



CALIFORNIA  
HEALTH BENEFITS REVIEW PROGRAM

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## Analysis of Assembly Bill 1825: Maternity Services

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A Report to the 2009-2010 California Legislature  
April 16, 2010

CHBRP 10-02



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](http://www.chbrp.org).

# **A Report to the 2009-2010 California State Legislature**

## **Analysis of Assembly Bill 1825: Maternity Services**

**April 16, 2010**

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## PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill 1825, a bill to mandate the coverage of Maternity Services. In response to a request from the California Assembly Committee on Health on February 12, 2010, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the program's authorizing statute. Edward Yelin, PhD, Janet Coffman, MPP, PhD, and Chris Tonner, MPH, all of the University of California, San Francisco, prepared the medical effectiveness analysis. Min-Lin Fang, MLIS, of the University of California, San Francisco, conducted the literature search. Helen Halpin, PhD, Sara McMnamin, PhD, and Alexis Muñoz, MPH, of the University of California, Berkeley, prepared the public health impact analysis. Robert Kaplan, PhD, Dasha Cherepanov, PhD, Tanya G. K. Bentley, PhD, and Yair Babad, PhD, all of the University of California, Los Angeles, prepared the cost impact analysis. Robert Cosway, FSA, MAAA, of Milliman, provided actuarial analysis. Alina Salganicoff, PhD, of the Kaiser Family Foundation, and Aaron Caughey, MD, PhD, of the University of California, San Francisco, provided technical assistance with the literature review and expert input on the analytic approach. Garen Corbett, MS, and Susan Philip, MPP, of CHBRP staff prepared the background section and synthesized the individual sections into a single report. Sarah Ordódy provided editing services. A subcommittee of CHBRP's National Advisory Council (see final pages of this report) and a member of the CHBRP Faculty Task Force, Susan Ettner, PhD, of the University of California, Los Angeles, 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 1825

The California Health Benefits Review Program (CHBRP) undertook the analysis of Assembly Bill (AB) 1825 in response to a request from the California Assembly Committee on Health on February 12, 2010, pursuant to the provisions of Senate Bill 1704 (Chapter 684, Statutes of 2006) as chaptered in Section 127660, et seq. of the California Health and Safety Code. This report provides an analysis of the medical, financial, and public health impacts of AB 1825.

AB 1825, introduced by Assembly Member Hector De La Torre, would require health insurance policies regulated by the California Department of Insurance (CDI) to cover maternity services.<sup>1</sup> AB 1825 defines maternity services to include prenatal care, ambulatory care maternity services, involuntary complications of pregnancy, neonatal care, and inpatient hospital maternity care including labor and delivery and postpartum care. AB 1825 is similar to legislation introduced in prior sessions: AB 98 (2009), AB 1962 (2008), Senate Bill (SB) 1555 (2004), and SB 897 (2003). AB 98, AB 1962, and SB 1555 passed the Legislature during their respective sessions and were vetoed by the Governor.<sup>2</sup>

AB 1825 would apply only to CDI-regulated policies (primarily preferred provider organizations), which represent approximately 13% of privately funded insurance subject to California regulation. Health care service plans (including health maintenance organizations, point-of-service plans, and some preferred provider organizations) regulated by the Department of Managed Health Care (DMHC) make up the remaining portion of the privately funded, California-regulated market. Although DMHC-regulated plans constitute the majority of this market, which contains both the group and individual market segments, CDI-regulated policies represent a substantial portion of the *individual* market—about 60%.

Current laws and regulations governing DMHC-regulated health care service plans require coverage for maternity services under provisions related to “basic health care services.” DMHC-regulated plans are required to cover maternity and pregnancy-related care under laws governing emergency and urgent care.<sup>3</sup> Regulations defining basic health care services specifically include prenatal care as preventive care that must be covered.<sup>4</sup> CDI-regulated policies currently have no such requirements.

The federal Civil Rights Act requires employers that offer health insurance and have 15 or more employees to cover maternity services benefits at the same level as other health care benefits.<sup>5</sup> Complications of pregnancy are generally covered regardless of whether the health insurance

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<sup>1</sup> AB 1825 would add Section 10123.865 to the California Insurance Code.

<sup>2</sup> The legislative history of AB 98, AB 1962, SB 1555, and SB 897 are available at [www.leginfo.ca.gov](http://www.leginfo.ca.gov). CHBRP conducted analyses of these bills and those reports are available at [http://www.chbrp.org/completed\\_analyses/index.php](http://www.chbrp.org/completed_analyses/index.php).

<sup>3</sup> Section 1317.1 of the California Health and Safety Code

<sup>4</sup> Section 1300.67 of the California Code of Regulations, Title 28

<sup>5</sup> The Pregnancy Discrimination Act under Title VII of the Civil Rights Act of 1964

policy provides coverage for maternity benefits. Insurers are also required to cover newborns for the first 30 days of life regardless of whether the health insurance policy covers maternity services.<sup>6</sup>

The bill's definition of maternity services is generally consistent with the definitions of maternity services under health insurance: prenatal care (such as office visits and screening tests), labor and delivery services (including hospitalization), care resulting from complications related to a pregnancy, and postpartum/postnatal care.

In 2008, the birth rate in California was 69.0 per 1,000 women of childbearing age (CDPH, 2008b). In 2006, the majority (85.9%) of births were to mothers who initiated prenatal care in the first trimester, with only 0.6% of women receiving no prenatal care (CDPH, 2008b). Overall in California, there are approximately 75 maternal pregnancy-related deaths and 3,000 infant deaths per year (CDPH, 2007b; MOD 2003-2005). Infant mortality is most frequently caused by birth defects (23.5% of deaths), followed by prematurity and low birth weight (15.6% of deaths), maternal complications of pregnancy (6.0% of deaths), and SIDS (5.2% of deaths) (CDPH, 2005). As will be discussed in further detail in the *Medical Effectiveness* section, specific prenatal care services can be effective in reducing the rate of preterm births, low-birth weight babies, transmission of infectious diseases, and other related infant and maternal morbidity and mortality.

#### Potential Effects of Federal Health Care Reform

On March 23, 2010, the federal government enacted the federal "Patient Protection and Affordable Care Act" (P.L.111-148), which was amended by the "Health Care and Education Reconciliation Act" (H.R.4872) that the President signed into law on March 30, 2010. These laws (referred to as P.L.111-148) came into effect after CHBRP received a request for analysis for AB 1825. There are provisions in P.L.111-148 that have effective dates of 2014 and beyond that would dramatically affect the California health insurance market and its regulatory environment. For example, the law would establish state-based health insurance exchanges with minimum benefit standards for the small-group and individual markets. How these provisions are implemented in California would largely depend on regulations to be promulgated by federal agencies, and statutory and regulatory actions to be undertaken by the California state government.

There are also provisions in P.L.111-148 that go into effect within the short term or within 6 months of enactment that would expand the number of Californians obtaining health insurance and their sources of health insurance. For example, one provision would allow children to enroll onto their parent's health plan or policy until they turn 26 years of age (effective 6 months following enactment). This may decrease the number of uninsured and/or potentially shift those enrolled with individually purchased insurance to group purchased insurance. These and other short-term provisions would affect CHBRP's baseline estimates of the number and source of health insurance for Californians in 2010. Given the uncertainty surrounding implementation of these provisions and given that P.L.111-148 was only recently enacted, the potential effects of

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<sup>6</sup> Insurance Code Section 10119 and *Redlands Community Hospital v. New England Mutual* (1994) 23 Cal. App. 4th 89

these short-term provisions are not taken into account in the baseline estimates presented in this report. 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 state mandate would impact coverage, utilization, costs, and public health, holding all other factors constant.

## **Medical Effectiveness**

The *Medical Effectiveness* and *Public Health Impacts* sections of this report focus on the outcomes associated with prenatal care services because (1) a majority of births occur in the hospital setting regardless of insurance status, (2) prenatal care services use would be most affected by the potential for out-of-pocket costs and thus most directly impacted by AB 1825, and (3) AB 1825 would not affect coverage for infants. The *Utilization, Cost, and Benefit Coverage Impacts* analysis includes the full range of services that are considered to be “maternity services.”

Studies of prenatal care can be divided into two major groups:

- Studies of the impact of variation in the number of prenatal care visits that pregnant women receive, and
- Studies of the effectiveness of specific medical services provided to pregnant women (e.g., laboratory tests and medications).

Randomized controlled trials (RCTs) have consistently found no statistically significant association between the number of prenatal visits pregnant women receive and birth outcomes for either infants or for mothers. However, there is clear and convincing evidence from multiple RCTs that the following prenatal care services are effective in producing better birth outcomes for mothers and infants:

- Smoking cessation counseling
- Ultrasound to identify structural abnormalities and determine gestational age
- Folic acid to prevent neural tube defects
- Screening and treatment for asymptomatic bacteriuria
- Screening for hepatitis B
- Screening and treatment for human immunodeficiency virus
- Calcium supplements and aspirin for prevention of preeclampsia
- Magnesium sulfate for prevention of eclamptic seizures in women with preeclampsia
- Screening and prophylactic and therapeutic treatment for Rh(D) incompatibility
- Progestational agents to prevent preterm delivery

- Corticosteroids to promote maturation of lungs in fetuses scheduled for preterm delivery due to preeclampsia or other complications
- Magnesium sulfate to prevent neurological impairment in fetuses at risk for preterm delivery
- External cephalic version for breech presentation at term
- Membrane sweeping and induction of labor for prevention of postterm pregnancies

In addition, there is a preponderance of evidence from nonrandomized studies and/or a small number of RCTs that the following prenatal care services are effective:

- Screening for domestic violence
- Screening for Down syndrome, hemoglobinopathies, and Tay-Sachs disease
- Screening and treatment for chlamydia, gonorrhea, and syphilis
- Screening for group B streptococcus
- Screening and treatment for gestational diabetes
- Screening and treatment for bacterial vaginosis, trichomonas vaginalis, and Candida species to prevent preterm delivery
- Iron supplements for treatment of iron deficiency anemia
- Blood pressure monitoring to screen for hypertensive disorders
- Screening for atypical red blood cell alloantibodies other than Rh(D) incompatibility
- Ultrasound to diagnose placenta previa

## **Utilization, Cost, and Benefit Coverage Impacts**

### Current Coverage of Maternity Benefits

AB 1825 would apply only to CDI-regulated health insurance policies subject to the California Insurance Code. It would require all CDI-regulated policies to cover maternity services. About 2,438,000 Californians, or 13% of enrollees in health insurance plans and policies subject to state regulation, are in the CDI-regulated market.

CHBRP's survey of the largest health plans and insurers in the state indicates the following:

- *Entire CDI-regulated market:* Among the Californians who are estimated to be currently enrolled in CDI-regulated policies, 61% have coverage for maternity benefits, including prenatal care and delivery services. All enrollees have coverage for complications of pregnancy.

- *CDI-regulated policies in the large- and small-group insurance markets:* An estimated 100% of enrollees currently have maternity benefits. Therefore, the proposed mandate would impact only the enrollees in individual (non-group) CDI-regulated policies.
- *CDI-regulated policies in the individual (non-group) insurance market:* An estimated 18% of all enrollees and 19% of female enrollees aged 20 to 44 currently have maternity coverage.
  - Of those who do not currently have coverage for maternity services, about 25% are women of childbearing age (19 to 44).
  - There is evidence that risk segmentation has already had a substantial impact on the CDI-regulated individual market, because in a previous analysis of SB 1555 in 2004, CHBRP estimated that approximately 82% of those in the individual market had maternity benefits.
- *Public programs:* The Medi-Cal and Aid to Infants and Mothers (AIM) programs cover maternity services for women who qualify. Pregnant women who are in households with incomes less than or equal to 200% of the federal poverty level (FPL) generally qualify for Medi-Cal. AIM provides coverage for both uninsured and underinsured women between 200% and 300% of the FPL. AIM defines underinsured women as those with privately funded insurance who face out-of-pocket costs for maternity services greater than \$500. CHBRP estimates that approximately 3,483 or 29% of women with privately funded insurance who will deliver babies during 2010 and have no maternity benefits when they become pregnant may qualify for Medi-Cal or AIM.
  - Based on data from AIM, there is evidence of current cost-shifting to that program. As of 2009, 1,433 or 9% of the women enrolled in AIM were simultaneously enrolled in privately funded health insurance policies that did not cover maternity services. Another 1,741 or 10% of AIM enrollees were enrolled in privately funded insurance policies that did cover maternity services.
  - CHBRP estimates that 12,172 or 3% of women enrolled in CDI-regulated policies with no maternity benefits at the time of pregnancy would give birth during 2010.
    - Of these women, CHBRP estimates that 2,666 would switch to Medi-Cal and another 817 would enroll in AIM following pregnancy. This is because their income eligibility would change following pregnancy (since pregnant women are considered a household of two and presumably their household income would not increase).
    - Another 391 of these women may transfer to policies covering maternity that are offered by their existing carrier.
    - The remaining 8,298 women would not have insurance coverage pre-mandate for their prenatal care and delivery.

## Post-mandate Benefit Coverage, Cost, and Utilization

- AB 1825 would expand maternity services coverage to approximately 963,000 enrollees with CDI-regulated individual policies, including about 240,700 women aged 19 to 44 years.
- CHBRP estimates that there would not be a direct impact on Medi-Cal enrollment as a result of AB 1825. Those 2,666 women who currently have no maternity coverage and qualify for Medi-Cal after pregnancy would still shift to Medi-Cal post-mandate due to their income levels.
- There are 1,433 women enrolled in AIM who are currently enrolled in CDI-regulated individual policies that do not cover maternity services; these women would have maternity coverage post-mandate. However, the out-of-pocket cost of maternity services in those policies would likely still be greater than \$500 (adding up deductibles and copayments), so those women would still qualify for AIM. As AIM would be the secondary payer if women retain their privately funded policies, there may be a shift of costs from AIM onto the private insurers, depending on whether AIM plans seek reimbursement from those insurers.
- CHBRP estimates that approximately 8,298 pregnancies would be newly covered under CDI-regulated insurance policies post-mandate. The impact of expanded benefit coverage on utilization is summarized below:
  - Overall, the mandate is estimated to have no impact on the number of deliveries, since the birth rate is not expected to change post-mandate.
  - Most women are likely to continue to face large out-of-pocket expenditures for maternity services regardless of whether or not their insurance policy includes maternity benefits. This is because about 70% of the women in CDI-regulated individual policies are currently in high-deductible health plans (HDHPs) and prenatal care is usually subject to an HDHP minimum annual deductible of \$1,200 for individual plans and \$2,400 for family plans as reported by the federal Internal Revenue Service (IRS). HDHPs generally do not exempt maternity/prenatal services from the high deductibles (KFF, 2007a), so a high level of cost sharing is required for maternity services. Even the women currently enrolled in non-HDHPs frequently face high cost-sharing requirements in the CDI-regulated individual market, and some might also choose to switch to HDHPs post-mandate in order to save on premiums.
  - Certain types of screening tests are not included in the standard prenatal care fee and might be used more frequently post-mandate if they are part of the maternity benefit, thereby affecting costs. The amount of the increase is difficult to estimate, as these tests would be subject to HDHP deductibles and women may treat them as out-of-pocket costs.
- Among all enrollees in state-regulated policies (both CDI-regulated and DMHC-regulated), total annual health expenditures are estimated to increase by \$40 million, or 0.1%, as a result of this mandate (“Total Annual Expenditures” in Table 1). As the total number of deliveries and average cost associated with each delivery is not expected to increase, the mandate primarily shifts costs from individuals to insurers. CHBRP assumes that the administrative expenses for health policies would increase in proportion to the increase in their covered

health care costs, leading to an estimated increase in overall expenditures. Note that the increase in total expenditures is a total of:

- The increase in premium expenditures in the individual market: \$120 million, or 2%, (“Premium expenditures for individually purchased insurance” in Table 1).
- The increase in out-of-pocket expenditures for maternity benefits covered by insurance (e.g., copayments and deductibles): \$28.8 million, or 0.5%, (“Individual out-of-pocket expenditures for covered benefits” in Table 1).
- The reduction in out-of-pocket expenditures for maternity benefits not currently covered by insurance: \$108.8 million (“Out-of-pocket expenditures for noncovered benefits” in Table 1).
- All of the costs of the mandate would be concentrated in the CDI-regulated individual market, where total expenditures are estimated to increase by 1% and premiums by 5% (“Total Expenditure” and “Insured Premiums”, Table 5). Per member per month (PMPM) premiums are estimated to increase by an *average* of \$8.48 in this market.
  - In 2009, California passed AB 119 into law prohibiting insurers from gender rating, or charging differential premiums based on gender for contracts issued, amended, or renewed on or after January 1, 2011. Therefore, the premium and cost calculations in this report assume all gender-rated policies would be converted to gender-neutral pricing prior to the implementation of AB 1825.
  - Insurance premiums in the individual market are stratified by age bands, so premiums are likely to increase more for younger individuals (particularly ages 19 to 29) than for older individuals (ages 30 to 64). CHBRP estimates that for the majority of individuals in the CDI-regulated individual market who do not currently have maternity benefits, AB 1825 would *increase* average premiums by 2% to 28% among those aged 19 to 44 years, depending on the age of the enrollee. Among the minority of individuals aged 19 to 44 years in the CDI-regulated individual market who currently have maternity benefits, AB 1825 is expected to *decrease* average premiums by 0.5% to 20%.
  - In addition to varying with age, premium changes could vary across policies. Post-mandate, women of a given age might self-select into policies with a high or low level of cost sharing based on their expected need for maternity care.
- The estimated premium increases may result in approximately 9,335 newly uninsured. It is likely that these newly uninsured would disproportionately consist of younger people, if they experience the greatest premium increases.

### **Public Health Impacts**

- CHBRP is unable to estimate what the impact of AB 1825 would have on the utilization of prenatal care, but a range is provided. A lower bound estimate would assume that there would be no increase in the utilization of effective prenatal care services because these pregnant women would likely still face high out-of-pocket costs. An upper bound estimate

would assume that all 8,298 newly covered pregnancies would have financial barriers to prenatal care removed and thus an increase in the utilization of effective prenatal care services would be expected. To the extent that AB 1825 increases utilization of effective prenatal care services, there is a potential that this mandate could lead to a reduction in infant and maternal mortality and improve health outcomes, such as the rates of low birth weight or preterm births, infectious disease transmissions, and respiratory distress syndrome.

- Females enrolled in plans in the individual health insurance market without coverage for maternity benefits are currently paying \$108.8 million out-of-pocket for noncovered maternity services. AB 1825 would shift these costs from female enrollees to increase premiums across both male and female enrollees. Therefore, this mandate would differentially reduce the out-of-pocket costs for female enrollees.
- Racial disparities in utilization of prenatal care exist in California, with black women utilizing prenatal care at lower rates. In addition, babies born to black women have poorer health outcomes, such as increased rates of preterm birth, low birth weight, and infant mortality. There is no evidence to suggest that AB 1825 would have an impact on prenatal care utilization rates among black women specifically, or reduce these disparities in health outcomes.
- In California, 10.9% of babies are born preterm and there are 3,000 infant deaths each year. It is estimated that each premature birth costs society approximately an average of \$51,600. To the extent that AB 1825 increases the utilization of effective prenatal care that can reduce outcomes such as preterm births and related infant mortality, there is a potential to reduce morbidity and mortality and the associated societal costs.
- As a result of AB 1825, premiums in the CDI-regulated individual market are estimated to increase on average by approximately 4.7%, thus increasing the number of uninsured by approximately 9,335 people. Losing one's health insurance has many harmful consequences beyond the health outcomes presented in this analysis.

**Table 1. AB 1825 Impacts on Benefit Coverage, Utilization, and Cost, 2010**

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
<b>Benefit Coverage</b>				
Total enrollees with health insurance subject to state-level benefit mandates (a)	19,487,000	19,487,000	0	0%
Total enrollees with health insurance subject to AB 1825				
In large and small group plans	1,259,000	1,259,000	0	0%
In individual plans	1,179,000	1,179,000	0	0%
Total	2,438,000	2,438,000	0	0%
Percentage of enrollees with maternity coverage				
In large and small group plans	100%	100%	0%	0%
In individual plans	18%	100%	82%	446%
Total	61%	100%	39%	65%
Number of enrollees with coverage				
In large and small group plans	1,259,000	1,259,000	0	0%
In individual plans	216,000	1,179,000	963,000	446%
Total	1,475,000	2,438,000	963,000	65%
<b>Utilization and Cost</b>				
Number of enrollees with uncomplicated pregnancies				
Covered by insurance	19,041	27,339	8,298	44%
Covered by AIM or Medi-Cal	3,483	3,483	0	0%
Not covered by insurance	8,298	0	(8,298)	-100%
Total	30,822	30,822	0	0%
Average cost per uncomplicated delivery	\$12,959	\$12,959	\$0	0%
<b>Expenditures</b>				
Premium expenditures by private employers for group insurance	\$43,519,324,000	\$43,519,324,000	\$0	0%
Premium expenditures for individually purchased insurance	\$5,992,795,000	\$6,112,798,000	\$120,003,000	2%
Premium expenditures by persons with group insurance, CalPERS HMOs, Healthy Families Program, AIM or MRMIP (b)	\$12,820,614,000	\$12,820,614,000	\$0	0%
CalPERS HMO employer expenditures	\$3,267,842,000	\$3,267,842,000	\$0	0%
Medi-Cal HMOs state expenditures	\$4,015,596,000	\$4,015,596,000	\$0	0%
Healthy Families state expenditures (c)	\$910,306,000	\$910,306,000	\$0	0%
Enrollee out-of-pocket expenses for covered benefits (deductibles, copayments, etc.)	\$5,961,186,000	\$5,989,966,000	\$28,780,000	0.5%
Enrollee expenses for noncovered benefits	\$108,756,000	\$0	(\$108,756,000)	-100%
<b>Total Annual Expenditures</b>	<b>\$76,596,419,000</b>	<b>\$76,636,446,000</b>	<b>\$40,027,000</b>	<b>0.1%</b>

Source: California Health Benefits Review Program, 2010.

Notes: (a) This population includes privately funded (group and individual) and publicly funded (e.g., CalPERS HMOs, Medi-Cal HMOs, Healthy Families Program, AIM, MRMIP) individuals enrolled in health insurance plans/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) Premium expenditures by individuals include employee contributions to employer-sponsored health insurance and member contributions to public insurance. (c) Healthy Families Program state expenditures include expenditures for 7,000 persons covered by the Major Risk Medical Insurance Program (MRMIP) and 7,000 persons covered by the Access for Infants and Mothers (AIM) program. Key: AIM=Access for Infants and Mothers; CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health Care.

## INTRODUCTION

Assembly Bill (AB) 1825, introduced by Assembly Member Hector De La Torre, would require health insurance policies regulated by the California Department of Insurance (CDI) to cover maternity services.<sup>7</sup> The California Health Benefits Review Program (CHBRP) undertook the analysis of AB 1825 in response to a request from the California Assembly Committee on Health on February 12, 2010, pursuant to the provisions of Senate Bill (SB)1704 (Chapter 684, Statutes of 2006) as chaptered in Section 127660, et seq. of the California Health and Safety Code.

### Potential Effects of Federal Health Care Reform

On March 23, 2010, the federal government enacted the federal “Patient Protection and Affordable Care Act” (P.L.111-148), which was further amended by the “Health Care and Education Reconciliation Act” (H.R.4872) that the President signed into law on March 30, 2010. These laws (referred to as “P.L.111-148”) came into effect after CHBRP received a request for analysis for AB 1825.

There are provisions in P.L.111-148 that have effective dates of 2014 and beyond that would dramatically affect the California health insurance market and its regulatory environment. These major long-term provisions of P.L.111-148 would require that most U.S. citizens and qualified legal resident have health insurance and that large employers offer health insurance coverage or a tax-free credit to their employees. It would establish state-based health insurance exchanges with minimum benefit standards for the small-group and individual markets. Subsidies for low-income individuals would be available to purchase into the exchanges. How these provisions are implemented in California would largely depend on regulations to be promulgated by federal agencies, and statutory and regulatory actions to be undertaken by the California state government.

There are also short-term provisions in P.L.111-148 that are effective within 6 months or less of enactment that would expand the number of Californians obtaining health insurance and their sources of health insurance. For example:

- Children and young adults up to 26 years of age would be allowed to enroll onto their parent’s health plan or policy (effective 6 months following enactment). This provision may decrease the number of uninsured and/or potentially shift those enrolled with individually purchased insurance to group purchased insurance.
- A temporary high-risk pool for those with pre-existing conditions would be established (effective 90 days following enactment). How California chooses to implement this provision would have implications for health insurance coverage for those high-risk individuals who are currently without health insurance and/or are covered by California’s Major Risk Medical Insurance Plan (MRMIP).
- P.L.111-148 also requires plans and policies to cover preventive services with no copayments, while preventive services will be exempt from deductibles. Required preventive services would include those rated “A” or “B” by the U.S. Preventive Services Task Force (USPSTF); recommended immunizations; preventive care for infants,

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<sup>7</sup> AB 1825 would add Section 10123.865 to the California Insurance Code.

children, and adolescents; and additional preventive care and screenings for women (effective 6 months after enactment). Certain prenatal care services are recommended by the USPSTF and have a Grade A or B recommendation. These would be covered and therefore could diminish the marginal cost impact and public health impacts presented in this analysis.<sup>8</sup>

- Maternity services will be considered part of the essential health benefits package to be provided by qualified health plans providing coverage in the small-group and individual markets through the state-based insurance exchanges, effective in 2014. Therefore, any effects of AB 1825 would be diminished by the P.L.111-148 requirements following 2014.<sup>9</sup>

These and other short-term provisions would affect CHBRP's baseline estimates of the number and source of health insurance for Californians and corresponding total costs for 2010. Given the uncertainty surrounding implementation of these provisions and given that P.L.111-148 was only recently enacted, the potential effects of these short-term provisions are not taken into account in the baseline estimates presented in this report. 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 state mandate would impact coverage, utilization, costs, and public health, holding all other factors constant.

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

Uniquely, California has a bifurcated system of regulation for health insurance subject to state law. The California Department of Managed Health Care (DMHC)<sup>10</sup> regulates Knox-Keene health care service plans, which offer coverage for benefits to their enrollees through health plan contracts. The CDI regulates health insurers<sup>11</sup>, which offer coverage for benefits to their enrollees through health insurance policies.

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<sup>8</sup> For example, USPSTF “strongly recommends Rh(D) blood typing and antibody testing for all pregnant women during their first visit for pregnancy-related care (USPSTF, 2008).

<sup>9</sup> (Subtitle D, Sec. 1302, as modified by Sec. 10104) “Requires the essential health benefits package to provide essential health benefits and limit cost-sharing. Directs the Secretary to: (1) define essential health benefits and include emergency services, hospitalization, maternity and newborn care, mental health and substance use disorder services, prescription drugs, preventive and wellness services and chronic disease management, and pediatric services, including oral and vision care; (2) ensure that the scope of the essential health benefits is equal to the scope of benefits provided under a typical employer plan; and (3) provide notice and an opportunity for public comment in defining the essential health benefits. Establishes: (1) an annual limit on cost-sharing beginning in 2014; and (2) a limitation on the deductible under a small group market health plan.” (CRS, 2010)].

<sup>10</sup> The DMHC was established by the Knox-Keene Health Care Service Plan of 1975. See Health and Safety Code, Section 1340.

<sup>11</sup> The CDI licenses “disability insurers.” Disability insurers may offer forms of insurance that are not health insurance. This report considers only the impact of the benefit mandate on health insurance policies, as defined in Insurance Code, Section 106(b) or subdivision (a) of Section 10198.6.

## **Background of Disease or Condition**

Maternity services benefits generally include prenatal care, such as office visits and screening tests; labor and delivery services, including hospitalization; care resulting from complications related to a pregnancy; and postnatal care. In 2008, the birth rate in California was 69.0 per 1,000 women of childbearing age (CDPH, 2008b), or more than 551,000 births (CDPH, 2008a). During the next decade, the state's total number of annual births is projected to increase about 56,000 (10.1%) from the 2008 level, to total over 607,000 by 2018 (California Department of Finance, 2009).

In California during 2008, the majority (80.7%) of births were to mothers who initiated prenatal care in the first trimester (RAND, 2008). Another 14.1% started prenatal care in the second trimester, while 2.7% started care in the third trimester (defined as "late" prenatal care) (RAND, 2008). In addition, only 0.5% of births were to women receiving no prenatal care, 2.0% of live births were to women having 1 to 4 prenatal visits, 15.4% had 5 to 9 visits, 58.0% had 10 to 14 visits, while 20.9% had 15 or more visits (RAND, 2008). Overall, 3.2% of births in California are to women receiving "late" or no prenatal care (RAND, 2008).

Three of the major health outcomes of maternity care and utilization of prenatal services are birth weight, preterm deliveries, and infant and maternal mortality. Major risk factors for low birth weight and preterm births include multifetal pregnancy, history of preterm delivery, birth defects, chronic maternal health problems, smoking, alcohol and illicit drug use, maternal and fetal infections, placental problems, inadequate maternal nutrition, and socioeconomic factors (MOD, 2004). An infant is considered low birth weight if the baby is below 2,500 grams at birth. In California, 5.7% of babies born weigh less than 2,500 grams, and 1.1% of all births are considered very low birth weight (i.e., less than 1,500 grams) (RAND, 2008).

A full-term pregnancy is defined as a gestational length of 37 to 42 weeks. Babies born before 37 weeks of gestation are classified as preterm, while babies born before 32 weeks of gestation are classified as very preterm. In California, 10.6% of births were preterm in 2006, with approximately 1.5% of all births being very preterm (MOD, 2006). Both preterm and very preterm babies are at higher risk for death and disabilities such as cerebral palsy, mental retardation, visual impairment, and hearing loss (IOM, 2006). The causes of preterm birth are not well understood, but medical conditions such as chronic hypertension, diabetes, infections, and stress are associated with preterm birth (IOM, 2006). In addition, a family or personal history of preterm birth or having a multifetal pregnancy also increase the risk of preterm birth (IOM, 2006).

Overall in California, the rate of maternal pregnancy-related mortality is 16.9 deaths per 100,000 live births (CDPH, 2009). This rate has trended upward since the late 1990s. In 1998, the rate was 6.7 per 100,000; in 2000 it was 10.9; by 2005 the rate was 11.7; and in 2006, 16.9 per 100,000. The 2006 rate of 16.9 deaths per 100,000 live births translates into nearly 100 maternal deaths in California each year. Infant mortality rates in California are 530 deaths per 100,000 live births, resulting in close to 3,000 deaths annually (CDPH, 2005). Infant mortality, or death of an infant in the first year of life, is most frequently caused by birth defects (23.5% of deaths),

followed by prematurity and low birth weight (15.6% of deaths), maternal complications of pregnancy (6.0% of deaths), and SIDS (5.2% of deaths) (CDPH, 2005). A myriad of other causes make up the remaining half of reported infant deaths.

## **Background of AB 1825**

According to the bill author, the problem the bill seeks to address is one in which individuals sign up for health insurance plan contracts and policies without maternity coverage because these products are more affordable, and end up paying out of pocket for maternity services when they become pregnant. Furthermore, there has been a trend toward “bare bones” plan contracts and policies, primarily in the individual market, targeting younger women. This trend, according to the bill author, negatively affects the market because as health plans and insurers carve out risks, there is greater risk-segmentation in the market. The primary goal of AB 1825 is to ensure that no pregnant women find themselves unintentionally enrolled in a health insurance policy that does not cover maternity services. The “principle tenet” of the bill is to ensure that women without coverage for maternity services do not end up in public programs and add to the state’s fiscal burden.

In addition, AB 1825 is also intended to “level the playing field” between health care service plans that are regulated by the DMHC (which are required to cover maternity services) and health insurers regulated by the CDI (which presently are not). Presumably, requiring all insurers to cover maternity service would halt the current risk segmentation of the market, which is the dynamic of insurers selling low-cost policies to individuals who would use less health care services (in this case no maternity services), and higher-cost policies to those who would use more health care services. With each sequence of segmentation, fewer individuals choose higher-cost policies, in turn raising costs for those who do and reducing the opportunity to amortize the costs of treating those who need care over a greater number of individuals.

CHBRP has analyzed four similar bills: two introduced by Assembly Member De La Torre in 2009 and 2008 (AB 98 and AB 1962) and two introduced by Senator Jackie Speier in 2003 and 2004 (SB 897 and SB 1555).<sup>12</sup> In 2004, CHBRP estimated that approximately 82% of those in the individual market had coverage for maternity services, leaving about 192,000 individuals without coverage for maternity services in the individual market. As will be discussed in further detail in the *Utilization, Cost, and Benefit Coverage Impacts* section, the percentage of individuals who have coverage for maternity services in the individual market has dropped to 18%. In other words, about 963,000 of individuals with privately funded insurance in the CDI-regulated market currently do not have coverage for maternity services. This indicates that risk segmentation has already had a substantial impact on the individual (non-group) insurance market.

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<sup>12</sup> Analyses of the four bills are available on CHBRP’s Web site at [http://www.chbrp.org/completed\\_analyses/index.php](http://www.chbrp.org/completed_analyses/index.php)

## Current Requirements

There are state and federal laws and regulations currently in place related to health insurance coverage of maternity services. As mentioned, health care service plans regulated by the DMHC are required to provide coverage for maternity services under provisions related to “basic health care services.” While this coverage requirement is not explicit in statute, regulations defining basic health care services specifically include prenatal care as preventive care that must be covered. DMHC-regulated plans are also required to cover maternity and pregnancy-related care under statutes governing emergency and urgent care.<sup>13</sup> Thus, under existing California laws and regulations, the 89.6% of the market enrolled in privately funded DMHC-regulated plans has coverage for maternity services.<sup>14</sup>

Under Title VII of the federal Civil Rights Act, employers may not discriminate on the “basis of pregnancy, childbirth, or related medical conditions.” Employers that offer health insurance and have 15 or more employees must cover maternity services benefits at the same level as other health care benefits.<sup>15</sup> Thus, under federal law all members obtaining health insurance in the large-group market (groups with more than 50 employees) have coverage for maternity services. As determined in CHBRP’s survey of the largest insurers in California, which will be discussed in detail in the *Utilization, Cost, and Benefit Coverage Impacts* section, small-group members also have coverage for maternity services.

In addition to general requirements on coverage, there are a set of existing laws and regulations related to the maternity services benefit *if* the health insurance plan/policy includes this benefit. Specifically:

- Minimum length of stay for maternity services: Health plan contracts and policies that provide maternity coverage are prohibited from restricting “benefits for inpatient hospital care to a time period less than 48 hours following a normal vaginal delivery and less than 96 hours following a delivery by cesarean section.”<sup>16</sup> This is also a federal protection under the Newborns’ and Mothers’ Health Protection Act of 1996.<sup>17</sup>
- Limitation on copayments and deductibles for specified maternity services: Health plan contracts and policies that provide maternity coverage are prohibited from charging members copayments and deductibles for maternity services that “exceeds the most common amount of the copayment or deductible” for inpatient and outpatient services.<sup>18</sup>

California law includes provisions related to accessing health insurance in the *group* market if the enrollee is pregnant. Currently, health plans and insurers issuing group contracts or policies “may not impose a pre-existing condition exclusion to... a condition relating to benefits for pregnancy or maternity care.” The federal Health Insurance Portability and Accountability Act, which amends the Employee Retirement Income Security Act, prohibits employer-based plans from applying pre-existing condition exclusions to pregnancy, whether or not the woman had

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<sup>13</sup> Section 1300.67 of the California Code of Regulations, Title 28

<sup>14</sup> CHBRP’s methods of calculating enrollment in private and public programs that would be affected by the mandate are described in Appendix D.

<sup>15</sup> The Pregnancy Discrimination Act under Title VII of the Civil Rights Act of 1964

<sup>16</sup> California Health and Safety Code, Section 1367.621; California Insurance Code, Section, 10123.87

<sup>17</sup> Newborns’ and Mothers’ Health Protection Act of 1996. Pub L No.104–204, §601 (1996)

<sup>18</sup> California Health and Safety Code, Section 1373.4; California Insurance Code, Section 10119.5

previous coverage. However, health plans and insurers that write *individual* policies have the right to deny issuing policies to applicants that have certain conditions, including pregnancy, pregnancy of a spouse or covered dependent, or planned surrogacy or adoption in process.<sup>19</sup> Under California law, plans and insurers are required to issue health insurance to a newborn for the first 30 days of his or her life. This requirement applies to CDI-regulated individual policies that do not cover maternity services.<sup>20</sup>

In 2009, California passed AB 119 into law prohibiting insurers from gender rating, or charging differential premiums based on gender for contracts issued, amended, or renewed on or after January 1, 2011. AB 1825 would have the same general effective date as the gender rating ban. Thus, the combined effect of both AB 1825 and the gender rating ban would be to spread the risk for women and women who may use maternity services more evenly across the individual CDI-regulated market. Therefore, the premium and cost calculations in this report assume all gender-rated policies will be converted to gender-neutral pricing prior to the implementation of AB 1825.

### State Activities

If a woman does not have maternity services coverage through her health insurance, she may qualify to receive maternity care through the Access for Infants and Mothers (AIM) program administered by the Managed Risk Medical Insurance Board (MRMIB).

To qualify, a woman must:

- be pregnant (though no more than 30 weeks)
- be a California resident
- not be enrolled in another publicly funded program
- not have coverage from privately funded insurance that costs less than \$500 (for example, a woman may be in a high-deductible health plan [HDHP] facing deductibles and co-insurance higher than \$500)
- be below 300% of the federal poverty level

There are 18 states, including California, that currently have a requirement related to the coverage of maternity services (KFF, 2009). State laws related to maternity coverage vary by the market that is targeted (e.g., individual or group) or by provisions related to the terms and conditions that maternity services must be covered (e.g., cost-sharing levels). For example, maternity services are required to be covered as part of Hawaii's rules for prepaid health plans in the group market.<sup>21</sup> Washington requires carriers that sell individual health plans (except catastrophic coverage plans)<sup>22</sup> to (1) provide coverage for maternity services and (2) ensure cost-sharing levels are the same as other health care benefits.<sup>23</sup> New Hampshire requires carriers

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<sup>19</sup> California Health and Safety Code, Sections 1357.06 and 1357.51; California Insurance Code, Section 10198.7 and 10708. Also see [http://www.dmhc.ca.gov/dmhc\\_consumer/hp/hp\\_individual.asp](http://www.dmhc.ca.gov/dmhc_consumer/hp/hp_individual.asp).

<sup>20</sup> Insurance Code Section 10119 and *Redlands Community Hospital v. New England Mutual* (1994) 23 Cal. App. 4th 898.

<sup>21</sup> Hawaii Statute §393-7 "Required health care benefits"

<sup>22</sup> Washington State Division of Insurance <http://www.insurance.wa.gov/publications/health/2105-Mandates.pdf>

<sup>23</sup> Washington Insurance Code RCW 48.43.041

selling individual health policies to offer a maternity rider if the policy does not cover maternity services in its base plan.<sup>24</sup>

### Bill Provisions, Key Assumptions, and Analytic Approach

AB 1825 would require the entire CDI-regulated market to cover maternity services by requiring new forms for health insurance policies submitted to the department after January 1, 2011.<sup>25</sup> The CDI-regulated market constitutes approximately 12.8% of enrollees with privately funded health insurance in California. Enrollees in CDI-regulated policies represent about 60.0% of the individual market and about 28.1% of the privately funded small-group market. Because all group policies are required to and in practice currently cover maternity services, the *Utilization, Cost, and Benefit Coverage Impacts* analysis will focus on the CDI-regulated individual market. That section specifically examines the impact of adding maternity services to those CDI-regulated individual policies that do not currently cover those services.

AB 1825 would not directly affect populations that are enrolled in health insurance plans or policies that are not subject to benefit mandates such as those enrolled in self-insured employer plans and do not apply to those who are uninsured.<sup>26</sup> In addition, AB 1825 would not place any new requirements on publicly funded programs such as CalPERS, Medi-Cal, or AIM.

As discussed above, there are existing laws related to underwriting and these would not be affected by AB 1825. AB 1825 is silent on rules related to underwriting and thus would allow health insurance policies and plans regulated by the CDI and the DMHC to continue to apply pre-existing condition limitations for individual (non-group) insurance. Finally, AB 1825 does not place new requirements on coverage of newborns.

AB 1825 defines “maternity services” to include prenatal care, ambulatory care maternity services, involuntary complications of pregnancy, neonatal care, and inpatient hospital maternity care including labor and delivery and postpartum care. The *Medical Effectiveness* and *Public Health Impacts* sections of this report focus on the outcomes associated with prenatal care services because (1) a majority of births occur in the hospital setting regardless of insurance status and hospitalizations are already covered, (2) prenatal care services use would be most affected by the potential for out-of-pocket costs and thus most directly impacted by AB 1825, and (3) AB 1825 would not affect coverage for infants. The *Utilization, Cost, and Benefit Coverage Impacts* section includes the full range of services that are considered to be “maternity services.” That section will also focus on the CDI-regulated individual market because all group policies are required to and in practice currently cover maternity services.

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<sup>24</sup> New Hampshire Statute Section 415:6-d

<sup>25</sup> The requirement of new policy forms was a Senate Floor Amendment to AB 98 (2009, De La Torre), added on September 4, 2009.

<sup>26</sup> CHBRP’s authorizing legislation defines a benefit mandate bill as “a proposed statute that requires a health care service plan or a health insurer, or both, to ...offer or provide coverage of a particular type of health care treatment or service.” Thus, the portion of the population directly affected by a benefit mandate bill are those enrolled in a health insurance plan contract or policy offered by health care service plans or health insurers.

## MEDICAL EFFECTIVENESS

As noted in the *Introduction*, AB 1825 defines maternity services to include prenatal care, ambulatory care maternity services, involuntary complications of pregnancy, neonatal care, and inpatient hospital maternity care including labor and delivery and postpartum care. Each of these categories of maternity services in turn encompasses multiple screening tests, diagnostic tests, monitoring services, and treatments. Conducting a medical effectiveness analysis on the full range of maternity services is not feasible for this analysis. In addition, because AB 1825 is most likely to affect utilization of prenatal care, CHBRP focuses this review of the literature on the effectiveness of prenatal care services. Regardless of health insurance status, the vast majority of women in the United States deliver their babies in hospitals, and AB 1825 would not affect coverage for infants.

### Literature Review Methods

Due to the large amount of literature on prenatal care services, CHBRP limited its literature search to meta-analyses, systematic reviews, and evidence-based guidelines because such syntheses of multiple studies are the strongest forms of evidence of the effectiveness of medical interventions. Syntheses of studies of the effects of prenatal care services were identified through searches of MEDLINE (PubMed), the Cochrane Database of Systematic Reviews, the Cochrane Register of Controlled Clinical Trials, Web of Science, and EconLit. In addition, Web sites maintained by the following organizations that index or publish systematic reviews and evidence-based guidelines were searched: Agency for Healthcare Research and Quality, Institute for Clinical Systems Improvement, International Network of Agencies for Health Technology Assessment, National Health Service Centre for Reviews and Dissemination, National Institutes of Health, National Guidelines Clearinghouse, National Institute of Clinical Evidence, Scottish Intercollegiate Guideline Network, the U.S. Preventive Services Task Force, and the World Health Organization.

The search was limited primarily to studies published in English from January 2009 to present. The time frame for the search was truncated because CHBRP conducted a search of the literature on the effectiveness of prenatal care services published from 2004 through 2009 for a report issued in 2009 on AB 98 and from 1995 through 2007 for a report it issued in 2008 on AB 1962, identical bills regarding coverage for maternity services. Eight additional pertinent studies were identified, retrieved, and reviewed. Findings from these studies were integrated with findings from 16 studies that were analyzed for CHBRP's report on AB 98 and with 28 studies that were analyzed for CHBRP's report on AB 1962. A more thorough description of the methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure is presented in *Appendix B: Literature Review Methods*. *Appendix C* includes tables that describe the studies that CHBRP reviewed and their findings. A table that lists effective prenatal care services appears at the end of this section of the report (Table 2).

## Outcomes Assessed

The literature search focused on the impact of prenatal care services<sup>27</sup> on health outcomes for pregnant women and infants. Findings from studies of the accuracy of screening tests were examined only for purposes of determining whether accurate tests of a given disease or condition are available. Findings regarding the effectiveness of treatments were reviewed but are not summarized below because CHBRP is most interested in whether receiving treatment is associated with better birth outcomes for mothers and infants.

Maternal health outcomes assessed include:

- Maternal mortality
- Eclampsia
- Preeclampsia
- Kidney infection
- Antepartum hemorrhage
- Placental abruption
- Preterm premature rupture of membranes
- Induction of labor
- Postpartum hemorrhage

Infant health outcomes assessed include:

- Preterm birth
- Low birth weight
- Small birth weight for gestational age
- Fetal, neonatal, and infant mortality
- Admission to neonatal intensive care unit
- Transmission of infectious disease
- Alloimmune hemolytic disease
- Cerebroventricular or intraventricular hemorrhage
- Respiratory distress syndrome
- Cerebral palsy

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<sup>27</sup> For the purposes of this report, CHBRP defines prenatal care services as encompassing all services provided to pregnant women during the prenatal period. Some of these services, such as the use of magnesium sulfate to prevent eclamptic seizures, are used to address pregnancy complications. As indicated in the *Introduction*, some health insurance policies that do not cover maternity services generally may cover pregnancy complications. However, there is not universal agreement as to what conditions constitute pregnancy complications. Some health insurance policies do not define this term and some insurers make coverage decisions on a case by case basis (KKF, 2007a).

- Gross motor dysfunction

## Study Findings

Studies of prenatal care can be divided into two major groups:

- Studies of the impact of variation in the number of prenatal care visits that pregnant women receive, and
- Studies of the effectiveness of specific services provided during prenatal care visits or in conjunction with them (e.g., laboratory tests, medications).

These two sets of studies are summarized separately below.

### Studies of the Impact of the Number of Prenatal Care Visits

Randomized controlled trials (RCTs) generally have found no statistically significant association between the number of prenatal visits and birth outcomes for either infants or mothers (Alexander and Korenbrot, 1995). Of the 11 RCTs included in a systematic review published in 1995, all of them found that pregnant women who had greater numbers of prenatal care visits (either office or home visits) were no less likely than women who had fewer visits to have a preterm birth or a low-birth weight infant (Fiscella, 1995). More recently, a meta-analysis synthesized findings from seven RCTs that compared the effects of different numbers of prenatal care visits on birth outcomes (Villar et al., 2001). The number of visits provided to pregnant women in the intervention group ranged from 4 to 12 visits and the number provided to pregnant women in the control group ranged from 6 to 11 visits. The difference in the number of visits received by women in the intervention and control groups ranged from 2 to 3 visits. The meta-analysis found that the number of visits does not affect the odds of having a preterm birth, delivering a low-birth weight infant, or admission of a newborn to a neonatal intensive care unit. This meta-analysis also reported that the number of visits was not associated with the odds of maternal mortality, preeclampsia, and antepartum or postpartum hemorrhage.

Most studies of prenatal care do not include a control group of pregnant women who receive no prenatal care. Providing prenatal care has been an established standard of medical practice for so long that it is considered unethical to randomize pregnant women to receive no prenatal care. Thus, the effect of having no prenatal care is unlikely to ever be studied in prospective RCTs (Alexander and Kotelchuck, 2001; Fiscella, 1995). As a consequence, researchers typically study the impact of more versus fewer prenatal care visits. In several studies, the differences studied have been as small as two visits (Villar et al., 2001). It is more difficult to detect an effect of a small difference in the number of prenatal visits than to detect a difference between a standard number of visits and no visits.<sup>28</sup>

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<sup>28</sup> Some nonrandomized studies have found that women who obtained more prenatal care visits delivered infants with larger mean birth weights and that their infants had a lower risk of death (Alexander and Korenbrot, 1995; Fiscella, 1995). However, many of these nonrandomized studies did not adequately adjust for preterm birth or for individual and socio-economic factors associated with poor birth outcomes, such as having a low income, having a low level of education, and having a substance use disorder (Alexander and Korenbrot, 1995; Alexander and Kotelchuck, 2001; Fiscella, 1995). These studies may also have not controlled adequately for the possibility that pregnant women who received more prenatal care visits may have been more health conscious than those who received fewer visits. To the extent that occurs, differences in birth outcomes reported in observational studies may

There is clear and convincing evidence that having more prenatal care visits is not associated with better birth outcomes for either infants or mothers, but the threshold above which there is no benefit to additional visits has not been established.

### Studies of the Effectiveness of Specific Prenatal Care Services

Although the number of prenatal care visits is not associated with birth outcomes, there is evidence that a number of services provided to pregnant women during or in conjunction with prenatal care visits are effective. These services include screening tests, diagnostic tests, monitoring services, and treatments for diseases or conditions associated with poorer birth outcomes. Some prenatal care services, such as blood pressure monitoring and ultrasound testing, are typically performed as part of an office visit. In other cases, samples of blood, urine, or other bodily fluids are collected in a medical office and then analyzed in a medical laboratory. In still other cases, women who have positive results on screening tests for diseases or conditions associated with poorer birth outcomes are prescribed medications to cure or mitigate these conditions. However, the impact of these services on overall rates of poor birth outcomes is likely to be small, because the percentages of pregnant women who have many of these diseases and conditions are small.

The evidence of the effectiveness of these services is discussed below. Evidence was drawn primarily from meta-analyses and systematic reviews published by the Cochrane Collaboration or in peer-reviewed journals and from systematic reviews conducted in conjunction with the preparation of evidence-based guidelines issued by the Institute for Clinical Systems Improvement (ICSI),<sup>29</sup> the National Collaborating Centre for Women's and Children's Health (NCCWCH),<sup>30</sup> the New Zealand Ministry of Health, the United States Preventive Services Task Force (USPSTF), and the United States Public Health Service. Findings from studies of these services are grouped into categories below based on the nature of the disease or condition for which screening and/or diagnostic tests are performed, and monitoring or treatment provided.

#### *Behavioral risk factors*

**Smoking.** Smoking during pregnancy is a major risk factor for preterm birth and low birth weight (Fiscella, 1995). Two meta-analyses and three systematic reviews of RCTs have examined the impact of brief advice to quit smoking and/or smoking cessation counseling on these birth outcomes (Lu et al., 2003; Lumley et al., 2009; NCCWCH, 2008; NZMOH, 2008; US DHHS, 2008). All five studies concluded that brief advice and/or counseling regarding smoking cessation increases the likelihood that pregnant women will stop smoking. One meta-analysis found that providing counseling and other psychosocial interventions were more effective than brief advice, self-help materials, and referral to smoking cessation programs (US DHHS, 2008).

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have been due to differences in health behaviors rather than numbers of prenatal visits. Nonrandomized studies that did not adequately control for these factors may have overstated the benefits of having more prenatal care visits.

<sup>29</sup> The Institute for Clinical Systems Improvement is an independent, not-for-profit organization that promotes quality improvement among health plans, hospitals, and medical groups in Minnesota. This citation is to an evidence-based guideline for routine prenatal care.

<sup>30</sup> The National Collaborating Centre for Women's and Children's Health is one of seven [National Collaborating Centres](#) in the United Kingdom that are funded by the [National Institute for Health and Clinical Excellence](#) (NICE) to develop the clinical guidelines for the National Health Service.

The studies also determined that smoking cessation advice and/or counseling reduces the risk of giving birth preterm or delivering a low–birth weight infant. The most recent meta-analysis found that smoking cessation advice or counseling decreased the risk of giving birth preterm by 14% and the risk of delivering a low–birth weight infant by 17% (Lumley et al., 2009).<sup>31</sup>

**Alcohol use.** While there is limited evidence on the efficacy of multi-contact counseling interventions among pregnant women on cessation of alcohol consumption (USPSTF, 2004), two organizations that make evidence-based guidelines recommend screening pregnant women for alcohol use, counseling them about the harmful effects of drinking on the fetus, and encouraging them to abstain from drinking alcohol during pregnancy (NCCWCH, 2008; USPSTF, 2004).

**Cannabis use.** There is insufficient evidence on the effects of maternal cannabis use on pregnancy outcomes. A major limitation of such research is accurately measuring the amount of cannabis consumed as it is often smoked with tobacco. Other limitations include confounding effects of alcohol use, smoking tobacco, and use of other drugs (NCCWCH, 2008). The NCCWCH recommends that women be discouraged from using cannabis during pregnancy, as cannabis use is associated with smoking, a known risk factor for poor pregnancy outcomes (NCCWCH, 2008).

**Domestic violence.** Domestic violence during pregnancy can cause injury to both pregnant women and their fetuses. The authors of one systematic review conducted in conjunction with the preparation of an evidence-based guideline assessed evidence of the effectiveness of screening pregnant women to identify those being abused (ICSI, 2008). The systematic review identified several nonrandomized studies with comparison groups that reported findings that favored screening.

#### *Fetal abnormalities*

Tests are available to screen pregnant women and, in some cases, their partners, for genetic traits for disorders that are associated with poor birth outcomes and serious illness or disability among children. Diagnostic tests are conducted on fetuses whose parents have these traits or are otherwise at elevated risk for these disorders.

**Down syndrome.** Down syndrome (commonly caused by trisomy 21) is a genetic disorder that causes mental retardation, heart defects, and other major health problems. Two systematic reviews conducted in conjunction with the preparation of an evidence-based guideline have assessed evidence regarding the accuracy of screening tests for Down syndrome (ICSI, 2008; NCCWCH, 2008). Both concluded that there is sufficient evidence to recommend counseling all women about screening for Down syndrome and providing screening to those who would like to be screened using ultrasound for nuchal translucency and/or blood tests for biomarkers (ICSI, 2008; NCCWCH, 2008). Exposure to diagnostic B-mode and Doppler ultrasound have been shown to be a safe (Torloni et al., 2009). Women whose results for these tests suggest they are at elevated risk for carrying a child with Down syndrome are encouraged to undergo either an amniocentesis or chorionic villus sampling test, each of which has a small risk of causing a miscarriage, to determine if their fetuses have the disorder (ICSI, 2008; NCCWCH, 2008). The

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<sup>31</sup> All risk reductions, odds, and percentage differences cited in this section of the report are statistically significant at  $p < 0.05$ .

purpose of this two-stage approach is to ensure that invasive diagnostic testing is targeted at women who are at high risk of carrying a fetus with Down syndrome. In the past, maternal age of 35 years or older was used as the sole criterion for determining which pregnant women should receive amniocentesis or chorionic villus sampling, even though this approach detects only one third of Down syndrome cases (ICSI, 2008).

**Hemoglobinopathies.** Two evidence-based guidelines recommend screening for hemoglobinopathies, such as sickle cell anemia and thalassemias, in populations at higher risk of carrying the gene mutations associated with these disorders (ICSI, 2008; NCCWCH, 2008). When both parents have the genetic mutations that cause the disorder (i.e., are carriers), they can unwittingly pass the disorder on to their child. In the United States, parents of African ancestry are at greatest risk of being carriers for the sickle cell mutation. Parents of southeast Asian ancestry are at greater risk of being carriers of alpha thalassemia mutations, and parents of Mediterranean ancestry are at greatest risk for being carriers of beta thalassemia mutations. One guideline recommends offering complete blood count tests to all pregnant women and their partners and additional tests to pregnant women from racial/ethnic groups at increased risk of carrying a fetus with one of these disorders (ICSI, 2008). The other guideline makes two recommendations for screening depending on the prevalence of hemoglobinopathies in a population of pregnant women (NCCWCH, 2008). Where the prevalence of hemoglobinopathies is high, the guideline recommends offering blood tests to all pregnant women and their partners. Where the prevalence is low, the guideline recommends using a questionnaire about family origin to identify pregnant women at high risk for carrying a fetus with one of these disorders and offering testing to high-risk women and their partners.

**Tay-Sachs disease.** Tay-Sachs disease is a fatal genetic disorder that causes harmful quantities of a fatty substance called ganglioside  $G_{M2}$  to build up in the brain. The disorder occurs where both parents are carriers of specific gene defect associated with the disease. Ashkenazi Jews have the highest risk of carrying these genetic mutations. One evidence-based guideline published in the United States recommends offering screening for this disorder to all Jewish parents because most Jews in the United States are of Ashkenazi descent (ICSI, 2008).

**Neural tube defects.** Neural tube defects are birth defects that affect the brain and spinal cord. They include spina bifida, anencephaly, and encephalocele (NCCWCH, 2008). Based on findings from a systematic review and individual studies, one evidence-based guideline recommended that all pregnant women be offered an ultrasound scan to screen for neural tube defects and other structural anomalies, ideally between 18 and 20 weeks of gestation (NCCWCH, 2008). One individual RCT cited in this guideline found that the detection rate for fetal structural abnormalities was higher for routine screening of all pregnant women than for selective screening of women at high risk for carrying a fetus with structural abnormalities. Two systematic reviews found that evidence from RCTs indicates that consumption of folic acid prior to conception is associated with a statistically significant reduction in the risk of giving birth to an infant with neural tube defects (ICSI, 2008; NCCWCH, 2008). One meta-analysis cited in these systematic reviews reported that consumption of folic acid prior to conception was associated with a 72% lower risk of giving birth to a child with a neural tube defect. The Centers for Disease Control and Prevention (CDC) and the Institute of Medicine (IOM) recommend that women of childbearing age consume 400 micrograms of folic acid per day prior to conception

and 600 micrograms per day during pregnancy from fortified foods and supplements (ICSI, 2008). The United Kingdom's Department of Health recommends that both pregnant and non-pregnant women take 400 micrograms per day (NCCWCH, 2008). In May of 2009, the USPSTF updated their recommendation for women planning pregnancy, as well as women capable of pregnancy to take 400 to 800 micrograms per day (USPSTF, 2009a). This update was based on recent studies that found that a multivitamin with 800 micrograms of folic acid reduces the risk for neural tube defects. Folic acid supplements and food fortified with folic acid are not typically covered by health plans regardless of whether a woman has maternity benefits. However, a pregnant woman who does not have maternity benefits might delay obtaining prenatal care and, thus, not receive timely advice about consuming an adequate quantity of folic acid.

**Other structural anomalies.** Ultrasound can be used to determine whether a fetus has structural anomalies in other organ systems, such as the cardiovascular system, face, gastrointestinal system, pulmonary system, skeleton, or urinary system. As noted previously, one evidence-based guideline recommended that all pregnant women be offered an ultrasound scan to screen for structural anomalies (NCCWCH, 2008). Two meta-analyses have assessed the accuracy of providing an ultrasound including a nuchal translucency measurement during the first trimester to identify congenital heart defects (Makrydimas et al., 2003; Wald et al., 2008). This test is often offered to pregnant women because it is an effective screening test for Down syndrome and other chromosomal abnormalities (NCCWCH, 2008). The most recent meta-analysis concluded that nuchal translucency measurement can detect 52% of fetuses with congenital heart defects for which diagnosis could affect management of a pregnancy (Wald et al., 2008).

### *Infectious disease*

Pregnant women who have infectious diseases are at elevated risk for preterm delivery, low birth weight, and other poor birth outcomes. In addition, some infectious diseases can be transmitted from mother to child, which, if untreated, can cause blindness, liver disease (e.g., hepatitis), or death. Meta-analyses and systematic reviews have identified seven infectious diseases for which screening during pregnancy is beneficial for all women or women at elevated risk: asymptomatic bacteriuria, hepatitis B, human immunodeficiency virus, syphilis, chlamydia, gonorrhea, and group B streptococcus.

**Asymptomatic bacteriuria.** One meta-analysis and four systematic reviews of RCTs have examined the effectiveness of screening pregnant women for asymptomatic bacteriuria with urine culture, and prescribing antibiotics to those with positive urine cultures (ICSI, 2008; Lin and Fajardo, 2008; Lu et al., 2003; NCCWCH, 2008; Smaill and Vazquez, 2007). All five studies conclude that screening and treatment for asymptomatic bacteriuria reduce the risks that a pregnant woman will have a kidney infection, deliver preterm, or deliver a low-birth weight infant. The meta-analysis found that the risk of delivering a low-birth weight infant was 34% lower among women with asymptomatic bacteriuria who received antibiotics. The risk of having a kidney infection was 77% lower among pregnant women who were treated (Smaill and Vazquez, 2007). The USPSTF and ICSI recommend that pregnant women be screened for asymptomatic bacteriuria with a urine culture obtained at 12 to 16 weeks of pregnancy (ICSI, 2008; USPSTF, 2008). The NCCWCH recommends performing a urine culture early in pregnancy but does not specify a particular time interval (NCCWCH, 2008).

**Hepatitis B.** One meta-analysis and three systematic reviews of RCTs have examined the effectiveness of screening pregnant women for hepatitis B and administering hepatitis B vaccine and/or hepatitis B immune globulin to newborns whose mothers have hepatitis B (ICSI, 2008; Krishnaraj, 2004; Lee et al., 2006; NCCWCH, 2008). All four studies conclude that vaccination and/or prophylaxis with immune globulin reduces the risk that a child will develop chronic hepatitis B infection, which is associated with serious liver problems. The meta-analysis found that the risk of developing chronic hepatitis B was 50% lower for infants who received hepatitis B immune globulin, 72% lower for those who received hepatitis B vaccine, and 92% lower for infants who received both hepatitis B immune globulin and vaccine (Lee et al., 2006). The USPSTF recommends screening for hepatitis B virus infection in pregnant women at the first prenatal visit (USPSTF, 2009b).

**Human immunodeficiency virus (HIV).** Three systematic reviews have evaluated the effectiveness of screening pregnant women for HIV, and providing treatment and harm reduction interventions to women who are HIV-positive and their infants (Chou et al., 2005; ICSI, 2008; NCCWCH, 2008). All three systematic reviews concluded that all pregnant women should be screened for HIV and that treatment and harm reduction interventions reduce the risk of mother-to-child transmission of HIV. A meta-analysis of RCTs cited in one of the systematic reviews reported that providing antiretroviral therapy to pregnant women with HIV substantially reduces the odds of mother-to-child transmission of HIV, stillbirth, and death within the first year of life (Chou et al., 2005). Individual studies cited in this systematic review found that HIV-positive women who delivered their babies by cesarean section were substantially less likely to transmit HIV to their babies than those who delivered vaginally (Chou et al., 2005). Other individual studies reported that mothers who fed their infants with formula were less likely to transmit HIV to their children than those who breastfed (Chou et al., 2005).

**Sexually transmitted infections.** Six systematic reviews have assessed the effectiveness of screening pregnant women for sexually transmitted infections (Glass et al., 2005; ICSI, 2008; Meyers et al., 2007; NCCWCH, 2008; Nelson et al., 2004; USPSTF, 1996). Findings from nonrandomized studies suggest that prescribing penicillin or other antibiotics to pregnant women with syphilis substantially reduces mother-to-child transmission of this disease (ICSI, 2008; NCCWCH, 2008; Nelson et al., 2004; USPSTF, 1996). Nonrandomized studies also indicate that providing prophylaxis to infants born to mothers with gonorrhea was associated with substantial decreases in the rate of conjunctivitis or blindness (ICSI, 2008; USPSTF, 1996). In addition, nonrandomized studies suggest that prescribing antibiotics to pregnant women who have chlamydia reduces the risk of preterm premature rupture of membranes, low birth weight, and infant mortality (ICSI, 2008; USPSTF, 1996). The effectiveness of screening for sexually transmitted infections depends on the prevalence of a disease in a population, as well as the accuracy of screening tests and the benefits of treatment. Based upon the systematic reviews it commissioned, the USPSTF recommends screening all pregnant women for syphilis, pregnant women at increased risk for gonorrhea, and women 25 years and older at increased risk and all women aged 24 years or younger for chlamydia (USPSTF, 2008; USPSTF, 2009c).

**Group B streptococcus.** Three systematic reviews conducted in conjunction with the development of evidence-based guidelines evaluated the effectiveness of screening pregnant

women for group B streptococcus by culturing tissue sampled from the vaginal or perianal area during the third trimester and administering antibiotics during delivery to those who tested positive (ICSI, 2008; NCCWCH, 2008; Schrag et al., 2002). Based on these systematic reviews of nonrandomized studies with comparison groups, the authors of two of the evidence-based guidelines recommend screening all pregnant women for group B streptococcus (ICSI, 2007; Schrag et al., 2002). However, the authors of the other evidence-based guideline conclude that the evidence regarding effectiveness and cost-effectiveness of screening for group B streptococcus is inconclusive (NCCWCH, 2008).

#### *Metabolic, nutritional, and endocrine conditions*

There is less evidence of beneficial effects of screening and treatment for metabolic, nutritional, and endocrine conditions relative to infectious disease.

**Gestational diabetes.** Three systematic reviews and one meta-analysis assessed the evidence of the impact of screening pregnant women for high blood glucose (i.e., high blood sugar) and providing dietary advice to women with high blood sugar and insulin, if needed (Alwan et al., 2009; ICSI, 2008; NCCWCH, 2008; USPSTF, 2008). The meta-analysis identified one study that found that dietary and glucose monitoring counseling and insulin therapy was associated with a reduction in the risk of pre-eclampsia and with a composite outcome of perinatal morbidity (infant mortality, shoulder dystocia, bone fracture, and nerve palsy) (Alwan et al., 2009). The authors of two systematic reviews concluded that all pregnant women should be screened for gestational diabetes (ICSI, 2008; NCCWCH, 2008). However, the other systematic review determined that there was insufficient evidence to recommend for or against universal screening for this disorder (USPSTF, 2008).

**Iron deficiency anemia.** Three systematic reviews evaluated evidence of the impact of screening pregnant women for iron deficiency anemia and prescribing iron supplements to those who are anemic (Helfand et al., 2006; ICSI, 2008; NCCWCH, 2008). The majority of studies on iron supplementation have not found that it improves birth outcomes. However, a poorly implemented RCT<sup>32</sup> that was recently conducted in the United States reported that iron supplementation reduced the percentage of low-birth weight infants born to women with iron deficiency anemia (Helfand et al., 2006). Three organizations have issued evidence-based guidelines that recommend screening asymptomatic pregnant women for iron deficiency anemia (ICSI, 2008; NCCWCH, 2008; USPSTF, 2008).

#### *Other medical conditions*

There is also evidence of effectiveness for screening and treatment for hypertensive disorders and red blood cell antibody disorders.

**Hypertensive disorders.** Preeclampsia encompasses a variety of hypertensive disorders in pregnancy, including pregnancy-induced or gestational hypertension. These disorders occur in 2% to 8% of pregnancies (Duley et al., 2007). They can cause headaches, dizziness, nausea,

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<sup>32</sup> Randomization of pregnant women to the treatment and control groups was not successful. Women in the control group had higher weight pre-pregnancy and had higher levels of ferritin (the main iron storage protein) at the time they enrolled in the study. In addition, 23% of these women had to be excluded from the analysis because the researchers could not obtain birth weight data for their infants (previous study was cited in Helfand et al., 2006).

vomiting, changes in vision, and upper abdominal pain. In severe cases, preeclampsia is associated with hemolysis, placental abruption, and lack of blood flow to the placenta, which can lead to preterm birth and small-for-gestational-age birth. To prevent or mitigate these complications, pregnant women with preeclampsia are often scheduled for preterm delivery. A small percentage of women with uncontrolled preeclampsia develop eclampsia, a condition that can cause coma, brain damage, and death for both mother and baby, if not treated.

Three organizations that issue evidence-based guidelines recommend screening all pregnant women for preeclampsia through blood pressure monitoring and urinalysis to detect proteinuria, although no controlled studies on this topic have been published (ICSI, 2008; NCCWCH, 2008; USPSTF, 1996). Controlled studies have not been undertaken because blood pressure monitoring for hypertension has been a standard practice for so long that it would be unethical to withhold it from pregnant women. In addition, both blood pressure monitoring and urine culture testing are inexpensive and noninvasive. However, RCTs have been conducted on three treatments to improve birth outcomes for women with preeclampsia.

One meta-analysis and three systematic reviews of RCTs have assessed the effects of providing **calcium supplements** to all pregnant women regardless of their risk of hypertensive disorders. (Hofmeyr et al., 2006; ICSI, 2008; Meads et al., 2008; NCCWCH, 2008). All three concluded that calcium supplements reduce the risk of preeclampsia and maternal death or serious morbidity. The meta-analysis concluded that pregnant women with preeclampsia who took calcium supplements had a 20% lower risk of death or serious morbidity (Hofmeyr et al., 2006).

Three meta-analyses and one systematic review of RCTs evaluated the impact of prescribing low doses of aspirin or other **antiplatelet agents** to pregnant women at risk for preeclampsia (Askie et al., 2007; Duley et al., 2007; Meads et al., 2008; Ruano et al., 2005). The authors of the most thorough meta-analysis reported that pregnant women who used antiplatelet agents were 17% less likely to develop preeclampsia than pregnant women who received a placebo or no treatment (Duley et al., 2007). This meta-analysis also found that use of antiplatelet agents was associated with reductions in the risk of preterm birth, small-for-gestational-age birth, and fetal or neonatal death. A meta-analysis of individual patient data from a subset of studies analyzed in the aforementioned meta-analysis reached the same conclusions regarding the impact of anti-platelet agents on the risks of preeclampsia and preterm birth but found no statistically significant difference in risks of small-for-gestational-age birth or fetal or neonatal death (Askie et al., 2007).

One meta-analysis of RCTs investigated the impact of administering **magnesium sulfate** to pregnant women to prevent seizures associated with eclampsia (Duley et al., 2003). The authors of one meta-analysis reported that women who received magnesium sulfate during delivery had a 59% lower risk of eclampsia and a 36% lower risk of placental abruption.

**Rh(D) incompatibility.** Three systematic reviews have addressed the impact of Rh(D) immune globulin for treatment of Rh(D) incompatibility (ICSI, 2008; NCCWCH, 2008; USPSTF, 1996). If Rh(D) incompatibility is not diagnosed and treated, children born to Rh(D) negative mothers are at high risk for hemolytic disease, a serious disease whose symptoms include anemia, body swelling, difficulty breathing, and jaundice. Based on controlled studies conducted in the 1960s,

all three systematic reviews concluded that screening for Rh(D) incompatibility and administration of Rh(D) immune globulin is effective. One systematic review also recommends screening for other atypical red blood cell alloantibodies and referral of pregnant women with abnormalities to a maternal-fetal medicine subspecialist (NCCWCH, 2008).

### *Pregnancy outcomes*

There is also evidence that some interventions that are targeted at preventing preterm birth are effective, as are some interventions for preventing complications at term.

**Progestational agents to prevent preterm delivery.** Four meta-analyses and three systematic reviews of RCTs have assessed studies of the effectiveness of progestational agents in preventing preterm delivery among women at risk for it (Dodd et al., 2006; Dodd et al., 2008; ICSI, 2008; Lu et al., 2003; Mackenzie et al., 2006; Rode et al., 2009; Sanchez-Ramos et al., 2005). Progesterone is a hormone that occurs naturally in the body. RCTs have assessed the effectiveness of administering either natural progesterone in the form of vaginal suppositories or intramuscular injection of synthetic progesterone (17  $\alpha$ -hydroxyprogesterone caproate). All seven studies determined that prescribing progestational agents to pregnant women reduces the likelihood of preterm birth and/or delivering a low-birth weight infant. The authors of the most rigorous and inclusive systematic review found that prescribing progestational agents was associated with a 23% reduction in the risk of preterm birth at less than 37 weeks, a 38% reduction in the risk of low birth weight, and a significant reduction in prenatal death (Rode et al., 2009). This meta-analysis also found that taking progestational agents was also associated with a statistically significant reduction in intraventricular hemorrhage, a risk factor for development of cerebral palsy.

**Corticosteroids to promote maturation of lungs in fetuses scheduled for preterm delivery.** One systematic review and one meta-analysis of RCTs examined studies of the effect of prescribing **corticosteroids** to pregnant women to promote maturation of the lungs in fetuses scheduled for preterm delivery due to preeclampsia or other complications (Lu et al., 2003; Roberts and Dalziel, 2006). Both found that prescribing corticosteroids during pregnancy improved birth outcomes for newborns. The meta-analysis reported that treatment with corticosteroids was associated with a 31% lower risk of neonatal mortality as well as with lower risks of respiratory distress syndrome, cerebrovascular hemorrhage, necrotizing enterocolitis (i.e., infection and inflammation that destroys the bowel or part of the bowel), and admission to neonatal intensive care units (Roberts and Dalziel, 2006).

**Magnesium sulfate to prevent neurological impairment in fetuses at risk for preterm delivery.** One meta-analysis has assessed whether prescribing magnesium sulfate to pregnant women at risk for preterm birth reduces the risk of bearing a child with a neurological impairment (Doyle et al., 2009). Infants who are born prematurely are at increased risk of having severe neurological impairments such as cerebral palsy, cognitive dysfunction, blindness, and deafness. The meta-analysis found that prescribing magnesium sulfate was associated with a 32% reduction in the risk that a newborn would have cerebral palsy and a 39% reduction in the risk of substantial gross motor dysfunction.

**Screening and treatment for lower genital tract infection preterm delivery.** One meta-analysis identified one study that examined whether receiving the results from simple infection screening test would prevent preterm delivery. All women were screened for bacterial vaginosis, trichomonas vaginalis, or candidiasis infection using a Gram stain. Preterm births were lower among women who received the screening results and treatment when compared to women who did not receive the results to the screen (3% versus 5% in the control group) (Sangkomkamhang et al., 2009). While this study found the use of a single screening test for multiple lower genital tract infections to prevent preterm birth, the USPSTF found no benefit for screening solely for bacterial vaginosis (Nygren et al., 2008).

**Placenta previa.** Placenta previa is a condition under which the placenta covers the cervix, which can lead a pregnant woman to experience placental abruption or antenatal or postpartum hemorrhage. This condition can also lead to intrauterine growth restriction, which can cause a newborn to be small for his or her gestational age. One systematic review evaluated the use of ultrasound to detect and monitor placenta previa (NCCWCH, 2008). The authors concluded that ultrasound should be performed at 20 weeks, and again at 32 weeks if the scan at 20 weeks is positive. This practice accurately identifies most women for whom placenta previa will persist until term, enabling pregnant women and their physicians to anticipate and treat complications.

**Breech presentation at delivery.** In order for a fetus to move through the birth canal properly, the fetus must be able to proceed head first. Most fetuses move into this position prior to term but some remain in a feet-first (breech) position, which places them at increased risk for poor birth outcomes unless they are delivered by elective cesarean section. While beneficial to babies in the breech position at term, cesarean section is a major abdominal surgery that has a greater risk of complications than vaginal delivery. Two systematic reviews have examined RCTs regarding the effectiveness of external cephalic version (application of pressure to the pregnant woman's abdomen to encourage the fetus to turn to the head-first position) (Hutton and Hofmeyr, 2006; NCCWCH, 2008). Both found that external cephalic version was associated with lower risks of breech presentation at birth and delivery by cesarean section.

**Postterm delivery.** Once a pregnancy has reached term, continuation can be detrimental to the fetus and can lead to perinatal death. If a pregnancy continues beyond term, labor may be induced with pharmaceutical agents, but the risks of induction may outweigh benefits unless the fetus is truly past term (Baxley, 2003).<sup>33</sup> Determining whether a pregnancy has continued past term is not simple. Identifying a fetus's gestational age based on a pregnant woman's recollection of the date of her last menstrual period is subject to significant recall bias. One systematic review of RCTs concluded that performing **ultrasound** between the 10<sup>th</sup> and 14<sup>th</sup> weeks of pregnancy is a reliable method **for determining gestational age** (NCCWCH, 2008). The authors compared rates of labor induction for postterm pregnancy between pregnant women who received ultrasound screening during the first trimester of pregnancy and pregnant women

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<sup>33</sup> Risks associated with elective induction of labor include iatrogenic prematurity, uterine hyperstimulation, fetal heart rate abnormalities, shoulder dystocia, postpartum hemorrhage, and cesarean section. The risk that labor induction will result in an unplanned cesarean section is especially high for nulliparous women (i.e., women giving birth to their first child), who are also at increased risk for delivery with forceps and admission of their infants to neonatal intensive care units (Baxley, 2003).

who received it during the second trimester. They found that first trimester ultrasound was associated with lower odds of labor induction due to postterm pregnancy (NCCWCH, 2008).

Two systematic reviews have assessed RCTs on **membrane sweeping** to encourage spontaneous labor to prevent postterm pregnancies (ICSI, 2008; NCCWCH, 2008). To sweep the membranes, a woman's physician or nurse midwife inserts a finger into the cervix and moves it in a circular fashion to separate the membranes from the cervix. Both systematic reviews concluded that membrane sweeping reduces the probability that labor will have to be induced with pharmaceutical agents.

Two systematic reviews and two meta-analyses examined RCTs on the impact of **inducing labor with pharmaceutical agents** among women whose pregnancies continued beyond term relative to monitoring and waiting for spontaneous labor (Gülmezoglu et al., 2006; ICSI, 2008; NCCWCH, 2008; Sanchez-Ramos et al., 2003). All four found that inducing labor with pharmaceutical agents reduces the risk of perinatal death. One meta-analysis reported that induction of labor was associated with a 70% lower risk of perinatal death that was statistically significant (Gülmezoglu et al., 2006) and the other reported a difference that was not statistically significant (Sanchez-Ramos et al., 2003). The meta-analyses also found that women whose labor was induced were at a lower risk of cesarean section (Gülmezoglu et al., 2006; Sanchez-Ramos et al., 2003).

### Summary of Findings

Randomized controlled trials (RCTs) have consistently found no association between the numbers of prenatal visits pregnant women receive and birth outcomes for either infants or mothers.

However, there is clear and convincing evidence from multiple RCTs that the following prenatal care services are effective:

- Smoking cessation counseling
- Ultrasound to identify structural abnormalities and determine gestational age
- Folic acid to prevent neural tube defects
- Screening and treatment for asymptomatic bacteriuria
- Screening for hepatitis B
- Screening and treatment for human immunodeficiency virus
- Calcium supplements and aspirin for prevention of preeclampsia
- Magnesium sulfate for prevention of eclamptic seizures in women with preeclampsia
- Screening and prophylactic and therapeutic treatment for Rh(D) incompatibility
- Progestational agents to prevent preterm delivery
- Corticosteroids to promote maturation of lungs in fetuses scheduled for preterm delivery due to preeclampsia or other complications

- Magnesium sulfate to prevent neurological impairment in fetuses at risk for preterm delivery
- External cephalic version for breech presentation at term
- Membrane sweeping and induction of labor for prevention of postterm pregnancies

There is also a preponderance of evidence from nonrandomized studies and/or a small number of RCTs that the following prenatal care services are effective:

- Screening for domestic violence
- Screening for Down syndrome, hemoglobinopathies, and Tay-Sachs disease
- Screening and treatment for chlamydia, gonorrhea, and syphilis
- Screening for group B streptococcus
- Screening and treatment for gestational diabetes
- Screening and treatment for bacterial vaginosis, trichomonas vaginalis, and Candida species to prevent preterm delivery
- Iron supplements for treatment of iron deficiency anemia
- Blood pressure monitoring for hypertensive disorders
- Screening for atypical red blood cell alloantibodies other than Rh(D) incompatibility
- Ultrasound to diagnose placenta previa

**Table 2. Medically Effective Prenatal Care Services**

<b>Risk Factor/Problem</b>	<b>Prenatal Screening Test</b>	<b>Treatment</b>	<b>Effect of Treatment on Health Outcomes</b>	<b>Source</b>
<b>Behavioral</b>				
Domestic violence	Interview patient	Refer patient to specialized professionals and community resources	Reduction in risk of injury to mother and fetus	ICSI, 2008 <sup>34</sup>
Smoking	Ask patient whether she smokes	Provide brief advice, counseling, and/or written self-help materials to mother	Reduction in risk of preterm delivery and low birth weight	Lu et al., 2003; Lumley et al., 2009; NCCWCH, 2008 <sup>35</sup> ; NZMOH, 2008 <sup>36</sup> ; US DHHS, 2008 <sup>37</sup>
<b>Genetic Disorders</b>				
Down syndrome	Ultrasound during 1 <sup>st</sup> trimester for nuchal translucency scan plus blood test for biochemical markers followed by diagnostic testing for mothers at high risk (amniocentesis or chorionic villus sampling)	None available	Not applicable	ICSI, 2008; NCCWCH, 2008

<sup>34</sup> ICSI = Institute for Clinical Systems Improvement. ICSI is an independent, not-for-profit organization that promotes quality improvement among health plans, hospitals, and medical groups in Minnesota. This citation is to an evidence-based guideline for routine prenatal care.

<sup>35</sup> NCCWCH = British National Collaborating Centre for Women’s and Children’s Health. This citation is to an evidence-based guideline for routine prenatal care that was prepared for the National Institute for Clinical Excellence.

<sup>36</sup> NZMOH = New Zealand Ministry of Health. This citation is to a systematic review that was commissioned for use in the development of an evidence-based guideline for smoking cessation.

<sup>37</sup> US DHHS = United States Department of Health and Human Services. This citation is to an evidence-based guideline for smoking cessation.

**Table 2. Medically Effective Prenatal Care Services (Cont'd)**

<b>Risk Factor/Problem</b>	<b>Prenatal Screening Test</b>	<b>Treatment</b>	<b>Effect of Treatment on Health Outcomes</b>	<b>Source</b>
Hemoglobinopathies <sup>38</sup>	Questionnaires regarding family history and blood tests for abnormal hemoglobinopathies followed by diagnostic testing for mothers at high risk (amniocentesis or chorionic villus sampling) <sup>39</sup>	None available	Not applicable	ICSI, 2008; NCCWCH, 2008
Tay-Sachs disease	Genetic testing for parents to determine whether they are Tay-Sachs carriers	No curative treatment available	Not applicable	ICSI, 2008
Neural tube defects <sup>40</sup>	Ultrasound to determine whether the fetus has a neural tube defect	No curative treatment available but risk can be reduced by mother's consumption of adequate amounts of folic acid	Reduction in risk of giving birth to a child with a neural tube defect	ICSI, 2008; NCCWCH, 2008
Other structural anomalies <sup>41</sup>	Ultrasound during 1 <sup>st</sup> trimester for nuchal translucency scan or ultrasound during 2 <sup>nd</sup> trimester including fetal echocardiography	None available in most cases	Not applicable	Ultrasound during 1 <sup>st</sup> trimester: Makrydimas et al., 2003; Wald et al., 2008  Ultrasound during 2 <sup>nd</sup> trimester: NCCWCH, 2008

<sup>38</sup> Hemoglobinopathies are disorders in the genes that control the expression of hemoglobin protein. These genetic disorders can result in anemia and abnormal hemoglobins. Sickle cell anemia and thalassemia are two of the most common types of hemoglobinopathies.

<sup>39</sup> Blood tests are generally recommended only for mothers at risk for being a carrier of genetic traits associated with hemoglobinopathies.

<sup>40</sup> Neural tube defects are birth defects that affect the spine and brain, such as spina bifida.

<sup>41</sup> Structural anomalies are abnormalities in the development of the fetus. Congenital heart defects are the most common structural anomalies. Other structural anomalies that can be detected via ultrasound include anterior abdominal wall defects, congenital hydrocephalus, craniofacial abnormalities, dwarfism, neural tube defects, and renal defects (NCCWCH, 2008).

**Table 2.** Medically Effective Prenatal Care Services (Cont'd)

<b>Risk Factor/Problem</b>	<b>Prenatal Screening Test</b>	<b>Treatment</b>	<b>Effect of Treatment on Health Outcomes</b>	<b>Source</b>
<b>Infectious Disease</b>				
Asymptomatic bacteriuria	Urine culture	Prescribe antibiotics to mother	Reduction in risk of kidney infection in mother, preterm delivery, and low birth weight	ICSI, 2008; Lin and Fajardo, 2008; Lu et al., 2003; NCCWH, 2008; Smaill and Vazquez, 2007
Chlamydia	Nucleic acid amplification tests on specimens obtained from urine or vaginal swabs	Prescribe antibiotics to mother and prophylaxis to newborns	Reduction in risk of preterm premature rupture of membranes, preterm delivery, low birth weight, infant mortality, and conjunctivitis among newborns	ICSI, 2008; USPSTF, 1996 <sup>42</sup>
Gonorrhea <sup>43</sup>	Tests on specimens obtained from urine or swabs of the vagina, rectum, urethra, or pharynx	Prescribe antibiotics to mother; provide ocular prophylaxis with silver nitrate, erythromycin, or tetracycline to newborn	Reduction in risk of conjunctivitis and blindness among newborns	ICSI, 2008; USPSTF, 1996
Group B Streptococcus	Culture sample from lower vagina or perianal area	Administer antibiotics during delivery	Reduction in incidence of meningitis, pneumonia, and sepsis among newborns	ICSI, 2008; Schrag et al., 2002
Hepatitis B	Blood test for detecting hepatitis B surface antigen	Administer hepatitis B vaccine and hepatitis B immune globulin to newborn	Reduction in risk of newborn developing chronic hepatitis B	ICSI, 2008; Krishnaraj, 2004; Lee et al., 2006; NCCWCH, 2008

<sup>42</sup> The US Preventive Services Task Force (USPSTF) recommends only for pregnant women who are aged 24 years or younger and older pregnant women at increased risk of chlamydia infection (USPSTF, 2008).

<sup>43</sup> USPSTF recommends only for pregnant women at increased risk of gonorrhea infection (USPSTF, 2008).

**Table 2.** Medically Effective Prenatal Care Services (Cont'd)

<b>Risk Factor/Problem</b>	<b>Prenatal Screening Test</b>	<b>Treatment</b>	<b>Effect of Treatment on Health Outcomes</b>	<b>Source</b>
Human Immunodeficiency Virus	HIV test (blood or oral fluid)	Prescribe antiretroviral therapy to mother, perform cesarean section, avoid breastfeeding	Reduction in risk of mother-to-child transmission of HIV	Chou et al., 2005; ICSI, 2008; NCCWCH, 2008
Bacterial vaginosis, Trichomonas vaginalis, and Candida species	Gram stain	Receive results of the test and standard antibiotic treatment if positive screen	Reduction in preterm births	Sangkomkamhang et al., 2008
Syphilis	Blood test for syphilis	Prescribe penicillin to mother	Reduction in proportion of infants with syphilis and infant mortality	ICSI, 2008; NCCWCH, 2008; Nelson et al., 2004
<b>Metabolic, Nutritional, and Endocrine Conditions</b>				
Gestational diabetes	Assess risk factors, perform blood test for glucose tolerance	Dietary changes to control blood glucose, monitoring of blood glucose, insulin	Reduction in risk of infant death, shoulder dystocia, bone fracture, nerve palsy, and pre-eclampsia	ICSI, 2008; NCCWCH, 2008 Alwan et al., 2009
Iron deficiency anemia	Hemoglobin or hematocrit test	Prescribe iron supplements to mother	Reduction in risk of low birth weight	Helfand et al., 2006; ICSI, 2008

**Table 2. Medically Effective Prenatal Care Services (Cont'd)**

Risk Factor/Problem	Prenatal Screening Test	Treatment	Effect of Treatment on Health Outcomes	Source
<b>Other Medical Conditions</b>				
Hypertensive disorders	Assess risk of preeclampsia, monitor blood pressure, test urine for proteinuria	Prescribe calcium supplements, antiplatelet agents (e.g., aspirin), and/or corticosteroids to mother; administer anti-convulsants (e.g., magnesium sulfate) during delivery	<p>Calcium supplements: reduction in risk of preeclampsia and maternal death or serious morbidity (e.g., kidney failure)</p> <p>Antiplatelet agents: Reduction in risk of preeclampsia, preterm birth, small for gestational age birth, and fetal or neonatal death</p> <p>Anti-convulsants: reduction in risk of eclampsia, placental abruption, and cerebral palsy and gross motor dysfunction in newborns</p>	<p>Blood pressure and urine testing: ICSI, 2008; NCCWCH, 2008</p> <p>Calcium supplements: Hofmyer et al., 2006; ICSI, 2008; Meads et al., 2008; NCCWCH, 2008</p> <p>Antiplatelet agents: Askie et al., 2007; Duley et al., 2007; Meads et al., 2008; Ruano et al., 2005</p> <p>Anti-convulsants: Duley et al., 2003</p>
Rh(D) incompatibility	Blood test for Rh typing and antibody screening	Administer Rh(D) immune globulin to mother	Reduction in risk of hemolytic disease in neonates and newborns	ICSI, 2008; NCCWCH, 2008; USPSTF, 1996

**Table 2.** Medically Effective Prenatal Care Services (Cont'd)

<b>Risk Factor/Problem</b>	<b>Prenatal Screening Test</b>	<b>Treatment</b>	<b>Effect of Treatment on Health Outcomes</b>	<b>Source</b>
Other atypical red blood cell alloantibodies	Blood test for atypical red blood cell alloantibodies	Referral to specialist	Reduction in risk of hemolytic disease <sup>44</sup> in neonates and newborns	NCCWCH, 2008
<b>Pregnancy Outcomes</b>				
Placenta previa	Ultrasound in 2 <sup>nd</sup> trimester at 20 weeks to determine if placenta covers opening to vagina with follow-up scan at 32 weeks if the previous scan was positive	Hospitalization of mother if she becomes symptomatic	Reduction in risk of placental abruption, hemorrhage, intrauterine growth restriction	NCCWCH, 2008
Prevention of preterm delivery	Any test for a condition or behavior associated with increased risk of preterm delivery	Prescribe progesterational agents to mother	Reduction in risk of preterm delivery, low birth weight and infant mortality	Progesterational agents: Dodd et al., 2006; Dodd et al., 2008; ICSI, 2008; Lu et al., 2003; Mackenzie et al., 2006; Rode et al., 2009; Sanchez-Ramos et al., 2005

<sup>44</sup> Symptoms of hemolytic disease include anemia, jaundice, body swelling, and difficulty breathing.

**Table 2. Medically Effective Prenatal Care Services (Cont'd)**

Risk Factor/Problem	Prenatal Screening Test	Treatment	Effect of Treatment on Health Outcomes	Source
Reduce risk of severe neonatal morbidity in fetuses at risk for preterm delivery	Any test for a condition or behavior associated with increased risk of preterm delivery	Prescribe corticosteroids to promote maturation of fetal lungs, prescribe magnesium sulfate to prevent neurological impairment	<p>Corticosteroids: Reduction in risk of neonatal death, respiratory distress syndrome, cerebroventricular hemorrhage, necrotising enterocolitis, systemic infection, and intensive care admissions among newborns</p> <p>Magnesium sulfate: Reduction in risk of cerebral palsy and substantial gross motor dysfunction</p>	<p>Corticosteroids: Lu et al., 2003; Roberts and Dalziel, 2006</p> <p>Magnesium sulfate: Doyle et al., 2009</p>
Breech presentation at term	Abdominal palpitations at 36 weeks or later	External cephalic version <sup>45</sup>	Reduction in risk of baby being born in breech position and cesarean section	Hutton and Hofmeyr, 2006; NCCWCH, 2008
Postterm delivery (after 41 or 42 weeks)	Perform ultrasound during 1st trimester of pregnancy to determine the gestational age of the fetus	Membrane sweeping; induction of labor	<p>Membrane sweeping: lower odds of induction of labor;</p> <p>Induction of labor: lower risk of perinatal death</p>	<p>Ultrasound screening for gestational age: NCCWCH, 2008</p> <p>Membrane sweeping: ICSI, 2008; NCCWCH, 2008</p> <p>Induction of labor: Gülmezoglu et al., 2006; ICSI, 2008; NCCWCH, 2008; Sanchez-Ramos et al., 2003</p>

<sup>45</sup> Health professional applies pressure to mother's abdomen to encourage the fetus to turn from feet-first to head-first position.

## UTILIZATION, COST, AND BENEFIT COVERAGE IMPACTS

AB 1825 would apply only to CDI-regulated health insurance policies subject to the California Insurance Code. It would require all CDI-regulated policies to cover maternity services. The bill defines “maternity services” to include “prenatal care, ambulatory care maternity services, involuntary complications of pregnancy, neonatal care, and inpatient hospital maternity care, including labor and delivery and postpartum care.” Prenatal care typically includes office visits and screening tests while labor and delivery services include hospitalization. Since all CDI-regulated group policies are estimated to currently cover maternity benefits, the bill would primarily affect the CDI-regulated individual market.

This section presents first the current, or baseline, costs and coverage related to maternity coverage and then details the estimated utilization, cost, and benefit coverage impacts of AB 1825. This analysis excluded complications of pregnancy because all health insurance policies provide coverage for such complications. For further details on the underlying data sources and methods, please see *Appendix D*.

### Present Baseline Cost and Benefit Coverage

#### Current Coverage of the Mandated Benefit

To estimate current coverage of maternity benefits, CHBRP surveyed the largest major health insurers in California. Responses to this survey represented 79% of the CDI-regulated market.<sup>46</sup> Coverage for maternity services is almost universal, particularly in the public sector and for individuals and families who receive employment-based health insurance.

#### *Public programs*

All public programs include maternity benefits for eligible recipients. As discussed in the *Introduction*, pregnant women with incomes less than 200% of the federal poverty level (FPL) qualify for maternity benefits under the Medi-Cal program. In addition, women who have incomes between 200% and 300% of the FPL qualify for maternity benefits through the AIM program, even if they simultaneously have privately funded insurance with maternity benefits but are subject to high deductibles or copayments.

#### *Privately funded insurance*

Because maternity benefits are required to be provided by Knox-Keene licensed DMHC-regulated health plan contracts,<sup>47</sup> AB 1825 targets CDI-regulated insurance policies. The distribution of enrollees in CDI-regulated policies is summarized as follows:

- About 2,438,000 Californians, or 13% of enrollees in health insurance plans and policies subject to state regulation, are in the CDI-regulated market.

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<sup>46</sup> One insurer was unable to respond to this survey, and resubmitted data provided to CHBRP in 2009 for its analysis of the similar maternity bill, AB 98. CHBRP used this data as a proxy response for this insurer’s current share of the market, and it is therefore included in the figure presented here.

<sup>47</sup> Health maintenance organizations in California are licensed under the Knox-Keene Health Care Services Plan Act, which is part of the California Health and Safety Code.

- Within the CDI-regulated market, 100% of large- and small-group policies cover maternity services, according to CHBRP's survey of insurers.
- Therefore, the proposed mandate would affect the 1,179,000 enrollees in individual (non-group) CDI-regulated policies.
- Within the CDI-regulated *individual* market, 18% of enrollees or 216,000 individuals have coverage for maternity services and 963,000 (82%) do not.
- For the women aged 19 to 44 years who are most likely to use maternity services, approximately 19% of enrollees or about 54,900 individuals within the CDI-regulated *individual* market have coverage for maternity services.
- Of those that do not currently have coverage for maternity services, about one-quarter, or approximately 240,700, are women of childbearing age (19 to 44).
- In addition, about 152,400 Californians in CDI-licensed individual policies that include maternity benefits are in HDHPs (defined by the federal Internal Revenue Service as deductibles of \$1,200 or higher for individual policies). HDHPs generally do not exempt maternity/prenatal services from the high deductibles (KFF, 2007a), so a high level of cost sharing is required for maternity services.

As a result of the broad availability of maternity benefits within the privately funded insurance markets and through public programs, only a small proportion of deliveries in California are not covered by some form of insurance (RAND Corporation, 2009). In 2008, 49.6% of deliveries were covered by Medi-Cal and 46.3% were covered by privately funded insurance; self-pay accounted for only 2.1%<sup>48</sup>. However, since 2004, when CHBRP conducted its analysis of SB 1555, the number of insured Californians (men and women) in CDI-regulated individual policies without maternity benefits has increased five-fold from an estimated 192,000 in 2004 to an estimated 963,000 in 2010.

Table 3 summarizes the rates of maternity coverage among those enrolled in CDI-regulated individual policies, by age and gender of the enrollee.

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<sup>48</sup> The remainder was provided by other government and non-government programs, or unknown.

**Table 3.** Percentage of Enrollees in Individual CDI-Regulated Policies with Maternity Coverage

Age of Covered Individual	Male	Female	Total
0-19	20%	21%	21%
20-24	10%	16%	13%
25-29	8%	17%	13%
30-34	12%	21%	16%
35-39	15%	21%	18%
40-44	18%	20%	19%
45-49	20%	20%	20%
50-54	22%	21%	22%
55-59	26%	24%	25%
60-64	30%	28%	29%
<b>Under 65 Total</b>	17%	20%	18%

Source: California Health Benefits Review Program, 2010.

### Current Utilization Levels and Costs of the Mandated Benefit

#### *Current utilization levels, births*

CHBRP estimates that 30,822 births would occur among women enrolled in CDI-regulated policies in 2010 (Table 1). Of those births, 8,298 would be to women who did not have coverage for maternity services at the time of pregnancy. All of these 8,298 women would be individual policy enrollees. These estimates are based on the Milliman Health Cost Guidelines estimates of age/gender pregnancy rates among all female employees with privately funded insurance with maternity coverage and the age and gender distribution of the 2,438,000 Californians enrolled in all CDI-regulated policies (i.e., group and individual). Birth rates among women with CDI-regulated individual policies were assumed to be comparable to those among female employees with privately funded insurance, because after weighting for age group, the aggregate birth rate calculated using Milliman’s estimates for female employees was very similar to the birth rates provided by respondents to CHBRP’s coverage survey.

The estimated number of births to women with no maternity coverage assumes that age-adjusted birth rates are the same among women who have maternity benefits and women who do not have maternity benefits, or no “selection effects.” There are several reasons to support this assumption:

- **Richer benefits:** Although there is clearly good reason to believe that women who choose insurance policies in the individual market without maternity benefits would have lower birth rates due to self-selection, CHBRP’s survey of health plan enrollment data by age and gender indicates that many women who are 50 years or older have policies with maternity benefits. This finding suggests that policies with maternity benefits are appealing for reasons other than the maternity benefit. For example, these policies usually provide a much richer mix of benefits beyond maternity benefits. Thus, women of childbearing age are also likely to find these policies valuable for reasons other than the maternity benefit.

- **Unplanned pregnancies:** A recent Centers for Disease Control and Prevention (CDC) study reports that 49% of pregnancies are unplanned, suggesting that even among women who self-select into policies without maternity benefits, birth rates may be higher than the women themselves intend (Finer and Henshaw, 2006).
- **Insuring against financial risk:** Women (and men) may be selecting insurance policies without maternity benefits primarily to provide protection against large financial risks, and may view pregnancy as a reasonable financial risk against which they should self-insure.

Because CHBRP assumes that birth rates are the same for policies that currently do and do not offer maternity coverage (i.e., no selection effects), the estimates of total expenditures derived using this assumption should be considered an upper bound. In other words, if the women who purchase individual coverage without maternity benefits have lower pregnancy rates than women who purchase individual coverage with maternity benefits, even after adjusting for age, then CHBRP's estimate of the impact of AB 1825 on covered deliveries, total expenditures, and premiums could be lower than presented in this analysis.

As an alternative, CHBRP estimated the impact of AB 1825 on premiums under a different set of assumptions that allow for self-selection into maternity coverage based on factors other than age and gender. Women who do not currently have maternity benefits were assumed to have age-specific pregnancy rates lower than those of women who currently have maternity benefits. The effect of the alternative assumptions about relative birth rates on the estimated premium increase is summarized in the subsection "Impacts for Each Category of Payer Resulting from the Benefit Mandate."

#### *Prenatal care utilization*

Assessing the utilization of prenatal services requires analysis both of frequency of care (how many office visits) and when in the pregnancy a woman initiates care. Most estimates define adequate utilization of prenatal services as care that is initiated in the first trimester and with a total of between 8 and 13 visits (Braveman et al., 2003). The combination of these two dimensions of care can be an indicator of the adequacy of prenatal care (Kotelchuck, 1994).

In 2008, the birth rate in California was 69.0 per 1,000 women of childbearing age (CDPH, 2008a). In 2006, the vast majority of those live births (86.1%) were preceded by at least nine prenatal visits, and 85.9% were preceded by prenatal care initiated during the first trimester. However, about 0.6% of live births were preceded by no prenatal care, and about 2.1% of live births were preceded by only one to four prenatal visits (CDPH, 2009).

#### *Unit price*

CHBRP's estimates of the utilization and cost for uncomplicated deliveries in California were based on age-specific rates of utilization for the following categories of services: hospital inpatient, hospital outpatient, lab, and physician care. When aggregated across all categories of service and age categories, CHBRP estimates that the average cost of an uncomplicated delivery in California is \$12,959.

### *Expenditures*

CHBRP estimates that within the CDI-regulated market (group and non-group), the current (pre-mandate) portion of the total per member per month (PMPM) expenditures attributable to maternity is \$13.65, broken down as follows:

- \$6.12 PMPM of the total is currently covered by insurance,
- \$2.25 PMPM is paid by individuals in the form of copayments and deductibles for covered services,
- \$3.72 is paid by individuals in the form of out-of-pocket expenditures for noncovered services, and
- \$1.56 is paid for by Medi-Cal or AIM on behalf of women who qualify for maternity benefits because their insurance does not cover maternity or they face costs for maternity services exceeding \$500.

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

#### *Cost-shifting to public programs*

Uninsured women whose income is less than 200% of the FPL may qualify for Medi-Cal when they become pregnant, and receive coverage for maternity services through that program. In 2007, about 47% of California births were covered by Medi-Cal (RAND, 2009).

AIM provides coverage for both uninsured and underinsured women between 200% and 300% of the FPL. Data provided to CHBRP from the AIM program indicate that in 2009, about 19% of births covered by AIM were for women who either had insurance but no coverage for maternity services, or who had maternity benefits but faced costs for services greater than \$500.<sup>49</sup> Therefore, there is evidence that some cost-shifting occurs to these programs from the privately funded market.

#### *Risk segmentation and adverse selection*

The absence of a mandate allows CDI-regulated insurers to offer a greater number of lower-cost individual policies that exclude maternity services, resulting in greater risk segmentation. The net impact of this trend toward greater market segmentation is debatable. Advocates for greater segmentation argue that the current health insurance market generally provides an insufficient number of policies with basic benefits, effectively forcing individuals to purchase more generous benefits than they prefer. The underlying belief is that it is inequitable to charge individuals who are unlikely to need certain benefits to subsidize individuals who do. In contrast, opponents argue that the failure to spread risk across larger populations is inequitable and that segmentation drives up the cost of higher-cost policies (such as those that cover maternity services) for those most in need of insurance, because only higher-risk people purchase them, with lower-risk individuals self-selecting instead into lower-cost policies.

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<sup>49</sup> Personal communication with Legislative Coordinator, Managed Risk Medical Insurance Board (MRMIB), March 15, 2010.

The continued growth of HDHPs, as well as insurance policies without maternity benefits, in the individual market is evidence that risk segmentation has already had a substantial impact on the individual (non-group) insurance market. The number of insured Californians without maternity benefits has increased five-fold, from an estimated 192,000 in 2004 (CHBRP, 2004) to the current estimate of 963,000 (CHBRP, 2010). This risk segmentation produces adverse selection among policies that still offer maternity benefits. At least in theory, the premiums in those policies experiencing adverse selection could increase disproportionately, as low-risk individuals abandon those policies in search of lower-cost policies. However, it is an empirical question as to whether or not a premium spiral has occurred.

### Public Demand for Benefit Coverage<sup>50</sup>

While coverage for maternity benefits is widely available and essentially universal in the group insurance market, there is clearly a growing demand for lower-premium insurance policies in the individual market, including those without maternity services. The number of enrollees in plans that do not cover maternity services has about tripled during the last five years (CHBRP, 2010).

### **Impacts of Mandated Benefit Coverage**

#### How Would Changes in Coverage Related to the Mandate Affect the Benefit of the Newly Covered Service and the Per-Unit Cost?

##### *Changes in benefit coverage*

The enactment of AB 1825 would require all CDI-regulated individual policies that do not cover maternity service to do so, thus expanding maternity services coverage to 963,000 enrollees, including 240,700 women aged 19 to 44 years. However, most women are likely to continue to face large out-of-pocket expenditures for maternity services regardless of whether or not their insurance policy includes maternity benefits. This is because about 70% of the women in CDI-regulated individual policies are currently in HDHPs and prenatal care is usually subject to the HDHP deductible. Even the women currently enrolled in non-HDHPs frequently face high cost-sharing requirements in the CDI-regulated individual market, and some might also choose to switch to HDHPs post-mandate in order to save on premiums.

The changes in premiums resulting from AB 1825 would affect the number of individuals who maintain privately funded health insurance. This is discussed in further detail in the subsection “Changes in coverage as a result of premium increases.”

##### *Impact on supply and on the health benefit*

There is no evidence that the proposed mandate would change the effectiveness of maternity services. It is conceivable that there is currently self-selection of the highest-risk women into

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<sup>50</sup> Based on criteria specified under SB 1704 (2007), CHBRP is to report on the extent to which collective bargaining entities negotiate for, and the extent to which self-insured plans currently have, coverage for the benefits specified under the proposed mandate to determine “public demand.” However, given that all group policies cover maternity services, including those that are self-insured, the standard criteria for evaluating public demand is not relevant.

insurance policies with maternity benefits. If so, then the average effectiveness of prenatal care and screening tests could be lower for the newly covered women than for those who already have maternity benefits.

#### *Impact on per-unit cost*

There is no evidence that the proposed mandate would change the per-unit cost of individual services (e.g., prenatal screenings) or the package of maternity services.

#### How Would Utilization Change as a Result of the Mandate?

CHBRP estimates that approximately 8,298 pregnancies would be newly covered under CDI-regulated individual policies post-mandate. The impact of expanded coverage on utilization is summarized below:

- Overall, the mandate is estimated to have no impact on the number of deliveries, since the birth rate is not expected to change post-mandate.
- Most women are likely to continue to face large out-of-pocket expenditures for maternity services regardless of whether or not their insurance policy includes maternity benefits. This is because approximately 70% of the women in CDI-regulated individual policies are currently in HDHPs and prenatal care is usually subject to the HDHP deductible. Even the women currently enrolled in non-HDHPs frequently face high cost-sharing requirements in the CDI-regulated individual market, and some might also choose to switch to HDHPs post-mandate in order to save on premiums.
- Certain types of screening tests are not included in the standard prenatal care fee and might be used more frequently post-mandate if they are part of the maternity benefit, thereby affecting costs. The amount of the increase is difficult to estimate, as these tests would be subject to HDHP deductibles and women may treat them as out-of-pocket costs.
- Length of stay is likely to be shorter for mothers who are self-pay or for those women whose obstetricians or midwives are paid a fixed fee for postpartum care (Galbraith et al., 2003; Malkin et al., 2003). However, the latter would not change as a result of the mandate, and women in HDHPs are likely to pay the obstetrician or midwife fee out of their deductible anyway, implying that the mandate would have little impact on the number of women who self-pay. For this reason, CHBRP estimates no overall impact on maternity-related length of stay.

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

Insurance policies include a component for administration and profit in their premiums. In estimating the impact of this mandate on premiums, CHBRP assumes that health policies would apply their existing administration and profit loads to the marginal increase in health care costs produced by the mandate. The mandate would therefore increase the administrative expenses for health policies proportionate to the increase in health care costs. Claims administration costs may go up slightly due to an increase in maternity claims. It is also conceivable that claims

administration costs could decline slightly, by eliminating the need to distinguish different benefit structures in claims processing.

Insurers would have to modify some insurance contracts and member materials. Based on CHBRP's survey of the largest health plans and insurers in the California, administrative costs may include accrued expenses due to mandatory maternity benefit riders to all individual plan contracts and policies and non-renewals for members that have voluntarily purchased a policy without maternity. The enactment of the bill would require revisions in evidence of coverage of member-related materials, employer contracts, benefit policies, changes in provider and member updates, internal policies, procedures and guidelines for departments such as claim processing, network management, medical management, customer service and administration staff, and training for internal staff.

#### *Impact of the Mandate on Total Health Care Costs Changes in total expenditures*

Among all enrollees in state-regulated policies (both CDI-regulated and DMHC-regulated), total annual health expenditures are estimated to increase by \$40 million, or 0.1%, as a result of this mandate (see row labeled "Total annual expenditures" in Table 1). As the total number of deliveries and average cost associated with each delivery is not expected to increase, the mandate primarily shifts costs from individuals to insurers. CHBRP assumes that the administrative expenses for health policies would increase in proportion to the increase in their covered health care costs, leading to an estimated increase in overall expenditures. Note that the increase in total expenditures is a total of:

- the increase in premium expenditures in the individual market: \$120 million (see row labeled "Premium expenditures for individually purchased insurance" in Table 1).
- the increase in out-of-pocket expenditures for maternity benefits covered by insurance (e.g., copayments and deductibles): \$28.8 million (see row labeled "Enrollee out-of-pocket expenditures for covered benefits").
- the reduction in out-of-pocket expenditures for maternity benefits not currently covered by insurance: \$108.8 million (see row labeled "Enrollee expenses for noncovered benefits").

#### *Impact on long-term costs*

If women with maternity benefits were more likely to receive adequate prenatal care, and a lack of prenatal care were clearly shown to have an adverse effect on neonatal outcomes and downstream health care costs, then the long-term beneficial cost consequences could be considerable. Although there is evidence that many prenatal care services are associated with improvements in birth outcomes, AB 1825 does not stipulate which services health insurance policies must provide as part of prenatal care. The analyses summarized in the *Medical Effectiveness* section found no significant association between the number of prenatal care visits and birth outcomes. For example, a meta-analysis that synthesized findings from seven RCTs that compared the effects of different numbers of prenatal care visits on birth outcomes found that the number of visits does not affect the odds of having a preterm birth, delivering a low-birth weight infant, or admission of a newborn to a neonatal intensive care unit. (Villar et al., 2001). This meta-analysis also reported that the number of visits was not associated with the

odds of maternal mortality, preeclampsia, and antepartum or postpartum hemorrhage. Furthermore, as noted above, HDHPs have become the predominant form of insurance in the individual market. As a result, the majority of pregnant women in this market face financial barriers to receiving prenatal care that are not addressed by this mandate. Therefore, to the extent that HDHPs reduce or delay access to prenatal care—leading to negative neonatal outcomes and thus higher long-term costs—these negative consequences would not be ameliorated by this mandate, which does nothing to address the growth or limits of such policies. For these reasons, the mandate is likely to have minimal impact on long-term costs.

### Impacts for Each Category of Payer Resulting from the Benefit Mandate

#### *Changes in expenditures and PMPM amounts by payer category*

Mandating maternity coverage is expected to increase per member per month (PMPM) premiums for CDI-regulated individual policies by \$8.48, or 5%, on average (Table 5). Premium impacts are summarized as follows:

- CHBRP estimates that for the majority (82%) of individuals in the CDI-regulated individual market who do not currently have maternity benefits, AB 1825 would *increase* average premiums by 2% to 28% among those 19 to 44 years old, depending on the age of the enrollee (see Table 6).
- Among the minority (18%) of individuals in the CDI-regulated market who currently have maternity benefits, AB 1825 is expected to *decrease* average premiums by 0.5% to 20%, depending on the age of the enrollee (see Table 6).

The actual premium increase of those policies depends on a number of market factors, including but not limited to the changes in actuarial costs. CHBRP uses the actuarial value of the maternity benefit as the best estimate of the change in premiums that would occur under the mandate. The alternative is to use the observed differences in premiums between plans and policies with and without maternity coverage. However, these differences might yield a misleading estimate of the impact of adding maternity benefits to a health insurance plan or policy that currently has none, since those that currently include maternity benefits also include other benefits not typically found in plans and policies without maternity benefits and may attract adverse selection based on those additional benefits. Premium differences between health insurance plans and policies with and without maternity benefits, controlling for other differences in benefits, would be an issue worthy of further and systematic review.

#### *Impact of gender rating*

In 2009, California passed AB 119 into law prohibiting insurers from gender rating, or charging differential premiums based on gender for contracts issued, amended, or renewed on or after January 1, 2011. By the time the gender-rating ban goes into effect on January 1, 2011, carriers could have amended policies with maternity services at an even higher rate than used now. The greatest impact of the gender-rating ban would be expected on the premiums of health insurance plans/policies that already include maternity services and currently use gender rating. However, these contracts are already compliant with AB 1825. Given that AB 1825 and AB 119 would have the same effective date; AB 119 would spread the risks more evenly across men and women within the same policies while AB 1825 would then spread risks more evenly across

insured people in the individual CDI-regulated market. Hence, the premium and cost calculations in this report assume all gender-rated policies would be converted to gender-neutral pricing prior to the implementation of AB 1825.

### *Impact of self-selection*

In addition to varying with age, premium changes resulting from the mandate could vary substantially across policies, depending on how women self-select into different policies in the pre-mandate versus post-mandate period. Women with individual CDI-regulated policies who currently have maternity coverage may have self-selected into these policies since they have a higher likelihood of getting pregnant in the future than women of the same age who self-selected into policies without maternity coverage. If so, the cost of extending maternity benefits to previously uncovered women could be overstated by the CHBRP model assumptions. For example, if women who currently do not have maternity benefits have half the birth rate of the women who do have maternity benefits (rather than the same birthrate, as assumed in the tables), then the estimated percent premium increase across all enrollees in the CDI-regulated individual market would be about 2.11% on average (vs. the estimated 5% increase when birth rates are assumed to be the same).

However, the impact of AB 1825 on the premiums for any particular insurance policy could be quite different from that suggested by the average premium increase. For example, a “bare-bones” policy that previously attracted only healthy young males might attract a number of otherwise healthy young women with a disproportionately high likelihood of pregnancy if the mandate were implemented. Under that scenario, it is conceivable that premiums in the policy attracting adverse selection could go up substantially. At the same time, however, these women would be switching out of other policies (presumably those with maternity coverage prior to the mandate) whose premiums would then decline more than the average. Thus, equalization of the maternity risk across policies could result in a commensurate narrowing of premium differentials in the individual CDI-regulated market, with some policies experiencing disproportionate increases and others experiencing disproportionate decreases.

### *Changes in coverage as a result of premium increases*

CHBRP estimates the impact on the number of insured when the premium increase (or decrease) faced by any segment of the population is at least a 1% increase.<sup>51</sup> Using CHBRP’s standard methodology, premium changes associated with AB 1825 are projected to lead to a net *increase* of approximately 9,335 uninsured Californians. CHBRP estimates that these newly uninsured would disproportionately consist of younger individuals (e.g., those aged 19 to 29 years) since premiums are age-stratified and premium increases are concentrated among this population.

### *Impact of changes in privately funded health insurance on publicly funded programs*

Although all insured women would have maternity benefits after enactment of AB 1825, it is likely that women who qualify for Medi-Cal after pregnancy would still shift to Medi-Cal post-mandate, due to their low income levels and desire to avoid the premiums associated with privately funded insurance. National data from the Medical Expenditure Panel Survey (MEPS)

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<sup>51</sup> See [http://www.chbrp.org/analysis\\_methodology/cost\\_impact\\_analysis.php](http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php) for more information on CHBRP’s methods for calculating the number of uninsured as a result of premium changes.

showed that only 0.20% of female Medicaid beneficiaries aged 18 to 45 have any month in which they had both individually purchased privately funded insurance and Medicaid coverage.<sup>52</sup> Even some of that apparent overlap may have been the result of switching insurance mid-month. These data suggest that women in California will not pay to retain their privately funded insurance if they become eligible for Medi-Cal as a result of their pregnancy. Conversely, it seems unlikely that many of the individuals projected to drop privately funded insurance as a result of the premium increases associated with AB 1825 would qualify for Medi-Cal, since they probably would have enrolled in Medi-Cal prior to the mandate, had they been eligible. Hence, CHBRP estimates that there would not be a direct impact on Medi-Cal enrollment as a result of AB 1825. Those 2,666 women who currently have no maternity coverage and qualify for Medi-Cal after pregnancy would still shift to Medi-Cal post-mandate due to their income levels.

The extent to which AB 1825 would affect the shift of maternity costs from privately funded policies onto AIM depends on whether pregnant CDI-regulated individual policy enrollees who currently have no maternity coverage and qualify for AIM would continue to qualify and enroll in AIM after they are given maternity coverage through their health plan. HDHPs typically do not exempt prenatal care services from the high deductible and have high cost-sharing levels to reduce monthly premiums, so HDHPs with maternity benefits may still be viewed as inadequate coverage by low-income women. Since the cost of maternity services in HDHPs would likely still be greater than \$500 (adding up deductibles and copayments), women enrolled in HDHPs would still qualify for AIM post-mandate.

About 70% of enrollees in CDI-regulated individual policies are already in HDHPs and it seems likely that even more low-income women who currently do not have maternity coverage would enroll in HDHPs after enactment of AB 1825. Because individuals currently choosing policies without maternity services are doing so to save on monthly premiums, those who can afford to (and do not drop insurance entirely) may purchase the next “cheapest” option post-mandate—HDHPs. If low-income women who are currently enrolled in policies that do not cover maternity services would enroll in HDHPs that *do* cover maternity services post-mandate, then either way they are likely to qualify for, and enroll in, AIM. Thus, it is not likely that AB 1825 would reduce enrollment in AIM.

The other consideration, however, is the extent to which AIM plans seek reimbursement from the privately funded insurers for the maternity costs of dual enrollees. AIM is a secondary payer, with the privately funded insurer paying first if the enrollee’s coverage includes maternity benefits. This suggests that AIM’s costs could decrease since all enrollees would have maternity coverage. Thus, for the approximately 1,433 enrollees in CDI-regulated individual policies who would simultaneously enroll in the AIM program based on CHBRP’s model, the enrollee’s privately funded insurance would pay for maternity services first and AIM would be the secondary payer.

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<sup>52</sup> This was computed using data from the MEPS web site, [http://www.meps.ahrq.gov/mepsweb/data\\_stats/MEPSnetHC.jsp](http://www.meps.ahrq.gov/mepsweb/data_stats/MEPSnetHC.jsp)

### Impact on Access and Health Service Availability

As discussed previously, the mandate is estimated to have a minimal impact on access to and availability of maternity services, primarily because the benefit is currently so widely available in the DMHC- and CDI-regulated insurance market. However, maternity services will be considered part of the essential health benefits package to be provided by qualified health plans providing coverage in the small group and individual markets through the state-based insurance exchanges, effective in 2014. Therefore, any effects of AB 1825 would be diminished by the P.L.111-148 requirements following 2014.

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

	DMHC-Regulated							CDI-Regulated			Total Annual
	Privately Funded			CalPERS HMOs	Medi-Cal HMOs		Healthy Families Program HMOs (c)	Privately Funded			
	Large Group	Small Group	Individual		65 and Over (b)	Under 65		Large Group	Small Group	Individual	
Total enrollees in plans/policies subject to mandates (a)	9,445,000	2,394,000	785,000	820,000	175,000	2,616,000	814,000	324,000	935,000	1,179,000	19,487,000
Total enrollees in plans/policies subject to AB 1825	0	0	0	0	0	0	0	324,000	935,000	1,179,000	2,438,000
Average portion of premium paid by employer	\$290.96	\$223.84	\$0.00	\$332.10	\$223.00	\$113.00	\$93.19	\$346.40	\$246.40	\$0.00	\$51,713,067,000
Average portion of premium paid by employee	\$72.11	\$92.31	\$364.68	\$58.61	\$0.00	\$0.00	\$11.78	\$105.37	\$79.68	\$180.77	\$18,813,408,000
<b>Total Premium</b>	\$363.07	\$316.14	\$364.68	\$390.70	\$223.00	\$113.00	\$104.97	\$451.77	\$326.08	\$180.77	\$70,526,476,000
Enrollee expenses for covered benefits (Deductibles, copays, etc.)	\$19.77	\$25.74	\$64.43	\$20.15	\$0.00	\$0.00	\$1.52	\$58.78	\$116.51	\$44.19	\$5,961,186,000
Enrollee expenses for benefits not covered	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$7.69	\$108,756,000
<b>Total Expenditures</b>	\$382.84	\$341.88	\$429.11	\$410.85	\$223.00	\$113.00	\$106.50	\$510.56	\$442.59	\$232.64	\$76,596,418,000

Source: California Health Benefits Review Program, 2010.

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

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

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

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

	DMHC-Regulated							CDI-Regulated			Total Annual
	Privately Funded			CalPERS HMOs	Medi-Cal HMOs		Healthy Families Program HMOs (c)	Privately Funded			
	Large Group	Small Group	Individual		65 and Over (b)	Under 65		Large Group	Small Group	Individual	
Total enrollees in plans/policies subject to mandates (a)	9,445,000	2,394,000	785,000	820,000	175,000	2,616,000	814,000	324,000	935,000	1,179,000	19,487,000
Total enrollees in plans/policies subject to AB 1825	0	0	0	0	0	0	0	324,000	935,000	1,179,000	2,438,000
Average portion of premium paid by employer	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Average portion of premium paid by employee	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$8.48	\$120,004,000
<b>Total Premium</b>	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$8.48	\$120,004,000
Enrollee expenses for covered benefits (Deductibles, copays, etc.)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$2.03	\$28,780,000
Enrollee expenses for benefits not covered	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	-\$7.69	-\$108,756,000
<b>Total Expenditures</b>	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$2.83	\$40,028,000
<b>Percentage Impact of Mandate</b>											
Insured Premiums	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	4.69%	0.17%
Total Expenditures	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	1.22%	0.05%

Source: California Health Benefits Review Program, 2010.

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

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

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

**Table 6.** Estimated Impact on Individual Per Member Per Month Premiums by Age Group

	Age	Estimated Premiums					
		Pre-mandate		Post-mandate		% Impact on Premium (a)	
		Covered w/ Maternity	Covered w/o Maternity	Covered w/ Maternity	Covered w/o Maternity	Covered w/ Maternity Pre-mandate	Covered w/o Maternity Pre-mandate
Child	0-1	\$291	\$291	\$291	\$291	0.00%	0.00%
Child	2-6	\$66	\$66	\$66	\$66	0.00%	0.00%
Child	7-18	\$76	\$76	\$76	\$76	-0.20%	0.66%
Child (b)	19-22	\$106	\$104	\$106	\$106	-0.47%	1.56%
Adult (c)	To 25	\$155	\$110	\$134	\$134	-13.82%	21.89%
Adult	25-29	\$201	\$125	\$160	\$160	-20.28%	28.00%
Adult	30-34	\$215	\$146	\$182	\$182	-15.67%	24.68%
Adult	35-39	\$205	\$170	\$190	\$190	-7.36%	11.71%
Adult	40-44	\$208	\$201	\$206	\$206	-1.36%	2.04%
Adult	45-49	\$245	\$245	\$245	\$245	0.06%	0.09%
Adult	50-54	\$311	\$311	\$311	\$311	0.13%	-0.03%
Adult	55-59	\$392	\$392	\$392	\$392	0.02%	-0.01%
Adult	60-64	\$501	\$500	\$500	\$500	-0.13%	0.05%
	Total	\$213	\$177	\$204	\$190	-4.16%	7.20%

Source: California Health Benefits Review Program, 2010.

Notes: (a) Percent impact on premiums may not correspond to ratio of pre-mandate vs. post-mandate premiums shown in table, due to rounding.

(b) This analysis is based on Milliman's claims analysis and the claims database identifies "Child 19-22" as those young adults who are dependent on another individual enrollee.

(c) "Adult, To 25" means those young adults who are individual enrollees.

## PUBLIC HEALTH IMPACTS

AB 1825 mandates coverage for maternity services. Maternity services benefits generally include prenatal care, such as office visits and screening tests; labor and delivery services, including hospitalization; care resulting from complications related to a pregnancy; and postnatal care. In 2008, there were more than 551,000 births in California, of which 3.2% were to women either not receiving prenatal care or receiving prenatal care starting in the third trimester (CDPH, 2008b). Three major health outcomes in relation to maternity care and utilization of prenatal services are birth weight, preterm deliveries, and infant and maternal mortality. This section presents the overall public health impact of passage of AB 1825 followed by analysis examining the potential for reduction in gender and racial/ethnic disparities in health outcomes, and the potential for the mandate to reduce premature death and societal economic losses as a result of utilization of prenatal care. The *Public Health Impact* section focuses primarily on prenatal care, because (1) a majority of births occur in the hospital setting regardless of insurance status (2) prenatal care services use would be most affected by the potential for out-of-pocket costs and thus most directly impacted by AB 1825, and (3) AB 1825 would not affect coverage for infants.

### **Impact of the Proposed Mandate on the Public's Health**

As presented in the *Medical Effectiveness* section, the prenatal care services that are effective in improving health outcomes are: counseling on behavioral risks such as smoking and domestic violence; screening and counseling for genetic disorders; screening for and treating infectious diseases such as asymptomatic bacteriuria, hepatitis B, HIV, STIs, and group B streptococcus; screening and management of hypertensive disorders, gestational diabetes, anemia, and Rh(D) incompatibility; and screening and management of women at risk for preterm deliveries.

The *Utilization, Cost, and Benefit Coverage Impacts* section estimates that 8,298 pregnancies would be newly covered as a result of AB 1825. Although the previously mentioned specific prenatal care services are effective, the extent to which AB 1825 would increase the utilization of these services is unknown, therefore a range estimate is provided. This section will present both the lower bound and upper bound estimates of the change in utilization of effective prenatal care services and the resulting public health impact of this mandate to illustrate the range in potential public health impacts.

#### Lower Bound Estimate

A lower bound estimate of the public health impact of AB 1825 assumes that utilization of effective prenatal care services would not increase post-mandate. The justification for this assumption is that the women enrolled in the CDI-regulated policies without maternity benefits chose this health insurance option due to its low cost. We assume that as insurers comply with AB 1825, these women would still enroll in the lower cost plans, which would still have high levels of cost sharing. Therefore, in this lower bound estimate, it is assumed that there is no increase in the utilization of effective prenatal care services and thus no impact on public health as a result of AB 1825 would be expected.

### Upper Bound Estimate

To estimate the upper bound of the public health impact of AB 1825, it is assumed that pregnant women previously enrolled in CDI-regulated policies without maternity benefits would switch to insurance plans without substantial cost sharing for prenatal care post-mandate. In this scenario, we would expect to see an increase in utilization of effective prenatal services by all 8,298 newly covered pregnant women.

As an example of how AB 1825 could affect health outcomes, Table 7 presents the upper bound estimates of potential public health impacts of receipt of effective prenatal care services. The impact is estimated assuming that pre-mandate, none of these 8,298 women would receive prenatal care and that post-mandate 100% of these women would receive effective prenatal care services. In an average population of women, we would expect that 8.7% of pregnant women smoke during their pregnancy, between 2% and 10% screen positive for asymptomatic bacteriuria, 5.6% test positive for hepatitis B, 0.2% test positive for HIV, 5% are diagnosed with a hypertensive disorder, and 1.9% are at risk for respiratory distress syndrome (RDS) as a result of preterm delivery. Assuming that as a result of AB 1825, all newly covered pregnant women received the necessary prenatal service, it is estimated that AB 1825 could result in 43 pregnant women quitting smoking, 169 fewer low-birth weight births, and the prevention of 232 hepatitis B transmissions, 16 HIV transmissions 216 cases of preeclampsia, and 54 cases of RDS (Table 7).

**Table 7.** Upper Bound Estimates of Public Health Impacts of AB 1825

<b>Prenatal care service</b>	<b>Prevalence of Condition</b>	<b>Medical Effectiveness of Intervention</b>	<b>Public Health Impact (a)</b>
Smoking cessation counseling (b)	8.7% smoke during pregnancy	RR = 0.94	43 pregnant women quit smoking
Screening and treatment for asymptomatic bacteriuria (c)	2%-10% of pregnancies	RR = 0.66	Prevent 169 low-birth weight babies
Screening and treatment for hepatitis B (d)	5.6%	RR = 0.50	Prevented 232 hepatitis B transmissions
Screening and treatment for HIV (e)	0.2%	RR = 0.13	Prevented 16 HIV transmissions
Prophylaxis for hypertensive disorders (f)	5%	RR = 0.48	Prevented 216 cases of preeclampsia
Corticosteroids and progesterational agents for women at increased risk for preterm delivery (g)	1.9%	RR = 0.66 (Corticosteroids) RR = 0.65 (Progesterational agents)	Reduction in RDS by 54 cases

Source: California Health Benefits Review Program, 2010.

Notes: (a) Calculations used the estimated 8,298 pregnancies newly covered under AB 1825 as presented in the *Utilization, Cost, and Benefit Coverage Impacts* section.

(b) Data taken from Lumley et al., 2009, and CDPH, 2006a.

(c) Data taken from Smaill and Vazquez, 2007.

(d) Prevalence data taken from McQuillan et al., 2004; RR taken from Lee et al., 2006.

(e) Prevalence data taken from CDC, 2008; OR taken from Chou et al., 2005. The OR is labeled as the RR for consistency. In cases where the prevalence of the condition is <1%, the OR and the RR are virtually identical.

(f) Data taken from Hofmeyr et al., 2006.

(g) Data taken from Roberts and Dalziel, 2006; Dodd et al., 2006; and March of Dimes, Peristats.

Key: RR = risk ratio; HIV = human immunodeficiency virus; RDS = respiratory distress syndrome

CHBRP is unable to estimate what the impact of AB 1825 would be on the utilization of prenatal care. A lower bound estimate would assume that there would be no increase in the utilization of effective prenatal care services because these pregnant women would likely still face high levels of cost sharing found in the least expensive health insurance plans. As presented in Table 7, an upper bound estimate would assume that all 8,298 newly covered pregnancies would have financial barriers to prenatal care removed and thus an increase in the utilization of effective prenatal care services and an improvement in corresponding health outcomes would be expected. Most likely, the overall public health impact lies somewhere between the lower and upper bounds presented in this section.

### **Impact on the Health of the Community Where Gender and Racial Disparities Exist**

Several competing definitions of “health disparities” exist. CHBRP relies on the following definition by Braveman, 2006: *A health disparity/inequality is a particular type of difference in*

*health or in the most important influences of health that could potentially be shaped by policies; it is a difference in which disadvantaged social groups (such as the poor, racial/ethnic minorities, women, or other groups that have persistently experienced social disadvantage or discrimination) systematically experience worse health or greater health risks than more advantaged groups.*

CHBRP investigated the effect that AB 1825 would have on health disparities by gender, race, and ethnicity. Evaluating the impact on racial and ethnic disparities is particularly important because racial and ethnic minorities report having poorer health status and poorer health indicators (KFF, 2007). One important contributor to racial and ethnic health disparities is differential insurance rates, where minorities are more likely than whites to be uninsured; however, disparities still exist within the insured population (Kirby et al., 2006; Lillie-Blanton and Hoffman, 2005). Since AB 1825 would only affect the insured population, a literature review was conducted to determine whether there are gender, racial, or ethnic disparities associated with prenatal care utilization and poor birth outcomes outside of disparities between uninsured and insured individuals.

#### Impact on Gender Disparities

Females enrolled in plans in the individual health insurance market without coverage for maternity benefits are currently paying \$108.8 million out of pocket for noncovered maternity services. It is estimated that as a result of AB 1825, a portion of these costs (\$28.8 million) would shift from out-of-pocket costs for noncovered maternity services to out-of-pocket costs for covered maternity services (e.g., copayments and deductibles), and that the remaining costs would be shifted to insurance policies and ultimately enrollees through higher premiums. It is estimated that there would be a \$120 million increase in premium expenditures across males and females in the individual market. Since the decrease in out-of-pocket costs would come from a population of enrollees that are entirely female and the increase in premiums would be spread across both male and female enrollees, this mandate would differentially reduce the financial burden faced by female enrollees.

#### Impact on Racial/Ethnic Disparities

Of the more than 551,000 live births each year in California, over half (52.1%) are to Hispanic women (CDPH, 2008a). Among non-Hispanic women, the largest number of births are to non-Hispanic white women (26.5%), followed by Asian women (11.8%), black women (5.3%), and Native American women (0.4%) (CDPH, 2008a). The birth rates across these groups differ dramatically; with the rate of births to Hispanic women of childbearing age almost double those of other race/ethnic groups (Table 8).

**Table 8.** Births in California by Race/Ethnicity of Mother, 2008

<b>Race/Ethnicity of Mother</b>	<b>Number of Live Births (a)</b>	<b>Percent of Live Births (b)</b>	<b>General Fertility Rate (c)</b>
Total	551,567	100%	69.0
Hispanic	287,323	52.1%	90.1
Non-Hispanic			
White	146,309	26.5%	51.5
Asian	64,825	11.8%	63.4
Black	29,428	5.3%	56.5
Native American	2,032	0.4%	39.3

*Sources and Notes:*

(a) Data taken from CDPH, 2008a, Table 2-7 based on 2008 California birth certificate information.

(b) Data calculated from the number of live births taken from CDPH, 2008a. The sum does not equal 100% because women of other or unknown race/ethnicity are not included.

(c) Data taken from CDPH, 2008b, Table 2-2. The general fertility rate is the number of live births per 1,000 women of childbearing age (15-44).

Overall, 2.8% of births in California are to women receiving late or no prenatal care (CDPH, 2006b). This varies by race/ethnicity with Native Americans having the highest rates of receiving late or no prenatal care (7.2%), and Asians and non-Hispanic whites having the lowest rates (1.8% and 2.1%, respectively) (Table 9). The rate of low-birth weight babies varies significantly by race/ethnicity, with babies born to black women classified as low birth weight or very low birth weight twice as often as babies born to other racial/ethnic groups (CDPH, 2006b). In addition, black women have the highest rates of preterm births (15.7% of births). Accordingly, infant mortality rates are also more than twice as high for babies born to black women compared to other racial/ethnic groups (11.4 per 1,000 live births to black women compared to 5.2 per 1,000 live births overall).

As discussed in the *Medical Effectiveness* section, there are specific prenatal services that are effective in reducing low-birth weight births, preterm births, and infant mortality. To the extent that the utilization of these services could increase among black women as a result of the mandate, there is potential to reduce the health disparities associated with births in this population. However, there is no evidence that, as a result of AB 1825, utilization of effective prenatal care services would increase specifically among black women thus leading to better health outcomes for pregnant black women and their babies.

**Table 9.** Birth Characteristics in California by Race/Ethnicity of Mother

<b>Race/Ethnicity of Mother</b>	<b>Late or No Prenatal Care (a)</b>	<b>Low-Birth Weight Births (b)</b>	<b>Preterm Births (c)</b>	<b>Infant Mortality Rates (d)</b>
Total	2.8%	6.9%	10.9%	5.2
Hispanic	3.2%	6.3%	11.0%	5.0
Non-Hispanic				
White	2.1%	6.3%	10.0%	4.6
Asian	1.8%	7.7%	10.3%	4.1
Black	3.9%	12.3%	15.7%	11.4
Native American	7.2%	6.7%	12.6%	6.9

*Sources and Notes:*

(a) Data taken from CDPH, 2006b, Table 2-6. Late prenatal care is defined as prenatal care starting in the third trimester.

(b) Data taken from CDPH, 2006b, Table 2-6. Low birth weight is defined as less than 2,500 grams (5.5 pounds).

(c) Data taken from CDPH, 2006b, Table 2-6. Preterm births are births prior to 37 weeks of gestation.

(d) Data taken from MOD, 2003-2005. An infant death is a death occurring within the first year of life. Rates are expressed as the number of deaths per 1,000 live births.

### **The Extent to which the Proposed Service Reduces Premature Death and the Economic Loss Associated with Disease**

#### Premature Death

Overall in California, the rate of maternal pregnancy-related mortality is 16.9 deaths per 100,000 live births (CDPH, 2009). Infant mortality rates are much higher, with approximately 522 deaths per 100,000 live births, and more than twice this rate for babies of black mothers (MOD, 2003-2005). As presented in the *Medical Effectiveness* section, there are specific prenatal care services that are effective in reducing the risk of preterm deliveries, low-birth weight babies, and other causes of infant and maternal mortality. To the extent that pregnant women gain access to health insurance plans that reduce out-of-pocket costs for prenatal care, it is possible that utilization of effective prenatal care services could increase, resulting in a reduction in premature death.

#### Economic Loss

The economic loss associated with poor pregnancy health outcomes consists of the direct costs of providing medical care and the indirect costs related to lost productivity and other special services needed to treat infants with additional health care needs. It has been estimated that the annual societal economic burden associated with preterm births is an average of \$51,600 per infant born preterm (IOM, 2006). More than one-fifth of this cost (\$11,200 per preterm infant) is associated with lost household and labor market productivity (IOM, 2006). In California, 10.9% of babies are born prematurely, translating to 904 births with an economic burden of nearly \$47 million in the 8,298 pregnancies that would be covered as a result of AB 1825. To the extent that AB 1825 could increase the utilization of effective prenatal care that can reduce outcomes such as preterm births and related infant mortality, there is a potential to reduce morbidity and mortality and the associated societal costs.

## **Long-Term Public Health Impacts**

As presented in the *Utilization, Cost, and Benefit Coverage Impacts* section, AB 1825 is expected to increase premiums on average in the CDI-regulated individual market by approximately 4.7%, thus increasing the number of uninsured by approximately 9,335 people. Losing one's health insurance has many harmful consequences. Compared to those who remain insured, persons who lose their health insurance report more reduced access to needed health care and receive fewer services (Kasper et al., 2000). A review of the literature on insurance status and health found that compared to the insured, uninsured persons obtain less preventive, diagnostic, and therapeutic care; are diagnosed at more advanced stages of illness; and have a higher risk of death (Hadley, 2003). In addition to the issues of health and health care access, the loss of health insurance can also cause substantial stress and worry due to lack of health insurance as well as financial instability if health problems emerge (Lave et al., 1998).

Maternity services will be considered part of the essential health benefits package to be provided by qualified health plans providing coverage in the small group and individual markets through the state-based insurance exchanges, effective in 2014. Therefore, any effects of AB 1825 would be diminished by the P.L.111-148 requirements following 2014.

## APPENDICES

### Appendix A: Text of Bill Analyzed

BILL NUMBER: AB 1825 INTRODUCED  
BILL TEXT

INTRODUCED BY Assembly Member De La Torre

FEBRUARY 11, 2010

An act to add Section 10123.865 to the Insurance Code, relating to health care coverage.

#### LEGISLATIVE COUNSEL'S DIGEST

AB 1825, as introduced, De La Torre. Maternity services.

Existing law provides for the regulation of health insurers by the Department of Insurance. Under existing law, a health insurer that provides maternity coverage may not restrict inpatient hospital benefits, as specified, and is required to provide notice of the maternity services coverage.

This bill would require new forms for health insurance policies submitted to the department after January 1, 2011, to provide coverage for maternity services, as defined. With respect to policy forms on file with the department as of January 1, 2011, the bill would require health insurers to submit to the department, on or before March 1, 2011, revised policy forms that provide coverage for maternity services and would require insurers to include that coverage in the corresponding policies that are issued, amended, or renewed following the department's approval of the revised forms, as specified.

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

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

SECTION 1. The Legislature finds and declares the following:

(a) In actual practice, health care service plans have been required by the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the

Health and Safety Code) to provide maternity services as a basic health care benefit.

(b) At the same time, existing law does not require health insurers to provide designated basic health care services and, therefore, health insurers are not required to provide coverage for maternity services.

(c) Therefore, it is essential to clarify that all health care coverage made available to California consumers, whether issued by health care service plans regulated by the Department of Managed Health Care or by health insurers regulated by the Department of Insurance, must include maternity services.

SEC. 2. Section 10123.865 is added to the Insurance Code, to read:

10123.865. (a) With respect to a pending or approved individual or group health insurance policy form on file with the department as of January 1, 2011, a health insurer shall submit to the department, on or before March 1, 2011, a revised policy form that provides coverage for maternity services. The corresponding policy issued, amended, or renewed on or after 30 days following the department's approval of the revised form shall include coverage for maternity services.

(b) New forms for individual or group policies of health insurance submitted to the department after January 1, 2011, shall provide coverage for maternity services.

(c) For purposes of this section, "maternity services" include prenatal care, ambulatory care maternity services, involuntary complications of pregnancy, neonatal care, and inpatient hospital maternity care, including labor and delivery and postpartum care.

(d) This section shall not apply to specialized health insurance, Medicare supplement insurance, short-term limited duration health insurance, CHAMPUS-supplement insurance, or TRI-CARE supplement insurance, or to hospital indemnity, accident-only, or specified disease insurance.

## Appendix B: Literature Review Methods

Appendix B describes methods used in the medical effectiveness literature review for AB 1825, a bill that would require health insurance policies issued by insurance companies regulated by the CDI to provide coverage for maternity services.

As noted in the *Introduction*, AB 1825 defines maternity services to include prenatal care, ambulatory care maternity services, involuntary complications of pregnancy, neonatal care, and inpatient hospital maternity care including labor and delivery and postpartum care. Each of these categories of maternity services in turn encompasses multiple screening tests, diagnostic tests, monitoring services, and treatments. Conducting a medical effectiveness analysis on the full range of maternity services was not feasible during the time frame within which this report had to be completed. Because AB 1825 is most likely to affect utilization of prenatal care, CHBRP focuses its review of the medical effectiveness literature on studies of the effectiveness of prenatal care services. Regardless of health insurance status, the vast majority of women in the United States deliver their babies in hospitals. In addition, AB 1825 would not affect coverage for infants.

Due to the large amount of literature on prenatal care services, CHBRP limited its literature search to meta-analyses, systematic reviews, and evidence-based guidelines. Such syntheses of multiple studies are the strongest forms of evidence of the effectiveness of medical interventions. The medical librarian's search encompassed both studies of the impact of receiving more or fewer prenatal care services, and studies of the effectiveness of screening tests, diagnostic tests, monitoring services, and treatments provided during or in conjunction with prenatal care visits. CHBRP also searched for literature on the impact of cost sharing for prenatal care and other preventive services, because AB 1825 could result in lower out-of-pocket costs for prenatal care among women of childbearing age who previously had health insurance policies that did not cover maternity services.

The search was limited primarily to studies published in English from January 2009 to present. The time frame for the search was truncated because CHBRP conducted a search of the literature on the effectiveness of prenatal care services published from 2004 through 2009 for a report issued in 2009 on AB 98 and from 1995 through 2007 for a report it issued in 2008 on AB 1962, identical bills regarding coverage for maternity services. Pertinent studies retrieved during the previous literature search are discussed in this report along with studies obtained from the new search.

The following databases that index peer-reviewed literature were searched: PubMed, the Web of Science, EconLit, and the Cochrane Library (including the Cochrane Database of Systematic Reviews and the Cochrane Register of Controlled Clinical Trials). Web sites maintained by the following organizations that publish systematic reviews and evidence-based guidelines were searched: Agency for Healthcare Research and Quality (including the U.S. Preventive Services Task Force), American College of Obstetricians and Gynecologists, Centers for Disease Control and Prevention, Institute for Clinical Systems Improvement, International Network of Agencies for Health Technology Assessment, National Guideline Clearinghouse, National Health Service

Centre for Reviews and Dissemination, National Institute for Health and Clinical Excellence, National Institutes of Health, and the Scottish Intercollegiate Guideline Network.

The literature search yielded a total of 339 studies regarding the effectiveness of maternity services or the impact of cost sharing on the use of prenatal care or other preventive services. At least two reviewers screened the title and abstract of each citation returned by the literature search to determine eligibility for inclusion. The reviewers obtained the full text of articles that appeared to be eligible for inclusion in the review and reapplied the initial eligibility criteria. Eight studies met the inclusion criteria and were included in the medical effectiveness review. These studies included updated editions of three evidence-based guidelines.

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

- Research design
- Statistical significance
- Direction of effect
- Size of effect
- 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
- 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 are well-implemented randomized controlled trials 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 or from small RCTs with weak research designs. 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 has 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 where there is little if any evidence of an intervention’s effect.

### Search Terms

The search terms used to locate studies relevant to the AB 1825 were as follows:

#### *MeSH Terms Used to Search PubMed*

Anemia, Iron Deficiency  
Aspirin  
Bacteriuria  
Beta-Thalassemia/genetics/prevention & control  
Biological Markers/blood  
Blood Group Incompatibility  
Calcium/therapeutic use  
Calcium, Dietary  
Chorionic Villi Sampling  
Cost-Benefit Analysis  
Cost Savings  
Cost Sharing  
Counseling  
Deductibles and Coinsurance  
Delivery, Obstetric  
Diabetes, Gestational/prevention & control  
Diagnosis Imaging  
Dietary Supplements  
Disease Transmission, Infectious/prevention & control  
Domestic Violence/prevention & control  
Eclampsia  
Evidence-Based Medicine  
Fetal Diseases/genetics/ultrasonography  
Folic Acid  
Genetic Counseling  
Genetic Screening/economics  
Genetic Testing  
Glucocorticoids/therapeutic use  
Health Benefit Plans, Employee  
Health Services Accessibility  
Hepatitis B/prevention & control/transmission  
Hepatitis C/diagnosis  
HIV  
Hypertension, pregnancy-induced/ prevention & control

Infant, Low Birth Weight  
Infant Mortality  
Infant, Newborn  
Infant, Premature  
Infant, Premature, Diseases/ prevention & control  
Infant, Very Low Birth Weight  
Insurance Coverage  
Iron, Dietary/therapeutic use  
Labor, Induced  
Length of Stay  
Magnesium Sulfate/therapeutic use  
Managed Care Programs/economics/utilization  
Mass Screening  
Maternal Mortality  
Medical Savings Accounts/economics/utilization  
Neonatal Screening/economics/ methods  
Neural Tube Defects/diagnosis  
Nuchal Translucency Measurement  
Obstetric Labor, Premature  
Perinatal Care  
Placenta Previa/diagnosis  
Postnatal Care/economics/utilization  
Predictive Value of Tests  
Preeclampsia/prevention & control  
Pregnancy  
Pregnancy Complications/prevention & control  
Pregnancy Complications, Hematologic  
Pregnancy Complications, Infectious/diagnosis/therapy  
Pregnancy in Diabetics  
Pregnancy Outcome  
Pregnancy, Prolonged  
Premature Birth  
Prenatal Care/economics/utilization  
Prenatal Diagnosis  
Progesterone/therapeutic use  
Program Evaluation  
Prospective Studies  
Rh-Hr Blood-Group System/blood  
Sexually Transmitted Diseases/prevention & control  
Smoking Cessation  
Streptococcus agalactiae  
Tay Sachs Disease  
Treatment Outcome  
Ultrasonography, prenatal  
Uterine hemorrhage  
Vaginosis, Bacterial/prevention & control

Publication Types:

Meta-Analysis

Multicenter Study

Practice Guideline

Randomized Control Trial

Reviews

Systematic Reviews

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

access for infants and mothers, adverse selection, antepartum hemorrhage, aspirin, bacterial vaginosis, bacteriuria, birth outcome\*, calcium supplement\*, Chorionic Villi Sampling, coinsurance, consumer direct health plan\*, consumer health plan\*, copayment, cost\*, cost benefit analysis, cost effective\*, cost saving\*, cost sharing, cost shift\*, counseling, deductibles, diagnosis imaging, dietary calcium supplement\*, domestic violence, eclampsia, effective\*, folic acid, genetic (counseling OR screening OR testing), health care accessibility, hepatitis B, hepatitis C, high deductible health plan\*, HIV, hospital stay, human immunodeficiency virus, induction of labor, intrapartum care, iron deficiency anemia, iron supplements, length of stay, low birth weight, magnesium sulfate, mass screening, maternal blood pressure, maternal infection\*, maternity service\*, medi-cal, neural tube defects, nuchal translucency, perinatal (care or service\*), placenta previa, postnatal service\*, postpartum service\*, postterm pregnancy\*, practice guideline\*, preeclampsia, pregnancy, pregnancy complication\*, pregnancy outcome\*, prenatal (care or service\*), prenatal screening, preterm birth, preventive care, progesterone, prospective studies, public financing, Rh(d) incompatibility, sexually transmitted disease\*, screening, self selection, smoking cessation, streptococcus agalactiae, tay sachs disease, treatment outcome\*, transmission of infectious disease, ultrasound

## Appendix C: Summary Findings on Medical Effectiveness

Appendix C describes the studies on prenatal care services that were analyzed by the medical effectiveness team. Tables C-1a through C-1c present information regarding the citation, type of study, intervention and comparison groups, population studied, and the location at which a study was conducted. Tables C-2a through C-2b summarize findings from the studies reviewed. These tables include studies that were reviewed for the report CHBRP issued on AB 98 and AB 1962, identical bills introduced in 2009 and 2008, respectively, and new studies, indicated in bold in the tables below, which have been added for the medical effectiveness review for AB 1825.

**Table C-1.** Description of Published Studies on Effectiveness of Prenatal Care Services

**Table C-1a.** Studies that Examined the Effectiveness of Different Numbers of Prenatal Visits

Citation	Type of Trial <sup>53</sup>	Intervention vs. Comparison Group	Population Studied	Location
Fiscella, 1995	Systematic review	Multiple intervention and comparison groups	Pregnant women	N/A
Villar et al., 2001	Meta-analysis	Reduced number of prenatal visits vs. standard number of prenatal visits	Pregnant women at low risk of developing complications during pregnancy or labor	N/A

<sup>53</sup> Level I = Well-implemented RCTs and cluster RCTs, Level II = RCTs and cluster RCTs with major weaknesses, Level III = Nonrandomized studies that include an intervention group and one or more comparison group, time series analyses, and cross-sectional surveys, Level IV = Case series and case reports, Level V = Clinical/practice guidelines based on consensus or opinion.

**Table C-1b. Studies that Examined the Effectiveness of Multiple Interventions**

<b>Citation</b>	<b>Type of Trial</b>	<b>Intervention vs. Comparison Group</b>	<b>Population Studied</b>	<b>Location</b>
ICSI, 2008 <sup>54</sup>	Evidence-based guideline	Multiple intervention and comparison groups	Pregnant women	N/A
Lu et al., 2003	Systematic review	Multiple intervention and comparison groups	Pregnant women	N/A
NCCWCH, 2008 <sup>55</sup>	Evidence-based guideline	Multiple intervention and comparison groups	Pregnant women	N/A
USPSTF, 1996 <sup>56</sup>	Evidence-based guideline	Multiple intervention and comparison groups	All persons—reviewed sections that address pregnant women	N/A
USPSTF, 2008 <sup>57</sup>	Evidence-based guideline	Multiple intervention and comparison groups	All persons—reviewed sections that address preventive services for pregnant women	N/A

<sup>54</sup> ICSI = Institute for Clinical Systems Improvement. ICSI is an independent, not-for-profit organization that promotes quality improvement among health plans, hospitals, and medical groups in Minnesota. This citation is to an evidence-based guideline for routine prenatal care.

<sup>55</sup> NCCWCH = British National Collaborating Centre for Women’s and Children’s Health. This citation is to an evidence-based guideline for routine prenatal care that was prepared for the National Institute for Clinical Excellence.

<sup>56</sup> USPSTF = United States Preventive Services Task Force.

<sup>57</sup> For this new report on AB 1825, the 2008 edition of this guideline was used

**Table C-1c.** Studies that Examined the Effectiveness of Specific Interventions

Type of Risk Factor/Problem and Service	Citation	Type of Trial	Intervention vs. Comparison Group	Population Studied	Location
<b>Behavioral</b>					
Tobacco cessation counseling	Lumley et al., 2009	Meta-analysis	Brief advice vs. usual care Individual counseling vs. usual care Group counseling vs. usual care	Pregnant women who smoke	N/A
	NZMOH, 2008 <sup>58</sup>	Systematic review	Brief advice vs. usual care Individual counseling vs. usual care Group counseling vs. usual care	Pregnant women who smoke	N/A
	US DHHS, <sup>59</sup> 2008	Meta-analysis	Individual counseling vs. usual care	Pregnant women who smoke	N/A
<b>Genetic Disorders</b>					
Congenital heart defects	Makrydimas et al., 2003	Meta-analysis	Accuracy of nuchal translucency ultrasound scan for detecting major congenital heart defects—no control group	Pregnant women with chromosomally normal fetuses (i.e., did not have Down syndrome or other chromosomal disorder)	N/A
	Wald et al., 2008	Meta-analysis	Accuracy of nuchal translucency ultrasound scan for detecting major congenital heart defects—no control group	Pregnant women with chromosomally normal fetuses	N/A

<sup>58</sup> NZMOH = New Zealand Ministry of Health.

<sup>59</sup> US DHHS = United States Department of Health and Human Services. This citation is to an evidence-based guideline for smoking cessation..

**Table C-1c. Studies that Examined the Effectiveness of Specific Interventions (Cont'd)**

Type of Risk Factor/Problem and Service	Citation	Type of Trial	Intervention vs. Comparison Group	Population Studied	Location
<b>Infectious Disease</b>					
Antibiotics for treatment of asymptomatic bacteriuria	Lin and Fajardo, 2008	Systematic review	Antibiotics vs. placebo or no treatment	Pregnant women with asymptomatic bacteriuria	N/A
	Smaill and Vazquez, 2007	Meta-analysis	Antibiotics vs. placebo or no treatment	Pregnant women with asymptomatic bacteriuria	N/A
Screening for chlamydia	Meyers et al., 2007	Systematic review	Screening for chlamydia vs. not screening	Women at increased risk for chlamydia	N/A
Screening for gonorrhea	Glass et al., 2005	Systematic review	Screening for gonorrhea vs. not screening	N/A – no new studies found since literature review completed for USPSTF, 1996	N/A
Screening for group b streptococcus	Schrag et al., 2002	Evidence-based guideline	Universal screening for group b streptococcus vs. assessment of clinical risk factors	Pregnant women	
Vaccination for hepatitis B	Krishnaraj, 2004	Systematic review	Vaccination for hepatitis b vs. placebo or no treatment	Infants born to women with hepatitis B	N/A
Vaccination and/or immune globulin for hepatitis B	Lee et al., 2006	Meta-analysis	Hepatitis B vaccine vs. placebo or no treatment; Hepatitis B immune globulin vs. placebo or no treatment; Hepatitis B vaccine and immune globulin vs. placebo or no treatment	Infants born to women who have hepatitis B	N/A

**Table C-1c. Studies that Examined the Effectiveness of Specific Interventions (Cont'd)**

<b>Type of Risk Factor/Problem and Service</b>	<b>Citation</b>	<b>Type of Trial</b>	<b>Intervention vs. Comparison Group</b>	<b>Population Studied</b>	<b>Location</b>
Antiretroviral therapy and other interventions to prevent transmission of HIV <sup>60</sup> to newborns	Chou et al., 2005	Systematic review	Antiretroviral therapy vs. placebo or no treatment; Elective cesarean section vs. vaginal delivery; Formula feeding vs. breastfeeding	Pregnant women with HIV	N/A
Screening for syphilis	Nelson et al., 2004	Systematic review	Screening for syphilis vs. not screening	Pregnant women	N/A
Metabolic, Nutritional, and Endocrine Conditions					
Gestational diabetes					
	<b>Alwan et al., 2009</b>	<b>Meta-analysis</b>	<b>Dietary advice or drug treatment including insulin and oral drugs in addition to routine care vs. routine care</b>	<b>Pregnant women with gestational diabetes or impaired glucose tolerance</b>	<b>N/A</b>
	Hillier et al., 2008	Systematic review	Dietary advice, training in self-monitoring of blood glucose, and insulin vs. no treatment;  Insulin vs. no treatment	Pregnant women with gestational diabetes	N/A
Iron supplementation for anemia	Helfand et al., 2006	Systematic review	Iron supplements vs. placebo	Pregnant women with iron deficiency anemia	N/A

<sup>60</sup> HIV = Human Immunodeficiency Virus

**Table C-1c. Studies that Examined the Effectiveness of Specific Interventions (Cont'd)**

<b>Type of Risk Factor/Problem and Service</b>	<b>Citation</b>	<b>Type of Trial</b>	<b>Intervention vs. Comparison Group</b>	<b>Population Studied</b>	<b>Location</b>
<b>Hypertensive Disorders</b>					
Calcium supplementation to prevent hypertensive disorders	Hofmeyr et al., 2006	Meta-analysis	Calcium supplementation vs. placebo	Pregnant women regardless of risk of hypertensive disorders	N/A
Antiplatelet agents to prevent preeclampsia and associated complications	Askie et al., 2007	Meta-analysis	Antiplatelet agents (e.g., low-dose aspirin) vs. placebo or no medication	Pregnant women at risk for preeclampsia	N/A
	Duley et al., 2007	Meta-analysis	Antiplatelet agents vs. placebo or no treatment	Pregnant women at risk for preeclampsia	N/A
	Ruano et al., 2005	Meta-analysis	Low-dose aspirin vs. placebo	Pregnant women at low risk for preeclampsia  Pregnant women at high risk for preeclampsia	N/A
Anti-convulsants for treatment of preeclampsia	Duley et al., 2003	Meta-analysis	Anti-convulsant drugs vs. placebo	Women with preeclampsia before or after delivery	N/A
Multiple interventions to prevent preeclampsia	Meads et al., 2008	Meta-analysis	Intervention vs. placebo, no treatment, or usual care	Pregnant women at risk for preeclampsia	N/A

**Table C-1c. Studies that Examined the Effectiveness of Specific Interventions (Cont'd)**

Type of Risk Factor/Problem and Service	Citation	Type of Trial	Intervention vs. Comparison Group	Population Studied	Location
<b>Pregnancy Outcomes</b>					
Progestational agents to prevent preterm birth	Dodd et al., 2006	Meta-analysis	Progestational agents vs. placebo	Pregnant women at risk for preterm delivery	N/A
	Dodd et al., 2008	Meta-analysis	Progestational agents vs. placebo	Pregnant women at risk for preterm delivery	N/A
	Mackenzie et al., 2006	Meta-analysis	Progestational agents administered during 2 <sup>nd</sup> trimester vs. placebo	Pregnant women at risk for preterm delivery	N/A
	Sanchez-Ramos et al., 2005	Meta-analysis	Progestational agents vs. placebo	Pregnant women at risk for preterm delivery	N/A
	<b>Rode et al., 2009</b>	<b>Meta-analysis</b>	<b>Progestational agents vs. placebo</b>	<b>Nonsymptomatic women and women with preterm labor</b>	<b>N/A</b>
Lower genital tract infection detection and treatment to prevent preterm birth	<b>Sangkomkamhang et al., 2008</b>	<b>Meta-analysis</b>	<b>Receive lower genital tract infection screening results and treatment vs. do not receive screening results</b>	<b>Pregnant women presenting for routine prenatal visits between 15 and 19 weeks' gestation</b>	<b>Austria</b>
Corticosteroids to accelerate maturation of lungs in fetuses scheduled for preterm birth	Roberts and Dalziel, 2006	Meta-analysis	Corticosteroid drug capable of crossing the placenta vs. placebo or no treatment	Pregnant women expected to deliver their babies preterm due to spontaneous preterm labor, preterm prelabor rupture of membranes, or elective preterm labor	N/A
Magnesium sulfate to prevent neurological impairment in fetuses at risk for preterm delivery	Doyle et al., 2009	Meta-analysis	Anti-convulsant drugs (e.g., magnesium sulfate) vs. placebo or no treatment	Pregnant women at risk for preterm birth	N/A
External cephalic version for breech presentation before term	Hutton and Hofmeyr, 2006	Systematic review	External cephalic version vs. no intervention	Pregnant women whose fetuses are in breech position before term (i.e., before 37 weeks)	N/A

**Table C-1c. Studies that Examined the Effectiveness of Specific Interventions (Cont'd)**

<b>Type of Risk Factor/Problem and Service</b>	<b>Citation</b>	<b>Type of Trial</b>	<b>Intervention vs. Comparison Group</b>	<b>Population Studied</b>	<b>Location</b>
Induction of labor at or beyond term	Gülmezoglu et al., 2006	Meta-analysis	Induction of labor vs. waiting for spontaneous onset of labor	Pregnant women whose pregnancies continued beyond term	N/A
	Sanchez-Ramos et al., 2003	Meta-analysis	Induction of labor vs. waiting for spontaneous onset of labor	Pregnant women whose pregnancies continued beyond term	N/A

**Table C-2.** Summary of Findings from Studies of the Effectiveness of Prenatal Care Services

**Table C-2a.** Studies that Examined the Effectiveness of Different Numbers of Prenatal Visits

<b>Outcome</b>	<b>Research Design<sup>61</sup></b>	<b>Statistical Significance</b>	<b>Direction of Effect</b>	<b>Size of Effect</b>	<b>Generalizability</b>	<b>Conclusion</b>
Low birth weight	1 meta-analysis and 1 systematic review of Level II studies	• No statistically significant difference	• No effect	• No effect	• Somewhat generalizable—includes pregnant women from both developed and developing countries	• Changing the number of prenatal visits does not affect the odds of having a low-birth weight infant
Preterm birth	1 meta-analysis and 1 systematic review of Level II studies	• No statistically significant difference	• No effect	• No effect	• Somewhat generalizable—includes pregnant women from both developed and developing countries	• Changing the number of prenatal visits does not affect the odds of giving birth preterm
Admission to neonatal intensive care unit	1 meta-analysis and 1 systematic review of Level II studies	• No statistically significant difference	• No effect	• No effect	• Somewhat generalizable—includes pregnant women from both developed and developing countries	• Changing the number of prenatal visits does not affect the odds that a newborn will be admitted to a neonatal intensive care unit
Maternal mortality	1 meta-analysis and 1 systematic review of Level II studies	• No statistically significant difference	• No effect	• No effect	• Generalizable—includes pregnant women from developed countries	• Changing the number of prenatal visits does not affect the odds of maternal death
Antepartum or postpartum hemorrhage	1 meta-analysis and 1 systematic review of Level II studies	• No statistically significant difference	• No effect	• No effect	• Somewhat generalizable—includes pregnant women from both developed and developing countries	• Changing the number of prenatal visits does not affect the odds of antepartum or postpartum hemorrhage

<sup>61</sup> Level I = Well-implemented RCTs and cluster RCTs; Level II = RCTs and cluster RCTs with major weaknesses; Level III = Nonrandomized studies that include an intervention group and one or more comparison group, time series analyses, and cross-sectional surveys; Level IV = Case series and case reports; Level V = Clinical/practice guidelines based on consensus or opinion.

**Table C-2a.** Studies that Examined the Effectiveness of Different Numbers of Prenatal Visits (Cont'd)

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Preeclampsia	1 meta-analysis and 1 systematic review of Level II studies	<ul style="list-style-type: none"> <li>• No statistically significant difference</li> </ul>	<ul style="list-style-type: none"> <li>• No effect</li> </ul>	<ul style="list-style-type: none"> <li>• No effect</li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable —includes pregnant women from both developed and developing countries</li> </ul>	<ul style="list-style-type: none"> <li>• Changing the number of prenatal visits does not affect the odds of having preeclampsia</li> </ul>

**Table C-2b. Studies that Examined the Effectiveness of Specific Interventions**

<b>Risk Factor/ Intervention</b>	<b>Outcome</b>	<b>Research Design</b>	<b>Statistical Significance</b>	<b>Direction of Effect</b>	<b>Size of Effect</b>	<b>Generalizability</b>
<b>Behavioral</b>						
Smoking cessation counseling	Abstinence from smoking	2 meta-analyses and 1 systematic review of Level I-II studies	<ul style="list-style-type: none"> <li>Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>Favors smoking cessation counseling</li> </ul>	<ul style="list-style-type: none"> <li>OR<sup>62</sup> = 1.8 (95% CI<sup>63</sup> = 1.4, 2.3)<sup>64</sup></li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</li> </ul>
	Reduction in risk of low birth weight	1 meta-analysis and 3 systematic reviews of Level I-II studies	<ul style="list-style-type: none"> <li>Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>Favors smoking cessation counseling</li> </ul>	<ul style="list-style-type: none"> <li>RR<sup>65</sup> = 0.83 (95% CI = 0.73, 0.95)<sup>66</sup></li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</li> </ul>
	Reduction in risk of preterm birth	1 meta-analysis and 3 systematic reviews of Level I-II studies	<ul style="list-style-type: none"> <li>Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>Favors smoking cessation counseling</li> </ul>	<ul style="list-style-type: none"> <li>RR = 0.86 (95% CI = 0.74, 0.98)</li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</li> </ul>
Screening for domestic violence	Reduction in risk of injury to mother and fetus	1 systematic review of Level III studies	<ul style="list-style-type: none"> <li>Results of formal test of statistical significance not reported</li> </ul>	<ul style="list-style-type: none"> <li>Favors screening</li> </ul>	<ul style="list-style-type: none"> <li>Not reported</li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</li> </ul>

<sup>62</sup> OR = Odds ratio

<sup>63</sup> CI = Confidence interval

<sup>64</sup> Results for the effect of smoking cessation counseling on abstinence from smoking were reported in US DHHS (2008). This meta-analysis compared the effectiveness of providing counseling and other psychosocial interventions relative to brief advice, self-help materials, or referral to a smoking cessation program.

<sup>65</sup> RR = Risk ratio

<sup>66</sup> Results for the impact of smoking cessation counseling on the risks of low birth weight and preterm birth were reported in Lumley et al. (2004).

**Table C-2b.** Studies that Examined the Effectiveness of Specific Interventions (Cont'd)

<b>Risk Factor/ Intervention</b>	<b>Outcome</b>	<b>Research Design</b>	<b>Statistical Significance</b>	<b>Direction of Effect</b>	<b>Size of Effect</b>	<b>Generalizability</b>
<b>Congenital Disorders</b>						
Screening for Down syndrome with ultrasound and/or blood tests for biochemical markers	Accurate diagnosis	2 systematic reviews of Level III-IV studies	<ul style="list-style-type: none"> <li>• N/A—studies of test accuracy</li> </ul>	<ul style="list-style-type: none"> <li>• N/A—studies of test accuracy</li> </ul>	<ul style="list-style-type: none"> <li>• Detection rates ranged from 80% to 96%; false positive rate ranged from 3% to 9%<sup>67</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>
Screening for hemoglobinopathies <sup>68</sup>	Accurate diagnosis	2 systematic reviews	<ul style="list-style-type: none"> <li>• N/A—studies of test accuracy</li> </ul>	<ul style="list-style-type: none"> <li>• N/A—studies of test accuracy</li> </ul>	<ul style="list-style-type: none"> <li>• Not stated</li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>
Screening for Tay-Sachs disease	Accurate diagnosis	1 systematic review	<ul style="list-style-type: none"> <li>• N/A—studies of test accuracy</li> </ul>	<ul style="list-style-type: none"> <li>• N/A—studies of test accuracy</li> </ul>	<ul style="list-style-type: none"> <li>• Not stated</li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>
Screening for structural anomalies <sup>69</sup>	Accurate diagnosis	2 meta-analyses and 1 systematic review	<ul style="list-style-type: none"> <li>• N/A—studies of test accuracy</li> </ul>	<ul style="list-style-type: none"> <li>• N/A—studies of test accuracy</li> </ul>	<ul style="list-style-type: none"> <li>• For congenital heart defects, detection rate of 52% (95% CI = 42%, 71%) with a false positive rate of 5%<sup>70</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>
Folic acid to prevent neural tube defects	Prevention of neural tube defects	2 systematic reviews	<ul style="list-style-type: none"> <li>• Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>• Favors folic acid</li> </ul>	<ul style="list-style-type: none"> <li>• RR = 0.28 (95% CI = 0.13, 0.58)</li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>

<sup>67</sup> Detection rates and false positive rates are from previous studies cited in NCCWCH (2008) and are for the screening strategy recommended by NCCWCH (i.e., combined ultrasound and maternal serum biochemistry tests).

<sup>68</sup> Hemoglobinopathies are genetic disorders in the genes that control the expression of hemoglobin protein. Disorders of these genes can result in anemia and abnormal hemoglobins. Sickle cell anemia and thalassemia are two of the most common types of hemoglobinopathies.

<sup>69</sup> Structural anomalies are abnormalities in the development of the fetus. Congenital heart defects are the most common structural anomalies. Other structural anomalies that can be detected via ultrasound include anterior abdominal wall defects, congenital hydrocephalus, craniofacial abnormalities, Dwarfism, neural tube defects, and renal defects (NCCWCH, 2008).

<sup>70</sup> Detection rate and false positive rate for congenital heart defects are reported in Wald (2008) and apply only to congenital heart defects for which diagnosis could affect management of a pregnancy.

**Table C-2b.** Studies that Examined the Effectiveness of Specific Interventions (Cont'd)

Risk Factor/ Intervention	Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability
<b>Infectious Disease</b>						
Screening with urine culture and antibiotics for treatment of asymptomatic bacteriuria	Reduction in risk of kidney infection in mother	1 meta-analysis and 4 systematic reviews of Level II studies	<ul style="list-style-type: none"> <li>Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>Favors antibiotics</li> </ul>	<ul style="list-style-type: none"> <li>RR = 0.23 (95% CI = 0.13, 0.41)<sup>71</sup></li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</li> </ul>
	Reduction in risk of low birth weight	1 meta-analysis and 4 systematic reviews of Level II studies	<ul style="list-style-type: none"> <li>Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>Favors antibiotics</li> </ul>	<ul style="list-style-type: none"> <li>RR = 0.66 (95% CI = 0.49, 0.89)</li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</li> </ul>
	Reduction in odds of preterm birth	1 meta-analysis and 2 systematic reviews? (at least 1) of Level II studies	<ul style="list-style-type: none"> <li>Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>Favors antibiotics</li> </ul>	<ul style="list-style-type: none"> <li>OR = 0.60 (95% CI = 0.45, 0.80)<sup>72</sup></li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</li> </ul>
Antibiotics for chlamydia	Reduction in risk of premature rupture of membranes	2 systematic reviews of Level III studies	<ul style="list-style-type: none"> <li>Statistically significant</li> <li>Approaches statistical significance (p = 0.08)</li> </ul>	<ul style="list-style-type: none"> <li>Favors antibiotics</li> </ul>	<ul style="list-style-type: none"> <li>Treated = 3%; untreated = 5%<sup>73</sup></li> </ul>	<ul style="list-style-type: none"> <li>Generalizable—studies conducted in Ohio and Tennessee</li> </ul>
	Reduction in risk of low birth weight	2 systematic reviews of Level III studies	<ul style="list-style-type: none"> <li>Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>Favors antibiotics</li> </ul>	<ul style="list-style-type: none"> <li>Treated = 11%; untreated = 20%</li> </ul>	<ul style="list-style-type: none"> <li>Generalizable—studies conducted in Ohio and Tennessee</li> </ul>

<sup>71</sup> Results for outcomes of antibiotics for treatment of asymptomatic bacteriuria on risk of kidney infection and low birth weight were reported in Smaill and Vazquez, 2007.

<sup>72</sup> Lu et al. (2003) reported results from a previous meta-analysis.

<sup>73</sup> Results for all three outcomes of treating chlamydia with antibiotics are from a previous study cited in USPSTF (1996).

**Table C-2b.** Studies that Examined the Effectiveness of Specific Interventions (Cont'd)

<b>Risk Factor/ Intervention</b>	<b>Outcome</b>	<b>Research Design</b>	<b>Statistical Significance</b>	<b>Direction of Effect</b>	<b>Size of Effect</b>	<b>Generalizability</b>
	Reduction in risk of neonatal mortality	2 systematic reviews of Level III studies	<ul style="list-style-type: none"> <li>Approaches statistical significance (p = 0.08)</li> </ul>	<ul style="list-style-type: none"> <li>Favors antibiotics</li> </ul>	<ul style="list-style-type: none"> <li>Treated = 1%; untreated = 2%</li> </ul>	<ul style="list-style-type: none"> <li>Generalizable—studies conducted in Ohio and Tennessee</li> </ul>
Screening for lower genital tract infection and treatment to prevent preterm delivery	Reduction in risk of preterm delivery	1 meta-analysis of Level 1 study	<ul style="list-style-type: none"> <li>Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>Favors screening and treatment</li> </ul>	<ul style="list-style-type: none"> <li>RR = 0.55 (95% CI = 0.41, 0.75)</li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</li> </ul>
Prophylaxis for infants born to mothers with gonorrhea	Reduction in rates of conjunctivitis and blindness in newborns	2 systematic reviews of Level III studies	<ul style="list-style-type: none"> <li>No formal tests of statistical significance</li> </ul>	<ul style="list-style-type: none"> <li>Favors prophylaxis</li> </ul>	<ul style="list-style-type: none"> <li>83% decrease in infants treated with silver nitrate</li> <li>93% decrease in infants treated with tetracycline<sup>74</sup></li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable—studies conducted in Africa</li> </ul>
Antibiotics for group B streptococcus	Reduction in incidence of group B streptococcus in newborns and associated conditions	2 systematic reviews of indirect evidence from Level III-IV studies	<ul style="list-style-type: none"> <li>No formal tests of statistical significance reported</li> </ul>	<ul style="list-style-type: none"> <li>Favors antibiotics</li> </ul>	<ul style="list-style-type: none"> <li>Not reported</li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</li> </ul>

<sup>74</sup> USPSTF (1996) reported results from previous studies.

**Table C-2b.** Studies that Examined the Effectiveness of Specific Interventions (Cont'd)

<b>Risk Factor/ Intervention</b>	<b>Outcome</b>	<b>Research Design</b>	<b>Statistical Significance</b>	<b>Direction of Effect</b>	<b>Size of Effect</b>	<b>Generalizability</b>
Hepatitis B vaccination and/or hepatitis B immune globulin for hepatitis B	Reduction in risk of infant developing chronic hepatitis B	1 meta-analysis and 3 systematic reviews of Level I-II studies	<ul style="list-style-type: none"> <li>• Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>• Favors vaccination and/or immune globulin</li> </ul>	<ul style="list-style-type: none"> <li>• RR = 0.08 (95% CI = 0.03, 0.17) for vaccine plus immune globulin</li> <li>• RR = 0.28 (95% CI = 0.20, 0.40) for vaccine</li> <li>• RR = 0.50 (95% CI = 0.41, 0.60) for immune globulin<sup>75</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable—most studies conducted in developing countries</li> </ul>
Screening for human immunodeficiency virus (HIV) and antiretroviral therapy	Reduction in risk of mother-to-child transmission of HIV	3 systematic reviews of Level I-III studies	<ul style="list-style-type: none"> <li>• Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>• Favors antiretroviral therapy</li> </ul>	<ul style="list-style-type: none"> <li>• OR = 0.13 (95% CI = 0.06, 0.27)<sup>76</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable—some studies conducted in developing countries</li> </ul>
Elective cesarean section for mothers with HIV	Reduction in risk of mother-to-child transmission of HIV	2 systematic reviews of Level I-III studies	<ul style="list-style-type: none"> <li>• Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>• Favors cesarean section</li> </ul>	<ul style="list-style-type: none"> <li>• Transmission rate: cesarean section = 2%; Vaginal delivery = 11%<sup>77</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>

<sup>75</sup> Lee et al., 2006

<sup>76</sup> All results for outcomes of treatments to prevent mother-to-child transmission of HIV are from previous studies that are cited in Chou et al. (2005).

<sup>77</sup> Some women in both the cesarean section and vaginal delivery groups took an antiretroviral drug (zidovudine) during pregnancy. Among women who took zidovudine and had an elective cesarean section had a transmission rate of 1% (Chou et al., 2005).

**Table C-2b.** Studies that Examined the Effectiveness of Specific Interventions (Cont'd)

<b>Risk Factor/ Intervention</b>	<b>Outcome</b>	<b>Research Design</b>	<b>Statistical Significance</b>	<b>Direction of Effect</b>	<b>Size of Effect</b>	<b>Generalizability</b>
Screening for human immunodeficiency virus (HIV) and antiretroviral therapy	Reduction in risk of mother-to-child transmission of HIV	3 systematic reviews of Level I-III studies	Statistically significant	Favors antiretroviral therapy	OR = 0.13 (95% CI = 0.06, 0.27) <sup>78</sup>	Somewhat generalizable—some studies conducted in developing countries
Avoiding breastfeeding infants whose mothers have HIV	Reduction in risk of mother-to-child transmission of HIV	3 systematic reviews of Level I-III studies	<ul style="list-style-type: none"> <li>Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>Favors formula</li> </ul>	<ul style="list-style-type: none"> <li>Transmission rate: Formula = 21%; Breast-feeding = 37%<sup>79</sup></li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable—some studies conducted in developing countries</li> </ul>
Antibiotics for syphilis	Reduction in mother-to-child transmission of syphilis	4 systematic reviews of Level III-IV studies	<ul style="list-style-type: none"> <li>No formal test of statistical significance</li> </ul>	<ul style="list-style-type: none"> <li>Favors penicillin</li> </ul>	<ul style="list-style-type: none"> <li>Prevented transmission in 98.2% of infants<sup>80</sup></li> </ul>	<ul style="list-style-type: none"> <li>Generalizable—conducted in Texas</li> </ul>

<sup>78</sup> All results for outcomes of treatments to prevent mother-to-child transmission of HIV are from previous studies that are cited in Chou et al. (2005).

<sup>79</sup> Chou et al. (2005) reported results from previous study. Mothers enrolled in the study cited had not taken antiretroviral drugs during pregnancy. Taking these drugs would probably attenuate the effect of feeding infants formula instead of breast milk.

<sup>80</sup> NCCWCH (2008) reported results from a previous study.

**Table C-2b.** Studies that Examined the Effectiveness of Specific Interventions (Cont'd)

<b>Risk Factor/ Intervention</b>	<b>Outcome</b>	<b>Research Design</b>	<b>Statistical Significance</b>	<b>Direction of Effect</b>	<b>Size of Effect</b>	<b>Generalizability</b>
<b>Metabolic, Nutritional, and Endocrine Conditions</b>						
Dietary advice regarding gestational diabetes (and insulin if necessary)	Reduction in risk of a composite measure of perinatal morbidity (infant mortality, shoulder dystocia, bone fracture and nerve palsy)	1 systematic review of Level I-III studies	• Statistically significant	• Favors treatment	• RR = 0.32 (95% CI = 0.14, 0.73) <sup>81</sup>	• Somewhat generalizable
	Reduction in risk of pre-eclampsia	1 systematic review of Level I-III studies	• Statistically significant	• Favors treatment	• RR = 0.65 (95% CI = 0.48, 0.88)	• Somewhat generalizable
Iron supplements for iron deficiency anemia	Reduction in risk of low birth weight	2 systematic reviews of Level I-II studies	• Statistically significant	• Favors iron supplements	• Intervention = 4% of infants had birth weight <2,500 grams, Control = 17% of infants had birth weight less < 2,500 grams <sup>82</sup>	• Generalizable —conducted in Ohio
<b>Hypertensive Disorders</b>						
Blood pressure monitoring and urine culture to detect preeclampsia	Early identification of preeclampsia	No direct evidence because unethical to withhold blood pressure monitoring	• No formal tests of statistical significance	• Favors monitoring blood pressure	• No direct evidence	• Somewhat generalizable

<sup>81</sup> Crowther et al., 2005, as referenced in Alwan, 2009.

<sup>82</sup> Helfand et al. (2006) reported results from a previous study.

**Table C-2b. Studies that Examined the Effectiveness of Specific Interventions (Cont'd)**

<b>Risk Factor/ Intervention</b>	<b>Outcome</b>	<b>Research Design</b>	<b>Statistical Significance</b>	<b>Direction of Effect</b>	<b>Size of Effect</b>	<b>Generalizability</b>
Calcium supplements for hypertensive disorders	Reduction in risk of preeclampsia	1 meta-analyses and 3 systematic reviews of Level I-II studies	<ul style="list-style-type: none"> <li>• Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>• Favors calcium supplements</li> </ul>	<ul style="list-style-type: none"> <li>• RR = 0.48 (95% CI = 0.33, 0.69)<sup>83</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>
	Reduction in risk of maternal death and serious morbidity	2 meta-analyses and 2 systematic reviews of Level I-II studies	<ul style="list-style-type: none"> <li>• Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>• Favors calcium supplements</li> </ul>	<ul style="list-style-type: none"> <li>• RR = 0.80 (95% CI = 0.65, 0.97)</li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>
Antiplatelet agents for women at risk for preeclampsia	Reduction in risk of preeclampsia	34 meta-analyses and 1 systematic review of Level I-II studies	<ul style="list-style-type: none"> <li>• Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>• Favors antiplatelet agents</li> </ul>	<ul style="list-style-type: none"> <li>• RR = 0.83 (95% CI = 0.77, 0.89)<sup>84</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>
	Reduction in risk of preterm birth	4 meta-analyses of Level I-II studies	<ul style="list-style-type: none"> <li>• Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>• Favors antiplatelet agents</li> </ul>	<ul style="list-style-type: none"> <li>• RR = 0.92 (95% CI = 0.88, 0.97)</li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>
	Reduction in risk of small for gestational age birth	4 meta-analyses of Level I-II studies	<ul style="list-style-type: none"> <li>• Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>• Favors antiplatelet agents</li> </ul>	<ul style="list-style-type: none"> <li>• RR = 0.90 (95% CI = 0.83, 0.98)</li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>
	Reduction in risk of fetal or neonatal death	4 meta-analyses of Level I-II studies	<ul style="list-style-type: none"> <li>• Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>• Favors antiplatelet agents</li> </ul>	<ul style="list-style-type: none"> <li>• RR = 0.86 (95% CI = 0.76, 0.98)</li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>
Magnesium sulfate to prevent eclampsia	Reduction in risk of eclampsia	1 meta-analysis of Level I-II studies	<ul style="list-style-type: none"> <li>• Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>• Favors magnesium sulfate</li> </ul>	<ul style="list-style-type: none"> <li>• RR = 0.41 (95% CI = 0.29, 0.58)<sup>85</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>
	Reduction in risk of placental abruption	1 meta-analysis of Level I-II studies	<ul style="list-style-type: none"> <li>• Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>• Favors magnesium sulfate</li> </ul>	<ul style="list-style-type: none"> <li>• RR = 0.64 (95% CI = 0.50, 0.83)</li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>

<sup>83</sup> Both results for outcomes of prescribing calcium supplements during pregnancy were reported in Hofmeyr et al. (2006).

<sup>84</sup> All results for outcomes of prescribing antiplatelet agents were reported in Duley et al. (2007).

<sup>85</sup> All results for outcomes of administering magnesium sulfate during delivery were reported in Duley et al. (2003).

**Table C-2b. Studies that Examined the Effectiveness of Specific Interventions (Cont'd)**

<b>Risk Factor/ Intervention</b>	<b>Outcome</b>	<b>Research Design</b>	<b>Statistical Significance</b>	<b>Direction of Effect</b>	<b>Size of Effect</b>	<b>Generalizability</b>
<b>Other Medical Conditions</b>						
Immune globulin for Rh(D) incompatibility	Reduction in risk of hemolytic disease <sup>86</sup> in newborns	3 systematic reviews of Level I-II studies	<ul style="list-style-type: none"> <li>Formal test of statistical significance not reported</li> </ul>	<ul style="list-style-type: none"> <li>Favors screening</li> </ul>	<ul style="list-style-type: none"> <li>Not stated</li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</li> </ul>
Referral to specialist for other atypical red blood cell alloantibodies	Reduction in risk of hemolytic disease in newborns	1 systematic review of Level III-IV studies	<ul style="list-style-type: none"> <li>No formal test of statistical significance</li> </ul>	<ul style="list-style-type: none"> <li>Favors screening</li> </ul>	<ul style="list-style-type: none"> <li>Not stated</li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</li> </ul>
<b>Pregnancy Outcomes</b>						
Ultrasound to diagnose placenta previa <sup>87</sup>	Accurate diagnosis	1 systematic review of Level II-IV studies	N/A—studies of test accuracy	N/A—studies of test accuracy	<ul style="list-style-type: none"> <li>In 73% of women diagnosed with placenta previa at 32-35 weeks, condition persisted to delivery</li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</li> </ul>
Progestational agents to prevent preterm delivery	Reduction in risk of preterm delivery	4 meta-analysis and 2 systematic reviews of Level I-II studies	Statistically significant	Favors progestational agents	<ul style="list-style-type: none"> <li>RR = 0.65 (95% CI = 0.54, 0.79)<sup>88</sup></li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</li> </ul>

<sup>86</sup> Symptoms of hemolytic disease include anemia, jaundice, body swelling, and difficulty breathing.

<sup>87</sup> A diagnosis of placenta previa indicates that the placenta covers the opening to the vagina, which is associated with placental abruption, hemorrhage, intrauterine growth restriction.

<sup>88</sup> All results for outcomes of prescribing progestational agents were reported in Dodd et al. (2006).

**Table C-2b.** Studies that Examined the Effectiveness of Specific Interventions (Cont'd)

<b>Risk Factor/ Intervention</b>	<b>Outcome</b>	<b>Research Design</b>	<b>Statistical Significance</b>	<b>Direction of Effect</b>	<b>Size of Effect</b>	<b>Generalizability</b>
	Reduction in risk of low birth weight	4 meta-analysis and 2 systematic reviews of Level I-II studies	<ul style="list-style-type: none"> <li>• Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>• Favors progesterational agents</li> </ul>	<ul style="list-style-type: none"> <li>• RR = 0.63 (95% CI = 0.49, 0.81)</li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>
	Reduction in risk of intra-ventricular hemorrhage	4 meta-analysis and 2 systematic reviews of Level I-II studies	<ul style="list-style-type: none"> <li>• Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>• Favors progesterational agents</li> </ul>	<ul style="list-style-type: none"> <li>• RR = 0.25 (95% CI = 0.08, 0.82)</li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>
	Reduction in risk of infant mortality	1 meta-analysis of Level 1 study	<ul style="list-style-type: none"> <li>• Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>• Favors progesterational agents</li> </ul>	<ul style="list-style-type: none"> <li>• RR = 0.54 (95% CI = 0.31-0.93)</li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>
Corticosteroids to accelerate fetal lung maturation	Reduction in risk of neonatal mortality	1 meta-analysis and 1 systematic review of Level I-II studies	<ul style="list-style-type: none"> <li>• Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>• Favors corticosteroids</li> </ul>	<ul style="list-style-type: none"> <li>• RR = 0.69 (95% CI = 0.58, 0.81)<sup>89</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>
	Reduction in risk of respiratory distress syndrome	1 meta-analysis and 1 systematic review of Level I-II studies	<ul style="list-style-type: none"> <li>• Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>• Favors corticosteroids</li> </ul>	<ul style="list-style-type: none"> <li>• RR = 0.66 (95% CI = 0.59, 0.73)</li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>
	Reduction in risk of cerebro-ventricular hemorrhage	1 meta-analysis and 1 systematic review of Level I-II studies	<ul style="list-style-type: none"> <li>• Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>• Favors corticosteroids</li> </ul>	<ul style="list-style-type: none"> <li>• RR = 0.54 (95% CI = 0.43, 0.69)</li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>
	Reduction in risk of necrotizing enterocolitis	1 meta-analysis of Level I-II studies	<ul style="list-style-type: none"> <li>• Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>• Favors corticosteroids</li> </ul>	<ul style="list-style-type: none"> <li>• RR = 0.46 (95% CI = 0.29, 0.74)</li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>
	Reduction in risk of intensive care admission	1 meta-analysis of Level I-II studies	<ul style="list-style-type: none"> <li>• Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>• Favors corticosteroids</li> </ul>	<ul style="list-style-type: none"> <li>• RR = 0.80 (95% CI = 0.65, 0.99)</li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>

<sup>89</sup> All results for outcomes of prescribing antenatal corticosteroids were reported in Roberts and Dalziel (2006).

**Table C-2b.** Studies that Examined the Effectiveness of Specific Interventions (Cont'd)

<b>Risk Factor/ Intervention</b>	<b>Outcome</b>	<b>Research Design</b>	<b>Statistical Significance</b>	<b>Direction of Effect</b>	<b>Size of Effect</b>	<b>Generalizability</b>
Magnesium sulfate to prevent neurological impairment in fetuses of women at risk for preterm delivery	Reduction in risk of cerebral palsy	1 meta-analysis of Level I-II studies	<ul style="list-style-type: none"> <li>Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>Favors magnesium sulfate</li> </ul>	<ul style="list-style-type: none"> <li>RR = 0.68 (95% CI = 0.54, 0.87)<sup>90</sup></li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</li> </ul>
	Reduction in risk of substantial gross motor dysfunction	1 meta-analysis of Level I-II studies	<ul style="list-style-type: none"> <li>Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>Favors magnesium sulfate</li> </ul>	<ul style="list-style-type: none"> <li>RR = 0.61 (95% CI = 0.44, 0.85)</li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</li> </ul>
External cephalic version <sup>91</sup> for breech presentation at term	Reduction in risk of baby being born in breech position	1 meta-analysis and 1 systematic review of Level I-II studies	<ul style="list-style-type: none"> <li>Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>Favors external cephalic version</li> </ul>	<ul style="list-style-type: none"> <li>RR = 0.59 to 1.0 if performed preterm<sup>92</sup></li> <li>RR = 0.42 (95% CI = 0.35, 0.50)<sup>93</sup> if performed at term</li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</li> </ul>
	Reduction in risk of cesarean section	1 meta-analysis and 1 systematic review of Level I-II studies	<ul style="list-style-type: none"> <li>Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>Favors external cephalic version</li> </ul>	<ul style="list-style-type: none"> <li>RR = 0.52 (95% CI = 0.39, 0.71) if performed at term</li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</li> </ul>

<sup>90</sup> Both results for the outcomes of prescribing magnesium sulfate to prevent neurological impairment were reported in Doyle et al. (2009).

<sup>91</sup> Health professional applies pressure to the mother's abdomen to encourage the fetus to turn from feet first to head first.

<sup>92</sup> Effect of external cephalic version performed preterm on risk of baby being born in breech position was reported in Hutton and Hofmeyr (2006).

<sup>93</sup> NCCWCH (2008) reported results of a previously published meta-analysis for both outcomes of external cephalic version performed at term for breech presentation.

**Table C-2b.** Studies that Examined the Effectiveness of Specific Interventions (Cont'd)

<b>Risk Factor/ Intervention</b>	<b>Outcome</b>	<b>Research Design</b>	<b>Statistical Significance</b>	<b>Direction of Effect</b>	<b>Size of Effect</b>	<b>Generalizability</b>
Ultrasound to determine gestational age	Reduction in odds of inducing labor	1 systematic review of Level I-II studies	<ul style="list-style-type: none"> <li>• Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>• Favors routine ultrasound</li> </ul>	<ul style="list-style-type: none"> <li>• OR = 0.61 (95% CI = 0.52, 0.72)<sup>94</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>
Membrane sweeping to induce labor in postterm pregnancies	Reduction in odds of inducing labor	2 systematic reviews of Level II studies	<ul style="list-style-type: none"> <li>• Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>• Favors membrane sweeping</li> </ul>	<ul style="list-style-type: none"> <li>• RR = 0.59 (95% CI = 0.50, 0.70)<sup>95</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>
Routine induction of labor with pharmaceuticals in postterm pregnancies	Reduction in odds of cesarean section	1 meta-analysis of Level I-II studies	<ul style="list-style-type: none"> <li>• Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>• Favors induction of labor</li> </ul>	<ul style="list-style-type: none"> <li>• OR = 0.88 (95% CI = 0.78, 0.99)<sup>96</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>
	Reduction in odds of perinatal death	2 meta-analyses and 2 systematic reviews of Level I-II studies	<ul style="list-style-type: none"> <li>• Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>• Favors induction of labor</li> </ul>	<ul style="list-style-type: none"> <li>• RR = 0.30 (95% CI = 0.09, 0.99)<sup>97</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>

<sup>94</sup> NCCWCH (2008) reported results of a previously published meta-analysis.

<sup>95</sup> NCCWCH (2008) reported results from a previous meta-analysis.

<sup>96</sup> Sanchez-Ramos et al., 2003

<sup>97</sup> Gülmezoglu et al., 2006

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

This appendix describes data sources, as well as general and mandate-specific caveats and assumptions used in conducting the cost impact analysis. For additional information on the cost model and underlying methodology, please refer to the CHBRP Web site at [http://www.chbrp.org/analysis\\_methodology/cost\\_impact\\_analysis.php](http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php).

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

### Data Sources

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

#### *Health insurance*

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

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

### *Publicly funded insurance subject to state benefit mandates*

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

### General Caveats and Assumptions

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

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

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

- Cost impacts are shown only for plans and policies subject to state benefit mandate laws.
- Cost impacts are only for the first year after enactment of the proposed mandate
- Employers and employees will share proportionately (on a percentage basis) in premium rate increases resulting from the mandate. In other words, the distribution of premium paid by the subscriber (or employee) and the employer will be unaffected by the mandate.
- For state-sponsored programs for the uninsured, the state share will continue to be equal to the absolute dollar amount of funds dedicated to the program.
- When cost savings are estimated, they reflect savings realized for one year. Potential long-term cost savings or impacts are estimated if existing data and literature sources are available and provide adequate detail for estimating long-term impacts. For more information on CHBRP's criteria for estimating long-term impacts please see: [http://www.chbrp.org/analysis\\_methodology/cost\\_impact\\_analysis.php](http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php).
- Several recent studies have examined the effect of private insurance premium increases on the number of uninsured (Chernew, et al., 2005; Hadley 2006; Glied and Jack 2003). Chernew et al. 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](http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php).
- There are other variables that may affect costs, but which CHBRP did not consider in the cost projections presented in this report. Such variables include, but are not limited to:
  - Population shifts by type of health insurance: If a mandate increases health insurance costs, some employer groups and individuals may elect to drop their health insurance. Employers may also switch to self-funding to avoid having to comply with the mandate.
  - Changes in benefit plans: To help offset the premium increase resulting from a mandate, subscribers/policyholders may elect to increase their overall plan deductibles or copayments. Such changes would have a direct impact on the distribution of costs between the health plan and policies and enrollees, and may also result in utilization reductions (i.e., high levels of patient cost sharing result in lower utilization of health care services). CHBRP did not include the effects of such potential benefit changes in its analysis.

- Adverse selection: Theoretically, individuals or employer groups who had previously foregone health insurance may now elect to enroll in a health plan or policy, post-mandate, because they perceive that it is to their economic benefit to do so.
- 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 post-mandate benefit coverage levels, CHBRP typically assumes that plans and policies subject to the mandate will be in compliance with the coverage requirements of the bill. Therefore, the typical post-mandate benefit coverage rates for populations subject to the mandate are assumed to be 100%.

#### Bill Analysis-Specific Caveats and Assumptions

This section highlights specific caveats and assumptions that are not already discussed in the *Utilization, Cost, and Benefit Coverage Impacts* section of the report.

- CHBRP estimates that in the absence of the mandate, there would be approximately 12,172 births in 2010 among women with no maternity benefits when they become pregnant. This estimate was based on birth rates in the population with privately funded insurance drawing from Milliman claims data, combined with data on the number of enrollees by plan type, gender and age group provided to CHBRP by the insurance carriers.
- According to CHIS 2005, among 616,000 women between the ages of 15 and 49 with individual insurance policies, approximately 21.9% of women are in households with incomes less than 200% of the FPL, making them eligible for Medi-Cal, and 12.5% are eligible for AIM (income 200-300% of FPL). Based on the previously described data from the Medical Expenditure Panel Survey (MEPS), CHBRP assumes that women would drop their privately funded insurance entirely when they become eligible for Medi-Cal.

- Based on AIM data on dually enrolled women (having both privately funded insurance and AIM) and CHBRP estimates of the number of women without maternity coverage at the time of pregnancy, CHBRP estimates that another 7% of women with privately funded insurance without maternity benefits would enroll in the AIM program.
- Thus, of the 12,172 women without maternity coverage at the time of pregnancy, about 2,666 may qualify for Medi-Cal and 817 may be covered by AIM. Based on the carrier survey, CHBRP estimates that about another 391 of these women would switch to plans with maternity benefits offered by their existing carrier prior to delivery.
- CHBRP estimates that the remaining 8,298 expected births among women who currently have no maternity benefits would not be covered by insurance pre-mandate. This is the population that would directly be impacted by AB 1825 and be newly covered for maternity services post-mandate.
- CHBRP assumes that the women who already have maternity coverage pre-mandate are unlikely to get maternity coverage from Medi-Cal or AIM<sup>98</sup> if they become pregnant. Women with incomes low enough to qualify for these public programs are unlikely to be willing to pay the higher premiums for policies with maternity coverage if lower-cost policies without maternity coverage are available.
- CHBRP assumes that post-mandate, men and women within the same age group would be equally distributed across policies that did and did not offer maternity coverage pre-mandate.
- Note that because the main CHBRP estimates (Table 5) assume that birth rates are the same for women who do and do not have maternity coverage pre-mandate, the post-mandate decrease in average premiums among women who already had maternity coverage (Table 6) is attributable to the last assumption.
- Post-mandate premiums were assumed to be the same for “covered w/maternity” and “covered w/o maternity” (Table 6) since there is no longer a distinction made between the two type of policies post-mandate (compared to the different view pre-mandate) since AB 1825 would require all policies to provide maternity services.
- In 2009, California passed AB 119 into law prohibiting insurers from gender rating, or charging differential premiums based on gender for contracts issued, amended, or renewed on or after January 1, 2011. Given that AB 1825 and AB 119 would have the same effective date, the combined effect would be to spread the risk for women and men who may use maternity services more evenly across the individual CDI-regulated market. Hence, the premium and cost calculations in this report assume all gender-rated policies will be converted to gender-neutral pricing prior to the implementation of AB 1825.

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<sup>98</sup> AIM enrollment data indicates that there are a proportion of AIM enrollees that currently have private insurance coverage and have maternity coverage.

## **Appendix E: Information Submitted by Outside Parties**

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

No information was submitted directly 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](http://www.chbrp.org/recent_requests/index.php).

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

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

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