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CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Analysis of Assembly Bill 513,
Health Care Coverage:
Breast-Feeding

A Report to the 2009-2010 California Legislature
April 17, 2009



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. In 2002, CHBRP was established to implement the provisions of Assembly Bill 1996 (California Health and Safety Code, Section 127660, et seq.) and was reauthorized by Senate Bill 1704 in 2006 (Chapter 684, Statutes of 2006). The statute defines a health insurance benefit mandate as a requirement that a health insurer or managed care health plan (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 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 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, reviews draft studies to ensure their quality before they are transmitted to the Legislature. Each report summarizes scientific evidence relevant to the proposed mandate, or proposed mandate repeal, but does not make recommendations, deferring policy decision making to the Legislature. The State funds this work through a small annual assessment on health plans and insurers in California. All CHBRP reports and information about current requests from the California Legislature are available at the CHBRP Web site, www.chbrp.org.

A Report to the 2009-2010 California State Legislature

Analysis of Assembly Bill 513, Health Care Coverage: Breast-Feeding

April 17, 2009

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Additional free copies of this and other CHBRP bill analyses and publications may be obtained by visiting the CHBRP Web site at www.chbrp.org.

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PREFACE

This report provides an analysis of the medical, financial, and public health impacts of AB 513, a bill to mandate the coverage of lactation consultation with an international board certified lactation consultant (IBCLC) and for the rental of a breast pump. In response to a request from the California Assembly Committee on Health on February 13, 2009, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the provisions of Senate Bill 1704 (Chapter 684, Statutes of 2006) as chaptered in Section 127600, et seq. of the California Health and Safety Code.

Janet Coffman, MPP, PhD, and Chris Tonner, MPH, of the University of California, San Francisco, prepared the medical effectiveness analysis. Bruce Abbott, MLS, of the University of California, Davis, conducted the literature search. Helen Halpin, ScM, PhD, and Nicole Bellows, PhD, of the University of California, Berkeley, prepared the public health impact analysis. Tanya G. K. Bentley, PhD, of the University of California, Los Angeles, prepared the cost impact analysis. Jay Ripps, FSA, MAAA, of Milliman, provided actuarial analysis. Valerie J. Flaherman, MD, MPH, of the University of California, San Francisco, provided technical assistance with the literature review and expert input on the analytic approach. John Lewis, MPA, of CHBRP staff prepared the background section and synthesized the individual sections into a single report. Cherie Wilkerson provided editing services. A subcommittee of CHBRP's National Advisory Council (see final pages of this report) and a member of the CHBRP Faculty Task Force, Wayne S. Dysinger, MD, MPH, of the School of Medicine at Loma Linda Medical Center reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

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

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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Assembly 513, Health Care Coverage: Breast-Feeding

The California Assembly Committee on Health requested on February 13, 2009, 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) 513. In response to this request, CHBRP undertook this analysis pursuant to the provisions of Senate Bill 1704 (Chapter 684, Statutes of 2006) as codified in Section 127600, et seq. of the California Health and Safety Code.

AB 513 places requirements on health insurance policies regulated by the California Department of Insurance (CDI) and health care service plans regulated by the Department of Managed Care (DMHC) that provide coverage for maternity services. For such plans and policies, the bill mandates coverage of lactation consultation provided by an International Board Certified Lactation Consultant (IBCLC) and coverage for the rental of a breast pump.

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.

Almost, but not all plans and policies regulated by DMHC and CDI provide maternity coverage and so would be subject to the mandate. Current laws and regulations governing DMHC-regulated health 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.¹ Regulations defining basic health care services specifically include prenatal care as preventive care that must be covered.² CDI-regulated policies do not have similar, state level requirements, but both DMHC regulated plans and CDI-regulated policies are subject to the Federal Civil Rights Act. The 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.³ Therefore, only two market segments may exclude maternity benefits: CDI-regulated small group policies and CDI-regulated individual market policies. Earlier CHBRP reports indicate that 100% of persons with coverage from large and small group policies regulated by CDI have coverage, as do 22% of persons with coverage through CDI regulated individual market policies (CHBRP, 2009). Therefore, only a portion of the CDI-regulated individual market would not be subject to this mandate.

¹ Section 1317.1 of the California Health and Safety Code

² Section 1300.67 of the California Code of Regulations, Title 28

³ The Pregnancy Discrimination Act under Title VII of the Civil Rights Act of 1964

Lactation consultation refers to education and guidance offered to mothers who have recently delivered babies as a means of encouraging breast-feeding and as a way to prevent or correct difficulties that may arise. Practitioners who pass the exam offered by the International Board of Lactation Consultant Examiners (IBLCE), are designated International Board Certified Lactation Consultants (IBCLCs). Breast pumps are medical devices regulated by the Food and Drug Administration (FDA) that are used by breast-feeding mothers to express breast milk.

CHBRP's survey of health plans and policies indicated that current coverage for outpatient lactation consultation and breast pump rental may be limited in scope. Lactation consultation can be restricted to the inpatient setting, and coverage for breast pump rental can be restricted unless there are medical complications on the part of mother or child.

Should AB 513 become law, the required scope of coverage would be expected to expand for DMHC-regulated plans but not for CDI-regulated policies. DMHC-regulated plans would likely be required to consider outpatient lactation consultation delivered by an IBCLC and breast pump rentals for any nursing mother as within the scope of covered services. For some plans, this would be an expansion of current scope. The expansion would be based on DMHC's consideration of medical necessity criteria for provision of mandated benefits. To establish medical necessity, DMHC considers current clinical guidelines and standards of care. Current clinical guidelines, as noted in the *Medical Effectiveness* section, recommend lactation consultation and breast pump use in order to promote the health benefits associated with breast-feeding. In contrast, CDI does not consider current clinical guidelines, and so would not be likely to require an expansion of scope among policies that currently cover these services.

Medical Effectiveness

National Guidelines

- Six government agencies and professional societies recommend breast-feeding, and four recommend that infants consume breast milk exclusively during the first 6 months of life.
- Recommendations of breast-feeding are based on evidence that breast-feeding is associated with numerous health benefits for children and their mothers.
 - Health benefits for children include a reduction in risk of acute otitis media (ear infections), gastroenteritis, severe lower respiratory tract infections, atopic dermatitis, asthma among young children, obesity, type 1 and type 2 diabetes, childhood leukemia, sudden infant death syndrome (SIDS), and necrotizing enterocolitis.

- Health benefits for mothers include reduced risks of type 2 diabetes and breast and ovarian cancer.
- All six organizations recommend that health professionals provide education and support to encourage mothers to initiate and continue breast-feeding.
- Three organizations recommend that breast pumps be available to all women who are separated from their infants for long periods of time, including mothers returning to work, as well as those who have sick or preterm infants.

International Board Certified Lactation Consultants (IBCLCs)

- No studies were identified that compared the effectiveness of lactation consultation delivered by IBCLCs, an internationally recognized board-certified credential, to lactation consultation provided by other health professionals.

Lactation Consultation

- All studies identified by the Medical Effectiveness team compared extra lactation consultation provided by a professional lactation consultant to standard breast-feeding support care (i.e., care typically provided by the hospital(s) and/or outpatient practice(s) at which the studies were conducted.
- No studies were identified that compared mothers and infants who received lactation consultation to mothers and infants who did not receive lactation consultation.
- Although AB 513 would extend coverage for lactation consultation by an IBCLC, only two randomized controlled trials (RCTs) explicitly state that the lactation providers studied were IBCLC certified. As a consequence, the medical effectiveness review also incorporated RCTs of lactation support provided by other health professionals who may or may not be IBCLCs.
- Studies conducted in hospitals participating in the Baby-Friendly Hospital Initiative (BFHI) were excluded, because BFHI's scope of services, which include in-rooming for mothers and infants on an institution-wide basis, are not comparable to services defined under an IBCLC scope of practice, that is, consultation on a one-to-one basis.
- Studies identified by the Medical Effectiveness team compared the effects of extra lactation consultation to standard breast-feeding care on the following outcomes:
 - Cessation of *any* breast-feeding up to 6 months after delivery
 - Cessation of *exclusive* breast-feeding (i.e., breast-feeding without supplemental formula feeding) for either 4 to 6 weeks after delivery or over a 6-month period after delivery
 - Infant health outcomes

- The evidence of the effectiveness of extra lactation consultation on cessation of any breastfeeding is ambiguous. Of 14 RCTs that compared the impact of extra lactation consultation to the impact of standard care on cessation of any breast-feeding up to 6 months after delivery, four RCTs found that lactation consultation reduced the likelihood of cessation of any breast-feeding whereas 10 RCTs found no evidence of a positive effect of lactation consultation.
- The preponderance of evidence suggests that extra lactation consultation does not affect cessation of exclusive breast-feeding before 4 to 6 weeks post delivery. Of five RCTs that examined cessation of exclusive breast-feeding before 4 to 6 weeks, only one reported a positive association with extra lactation consultation, whereas the remaining RCTs found no effect.
- There is clear and convincing evidence that extra lactation consultation does not affect cessation of exclusive breast-feeding up to 6 months after delivery. Five RCTs found that extra lactation consultation does not differ from standard care in its impact on cessation of exclusive breast-feeding before 6 months.
- One RCT reported no association between rates of gastrointestinal or respiratory tract infection among infants whose mothers receive lactation consultations compared to women who receive standard care.

Breast Pumps

- When infants are separated from their mothers, breast pumps allow infants to continue consuming their mothers' milk.
- The literature on breast pumps is limited in terms of number of studies and the populations studied.
- The effects of utilization of breast pumps have been studied for two groups of mothers:
 - Low-income mothers returning to work
 - Mothers of preterm infants
- Studies identified by the Medical Effectiveness team compared the effects of utilization of breast pumps and different breast pumping methods on the following outcomes:
 - Duration of breast-feeding
 - Volume of breast milk expressed
 - Time needed to express breast milk

- Findings from a single, nonrandomized study suggest that for low-income women returning to work who had delayed or immediate access to renting a breast pump, the odds of not using formula at 6 months were three to five times as large as the odds for women who did not rent a breast pump. At 12 months for women who had immediate access to a breast pump, the odds of not using formula were three times as large as the odds for women who did not rent a breast pump.
- One RCT found no difference between electric and manual hand-operated pumps on the volume of milk expressed.
- Evidence regarding the relative impact of simultaneous versus sequential pumping with an electric pump on the volume of milk expressed is ambiguous. Simultaneous pumping was associated with a higher volume of milk expressed in one RCT, whereas the second RCT found no difference in volume expressed.
- One RCT found pumping takes less time when using an electric pump compared to a manual, hand-operated pump.
- One RCT found simultaneous pumping took less time than sequential pumping when using an electric pump.
- One RCT found no effect of electric pumping or manual pumping on breast-feeding rates at 6 months.

Utilization, Cost, and Coverage Impacts

Table 1 summarizes the utilization, cost, and coverage impacts of AB 513.

Coverage

- Approximately 20.5 million people are enrolled in privately and publicly funded health plans and policies in California that are subject to state law and provide maternity coverage and so would be subject to this mandate. Among this population are an estimated 416,000 delivering women who would be directly impacted by the services included in the mandate. CHBRP's estimates of current coverage for the full population are as follows:
 - 20.5 million have coverage for lactation consultation when provided during delivery admission.
 - 10.5 million have coverage for outpatient lactation consultation (consultation provided after discharge from hospital for delivery admission).
 - 17.8 million have coverage for breast pump rental for certain medical conditions.
- AB 513 would impact scope of coverage only for enrollees in DMHC-regulated plans. As discussed earlier, this is due to differences in statutory and regulatory requirements for DMHC-regulated plans versus CDI-regulated policies.

- If the mandate is enacted, CHBRP makes the following estimates for changes in coverage:
 - 8.5 million enrollees would gain coverage for outpatient lactation consultation.
 - 2.8 million enrollees would gain coverage for breast pump rental.
- Among the estimated 416,000 delivering women in the population with coverage subject to the mandate, approximately 103,000 would gain coverage for outpatient lactation consultation and approximately 27,000 would gain coverage for breast pump rental. This means that approximately 6,000 current users of outpatient lactation consultation and 2,000 current renters of breast pumps would gain coverage for these services if this bill were to be passed.

Utilization

- Of the insured population covered by health plans and policies subject to this mandate, the approximately 416,000 delivering women are the anticipated users of the services included in the mandate. CHBRP estimates current utilization to be as follows:
 - 183,000 (44% of delivering women) consult with IBCLCs during delivery admission,
 - 25,000 (6% of delivering women) consult with IBCLCs in an outpatient setting, and
 - 26,000 (6.2% of delivering women) rent breast pumps.
- CHBRP estimates no postmandate change in the utilization rates for lactation consultation during delivery admission, outpatient lactation consultation, or breast pump rental. CHBRP's estimates are based on the following reasons:
 - Laction consultation during delivey admission: The service is already fully covered for 96.2% of enrollees, and expert clinical opinion suggests that almost all enrollees currently receive lactation consultation during delivery admission. Therefore, CHBRP assumes that demand for delivery admission constualtion is already met.
 - Outpatient lactation consultation: Although over half of all women utilizing outpatient lactation consultation must now pay for the service themselves, CHBRP assumes that demand is currently fully met because:
 - The service is usually accessed only once or twice, so the financial constraint is limited.
 - Less-expensive options other than fully priced private IBCLC consultations are available.

- Among lower-income women, for whom the price of outpatient lactation consultation may be a barrier to use, the service is currently fully covered by Medi-Cal.
- Breast pump rental: CHBRP assumes that due to the low cost (\$10/week) of rental, demand is met at the current 6.2% utilization level, regardless of coverage. Therefore, CHBRP assumes that utilization of breast pump rental services would remain constant.

Costs

Per-unit costs

- CHBRP estimates per-unit cost of lactation consultation during delivery admission at \$0.00; \$95 for outpatient lactation consultation; and \$10.00 per week of breast pump rental. If AB 513 were enacted, CHBRP does not anticipate any changes to the per-unit cost or demand for these products.
- For women who use these services but lack coverage for them, CHBRP estimates costs per user of \$0, \$143 (an average of 1.5 consultations), and \$260 (\$10/week * 26 weeks of use) for inpatient lactation consultation, outpatient lactation consultation, and breast pump rental, respectively.

Expenditures

- Currently, enrollees without coverage for lactation consultation or breast pump rental would incur an estimated \$1.767 million in out-of-pocket expenses annually for these services. After the passage of AB 513, approximately 75% (\$1.33 million) of those expenditures would be shifted to premiums charged by health plans and insurers, and the remainder would be paid by members who would continue to lack coverage for these services postmandate (e.g., those in CDI-regulated plans that do not provide maternity coverage). In addition, of the premandate \$6,384 million in out-of-pocket costs spent for covered benefits and for cost sharing for these services, approximately \$2.1 million (0.0336%) would be shifted from enrollees to insurers postmandate.
- Total expenditures are estimated to increase by \$607,000 (0.0007%) due to the additional administrative costs associated with providing coverage for persons who do not currently have this benefit as well as due to the increased utilization of breast pump rental among lower-income women. Because administrative costs are assumed to be a fixed proportion of premiums, there is an increase in administrative costs with the shift in costs from out-of-pocket expenditures to insurance premiums.

Premiums

- The mandate is estimated to increase premiums by about \$4.1 million. This increase would be distributed as follows:
 - Total premiums for private employers are estimated to increase by \$2,820,000, or 0.0056%.
 - Total employer premium expenditures for the California Public Employees' Retirement System (CalPERS) are estimated to increase by \$178,000, or 0.0056% (\$0.0214 PMPM).
 - Premiums paid by employees covered by group insurance (including CalPERS) would increase by an estimated \$756,000, or 0.0056%.
 - Total premiums for those with individually purchased insurance are estimated to increase by \$323,000, or 0.0054%.
 - State expenditures for Medi-Cal and those for Healthy Families are estimated to remain unchanged.

Impact on number of uninsured

- CHBRP estimates no measurable impact on the number of uninsured due to premium increases resulting from the mandate.

Public Health Impacts

- The overall consensus from the medical community is that breast-feeding has substantial health benefits to both infants and mothers. AB 513 is not expected to result in an increase in utilization lactation consultations or use of electric breast pumps. As a result, AB 513 is not expected to generate health benefits associated with breast-feeding. However, AB 513 is expected to decrease out-of-pocket costs for approximately 6,000 women utilizing outpatient lactation consultants and 2,000 already using electric breast pump rentals.
- In California, racial and ethnic minorities have lower rates of breast-feeding initiation compared to whites, which may contribute to disparities in health. Since AB 513 is not expected to result in an increase in lactation consultations or use of electric breast pumps, AB 513 is not expected to decrease racial health disparities.
- Since AB 513 is not expected to result in an increase in lactation consultations or use of electric breast pumps, AB 513 is not expected to result in a decrease in the economic burden associated with health conditions that could be prevented by increased breast-feeding.

- Since AB 513 is not expected to result in an increase in lactation consultations or use of electric breast pumps, AB 513 is not expected to result in long-term health benefits.

Table 1. Summary of Coverage, Utilization, and Cost Impacts of AB 513

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Coverage				
Total population in plans subject to state regulation (a)	21,340,000	21,340,000	0	0%
Total population in plans subject to AB 513	20,535,000	20,535,000	0	0%
Percentage of individuals with coverage for:				
Lactation consultation during delivery admission	96.2%	96.2%	0.0%	0%
Outpatient lactation consultation	49.1%	88.9%	39.8%	80.977%
Breast pump rental	83.2%	96.2%	13.1%	15.690%
Number of individuals with coverage for:				
Lactation consultation during delivery admission	20,535,000	20,535,000	0	0%
Outpatient lactation consultation	10,482,000	18,970,000	8,488,000	80.977%
Breast pump rental	17,750,000	20,535,000	2,785,000	15.690%
Utilization and Cost				
Number of delivering women	416,000	416,000	0	0%
Number of lactation consultations provided by IBCLC per delivering woman				
During delivery admission	0.44	0.44	0.00	0%
Outpatient	0.09	0.09	0.00	0%
Number of weeks of breast pump rental per delivering woman	1.61	1.61	0.00	0%
Average cost of lactation consultations provided by IBCLC				
During delivery admission	\$0.00	\$0.00	\$0.00	0%
Postpartum	\$95.00	\$95.00	\$0.00	0%
Average cost of breast pump rental per week	\$10.00	\$10.00	\$0.00	0%

Table 1. Summary of Coverage, Utilization, and Cost Impacts of AB 513 (Cont'd)

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Expenditures				
Premium expenditures by private employers for group insurance	\$50,546,207,000	\$50,549,027,000	\$2,820,000	0.0056%
Premium expenditures for individually purchased insurance	\$5,944,229,000	\$5,944,552,000	\$323,000	0.0054%
Premium expenditures by individuals with group insurance, CalPERS, Healthy Families, AIM, or MRMIP (b)	\$13,475,994,000	\$13,476,750,000	\$756,000	0.0056%
CalPERS employer expenditures (c)	\$3,161,160,000	\$3,161,338,000	\$178,000	0.0056%
Medi-Cal state expenditures (d)	\$4,112,865,000	\$4,112,865,000	\$0	0.0000%
Healthy Families state expenditures	\$643,247,000	\$643,247,000	\$0	0.0000%
Individual out-of-pocket expenditures for covered benefits (deductibles, copayments, etc.)	\$6,384,077,000	\$6,381,933,000	-\$2,144,000	-0.0336%
Out-of-pocket expenditures for noncovered benefits	\$1,767,000	\$441,000	-\$1,326,000	-75.0424%
Total Annual Expenditures	\$84,269,546,000	\$84,270,153,000	\$607,000	0.0007%

Source: California Health Benefits Review Program, 2009.

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

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

(c) Of the CalPERS employer expenditures, about 59% would be state expenditures for CalPERS members who are state employees. However, CHBRP estimates no impact on CalPERS employer expenditures during the year following implementation of the mandate.

(d) Medi-Cal state expenditures for members under 65 years of age include expenditures for 7,000 newly covered by the Major Risk Medical Insurance Program (MRMIP) and 7,000 newly covered in the Access for Infants and Mothers (AIM) program.

Key: AIM=Access for Infants and Mothers; CalPERS=California Public Employees' Retirement System; CDI=California Department of Insurance; DMHC=Department of Managed Health Care; IBCLC=International Board Certified Lactation Consultant; MRMIP=Major Risk Medical Insurance Program.

INTRODUCTION

Assembly Bill (AB) 513 contains two separate requirements. The bill requires plans and policies that provide maternity benefits to cover lactation consultation provided by an International Board Certified Lactation Consultant (IBCLC) and to cover the rental of a breast pump.

The California Health Benefits Review Program (CHBRP) undertook this analysis in response to a request from the California Assembly Committee on Health on February 13, 2009. AB 513 was introduced by Assembly Member Kevin de Leon on February 24th, 2009.

As a proposed benefit mandate bill, AB 513 would directly affect health insurance coverage subject to California law. Therefore, health plans regulated by the Department of Managed Health Care (DMHC) and the health insurance policies regulated by the California Department of Insurance (CDI) could be subject to the mandate, were the bill to become law.⁴ The mandate could affect plans and policies in all of the commercial markets: large group, small group, and individual. In addition, through its impact on the DMHC-regulated plans, AB 513 would affect the coverage of persons enrolled in the California Public Employees' Retirement System (CalPERS) Health Maintenance Organizations (HMOs), Medi-Cal Managed Care, Healthy Families, and other publicly funded programs. Changes in CDI-regulated health insurance policies would not affect public programs because public programs contract only with DMHC-regulated plans. (Please see Appendix D for a detailed description of the underlying assumptions related to the *Utilization, Cost, and Coverage Impacts* section of this analysis.)

AB 513 specifies that plans and policies providing maternity coverage would be subject to the mandate. 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.

All plans regulated by DMHC provide maternity coverage and so would be subject to the mandate. Most, but not all, CDI-regulated policies provide maternity coverage and so would also be subject to the mandate. Current laws and regulations governing DMHC-regulated health 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.⁵ Regulations defining basic health care services specifically include prenatal care as preventive care

⁴ Senate Bill (SB) 1704, 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, those enrolled in health insurance products offered by health care service plans or health insurers are the portion of the population directly affected by a benefit mandate bill.

⁵ Section 1317.1 of the California Health and Safety Code

that must be covered.⁶ CDI-regulated policies do not have similar, state level requirements, but both DMHC regulated plans and CDI-regulated policies are subject to the Federal Civil Rights Act. The 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.⁷ Therefore, only two market segments may exclude maternity benefits: CDI-regulated small group policies and CDI-regulated individual market policies. Earlier CHBRP reports indicate that 100% of persons with coverage from large and small group policies regulated by CDI have coverage, as do 22% of persons with coverage through CDI regulated individual market policies (CHBRP, 2009). Therefore, only a portion of the CDI-regulated individual market would not be subject to this mandate.

AB 513 would not directly affect coverage for populations enrolled in programs or health insurance products that are not subject to California benefit mandates, such as those enrolled in Medicare Advantage or those who have coverage through self-insured group plans (both of which are exempted from state regulation by federal law). AB 513 would not directly affect those who are uninsured and have no coverage. Similarly, AB 513 would not directly affect beneficiaries of the Women, Infants, and Children (WIC) Program. WIC is a federally funded program that provides education and nutrition, but not coverage, to qualifying individuals.

Bill Language

The full text of AB 513 can be found in Appendix A of this report.

AB 513 references both lactation consultation provided by International Board Certified Lactation Consultants (IBCLCs) and the rental of breast pumps.

Lactation consultation

Lactation consultation refers to education and guidance offered to mothers of newly delivered babies as a means of encouraging breast-feeding and as a way to prevent or correct difficulties in breast-feeding that may arise. Although breast-feeding is natural, a number of problems can occur. Examples of difficulties may include: a baby may not latch onto the breast (or does so only briefly); a mother may have damaged nipples; or a baby may never seem satiated or does not gain weight adequately.

Consultations may be more or less formal. They may be provided by professionals or by peer counselors. Consultations are frequently provided in hospitals but also may be provided at a doctor's office, at home, or at some other site.

International Board Certified Lactation Consultant

The International Board of Lactation Consultant Examiners (IBLCE) is a nonprofit organization established in 1985. The IBLCE develops and administers certification

⁶ Section 1300.67 of the California Code of Regulations, Title 28

⁷ The Pregnancy Discrimination Act under Title VII of the Civil Rights Act of 1964

examinations for lactation consultants. The IBLCE certification program for lactation consultants has been continuously accredited by the National Commission for Certifying Agencies since 1988. Candidates who pass the certification exam are awarded the designation International Board Certified Lactation Consultant (IBCLC) (IBLCE, 2009).

Not all lactation consultation in California (or nationally) is provided by IBCLCs. Physicians, nurses, nutritionists, peer counselors, and others may provide lactation consultation. However, there were 1,095 registered IBCLCs in California as of March 2009.⁸ A majority of these individuals are licensed as registered nurses and a majority is affiliated with a hospital. However, some hold other licenses (or no license), and some work independently, in conjunction with physician offices, or with public programs, such as the WIC Program.

Breast pumps

Breast pumps are medical devices regulated by the Food and Drug Administration (FDA). Breast pumps are used by breast-feeding women to extract (or express) breast milk. Breast pumps can also be used to:

- Maintain or increase a woman's milk supply.
- Feed multiple babies.
- Relieve engorged breasts and plugged milk ducts.
- Pull out flat or inverted nipples so a nursing baby can latch-on to its mother's breast more easily.

Women may use breast pumps to express and store breast milk upon return to work, when traveling, or when otherwise separated from a nursing baby.

All breast pumps consist of a few basic parts:

- A cone-shaped cup, called a breast shield, that fits over the nipple and the dark, circular area surrounding the nipple (the areola).
- A pump to create the gentle vacuum that expresses milk. The pump may be attached to the breast-shield or have plastic tubing to connect the pump to the breast-shield.
- A detachable milk collection container that fits below the breast shield. The container is typically a disposable bag or a reusable bottle that can be used to store the milk, or attached to a rubber nipple and used for feeding a baby.

The three main types of breast pumps are differentiated by the power source of the pump: manual, battery-powered, and electric. Whatever the power source, there are three

⁸ Personal communication, D. Moore, International Board of Certified Lactation Examiners, March 2009.

different pumping types: single, double, and sequential. Double pumps can be used to express milk from both breasts at the same time. Most manual breast pumps are single pumps. Sequential pumping pumps release suction from one breast before applying suction to the other breast. Electric pumps are commonly sequential pumping pumps.

Although hand pumps can be inexpensive, the motorized portion of an electric breast pump can cost several hundred dollars and so are often available as rentals. For all forms of breast pumps, for health reasons, sharing or transfer of breast shields and catchment devices is discouraged.

Existing California Requirements

Maternity coverage

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.⁹ Thus, under existing California laws and regulations, the 86.3% of the privately insured market that is enrolled in DMHC-regulated plans have coverage for maternity services.¹⁰

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

- **Minimum length of stay for maternity services:** Health plans 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.”¹¹ This is also a federal protection under the Newborns’ and Mothers’ Health Protection Act of 1996.¹²
- **Limitation on copayments and deductibles for specified maternity services:** Health plans and policies that provide maternity coverage are prohibited from charging members copayments and deductibles for maternity services that exceed the most common amount of the copayment or deductible for inpatient and outpatient services.¹³

⁹ Section 1300.67 of the California Code of Regulations, Title 28

¹⁰ CHBRP’s methods of calculating enrollment in private and public programs that would be affected by the mandate are described in *Appendix D*.

¹¹ California Health and Safety Code, Section 1367.621; California Insurance Code, Section, 10123.87

¹² Newborns’ and Mothers’ Health Protection Act of 1996. Pub L No.104–204, §601 (1996)

¹³ California Health and Safety Code, Section 1373.4; California Insurance Code, Section 10119.5

California law includes provisions related to accessing health insurance in the *group* market by pregnant women. 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.” 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.¹⁴

Under California law, plans and insurers are required to issue health insurance to a newborn for the first 30 days of his or her life. This requirement also applies to CDI-regulated individual policies that do *not* cover maternity services.¹⁵

Federal laws

Under Title VII of the Federal Civil Rights Act, employers may not discriminate on the “basis of pregnancy, childbirth, or related medical conditions.” In terms of health insurance coverage, 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.¹⁶ Thus, under federal law, those obtaining health insurance in the large-group market and those in the small-group market (in firms having 15 or more employees) must have coverage for maternity services. (As determined in CHBRP’s survey of the largest health insurers in California, which will be discussed in detail in the *Utilization, Cost, and Coverage Impacts* section, small-group members employed by firms having two or more employees also have coverage for maternity services.)

Lactation consultation and breast pump rental

Currently there are no benefit mandate laws in CA or in other states that reference lactation consultation or breast pumps (BCBSA, 2008).

DMHC-regulated plans are required¹⁷ to cover basic health care services. However, neither current law nor current regulation reference any form of lactation consultation or rental of a breast pump, and so DMHC does not consider either to explicitly qualify as a basic health care service.¹⁸

Medi-Cal policy currently requires Medi-Cal Managed Care Plans to provide breast-feeding education and counseling to enrollees and to cover associated durable medical

¹⁴ California Health and Safety Code, Sections 1357.06 and 1357.51; California Insurance Code, Section 10198.7 and 10708. Also see www.dmhc.ca.gov/dmhc_consumer/hp/hp_individual.asp#rights.

¹⁵ Insurance Code Section 10119 and *Redlands Community Hospital v. New England Mutual* (1994) 23 Cal. App. 4th 898.

¹⁶ The Pregnancy Discrimination Act under Title VII of the Civil Rights Act of 1964

¹⁷ Basic Health Care Services; California Health and Safety Code, Section 1345 and Section 1300.67 of the California Code of Regulations, Title 28; Cancer Screening; Health and Safety Code Section 1367.665 and Insurance Code Section 10123.8.

¹⁸ Personal communication, Sherrie Lowenstein, Department of Managed Care, February 2009.

equipment, such as breast pumps, when medically necessary (DHS, 1998). Medi-Cal policy is silent on utilization of IBCLCs.

Key Assumptions

Should AB 513 become law, the scope of related coverage would expand among DMHC-regulated plans to include outpatient lactation consultation delivered by IBCLCs and breast pump rental for any nursing mother. However, an expansion of scope would not be required of CDI-regulated policies.

As described in the *Utilization, Cost, and Coverage Impacts* section, scope of coverage restrictions impacting utilization of lactation consultation and breast pumps are common among carriers that cover maternity services. Lactation consultation may be covered only as an inpatient service, and breast pumps may be covered only when deemed medically necessary due to the presence of a complicating medical condition in the mother or child.

Should AB 513 become law, DMHC's use of current clinical guidelines to determine medical necessity for covered services would prompt a broader scope of coverage among the plans it regulates.¹⁹ As described in the *Medical Effectiveness* section (and as listed in Appendix C), current guidelines support outpatient as well as inpatient lactation consultation and also support the use of electric breast pumps for any reason, including a healthy mother's return to work. Therefore, DMHC-regulated plans would be required to cover outpatient lactation consultation delivered by an IBCLC and to cover the rental of an electric breast pump for any nursing mother.

The same would not be true for CDI-regulated policies. Unless legislation makes a specification, the scope of coverage for CDI-regulated products is not determined by prevailing clinical recommendations. Therefore, a carrier could comply with AB 513 by covering lactation consultation and breast pumps only in an inpatient environment and only when the carrier determines it medically necessary due to complicating medical conditions.²⁰

Relevant Populations and Prevalence

AB 513 applies primarily to the utilization of lactation consultation and breast pumps by childbearing women enrolled in health plans and policies with maternity coverage that are subject to regulation by DMHC or CDI. In 2007, approximately 95% of the more than 568,000 deliveries were covered by private insurance (46.1%), Medi-Cal (46.7%), or other government programs (2.2%) (RAND, 2008). This figure includes the 416,000

¹⁹ Personal communication, Sherrie Lowenstein, Department of Managed Care, February 2009.

²⁰ Personal communication, Bruce Hinze, California Department of Insurance, March 2009.

delivering women CHBRP estimates to have coverage regulated by DMHC and CDI, as well as women who have other forms of coverage, such as coverage through a self-insured employer's plan or Medi-Cal fee-for-service coverage.

The prevalence of breast-feeding among California babies can be examined with two data sources. The Centers for Disease Control and Prevention (CDC) collects breast-feeding data from a retrospective survey of caregivers of 19- to 35-month-old children. Information on short-term breast-feeding in the hospital is also captured by the California Newborn Screening Test Form and submitted to the California Department of Public Health (CDPH). The two data sources indicate that in recent years, at least 85% of California babies have breast-fed. According to CDC data, 85.1% of California children born in 2005 have ever breast-fed (CDC, 2008). Based on the California Newborn Screening Test Form, 86.6% of newborns in 2007 were breast-fed at some point in their hospital stay (CDPH, 2007).

The American Academy of Pediatrics recommends exclusive breast-feeding for the first 6 months of life and continued breast-feeding along with complementary foods for at least the first year of life (AAP, 2005). The CDC survey found that 62.0% of babies born in 2005 were breast-feeding at 6 months and 32.1% were breast-feeding at 1 year (CDC, 2008). Lower rates were reported for breast-feeding to the exclusion of supplementation with formula, with 41.1% reporting exclusive breast-feeding through 3 months and 17.6% reporting exclusive breast-feeding through 6 months (CDC, 2008). The California Newborn Screening data reports 42.7% of babies with exclusive breast-feeding while in the hospital (CDPH, 2007).

California and other western states have a higher prevalence of breast-feeding compared to other regions of the United States (CDC, 2008; Forste and Hoffman, 2008). According to the prevalence numbers reported above, California has achieved the Healthy People 2010 (objective 16-19) goal of 75% ever breast-feeding, 50% breast-feeding at 6 months, and 25% at 1 year (DHHS, 2000b). Nationally, these goals have not yet been met (CDC, 2008).

MEDICAL EFFECTIVENESS

As indicated in the *Introduction*, Assembly Bill (AB) 513 would mandate coverage for lactation consultation by an International Board Certified Lactation Consultant (IBCLC) and for rental of breast pumps. This section of the report summarizes clinical guidelines regarding the use of lactation support and breast pumps, and discusses findings from the studies that compared the addition of extra professional lactation support to standard hospital postpartum breast-feeding support and findings from studies of the effectiveness of breast pumps.

Current Guidelines

CHBRP reviewed clinical guidelines from the United States Department of Health and Human Services (USDHHS) and the United States Preventive Services Task Force (USPSTF) to identify their recommendations for breast-feeding, lactation consulting, and the use of breast pumps. Clinical guidelines issued by the following professional societies were also reviewed: the Academy of Breastfeeding Medicine (ABM), the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP), and the American College of Obstetricians and Gynecologists (ACOG). These agencies and professional societies were selected because they are the agencies and societies most focused on the health of mothers and children.

Summaries of these guidelines appear in Appendix C, Table C-1. The major findings from the review are as follows:

- All six organizations recommend breast-feeding and four (ABM, AAFP, AAP, and ACOG) recommend that infants consume breast milk exclusively during the first 6 months of life.
- Recommendations for breast-feeding are based on evidence that breast-feeding is associated with numerous health benefits for children and their mothers.
- Health benefits for children include a reduction in risk of acute otitis media (ear infections), gastroenteritis, severe lower respiratory tract infections, atopic dermatitis, asthma among young children, obesity, type 1 and type 2 diabetes, childhood leukemia, sudden infant death syndrome (SIDS), and necrotizing enterocolitis (Ip et al., 2007). Women with a history of lactation have reduced risks of type 2 diabetes and breast and ovarian cancer (Ip et al., 2007).
- All six organizations recommend that health professionals provide education and support to encourage mothers to initiate and continue breast-feeding.

- AAFP, AAP, ACOG, and the USDHHS recommend that breast-feeding education and support be provided after the mother and baby are discharged from the hospital, as well as during the hospital stay.
- None of the organizations specifically state that breast-feeding education and support must be provided by an IBCLC.
- AAFP, AAP, and the USDHHS recommend that breast pumps be available to all women who are separated from their infants for long periods of time, including mothers returning to work, as well as those who have sick or preterm infants.
- AAFP recommends use of hospital-grade, double electric breast pumps.

Literature Review Methods

Studies of the effectiveness of lactation consultation and breast pumps were identified through searches of PubMed (Medline), the Cochrane Library, the CABI Bioscience Database, EconLit, Global Health, Google Scholar, Scientific Web Plus, Scopus, and the Web of Science. Web sites maintained by the following organizations were also searched: the Agency for Healthcare Research and Quality, the Institute for Clinical Systems Improvement, the International Network of Agencies for Health Technology Assessment, the National Guideline Clearinghouse, the National Health Service Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence, the National Institutes of Health, the Scottish Intercollegiate Guideline Network, and the World Health Organization. Additional searches were performed for the cost and public health sections of the report.

The literature search was limited to articles published in English. The search encompassed all pertinent studies published from January 2007 to present. The timeframe for the literature search was truncated because the medical librarian identified three Cochrane Reviews (Becker et al., 2008; Britton et al., 2007; Dyson et al., 2005) and a systematic review produced for the United States Preventive Services Task Force (Chung et al., 2008) that synthesized literature on the effectiveness of lactation consulting and breast pumps published prior to January 2007. A total of 405 citations were retrieved, and eight pertinent studies were identified and reviewed. They included one meta-analysis of randomized controlled trials (RCTs), six individual RCTs, and one nonrandomized study with a comparison group.

The literature review was limited to studies of lactation consulting and breast pumps conducted in developed countries to help ensure that the populations of mothers and infants studied would be generalizable to the population to which AB 513 would apply. Studies in which lactation support was provided by a nonprofessional (i.e., a lay or peer counselor) were also excluded because AB 513 would require health plans to provide coverage only for lactation support services delivered by a specific group of health professionals (i.e., IBCLCs). Studies in which lactation support was provided by health professionals who were not IBCLCs were included because only two studies of the

effectiveness of IBCLCs have been published and because most IBCLCs who practice in California are registered nurses or other types of licensed health professionals.

In addition, studies that evaluated the Baby-Friendly Hospital Initiative²¹ were excluded from the review. The Baby-Friendly Hospital Initiative is a hospital-level initiative that consists of 10 elements that include practicing “rooming in” (i.e., having newborns stay in the same room as mothers) and avoiding the use of pacifiers and artificial nipples as well as providing lactation support. In these studies, the effects of lactation support cannot be separated from the effects of other elements of the intervention. Findings from these studies may not be generalizable to AB 513, which only addresses lactation consulting and breast pumps.

Outcomes Assessed

Lactation Consultation

Studies identified by the Medical Effectiveness team compared the effects of extra lactation consultation provided by a professional lactation consultant to standard breast-feeding support care (defined as regular postpartum breast-feeding care) on the following outcomes:

- Cessation of *any* breast-feeding before a child reaches age 6 months.
- Cessation of *exclusive* breast-feeding (i.e., breast-feeding without supplemental formula feeding) for either 4 to 6 weeks after delivery or over a 6-month period after delivery.
- Infant health outcomes.

Breast Pump Rentals

Studies identified by the Medical Effectiveness team assessed the effects of access to breast pump rentals on duration of breast-feeding, as well as on the effects of different types of breast pumps and methods of pumping on volume of milk expressed, time to express milk, and duration of breast-feeding.

²¹ The Baby-Friendly Hospital Initiative is a program sponsored by the World Health Organization and the United Nations Children’s Fund aimed at encouraging hospitals to promote breastfeeding. Information about the initiative is available at www.babyfriendlyusa.org/eng/03.html.

Study Findings

Lactation Consultation

The comparative effectiveness of extra professional lactation support and standard hospital breast-feeding support (defined as regular postpartum care) was assessed in 14 RCTs, 12 of which were included in a meta-analysis (Britton et al., 2007). In two of these RCTs, the extra professional lactation support was provided by an IBCLC (Bonuck et al., 2005, 2006), whereas in the remaining RCTs, the providers were midwives, hospital breast-feeding counselors, lactation consultants, lactation nurses, community health nurses, or regular nurses (Britton et al., 2007).

The scope of lactation consultation practice includes working with primary care providers to promote breast-feeding, but none of the studies stated that this type of collaboration was included in the lactation consultants' services.

Standard hospital breast-feeding support includes services that are typically bundled into maternity care, and the intensity of breast-feeding support may vary between hospitals.

Although the RCTs in this review are designed to measure the incremental effect of lactation consultant support when added to standard hospital breast-feeding support, there are two methodological problems in study design and assessing the results. First, the standard care provided in the hospital setting is not necessarily the same across studies. Secondly, the increment of consultant support is also not standardized across studies.

Findings regarding the effectiveness of extra professional lactation support are as follows:

Duration of breast-feeding

Cessation of any breast-feeding (mothers' milk exclusively or mother's milk plus formula) up to 6 months after delivery. Evidence of the effects of extra professional lactation support on the likelihood of stopping any breast-feeding up to 6 months after delivery is ambiguous. Of 14 RCTS, four found that extra professional lactation consultation had a positive effect on not stopping any breast-feeding before 6 months above standard hospital-based breast-feeding support (Bonuck et al., 2005, 2006; Britton et al., 2007). The remaining 10 RCTs found no statistically significant difference in the likelihood of not stopping any breast-feeding before 6 months (Britton et al., 2007).

Cessation of exclusive breast-feeding (mothers' milk) up to 6 months after delivery. The preponderance of evidence suggests that extra professional lactation consultation does not reduce the likelihood of stopping exclusive breast-feeding up to 6 months after delivery. Of 10 RCTS that assessed this outcome, one found that extra professional lactation support had a positive and statistically significant effect on exclusive breast-feeding above standard hospital breast-feeding care (Britton et al., 2007). Nine RCTS

found no statistically significant difference in likelihood of exclusive breast-feeding (Bonuck et al., 2005; Britton et al., 2007).

Infant health

An RCT conducted in the United States reported no association between rates of gastrointestinal or respiratory tract infection among infants whose mothers receive lactation consultations compared to women who received standard care (Bonuck et al., 2006).

Breast Pumps

The studies of the effectiveness of breast pumps were conducted in the United States and in the United Kingdom among either low-income mothers returning to work or mothers of preterm infants. Of the five studies identified by the Medical Effectiveness team, one assessed the effects of access to breast pump rentals (Meehan et al., 2008) and the four remaining studies compared the effects of electric and manual breast pumps (Fewtrell et al., 2001; Hayes et al., 2008), as well as the effects of simultaneous and sequential pumping on the duration of breast-feeding, the volume of milk expressed, and the time to express milk (Groh-Wrago et al., 1995; Jones et al., 2001).

Duration of breast-feeding

One nonrandomized study with a comparison group examined the effects of access to breast pump rentals on duration of exclusive breast-feeding. This study was conducted in the United States among low-income women participating in the Women, Infant, and Children Program (WIC), who were returning to work full-time. Using a quasi-experimental design, women were categorized into three groups: those who received an electric pump when requested, those who received an electric pump after a delay, and those who never received an electric pump because of lack of availability or who declined a pump. The women who had delayed or immediate access to renting a breast pump were three to five times less likely to use formula at 6 months compared to women who did not rent a breast pump. At 12 months, women who had immediate access to a breast pump rental were three times less likely to use formula compared to women who did not rent a breast pump (Meehan et al., 2008).

However, this study has several important limitations. First, once per month, WIC staff telephoned women who rented breast pumps to answer questions and encourage them to continue breast-feeding. WIC staff also sent their employers information about creating a work environment that supports breast-feeding and information about a state law that requires employers to make reasonable efforts to provide employees with facilities for expressing breast milk in close proximity to their work areas and to provide adequate break time to express breast milk (Meehan et al., 2008). These additional interventions, which are not addressed in AB 513, may have contributed to its success in increasing the duration of exclusive breast-feeding. Providing coverage for breast pump rental without providing additional support to women and information to employers may not have as great an impact on exclusive breast-feeding. In addition, the authors used the length of time before a woman requested formula from WIC as a proxy for duration of exclusive

breast-feeding. Mothers were not surveyed about their infant feeding practices. It is possible that some women obtained formula from other sources, although the study was limited to low-income women who would have had a financial incentive to obtain formula through WIC instead of paying for it directly.

One RCT study in the United States examined the effects of using an electric versus a manual pump on rates of any breast-feeding at 6 months among low-income women returning to work. This study found that breast-feeding rates do not differ between those using an electric or manual pump (Hayes et al., 2008).

Volume of milk expressed

Two RCTs compared simultaneous pumping to sequential pumping using electric pumps (Groh-Wrago et al., 1995; Jones et al., 2001). In these studies, simultaneous pumping was associated with a higher volume of milk expressed in one RCT, whereas the second RCT found no difference in volume of milk expressed. The third RCT compared the use of an electric pump to a manual hand-operated pump and found no statistically significant difference in the volume of breast milk expressed (Fewtrell et al., 2001).

Time to express milk

Two RCTs conducted among women of preterm infants evaluated the effectiveness of breast pumps on the amount of time to express milk. One study found pumping takes less time when using an electric pump compared to a manual hand-operated pump (Fewtrell et al., 2001). The other found that simultaneous pumping took less time than sequential pumping when using an electric pump (Groh-Wrago et al., 1995).

Summary of Findings

Lactation support

- The evidence of the effectiveness of extra lactation consultation on duration of any breastfeeding is ambiguous. Of 14 RCTs that compare the impact of extra lactation consultation to the impact of standard care on cessation of any breast-feeding before 6 months, four found that extra lactation consultation reduced the likelihood of cessation of any breast-feeding, while 10 RCTs found no evidence of a positive effect of lactation consultation.
- The preponderance of evidence suggests that extra lactation consultation does not affect cessation of exclusive breast-feeding before 4 to 6 weeks post delivery. Of five RCTs that examined cessation of exclusive breast-feeding before 4 to 6 weeks, only one reported a positive association with extra lactation support, whereas the remaining four found no additional effect.
- There is clear and convincing evidence that extra lactation consultation does not affect cessation of exclusive breast-feeding up to 6 months after delivery. Five RCTs found that lactation consultation does not differ from standard care in its impact on cessation of exclusive breast-feeding before 6 months.

- One RCT reported no association between rates of gastrointestinal or respiratory tract infection among infants whose mothers receive lactation consultations compared to women who received standard care.

Breast pumps

- Findings from a single, nonrandomized study suggest that for low-income women returning to work who had delayed or immediate access to renting a breast pump, the odds of not using formula at 6 months were three to five times as large as the odds for women who did not rent a breast pump. At 12 months, for women who had immediate access to a breast pump, the odds of not using formula were three times as large as the odds for women who did not rent a breast pump.
- One RCT found no difference between electric and manual foot pedal pump on the volume of milk expressed.
- Evidence regarding the relative impact of simultaneous versus sequential pumping with an electric pump on the volume of milk expressed is ambiguous. Simultaneous pumping was associated with a higher volume of milk expressed in one RCT, whereas the other RCT found no difference in volume of milk expressed.
- One RCT found pumping takes less time when using an electric pump compared to a manual foot pump.
- One RCT found simultaneous pumping takes less time than sequential pumping, when using an electric pump.
- One RCT found no effect of electric pumping or manual pumping on breast-feeding rates at 6 months.

UTILIZATION, COST, AND COVERAGE IMPACTS

AB 513 would require health plans regulated by the Department of Managed Health Care (DMHC) and policies regulated by the California Department of Insurance (CDI) to provide coverage for lactation consultation provided by International Board Certified Lactation Consultants (IBCLCs) and rental of breast pumps as part of health care service plan contracts or health insurance policies that provide maternity coverage. The mandate therefore provides coverage for such services provided in-hospital for delivery admission, as well as outpatient after-delivery admission, and applies to enrollees in group (large and small) and individual markets. As mentioned previously, maternity coverage is present in all DMHC-regulated plans and almost all CDI-regulated policies. The CDI-regulated individual market is the exception, where only 22% of persons with coverage have maternity service benefits. AB 513 would not directly affect populations that are enrolled in health insurance products that are not subject to state insurance regulations, such as those enrolled in self-insured plans or those who are uninsured. There are no provisions in the bill that affect utilization or medical-necessity reviews or the copayment, coinsurance, deductible, or other cost-sharing amounts set by health plans and insurers.

This first portion of this section presents the current, or baseline, costs and coverage of lactation consultation and breast pump rental. The section then provides the estimated utilization, cost, and coverage impacts of AB 513. For further details on the underlying data sources and methods, see Appendix D.

Present Baseline Cost and Coverage

Current Coverage of Mandated Benefit

Approximately 20,535,000 individuals in California are enrolled in health plans or policies offering maternity service benefits and that are subject to state regulation and are thus affected by this mandate, including approximately 416,000 delivering women who would be directly impacted by the services included in the mandate.

CHBRP surveyed the major private health plans and insurers regarding their coverage of lactation services and breast pump rental.²² Responses to this survey represented 77% of the CDI-regulated and 91% of the DMHC-regulated market, or a combined 88.4% of the privately insured market. Because Medi-Cal is a major payer for maternity services, and because enrollees in the Medi-Cal Managed Care Program would be directly impacted by AB 513, CHBRP also conducted a survey of the three largest Medi-Cal managed care plans in California and contacted the Department of Health Care Services.

²² Estimates based on 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.

The results of the CHBRP surveys suggest that, among people in privately and publicly funded health plans and policies, 96.2% of persons (20.5 million people) have coverage for lactation consultation provided during delivery admission, 49.1% (10.5 million) have coverage for outpatient lactation consultation (defined as consultation provided after discharge from hospital for delivery admission), and 83.2% (17.8 million people) have coverage for breast pump rental.

Coverage varies by market segment.

Privately insured market

Inpatient lactation consultation:

- Whereas inpatient lactation consultant coverage (during delivery admission) is available to approximately 100% of people in DMHC-regulated plan, it is available only to about 66% of those in health insurance policies regulated by the California Department of Insurance (CDI), ranging from 100% in both large and small group CDI markets, to 22% in individual CDI markets.

Outpatient lactation consultation:

- Similarly, whereas CHBRP estimates that no individuals in CDI-regulated insurance products are covered for outpatient lactation consultation, approximately 50% of those in DMHC-regulated health plans have coverage for this service, ranging from 53% in the large group, 41% in the small group, to 44% in the individual market.

Breast pump rental:

- Approximately 89% of those in DMHC-regulated privately insured plans have coverage, whereas about 54% of those in CDI-regulated insurance products are covered.
- In DMHC-regulated plans, approximately 90% of the large-group market, 84% of the small group, and 80% of the individual market have coverage for breast pump rental.
- In CDI-regulated products, these proportions are approximately 97%, 76%, and 18%, respectively.

Publicly funded

Inpatient lactation consultation:

- CHBRP estimates that 100% of enrollees in publicly-funded insurance plans or policies have coverage for lactation consultation during delivery admission.

Outpatient lactation consultation:

- While approximately 100% of enrollees in Medi-cal have coverage for outpatient lactation consultation, only about 53% of enrollees in CalPERS have such coverage.

Breast pump rental:

- Similarly, while about 100% of enrollees in Medi-cal have coverage for outpatient lactation consultation, only approximately 90% of enrollees in CalPERS have such coverage.

Current Utilization Levels and Costs of the Mandated Benefit

Current utilization levels

CHBRP estimates that currently, approximately 44% of women in hospital for delivery admission receive lactation consultation from IBCLCs during delivery admission; 6% receive IBCLC outpatient lactation consultation; and 6.2% rent breast pumps (for an average duration of 6 months per rental). These prevalence rates indicate that, of the 416,000 total delivering women in California affected by AB 513, there are approximately 233,000 current users of all services that are addressed in the proposed mandate.

The percentage of delivering women who currently use lactation consultation from IBCLCs or rent breast pumps is difficult to measure using claims data for a number of reasons, including:

- lactation consultation, when provided during delivery admission or outpatient from a physician's office, is billed as part of the bundled fee for delivery or physician visit, and thus is generally not reimbursed individually and therefore rarely appear in claims data;
- a great deal of lactation consultations are provided by IBCLCs who are also registered or licensed practical nurses (RNs and LPNs, respectively) and thus occur during visits whose primary purpose is the treatment of issues other than lactation consultation, and/or are billed without specifying lactation consultant provider type; and
- where breast pump rental is covered, it is only covered under strict criteria for specific medical conditions, so using diagnostic claims data would greatly underestimate utilization of breast pumps by delivering women who use them for

general purposes to maintain breast-feeding without other particular medical indications. For example, when Medstat claims data were run for this purpose, out of roughly 30 million claim records for outpatient services in California, 48 records were coded with the breast pump rental/purchase Current Procedural Terminology (CPT) codes (see Appendix D for more details). The combination of these problems results in a lack of sufficient and reliable quantitative data on utilization.

Because claims data were not reliable, CHBRP based its utilization estimates on information from a limited number of published studies and from information provided by our content expert.

IBCLC utilization during delivery admission

To estimate the proportion of women in hospital for delivery admission who receive lactation consultation from IBCLCs, CHBRP uses estimates from the literature (Kuan et al., 1999) that 44% of delivering women reported to have seen a lactation consultant during hospital admission. Although this number may overestimate utilization of IBCLCs because it may include women seeing non-IBCLE-certified consultants, it may also underestimate utilization for the following reasons:

- It does not include women who consulted with an IBCLC without the woman's specifically knowing that the person was a lactation consultant (e.g., receiving professional breast-feeding help from RNs, LPNs, or MDs who are IBCLCs but do not identify themselves as such to the patient),
- It is also based on data from 10 years ago, since which time the number and use of IBCLCs has increased dramatically (CDC, 2008).

The estimate of 44% of delivering women—which has been also deemed reasonable by CHBRP's content expert—is thus used. This means that approximately 243,000 delivering women in California receive IBCLC lactation consultation during delivery admission.

Outpatient IBCLC utilization

CHBRP estimates that overall, 6% of delivering women in California receive outpatient IBCLC lactation consultation. This is derived from:

- Estimates in the literature that 85.1% of delivering women in California initiate breast-feeding (CDC, 2008), and that 7.1% of breast-feeding women (Kuan et al., 1999) report seeing a lactation consultant after discharge from the hospital.
- CHBRP thus calculates that $7.1\% \times 85.1\%$ equals a total of 6% of delivering women who see an IBCLC on an outpatient basis.

Although this number may overestimate utilization of IBCLCs because it may include women seeing IBCLCs as well as those seeing non-IBCLE-certified consultants, it may also underestimate utilization for the same reasons as those listed above for IBCLC utilization estimates during delivery admission:

- It does not include women who consulted with an IBCLC via their physician's office (e.g., RNs and MDs who are also IBCLCs); and
- It is based on data from 10 years ago, since which time the number and use of IBCLCs has increased dramatically (CDC, 2008). Again CHBRP confirmed the validity of this 6% estimate with the content expert and thus uses it as the estimate of delivering women who see an outpatient IBCLC.

This means that approximately 25,000 delivering women affected by AB 513 will receive outpatient lactation consultation from an IBCLC.

CHBRP uses data from our content expert to estimate that women who see a lactation consultant on an outpatient basis see that provider on average 1.5 times. Therefore, approximately 37,500 ($25,000 \times 1.5$) outpatient IBCLC visits are provided to delivering women affected by AB 513.

Breast pump rental utilization

To estimate baseline breast pump utilization, CHBRP uses data from the published literature, grey literature (e.g. technical reports, white papers, or working papers), and content experts as follows:

- CHBRP assumes that 62% of delivering women in California are breast-feeding their babies for at least 6 months (CDC, 2008).
- CHBRP further assumes that 25% of these women who breast-feed for at least 6 months use breast pumps regularly. This is based on findings in the published literature that 25% of breast-feeding women with infants up to the age of 6 months report to having expressed milk on a regular schedule during the prior 2 weeks and/or at some time since the birth of their infant (Labiner-Wolfe et al., 2008). CHBRP assumes that women who express milk regularly use either rented or purchased electric pumps, or purchased battery-operated pumps. Based on information from content experts as well as on recommendations in the grey literature (CU, 2007), CHBRP assumes that women who pump sporadically would use manual pumps or would hand-express milk and thus not rent or purchase electric pumps.
- The 25% of women who rent or purchase electric pumps is further divided into two groups: those who rent and those who purchase pumps; only the rental of breast pumps is covered under this mandate.
- CHBRP assumes that 10% of breast-feeding women rent pumps, and that 15% purchase pumps for reasons of convenience or personal preference (not for reasons of cost). Therefore CHBRP estimates baseline breast pump rental utilization at 10% of the 62% of delivering women who breast-feed for at least 6 months. This equates with 6.2% of delivering women in California, or approximately 34,200 women renting breast pumps.

Unit price

CHBRP estimates an average incremental cost of \$0.00 per delivering woman with maternity coverage for lactation consultation during delivery admission; this is because these costs are bundled in to inpatient delivery admission costs, so there is no incremental cost of IBCLC services during delivery admission.

CHBRP estimates an average unit cost of \$95.00 per consultation for outpatient IBCLC lactation consultation. In the absence of claims data on the level of use of these services, the unit cost is calculated using a weighted utilization distribution of IBCLCs serving in public agencies, working as private consultants, and providing in-home private consultations; average unit costs in each such sector (\$65, \$100, and \$125 for public agency, private, and in-home consultations, respectively); and average utilization of such services (see Appendix D for additional details). For outpatient lactation consultation provided by public agencies, CHBRP estimates that the total \$65 fee charged by IBCLCs to the agency for the service is subsidized by the agency, such that women pay \$10 out of pocket and the agency pays \$55.

CHBRP estimates an average cost of \$16.00 per delivering woman for breast pump rental. This cost is calculated using data provided by content experts for: average unit costs of breast pump rental at \$10 per rental week; average breast pump utilization by 6.2% of delivering women; and average utilization duration of 6 months per rental.

For women who use these services but lack coverage for them, CHBRP estimates costs per user of \$0, \$143 (an average of 1.5 consultations at an average cost of \$95 per consultation), and \$260 (\$10/week * 26 weeks of use) for inpatient lactation consultation, outpatient lactation consultation, and breast pump rental, respectively.

The baseline costs associated with the mandate given current coverage levels and utilization are presented in Table 3.

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

CHBRP estimates that costs resulting from lack of coverage may be shifted to other payers among public agencies who subsidize outpatient lactation consultation (\$55 of the total \$65 cost per consultation). There would be no such cost shift for inpatient lactation consultation during delivery admission because this is currently fully covered for all people with maternity benefits. For breast pump rental, WIC provides free breast pump rental (loan) to qualified persons (based on income eligibility requirements); however, utilization of this service is limited by problems of waiting time (Meehan et al., 2008). In California, WIC reports a supply of 7,500 pumps for the approximately 312,000 lower-income delivering women in California. In addition, because Medi-Cal provides coverage for breast pump rental, many women who might use this service through WIC would likely already have coverage for rental through Medi-Cal. CHBRP therefore assumes that although there could be a small shift in utilization for noncovered breast pump rental to WIC agencies, this effect is negligible and therefore assumed at zero for the purposes of this analysis.

Public Demand for Coverage

As a way to determine whether public demand exists for the proposed mandate (based on criteria specified under Senate Bill 1704 [2007]), CHBRP reports on the extent to which collective bargaining entities negotiate for, and the extent to which self-insured plans currently have, coverage for the benefits specified under the proposed mandate.

Currently, the largest public self-insured plans are the preferred provider organization (PPO) plans offered by CalPERS. These plans provide coverage and benefits similar to those offered in the commercial market (which are described fully in the preceding section on premandate coverage). To further investigate public demand, CHBRP also utilized the analysis specific carrier survey to ask carriers administering plans or policies for other (non-CalPERS) self-insured groups whether the relevant coverage and benefits differed from what is offered in the commercial markets. The responding carriers indicated that there were no substantive differences, again suggesting that the market is meeting public demand.

Based on conversations with the largest collective bargaining agents in California, CHBRP concluded that unions currently do not include service-level details such as lactation consultation or breast pump rental in their health insurance policy negotiations, especially for relatively small cost items. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and coinsurance levels.²³

Given the lack of specificity in labor negotiated benefits and the general match between commercial and self-insured health insurance products, CHBRP concludes that public demand is essentially satisfied by the current state of the market.

Impacts of Mandated Coverage

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

Impact on supply and on the health benefit

CHBRP assumes that there is no impact on the supply or health benefit (i.e., medical effectiveness) of this mandate.

Impact on per-unit cost

Currently, lactation consultant and breast pump rental are services used by individuals for whom such treatment either meets specific criteria for medical necessity (e.g., medical conditions of the infant or nursing mother prevent the infant from latching-on to breast-feed, and/or result in separation between mother and infant), or is needed in order to

²³ Personal communication with the California Labor Federation and member organizations, January 2007.

continue effectively breast-feeding. Current use of these services for breast-feeding women is generally effective in helping them to continue breast-feeding at the desired levels. In addition, CHBRP assumes that the level of patient compliance/adherence in use of these services would not be affected by AB 513, except for the small increase in utilization of breast pump rental among lower-income women. Coverage for lactation consultation during delivery admission will remain constant at 96.2% of the population. Finally, outpatient lactation consulting and breast pump rental—the two services for which coverage would change as a results of this mandate—are not used by a large percentage of the population, and patient demand would not create price pressures postmandate. Since AB 513 would not affect the effectiveness or place price pressures on lactation consultant services or breast pump rentals, CHBRP does not anticipate any changes to the per-unit cost of these products due to AB 513.

Postmandate coverage

AB 513 would not change coverage for lactation consultation during delivery admission, which is already fully covered for all persons with maternity services benefits. However, the mandate would extend coverage for postpartum lactation consultation and breast pump rental to persons in DMHC and CDI-regulated products. The change in coverage is presented in Table 2. In addition, AB 513 would deepen the scope of coverage for persons enrolled in DHMC-regulated plans.

The impact that AB 513 would have on scope of coverage is dependent on whether plans or policies are regulated by DMHC or CDI. Should AB 513 become law, DMHC-regulated plans would likely be required to expand coverage to include outpatient lactation consultation delivered by an IBCLC and breast pump rentals for any nursing mother. The expansion would be due to the fact that DMHC-regulated plans are required to provide mandated benefits according to medical necessity criteria. To establish medical necessity for mandated services, DMHC uses current clinical guidelines and standards of care. CDI-regulated policies have no similar requirement, thus CDI considers only the language of the bill and contractual agreements between the insurer and the purchaser to establish what must be covered. Therefore, CDI-regulated policies could continue to restrict lactation consultation to the delivery admission and only cover breast pump rental if certain medical conditions are present in the mother or child. AB 513 would, however, require all CDI-regulated policies that provide maternity benefits to cover breast pump rental, which would increase the number of persons with the limited scope coverage.

CHBRP estimates that over 8.5 million people who currently do not have coverage for outpatient lactation consultation would gain this coverage if this mandate were enacted, and approximately 2.8 million who currently do not have coverage for breast pump rental would gain such coverage. Thus, of the 416,000 women affected by AB 513 who deliver babies, approximately 6,000 women who currently use outpatient lactation consultation, but do not have coverage, and approximately 2,000 who currently rent breast pumps, but do not have coverage, would gain coverage for these services were this mandate to be enacted.

Table 2. Impacts on Coverage Level by Market Segment, California, 2009

	DMHC-Regulated							CDI-Regulated		
	Large Group	Small Group	Individual	CalPERS HMO	Medi-Cal		Healthy Families Managed Care	Large Group	Small Group	Individual (a)
					Managed Care 65 and Over	Managed Care Under 65				
Pre-mandate coverage level										
Lactation Consultation During Delivery Admission	100%	100%	100%	100%	100%	100%	100%	100%	100%	22%
Lactation Consultation Postpartum	53%	41%	44%	53%	100%	100%	0%	0%	0%	0%
Breast Pump Rental	90%	84%	80%	90%	100%	100%	0%	97%	76%	18%
Post-mandate coverage level										
Lactation Consultation During Delivery Admission	100%	100%	100%	100%	100%	100%	100%	100%	100%	22%
Lactation Consultation Postpartum (b)	100%	100%	100%	100%	100%	100%	100%	0%	0%	0%
Breast Pump Rental	100%	100%	100%	100%	100%	100%	100%	100%	100%	22%
Change										
Lactation Consultation During Delivery Admission	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Lactation Consultation Postpartum	47%	59%	56%	47%	0%	0%	100%	0%	0%	0%
Breast Pump Rental	10%	16%	20%	10%	0%	0%	100%	3%	24%	5%

Source: *California Health Benefits Review Program, 2009*

Notes: (a), Only 22% of persons with coverage from CDI-regulated individual market policies have maternity benefits. The mandate would not extend maternity coverage, only mandate coverage of lactation consultation and breast pump rental among plans and policies that provide maternity benefits. (b) Change in the scope of coverage for lactation consultation would impact postpartum coverage only for persons enrolled in DMHC-regulated plans.

Key: CalPERS=California Public Employees' Retirement System; HMO=health maintenance organization and point of service plan

Changes in coverage as a result of premium increases

This estimated premium increase associated with this mandate would not have a measurable impact on the number of individuals who are uninsured. CHBRP calculates an estimate of the number of enrollees who would drop health insurance if premium increases are estimated to be more than 1%.²⁴ CHBRP does not anticipate loss of insurance coverage, changes in availability of the benefit beyond those subject to the mandate, changes in offer rates of insurance, changes in employer contribution rates, changes in take-up of insurance by employees, or purchase of individual policies, due to the small size of the increase in premiums after the mandate.

How Would Utilization Change as a Result of the Mandate?

CHBRP estimates no postmandate change in the utilization rates for lactation consultation during delivery admission, outpatient lactation consultation, or breast pump rental.

IBCLC lactation consultation during delivery admission

The utilization of lactation consultation from IBCLCs during delivery admission or as an outpatient service is estimated to remain essentially unchanged under AB 513, as evidence from content experts suggests that such services are currently utilized at a level that meets demand, and evidence from the CDC indicates that breastfeeding in California is already at a relatively high rate (CDC, 2008). For lactation consultation during delivery admission, experts suggest that lactation consultation is provided on an as-needed basis during delivery admission and would not change with the passage of this mandate. Because these services are covered for all individuals with maternity coverage (or 96.2% of all populations subject to this mandate) currently, there would be no change in covered population and therefore no reason for the population using the services to change postmandate. Although not all in-hospital lactation services are provided by IBCLCs, because they are all billed as part of a bundled service, if these services were covered by IBCLCs due to the passage of this mandate, there is no evidence to suggest that insurers would pay more for the service than they currently are. CHBRP therefore assumes that billing would remain unchanged, that costs to all parties—patients, hospitals, IBCLCs, and payers—would remain unchanged, and thus that utilization would also remain unchanged.

Outpatient IBCLC lactation consultation

CHBRP also estimates no change in these utilization rates postmandate for outpatient lactation consultation for several reasons:

- The service is usually accessed only once or twice, so the financial constraint is limited.
- Among lower-income women, for whom the price of outpatient lactation consultation may be a barrier to use, the service is currently fully covered by Medi-Cal.

²⁴ CHBRP's methodology is available at: www.chbrp.org/documents/uninsured_020707.pdf.

- Options other than fully priced private IBCLC consultations are available. Free lactation consultation is available through organizations such as La Leche League and public agencies offer the service at costs between 50%-65% that of private IBCLCs (\$65 as compared with \$100-\$125, for public and private, respectively).

Therefore based on expert clinical opinion, there is not an under-utilization of this service among lactating women. Breast-feeding women who need outpatient lactation consultation or breast pump rental for noncovered reasons would have purchased it regardless of insurance coverage, or found less-costly alternatives if necessary in the case of outpatient lactation consultation. It is possible that persons who may have delayed or limited their use of outpatient lactation consultation or breast pump rental may increase their utilization with coverage for these services under AB 513. In some cases, individuals wanting private lactation consultation with an IBCLC may have instead used alternatives such as free services with organizations such as La Leche League, and coverage under AB 513 may shift some of this utilization to IBCLCs. However, CHBRP does not estimate a significant increase in utilization of lactation consultation or breast pump rental by these individuals. Lastly, neither the research literature nor claims data provide sufficient information to predict the percentage of individuals who would utilize lactation consultation from free services as compared with those who would use it with IBCLCs. As there is no evidence to suggest that such free lactation consultation services are less effective at helping women to maintain breast-feeding than those provided by IBCLCs, CHBRP has no evidence to suggest that utilization would change even if IBCLC services were covered at no or little cost.

Although financial difficulties resulting from the cost of these services may slightly reduce the utilization of outpatient consultation for those without current coverage, decreased demand because of limitations in insurance coverage are difficult to quantify, and expert opinion indicates that any such effect would be negligible. If outpatient lactation consultation were to be fully covered, although there may be a small shift in utilization from free or public lactation consultation to consultations by private IBCLCs, CHBRP assumes that any such effect would be negligible and that therefore no such change would occur.

CHBRP has estimated that the baseline utilization of lactation consultation is consistent with the amount demanded by lactating women and would not change postmandate. Any potential increases in utilization levels for both types of lactation consultation are considered to be negligible.

Breast pump rental

CHBRP assumes that due to the low cost (\$10/week) of breast pump rental, demand for renting breast pumps is currently being met at the current 6.2% utilization level, regardless of coverage. Therefore CHBRP assumes that utilization of breast pump rental services would remain constant at 6.2% of delivering women if it were to become a covered benefit with the passage of this mandate.

Although the bill does not preclude carriers from conducting health plan utilization or medical-necessity reviews for lactation consultation or breast pump rental, for DMHC-regulated plans who apply clinical guidelines to their medical necessity reviews, this hurdle would be lowered; this would not be the case for CDI policies. Because CHBRP does not assume that current utilization is impacted by these limits, any such reduction in medical necessity review that may occur postmandate would not affect utilization of these services and would only be seen in the shift of costs from members to plans.

AB 513 does not preclude carriers from charging copayments, coinsurance, deductibles, or other cost sharing for this benefit as is done for most currently covered services. Specifically, current coverage of breast pump rental is based on its coverage as durable medical equipment (DME), and therefore is subject to the same copayments, coinsurance, deductibles, or other cost sharing as that of DME. CHBRP assumes that insurers would continue to apply the same cost-sharing requirements to breast pump rental if it became covered under this mandate.

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

All health plans and insurers include a component for administration and profit in their premiums. The estimated impact of AB 513 on premiums includes the assumption that plans and insurers would apply their existing administration and profit loads to the marginal increase in health care costs produced by the mandate. Given that utilization rates would remain the same after the mandate, the estimated increase of total expenditures is mainly due to the increase of the administrative costs as a proportion of the premium. Under AB 513, CHBRP estimates an increase of \$607,000 in administrative costs—or 0.0007% of expenditures—for plans regulated by the DMHC and CDI.

Impact of the Mandate on Total Health Care Costs

Changes in total expenditures

CHBRP estimates an increase in total annual expenditures of \$607,000 (0.0007%) postmandate. The breakdown of how the total increase in expenditures is distributed among premiums and cost sharing is summarized below.

- Employers' (including CalPERS) share of premium increases is estimated to be \$2,820,000, or 0.0056%. In the large-group market, this is an increase of 0.0059% (\$0.0205 PMPM) in the DMHC-regulated market, and 0% (\$0 PMPM) in the CDI-regulated market. In the small-group market, this is an increase of 0.0075% (\$0.0238 PMPM) in the DMHC-regulated market, and 0% (\$0 PMPM) in the CDI-regulated market.
- Enrollees in individually purchased plans would face an increase of \$323,000, (0.0054%) in premiums. This is an increase of 0.0084% (\$0.0278 PMPM) in the DMHC-regulated market, and 0% (\$0 PMPM) in the CDI-regulated individual market.

- Enrollees' share of premium increases in the group plans is estimated to be \$756,000, or 0.0056%.
- CalPERS' employers' share of premium increases is estimated to be \$178,000, or 0.0056%. Of the amount CalPERS would pay in additional total premiums, about 59% (\$105,000) would be the cost borne by the General Fund for CalPERS members who are state employees.
- Copayments, deductibles, and other forms of cost sharing by all insured are estimated to decrease by approximately \$2,144,000 (-0.0336%).
- Out-of-pocket expenses for noncovered benefits are estimated to decrease by approximately \$1,326,000 out of about \$1,767,000 currently spent annually on lactation consultation and breast pump rental by enrollees without coverage, a decrease of 75.0424%.
- State expenditures for Medi-Cal and those for Healthy Families are estimated to remain unchanged.

Offsets

CHBRP estimates no perceptible savings or offsets in other health care costs due to AB 513 since the bill is not expected to significantly reduce or increase use of other types of health care services.

Impact on long-term costs

CHBRP estimates that there would be no measurable long-term impacts of AB 513 in addition to the ongoing annual impacts presented early in this section. As reviewed in the section on medical effectiveness of the mandate, we have investigated relevant outcomes and estimate there to be none based on existing, available evidence.

Impacts for Each Category of Payer Resulting From the Benefit Mandate

Changes in expenditures and PMPM amounts by payer category

The shift in expenditures from out-of-pocket to health plans and insurers results in a range of increases in premiums as follows:

- Large-group market: an estimated premium increase of 0.0059% (\$0.0205 PMPM) in the DMHC-regulated market, and 0% (\$0 PMPM) in the CDI-regulated market.
- Small-group market: an estimated premium increase of 0.0075% (\$0.0238 PMPM) in the DMHC-regulated market, and 0% (\$0 PMPM) in the CDI-regulated market.
- Individual market: an estimated premium increase of 0.0084% (\$0.0278 PMPM) in the DMHC-regulated market, and 0% (\$0 PMPM) in the CDI-regulated individual market.
- CalPERS: an estimated premium increase of 0.0056% (\$0.0214 PMPM).

The projected cost impacts as a result of AB 513 are detailed in Table 4.

Impact of changes in private coverage on public programs

CHBRP estimates that the mandate will produce no measurable impact on enrollment in public insurance programs or on utilization of covered benefits in the public sector.

Impact on Access and Health Service Availability

For AB 513, there is no way to use claims data to measure current availability or utilization of lactation consultation services with IBCLCs or breast pump rental. CHBRP has used information from carrier surveys, content experts, and the grey literature to obtain this information. AB 513 is estimated to affect access to lactation consultation and breast pump rental by removing potential financial barriers when these services are purchased without insurance coverage. The unit prices of these services may be substantial enough to be a hardship for some individuals who are currently without coverage. Because CHBRP is unable to estimate the degree to which access is limited because of such hardships, CHBRP is unable to estimate whether AB 513 will affect access to these services. AB 513 is also not expected to improve the ease of purchasing of such products; nor is it expected to change the availability of these products, because their current availability is estimated to already meet the current level of demand.

Consumer complaints

As of September 2008, the DMHC has received 51,372 complaints since 2001, of which 24 were related to lactation consultation and breast pump rental.

Appeals to the Independent Medical Review Program

Patients who dispute health plan denials, because procedures are not considered medically necessary or are considered experimental or investigational, can appeal to the California Independent Medical Review (IMR) Program. CHBRP searched DMHC's IMR database to identify patient disputes related to lactation consultation and breast pump rental for the services covered by AB 513. As of September 2008, DMHC had completed 8,382 independent medical reviews since 2000, and there were no patient disputes regarding the medical necessity of lactation consultation or breast pumps. However, it is important to note that only items that are considered covered make it to IMR.

Table 3. Baseline (Premandate) Per Member Per Month Premium and Expenditures by Market Segment, California, 2009

	DMHC-Regulated							CDI-Regulated			Total Annual
	Large Group	Small Group	Individual	CalPERS(b) HMO	Medi-Cal(c)		Healthy Families Managed Care	Large Group	Small Group	Individual	
					Managed Care 65 and Over	Managed Care Under 65					
Total population in plans subject to state regulation (a)	11,100,000	2,844,000	966,000	820,000	159,000	2,366,000	715,000	400,000	932,000	1,038,000	21,340,000
Total enrolled in plans subject to AB 513	11,100,000	2,844,000	966,000	820,000	159,000	2,366,000	715,000	400,000	932,000	1,038,000	21,340,000
Average portion of premium paid by employer	\$279.83	\$246.48	\$0.00	\$321.26	\$239.00	\$128.09	\$74.97	\$341.25	\$288.13	\$0.00	\$58,443,353,000
Average portion of premium paid by employee	\$69.94	\$71.52	\$330.89	\$56.69	\$0.00	\$0.71	\$10.22	\$97.61	\$54.11	\$169.28	\$19,440,350,000
Total premium	\$349.77	\$318.00	\$330.89	\$377.95	\$239.00	\$128.80	\$85.19	\$438.86	\$342.24	\$169.28	\$77,883,703,000
Member expenses for covered benefits (deductibles, copays, etc.)	\$18.90	\$24.61	\$54.10	\$19.49	\$0.00	\$0.59	\$2.32	\$53.72	\$124.95	\$41.39	\$6,384,077,000
Member expenses for benefits not covered	\$0.01	\$0.01	\$0.01	\$0.01	\$0.00	\$0.00	\$0.00	\$0.01	\$0.01	\$0.02	\$1,767,000
Total expenditures	\$368.68	\$342.63	\$385.01	\$397.45	\$239.00	\$129.39	\$87.51	\$492.59	\$467.21	\$210.69	\$84,269,547,000

Source: California Health Benefits Review Program, 2009.

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

(b) Of these CalPERS members, about 59% are state employees.

(c) Medi-Cal state expenditures for members under 65 years of age include expenditures for the Major Risk Medical Insurance Program (MRMIP) and the Access for Infants and Mothers (AIM) program. Medi-Cal state expenditures for members over 65 years of age include those with Medicare coverage.

Table 4. Impacts on Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2009

	DMHC-Regulated							CDI-Regulated			Total Annual
	Large Group	Small Group	Individual	CalPERS (b) HMO	Medi-Cal(c)		Healthy Families Managed Care	Large Group	Small Group	Individual	
					Managed Care 65 and Over	Managed Care Under 65					
Total population in plans subject to state regulation (a)	11,100,000	2,844,000	966,000	820,000	159,000	2,366,000	715,000	400,000	932,000	1,038,000	21,340,000
Total population in plans subject to AB 513	11,100,000	2,844,000	966,000	820,000	159,000	2,366,000	715,000	400,000	932,000	1,038,000	21,340,000
Average portion of premium paid by Employer	\$0.0164	\$0.0186	\$0.0000	\$0.0181	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$2,998,000
Average portion of premium paid by Employee	\$0.0041	\$0.0052	\$0.0278	\$0.0032	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$1,078,000
Total premium	\$0.0205	\$0.0238	\$0.0278	\$0.0214	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$4,077,000
Member expenses for covered benefits (deductibles, copays, etc.)	-\$0.0120	-\$0.0107	-\$0.0100	-\$0.0120	\$0.0000	\$0.0000	\$0.0000	\$0.0005	\$0.0043	\$0.0008	\$2,144,000
Member expenses for benefits not covered	-\$0.0061	-\$0.0084	-\$0.0089	-\$0.0061	\$0.0000	\$0.0000	\$0.0000	-\$0.0005	-\$0.0043	-\$0.0008	\$1,326,000
Total expenditures	\$0.0024	\$0.0046	\$0.0089	\$0.0032	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$607,000
Percentage Impact of Mandate											
Insured premiums	0.0059%	0.0075%	0.0084%	0.0056%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0052%
Total expenditures	0.0006%	0.0014%	0.0023%	0.0008%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0007%

Source: California Health Benefits Review Program, 2009.

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

(b) Of these CalPERS members, about 59% are state employees.

(c) Medi-Cal state expenditures for members under 65 years of age include expenditures for the Major Risk Medical Insurance Program (MRMIP) and the Access for Infants and Mothers (AIM) program. Medi-Cal state expenditures for members over 65 years of age include those with Medicare coverage.

Key: CalPERS=California Public Employees' Retirement System; HMO=health maintenance organization and point of service plan

PUBLIC HEALTH IMPACTS

The overall consensus from the medical community is that breast-feeding has substantial health benefits to both infants and mothers. An evaluation of the evidence of breast-feeding conducted by the Agency for Healthcare Research and Quality found that breast-feeding was associated with numerous health benefits for infants and children, including a reduction in risk of acute otitis media (ear infections), gastroenteritis, severe lower respiratory tract infections, atopic dermatitis, asthma among young children, obesity, type 1 and type 2 diabetes, childhood leukemia, sudden infant death syndrome (SIDS), and necrotizing enterocolitis (Ip et al., 2007). Additionally, Ip et al. (2007) found that a history of lactation was associated with a reduced risk of type 2 diabetes and breast and ovarian cancer.

The Impact of the Proposed Mandate on the Health of the Community

Due to the health benefits of breast-feeding, the American Academy of Pediatricians and American Academy of Family Physicians recommend exclusive breast-feeding for the first 6 months of life and continued breast-feeding for at least 1 year (AAP, 2005; Moreland and Coombs, 2000). The primary health impact evaluated for this analysis is whether by mandating insurance coverage for lactation consultants and electric breast pump rentals, AB 513 will increase breast-feeding initiation rates and duration of breast-feeding to the extent to realize these health benefits.

The *Medical Effectiveness* section concluded that the evidence indicates that electric breast pumps are effective in prolonging breast-feeding duration; however, additional professional lactation consultation was not found to be more effective than standard hospital-based lactation consultation in breast-feeding outcomes. Utilization of lactation consultants and electric breast pumps are not expected to increase in the short-term due to AB 513. As a result, AB 513 is not expected to generate health benefits associated with increased breast-feeding. However, AB 513 is expected to decrease the out-of-pocket costs for approximately 6,000 women utilizing outpatient lactation consultants and 2,000 who use electric breast pump rentals each year.

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

In California, breast-feeding initiation and duration rates vary by race and ethnicity. Table 5 describes racial and ethnic differences in ever breast-feeding and exclusive breast-feeding while infants are in the hospital. Compared to white women, all minority groups had statistically significant lower rates of ever breast-feeding and exclusive breast-feeding while in the hospital. The Centers for Disease Control and Prevention has also reported racial disparities with African American women having lower rates of breast-feeding and exclusive breast-feeding compared to white women and other minorities (CDC, 2008). Literature on racial and ethnic disparities in breast-feeding has found that minority immigrant women are more likely to breast-feed compared with women in the same racial/ethnic category who were born in the United States

(Gibson-Davis and Brooks-Gunn, 2006; Persad and Mensinger, 2008; Singh et al., 2007). An analysis of California mothers found that foreign-born Latina women were the most likely to breast-feed of all racial and ethnic groups (Heck et al., 2006).

Disparities in breast-feeding rates are important because of the health benefits associated with breast-feeding. However, little research has examined breast-feeding disparities as a link to racial and ethnic disparities in the United States. One study by Woo et al. (2008) found that breast-feeding differences were a mediator between racial disparities in adolescent obesity. Findings by Forste et al. (2001) suggest that decreasing breast-feeding disparities between African American women and white women could narrow the racial gap in infant mortality.

The literature has identified numerous factors that are associated with a woman's intention, initiation, and duration of breast-feeding. In addition to race and ethnicity, decreased breast-feeding rates has been found to be associated with younger maternal age, lower education, lower incomes, more children in household, smoker in household, living in nonwestern regions of the United States, and maternal full-time employment (Gibson-Davis and Brooks-Gunn, 2006; Kogan et al., 2008; McKinley and Hyde, 2004; Mitra et al., 2004; Persad and Mensinger, 2008; Ryan et al., 2006). Some literature was identified that discussed racial and ethnic differences in barriers to breast-feeding initiation and continuation. In analyzing reasons for stopping breast-feeding before the recommended time period, the most common reason among all women was the perception that their breast milk supply was insufficient to nurture their baby and Latino women are more likely than white or African American women to report this perceived problem (Hurley et al., 2008; Li et al., 2008). African American women were more likely than white women to report that they "preferred bottle feeding" as the reason for not starting breast-feeding and that they stopped breast-feeding earlier to return to work (Forste et al., 2001; Hurley et al., 2008).

No literature was found that discussed racial disparities in breast-feeding associated with differential cost or coverage of lactation consultants or breast pump rentals. Since AB 513 is not expected to result in an increase in lactation consultations or electric breast pumps, AB 513 is not expected to result in a decrease in racial health disparities.

Table 5. California In-Hospital Breast-Feeding, 2007

Race/Ethnicity	Any Breast-Feeding	Exclusive Breast-Feeding
All	86.6 (86.5-86.7)	42.7 (42.6-42.9)
African American	74.7 (74.1-75.2)	33.1 (32.5-33.7)
American Indian	87.1 (84.5-89.3)	56.6 (53.0-60.1)
Asian	88.2 (87.9-88.4)	43.8 (43.4-44.2)
Multiple race	88.4 (87.9-88.8)	55.8 (55.1-56.6)
Pacific Islander	75.7 (72.8-78.4)	36.3 (33.3-39.4)
Other	83.3 (82.4-84.2)	44.3 (43.1-45.5)
Hispanic	85.8 (85.7-85.9)	32.4 (32.2-32.6)
White	90.0 (89.9-90.2)	63.6 (63.3-63.9)

Source: California In-Hospital Breast-Feeding as Indicated on the Newborn Screening Test Form. (CDPH, 2007).

The Extent to Which the Proposed Service Reduces Premature Death and the Economic Loss Associated With Disease

Many of the health outcomes found to be associated with breast-feeding are serious illnesses that can result in premature death. In particular, breast-feeding is associated with the prevention of childhood leukemia, sudden infant death syndrome, and necrotizing enterocolitis among infants and children, as well as the prevention of breast and ovarian cancer in mothers, which are causes of premature death. Since AB 513 is not expected to result in an increase in lactation consultation or use of electric breast pumps, AB 513 is not expected to reduce premature death.

There are important economic benefits associated with breast-feeding. One analysis stated that an increase in breast-feeding rates could lead to a decrease in medical expenditures, a decrease in formula expenditures, and a decrease in lost earnings of parents when caring for sick children (Weimer, 2001). In one managed care plan, Ball and Wright (1999) estimated that for every child that never breast-fed, the managed care system had increased medical costs of \$331 to \$475, based on three preventable illnesses and that additional economic costs associated with lost productivity would also be incurred. Since AB 513 is not expected to result in an increase in lactation consultation or use of electric breast pumps, AB 513 is not expected to decrease the

economic burden associated with health conditions that could be prevented through increased breast-feeding.

Long-Term Health Impacts

There are long-term health impacts associated with breast-feeding, particularly in the reduction of risk for health conditions such as asthma, obesity, type 1 and type 2 diabetes, and childhood leukemia among young children who breast-fed and a reduction in the risk of breast cancer, ovarian cancer, and type 2 diabetes for mothers who breast-fed (Ip et al., 2007). Since AB 513 is not expected to result in an increase in lactation consultation or use of electric breast pumps, AB 513 is not expected to result in long-term health benefits.

APPENDICES

Appendix A: Text of Bill Analyzed

BILL NUMBER: AB 513 INTRODUCED
BILL TEXT

INTRODUCED BY Assembly Member De Leon

FEBRUARY 24, 2009

An act to add Section 1367.625 to the Health and Safety Code, and to add Section 10123.875 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 513, as introduced, De Leon. Health care coverage: breast-feeding.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975 (Knox-Keene Act), provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of that act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Under existing law, health care service plans and health insurers are required to offer specified types of coverage as part of their health care service plan contracts or health insurance policies. Existing law imposes specified requirements upon a health care service plan contract or health insurance policy that provides maternity coverage.

This bill would require a health care service plan and a health insurer to include coverage for lactation consultation and for the rental of breast pumps as part of their health care service plan contracts or health insurance policies that provide maternity coverage.

Because this bill would specify additional requirements under the Knox-Keene Act, the willful violation of which would be a crime, it would impose a state-mandated local program.

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

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

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

State-mandated local program: yes.

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

SECTION 1. The Legislature finds and declares the following:

(a) Breast-feeding significantly reduces children's risk for chronic diseases, such as diabetes, asthma, allergies, and infections in the gastrointestinal, urinary, and respiratory tracts. Breast-fed children have fewer visits to the doctor's office, fewer days of hospitalization, and take fewer medications than children who were formula-fed. Research provides strong evidence that breast-feeding decreases the incidence or severity of diarrhea, lower respiratory infection, otitis media, bacteremia, bacterial meningitis, botulism, and necrotizing enterocolitis. There are a number of studies that show a possible protective effect of exclusive breast-feeding against sudden infant death syndrome (SIDS), insulin-dependent diabetes mellitus, Crohn's disease, ulcerative colitis, lymphoma, allergic diseases, and other chronic digestive diseases. Breast-feeding has also been related to possible enhancement of cognitive development and a decreased chance of obesity in childhood and adulthood. Studies show that breast-feeding also reduces the mother's risk for type 2 diabetes and breast and ovarian cancers.

(b) All major health organizations recommend that babies get no other food or drink besides breast milk for the first six months of their life, with continued breast-feeding for at least the first one to two years of life, as long as it is mutually desired. Exclusive breast-feeding for three months has been shown to reduce health care costs for infants in the first year of life alone by up to four hundred seventy-five dollars (\$475), compared to nonbreast-fed infants.

(c) Lactation consultation provided by an international board certified lactation consultant (IBCLC) has been shown to help women address the difficulties with breast-feeding and can assist with the initiation and continuance of breast-feeding.

(d) Therefore, it is essential to clarify that all health coverage made available to California consumers that provides maternity coverage, 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, shall include coverage for lactation consultation by an international board certified lactation consultant (IBCLC) and coverage for the rental of breast pumps.

SEC. 2. Section 1367.625 is added to the Health and Safety Code,

to read:

1367.625. Every health care service plan contract, except a specialized health care service plan contract, that provides maternity coverage, and that is issued, amended, renewed, or delivered on or after January 1, 2010, shall provide coverage for lactation consultation with an international board certified lactation consultant (IBCLC) and for the rental of breast pumps.

SEC. 3. Section 10123.875 is added to the Insurance Code, to read:

10123.875. Every policy of health insurance that provides maternity coverage, and that is issued, amended, renewed, or delivered on or after January 1, 2010, shall provide coverage for lactation consultation with an international board certified lactation consultant (IBCLC) and for the rental of breast pumps.

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

Appendix B: Literature Review Methods

Appendix B describes methods used in the medical effectiveness literature review for AB 513, a bill that would require health plans to provide coverage for lactation consulting provided by an International Board Certified Lactation Consultant (IBCLC) and rental of breast pumps.

A literature search was conducted to assess the medical effectiveness of these services. The search encompassed all pertinent studies published from January 2007 to present. The timeframe for the literature search was truncated because the medical librarian identified three Cochrane Reviews (Becker et al., 2008; Britton et al., 2007; Dyson et al., 2005) and a systematic review produced for the United States Preventive Services Task Force (Chung et al., 2008) that synthesized literature on the effectiveness of lactation consulting and breast pumps published prior to January 2007. The literature search was limited to articles published in English.

PubMed (Medline), the Cochrane Library, the CABI Bioscience Database, EconLit, Global Health, Google Scholar, Scientific Web Plus, Scopus, and the Web of Science were searched. Web sites maintained by the following organizations were also searched: the Agency for Healthcare Research and Quality, the Institute for Clinical Systems Improvement, the International Network of Agencies for Health Technology Assessment, the National Guideline Clearinghouse, the National Health Service Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence, the National Institutes of Health, the Scottish Intercollegiate Guideline Network, and the World Health Organization. Additional searches were performed for the cost and public health sections of the report.

A total of 405 citations were retrieved. At least two reviewers screened the title and abstract of each citation returned by the literature search to determine eligibility for inclusion. The reviewers obtained the full text of articles that appeared to be eligible for inclusion in the review and reapplied the initial eligibility criteria. Eight pertinent studies were identified and reviewed. They included one meta-analysis of randomized controlled trials (RCTs), six individual RCTs, and one nonrandomized study with a comparison group.

The literature review was limited to studies of lactation consulting and breast pumps conducted in developed countries to help ensure that the populations of mothers and infants studied would be generalizable to the population to which AB 513 would apply. Studies in which lactation support was provided by a nonprofessional (i.e., a lay or peer counselor) were also excluded because AB 513 would require health plans to provide coverage only for lactation support services delivered by a specific group of health professionals (i.e., IBCLCs). Studies in which lactation support was provided by health professionals who were not IBCLCs were included because only two studies of the effectiveness of IBCLCs have been published and because most IBCLCs who practice in California are registered nurses or other types of licensed health professionals.

In addition, studies that evaluated the Baby-Friendly Hospital Initiative²⁵ were excluded from the review. The Baby-Friendly Hospital Initiative is a hospital-level initiative that consists of 10 elements that include practicing “rooming in” (i.e., having newborns stay in the same room as mothers) and avoiding the use of pacifiers and artificial nipples as well as providing lactation support. In these studies, the effects of lactation support cannot be separated from the effects of other elements of the intervention. Findings from these studies may not be generalizable to AB 513, which only addresses lactation consulting and breast pumps.

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 (RCTs) 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.

²⁵ The Baby-Friendly Hospital Initiative is a program sponsored by the World Health Organization and the United Nations Children’s Fund aimed at encouraging hospitals to promote breastfeeding. Information about the initiative is available at www.babyfriendlyusa.org/eng/03.html.

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.

The search terms used to locate studies relevant to the AB 513 were as follows:

PubMed (MEDLINE)

For literature on lactation consulting:

((“Breast Feeding”[Mesh] AND “Consultants”[MeSH Terms]) OR “IBCLC”[text] OR lactation consulta*[text}) AND “Health Care Evaluation Mechanisms”[Mesh]

For literature on breast pumps:

(“Breast Feeding”[Mesh]) AND (“Suction/instrumentation”[Mesh]) OR breast pump*[txt]

CABI Bioscience Database, Cochrane Library, EconLit, Global Health, Google Scholar, Scientific Web Plus, Scopus, and Web of Science

breast pumps

breastfeeding consultants

IBCLC

lactation consulta*

* indicated that the term was truncated to retrieve citations in which multiple variants on the term were used (e.g., lactation consultant, lactation consultants, lactation consultation)

Appendix C: Summary Findings on Medical Effectiveness

CHBRP reviewed clinical guidelines from the United States Department of Health and Human Services (USDHHS) and the United States Preventive Services Task Force (USPSTF) to identify the recommendations they have made regarding breast-feeding, lactation consulting, and the use of breast pumps. Clinical guidelines issued by the following professional societies were also reviewed: the Academy of Breastfeeding Medicine (ABM), the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP), and the American College of Obstetricians and Gynecologists (ACOG). These agencies and professional societies were selected because they are the agencies and societies most focused on the health of mothers and children. Table C-1 presents information from the guideline review.

Table C-1. Summary of Guidelines Regarding Breast-Feeding, Lactation Counseling, and Breast Pumps

Organization (Year Issued)	Recommended Breast-Feeding Schedule	Recommended Lactation Counseling	Recommended Use of Breast Pumps
Academy of Breastfeeding Medicine (2007, 2008)	Recommends exclusive human milk for first 6 months of life. Continued breast-feeding for the first one to two years of life.	Recommends that medical professionals and health systems promote and support breast-feeding.	Recommends that mothers who need to be separated from a sick or premature infant be taught to hand-express milk or to use a double electric breast pump.
American Academy of Family Physicians (2007)	Recommends exclusive human milk for first 6 months of life.	Recommend that family physicians provide breast-feeding support and education after mother and baby are discharged from the hospital and “develop a working relationship with professionals with expertise in lactation issues, such as IBCLCs.”	Recommends that women use a hospital-grade double electric pump if separations from the infant will be long and frequent.
American Academy of Pediatrics (2005)	Recommends exclusive human milk for first 6 months of life. Continued breast-feeding for first 12 months of life.	Recommends prenatal- and postpartum breast-feeding education and postpartum inpatient breast-feeding evaluation by “trained caregivers” at least twice daily. During postpartum visits, recommends that pediatricians observe breast-feeding, identify and help the mother correct breast-feeding problems, and provide breast-feeding education and support. Encourages pediatricians to become familiar with organizations in their communities that provide breast-feeding education and support.	Recommends providing expressed breast milk when it is not feasible to directly breast-feed. Recommends that hospitals provide breast pumps and private lactation areas to breast-feeding patients. Encourages pediatricians to become familiar with entities in their communities that rent breast pumps.

American College of Obstetricians and Gynecologists (2007)	Recommends exclusive breast-feeding for the first 6 months of life.	Recommends that obstetrician/gynecologists and other health professionals provide breast-feeding education and support. Calls on obstetrician/gynecologists to promptly evaluate and treat breast-feeding problems and provide breast-feeding advice on a 24-hour basis.	No recommendation
United States Department of Health and Human Services (2000)	Recommends breast-feeding (no time frame specified)	Recommends that all breast-feeding mothers must have access to lactation management support provided by trained health professionals, especially during the first several weeks following birth	Encourages employers to provide access to hospital-grade, autocycling breast pumps, private lactation areas, and refrigerators for storing milk and/or on-site or nearby child care facilities at which mothers can breast-feed infants during the work day.
United States Preventive Services Task Force (2008)	Recommends breast-feeding (no time frame specified)	Recommends that health professionals provide interventions to increase the rates of initiation, duration, and exclusivity of breast-feeding.	No recommendation

Sources: AAFP, 2008; AAP, 2005; ABM, 2007, 2008; ACOG, 2007; DHHS, 2000a; USPSTF, 2008.

The following tables describe the meta-analyses and individual studies on the effectiveness of lactation support and the utilization of breast pumps on breast-feeding outcomes that were analyzed by the medical effectiveness team. Table C-2 presents information regarding the citation, type of study, topic and population studied, and the location at which a study was conducted. Tables C-3a through C-3c list studies of the effects of lactation consultation. Tables C-4a through Tables C-4c list studies of the effectiveness of breast pumps.

Table C-2. Summary of Published Studies on Effectiveness of Extra Lactation Support and Breast Pumps on Breast-Feeding

Citation	Type of Trial	Topic	Population Studied	Location^(a)
Britton et al., 2007	Meta-analysis	Lactation support ^(b) vs. standard care ^(c)	Breast-feeding mothers	Developed Countries
Bonuck et al., 2005	RCT	International Board Certified Lactation Consultant (IBCLC) support vs. standard care	Breast-feeding mothers	United States
Bonuck et al., 2006	RCT	International Board Certified Lactation Consultant (IBCLC) support vs. standard care	Breast-feeding mothers	United States
Fewtrell et al., 2001	RCT	Electric vs. manual breast pumps	Mothers of preterm infants	United Kingdom
Hayes et al., 2008	RCT	Electric vs. manual breast pumps	Mothers returning to work	United States
Groh-Wargo et al., 1995	RCT	Simultaneous vs. sequential pumping	Mothers of preterm infants	United States
Jones et al., 2001	RCT	Simultaneous vs. sequential pumping	Mothers of preterm infants	United Kingdom
Meehan et al., 2008	Quasi-RCT	Effect of breast pump rentals on breast-feeding duration	Mothers returning to work	United States

Notes:

(a) Trials performed in underdeveloped counties were excluded from this review.

(b) The following types of trials were excluded from this review: those performed in underdeveloped counties, those in which lactation support was provided by a nonprofessional (lay or peer counselors), those that evaluated prenatal intervention only, and those in which the mothers and infants had high-risk conditions. Trials that evaluated the Baby-Friendly Hospital Initiative (an intervention at the level of the entire hospital versus the individual mother and infant) were also excluded.

((c) Standard care refers to usual postpartum care that varies within and between countries.

Key: RCT=randomized controlled trial.

Table C-3a. Summary of Evidence of Effect of Additional Lactation Support versus Standard Care on Cessation of Any Breast-Feeding Before Child Reaches Age Six Months

Citation	Research Design ²⁶	Provider of Lactation Support	Statistical Significance	Direction of Effect	Size of Effect
Britton et al., 2007	Level I	Lactation consultant	Statistically significant	Favors additional lactation support	RR: 0.74 (0.61-0.90) ²⁷
	Level I	Midwives	No difference		
	Level I	Hospital breast-feeding counselor	No difference		
	Level I	RN community nurse	No difference		
	Level I	Breast-feeding counselor	No difference		
	Level II	RN lactation counselor	No difference		
	Level II	Lactation nurse	Statistically Significant	Favors additional lactation support	RR: 0.86 (0.76-0.97)
	Level I	MCH nurse lactation counseling	No difference		
	Level III	Breast-feeding consultant	No difference		
	Level I	Research midwife	No difference		
	Level I	Midwife	Statistically significant	Favors additional lactation support	RR: 0.12 (0.02-0.86)
	Level II	Community health nurse/peer counselor team	No difference		
	Level I	Certified nurse midwife	No difference		
Bonuck et al., 2005	Level II	IBCLC	Statistically significant	Favors additional lactation support	53% in intervention group vs. 39% in control group

²⁶ 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.

²⁷ RR = relative risk. In this table an RR below 1 indicates that women who receive additional lactation support were less likely to cease breast-feeding before their children reached age 6 months.

Table C-3b. Summary of Evidence on Effect of Lactation Support versus Standard Care on Cessation of Exclusive Breast-Feeding (i.e., Breast-feeding Without Supplemental Formula Feeding)

Citation	Research Design	Provider of Lactation Support	Time of Stopping	Statistical Significance	Direction of Effect	Size of Effect
Britton et al., 2007	Level I	Hospital breast-feeding counselor	Before 4 to 6 weeks	No difference		
	Level I	RN community nurse	Before 4 to 6 weeks	No difference		
	Level I	Trained breast-feeding counselor	Before 4 to 6 weeks	No difference		
	Level I	Midwife	Before 4 to 6 weeks	Statistically significant	Favors additional lactation support	RR: 0.29 (0.12-0.67)
	Level I	Hospital breast-feeding counselor	Before 3 months	No difference		
	Level I	MCH nurse lactation counseling	Before 3 months	No difference		
	Level II	Community health nurse/peer counselor team	Before 3 months	No difference		
	Level I	Research midwife	Before 4 to 6 months	No difference		
	Level II	Community health nurse/peer counselor team	Before 4 to 6 months	No difference		
Bonuck et al., 2005	Level II	IBCLC	Before 4 to 6 weeks	No difference		

Table C-3c. Summary of Evidence on Effect of Lactation Support versus Standard Care on Infant Health Outcomes

Citation	Research Design	Provider of Lactation Support	Outcome	Statistical Significance	Direction of Effect	Size of Effect
Bonuck et al., 2006	Level II	IBCLC	Gastrointestinal infections	No difference		
			Respiratory tract infections	No difference		

Table C-4a. Summary of Evidence on Effect of Breast Pumps on Duration of Infant Breast Milk Consumption and Breast-Feeding

Citation	Research Design	Intervention	Outcome	Statistical Significance	Direction of Effect	Size of Effect
Meehan et al., 2008	Level II	Women who immediately rented an electrical pump vs. women who did not rent a pump	No use of formula up to 6 months	Statistically significant	Favors immediate breast pump rental	OR: 5.5 (2.0-15.1) ²⁸
			No use of formula up to 12 months	Statistically significant	Favors immediate breast pump rental	OR: 3.0 (1.2-7.2)
	Women who were wait-listed to rent an electrical pump vs. women who did not rent a pump	No use of formula up to 6 months	Statistically significant	Favors delayed breast pump rental	OR: 2.9 (1.1-7.7)	
		No use of formula up to 12 months	No difference			
Hayes et al., 2008	Level 1	Electric pump vs. manual pump	Breast-feeding for 6 months	No difference		

²⁸ OR = odds ratio. An odds ratio above 1.0 indicates that women who rented a breast pump were more likely not to use formula to feed their infants for the time period specified.

Table C-4b. Summary of Evidence of Effect on Breast Pumps on Volume of Milk Expressed

Citation	Research Design	Intervention	Outcome	Statistical Significance	Direction of Effect	Size of Effect
Fewtrell et al., 2001	Level 1	Electric pump vs. manual foot pedal pump	Volume (ml) expressed per day	No difference		
Groh-Wrago et al., 1995	Level 1	Simultaneous vs. sequential pumping	Volume (ml) expressed per week	No difference		
Jones et al., 2001	Level 1	Simultaneous vs. sequential pumping	Volume (g) expressed per expression	Statistically significant	Favors simultaneous pumping	p < 0.01

Table C-4c. Summary of Evidence of Effect on Breast Pumps on Time to Express Milk

Citation	Research Design	Intervention	Outcome	Statistical Significance	Direction of Effect	Size of Effect
Fewtrell et al., 2001	Level 1	Electric pump vs. manual foot pedal pump	Minutes per day spent to express breast milk	Statistically significant	Favors electric pump	MD: -20 (-28, -12) ²⁹
Groh-Wrago et al., 1995	Level 1	Simultaneous vs. sequential pumping	Hours per week to express breast milk	Statistically significant	Favors simultaneous pumping	MD: -3.5 (-5.6, -1.4)

²⁹ MD = mean difference. A mean difference less than zero (i.e., a negative mean difference) indicates that women who used an electric breast pump or engaged in simultaneous pumping devoted less time to expressing breast milk.

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

This appendix describes data sources, as well as general and mandate-specific caveats and assumptions used in conducting the cost impact analysis. For additional information on the cost model and underlying methodology, please refer to the CHBRP Web site at www.chbrp.org/costimpact.html.

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

Data Sources

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

Private Health Insurance

1. The latest (2007) California Health Interview Survey (CHIS), which is used to estimate insurance coverage for California's population and distribution by payer (i.e., employment-based, privately purchased, or publicly financed). The biannual CHIS is the largest state health survey conducted in the United States, collecting information from over approximately 53,000 households. More information on CHIS is available at www.chis.ucla.edu/.
2. The latest (2008) California Employer Health Benefits Survey is used to estimate:
 - size of firm,
 - percentage of firms that are purchased/underwritten (versus self-insured),
 - premiums for plans regulated by the Department of Managed Health Care (DMHC) (primarily health maintenance organizations [HMOs] and Point of Service Plans [POS]),
 - premiums for 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 covered under employment-based health insurance.

This annual survey is currently released by the California Health Care Foundation/National Opinion Research Center (CHCF/NORC) and is similar to the national employer survey released annually by the Kaiser Family Foundation and the Health Research and Educational Trust. Information on the CHCF/NORC data is available at: www.chcf.org/topics/healthinsurance/index.cfm?itemID=133543.

3. Milliman data sources are relied on to estimate the premium impact of mandates. Milliman’s projections derive from the Milliman Health Cost Guidelines (HCGs). The HCGs are a health care pricing tool used by many of the major health plans in the United States. See www.milliman.com/expertise/healthcare/products-tools/milliman-care-guidelines/index.php. Most of the data sources underlying the HCGs are claims databases from commercial health insurance plans. The data are supplied by health insurance companies, Blues plans, HMOs, self-funded employers, and private data vendors. The data are mostly from loosely managed healthcare plans, generally those characterized as preferred provider plans or PPOs. The HCGs currently include claims drawn from plans covering 4.6 million members. In addition to the Milliman HCGs, CHBRP’s utilization and cost estimates draw on other data, including the following:
 - An annual survey of HMO and PPO pricing and claim experience. The most recent survey (2008 Group Health Insurance Survey) contains data from seven major California health plans regarding their 2007 experience.
 - Ingenix MDR Charge Payment System, which includes information about professional fees paid for healthcare services, based upon approximately 800 million claims from commercial insurance companies, HMOs, and self-insured health plans.

These data are reviewed for applicability by an extended group of experts within Milliman but are not audited externally.
4. An annual survey by CHBRP of the seven largest providers of health insurance in California (Aetna, Anthem Blue Cross of California, Blue Shield of California, CIGNA, Health Net, Kaiser Foundation Health Plan, and PacifiCare) to obtain estimates of baseline enrollment by purchaser (i.e., large and small group and individual), type of plan (i.e., DMHC- or CDI-regulated), cost-sharing arrangements with enrollees, and average premiums. Enrollment in these seven firms represents 96.0% of the privately-insured market: 98.0% of privately insured enrollees in full-service health plans regulated by DMHC and 82% of lives privately insured health insurance products regulated by CDI.

Publicly Funded Coverage

5. Premiums and enrollment in DMHC- and CDI-regulated plans by self-insured status and firm size are obtained annually from CalPERS for active state and local government public employees and their family members who receive their benefits through CalPERS. Enrollment information is provided for fully funded, Knox-Keene licensed health care service plans covering non-Medicare beneficiaries—comprise about 75% of CalPERS total enrollment. CalPERS self-funded plans—approximately 25% of enrollment—are not subject to state mandates. In addition, CHBRP obtains information on current scope of benefits from health plans’ evidence of coverage (EOCs) publicly available at www.calpers.ca.gov.
6. Enrollment in Medi-Cal Managed Care (Knox-Keene licensed plans regulated by DMHC) is estimated based on CHIS and data maintained by the Department of Health Care Services (DHCS). DHCS supplies CHBRP with the statewide average premiums negotiated for the Two-Plan Model, as well as generic contracts that summarize the

current scope of benefits. CHBRP assesses enrollment information online at www.dhcs.ca.gov/dataandstats/statistics/Pages/BeneficiaryDataFiles.aspx.

7. Enrollment data for other public programs—Healthy Families, 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 plans under these programs must comply with all requirements of the Knox-Keene Act, and thus these plans are affected by changes in coverage for Knox-Keene licensed plans. CHBRP does not include enrollment in the Post-MRMIP Guaranteed-Issue Coverage Products as these individuals are already included in the enrollment for individual health insurance products offered by private carriers. Enrollment figures for AIM and MRMIP are included with enrollment for Medi-Cal in presentation of premium impacts. Enrollment information is obtained online at www.mrmib.ca.gov/. Average statewide premium information is provided to CHBRP by MRMIB staff.

General Caveats and Assumptions

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

- Prevalence of mandated benefits before and after the mandate may be different from CHBRP assumptions.
- Utilization of mandated services 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 products subject to state-mandated health insurance benefits.
- Cost impacts are only for the first year after enactment of the proposed mandate
- Employers and employees will share proportionately (on a percentage basis) in premium rate increases resulting from the mandate. In other words, the distribution of premium paid by the subscriber (or employee) and the employer will be unaffected by the mandate.
- For state-sponsored programs for the uninsured, the state share will continue to be equal to the absolute dollar amount of funds dedicated to the program.
- When cost savings are estimated, they reflect savings realized for one year. Potential long-term cost savings or impacts are estimated if existing data and literature sources are available and provide adequate detail for estimating long-term impacts. For more information on CHBRP's criteria for estimating long-term impacts please see: www.chbrp.org/documents/longterm_impacts_final011007.pdf.

- Several recent studies have examined the effect of private insurance premium increases on the number of uninsured (Chernew, et al., 2005; Glied and Jack, 2003; Hadley, 2006). Chernew et al. 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 individuals (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 for every 1% increase in premiums. Because each of these studies reported results for the large-group, small-group, and individual insurance markets combined, CHBRP employs the simplifying assumption that the elasticity is the same across different types of markets. For more information on CHBRP's criteria for estimating impacts on the uninsured please see: www.chbrp.org/documents/uninsured_020707.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 coverage: If a mandate increases health insurance costs, then some employer groups and individuals may elect to drop their coverage. 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, health plan members 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 the insured person, 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 insurance may now elect to enroll in an insurance plan postmandate because they perceive that it is to their economic benefit to do so.
- Health plans may react to the mandate by tightening their 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).
- Variation in existing utilization and costs, and in the impact of the mandate, by geographic area and delivery system models: Even within the plan 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 these plan types. Utilization also differs within California due to differences in the health status of the local commercial 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 health plans and providers. 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

Bill Analysis-Specific Caveats and Assumptions

The estimate for number of delivering women in California for commercially insured population subject to AB 513 is derived using the annual number of uncomplicated deliveries per member of 0.0132, which in this case is used to represent the delivery admission rate. This value is a reference number from the Milliman Health Cost Guidelines, which assume a certain distribution of members across age/sex categories, developed using commercial HMO/PPO membership. To calculate the number of women who deliver in a year for commercially insured population subject to AB 513, CHBRP multiplies the delivery admission rate by the total membership count for commercially insured population subject to AB 513.

The estimate for number of delivering women in California for Medi-Cal enrollees subject to AB 513 is derived using the annual number of births paid by Medi-Cal of 250,000, multiplied by 75% to reflect the portion of total Medi-Cal population subject to AB 513. The annual number of births paid by Medi-Cal is a published number included in *Maternal and Child Health Update: States Increase Eligibility for Children's Health in 2007*, National Governors Association, Appendix A. The portion of total Medi-Cal population subject to AB 513 is calculated using a summary of enrollment counts by aid category and age group for Medi-Cal enrollees who were enrolled in January, 2008. This summary is published on California Department of Health Services website.

Utilization-specific caveats and assumptions

- Based on information from content experts, individuals who receive lactation consultation are assumed to receive an average of 1.5 visits, as women who have consultation tend to receive an average of between one to two visits.
- The distribution of consultants and utilization of IBCLCs as an outpatient service—and not including those in-hospital, who are assumed to provide consultation during delivery admission only—is assumed as follows:
 - Public agency: 17%
 - Private consultant: 79%
 - Private in-home consultation: 4%
- CHBRP analyzed the 2006 MedStat data for claims with breast pump rental/purchase CPT codes. The breast pump rental/purchase CPT codes used were identified by various health plans that responded to CHBRP surveys in the health plans' breast pump guidelines. The following CPT codes were considered:
 - E0602—Breast pump, manual, any type

- E0603—Breast pump, electric (AC and/or DC), any type
- E0604—Breast pump, hospital grade, electric (AC and/or DC), any type

Out of roughly 30 million claim records for outpatient services in California, 48 records were coded with the breast pump rental/purchase CPT codes. Given the small number of records, CHBRP did not use the results of this analysis to calculate breast pump utilization rate.

Cost-specific caveats and assumptions

Because claims data are unavailable, data on unit costs and utilization of lactation consultants were provided to CHBRP by content experts, and were also based on information provided by the International Board of Lactation Consultant Examiners (IBLCE) regarding the distribution of public, private, and in-home consultants. The United States Lactation Consultants Association (USLCA) provided information regarding fees charged by IBCLCs for private outpatient visits, private in-home visits, and public agency visits as well as the proportion of IBCLCs who work part-time versus full-time in inpatient settings. We assume the following costs for IBCLC services, by setting:

- Public agency: \$65
- Private consultant: \$100
- Private in-home consultation: \$125

Based on input from content experts, CHBRP assumes that lactation consultation during delivery admission is billed as part of the bundled service of delivery admission, and is billed the same regardless of whether or not the service is provided by an IBCLC or non-IBCLC. Similarly for lactation consultation provided through physician's offices after discharge from delivery admission, billing is assumed to occur as part of the bundled service, and the same through IBCLCs as non-IBCLCs. In both cases, billing is assumed to remain unchanged if the mandate were to pass, as there is no evidence to indicate that insurers would pay more and/or unbundle the billing if they were covered services under this mandate.

Postmandate cost sharing is assumed to be set at a rate similar to that for physician office visits (\$10 per visit) for outpatient lactation consultation, and to that for durable medical equipment (DME; 20%) for breast pump rental. Because inpatient lactation consultation during delivery admission is already covered as part of the bundled cost and would not change with the passage of this bill, no change in cost sharing is applied to this service postmandate

Appendix E: Information Submitted by Outside Parties

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

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

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

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California Health Benefits Review Program Committees and Staff

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

As required by the CHBRP authorizing legislation, UC contracts with a certified actuary, Milliman Inc. (Milliman), to assist in assessing the financial impact of each benefit mandate bill. 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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