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Analysis of Assembly Bill 185: Maternity Services

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CALIFORNIA  
HEALTH BENEFITS REVIEW PROGRAM

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## Analysis of Assembly Bill 185: Maternity Services

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A Report to the 2011-2012 California Legislature  
March 27, 2011

CHBRP 11-06



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 2011-2012 California State Legislature**

## **Analysis of Assembly Bill 185: Maternity Services**

**March 27, 2011**

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## **PREFACE**

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill 185. In response to a request from the California Assembly Committee on Health on January 26, 2011, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the program's authorizing statute.

Janet Coffman, MPP, PhD, and Chris Tonner, MPH, both of the University of California, San Francisco prepared the medical effectiveness analysis. Min-Lin Fang, MLIS, of the University of California, San Francisco, conducted the literature search. Joy Melnikow, MD, MPH, and Heather J. Hether, PhD, both of the University of California, Davis, prepared the public health impact analysis. Jennifer Lewsey, MS, of the University of California, San Diego, prepared the cost impact analysis. Robert Cosway, FSA, MAAA of Milliman, provided actuarial analysis. Aaron Caughey, MD, PhD, of the Oregon Health & Science University provided technical assistance with the literature review and expert input on the analytic approach. Garen Corbett, MS, of CHBRP staff prepared the introduction and synthesized the individual sections into a single report. A subcommittee of CHBRP's National Advisory Council (see final pages of this report) and a member of the CHBRP Faculty Task Force, Sylvia Guendelman, PhD, LCSW, of the University of California, Berkeley, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

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

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Susan Philip, MPP  
Director

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## EXECUTIVE SUMMARY

### California Health Benefits Review Program Analysis of Assembly Bill 185

AB 185 would apply only to policies regulated by the California Department of Insurance (CDI) (primarily preferred provider organizations), which represent approximately 17% 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 65%.

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>1</sup> Regulations defining basic health care services specifically include prenatal care as preventive care that must be covered.<sup>2</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>3</sup> Complications of pregnancy are generally covered regardless of whether the health insurance 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>4</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.

#### Analysis of AB 185

Approximately 21.9 million Californians (59%) have health insurance that may be subject to a health benefit mandate law passed at the state level.<sup>5</sup> Of the rest of the state’s population, a portion is uninsured (and so has no health insurance subject to any benefit mandate) and another portion has health insurance subject to other state law or only to federal laws.

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<sup>1</sup> Section 1317.1 of the California Health and Safety Code

<sup>2</sup> Section 1300.67 of the California Code of Regulations, Title 28

<sup>3</sup> The Pregnancy Discrimination Act under Title VII of the Civil Rights Act of 1964

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

<sup>5</sup> CHBRP’s estimates are available at [http://www.chbrp.org/documents/insur\\_source\\_est\\_2011.pdf](http://www.chbrp.org/documents/insur_source_est_2011.pdf).



Uniquely, California has a bifurcated system of regulation for health insurance subject to state-level benefit mandates. The DMHC<sup>6</sup> regulates health care service plans, which offer benefit coverage to their enrollees through health plan contracts. The CDI regulates health insurers<sup>7</sup>, which offer benefit coverage to their enrollees through health insurance policies.

AB 185 would require health insurance policies regulated by the CDI to cover maternity services,<sup>8</sup> therefore affecting the health insurance of approximately 2.86 million Californians (13% under state-regulated health insurance).

## **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 affected by AB 185, and (3) AB 185 would not affect coverage for infants. The *Benefit Coverage, Utilization, and Cost 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

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<sup>6</sup> The DMHC was established in 2000 to enforce the Knox-Keene Health Care Service Plan Act of 1975; see Health and Safety Code, Section 1340.

<sup>7</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.

<sup>8</sup> AB 185 would add Section 10123.865 to the California Insurance Code.

- 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 recurrent preterm delivery
- Maternal corticosteroids to promote maturation of lungs in fetuses delivered preterm
- 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 and prophylaxis 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

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

#### Benefit Coverage Impacts

- AB 185 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 2,858,000 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, 59% 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 12% of all enrollees and 13% 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 (which results in individuals at lower risk able to purchase less expensive policies) and the resulting adverse selection (where premiums for individuals that wish to purchase coverage are subjected to disproportionate increases) have already had a substantial impact on the CDI-regulated individual market. This is evidenced by the rise in the proportion of individuals uninsured for maternity services from 18% to 87% in the last 7 years.

*Public programs:*

- The Medi-Cal and Access for 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 3,683 or 29% of women with privately funded insurance who will deliver babies during 2011 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 2011, 1,565 or 9.6% of the women enrolled in AIM were simultaneously enrolled in privately funded health insurance policies that did not cover maternity services. Another 1,933 or 11.9% of AIM enrollees were enrolled in privately funded insurance policies that did cover maternity services.
- CHBRP estimates that 12,663 or 1.1% of women enrolled in CDI-regulated policies with no maternity benefits at the time of pregnancy would give birth during 2011.

- Of these women, CHBRP estimates that 2,773 would obtain Medi-Cal coverage and another 909 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 407 of these women are expected to transfer to policies covering maternity that are offered by their existing carrier.
  - The remaining 8,574 women would not have insurance coverage premandate for their prenatal care and delivery.
- AB 185 would expand maternity services coverage to approximately 1,184,000 enrollees with CDI-regulated individual policies, including about 268,181 women aged 19 to 44 years.
  - CHBRP estimates that there would be no decrease in Medi-Cal enrollment as a result of AB 185. Those 2,773 women who currently have no maternity coverage and qualify for Medi-Cal after pregnancy would still shift to Medi-Cal postmandate due to their income levels.
  - There are 1,565 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 postmandate. 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.
  - The estimated premium increases, enumerated below, may result in approximately 9,778 newly uninsured. It is likely that these newly uninsured would disproportionately consist of younger people as they are most likely to experience the greatest premium increases and because they are price-sensitive purchasers.

### Utilization Impacts

- CHBRP estimates that approximately 8,574 pregnancies would be newly covered under CDI-regulated insurance policies postmandate. 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 postmandate.
  - 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 76% 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, 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 postmandate in order to save on premiums.

- Certain types of screening tests that are not current standard of care and yet are included in the standard prenatal care fee might be used more frequently postmandate 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.

### Cost Impacts

- Among all enrollees in state-regulated policies (both CDI-regulated and DMHC-regulated), total annual health expenditures are estimated to increase by \$22.2 million, or 0.02%, 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 since the number of newly covered mothers is too small to have a measurable effect on costs, 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: \$111.5 million, or 1.66%, (“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): \$32.1 million, or 0.43%, (“Enrollee 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: \$121.5 million. This assumes that all women without coverage pay out of pocket. (“Enrollee expenses 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 0.52% and premiums by 3.48% (“Total Expenditure” and “Insured Premiums”, Table 7). Per member per month (PMPM) premiums are estimated to increase by an *average* of \$6.92 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 have been converted to gender-neutral pricing prior to the implementation of AB 185.
- 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 185 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 185 is expected to *decrease* average premiums by 0.5% to 23%.

- In addition to varying with age, premium changes could vary across policies. Postmandate, 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.

## **Public Health Impacts**

- CHBRP is unable to estimate the precise impact AB 185 would have on the utilization of prenatal care. However, given data on current utilization of prenatal services, CHBRP assumes an upper bound estimate that all 8,574 newly covered pregnancies would have financial barriers to prenatal care reduced and thus an increase in the utilization of effective prenatal care services would be expected. To the extent that AB 185 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 currently are potentially responsible for \$121.5 million in out-of-pocket costs for noncovered maternity services, if they all sought prenatal health care services. AB 185 would shift these costs from female enrollees to increased 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. However, the racial/ethnic distribution of pregnant women with the type of coverage affected by the mandate is unknown, so the specific impact of AB 185 cannot be established.
- In California, 10.1% of babies are born preterm and there are just under 3,000 infant deaths each year. It is estimated that each premature birth costs society approximately \$51,600. To the extent that AB 185 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 185, premiums in the CDI-regulated individual market are estimated to increase by greater than 1%, thus increasing the number of uninsured by approximately 9,778 people. Losing one's health insurance has many harmful consequences beyond the health outcomes presented in this analysis.

## Potential Effects of the Federal Affordable Care Act

The federal “Patient Protection and Affordable Care Act” (P.L.111-148) and the “Health Care and Education Reconciliation Act” (H.R.4872) were enacted in March 2010. These laws (together referred to as the “Affordable Care Act [ACA]”) are expected to dramatically affect the California health insurance market and its regulatory environment, with most changes becoming effective in 2014. How these provisions are implemented in California will largely depend on pending legal actions, funding decisions, regulations to be promulgated by federal agencies, and statutory and regulatory actions to be taken by California state government. The provisions that go into effect during these transitional years would affect the baseline, or current enrollment, expenditures, and premiums. It is important to note that CHBRP’s analysis of specific mandate bills typically addresses the marginal effects of the mandate bill—specifically, how the proposed mandate would impact benefit coverage, utilization, costs, and public health, holding all other factors constant. CHBRP’s estimates of these marginal effects are presented in this report.

### Essential health benefits offered by qualified health plans in the Exchange and potential interactions with AB 185

Essential Health Benefits (EHBs) explicitly include “Maternity and newborn care.”<sup>9</sup> In addition, the U.S. Department of Health and Human Services when promulgating regulations on EHBs is to ensure that the EHB floor “is equal to the scope of benefits provided under a typical employer plan.” Virtually all employer coverage includes maternity services and the scope of services under AB 185 is considered standard maternity care coverage under most employer-based plans (i.e., prenatal care, ambulatory care maternity services, involuntary complications of pregnancy, neonatal care, and inpatient hospital maternity care, including labor and delivery and postpartum care). Therefore, it is highly likely that any impacts of AB 185 projected in this report in the longer term (beyond 2014) would be mitigated by these ACA requirements.

Due to the fact that “maternity services,” as defined under AB 185 is considered standard coverage for employer-based plans, and because it is likely to be considered part of EHBs, it is unlikely that there would be an additional fiscal liability to the state as a result of this mandate for qualified health plans offered in the Exchange.

### Preventive services required under ACA and AB 185

“New plans” (i.e., those not covered under the ACA’s “grandfather” provisions) were required to cover certain preventive services at zero cost sharing beginning September 23, 2010. Required preventive services include those rated “A” or “B” by the U.S. Preventive Services Task Force (USPSTF); recommended immunizations; preventive care for infants, 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

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<sup>9</sup> Affordable Care Act, Section 1302(b)(1)(E).

recommendation. These would be covered and therefore could diminish the marginal cost impact and public health impacts presented in this analysis.<sup>10</sup> It is possible that certain policies technically cover certain prenatal care services at zero cost sharing, but still exclude maternity services. For the purposes of this analysis, the more relevant question is whether CDI-regulated individual policies currently cover the bundle of maternity services, including prenatal care services. Therefore, this analysis does not attempt to parse out the portion of the market that may have coverage for recommended prenatal care services but does not have coverage for maternity services.

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<sup>10</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).



**Table 1. AB 185 Impacts on Benefit Coverage, Utilization, and Cost, 2011**

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
<b>Coverage</b>				
Total enrollees with health insurance subject to state-level benefit mandates (a)	21,902,000	21,902,000	0	0.00%
Total enrollees with health insurance subject to AB 185				
In large- and small-group plans	1,515,000	1,515,000	0	0.00%
In individual plans	1,343,000	1,343,000	0	0.00%
Total	2,858,000	2,858,000	0	0.00%
Percentage of enrollees with maternity coverage				
In large- and small-group plans	100%	100%	0.00%	0.00%
In individual plans	12%	100%	88.16%	744.65%
Total	59%	100%	41.43%	70.73%
Number of enrollees with maternity coverage				
In large- and small-group plans	1,515,000	1,515,000	0	0.00%
In individual plans	159,000	1,343,000	1,184,000	744.65%
Total	1,674,000	2,858,000	1,184,000	70.73%
<b>Utilization and cost</b>				
Number of enrollees with uncomplicated pregnancies				
Covered by insurance	19,072	27,646	8,574	44.96%
Covered by AIM or Medi-Cal	3,682	3,682	0	0.00%
Not covered by insurance	8,574	0	-8,574	-100.00%
Total	31,328	31,328	0	0.00%
Average cost per uncomplicated delivery	\$14,044	\$14,044	\$0	0.00%
<b>Expenditures</b>				
Premium expenditures by private employers for group insurance	\$52,713,266,000	\$52,713,266,000	\$0	0.00%
Premium expenditures for individually purchased insurance	\$6,724,851,000	\$6,836,376,000	\$111,525,000	1.66%
Premium expenditures by enrollees with privately funded and publicly funded group insurance (b)	\$15,173,472,000	\$15,173,472,000	\$0	0.00%
CalPERS HMO employer expenditures	\$3,465,785,000	\$3,465,785,000	\$0	0.00%
Medi-Cal Managed Care Plan state expenditures	\$8,657,688,000	\$8,657,688,000	\$0	0.00%
MRMIB plan expenditures (c)	\$1,050,631,000	\$1,050,631,000	\$0	0.00%
Enrollee out-of-pocket expenses for covered benefits (deductibles, copayments, etc.)	\$7,548,415,000	\$7,580,553,000	\$32,138,000	0.43%
Enrollee expenses for noncovered benefits (d)	\$121,468,000	\$0	-\$121,468,000	-100.00%
<b>Total Annual Expenditures</b>	<b>\$95,455,576,000</b>	<b>\$95,477,771,000</b>	<b>\$22,195,000</b>	<b>0.02%</b>

*Source:* California Health Benefits Review Program, 2011.

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

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

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

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

Key: AIM=Access for Infants and Mothers; CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health; MRMIB =Managed Risk Medical Insurance Board; MRMIP=Major Risk Medical Insurance Program.

## INTRODUCTION

The California Assembly Committee on Health requested on January 26, 2011, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 185, a bill that would impose a health benefit mandate. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.<sup>11</sup>

### Analysis of AB 185

Approximately 21.9 million Californians (59%) have health insurance that may be subject to a health benefit mandate law passed at the state level.<sup>12</sup> Of the rest of the state's population, a portion is uninsured (and so has no health insurance subject to any benefit mandate) and another portion has health insurance subject to other state law or only to federal laws.

Uniquely, California has a bifurcated system of regulation for health insurance subject to state-level benefit mandates. The California Department of Managed Health Care (DMHC)<sup>13</sup> regulates health care service plans, which offer benefit coverage to their enrollees through health plan contracts. The California Department of Insurance (CDI) regulates health insurers<sup>14</sup>, which offer benefit coverage to their enrollees through health insurance policies.

CDI-regulated individual (non-group) and group (large and small) policies (under 15 employees) would be subject to AB 185. Therefore, the mandate would affect the health insurance of approximately 2.86 million Californians (or 13% of all enrollees subject to state insurance regulation).

### *Background of 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. Births in California account for 13% of all US births. In 2009, the birth rate in California was 65.5 per 1,000 women of childbearing age (CDPH, 2009a), or more than 526,000 births (CDPH, 2009b). This represents an approximate decrease of 4.5% live births from 2008, when there were more than 551,000 live births in California (CDPH, 2008a). Despite the recent reduction in the birth rate, during the next decade, the state's

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<sup>11</sup> CHBRP's authorizing statute is available at: [http://www.chbrp.org/documents/authorizing\\_statute.pdf](http://www.chbrp.org/documents/authorizing_statute.pdf)

<sup>12</sup> CHBRP's estimates are available at: [http://www.chbrp.org/documents/insur\\_source\\_est\\_2011.pdf](http://www.chbrp.org/documents/insur_source_est_2011.pdf)

<sup>13</sup> DMHC was established in 2000 to enforce the Knox-Keene Health Care Service Plan of 1975; see Health and Safety Code, Section 1340.

<sup>14</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.

total number of annual births is projected to increase about 65,500 (12.4%) from the 2009 level, to more than 592,000 by 2019 (California Department of Finance, 2010).

In California during 2009, the majority (81.3%) of births were to mothers who initiated prenatal care in the first trimester (CDPH, 2009c). Another 13.6% started prenatal care in the second trimester, while 2.6% started care in the third trimester (defined as “late” prenatal care) (CDPH, 2009c). In addition, 0.5% of births were to women receiving no prenatal care, 1.8% of live births were to women having 1 to 4 prenatal visits, 15.2% had 5 to 9 visits, 59.1% had 10 to 14 visits, while 20.6% had 15 or more visits (RAND, 2009). Overall, 3.1% of births in California were to women receiving “late” or no prenatal care (CDPH, 2009c, 2009d).

Four of the major health outcomes of maternity care and utilization of prenatal services are birth weight, preterm delivery, and infant and maternal mortality. Major risk factors for low birth weight and preterm birth 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, and socioeconomic factors (MOD, 2011). An infant is considered low birth weight if the baby is below 2,500 grams at birth. In California, 6.8% of babies born weigh less than 2,500 grams, and 1.2% of all births are considered very low birth weight (i.e., less than 1,500 grams) (CDPH, 2009d; CDPH, 2011).

A full-term pregnancy is defined as a gestational length of 37 to 42 weeks (MOD, 2011). Babies born before 37 weeks of gestation are classified as preterm. In California, 10.1% of births were preterm in 2009 (CDPH, 2009d). Preterm babies are at higher risk for many complications, such as respiratory, gastrointestinal, immune system, central nervous system, hearing, and visual problems. Longer term health issues also include cerebral palsy, mental retardation, visual impairment, and hearing loss. Babies born before the gestational age of 32 weeks are also at the greatest risk for death and poor health outcomes (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. In addition, a family or personal history of preterm birth, or having a multifetal pregnancy, also increases 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, 2010). This rate has trended upward since the late 1990s. In 1998, the rate was 6.5 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 more than 100 maternal deaths in California each year (CDPH, 2006a). Infant mortality rates in California are 509 deaths per 100,000 live births, resulting in just under 3,000 deaths annually (CDPH, 2008b). Infant mortality, or death of an infant in the first year of life, is most frequently caused by birth defects (25.8% of deaths), followed by prematurity and low birth weight (13.1% of deaths), Sudden Infant Death Syndrome (SIDS) (7.2% of deaths), and maternal complications of pregnancy (7.0% of deaths) (CDPH, 2008c). A myriad of other causes make up the remaining number of infant deaths.

### *Background of AB 185*

According to the bill author, the problem the bill seeks to address is reducing birth complications and preterm births through enhanced access to prenatal and other maternity services. According to the Centers for Disease Control and Prevention in 2008, 10.5% of all child births in California were preterm births. Moreover, 11% or 57,770 of all preterm child births in the United States were in California (CDC, 2008). These birth complications, the author noted, are exacerbated by the lack of proper prenatal and postnatal care for expecting mothers. Further, according to the bill author, low-income minority communities are especially affected by the lack of maternity care. Infants born to low-income minority women suffer disproportionately from low birth weight, making it a significant pregnancy related health disparity.

In addition, according to the bill author, AB 185 is cost effective and has important public health considerations. Prenatal, neonatal, postpartum, and other maternity care are needed to ensure the health and well-being of women and babies. These services are preventative care measures, which reduce future birth complications. Lastly, the bill author noted that this bill would aid in easing in the 2014 Affordable Care Act implementation in California. As the federal health care reform rolls out and provides “essential benefits package,” AB 185 would help alleviate the price shock that insurance providers will experience.

CHBRP has analyzed five similar bills: AB 1825 (De La Torre, 2010), AB 98 (De La Torre, 2009), AB 1962 (De La Torre, 2008), SB 1555 (Speier, 2004) and SB 987 (Speier, 2003).<sup>15</sup> In this legislative session, CHBRP is analyzing a Senate version of the same bill (SB 155, Evans).

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 *Benefit Coverage, Utilization, and Cost Impacts* section, the percentage of individuals who have coverage for maternity services in the individual market has dropped to 12%. In other words, about 1,184,000 individuals in 2011 with privately funded insurance in the CDI-regulated market currently do not have coverage for maternity services. This indicates that risk segmentation (which results in individuals at lower risk able to purchase less expensive policies) and the resulting adverse selection (where premiums for individuals that wish to purchase coverage are subjected to disproportionate increases) has already had a substantial impact on the individual (non-group) insurance market.

### 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>16</sup> Thus, under existing California laws and

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<sup>15</sup> Analyses of the five bills are available on CHBRP’s Web site at <http://www.chbrp.org/analyses.html>

<sup>16</sup> Section 1300.67 of the California Code of Regulations, Title 28

regulations, the 83% of the privately funded market enrolled in DMHC-regulated plans has coverage for maternity services.<sup>17</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>18</sup> Because of this federal law, all members obtaining health insurance in the large-group market (groups with more than 50 employees) would 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 *Benefit Coverage, Utilization, and Cost 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>19</sup> This is also a federal protection under the Newborns’ and Mothers’ Health Protection Act of 1996.<sup>20</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>21</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 (HIPAA), which amends the Employee Retirement Income Security Act (ERISA), prohibits employer-based plans from applying pre-existing condition exclusions to pregnancy, whether or not the woman had 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>22</sup> Under California law, plans and insurers are required to issue health

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<sup>17</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>18</sup> The Pregnancy Discrimination Act under Title VII of the Civil Rights Act of 1964

<sup>19</sup> California Health and Safety Code, Section 1367.621; California Insurance Code, Section, 10123.87

<sup>20</sup> Newborns’ and Mothers’ Health Protection Act of 1996. Pub L No.104–204, §601 (1996)

<sup>21</sup> California Health and Safety Code, Section 1373.4; California Insurance Code, Section 10119.5

<sup>22</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).

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>23</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. The combined effect of both AB 185 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.

### 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<sup>24</sup>:

- be pregnant (though no more than 30 weeks)
- be a California resident
- not be enrolled in other programs (no-cost Medi-Cal or Medicare Part A and Part B)
- not have coverage from privately funded insurance, except in the case that it has a maternity-only deductible or copayment greater than \$500
- have a monthly household income after income deductions that is above 200 percent of the federal poverty level but below 300 percent of the federal poverty level.<sup>25</sup>

There are 18 states, including California, that currently have a requirement related to the coverage of maternity services (KFF, 2010). 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). Twelve states have a requirement related to maternity for individual plans (KFF, 2010). For example, maternity services are required to be covered as part of Hawaii's rules for prepaid health plans in the group market.<sup>26</sup> Washington requires carriers that sell individual health plans (except catastrophic coverage plans)<sup>27</sup> to (1) provide coverage for maternity services and (2) ensure that cost-sharing levels are the same as other health care benefits.<sup>28</sup> New Hampshire requires carriers selling individual health policies to offer a maternity rider if the policy does not cover maternity services in its base plan.<sup>29</sup>

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

<sup>24</sup> [http://www.aim.ca.gov/AIM\\_Program/](http://www.aim.ca.gov/AIM_Program/)

<sup>25</sup> CA Code of Regs Title 10, § 2699.200

<sup>26</sup> Hawaii Statute §393-7 "Required health care benefits"

<sup>27</sup> Washington State Division of Insurance <http://www.insurance.wa.gov/publications/health/2105-Mandates.pdf>

<sup>28</sup> Washington Insurance Code RCW 48.43.041

<sup>29</sup> New Hampshire Statute Section 415:6-d

## Potential Effects of Federal Affordable Care Act

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

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

A number of ACA provisions will need regulations and further clarity. One example is the ACA’s requirement for certain health insurance to cover “essential health benefits.” Effective 2014, Section 1302(b) will require small group and individual health insurance, including “qualified health plans” that will be sold in the California Exchange, to cover specified categories of benefits. These essential health benefits (EHBs) are defined as ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care. The Secretary of Health and Human Services (HHS) is charged with defining these categories through regulation, ensuring that the EHB floor “is equal to the scope of benefits provided under a typical employer plan.” In addition, the ACA would allow a state to “require that a qualified health plan offered in [the Exchange] offer benefits in addition to the essential health benefits.” If the state does so, the state must make payments to defray the cost of those additionally mandated benefits, either by paying the individual directly, or by paying the qualified health plan. This ACA requirement could interact with existing and proposed California benefit mandates, especially if California decided to require qualified health plans to cover California-specific mandates, and those mandates were determined to go beyond the EHB floor. Federal regulations regarding which benefits are to be covered under these broad EHB categories and other details, such as how the subsidies for purchasers of qualified health plans are structured, are forthcoming.<sup>30</sup>

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<sup>30</sup> For further discussion on EHBs and potential interaction with state mandates, please see, *California's State Benefit Mandates and the Affordable Care Act's "Essential Health Benefits"* available here: <http://www.chbrp.org/documents/ACA-EHB-Issue-Brief-011211.pdf>.



*Essential health benefits offered by qualified health plans in the Exchange and potential interactions with AB 185*

As mentioned, EHBs explicitly include “Maternity and newborn care.”<sup>31</sup> In addition, when promulgating regulations on EHBs, HHS is to ensure that the EHB floor “is equal to the scope of benefits provided under a typical employer plan.” Virtually all employer coverage includes maternity services and the scope of services under AB 185 is considered standard maternity care coverage under most employer-based plans (i.e., prenatal care, ambulatory care maternity services, involuntary, complications of pregnancy, neonatal care, and inpatient hospital, maternity care, including labor and delivery and postpartum care). Therefore, it is highly likely that any impacts of AB 185 projected in this report in the longer term (beyond 2014), would be mitigated by these ACA requirements.

The ACA requires that beginning in 2014 states “make payments...to defray the cost of any additional benefits” required of Qualified Health Plans (QHPs) sold in the Exchange. This potential liability would depend on three factors:

- Differences in the scope of “Maternity and newborn care” benefits in the final EHB package and the scope of mandated benefits in AB 185/SB 155;
- The number of enrollees in QHPs; and,
- The methods used to define and calculate the cost of additional benefits.

Again, because “maternity services” as defined under AB 185 is considered standard coverage for employer-based plans, and because it likely to be considered part of EHBs, it is unlikely that there would be an additional fiscal liability to the state as a result of this mandate for qualified health plans offered in the Exchange.

*Preventive services required under ACA and AB 185*

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

- Alcohol misuse counseling (including pregnant women)
- Bacteriuria Screening for pregnant women
- Breastfeeding counseling
- Chlamydial infection screening for pregnant women
- Folic acid supplementation

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<sup>31</sup> Affordable Care Act, Section 1302(b)(1)(E).

- Gonorrhea prophylactic medication for newborns
- Gonorrhea screening for women (including pregnant women)
- Hearing loss screening for newborns
- Hemoglobinopathies screening for newborns (screening for sickle cell disease)
- Hepatitis B screening for pregnant women
- Hypothyroidism screening for newborns
- Phenylketonuria (PKU) screening in newborns
- Rh blood typing and antibody screening for pregnant women at first visit for pregnancy-related care
- Repeated Rh blood typing and antibody testing for pregnant women at 24 to 28 weeks gestation (unless biological father is known to be Rh(D)–negative)
- Tobacco use counseling for pregnant women
- Syphilis screening for pregnant women

It is possible that certain policies technically cover certain prenatal care services at zero cost sharing, but still exclude maternity services. For the purposes of this analysis, the more relevant question is whether CDI-regulated individual policies currently cover the bundle of maternity services, including prenatal care services. Therefore, this analysis does not attempt to parse out the portion of the market that may have coverage for recommended prenatal care services but does not have coverage for maternity services.

### *Bill language*

The full text of AB 185 can be found in Appendix A.

AB 185, introduced by Assembly Member Roger Hernández, would require health insurance policies regulated by the CDI to cover maternity services.<sup>32</sup> CHBRP undertook the analysis of AB 185 in response to a request from the California Assembly Committee on Health on January 26, 2011, 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.

### *Analytic approach and key assumptions*

AB 185 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, 2012. The CDI-regulated market constitutes approximately 17.4% of enrollees with privately funded health

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<sup>32</sup> AB 185 would add Section 10123.865 to the California Insurance Code.

insurance in California. Enrollees in CDI-regulated policies represent about 65.0% of the individual market and about 33.0% of the privately funded small-group market. Because all group policies are required to and in practice currently cover maternity services, the *Benefit Coverage, Utilization, and Cost Impacts* section 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 185 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>33</sup> In addition, AB 185 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 185. Finally, AB 185 does not place new requirements on coverage of newborns.

AB 185 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 185, and (3) AB 185 would not affect coverage for infants. The *Benefit Coverage, Utilization, and Cost 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>33</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 185 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 185 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 185 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 February 2010 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 February 2010 for reports issued in 2010 (AB 1825), 2009 (AB 98), 2008 (AB 1962), and 2004 (SB 987 and SB 1555), identical bills regarding coverage for maternity services. Seven additional pertinent studies were identified, retrieved, and reviewed. Findings from these studies were integrated with findings from eight studies that were analyzed for CHBRP's report on AB 1825 and with 16 and 28 studies that were analyzed for CHBRP's report on AB 98 and AB 1962, respectively. 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>34</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 for these conditions 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

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<sup>34</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).

- Alloimmune hemolytic disease
- Cerebroventricular or intraventricular hemorrhage
- Respiratory distress syndrome
- Cerebral palsy
- 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). One meta-analysis synthesized findings from seven RCTs that compared the effects of different numbers of prenatal care visits on birth outcomes among women at low risk for pregnancy complications (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. More recently, a meta-analysis synthesized findings from seven trials that examined the effects of reduced number of prenatal visits to standard care on maternal and neonatal outcomes (Dowswell et al., 2010). The pooled results demonstrated no strong evidence of an effect of reduced visits on maternal or infant mortality, preterm births, hypertensive disorders, or neonatal intensive care admission. However, in a sub-analysis of trials conducted among women in low-income countries there was some evidence that reduced visits may result in an increase in prenatal mortality.

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>35</sup>

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>36</sup> the National Collaborating Centre for Women's and Children's Health

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<sup>35</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 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>36</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.

(NCCWCH),<sup>37</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). 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>38</sup> Two evidence-based guidelines recommend that clinicians ask about tobacco use, provide advice, support, or counseling on how to quit smoking (NCCWCH, 2010<sup>39</sup>; USPSTF, 2009a).

**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, 2010; 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, 2010).

**Domestic violence.** Domestic violence during pregnancy can cause injury to both pregnant women and their fetuses (Shah et al., 2010). 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

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<sup>37</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.

<sup>38</sup> All risk reductions, odds, and percentage differences cited in this section of the report are statistically significant at  $p < 0.05$ .

<sup>39</sup> The 2010 NCCWCH report is an update of the 2008 NCCWCH Excellence report. The 2008 report provides a systematic review of the literature in addition to recommendation guidelines whereas the 2010 report only provides guidelines.



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 has 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 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). Over the past decade with advances in ultrasound technology, screening for Down's syndrome has increasingly been done at earlier gestational age (Hourrier et al., 2010). In 2010, the United Kingdom's Department of Health recommended that all pregnant women be offered screening using the "combined test" that involves nuchal translucency, beta-human chorionic gonadotrophin, and pregnancy-associated plasma protein-A (NCCWCH, 2010).

**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, 2010). 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, 2010). Where the prevalence of hemoglobinopathies is high, the guideline recommends offering blood tests to all pregnant women. 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 of folic acid per day (NCCWCH, 2010). 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, 2009b). 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.

**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, 2010). Two meta-analyses have assessed the accuracy of providing an ultrasound including a nuchal translucency measurement during the first trimester to identify risk for 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). One evidence-based guideline also recommends fetal echocardiography that involves a view of the fetal heart as part of a routine anomaly scan (NCCWCH, 2010).

### *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, 2010).

**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, 2009c).

**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, 2009d). The United Kingdom's Department of Health recommends that chlamydia screening not be offered as part of routine prenatal care (NCCWCH, 2010).

**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 preeclampsia and with a composite outcome of perinatal morbidity (infant mortality, shoulder dystocia, bone fracture, and nerve palsy) (Alwan et al., 2009). The guidelines on screening for this disorder are mixed. One guideline recommends that all pregnant women should be screened for gestational diabetes (ICSI, 2008), a second recommends that screening for gestational diabetes be contingent upon risk factors (NCCWCH, 2010), and a review found 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>40</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).

**Hypothyroidism.** One systematic review evaluated the effectiveness of pharmacological interventions for treating pregnant women with clinical and subclinical hypothyroidism (Reid et al., 2010). One trial in the review compared the effects of levothyroxine compared to no treatment on maternal and infant outcomes. That trial demonstrated that levothyroxine therapy did not reduce the rates of preeclampsia but did reduce the rates of preterm births. While levothyroxine is the standard treatment for clinical hypothyroidism, there remains a lack of evidence for or against universal screening for hypothyroidism.

#### *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, 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 seizures, coma, brain damage, and death for both mother and baby, if not treated.

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<sup>40</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).

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., 2010; 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., 2010).

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 antiplatelet 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., 2010). 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 prevention 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, including women with previous preterm birth (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)<sup>41</sup>. 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. A recently published systematic review assessed the effectiveness of progestational agents on preterm delivery among women with established or threatened preterm labor before 37 weeks of gestation. Pooled results from two trials showed a 67% reduction in the risk of preterm birth at less than 37 weeks. A single small trial found no difference in the risk for preterm birth at less than 35 weeks (Su et al., 2010).

**Corticosteroids to promote maturation of lungs in fetuses delivered preterm.** 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

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<sup>41</sup> On January 4, 2011, the U.S. Food and Drug Administration approved Makena (hydroxyprogesterone caproate) injection to reduce the risk of preterm delivery before 37 weeks of pregnancy, in pregnant women with a history of at least one spontaneous preterm birth.

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., 2008). 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).

**Placental dysfunction.** During the development of the placenta blood clots may form and cause damage to the placental tissue. This damage may result in poorer maternal cardiovascular response to the pregnancy that may precede the onset of preeclampsia. One systematic review examined the use of heparin, a medication that prevents the formation of blood clots on maternal and infant outcomes among women at risk for placental dysfunction (Dodd et al., 2010). While the results showed that heparin reduced the risk of preeclampsia, eclampsia, and infant low birth weight, the results should be interpreted with caution as the number of studies and subjects was small. Further research is needed to assess adverse infant and long-term childhood outcomes.

**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 2010 NCCWCH guidelines recommend a transabdominal scan be offered only to women whose placenta extends over the internal cervical os at 32 weeks. 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 head up (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>42</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 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

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<sup>42</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).

- 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 delivered preterm
- 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

Risk Factor/Problem	Prenatal Screening Test	Treatment/Preventive Intervention	Effect of Treatment on Health Outcomes	Source
<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>43</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>44</sup> ; NZMOH, 2008 <sup>45</sup> ; US DHHS, 2008 <sup>46</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>43</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>44</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>45</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>46</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)**

Risk Factor/Problem	Prenatal Screening Test	Treatment Preventive Intervention	Effect of Treatment on Health Outcomes	Source
Hemoglobinopathies <sup>47</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>48</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>49</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>50</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>47</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>48</sup> Blood tests are generally recommended only for mothers at risk for being a carrier of genetic traits associated with hemoglobinopathies.

<sup>49</sup> Neural tube defects are birth defects that affect the spine and brain, such as spina bifida.

<sup>50</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)

Risk Factor/Problem	Prenatal Screening Test	Treatment Preventive Intervention	Effect of Treatment on Health Outcomes	Source
<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>51</sup>
Gonorrhea <sup>52</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>51</sup> The U.S. 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>52</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 Preventive Intervention</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 preeclampsia	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 Preventive Intervention	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 anticonvulsants (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>Anticonvulsants: 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., 2010; 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>Anticonvulsants: Duley et al., 2010</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 Preventive Intervention</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>53</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 progestational agents to mother	Reduction in risk of preterm delivery, low birth weight and infant mortality	Progestational 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; Su et al., 2010

<sup>53</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 Preventive Intervention	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	Corticosteroids: Reduction in risk of neonatal death, respiratory distress syndrome, cerebroventricular hemorrhage, necrotising enterocolitis, systemic infection, and intensive care admissions among newborns  Magnesium sulfate: Reduction in risk of cerebral palsy and substantial gross motor dysfunction	Corticosteroids: Lu et al., 2003; Roberts and Dalziel, 2006  Magnesium sulfate: Doyle et al., 2009
Breech presentation at term	Abdominal palpitations at 36 weeks or later	External cephalic version <sup>54</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	Membrane sweeping: lower odds of induction of labor;  Induction of labor: lower risk of perinatal death	Ultrasound screening for gestational age: NCCWCH, 2008  Membrane sweeping: ICSI, 2008; NCCWCH, 2008  Induction of labor: Gülmezoglu et al., 2006; ICSI, 2008; NCCWCH, 2008; Sanchez-Ramos et al., 2003

<sup>54</sup> Health professional applies pressure to mother's abdomen to encourage the fetus to turn from feet-first to head-first position.

## **BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS**

AB 185 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 and postpartum 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 185. 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*.

### **Current (Baseline) Benefit Coverage, Utilization, and Cost**

#### 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 50% of the CDI-regulated market.<sup>55</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 Access for Infants and Mothers (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 currently required to be provided by Knox-Keene licensed DMHC- regulated health plan contracts,<sup>56</sup> AB 185 targets CDI-regulated insurance policies. The distribution of enrollees in CDI-regulated policies is summarized as follows:

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<sup>55</sup> CHBRP analysis of the share of enrollees included in CHBRP’s Bill-Specific Coverage Survey of the major carriers in the state is based on “CDI Licenses with HMSR Covered Lives Greater than 100,000” as part of the Accident and Health Covered Lives Data Call, December 31, 2009 by the California Department of Insurance, Statistical Analysis Division, data retrieved from The Department of Managed Health Care’s interactive Web site “Health Plan Financial Summary Report,” July-September 2010,” and CHBRP’s Annual Enrollment and Premium Survey. 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>56</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.

- About 2,858,000 Californians, or 13% of enrollees in health insurance plans and policies subject to state regulation, are in the CDI-regulated market.
- 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 1,343,000 enrollees in individual (non-group) CDI-regulated policies.
- Within the CDI-regulated *individual* market, 12% of enrollees or 159,000 individuals have coverage for maternity services and 1,184,000 (88%) do not.
- For the women aged 19 to 44 years who are most likely to use maternity services, approximately 13% of enrollees or about 38,186 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 246,000, are women of childbearing age (19 to 44).
- In addition, about 120,500 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, 2007), 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>57</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 six-fold from an estimated 192,000 in 2004 to an estimated 1,184,000 in 2011.

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<sup>57</sup> The remainder was provided by other government and non-government programs, or unknown.

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

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

Age of Covered Individual	Male	Female	Total
00-19	11%	12%	12%
20-24	8%	11%	9%
25-29	5%	11%	8%
30-34	6%	17%	11%
35-39	8%	16%	12%
40-44	9%	13%	11%
45-49	11%	12%	11%
50-54	13%	13%	13%
55-59	15%	15%	15%
60-64	23%	19%	20%
<b>Under 65 Total</b>	10%	13%	12%

Source: California Health Benefits Review Program, 2011.

### Current Utilization Levels

#### *Current utilization levels, births*

CHBRP estimates that 31,328 pregnancies would occur among women enrolled in CDI-regulated policies in 2011 (Table 1). Of those births, 8,574 would be to women who did not have coverage for maternity services at the time of pregnancy. All of these 8,574 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 2,858,000 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, and, thus, that there are 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, with maternity services

as a rider in isolation not being an option. Thus, women of childbearing age are also likely to find these policies valuable for reasons other than the maternity benefit.

- **Unplanned pregnancies:** A 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 an event with low enough probability to accept the financial risk of having to pay out of pocket if pregnancy did occur.

Because CHBRP assumes that pregnancy 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 185 on covered deliveries, total expenditures, and premiums could be lower than presented in this analysis.

As an alternative, CHBRP estimated the impact of AB 185 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 2009, the birth rate in California was 71 per 1,000 women of childbearing age (CDPH, 2009e). In California during 2009, the majority (81.3%) of births were to mothers who initiated prenatal care in the first trimester (CDPH, 2009c). Another 13.6% started prenatal care in the second trimester, while 2.6% started care in the third trimester (defined as "late" prenatal care) (CDPH, 2009c). In addition, 0.5% of births were to women receiving no prenatal care, 1.8% of live births were to women having 1 to 4 prenatal visits, 15.2% had 5 to 9 visits, 59.1% had 10 to 14 visits, while 20.6% had 15 or more visits (RAND, 2009). Overall, 3.1% of births in California were to women receiving "late" or no prenatal care (CDPH, 2009c, 2009d).

#### *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.

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 six-fold, from an estimated 192,000 in 2004 (CHBRP, 2004) to the current estimate of 1,184,000 (CHBRP, 2011). 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.

#### *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 \$14,044.

#### Current (Baseline) Premiums and Expenditures

CHBRP estimates that within the CDI-regulated market (group and non-group), the current (premandate) portion of the total per member per month (PMPM) expenditures attributable to maternity is \$12.83, broken down as follows:

- \$5.62 PMPM of the total is currently covered by insurance,
- \$2.14 PMPM is paid by individuals in the form of copayments and deductibles for covered services,
- \$3.54 is paid by individuals in the form of out-of-pocket expenditures for noncovered services, and
- \$1.52 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 Coverage Are Shifted to Other Payors, Including Both Public and Private Entities

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 2010, about 21% 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>58</sup> Therefore, there is evidence that some cost-shifting occurs to these programs from the privately funded market.

### Public Demand for Benefit Coverage

Considering the criteria specified by CHBRP's authorizing statute, CHBRP reviews public demand for benefits relevant to a proposed mandate in two ways. CHBRP considers the bargaining history of organized labor and compares the benefits provided by self-insured health plans or policies (which are not regulated by the DMHC or CDI and so not subject to state-level mandates) with the benefits that are provided by plans or policies that would be subject to the mandate.

On the basis of conversations with the largest collective bargaining agents in California, CHBRP concluded that unions currently do not include cost sharing arrangements for maternity services in their health insurance negotiations. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.<sup>59</sup>

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

To further investigate public demand, CHBRP used the bill-specific coverage survey. In the survey, CHBRP asked carriers who act as third-party administrators for the self-insured group health insurance programs whether the relevant benefit coverage differed from what is offered in group market plans or policies that would be subject to the mandate. 100% of group CDI plans offer maternity, which is different than the individual market.

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 seven years as discussed in the *Introduction*.

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<sup>58</sup> Personal communication with Legislative Coordinator, Managed Risk Medical Insurance Board (MRMIB), March 1, 2011.

<sup>59</sup> Personal communication, S Flocks, California Labor Federation, January 2011.

## **Impacts of Mandated Benefit Coverage**

The enactment of AB 185 would require all CDI-regulated individual policies that do not cover maternity service to do so, thus expanding maternity services coverage to 1,184,000 enrollees, including 263,600 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 76% of the enrollees 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 postmandate in order to save on premiums.

The changes in premiums resulting from AB 185 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.”

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

#### *Impact on access and health 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 185 would be diminished by the P.L.111-148 requirements following 2014.

#### *Impact on the health benefit of the newly covered treatment/service*

There is no evidence that the proposed mandate would change the effectiveness of maternity services.

#### *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. This is because almost all births are already covered by group plans and public programs.



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

CHBRP estimates that approximately 8,574 pregnancies would be newly covered under CDI-regulated individual policies postmandate. 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 postmandate.
- 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 76% of the enrollees in CDI-regulated individual policies are currently in HDHPs and prenatal care is usually subject to the HDHP deductible (CHIS, 2010). 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 postmandate 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 postmandate 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, 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.

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

Although all insured women would have maternity benefits after enactment of AB 185, it is likely that women who qualify for Medi-Cal after pregnancy would still shift to Medi-Cal postmandate, 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) 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>60</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

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<sup>60</sup> This was computed using data from the MEPS web site, [http://www.meeps.ahrq.gov/meepsweb/data\\_stats/MEPSnetHC.jsp](http://www.meeps.ahrq.gov/meepsweb/data_stats/MEPSnetHC.jsp)

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 185 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 185. This assumes that unemployment is constant.

Those 2,774 women who currently have no maternity coverage and qualify for Medi-Cal after pregnancy would still shift to Medi-Cal postmandate due to their income levels.

The extent to which AB 185 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 postmandate.

About 76% 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 185. 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 postmandate—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 postmandate, then either way they are likely to qualify for, and enroll in, AIM. Thus, it is not likely that AB 185 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 1,565 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.

### 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 \$22.2 million, or 0.02%, 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: \$111.5 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): \$32.1 million (see row labeled "Enrollee out-of-pocket expenditures for covered benefits"), and
- the reduction in out-of-pocket expenditures for maternity benefits not currently covered by insurance: \$121.5 million (see row labeled "Enrollee expenses for non-covered 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 185 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 impact of the mandate on long-term costs is unknown.

### Impacts for Each Category of Payor 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 \$6.92, or 3.5%, on average (Table 6). Premium impacts are summarized as follows:

- CHBRP estimates that for the majority (88%) of enrollees in the CDI-regulated individual market who do not currently have maternity benefits, AB 185 would *increase* average premiums by 2% to 28% among those aged 19 to 44 years, depending on the age of the enrollee (see Table 4).
- Among the minority (12%) of enrollees in the CDI-regulated individual market who currently have maternity benefits, AB 185 is expected to *decrease* average premiums by 0.5% to 23%, depending on the age of the enrollee among those aged 19-44 years (see Table 4).

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. AB 119 would spread the risks more evenly across men and women within the same policies while AB 185 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 have been converted to gender-neutral pricing prior to the implementation of AB 185 in January, 2012.

**Table 4.** Estimated Impact on Individual Per Member Per Month Premiums by Age Group

	Age	Premandate		Postmandate		% Impact on Premiums (a)	
		Covered w/ Maternity	Covered w/o Maternity	Covered w/ Maternity	Covered w/o Maternity	Covered w/ Maternity	Covered w/o Maternity
Child	0 - 1	\$268	\$268	\$268	\$268	0.00%	0.00%
Child	2 - 6	\$59	\$59	\$59	\$59	0.00%	0.00%
Child	7 - 18	\$67	\$66	\$67	\$67	-0.23%	0.64%
Child (b)	19 - 22	\$93	\$92	\$93	\$93	-0.54%	1.52%
Adult (c)	To 25	\$132	\$93	\$115	\$115	-13.43%	22.62%
Adult	25 - 29	\$179	\$107	\$138	\$138	-23.04%	28.05%
Adult	30 - 34	\$200	\$124	\$154	\$154	-22.99%	24.84%
Adult	35 - 39	\$184	\$144	\$161	\$161	-12.49%	12.03%
Adult	40 - 44	\$182	\$172	\$176	\$176	-3.33%	2.27%
Adult	45 - 49	\$211	\$210	\$210	\$210	-0.57%	0.19%
Adult	50 - 54	\$265	\$264	\$264	\$264	-0.06%	0.01%
Adult	55 - 59	\$330	\$330	\$330	\$330	0.00%	0.00%
Adult	60 - 64	\$410	\$409	\$409	\$409	-0.30%	0.08%
	<b>Total</b>	<b>\$207</b>	<b>\$169</b>	<b>\$197</b>	<b>\$178</b>	<b>-4.70%</b>	<b>5.54%</b>

Source: California Health Benefits Review Program, 2011.

Notes: (a) Percent impact on premiums may not correspond to ratio of premandate vs. postmandate 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.

### *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 premandate versus postmandate 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 1.81% on average (vs. the estimated 3.48% increase when birth rates are assumed to be the same).

However, the impact of AB 185 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.

### Impacts on the Uninsured and Public Programs As a Result of the Cost Impacts of the Mandate

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

CHBRP estimates 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>61</sup> Using CHBRP’s standard methodology, premium changes associated with AB 185 are projected to lead to a net *increase* of approximately 9,778 uninsured Californians. CHBRP estimates that these newly uninsured would disproportionately consist of younger individuals (e.g., those aged 19 to 29 years) since they are most likely to experience the greatest premium increases and because they are price sensitive purchasers.

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<sup>61</sup> See [http://chbrp.org/documents/uninsured\\_010109.pdf](http://chbrp.org/documents/uninsured_010109.pdf) for more information on CHBRP’s methods for calculating the number of uninsured as a result of premium changes.

**Table 5.** Baseline (Premandate) Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2011

	DMHC-Regulated							CDI-Regulated			Total
	Privately Funded Plans (by market)			CalPERS HMOs (b)	Medi-Cal Managed Care Plans		MRMIB Plans (d)	Privately Funded Policies (by market)			
	Large Group	Small Group	Individual		65 and Over (c)	Under 65		Large Group	Small Group	Individual	
Total enrollees in plans/policies subject to state Mandates (a)	10,526,000	2,241,000	733,000	831,000	285,000	3,539,000	889,000	397,000	1,118,000	1,343,000	21,902,000
Total enrollees in plans/policies subject to AB 185	0	0	0	0	0	0	0	397,000	1,118,000	1,343,000	2,858,000
Average portion of premium paid by Employer	\$317.59	\$267.09	\$0.00	\$347.55	\$346.00	\$176.00	\$98.48	\$375.44	\$270.30	\$0.00	\$65,887,370,000
Average portion of premium paid by Employee	\$82.91	\$83.47	\$399.69	\$86.89	\$0.00	\$0.00	\$13.79	\$122.08	\$64.15	\$199.13	\$21,898,323,000
<b>Total Premium</b>	\$400.51	\$350.57	\$399.69	\$434.44	\$346.00	\$176.00	\$112.27	\$497.52	\$334.45	\$199.13	\$87,785,693,000
Enrollee expenses for covered benefits (Deductibles, copays, etc.)	\$21.82	\$32.63	\$84.77	\$22.41	\$0.00	\$0.00	\$4.68	\$63.15	\$123.11	\$58.53	\$7,548,415,000
Enrollee expenses for benefits not covered (e)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$7.54	\$121,468,000
<b>Total Expenditures</b>	\$422.32	\$383.20	\$484.46	\$456.84	\$346.00	\$176.00	\$116.95	\$560.67	\$457.56	\$265.20	\$95,455,576,000

Source: California Health Benefits Review Program, 2011.

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

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

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

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

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

**Table 6.** Impacts of the Mandate on Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2011

	DMHC-Regulated							CDI-Regulated			Total
	Privately Funded Plans (by market)			CalPERS HMOs (b)	Medi-Cal Managed Care Plans		MRMIB Plans (d)	Privately Funded Policies (by market)			
	Large Group	Small Group	Individual		65 and Over (c)	Under 65		Large Group	Small Group	Individual	
Total enrollees in plans/policies subject to state Mandates (a)	10,526,000	2,241,000	733,000	831,000	285,000	3,539,000	889,000	397,000	1,118,000	1,343,000	21,902,000
Total enrollees in plans/policies subject to AB 185	0	0	0	0	0	0	0	397,000	1,118,000	1,343,000	2,858,000
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	\$6.92	\$111,525,000
<b>Total Premium</b>	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$6.92	\$111,525,000
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	\$1.99	\$32,138,000
Enrollee expenses for benefits not covered (e)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	-\$7.54	-\$121,468,000
<b>Total Expenditures</b>	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$1.38	\$22,195,000
<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%	3.48%	0.13%
Total Expenditures	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.52%	0.02%

Source: California Health Benefits Review Program, 2011.

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

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

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

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

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



## PUBLIC HEALTH IMPACTS

AB 185 mandates coverage for maternity services. Maternity services 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 2009, there were more than 526,000 births in California, of which 3.1% were to women either not receiving prenatal care or receiving prenatal care starting in the third trimester (CDPH, 2009c). Four 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 185 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 Impacts* 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 185, and (3) AB 185 would not affect coverage for infants.

CHBRP's analysis finds that AB 185 has the potential to positively affect public health outcomes to the extent that 8,574 newly covered pregnant women utilize prenatal services that could potentially be covered under AB 185.

### Public Health Impacts

As presented in the *Medical Effectiveness* section, among the prenatal care services that are effective in improving health outcomes are counseling on behavioral risks such as smoking and domestic violence; screening for genetic disorders and structural abnormalities; 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 *Benefit Coverage, Utilization, and Cost Impacts* section estimates that 8,574 pregnancies would be newly covered as a result of AB 185. Although the previously mentioned specific prenatal care services are effective, the precise extent to which AB 185 would increase the utilization of these services is unknown; however, data indicate that 95% of pregnancies in California receive prenatal care in the first or second trimester (CDPH, 2009c). Therefore, this section will present an upper bound estimate that 100% coverage would translate to 100% utilization of effective prenatal care services. The resulting potential public health impacts of AB 185 are discussed below.

To estimate the upper bound of the public health impact of AB 185, it is assumed that pregnant women previously enrolled in CDI-regulated policies without maternity benefits would, postmandate, have new maternity coverage that they would utilize, even with potentially high out-of-pocket costs. With this assumption, we would expect to see an increase in utilization of effective prenatal services by all 8,574 newly covered pregnant women.

As presented in Table 7, an upper bound estimate would assume that all 8,574 newly covered pregnancies would have financial barriers to prenatal care reduced and thus an increase in the utilization of effective prenatal care services and an improvement in corresponding health outcomes would be expected. However, it should be emphasized that this is an estimate of the upper bound potential impacts of this bill and the data suggest that at least 95% of women would, in fact, use prenatal services (CDPH, 2009c).

As an example of how AB 185 could affect health outcomes, Table 7 presents the upper bound estimates of specific potential public health impacts of the receipt of effective prenatal care services. The impact is estimated assuming that premandate, none of these 8,574 women would receive prenatal care and that postmandate 100% of these women would receive effective prenatal care services. In an average population of pregnant women, we would expect that 8.7% 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, 10.1% have preterm deliveries, and 0.6% of infants are born with respiratory distress syndrome (RDS). Assuming that as a result of AB 185, all newly covered pregnant women received the necessary and appropriate prenatal care services, it is estimated that AB 185 could result in 45 pregnant women quitting smoking; between 58 and 292 fewer low birth weight births attributable to asymptomatic bacteriuria; and the prevention of 240 hepatitis B transmissions, 15 HIV transmissions, 223 cases of preeclampsia, 303 preterm births, and 18 cases of respiratory distress syndrome (Table 7).

**Table 7.** Potential Upper Bound Estimates of Public Health Impacts of AB 185 on 8,574 Newly Covered Pregnancies

Prenatal care service	Prevalence of Condition	Medical Effectiveness of Intervention	Public Health Impact (a)
Smoking cessation counseling (b)	8.7% smoke during pregnancy	RR = 0.94	45 pregnant women quit smoking
Screening and treatment for asymptomatic bacteriuria (c)	2%-10% of pregnancies	RR = 0.66	Prevent 58 - 292 low birth weight babies
Screening and treatment for hepatitis B (d)	5.6%	RR = 0.50	Prevent 240 hepatitis B transmissions
Screening and treatment for HIV (e)	0.2%	RR = 0.13	Prevent 15 HIV transmissions
Prophylaxis for hypertensive disorders (f)	5%	RR = 0.48	Prevent 223 cases of preeclampsia
Progestational agents to prevent preterm delivery (g)	10.1%	RR = 0.65	Prevent 303 preterm births
Corticosteroids to reduce risk of respiratory distress syndrome (h)	0.6%	RR = 0.66	Prevent 18 cases of respiratory distress syndrome

Source: California Health Benefits Review Program, 2011.

Notes: (a) Calculations used the estimated 8,574 pregnancies newly covered under AB 185 as presented in the *Benefit Coverage, Utilization, and Cost Impacts* section. This table represents a sample of prenatal care services with reported Risk Reductions. (b) Data taken from Lumley et al., 2009, and CDPH, 2006b.

(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 Dodd et al., 2006; and CDPH, 2009d. Assumption does not consider prior experience with preterm birth.

(h) Data taken from Roberts and Dalziel, 2006. National prevalence: Martin et al., 2005.

Key: RR = risk ratio (percent reduction of risk as a result of the intervention); OR = Odds ratio (the chance of a particular event occurring in a specific population); HIV = human immunodeficiency virus

## Impact on Gender and Racial Disparities

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

CHBRP investigated the effect that AB 185 would have on health disparities by gender, race and ethnicity. Evaluating the impact on racial and ethnic disparities is particularly important because racial and ethnic minorities report having poorer health status and worse health indicators (KFF, 2007). One important contributor to racial and ethnic health disparities is differential rates of insurance, where minorities are more likely than whites to be uninsured; however disparities still

exist within the insured population (Kirby et al, 2006; Lille-Blanton and Hoffman, 2005). Since AB 185 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 attributable to differences between insured and uninsured populations.

#### Impact on Gender Disparities

Females enrolled in plans in the individual health insurance market without coverage for maternity benefits currently are potentially responsible for \$121.5 million out of pocket costs for noncovered maternity services, if they all sought prenatal health care services. It is estimated that as a result of AB 185, a portion of these costs (\$32.1 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 \$111.5 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 526,000 live births each year in California, more than half (51.2%) are to Hispanic women (CDPH, 2009b). Among non-Hispanic women of a single race/ethnicity, the largest number of births are to non-Hispanic white women (26.8%), followed by Asian women (11.9%), black women (5.4%), Pacific Islander (0.5%), and American Indian women (0.4%). (CDPH, 2009b). The birth rates across these groups differ dramatically; with the rate of births to Hispanic women of childbearing age 60% greater than that of whites, the next largest racial/ethnic group of births (CDPH, 2009a) (Table 8).

**Table 8.** Births in California by Race/Ethnicity of Mother, 2009

<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	526,774	100%	65.5
Hispanic	269,953	51.2%	82.7
Non-Hispanic			
White	141,193	26.8%	50.6
Asian	62,854	11.9%	61.4
Black	28,611	5.4%	55.0
Pacific Islander	2,397	0.5%	67.0
American Indian	1,987	0.4%	37.9

*Sources and Notes:*

(a) Data taken from CDPH, 2009b, Table 2-7, based on 2009 California birth certificate information.

(b) Data from CDPH, 2009b, Table 2-7. The sum does not equal 100% because women of other or unknown race/ethnicity are not included.

(c) Data taken from CDPH, 2009a, Table 2-2. The general fertility rate is the number of live births per 1,000 women of childbearing age (15-44).

Overall, 3.1% of births in California are to women receiving late or no prenatal care (CDPH, 2009c). This varies by race/ethnicity with Pacific Islanders and American Indians having the highest rates of receiving late or no prenatal care (8.0% and 6.3%, respectively), and Asians and non-Hispanic whites having the lowest rates (1.9% and 2.1%, respectively) (Table 9). The rate of low birth weight babies varies by race/ethnicity, with babies born to black women classified as low birth weight twice as often as babies born to other racial/ethnic groups (CDPH, 2009d). In addition, black women have the highest rates of preterm births (14.1% of births). Infant mortality rates are also more than twice as high for babies born to black women compared to other racial/ethnic groups (12.1 per 1,000 live births for black women compared to 5.1 per 1,000 live births overall) (CDPH, 2008d).

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

Race/Ethnicity of Mother	Late or No Prenatal Care (a)	Low Birth Weight Births (b)	Preterm Births (c)	Infant Mortality Rates (d)
Total	3.1%	6.8%	10.1%	5.1
Hispanic	3.7%	6.2%	10.2%	5.2
Non-Hispanic				
White	2.1%	6.2%	9.1%	4.2
Asian	1.9%	8.1%	9.6%	3.1
Black	4.5%	12.1%	14.1%	12.1
American Indian	6.3%	6.5%	11.2%	5.4
Pacific Islander	8.0%	6.3%	11.6%	6.0

*Sources and Notes:*

(a) Data taken from CDPH, 2009d, Table 2-6. Late prenatal care is defined as prenatal care starting in the third trimester.

(b) Data taken from CDPH, 2009d, Table 2-6. Low birth weight is defined as less than 2,500 grams (5.5 pounds).

(c) Data taken from CDPH, 2009d, Table 2-6. Preterm births are births prior to 37 weeks of gestation.

(d) Data taken from CDPH, 2008d, Table 4-7. 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.

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, the racial/ethnic distribution of pregnant women with the type of coverage affected by the mandate is unknown, so the specific impact of AB 185 cannot be established.

### **Impacts on Premature Death and Economic Loss**

Premature death is often defined as death before the age of 75 (Cox, 2006). The overall impact of premature death due to a particular disease can be measured in years of potential life lost prior to age 75 and summed for the population (generally referred to as “YPLL”) (Cox, 2006; Gardner and Sanborn, 1990). In California, it is estimated that there are nearly 102,000 premature deaths each year accounting for more than two million YPLL (Cox, 2006). In order to measure the impact of premature mortality across the population impacted by a proposed mandate, CHBRP first collects baseline mortality rates. Next, the medical effectiveness literature is examined to determine if the proposed mandated benefit impacts mortality. In cases where a reduction in mortality is projected, a literature review is conducted to determine if the YPLL has been established for the given condition. Some diseases and conditions do not result in death and therefore a mortality outcome is not relevant.

Economic loss associated with disease is generally presented in the literature as an estimation of the value of the YPLL in dollar amount (i.e., valuation of a population’s lost years of work over a lifetime). For CHBRP analyses, a literature review is conducted to determine if lost productivity has been established in the literature. In addition, morbidity associated with the

disease or condition of interest can also result in lost productivity; either by causing the worker to miss days of work due to their illness or due to their role as a caregiver for someone else who is ill.

### Premature Death

Overall in California, the rate of maternal pregnancy-related mortality is 16.9 deaths per 100,000 live births (CDPH, 2010). Infant mortality rates are much higher, with approximately 509 deaths per 100,000 live births, and more than twice this rate for babies of black mothers (CDPH, 2008b, 2008d). 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, 10.1% of babies are born prematurely, translating to 866 births with an economic burden of nearly \$44.7 million in the 8,574 pregnancies that would be newly covered as a result of AB 185. To the extent that AB 185 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 *Benefit Coverage, Utilization, and Cost Impacts* section, AB 185 is expected to increase premiums on average in the CDI-regulated individual market by greater than 1%, thus increasing the number of uninsured by approximately 9,778 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).

Premature birth and low birth weight are associated with a multitude of long-term health outcomes such as cerebral palsy, vision loss or blindness, hearing loss, and epilepsy (Hack et al, 2002; Moster et al., 2008). Cognitive impairment, a common and sometimes severe disability

affecting preterm and very low birth weight infants may impact educational attainment. Both preterm and very low birth weight school-aged children have been found to have significantly lower IQ scores and lower scores on test of academic achievement compared to their full term, normal birth peers (Arpino 2010; Hack et al., 2002). Compared to adolescents of normal birth weight, adolescents of low birth weight are more likely to repeat a grade in school (40% vs. 27%). Adolescents who were preterm or very low birth weight are less likely to graduate high school or receive their GED (74% vs. 83% and 67.7% vs. 75.4%, respectively) (Hack et al., 2002; Moster et al., 2008). Educational attainment is an important factor affecting economic loss. In California, it is estimated that the state gains \$169,000 in tax revenue from each new high school graduate, which translates into a gain of \$392,000 over the lifetime of each new graduate (Belfield CR & Levin HM, 2007).

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 185 would be diminished by the P.L.111-148 requirements following 2014.



## APPENDICES

### Appendix A: Text of Bill Analyzed

On January 26, 2011, the Assembly Committee on Health requested that CHBRP analyze AB 185.

BILL NUMBER: AB 185    INTRODUCED  
BILL TEXT

INTRODUCED BY    Assembly Member Hernández

JANUARY 25, 2011

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

### LEGISLATIVE COUNSEL'S DIGEST

AB 185, as introduced, Hernández. 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, 2012, to provide coverage for maternity services, as defined, except as specified. With respect to policy forms on file with the department as of January 1, 2012, the bill would require health insurers to submit to the department, on or before March 1, 2012, 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.

The bill would also specify findings and declarations of the Legislature regarding health care coverage for maternity services.

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 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, 2012, a health insurer shall submit to the department, on or before March 1, 2012, 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, 2012, 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 185, 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 185 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 185 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 185 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 185 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 February 2010 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 February 2010 for a reports issued in 2010 (AB 1825), 2009 (AB 98), 2008 (AB 1962), and 2004 (SB 1555 and SB 987), 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 270 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. Seven studies met the inclusion criteria and were included in the medical effectiveness review.

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 185 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 of Illness  
Costs per Quality of Life Year Gained  
Cost Savings  
Cost Sharing  
Counseling  
Deductibles and Coinsurance  
Delivery, Obstetric  
Diabetes, Gestational/prevention & control  
Diagnosis Imaging  
Dietary Supplements  
Disease Transmission, Infectious/prevention & control  
Disparity / Disparities  
Domestic Violence/prevention & control  
Eclampsia  
Economic Burden  
Economic Loss  
Ethnic Groups / Ethnicity  
Evidence-Based Medicine  
Fetal Diseases/genetics/ultrasonography  
Fetal Mortality  
Folic Acid  
Genetic Counseling  
Genetic Screening/economics  
Genetic Testing  
Glucocorticoids/therapeutic use

Health Benefit Plans, Employee  
Health Care Costs  
Health Services Accessibility  
Health Status Disparities  
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  
Live Birth  
Long Term Outcomes  
Magnesium Sulfate/therapeutic use  
Managed Care Programs/economics/utilization  
Mass Screening  
Maternal Mortality  
Medical Savings Accounts/economics/utilization  
Medically uninsured/underinsured  
Morbidity  
Mortality  
Neonatal Screening/economics/ methods  
Neural Tube Defects/diagnosis  
Nuchal Translucency Measurement  
Obstetric Labor, Premature  
Outcomes  
Parity  
Perinatal Care  
Perinatal Mortality  
Placenta Previa/diagnosis  
Postnatal Care/economics/utilization  
Poverty  
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/economics  
Prenatal Care/economics/utilization  
Prenatal Diagnosis  
Prevalence  
Productivity  
Progesterone/therapeutic use  
Program Evaluation  
Prospective Studies  
Race/Racial  
Respiratory Distress Syndrome  
Rh-Hr Blood-Group System/blood  
Sexually Transmitted Diseases/prevention & control  
Sick Leave  
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  
Reviews  
Systematic Reviews

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

access for infants and mothers, accuracy, +adverse selection into maternity benefits, , antepartum hemorrhage, aspirin, bacterial vaginosis ,bacteriuria, baseline utilization, birth outcome\*, calcium supplement\*, Chorionic Villi Sampling, coinsurance, consumer direct health plan\*, consumer health plan\*, copayment, cost\*, cost benefit, cost effective\*, cost offset, cost saving\*, cost sharing, cost shift\*, cost utility, costs per quality of life year gained, counseling, deductibles, demand, diagnosis imaging, dietary calcium supplement\*, disparit\*, domestic violence, eclampsia, economic burden, economic loss, effective\*, ethnicity, folic acid, gender rating, genetic (counseling OR screening OR testing), health care accessibility, hepatitis B, hepatitis C, high deductible health plan\*, HIV, hospital stay, human immunodeficiency virus, incremental cost effectiveness ratio 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, medically underinsured, medically uninsured, neural tube defects, nuchal translucency, perinatal (care or service\*), placenta previa, postnatal service\*, postpartum service\*, postterm pregnanc\*, practice guideline\*, preeclampsia, pregnancy, pregnancy complication\*, pregnancy outcome\*, prenatal (care or service\*), prenatal screening, preterm birth, preventive care, progesterone, prospective studies, public financing, racial/ethnic disparit\*, Rh(d) incompatibility, self selection, sexually transmitted disease\*, screening, self selection, smoking cessation, streptococcus agalactiae, tay sachs disease, transmission of infectious disease, treatment outcome\*, trends in use of gender as a factor in setting premiums, utilization, ultrasound, unit cost



## 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 1825, AB 98 and AB 1962, identical bills introduced in 2010, 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 185.

**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

<b>Citation</b>	<b>Type of Trial<sup>62</sup></b>	<b>Intervention vs. Comparison Group</b>	<b>Population Studied</b>	<b>Location</b>
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
Dowswell et al., 2010	Systematic review	Reduced number of prenatal visit vs. standard number of prenatal visits	Pregnant women at low risk of developing complications during pregnancy or labor	N/A

<sup>62</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>63</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>64</sup>	Evidence-based guideline	Multiple intervention and comparison groups	Pregnant women	N/A
USPSTF, 1996 <sup>65</sup>	Evidence-based guideline	Multiple intervention and comparison groups	All persons—reviewed sections that address pregnant women	N/A
USPSTF, 2008 <sup>66</sup>	Evidence-based guideline	Multiple intervention and comparison groups	All persons—reviewed sections that address preventive services for pregnant women	N/A

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<sup>63</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>64</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>65</sup> USPSTF = United States Preventive Services Task Force.

<sup>66</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>67</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>68</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>67</sup> NZMOH = New Zealand Ministry of Health.

<sup>68</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)**

Type of Risk Factor/Problem and Service	Citation	Type of Trial	Intervention vs. Comparison Group	Population Studied	Location
Antiretroviral therapy and other interventions to prevent transmission of HIV <sup>69</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
<b>Metabolic, Nutritional, and Endocrine Conditions</b>					
Gestational diabetes					
	Alwan et al., 2009	Meta-analysis	Dietary advice or drug treatment including insulin and oral drugs in addition to routine care vs. routine care	Pregnant women with gestational diabetes or impaired glucose tolerance	N/A
	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
Hypothyroidism therapy for clinical and subclinical hypothyroidism	Reid et al., 2010	Systematic review	Levothyroxine vs. no treatment	Pregnant women with clinical or subclinical hypothyroidism	N/A

<sup>69</sup> HIV = Human Immunodeficiency Virus

**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>Hypertensive Disorders</b>					
Calcium supplementation to prevent hypertensive disorders	Hofmeyr et al., 2010	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
Anticonvulsants for treatment of preeclampsia	Duley et al., 2010	Meta-analysis	Anticonvulsant 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>					
Progesterational agents to prevent preterm birth	Dodd et al., 2006	Meta-analysis	Progesterational agents vs. placebo	Pregnant women at risk for preterm delivery	N/A
	Dodd et al., 2008	Meta-analysis	Progesterational agents vs. placebo	Pregnant women at risk for preterm delivery	N/A
	Mackenzie et al., 2006	Meta-analysis	Progesterational 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	Progesterational agents vs. placebo	Pregnant women at risk for preterm delivery	N/A
	Rode et al., 2009	Meta-analysis	Progesterational agents vs. placebo	Nonsymptomatic women and women with preterm labor	N/A
	Su et al., 2010	Systematic review	Progesterational agents vs. placebo	Pregnant women diagnosed with established or threatened preterm labor	N/A
Lower genital tract infection detection and treatment to prevent preterm birth	Sangkomkamhang et al., 2008	Meta-analysis	Receive lower genital tract infection screening results and treatment vs. do not receive screening results	Pregnant women presenting for routine prenatal visits between 15 and 19 weeks' gestation	Austria
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	Anticonvulsant 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
Antithrombotic therapy for prevention of placental dysfunction	Dodd et al., 2010	Systematic review	Antithrombotic drugs vs. placebo	Women at risk of adverse outcomes from placental dysfunction	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

Outcome	Research Design <sup>70</sup>	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Low birth weight	1 meta-analysis and 2 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 2 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 2 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 2 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 2 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
Preeclampsia	1 meta-analysis and 2 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 preeclampsia

<sup>70</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-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>71</sup> = 1.8 (95% CI<sup>72</sup> = 1.4, 2.3)<sup>73</sup></li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</li> </ul>
	Reduction in risk of smoking in late pregnancy	1 meta-analysis	<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>74</sup> = 0.94 (95% CI = 0.93, 0.96)<sup>75</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 = 0.83 (95% CI = 0.73, 0.95)</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>71</sup> OR = Odds ratio

<sup>72</sup> CI = Confidence interval

<sup>73</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>74</sup> RR = Risk ratio

<sup>75</sup> Results for the impact of smoking cessation counseling on the risks of abstinence, low birth weight and preterm birth were reported in Lumley et al. (2009).

**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>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>76</sup></li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</li> </ul>
Screening for hemoglobinopathies <sup>77</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>78</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>79</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>76</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>77</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>78</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>79</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>80</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>81</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 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>82</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>80</sup> Results for outcomes of antibiotics for treatment of asymptomatic bacteriuria on risk of kidney infection and low birth weight were reported in Smail and Vazquez, 2007.

<sup>81</sup> Lu et al. (2003) reported results from a previous meta-analysis.

<sup>82</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)

Risk Factor/ Intervention	Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability
	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>83</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>
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>84</sup></li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable—most studies conducted in developing countries</li> </ul>

<sup>83</sup> USPSTF (1996) reported results from previous studies.

<sup>84</sup> Lee 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>
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>85</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>86</sup></li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</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	Statistically significant	Favors antiretroviral therapy	<ul style="list-style-type: none"> <li>OR = 0.13 (95% CI = 0.06, 0.27)<sup>87</sup></li> </ul>	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>88</sup></li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable—some studies conducted in developing countries</li> </ul>

<sup>85</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>86</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).

<sup>87</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>88</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.

**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>
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>89</sup></li> </ul>	<ul style="list-style-type: none"> <li>Generalizable—conducted in Texas</li> </ul>
<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	<ul style="list-style-type: none"> <li>Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>Favors treatment</li> </ul>	<ul style="list-style-type: none"> <li>RR = 0.32 (95% CI = 0.14, 0.73)<sup>90</sup></li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</li> </ul>
	Reduction in risk of preeclampsia	1 systematic review of Level I-III studies	<ul style="list-style-type: none"> <li>Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>Favors treatment</li> </ul>	<ul style="list-style-type: none"> <li>RR = 0.65 (95% CI = 0.48, 0.88)</li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</li> </ul>
Iron supplements for iron deficiency anemia	Reduction in risk of low birth weight	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 iron supplements</li> </ul>	<ul style="list-style-type: none"> <li>Intervention = 4% of infants had birth weight &lt;2,500 grams, Control = 17% of infants had birth weight less &lt; 2,500 grams<sup>91</sup></li> </ul>	<ul style="list-style-type: none"> <li>Generalizable—conducted in Ohio</li> </ul>

<sup>89</sup> NCCWCH (2008) reported results from a previous study.

<sup>90</sup> Crowther et al., 2005, as referenced in Alwan, 2009.

<sup>91</sup> Helfand et al. (2006) reported results from a previous study.

**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>Levothyroxine for hypothyroidism</b>	Reduction in risk for preeclampsia	1 systematic review of Level I study	<ul style="list-style-type: none"> <li>• Not statistically significant</li> </ul>			<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>
	Reduction in risk for preeclampsia	1 systematic review of Level I study	<ul style="list-style-type: none"> <li>• Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>• Favors treatment</li> </ul>	RR = 0.28 (95% CI = 0.10, 0.80)	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>
<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	<ul style="list-style-type: none"> <li>• No formal tests of statistical significance</li> </ul>	<ul style="list-style-type: none"> <li>• Favors monitoring blood pressure</li> </ul>	<ul style="list-style-type: none"> <li>• No direct evidence</li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat generalizable</li> </ul>
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 = 0.45 (95% CI = 0.31, 0.65)<sup>92</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>93</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>

<sup>92</sup> Both results for outcomes of prescribing calcium supplements during pregnancy were reported in Hofmeyr et al. (2006).

<sup>93</sup> All results for outcomes of prescribing antiplatelet agents were reported in Duley et al. (2007).



**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
	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>94</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>
<b>Other Medical Conditions</b>						
Immune globulin for Rh(D) incompatibility	Reduction in risk of hemolytic disease <sup>95</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>96</sup>	Accurate diagnosis	1 systematic review of Level II-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>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>

<sup>94</sup> All results for outcomes of administering magnesium sulfate during delivery were reported in Duley et al. (2010).

<sup>95</sup> Symptoms of hemolytic disease include anemia, jaundice, body swelling, and difficulty breathing.

<sup>96</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.

**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
Progestational agents to prevent preterm delivery	Reduction in risk of preterm delivery	5 meta-analysis and 2 systematic reviews of Level I-II studies	Statistically significant	Favors progestational agents	• RR = 0.65 (95% CI = 0.54, 0.79) <sup>97</sup>	• Somewhat generalizable
	Reduction in risk of low birth weight	4 meta-analysis and 2 systematic reviews of Level I-II studies	• Statistically significant	• Favors progestational agents	• RR = 0.63 (95% CI = 0.49, 0.81)	• Somewhat generalizable
	Reduction in risk of intra-ventricular hemorrhage	4 meta-analysis and 2 systematic reviews of Level I-II studies	• Statistically significant	• Favors progestational agents	• RR = 0.25 (95% CI = 0.08, 0.82)	• Somewhat generalizable
	Reduction in risk of infant mortality	1 meta-analysis of Level 1 study	• Statistically significant	• Favors progestational agents	• RR = 0.54 (95% CI = 0.31-0.93)	• Somewhat generalizable
Corticosteroids to accelerate fetal lung maturation	Reduction in risk of neonatal mortality	1 meta-analysis and 1 systematic review of Level I-II studies	• Statistically significant	• Favors corticosteroids	• RR = 0.69 (95% CI = 0.58, 0.81) <sup>98</sup>	• Somewhat generalizable
	Reduction in risk of respiratory distress syndrome	1 meta-analysis and 1 systematic review of Level I-II studies	• Statistically significant	• Favors corticosteroids	• RR = 0.66 (95% CI = 0.59, 0.73)	• Somewhat generalizable
	Reduction in risk of cerebro-ventricular hemorrhage	1 meta-analysis and 1 systematic review of Level I-II studies	• Statistically significant	• Favors corticosteroids	• RR = 0.54 (95% CI = 0.43, 0.69)	• Somewhat generalizable

<sup>97</sup> All results for outcomes of prescribing progestational agents were reported in Dodd et al. (2006).

<sup>98</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>
	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>
Antithrombotic therapy for prevention of placental dysfunction	Reduction in risk of preeclampsia	1 meta-analysis of Level II studies	<ul style="list-style-type: none"> <li>Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>Favors anti-thrombotic therapy</li> </ul>	<ul style="list-style-type: none"> <li>RR = 0.23 (95% CI = 0.08, 0.68)</li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</li> </ul>
	Reduction in risk of eclampsia	1 meta-analysis of Level II studies	<ul style="list-style-type: none"> <li>Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>Favors anti-thrombotic therapy</li> </ul>	<ul style="list-style-type: none"> <li>RR = 0.13 (95% CI = 0.02, 0.97)</li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</li> </ul>
	Reduction in risk of low infant birth weight	1 meta-analysis of Level II studies	<ul style="list-style-type: none"> <li>Statistically significant</li> </ul>	<ul style="list-style-type: none"> <li>Favors anti-thrombotic therapy</li> </ul>	<ul style="list-style-type: none"> <li>RR = 0.35 (95% CI = 0.20, 0.64)</li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</li> </ul>
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>99</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>

<sup>99</sup> Both results for the outcomes of prescribing magnesium sulfate to prevent neurological impairment were reported in Doyle et al. (2009).

**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
External cephalic version <sup>100</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>101</sup></li> <li>RR = 0.42 (95% CI = 0.35, 0.50)<sup>102</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>
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>103</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>104</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>105</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>106</sup></li> </ul>	<ul style="list-style-type: none"> <li>Somewhat generalizable</li> </ul>

<sup>100</sup> Health professional applies pressure to the mother's abdomen to encourage the fetus to turn from feet first to head first.

<sup>101</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>102</sup> NCCWCH (2008) reported results of a previously published meta-analysis for both outcomes of external cephalic version performed at term for breech presentation.

<sup>103</sup> NCCWCH (2008) reported results of a previously published meta-analysis.

<sup>104</sup> NCCWCH (2008) reported results from a previous meta-analysis.

<sup>105</sup> Sanchez-Ramos et al., 2003

<sup>106</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/costimpact.html>.

The cost analysis in this report was prepared by the members of cost team, which consists of CHBRP task force members and contributors from the University of California, San Diego, and the University of California, Los Angeles, as well as the contracted actuarial firm, Milliman, Inc. (Milliman). Milliman provides data and analyses per the provisions of CHBRP's authorizing legislation.

### Data Sources

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

#### *Health insurance*

1. The latest (2009) California Health Interview Survey (CHIS), which is used to estimate health insurance for California's population and distribution by payor (i.e., employment-based, individually purchased, or publicly financed). The biennial CHIS is the largest state health survey conducted in the United States, collecting information from approximately 50,000 households. More information on CHIS is available at <http://www.chis.ucla.edu>.
2. The latest (2010) California Employer Health Benefits Survey is used to estimate:
  - size of firm,
  - percentage of firms that are purchased/underwritten (versus self-insured),
  - premiums for health care service plans regulated by the Department of Managed Health Care (DMHC) (primarily health maintenance organizations [HMOs] and Point of Service Plans [POS]),
  - premiums for health insurance policies regulated by the California Department of Insurance (CDI) (primarily preferred provider organizations [PPOs] and fee-for-service plans [FFS]), and
  - premiums for high deductible health plans (HDHPs) for the California population with employment-based health insurance.
  - This annual survey is currently released by the California Health Care Foundation/National Opinion Research Center (CHCF/NORC) and is similar to the national employer survey released annually by the Kaiser Family Foundation and the Health Research and Educational Trust. Information on the CHCF/NORC data is available at: <http://www.chcf.org/publications/2010/12/california-employer-health-benefits-survey>.

3. Milliman data sources are relied on to estimate the premium impact of mandates. Milliman’s projections derive from the Milliman Health Cost Guidelines (HCGs). The HCGs are a health care pricing tool used by many of the major health plans in the United States. See <http://www.milliman.com/expertise/healthcare/products-tools/milliman-care-guidelines/index.php>. Most of the data sources underlying the HCGs are claims databases from commercial health insurance plans. The data are supplied by health insurance companies, Blues plans, HMOs, self-funded employers, and private data vendors. The data are mostly from loosely managed healthcare plans, generally those characterized as preferred provider plans or PPOs. The HCGs currently include claims drawn from plans covering 4.6 million members. In addition to the Milliman HCGs, CHBRP’s utilization and cost estimates draw on other data, including the following:
  - The MarketScan Database, which includes demographic information and claim detail data for approximately 13 million members of self-insured and insured group health plans.
  - An annual survey of HMO and PPO pricing and claim experience. The most recent survey (2010 Group Health Insurance Survey) contains data from seven major California health plans regarding their 2010 experience.
  - Ingenix MDR Charge Payment System, which includes information about professional fees paid for healthcare services, based upon approximately 800 million claims from commercial insurance companies, HMOs, and self-insured health plans.
  - These data are reviewed for applicability by an extended group of experts within Milliman but are not audited externally.
4. An annual survey by CHBRP of the seven largest providers of health insurance in California (Aetna, Anthem Blue Cross of California, Blue Shield of California, CIGNA, Health Net, Kaiser Foundation Health Plan, and PacifiCare) to obtain estimates of baseline enrollment by purchaser (i.e., large and small group and individual), type of plan (i.e., DMHC- or CDI-regulated), cost-sharing arrangements with enrollees, and average premiums. Enrollment in plans or policies offered by these seven firms represents an estimated 93.7% of the persons with health insurance subject to state mandates. This figure represents an estimated 94.4% of enrollees in full service (non-specialty) DMHC-regulated health plans and an estimated 90.1% of enrollees in full service (non-specialty) CDI-regulated policies.<sup>107</sup>

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<sup>107</sup> CHBRP analysis of the share of enrollees included in CHBRP’s Bill-Specific Coverage Survey of the major carriers in the state is based on "CDI Licenses with HMSR Covered Lives Greater than 100,000" as part of the Accident and Health Covered Lives Data Call, December 31, 2009 by the California Department of Insurance, Statistical Analysis Division, data retrieved from The Department of Managed Health Care’s interactive Web site “Health Plan Financial Summary Report,” July-September 2010," and CHBRP’s Annual Enrollment and Premium Survey.

*Publicly funded insurance subject to state benefit mandates*

5. Premiums and enrollment in DMHC-regulated health plans and CDI-regulated policies by self-insured status and firm size are obtained annually from CalPERS for active state and local government public employees and their dependents who receive their benefits through CalPERS. Enrollment information is provided for DMHC-regulated health care service plans covering non-Medicare beneficiaries—about 74% of CalPERS total enrollment. CalPERS self-funded plans—approximately 26% of enrollment—are not subject to state mandates. In addition, CHBRP obtains information on current scope of benefits from evidence of coverage (EOCs) documents publicly available at <http://www.calpers.ca.gov>.
6. Enrollment in Medi-Cal Managed Care (beneficiaries enrolled in Two-Plan Model, Geographic Managed Care, and County Operated Health System plans) is estimated based on CHIS and data maintained by the Department of Health Care Services (DHCS). DHCS supplies CHBRP with the statewide average premiums negotiated for the Two-Plan Model, as well as generic contracts that summarize the current scope of benefits. CHBRP assesses enrollment information online at [http://www.dhcs.ca.gov/dataandstats/statistics/Pages/RASS\\_General\\_Medi\\_Cal\\_Enrollment.aspx](http://www.dhcs.ca.gov/dataandstats/statistics/Pages/RASS_General_Medi_Cal_Enrollment.aspx).
7. Enrollment data for other public programs—Healthy Families Program (HFP), Access for Infants and Mothers (AIM), and the Major Risk Medical Insurance Program (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 <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://chbrp.org/documents/longterm\\_impacts08.pdf](http://chbrp.org/documents/longterm_impacts08.pdf).
- Several recent studies have examined the effect of private insurance premium increases on the number of uninsured (Chernew, et al., 2005; Hadley 2006; Glied and Jack 2003). Chernew et al. (2005) estimate that a 10% increase in private premiums results in a 0.74 to 0.92 percentage point decrease in the number of insured, while Hadley (2006) and Glied and Jack (2003) estimate that a 10% increase in private premiums produces a 0.88 and 0.84 percentage point decrease in the number of insured, respectively. The price elasticity of demand for insurance can be calculated from these studies in the following way. First, take the average percentage point decrease in the number of insured reported in these studies in response to a 1% increase in premiums (about -0.088), divided by the average percentage of insured persons (about 80%), multiplied by 100%, i.e., ( $\{-0.088/80\} \times 100 = -0.11$ ). This elasticity converts the *percentage point* decrease in the number of insured into a *percentage* decrease in the number of insured persons for every 1% increase in premiums. Because each of these studies reported results for the large-group, small-group, and individual insurance markets combined, CHBRP employs the simplifying assumption that the elasticity is the same across different types of markets. For more information on CHBRP's criteria for estimating impacts on the uninsured please see: [http://chbrp.org/documents/uninsured\\_010109.pdf](http://chbrp.org/documents/uninsured_010109.pdf).

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

- Population shifts by type of health insurance: If a mandate increases health insurance costs, some employer groups and individuals may elect to drop their health insurance. Employers may also switch to self-funding to avoid having to comply with the mandate.
- Changes in benefit plans: To help offset the premium increase resulting from a mandate, subscribers/policyholders may elect to increase their overall plan deductibles or copayments. Such changes would have a direct impact on the distribution of costs



between the health plan and policies and enrollees, and may also result in utilization reductions (i.e., high levels of patient cost sharing result in lower utilization of health care services). CHBRP did not include the effects of such potential benefit changes in its analysis.

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

### Potential Effects of the Federal Affordable Care Act

As discussed in the *Introduction*, there are a number of the ACA provisions that have already gone into or will go into effect over the next 3 years. Some of these provisions affect the baseline or current enrollment, expenditures, and premiums. This subsection discusses adjustments made to the 2011 Cost and Coverage Model to account for the potential impacts of the ACA that will have gone into effect by January 2011. It is important to emphasize that CHBRP's analysis of specific mandate bills typically address the marginal effects of the mandate bill—specifically, how the proposed mandate would impact benefit coverage, utilization, costs, and public health, holding all other factors constant. CHBRP's estimates of these marginal effects are presented in the *Benefit Coverage, Utilization and Cost Impacts* section of this report.

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

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

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

#### *Coverage for Adult Children*

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

#### *Minimum Medical Loss Ratio requirement*

PPACA Section 2718 requires health plans offering health insurance in group and individual markets to report to the Secretary of Health and Human Services the amount of premium revenue spent on clinical services, activities to improve quality, and other non-claim costs. Beginning in 2011, large group plans that spend less than 85% of premium revenue and small group/individual market plans that spend less than 80% of premium revenue on clinical services and quality must provide rebates to enrollees. According to the Interim Final Rule (45 CFR Part 158), "Issuers will provide rebates to enrollees when their spending for the benefit of policyholders on reimbursement for clinical services and quality improvement activities, in relation to the

premiums charged, is less than the MLR standards established pursuant to the statute.”<sup>108</sup> The requirement to report medical loss ratio is effective for the 2010 plan year, while the requirement to provide rebates is effective January 1, 2011. The MLR requirement, along with the rebate payment requirement, will affect premiums for 2011, but the effects are unknown and data are not yet available. There is potential for substantial impact on markets with higher administrative costs, including the small and individual group markets. Responses to CHBRP’s Annual Enrollment and Premiums Survey indicate that carriers intend to be in compliance with these requirements. For those that may not be in compliance, the requirement to pay rebates is intended to align the MLR retrospectively. Therefore, for modeling purposes, CHBRP has adjusted administrative and profit loads to reflect MLRs that would be in compliance with this provision.

#### *Pre-Existing Condition Insurance Plan (PCIP)*

PPACA Section 1101 establishes a temporary high-risk pool for individuals with pre-existing medical conditions, effective 90 days following enactment until January 1, 2014. In 2010, California enacted AB 1887 and SB 227, providing for the establishment of the California Pre-Existing Condition Insurance Plan (PCIP) to be administered by the Managed Risk Medical Insurance Board (MRMIB) and federally funded per Section 1101. MRMIB has projected average enrollment of 23,100 until the end of 2013, when the program will expire. As of December 2010, there were approximately 1,100 subscribers.<sup>109</sup> The California PCIP is not subject to state benefit mandates,<sup>110</sup> and therefore this change does not directly affect CHBRP’s Cost and Coverage Model. CHBRP has revised its annual update of *Estimates of the Sources of Health Insurance in California*.<sup>111</sup> to reflect that a slight increase in the number of those who are insured under other public programs that are not subject to state level mandates.

#### *Prohibition of pre-existing condition exclusion for children*

PPACA Sections 1201& 10103(e): Prohibits pre-existing condition exclusions for children. This provision was effective upon enactment). California’s recently enacted law, AB 2244 (2010) implements this provision. AB 2244 also prohibits carriers that sell individual plans or policies from refusing to sell or renew policies to children with pre-existing conditions. Carriers that do not offer new plans for children are prohibited from offering for sale new individual plans in California for 5 years.<sup>112</sup> This provision could have had significant premium effects, especially for the DMHC- and CDI-regulated individual markets. The premium information is included in the responses to CHBRP’s Annual Enrollment and Premium Survey. Thus the underlying data used in CHBRP annual model updates captured the effects of this provision.

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<sup>108</sup> Department of Health and Human Services, *Interim Final Rule: Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act*. 45 CFR Part 158. December 1, 2010.

<sup>109</sup> Enrollment report presented at the Managed Risk Medical Insurance Board Meeting, January 19, 2010. Available at: [http://www.mrmib.ca.gov/MRMIB/Agenda\\_Minutes\\_011911/Agenda\\_Item\\_9.a\\_PCIP\\_Board\\_Report\\_for\\_Dec\\_2010\\_FINAL.pdf](http://www.mrmib.ca.gov/MRMIB/Agenda_Minutes_011911/Agenda_Item_9.a_PCIP_Board_Report_for_Dec_2010_FINAL.pdf)

<sup>110</sup> Correspondence with John Symkowick, Legislative Coordinator, MRMIB, October 19, 2010.

<sup>111</sup> See: [http://www.chbrp.org/documents/insur\\_source\\_est\\_2010.pdf](http://www.chbrp.org/documents/insur_source_est_2010.pdf)

<sup>112</sup> See enacted language at: [http://www.leginfo.ca.gov/pub/09-10/bill/asm/ab\\_2201-2250/ab\\_2244\\_bill\\_20100930\\_chaptered.pdf](http://www.leginfo.ca.gov/pub/09-10/bill/asm/ab_2201-2250/ab_2244_bill_20100930_chaptered.pdf)

### *Prohibition of lifetime limits and annual benefit limit changes*

PPACA Section 2711 prohibits individual and group health plans from placing lifetime limits on the dollar value of coverage, effective September 23, 2010. Plans may only impose annual limits on coverage and these annual limits may be no less than \$750,000 for “essential health benefits.” The minimum annual limit will increase to \$1.25 million on Sept. 23, 2011, and to \$2 million on Sept. 23, 2012. In 2010, CHBRP conducted an analysis of SB 890 which sought to prohibit lifetime and annual limits for “basic health care services” covered by CDI-regulated policies. CHBRP’s indicated that DMHC-regulated plans were generally prohibited from having annual or lifetime limits. The analysis also indicated that less than 1% of CDI-regulated policies in the state had annual benefit limits and of those, the average annual benefit limit was approximately \$70,000 for the group market and \$100,000 for the individual market. Almost all CDI-regulated policies had lifetime limits in place and the average lifetime limits was \$5 million. After the effective date of the PPACA Section 2711, removal of these limits may have had an effect on premiums. As mentioned, premium information is included in the responses to CHBRP’s Annual Enrollment and Premium Survey. Thus the underlying data used in CHBRP annual model updates captured the effects of this provision to remove lifetime limits and to increase annual limits for those limited number of policies that had annual limits that fell below \$750,000.

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

While the PPACA allows states the option to expand coverage to those not currently eligible for Medicaid (Medi-Cal in California), large scale expansions are not expected to be seen during 2011. However, as a result of the 2010-2011 California Budget Agreement, there are expected to be shifts in coverage for seniors and persons with disabilities. Specifically, “Seniors and persons with disabilities who reside in certain counties which have managed care plans, and who are not also eligible to enroll in Medicare, will be required to enroll in a managed care plan under a phased-in process.”<sup>113</sup> The Medi-Cal Managed Care enrollment in CHBRP’s 2011 Cost and Coverage Model has been adjusted to reflect this change. Baseline premium rates have also been adjusted to reflect an increase in the number of seniors and persons with disabilities in Medi-Cal Managed Care. Information from DHCS indicates these changes will go into effect July 1, 2011, and would affect approximately 427,000 Medi-Cal beneficiaries.<sup>114</sup> CHBRP used data from DHCS to adjust enrollment in Medi-Cal Managed Care, and to adjust premiums to account for the change in acuity in the underlying populations.<sup>115</sup>

### Bill Analysis-Specific Caveats and Assumptions

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

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<sup>113</sup> Taylor, M. Legislative Analyst, *The Budget Package 2010-11 California Spending Plan*. LAO: November, 2010. Available at:

[http://www.lao.ca.gov/reports/2010/bud/spend\\_plan/spend\\_plan\\_110510.pdf](http://www.lao.ca.gov/reports/2010/bud/spend_plan/spend_plan_110510.pdf)

<sup>114</sup> Data from the Department of Health Care Services, Medi-Cal Managed Care Division. Received January 14, 2011.

<sup>115</sup> See the study conducted for DHCS by Mercer on this topic: Mercer, *Medi-Cal Acuity Study: Seniors and Persons with Disabilities*. September 28, 2010. Available at

[http://www.dhcs.ca.gov/provgovpart/Documents/Waiver%20Renewal/SPD\\_Study\\_092810.pdf](http://www.dhcs.ca.gov/provgovpart/Documents/Waiver%20Renewal/SPD_Study_092810.pdf)

- CHBRP surveys the largest insurers. There may be smaller insurers who, if they offer policies in the individual market, are less likely to offer individual policies with maternity cover given concerns regarding adverse selection. Therefore, the estimates of those with maternity coverage in this analysis may be considered an upper bound.
- CHBRP estimates that in the absence of the mandate, there would be approximately 12,663 births in 2011 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 8.5% of women with privately funded insurance without maternity benefits would enroll in the AIM program.
- Thus, of the 12,663 women without maternity coverage at the time of pregnancy, about 2,773 may qualify for Medi-Cal and 909 may be covered by AIM. Based on the carrier survey, CHBRP estimates that about another 407 of these women would switch to plans with maternity benefits offered by their existing carrier prior to delivery.
- CHBRP estimates that the remaining 8,574 expected births among women who currently have no maternity benefits would not be covered by insurance premandate. This is the population that would directly be impacted by AB 185 and be newly covered for maternity services postmandate.
- CHBRP assumes that the women who already have maternity coverage premandate are unlikely to get maternity coverage from Medi-Cal or AIM<sup>116</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.

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<sup>116</sup> AIM enrollment data indicates that there are a proportion of AIM enrollees that currently have private insurance coverage and have maternity coverage.

- CHBRP assumes that postmandate, men and women within the same age group would be equally distributed across policies that did and did not offer maternity coverage premandate.
- Note that because the main CHBRP estimates (Table 4) assume that birth rates are the same for women who do and do not have maternity coverage premandate, the postmandate decrease in average premiums among women who already had maternity coverage (Table 6) is due to the fact that the individuals that did not have coverage before the mandate are now paying for coverage through an increase in premium and the risk and associated premium costs are shared between a larger number of individuals.
- Postmandate 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 postmandate (compared to the different view premandate) since AB 185 would require all policies to provide maternity services.

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

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

*No information was submitted by interested parties for this analysis.*

For information on the processes for submitting information to CHBRP for review and consideration please visit: <http://www.chbrp.org/requests.html>.

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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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