for covered benefits (Deductibles, copays, etc.)	\$24.33	\$38.10	\$86.98	\$22.97	\$0.00	\$0.00	\$4.36	\$67.45	\$148.54	\$65.27	\$8,521,470,000
Enrollee expenses for benefits not covered (e)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0
Total expenditures	\$464.69	\$426.16	\$529.59	\$468.31	\$279.00	\$164.00	\$117.55	\$568.54	\$562.18	\$288.38	\$103,386,549,000

Source: California Health Benefits Review Program, 2012.

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, MRMIP) 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 members, about 58%, or 495,000, 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, 7,000 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.

Table 9. Impacts of the Mandate on Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2012

	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)	10,538,000	2,231,000	695,000	854,000	201,000	3,539,000	888,000	389,000	1,108,000	1,439,000	21,882,000
Total enrollees in plans/policies subject to AB 2064	10,538,000	2,231,000	695,000	854,000	201,000	3,539,000	888,000	389,000	1,108,000	1,430,000	21,873,000
Average portion of premium paid by employer	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0117	\$0.0109	\$0.0000	\$200,000
Average portion of premium paid by employee	\$0.0000	\$0.0000	\$0.0001	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0033	\$0.0033	\$0.0224	\$448,000
Total premium	\$0.0000	\$0.0000	\$0.0001	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0150	\$0.0142	\$0.0224	\$648,000
Enrollee expenses for covered benefits (Deductibles, copays, etc.)	\$0.0000	\$0.0000	-\$0.0001	\$0.0000	\$0.0000	\$0.0000	\$0.0000	-\$0.0118	-\$0.0113	-\$0.0167	-\$493,000
Enrollee expenses for benefits not covered (e)	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0
Total expenditures	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0032	\$0.0030	\$0.0058	\$155,000
Percentage impact of mandate											
Insured premiums	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0030%	0.0034%	0.0101%	0.0007%
Total expenditures	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0006%	0.0005%	0.0020%	0.0001%

Source: California Health Benefits Review Program, 2012.

- 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, MRMIP) 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 495,000 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, 7,000 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.

PUBLIC HEALTH IMPACTS

For plans and policies that provide coverage for childhood and adolescent immunizations, AB 2064 would prohibit cost sharing (deductibles, copayments, and coinsurance, and “other cost-sharing mechanisms”) for the administration of a childhood or adolescent immunization or for procedures related to administration. To determine whether this mandate would produce public health impacts, at least two criteria must be met: the procedure must be medically effective and there must be a change in the utilization of the procedure. In the case of AB 2064, medical effectiveness is established, and CHBRP estimates that there would be an increase of fewer than 100 immunizations.

The evidence presented in the *Medical Effectiveness* section indicates that the ACIP-recommended childhood and adolescent vaccines are medically effective in reducing or eliminating morbidity and mortality related to vaccine-preventable diseases. Immunization-related procedures are necessary to ensuring the medical effectiveness of those vaccines.

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, academic literature shows that decreased cost sharing is associated with increased immunization rates, thus CHBRP projects that AB 2064 would remove a cost-sharing barrier. CHBRP expects that utilization would mimic that of the population who had no cost sharing premandate; thus, utilization is estimated to increase by fewer than 100 immunizations postmandate.

Additionally, CHBRP estimates that approximately 89,000 immunization-related procedures would no longer be subject to cost-sharing postmandate [insert footnote]. This would result in a savings of about \$493,000 in out-of-pocket expenses (coinsurance and deductibles) for those enrollees with newly compliant coverage who use immunizations. The reduction in immunization-related procedures subject to cost-sharing and their subsequent cost savings to enrollees affect the CDI-regulated market only. The DMHC-regulated market is compliant with AB 2064 pre-mandate.

CHBRP estimates that the health insurance benefit mandate in AB 2064 would result in less than 100 additional immunizations administered postmandate. Therefore, CHBRP estimates that AB 2064 would have no statistically significant impact on California’s rates of immunizations and vaccine-preventable diseases and their related mortality.

CHBRP estimates that approximately 89,000 immunization-related procedures would be no longer subject to cost sharing postmandate. This would result in a savings of about \$493,000 in out-of-pocket expenses (coinsurance and deductibles) for those enrollees with newly compliant coverage who use immunizations. Those children whose parents abstained from or delayed immunization due to cost-sharing requirements for immunization-related procedures may benefit from AB 2064, as this cost barrier to completing recommended immunizations in a timely manner would be eliminated.

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).

Impact on Gender Disparities

CHBRP found evidence that there are no disparities in the ACIP-recommended childhood and adolescent immunization rates between males and females with the exception of the male rate of HPV immunization, which lags behind that of females. (See *Background on Immunization and Vaccine-Preventable Diseases* in the *Introduction*). However, this disparity is likely due to the later (2009) approval by the U.S. Food and Drug Administration (FDA) of the quadrivalent HPV vaccine’s use in males. The gap in uptake may close in the near future due to the more recent ACIP recommendation (2011) for routine use of that vaccine in males aged 11 to 12 years. Additionally, CHBRP found no evidence that there are gender disparities in incidence of vaccine-preventable diseases in children and adolescents.

Impact on Racial/Ethnic Disparities

Evaluating the impact on racial and ethnic health disparities is particularly important because racial and ethnic minorities report having poorer health status and worse health indicators (KFF, 2007). CHBRP found one recent California report suggesting that there are few, if any, racial or ethnic disparities in California’s rates of the 4:3:1:3:3:1 vaccine series (see *Background on Immunization and Vaccine-Preventable Diseases* in the *Introduction*) (CDPH, 2011a,b).

The incidence of vaccine-preventable diseases is low with the exception of pertussis (Table 7) and racial/ethnic disparities among those rates may not be statistically stable. Of the 12 reported vaccine-preventable diseases, CDPH reports differences in rates for three diseases. Rates of hepatitis A are 3.5 times higher in Hispanic children than in white children (0.78 cases/100,000 and 0.22 cases/100,000, respectively). Rates of acute hepatitis B are higher for Blacks (1 case/100,000) than other races (that range between 0.50 and 0.90 cases/100,000); however, 50% of the hepatitis B cases were in whites, and 25% in Hispanics. The recent outbreak of pertussis resulted in higher incidence rates for Blacks (32 cases/100,000) and Hispanics (35 cases/100,000) than whites (18 cases/100,000) and Asian/Pacific Islanders (15 cases/100,000) (CDPH, 2011b). CHBRP found no reports about racial/ethnic disparities in mortality related to vaccine-preventable diseases, most likely due to the rare occurrence.

CHBRP estimates that, to the extent that racial and ethnic disparities may exist in rates of immunization, vaccine-preventable disease incidence, and related mortality, AB 2064 would have no statistically significant impact on those disparities due to the use of fewer than 100 additional immunizations postmandate. Furthermore, CHBRP found no evidence of gender disparities in rates of immunization, and vaccine-preventable disease incidence and related mortality. CHBRP estimates no statistically significant changes in these rates due to AB 2064.

Impacts on Premature Death and Economic Loss

Premature death is often defined as death before the age of 75 years (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 (CDPH, 2010b; 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 whether the proposed mandated benefit impacts mortality. In cases where a reduction in mortality is projected, a literature review is conducted to determine whether 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 amounts (i.e., valuation of a population’s lost years of work over a lifetime). For CHBRP analyses, a literature review is conducted to determine whether 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

Premature death, morbidity, and disability attributable to childhood vaccine-preventable disease has declined significantly since the introduction of immunizations for pertussis, diphtheria, tetanus, polio, measles, mumps, rubella, hepatitis B, Hib, and varicella (CDPH, 2008). The rate of vaccine-preventable diseases in California ranged from 0 to 233 cases/1 million Californians for hepatitis A, acute hepatitis B, measles, meningococcal disease, mumps, rubella, tetanus, varicella, and Hib. An outbreak of pertussis in 2009 produced 9,156 cases in 2010, although rates are decreasing through 2012 (CDPH, 2010b; CDPH, 2011c). Without immunization programs in the U.S., experts estimate that 33,564 preventable deaths would occur each year, including 24,721 deaths from diphtheria and 1,049 deaths from pertussis (NVAC, 2009).

CHBRP expects AB 2064 would produce no statistically significant change in California’s premature death rates for vaccine-preventable diseases because CHBRP estimates that the bill would increase utilization by fewer than 100 immunizations postmandate.

Economic Loss

CHBRP found two studies that evaluated the overall impact of immunizations on reducing economic loss associated with vaccine-preventable diseases. Zhou et al. (2005) modeled a 2001 birth cohort and found that the 6-vaccine routine childhood immunization series⁴⁴ resulted in societal cost savings. The routine immunization saved almost \$10 billion in direct costs (outpatient and inpatient cost for treatment and complications of diseases) and \$43 billion in indirect costs (productivity loss due to premature death, permanent disability, and opportunity

⁴⁴ 4:3:1:3:3:1= ≥4DTaP4 DTaP; ≥3 polio; ≥1 MMR; ≥3Hib3 Hib; ≥3 Hep B; ≥1 varicella (chickenpox) vaccines

cost for caregivers missing work to care for the sick) (Zhou et al., 2005). Furthermore, the authors estimated 33,564 deaths without the vaccine series and 33,101 deaths prevented (saved) with the vaccine series. Additionally, the National Vaccine Advisory Committee reported that immunizations recommended prior to 2000 are cost-saving; each dollar spent on childhood immunization results in more than \$5 saved in medical costs and more than \$11 saved in societal costs. Those immunizations recommended post-2000 are cost-effective (NVAC, 2009).

Although vaccine-preventable diseases are known to cause economic loss, CHBRP expects AB 2064 would produce no statistically significant change in years of life saved or reductions in lost productivity due to less than an estimated 100 additional childhood and adolescent immunizations administered postmandate.

Long-Term Public Health Impacts

Evidence demonstrates that childhood and adolescent immunizations (including their administration) reduce economic loss, premature death, and disability. CHBRP estimates that beyond 12 months postmandate, AB 2064 would have no statistically significant impact on California's rates of immunizations and vaccine-preventable diseases and mortality due to an estimated increase of less than 100 additional immunizations administered; however, those persons who abstained from or delayed immunization due to cost-sharing requirements for immunization-related procedures may benefit from AB 2064 by helping them complete their recommended immunization schedule.

APPENDICES

Appendix A: Text of Bill Analyzed

On February 28, 2012, the Assembly Committee on Health requested that CHBRP analyze AB 2064.

Only one of the requirements in AB 2064 is a health insurance benefit mandate (as defined by CHBRP's authorizing statute⁴⁵). The benefit mandate would appear in the Health and Safety Code and the Insurance Code as follows:

AB 2064 would amend Section 1367.36 of the Health and Safety Code to read:

(g) A health care service plan contract issued, amended, or renewed on or after January 1, 2013, that provides coverage for childhood and adolescent immunizations pursuant to Section 1367.3 or 1367.35 shall not do either of the following:

(1) Impose a deductible, copayment, coinsurance, or other cost-sharing mechanism for the administration of a childhood or adolescent immunization or for procedures related to that administration. Nothing in this paragraph prohibits charging a deductible, copayment, coinsurance, or other cost-sharing mechanism for procedures, services, or treatment unrelated to an immunization.

(2) Contain a dollar limit provision for the administration of childhood and adolescent immunizations or include the cost of those immunizations in a dollar limit provision of the contract.

AB 2064 would amend Section 10123.56 of the Insurance Code to read:

(b) A health insurance policy issued, amended, or renewed on or after January 1, 2013, that provides coverage for childhood and adolescent immunizations pursuant to Section 10123.5 or 10123.55 shall not do either of the following:

(1) Impose a deductible, copayment, coinsurance, or other cost-sharing mechanism for the administration of a childhood or adolescent immunization or for procedures related to that administration. Nothing in this paragraph prohibits charging a deductible, copayment, coinsurance, or other cost-sharing mechanism for procedures, services, or treatment unrelated to an immunization.

(2) Contain a dollar limit provision for the administration of childhood and adolescent immunizations or include the cost of those immunizations in a dollar limit provision of the contract.

The full text of the bill follows.

ASSEMBLY BILL No. 2064

Introduced by Assembly Member V. Manuel Pérez

February 23, 2012

An act to amend Section 1367.36 of the Health and Safety Code, and to add Section 10123.56 to the Insurance Code, relating to health care coverage.

Legislative Counsel's Digest

AB 2064, as introduced, V. Manuel Pérez. Immunizations for

⁴⁵ Available at http://chbrp.org/documents/authorizing_statute.pdf

children: reimbursement of physicians.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of that act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Existing law requires every health care service plan or health insurer that covers hospital, medical, or surgical expenses on a group basis to provide certain preventive health care benefits for children, including immunizations. Existing law specifies the reimbursement rate with respect to immunizations that are not part of the current contract between a health care service plan and a physician or physician group.

This bill would require a health care service plan or health insurer that provides coverage for childhood and adolescent immunizations to reimburse a physician or physician group in an amount not less than the actual cost of acquiring the vaccine plus the cost of administration of the vaccine, as specified. The bill would prohibit a health care service plan contract or health insurance policy providing coverage for childhood or adolescent immunizations from imposing a deductible, copayment, coinsurance, or other cost-sharing mechanism for the administration of a childhood or adolescent immunization or for related procedures. The bill would also prohibit those contracts or policies from containing a dollar limit provision for the administration of childhood and adolescent immunizations or including the cost of those immunizations in a dollar limit provision.

Existing law prohibits a risk-based contract between a health care service plan and a physician or physician group from including a provision requiring the physician or physician group to assume financial risk for the acquisition costs of required immunizations for children. Existing law prohibits a plan from requiring a physician or physician group to assume financial risk for immunizations that are not part of the current contract.

This bill would make those provisions apply to all contracts between plans and physicians or physician groups rather than just risk-based contracts. The bill would prohibit a plan from requiring a physician or physician group to assume financial risk for immunizations, whether or not those immunizations are part of the current contract. The bill would make other related changes.

Existing law prohibits a health care service plan from including the acquisition costs associated with required immunizations for children in the capitation rate of a physician who is individually capitated.

This bill would additionally prohibit a plan from including in that capitation rate the administration costs of those immunizations.

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

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement. This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.

State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) Pediatric immunizations proved to be one of the most successful, safe, and cost-effective public health interventions of the 20th century. Worldwide, millions of childhood deaths are prevented by vaccinations every year. Vaccine-preventable disease levels are at or near record lows.

(b) Vaccines are among the most cost-effective components of preventive medical care. In 2003, the federal Centers for Disease Control and Prevention estimated a direct cost savings of six dollars and thirty cents (\$6.30) for every dollar spent on vaccinations. If societal costs are factored in, the savings increase to eighteen dollars and forty cents (\$18.40) per dollar spent.

(c) Due to increasing numbers of approved and recommended life-saving vaccines, as well as increasing prices, pediatric vaccine acquisition costs have increased dramatically in recent years and could triple by the year 2020.

(d) Physicians typically face higher vaccine prices than large public purchasers and usually lose money when they provide immunizations due to under-reimbursement, which may discourage physicians from purchasing adequate doses to meet the demand in their practices. This trend could shift the burden of vaccine financing to parents' out-of-pocket expenses or to local public health clinics or other public programs.

(e) As small businesses, physicians face severe financial strain when they continue to absorb the unreimbursed costs associated with vaccine acquisition and administration. The purchase of vaccines is the single most expensive part of a pediatric or family practice. When providers are not adequately reimbursed to cover the direct and indirect costs of providing immunizations, the viability of their practice is threatened.

(f) Insured children and their families can face financial barriers to immunization such as deductibles, copayments, and other out-of-pocket expenses.

(g) Unvaccinated children can contract a dangerous or

life-threatening disease at any time in their lives. In order to effectively protect the public health, it is imperative that we ensure continued access to disease-preventing vaccines in order to achieve maximum immunization for infants, children, and adolescents.

(h) Therefore, in order to maximize immunization rates to protect individual children and the general population from existing and emerging communicable diseases, it is the intent of the Legislature to ensure that physicians are fully reimbursed for the costs to acquire and administer recommended vaccines and that out-of-pocket expenses do not deter parents from immunizing their children.

(i) The Legislature further recognizes the importance of the California Immunization Registry in maximizing immunization rates and supports and encourages physicians and their specialty societies in efforts to increase physician participation in the registry.

SEC. 2. Section 1367.36 of the Health and Safety Code is amended to read:

1367.36. (a) A risk-based contract between a health care service plan and a physician or physician group that is issued, amended, delivered, or renewed in this state on or after January 1, 2001 2013, shall not include a provision that requires a physician or a physician group to assume financial risk for the acquisition costs of required immunizations for children as a condition of accepting the risk-based contract. A physician or physician group shall not be required to assume financial risk for immunizations that are not, *regardless of whether those immunizations are part of the current contract.*

(b) A health care service plan that provides coverage for childhood and adolescent immunizations pursuant to Section 1367.3 or 1367.35 shall reimburse a physician or physician group in an amount not less than the actual cost of acquiring the vaccine plus the cost of administration of the vaccine. For purposes of this subdivision, both of the following shall apply:

(1) The actual cost of acquiring the vaccine is the vaccine's private sector cost per dose, as published on the most current Pediatric Vaccine Price List of the Centers for Disease Control and Prevention, plus reasonable costs associated with shipping and handling.

(2) The cost of administration of the vaccine, which includes physician time, clinical staff time, and office staff time, as well as other practice expenses associated with providing the immunization such as storage, insurance, supplies, and medical equipment, shall be an amount not less than that specified in the most current annual Medicare physician fee schedule published pursuant to Section 1395w-4(b)(1) of Title 42 of the United States Code.

(b)

(c) Beginning January 1, 2001 2013, with respect to immunizations for children that are not part of the current contract between a health care service plan and a physician or physician group, *including, but not limited to, immunizations in the most current versions of the Recommended Childhood and Adolescent Immunization Schedules jointly approved by the federal Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians*, the health care service plan shall reimburse a physician or physician group at the lowest of the following, until the contract is renegotiated: (1) the physician's actual acquisition cost, (2) the "average wholesale price" as published in the Drug Topics Red Book, or (3) the lowest acquisition cost through sources made available to the physician by the health care service plan. Reimbursements *in an amount not less than that specified in subdivision (b)*.

(d) *Reimbursements pursuant to this section shall be made within 45 days of receipt by the plan of documents from the physician or physician group demonstrating that the immunizations were performed, consistent with Section 1371 or through an alternative funding mechanism mutually agreed to by the health care service plan and the physician or physician group. The alternative funding mechanism shall be based on reimbursements consistent with this subdivision section.*

(c)

(e) Physicians and physician groups may assume financial risk for providing required immunizations, if the immunizations have experiential data that has been negotiated and agreed upon by the health care service plan and the physician risk-bearing organization *or physician group*. However, a health care service plan shall not require a physician risk-bearing organization *or a physician group* to accept financial risk or impose additional risk on a physician risk-bearing organization *or physician group* in violation of subdivision (a) *or (b)*.

(d)

(f) A health care service plan shall not include the acquisition costs *or administration costs, as defined in subdivision (b)*, associated with required immunizations for children in the capitation rate of a physician who is individually capitated.

(g) *A health care service plan contract issued, amended, or renewed on or after January 1, 2013, that provides coverage for childhood and adolescent immunizations pursuant to Section 1367.3 or 1367.35 shall not do either of the following:*

(1) *Impose a deductible, copayment, coinsurance, or other cost-sharing mechanism for the administration of a childhood or*

adolescent immunization or for procedures related to that administration. Nothing in this paragraph prohibits charging a deductible, copayment, coinsurance, or other cost-sharing mechanism for procedures, services, or treatment unrelated to an immunization.

(2) Contain a dollar limit provision for the administration of childhood and adolescent immunizations or include the cost of those immunizations in a dollar limit provision of the contract.

(h) Subdivision (b) shall not apply to services provided pursuant to health care service plan contracts entered into with the Board of Administration of the Public Employees' Retirement System pursuant to the Public Employees' Medical and Hospital Care Act (Part 5 (commencing with Section 22750) of Division 5 of Title 2 of the Government Code).

SEC. 3. Section 10123.56 is added to the Insurance Code, to read:

10123.56. (a) A health insurer that provides coverage for childhood and adolescent immunizations pursuant to Section 10123.5 or 10123.55 shall reimburse a physician or physician group in an amount not less than the actual cost of acquiring the vaccine plus the cost of administration of the vaccine. For purposes of this subdivision, both of the following shall apply:

(1) The actual cost of acquiring the vaccine is the vaccine's private sector cost per dose, as published on the most current Pediatric Vaccine Price List of the Centers for Disease Control and Prevention, plus reasonable costs associated with shipping and handling.

(2) The cost of administration of the vaccine, which includes physician time, clinical staff time, and office staff time, as well as other practice expenses associated with providing the immunization such as storage, insurance, supplies, and medical equipment, shall be an amount not less than that specified in the most current annual Medicare physician fee schedule published pursuant to Section 1395w-4(b)(1) of Title 42 of the United States Code.

(b) A health insurance policy issued, amended, or renewed on or after January 1, 2013, that provides coverage for childhood and adolescent immunizations pursuant to Section 10123.5 or 10123.55 shall not do either of the following:

(1) Impose a deductible, copayment, coinsurance, or other cost-sharing mechanism for the administration of a childhood or adolescent immunization or for procedures related to that administration. Nothing in this paragraph prohibits charging a deductible, copayment, coinsurance, or other cost-sharing mechanism for procedures, services, or treatment unrelated to an immunization.

(2) Contain a dollar limit provision for the administration of

childhood and adolescent immunizations or include the cost of those immunizations in a dollar limit provision of the contract.

(c) Subdivision (a) shall not apply to services provided pursuant to health insurance policies entered into with the Board of Administration of the Public Employees' Retirement System pursuant to the Public Employees' Medical and Hospital Care Act (Part 5 (commencing with Section 22750) of Division 5 of Title 2 of the Government Code).

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 conducted for this report. A discussion of CHBRP's system for grading evidence, as well as lists of MeSH Terms, Publication Types, and Keywords, follows.

Evidence Grading System

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

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

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

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

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

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

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

The category “insufficient evidence” of an intervention’s effect is used when there is little if any evidence of an intervention’s effect.

Due to the rigor and thoroughness of the ACIP systematic review on the efficacy and safety of vaccines, for the purposes of this report, CHBRP assumes that any vaccine that has been recommended as part of the routine immunization schedule has clear and convincing evidence that it is effective in preventing disease.

Medical Effectiveness

It is not feasible for CHBRP to review the large volume of literature on the medical effectiveness of each of these vaccines and their associated form of immunization-related procedures within the 60-day time frame allotted for this analysis. Therefore, CHBRP restricted its review of the medical effectiveness literature to official ACIP recommendations released in the CDC’s journal, *Morbidity and Mortality Weekly Report*. The recommendations released by the ACIP were reviewed for information on immunization-related procedures and information specific to the 12 vaccines recommended for routine use among children and adolescents in the United States. The ACIP has 38 current vaccine-specific recommendations, along with one report summarizing general recommendations on immunization. Of the 39 current recommendations, 14 were excluded because they were not relevant (i.e., not for pediatric population, not a routine immunization, etc.). The 25 remaining recommendations were retrieved and reviewed. Due to the rigor and thoroughness of the ACIP systematic review on the efficacy and safety of vaccines, for the purposes of this report, CHBRP concludes that any vaccine that has been recommended as part of the routine immunization schedule has clear and convincing evidence that it is effective in preventing disease. The evidence grading system utilized by CHBRP in preparing our reports is detailed below.

Cost and Public Health

A separate literature search was conducted for the *Cost* and *Public Health* sections. The literature search was limited to studies published in English from 1992 to present. The following databases of peer-reviewed literature were searched: MEDLINE (PubMed), the Cochrane Database of Systematic Reviews, the Cochrane Register of Controlled Clinical Trials, the Cumulative Index of Nursing and Allied Health Literature, EconLit, and Web of Science. In addition, websites maintained by the following organizations that index or publish systematic reviews and evidence-based guidelines were searched: Agency for Healthcare Research and Quality, International Network of Agencies for Health Technology Assessment, National Health Service Centre for Reviews and Dissemination, National Guidelines Clearinghouse, National Institute for Health and Clinical Excellence, and the Scottish Intercollegiate Guideline Network.

Search Terms

The search terms used to locate cost and public health studies relevant to AB 2064 were as follows:

MeSH Terms Used to Search PubMed

Chickenpox Vaccine	Immunization/utilization
Cost of Illness	Immunization
Cost Sharing	Influenza Vaccines
Cost-Benefit Analysis	Insurance Coverage
Costs and Cost Analysis	Measles-Mumps-Rubella Vaccine
Deductibles and Coinsurance	Meningococcal Vaccines
Diphtheria-Tetanus-Pertussis Vaccine	Outcome Assessment Health Care
Direct Service Costs	Papillomavirus Vaccines
Ethnic Groups	Vaccination/statistics and numerical data
Health Expenditures	Sex Factors
Financing, Personal	Tetanus Toxoid
Health Services Needs and Demand	Vaccination/utilization
Health Services/utilization	Poliovirus Vaccines
Healthcare Disparities	Rotavirus Vaccines
Immunization Programs	Vaccines
Immunization/economics	Viral Hepatitis Vaccines
Immunization/supply and distribution	

Keywords used to search PubMed, Cochrane Library, EconLit, Web of Science, and relevant websites

“cost barrier”	“payment”[tiab]
“cost barriers”	“price elasticity”
“cost effective”[title]	“private coverage”
“cost effectiveness”[title]	“unit cost”
“cost of treatment”	“vaccination rates”
“cost offset”	“vaccine rates”
“cost savings”	adolescence
“cost-sharing”	adolescent
“cost-utility”	adolescents
“dollar limit”	calpers
“dollar limits”	child
“economic burden”	children
“economic burdens”	coinsurance
“economic loss”	co-insurance
“financial barrier”	copayment
“financial barriers”	co-payment
“financial burden”	copayments
“financial burdens”	cost sharing
“hepatitis a”	deductible
“hepatitis b”	diphtheria
“human papillomavirus”	disparities
“out of pocket”	disparity

dtap
ethnic*
gender
hib
hpv
immunisation
immunisations
immunise
immunised
immunization
immunizations
immunize
immunized
infant
infants
influenza
medi-cal
meningococcal

mmr
newborn
out-of-pocket
pertussis
pneumococcal
polio
poverty
racial*
rotavirus
tetanus
utilization[title]
vaccination
vaccinations
vaccine
vaccine series completion
vaccine-preventable
vaccines
varicella

Publication Types:

Clinical trial
Comparative Study
Controlled Clinical Trial
Meta-Analysis
Practice Guideline
Randomized Control Trial
Systematic Reviews

Appendix C: Summary Findings on Medical Effectiveness

Table C-1. Current ACIP Recommendations for Routine Immunization Among Children and Adolescents (Aged 0-18 Years)

Topic of Recommendation	Citation	Nature of Recommendations
General recommendation on immunization-related procedure	CDC, 2011c	Administration of vaccines, immunization-related procedures
Diphtheria, tetanus, acellular pertussis (DTaP)	CDC, 2000a	Pertussis immunization among infants and young children; recommend vaccines with acellular pertussis vaccine in addition to whole-cell pertussis vaccine
Diphtheria, tetanus, acellular pertussis (DTaP)	CDC, 2006a	5 doses given intramuscularly at 2m, 4m, 6m, 15-18m, 4-6yrs; vaccines using acellular pertussis are preferred
Diphtheria, tetanus, acellular pertussis (Tdap)	CDC, 2011j	Recommend a booster using Tdap at 11-18yrs (11-12yrs is the preferred age)
Diphtheria, tetanus, acellular pertussis (Tdap)	CDC, 1991	Recommend Tdap for children 7-10yrs who did not complete 5-dose series.
<i>Haemophilus influenzae</i> type b	CDC, 1993	Intramuscular injection (2-3 doses) at 2m, 4m (6m) + booster at 12-15m
<i>Haemophilus influenzae</i> type b	CDC, 2006b	When possible, use the same formulation of the Hib vaccine for all doses; the combination vaccine (Hib + DTaP) is acceptable substitute for Hib vaccine
Hepatitis A	CDC, 2005a	Intramuscular injection (2 doses) 6 to 18 months apart at 1yr
Hepatitis B	CDC, 2007c	Intramuscular injection (3 doses) at birth, 1-2m, and 6-18m; may have 4 doses if using combo vaccines
Human papillomavirus (HPV)	CDC, 2010g	Recommends quadrivalent (HPV4) vaccine for females via intramuscular injection (3 doses) at 11-12yrs, and 2 and 6 months from first dose; catch up immunization for females aged 13-26yrs
Human papillomavirus (HPV)	CDC, 2010h	Extends 2007 recommendations to include newly licensed bivalent vaccine (HPV2); immunization either HPV4 or HPV2 is recommended in females
Human papillomavirus (HPV)	CDC, 2011c	Advises that HPV4 may be given to males to prevent the likelihood of acquiring genital warts, but does not advise routine immunization

Table C-1. Current ACIP Recommendations for Routine Immunization Among Children and Adolescents (Aged 0-18 years) (Cont'd)

Topic of Recommendation	Citation	Nature of Recommendations
Human papillomavirus (HPV)	CDC, 2011g	Recommends routine immunization with quadrivalent (HPV4) vaccine for males & females via intramuscular injection (3 doses) at 11-12yrs, and 1-2 and 6 months from first dose.
Influenza	CDC, 2010b	Routine immunization for persons older than 6m on an annual basis, with one dose of inactivated (given as a shot) or weakened (given nasally) influenza vaccine.
Influenza	CDC, 2011d	Routine immunization for persons older than 6m is recommended even if they received previous year's vaccine
Measles, Mumps, Rubella (MMR)	CDC, 1998	Subcutaneous (2 doses at 12-15m and 4-6yrs)
Measles, Mumps, Rubella, & Varicella (MMRV)	CDC, 2010c	Recommends that MMR and Varicella are administered as separate vaccines for the 1 st dose at 12-15m and as the combination MMRV vaccine for the second dose at 4-6yrs
Meningococcal conjugate	CDC, 2005b	Given intramuscularly at 11-12yrs
Meningococcal conjugate	CDC, 2011i	Given intramuscularly at 11-12yrs with a booster dose at 16yrs
Pneumococcal conjugate	CDC, 2010e	Intramuscular Injection (4 doses) at 2m, 4m, 6m, 12-15m
Polio	CDC, 2000b	Subcutaneous or Intramuscular injection (4 doses) at 2m, 4m, 6-18m, 4-6yrs
Polio	CDC, 2009a	Maintains previous recommendations and clarifies recommendations regarding specific combination polio vaccines; changes the minimum interval between dose 3 and dose 4 from 4 weeks to 6 months
Rotavirus	CDC, 2009b	Given orally in 2 doses at 2m and 4m for RV1 or in 3 doses at 2m, 4m, and 6m for RV5; ACIP has no preference between RV1 and RV5
Varicella	CDC, 2007b	Subcutaneous (2 doses at 12-15m and 4-6 yrs); CDC prefers MMRV for second dose

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 website at http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

The cost analysis in this report was prepared by the members of the 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 payer (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 www.chis.ucla.edu.
2. The latest (2011) 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:

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 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 health care plans, generally those characterized as preferred provider plans or PPOs. The HCGs currently include claims drawn from plans covering 4.6 million members. In addition to the Milliman HCGs, CHBRP's utilization and cost estimates draw on other data, including the following:

- The 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-regulated or CDI-regulated), cost-sharing arrangements with enrollees, and average premiums. Enrollment in plans or policies offered by these seven firms represents an estimated 94.3% of the persons with health insurance subject to state mandates. This figure represents an estimated 93.9% of enrollees in full service (nonspecialty) DMHC-regulated health plans and an estimated 95.5% of enrollees in full service (nonspecialty) CDI-regulated policies. 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 on September 30, 2010, by the California Department of Insurance, Statistical Analysis Division, and data retrieved from the Department of Managed Health Care's interactive Web site "Health Plan Financial Summary Report," July-September 2011, 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 www.calpers.ca.gov.

6. Enrollment in Medi-Cal Managed Care (beneficiaries enrolled in Two-Plan Model, Geographic Managed Care, and County Operated Health System 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 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 (MRMIP)—are estimated based on CHIS and data maintained by the Managed Risk Medical Insurance Board (MRMIB). The basic minimum scope of benefits offered by participating health plans under these programs must comply with all requirements for DMHC-regulated health plans, and thus these plans are affected by state-level benefit mandates. CHBRP does not include enrollment in the Post-MRMIP Guaranteed-Issue Coverage Products as these persons are already included in the enrollment for individual market health insurance offered by DMHC-regulated plans or CDI-regulated insurers. Enrollment figures for AIM and MRMIP are included with enrollment for Medi-Cal in presentation of premium impacts. Enrollment information is obtained online at www.mrmib.ca.gov/. Average statewide premium information is provided to CHBRP by MRMIB staff.

General Caveats and Assumptions

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

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

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

- Cost impacts are shown only for plans and policies subject to state benefit mandate laws.
- Cost impacts are only for the first year after enactment of the proposed mandate.
- Employers and employees will share proportionately (on a percentage basis) in premium rate increases resulting from the mandate. In other words, the distribution of premium paid by the subscriber (or employee) and the employer will be unaffected by the mandate.

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

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

- Population shifts by type of health insurance: If a mandate increases health insurance costs, some employer groups and individuals may elect to drop their health insurance. Employers may also switch to self-funding to avoid having to comply with the mandate.
- Changes in benefit plans: To help offset the premium increase resulting from a mandate, subscribers/policyholders may elect to increase their overall plan deductibles or copayments. Such changes would have a direct impact on the distribution of costs between the health plan and policies and enrollees, and may also result in utilization reductions (i.e., high levels of patient cost sharing result in lower utilization of health care services). CHBRP did not include the effects of such potential benefit changes in its analysis.
- Adverse selection: Theoretically, individuals or employer groups who had previously foregone health insurance may now elect to enroll in a health plan or policy, 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 3 years. Some of these provisions affect the baseline or current enrollment, expenditures, and premiums. This subsection discusses adjustments made to the 2012 Cost and Coverage Model to account for the potential impacts of the ACA that have gone into effect by January 2012. 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 2012 Cost and Coverage model to reflect changes in enrollment and/or baseline premiums and these are discussed here.

Coverage for adult children

ACA 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. As a result of the ACA, many of these young adults have gained access to health insurance through a parent. This dynamic has both diminished the number of uninsured and also shifted some young adults from the individually purchased health insurance market into the group market. Responses to CHBRP's Annual Enrollment and Premium Survey have captured the effects of this provision.

Minimum medical loss ratio requirement

ACA 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."⁴⁶ The requirement to report medical loss ratio (MLR) 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 2012, but the effects are unknown and data are 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

ACA 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.⁴⁷ The California PCIP is not

⁴⁶ 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.

⁴⁷ Enrollment report presented at the Managed Risk Medical Insurance Board Meeting, January 19, 2011. Available at: www.mrmib.ca.gov/MRMIB/Agenda_Minutes_011911/Agenda_Item_9.a_PCIP_Board_Report_for_Dec_2010_FINAL.pdf.

subject to state benefit mandates,⁴⁸ 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*⁴⁹ 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

ACA 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 5 years.⁵⁰ This provision could have had significant premium effects, especially for the DMHC-regulated 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

ACA 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 increased to \$1.25 million on September 23, 2011, and will increase to \$2 million on September 23, 2012. 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 policies. CHBRP 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 ACA 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 ACA 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 2012. 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

⁴⁸ Correspondence with John Symkowick, Legislative Coordinator, MRMIB, October 19, 2010.

⁴⁹ See: http://www.chbrp.org/other_publications/index.php.

⁵⁰ See enacted language at: www.leginfo.ca.gov/pub/09-10/bill/asm/ab_2201-2250/ab_2244_bill_20100930_chaptered.pdf.

phased-in process.”⁵¹ The Medi-Cal Managed Care enrollment in CHBRP’s 2012 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 indicated that by November 2011, an estimated 289,000 seniors and persons with disabilities had enrolled in Medi-Cal Managed Care.⁵² 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.⁵³

Bill Analysis—Specific Caveats and Assumptions

CHBRP averages utilization of immunization-related procedures across all types of immunizations. For this analysis, utilization among children and adolescents was separated into three age groups: 0 to 4, 5 to 7, 8 to 18. These groups were based on the higher number of immunizations and well-child visits recommended for children under the age of 4, and on the school-readiness immunization schedule required for children aged 5 to 7 years. Utilization was assumed to be uniformly distributed within these three age groups, both premandate and postmandate.

CHBRP also used an average price for immunization-related procedures across all types of immunizations for estimating the impact of AB 2064. CHBRP assumes that these prices would not change due to the increased utilization if AB 2064 were to be enacted, as the increase of less than 100 immunizations would be too small to impact prices. CHBRP did not exclude any types of immunizations in the claims data based on type of vaccine.

If AB 2064 were enacted, utilization of vaccines as well as immunization-related procedures would increase, as the two are inseparable. The increased number of immunizations would also then include increased costs to carriers, who would be required to pay for vaccines as well as immunization-related procedures. CHBRP has assumed that the increased cost to carriers would then be passed along to enrollees in the form of increased premiums, which CHBRP took into account in the final postmandate calculations.

Impact on cost sharing

AB 2064 removes cost sharing for immunization-related procedures for children and adolescents. The member cost sharing will be \$0 postmandate. For this analysis, premandate member cost sharing was calculated, using the claims data underlying the Milliman Health Cost Guidelines, as follows:

Coinsurance: The coinsurance percentage multiplied by the cost of all immunization-related procedures for enrollees aged 0 to 18 years.

⁵¹ Taylor, M. Legislative Analyst, *The Budget Package 2010-11 California Spending Plan*. LAO: November, 2010. Available at:

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

⁵² Department of Health Care Services, Managed Care Implementation for Seniors and Persons with Disabilities: Monitoring Dashboard: February 2012. Available at:

http://www.dhcs.ca.gov/individuals/Documents/MMCD_SPD/ChartsRptsData/SPD_Dashboard.pdf.

⁵³ 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:

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

Copayment: The copayment is multiplied by the number of visits that included immunization-related procedures for enrollees aged 0 to 18 years. Copayments for vaccines remained at their existing levels. Consultation with content experts confirmed that the single copayment attributed to the vaccine would still apply for the entire immunization (including the vaccine itself and the immunization-related procedures) if AB 2064 were enacted. Therefore, CHBRP assumed no reduction for the copayment unless it was specifically coded as being for immunization-related procedures only.

Deductible: The cost of a benefit plan where the deductible applied to immunization-related procedures was compared to the cost of a benefit plan where the deductible does not apply. The percentage increase in cost was applied to the projected premium in the model to estimate the value of the deductible associated with coverage for immunization-related procedures.

Dollar limits were not included in the cost-sharing calculation as CHBRP is aware of no evidence from either the research literature or from the responses in the CHBRP survey of carriers in California that carriers impose this type of restriction on immunizations.

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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California Health Benefits Review Program Committees and Staff

A group of faculty and staff undertakes most of the analysis that informs reports by the California Health Benefits Review Program (CHBRP). The CHBRP **Faculty Task Force** comprises rotating representatives from six University of California (UC) campuses and three private universities in California. In addition to these representatives, there are other ongoing contributors to CHBRP from UC. This larger group provides advice to the CHBRP staff on the overall administration of the program and conducts much of the analysis. The **CHBRP staff** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and coordinates all external communications, including those with the California Legislature. The level of involvement of members of the CHBRP Faculty Task Force and staff varies on each report, with individual participants more closely involved in the preparation of some reports and less involved in others. As required by 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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