

# **EXECUTIVE SUMMARY**

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

> A Report to the 2009-2010 California Legislature April 17, 2009 Revised September 8, 2009

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Health Care Coverage:
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## **April 17, 2009**

Revised September 8,, 2009

Revisions: The first clarifies that a study comparing simultaneous electric pumping to sequential manual pumping found a difference in time needed to express breast milk - but no difference when sequential electric pumping was compared to sequential manual pumping. The second corrects an error in study characterization. The report stated that electric or manual pump use had no effect on breastfeeding rates, which implies that pump using mothers were compared to mothers using no pump. The revision specifies that the study only compared electric pump users to manual pump users. In the Executive Summary, revisions appear on page 6.

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#### **EXECUTIVE SUMMARY**

## California Health Benefits Review Program Analysis of Assembly Bill 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. Regulations defining basic health care services specifically include prenatal care as preventive care that must be covered. 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. 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.

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

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

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

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

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.
  - O 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.
  - o 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 ICBLC 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:
  - o Cessation of *any* breast-feeding up to 6 months after delivery
  - o Cessation of *exclusive* breast-feeding (i.e., breast-feeding without supplemental formula feeding) 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:
  - o Low-income mothers returning to work
  - o 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:
  - o Duration of breast-feeding
  - o Volume of breast milk expressed
  - o 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 to pump both breasts simultaneously compared to using a manual, hand-operated pump to pump sequentially.
- One RCT found simultaneous pumping took less time than sequential pumping when using an electric pump.
- One RCT found no difference in breast-feeding rates at 6 months between mothers who used an electric pump and those who used a manual pump.

## **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:
  - o <u>20.5 million have coverage for lactation consultation when provided during delivery admission.</u>
  - o 10.5 million have coverage for outpatient lactation consultation (consultation provided after discharge from hospital for delivery admission).
  - o 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:
  - o 8.5 million enrollees would gain coverage for outpatient lactation consultation.
  - o 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:
  - o 183,000 (44% of delivering women) consult with IBCLCs during delivery admission,
  - o 25,000 (6% of delivering women) consult with IBCLCs in an outpatient setting, and
  - o 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:
  - o Total premiums for private employers are estimated to increase by \$2,820,000, or 0.0056%.
  - o 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).
  - o Premiums paid by employees covered by group insurance (including CalPERS) would increase by an estimated \$756,000, or 0.0056%.
  - o Total premiums for those with individually purchased insurance are estimated to increase by \$323,000, or 0.0054%.
  - o 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 breastfeeding.
- 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		-	¢0.00	00/
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.

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

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## 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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