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CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Analysis of Senate Bill 1634
Health Care Coverage: Cleft Palates

A Report to the 2007-2008 California Legislature
April 11, 2008

CHBRP 08-08



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 2007-2008 California State Legislature

Analysis of Senate Bill 1634 Health Care Coverage: Cleft Palates

April 11, 2008

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Suggested Citation:

California Health Benefits Review Program (CHBRP). (2008). *Analysis of Senate Bill 1634, Health Care Coverage: Cleft Palates*. Report to California State Legislature. Oakland, CA: CHBRP. 08-08.

PREFACE

This report provides an analysis of the medical, financial, and public health impacts of SB 1634, a bill to mandate coverage for orthodontic services deemed necessary for medical reasons by a cleft palate or craniofacial team that is identified by the Cleft Palate Foundation for cleft palate procedures. In response to a request from the California Senate Committee on Health on February 29, 2008, 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.

Edward Yelin, PhD, of the University of California, San Francisco, prepared the literature analysis and review of medical effectiveness. Min-Lin Fang, MLIS, of the University of California, San Francisco, conducted the literature search. Henry A. Milczuk, MD, of the Oregon Health and Science University, provided technical assistance with the literature review and expert input on the analytic approach. Sara McMenamain, MPH, PhD, of the University of California, Berkeley, prepared the public health impact analysis. Gerald Kominski, PhD, and Meghan Cameron, MPH, both of the University of California, Los Angeles, prepared the cost impact analysis. Jay Ripps, FSA, MAAA, of Milliman, provided actuarial analysis. John Lewis, MPA, of CHBRP staff prepared the background section and synthesized the individual sections into a single report. Sarah Ordódy, BA, 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, Sheldon Greenfield, MD, of the University of California, Irvine, 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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Director

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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Senate Bill 1634

The California Senate Committee on Health requested on February 29, 2008, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Senate Bill (SB) 1634, Health Care Coverage: Cleft Palates. 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. According to the bill author, the SB 1634 will be amended to reflect the language submitted to CHBRP for analysis, as shown in *Appendix A* of this report. Henceforth, whenever this report refers to “SB 1634” it is referring to the amended version of the bill presented for analysis.

SB 1634 requires health care service plans and group insurance policies to provide coverage for orthodontic services deemed necessary for medical reasons by a cleft palate or craniofacial team identified by the Cleft Palate Foundation for oral cleft repair procedures. Throughout the report, the term “oral cleft” refers to cleft lip, cleft palate, or other craniofacial anomalies.

Health care service plans regulated by the Department of Managed Health Care (DMHC) and health insurance products regulated by the California Department of Insurance (CDI) are currently required to provide coverage for reconstructive surgery, including surgeries to correct or repair congenital defects and developmental abnormalities, such as oral clefts.¹ As is the case for other reconstructive surgeries that affect the mouth, dental and orthodontic procedures may be considered part of oral cleft reconstructive surgery if deemed medically necessary.²

Orthodontic services are coordinated with surgeries as standard care for treatment of oral clefts. Teams of experts, including orthodontists, provide coordinated care. The orthodontic services involved in oral cleft repair begin in the first weeks after birth and continue over the following years as the treatments proceed.

Oral clefts are one of the most common birth defects in California. According to the California Birth Defects Monitoring Program (CBDMP), oral clefts occur at a rate of 1.27 per 1,000 births, or one in every 790 babies. This translates into nearly 700 cases in California each year—approximately 300 of which are in plans affected by SB 1634. The problems associated with oral clefts include the following: breathing, skeletal growth and development, hearing, speech and language ability, learning difficulties, and social integration. Social integration problems are due both to having a severe chronic condition in general and the effect of disfigurement, especially among school-age children.

¹ California Health and Safety Code, Section 1367.63 and Section 10123.88 of the California Insurance Code.

² Personal communication, Sherrie Lowenstein, DMHC, March 2008.

Medical Effectiveness

- Orthodontic services, coordinated with the surgeries that take place over the development of the child, are a central part of the standard of care for treatment of oral clefts. Some of these services are to prepare the patient for surgeries as an infant. However, as part of this standard of care, orthodontic services are also provided throughout the developmental period culminating in post-adolescence. Because the provision of orthodontic services has become the standard of care and has been incorporated into treatment guidelines, most, if not all of those treated receive such services.
- Expert consensus for treatment of oral clefts is that teams of experts provide care, with all elements of the care coordinated within the team. Membership in the team may include individuals from the following professions: anesthesiology, audiology, diagnostic medical imaging/radiology, genetic counseling, genetics/dysmorphology, neurology, neurosurgery, nursing, ophthalmology, oral and maxillofacial surgery, orthodontics, otolaryngology, pediatrics, pediatric dentistry, physical anthropology, plastic surgery, prosthodontics, psychiatry, psychology, social work, and speech-language pathology (ACPA, 2007; David, et al., 2006; EuroCran 2003a; EuroCran, 2003b).
- Although the medical effectiveness team found no evidence with respect to the added benefit of orthodontic services or to the effect of team care, this in no way implies that such services are not effective. *No evidence of effect*, which is what the medical effectiveness team reports here, is not the same as *evidence of no effect*.
 - The medical effectiveness team uncovered no studies that directly addressed whether the additional coverage of orthodontic services beyond the previously mandated coverage of surgical care affects outcomes.
 - Because of the myriad bodily functions affected, a cleft palate or craniofacial team approach involving a range of health care professionals and explicit coordination of treatment has become the standard of care. The medical effectiveness team uncovered no studies that addressed the impact of cleft palate or craniofacial *team care*—care provided by tightly organized groups of professionals from a range of disciplines relevant to these problems—relative to care provided by isolated professionals without explicit coordination.
- The medical effectiveness team found no studies that addressed whether there is a delay to surgery while a prospective patient tries to secure coverage for orthodontic services and, if so, whether the delay affects the outcomes experienced. However, there are studies that show that delayed surgery is associated with adverse impacts on several outcomes, including speech and the persistent palatal fistula³ rate.

³ A fistula is an abnormal opening.

Utilization, Cost, and Coverage Impacts

- There are 18,973,000 individuals in California enrolled in health plans or policies that would be affected by this legislation. Of these, an estimated 76.5% (14,506,000) have coverage for orthodontic services related to oral cleft repair.⁴
- Based on input from clinical experts, CHBRP assumes that all individuals in need of such services, but without coverage through their health plan, receive them through assistance from charitable organizations or by paying out of pocket. Therefore, this bill is not estimated to affect the utilization or unit cost for orthodontic services related to oral cleft repair.
- Total lifetime costs in current dollars for all orthodontic services related to oral cleft repair and management is estimated to be approximately \$10,250. An individual's costs may vary based on the severity of the oral cleft
- SB 1634 is estimated to decrease out-of-pocket expenditures for non-covered services by approximately \$813,000.
- Total annual expenditures are estimated to increase by approximately \$146,000, or 0.0002% overall. For affected market segments, annual expenditures are estimated to increase from 0.0001% to 0.0008%. While there is no expected change in the number of orthodontic services provided for oral cleft repair, there are administrative costs associated with providing insurance coverage for services that are currently paid for privately.
- The mandate is estimated to increase premium expenditures by about \$884,000. The distribution of the impact is as follows:
 - Premium expenditures for private employers are estimated to increase by \$552,000 per year, or 0.0012%;
 - Premium expenditures for individually purchased insurance are estimated to increase by \$105,000 per year, or 0.0017%;
 - Enrollee contributions toward premiums for group insurance, CalPERS, Healthy Families, AIM, and MRMIP are estimated to increase by \$159,000 annually, or 0.0012%; and
 - CalPERS employer expenditures are estimated to increase by approximately \$68,000 per year, or 0.0023%.⁵

⁴ Carrier responses to the survey fielded by CHBRP indicate that most, but not all, plans and policies cover medically necessary orthodontic services for oral cleft repair. Coverage may be even broader than the responses indicate, as it is a standard practice among health plans for some services to undergo pre-service review with the plan medical director and specialist consultants before being deemed “medically necessary.” Orthodontic services connected to oral cleft repairs might well be approved during such a process.

⁵ Of the CalPERS employer expenditures, about 60% would be state expenditures for CalPERS members who are state employees.

- Health insurance premiums are estimated to increase on average by 0.0012% or \$0.0033 per member per month (PMPM). Increases measured by percentage change in premiums for affected markets are estimated to range from 0.0005% to 0.0029%. Increases as measured by PMPM premiums are estimated to range from \$0.0018 to \$0.0081. The greatest impact on premiums would be in the CalPERS HMO market.

Public Health Impacts

- There are approximately 300 children diagnosed with oral clefts each year in health plans affected by SB 1634. It is estimated that all children diagnosed with oral clefts currently get the orthodontia needed to prepare their mouth for later surgeries, regardless of insurance coverage, through either charitable organizations or paying out of pocket. To the extent that lack of coverage results in a delay in getting the orthodontia and the subsequent surgeries needed to repair the oral cleft, health outcomes such as speech may be affected. To the extent that SB 1634 reduces delays in surgery, there is potential for improvements in the health of children with oral clefts. In addition, SB 1634 would likely reduce the administrative burden and financial hardship faced by families with children with oral clefts.
- Males have higher rates of cleft lip with or without cleft palate, and females have higher rates of cleft palate alone. Non-Hispanic whites have the highest rates of both cleft lip (with or without cleft palate) and cleft palate alone compared to all other racial/ethnic groups. No information is available on the utilization of orthodontia in the treatment of oral clefts by race/ethnicity. Therefore, there is insufficient evidence to determine if SB 1634 would impact differences in gender or racial disparities in the use of orthodontia in the treatment of oral clefts.
- It is estimated that 15% of babies born with oral clefts die before age 1. Mortality among babies born with oral clefts is generally due to other associated birth defects such as malformation of the respiratory system. Since the majority of mortality associated with oral clefts is caused by other co-existing birth defects, orthodontia for treating oral clefts would not impact overall mortality.
- It is estimated that 11.7% of those with oral clefts are unable to work and an additional 17.2% are limited in their ability work. To the extent that SB 1634 would reduce delays in surgery, and reduced delays improve health outcomes, there is a potential for improvement in the health of children with oral clefts and a corresponding reduction in morbidity and lost productivity.

Table 1. Summary of Coverage, Utilization, and Cost Impacts of SB 1634

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Coverage				
Number of individuals subject to the mandate	18,973,000	18,973,000	0	0%
Percentage of individuals with coverage	76.5%	100.0%	23.5%	31%
Number of individuals with coverage	14,506,000	18,973,000	4,467,000	31%
Utilization and cost				
Enrollees in plans subject to the mandate who need oral cleft repair annually (a)	300	300	-	0%
Enrollees in plans subject to the mandate who have oral clefts but are not covered for orthodontic services for oral cleft repair	80	-	-80	
Average cost of orthodontic treatment per person	\$10,250.00	\$10,250.00	-	0%
Expenditures				
Premium expenditures by private employers for group insurance	\$47,088,966,000	\$47,089,518,000	\$552,000	0.0012%
Premium expenditures for individually purchased insurance	\$6,158,288,000	\$6,158,393,000	\$105,000	0.0017%
Premium expenditures by individuals with group insurance, CalPERS, Healthy Families, AIM, or MRMIP	\$12,819,308,000	\$12,819,467,000	\$159,000	0.0012%
CalPERS employer expenditures (b)	\$2,942,984,000	\$2,943,052,000	\$68,000	0.0023%
Medi-Cal state expenditures (c)	\$4,044,192,000	\$4,044,192,000	\$0	0.0000%
Healthy Families state expenditures	\$644,074,000	\$644,074,000	\$0	0.0000%
Individual out-of-pocket expenditures (deductibles, copayments, etc.)	\$5,602,060,000	\$5,602,135,000	\$75,000	0.0013%
Out-of-pocket expenditures for non-covered services	\$813,000	\$0	-\$813,000	-100%
Total annual expenditures	\$79,300,685,000	\$79,300,831,000	\$146,000	0.0002%

Source: California Health Benefits Review Program, 2008.

Notes: The population includes employees and dependents covered by employer-sponsored insurance (including CalPERS), individually purchased insurance, and public health insurance provided by a health plan subject to the requirements of the Knox-Keene Health Care Service Plan Act of 1975. All population figures include enrollees aged 0-64 years and enrollees 65 years or older covered by employer-sponsored insurance. Premium expenditures by individuals include employee contributions to employer-sponsored health insurance and member contributions to public health insurance. (a) Annual utilization includes utilization by members who pay out-of-pocket for orthodontic services. SB 1634 would mandate coverage for all self-pay orthodontic services related to oral cleft procedures; therefore, there is no net change in overall utilization of orthodontic services. (b) Of the CalPERS employer expenditures, about 60% would be state expenditures for CalPERS members who are state employees. (c) Medi-Cal state expenditures for members under 65 years of age include expenditures for Major Risk Medical Insurance Program (MRMIP) and Access for Infants and Mothers (AIM) program.

Key: CalPERS = California Public Employees' Retirement System.

INTRODUCTION

SB 1634 requires health care service plans regulated by the Department of Managed Health Care (DMHC) and group insurance policies regulated by the California Department of Insurance (CDI) to provide coverage for orthodontic services deemed necessary for medical reasons by a cleft palate or craniofacial team identified by the Cleft Palate Foundation (CPF) for oral cleft repair procedures. Throughout the report, the term “oral cleft” refers to cleft lip, cleft palate, or other craniofacial anomalies.

The California Health Benefits Review Program (CHBRP) undertook this analysis in response to a request from the California Senate Committee on Health on February 29, 2008. SB 1634 was introduced by Senator Darrell Steinberg on February 22, 2008. According to the bill author, SB 1634 will be amended to reflect the language submitted to CHBRP for analysis, as shown in *Appendix A* of this report. Henceforth, whenever this report refers to “SB 1634” it is referring to the amended version of the bill presented for analysis.

SB 1634 is a benefit mandate bill, which means it would place health benefits coverage requirements on health plans or insurers. Specifically, SB 1634 would affect the markets regulated by the DMHC and the CDI, including insurance products purchased in the large group, small group, and individual market. The bill exempts Medi-Cal Managed Care. The bill does not exempt CalPERS, Healthy Families, or other publicly funded insurances. SB 1634 would not directly affect populations that are enrolled in health insurance products not subject to California benefit mandates, such as those enrolled in Medicare Advantage or in self-insured plans (both of which are exempted by federal laws) or those who are uninsured.⁶ Please see *Appendix D* for a detailed description of the cost impact portion of this analysis.

Bill Language and Key Assumptions

The full text of SB 1634 and the amended language submitted to CHBRP by the author’s office can be found in *Appendix A* of this report.

The bill states that DMHC-regulated plans and CDI-regulated policies “shall cover orthodontic services deemed necessary for medical reasons by a cleft palate or craniofacial team that is identified by the Cleft Palate Foundation.” However, for DMHC-regulated plans and CDI-regulated policies, the bill also states that “the prior authorization and utilization review processes described in (e) shall apply to the services provided pursuant to this subsection.” Therefore, CHBRP assumes that existing plans’ methods of determining medical necessity would be unchanged.

CHBRP’s interpretation of SB 1634 is based on conversation with the bill author’s staff, discussions with regulatory agencies including the DMHC, and reasonable legal and layperson

⁶ 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, the portion of the population directly affected by a benefit mandate bill are those enrolled in a health insurance products offered by health care service plans or health insurers.

interpretation of the bill language. In addition, CHBRP makes assumptions for the purposes of analysis since the scope and intent of a bill must be defined in order to conduct an analysis.

Existing California Requirements

Health care service plans regulated by the DMHC and health insurance products regulated by the CDI are required to provide coverage for reconstructive surgery, including surgeries to correct or repair congenital defects and developmental abnormalities, such as oral clefts.⁷ However, orthodontic procedures for oral cleft repair are not explicitly included as covered services in the language of the reconstructive surgery statute.

Although health insurance does not normally cover dental or orthodontic procedures, reconstructive surgery may require exceptions. As is the case for other reconstructive surgeries that affect the mouth (such as repair work for teeth damaged in an automobile accident or an extraction required for cancer treatment), the DMHC considers dental and orthodontic procedures part of the oral cleft reconstructive surgery if the procedures are deemed medically necessary.⁸

Despite the position expressed by the DMHC, carrier responses to the survey fielded by CHBRP indicate that most, but not all, plans cover medically necessary orthodontic services for oral cleft repair. However, coverage may be broader than the responses indicate. It is a standard practice among health plans for some services to undergo pre-service review with the plan medical director and specialist consultants before being deemed “medically necessary.” Oral cleft repairs may be regularly reviewed and their associated orthodontic procedures might well be approved during such a process.

The following states (CPA, 2008; BCBSA, 2007) mandate health benefits for oral cleft repair: California, Colorado, Connecticut, Florida, Indiana, Louisiana, Maryland, Minnesota, North Carolina, South Carolina, Texas, Vermont, Virginia, and Wisconsin. Several of these states, including Connecticut, Florida, Indiana, Minnesota, South Carolina, and Virginia, explicitly include orthodontic procedures as part of the mandated oral cleft repair health benefit.

Background

Oral Clefts

Oral clefts are one of the most common birth defects in California and occur at a rate of 1.27 per 1,000 births or one in every 790 babies (CBDMP). This translates into nearly 700 cases in California each year. Approximately 300 of these cases would be enrolled in plans subject to SB 1634. A cleft lip is a separation of the two sides of the lip. The separation often includes the bones of the upper jaw and/or upper gum. A cleft palate is an opening in the roof of the mouth in which the two sides of the palate did not fuse, or join together, as the fetus was developing. Because the lip and the palate develop separately, it is possible for the child to have a cleft lip, a cleft palate, or both. Cleft lip (with or without cleft palate) occurs in California at a rate of 0.84 cases per 1,000 births, while cleft palate alone occurs at a rate of 0.43 cases per 1,000 births (CBDMP).

⁷ California Health and Safety Code, Section 1367.63 and Section 10123.88 of the California Insurance Code

⁸ Personal communication, Sherrie Lowenstein, DMHC, March 2008.

The causes of oral clefts are not clear, but it appears that there may be an interaction between genetic and environmental factors. For example, research has shown that there is an interaction between smoking during pregnancy and the presence of the cleft-susceptibility gene—babies with this gene are eight times more likely to have an oral cleft if their mother smoked during pregnancy than if they are born to a non-smoking mother (CBDMP). Inadequate folic acid intake has also been associated with increased rates of oral clefts (CBDMP). There is no systematic screening tool to diagnose oral clefts *in utero*, although they are occasionally diagnosed during the course of routine ultrasound. Generally a diagnosis of cleft lip or cleft palate is made in the delivery room soon after birth.

Oral clefts frequently are found in conjunction with other birth defects. Approximately 25% of babies born with cleft lip (with or without cleft palate) and 50% of babies born with cleft palate alone have additional major birth defects (CBDMP). Children born with oral clefts experience a multitude of problems both short and long term. Among babies, feeding problems are the main concern, because it may not be possible for the baby to latch on properly to feed. Among older children, frequent ear infections and hearing loss become concerns as well as long-term speech difficulties and orthodontic treatment. It is estimated that 15% of babies born with oral clefts die before age 1 (CBDMP).

Treatment for Oral Clefts

As outlined in several expert consensus panels, a child born with an oral cleft frequently requires several different types of services, e.g., surgery, dental/orthodontic care, and speech therapy, all of which need to be provided in a coordinated manner over a period of years. Coordinated care is often provided by an interdisciplinary cleft palate or craniofacial team comprising professionals from a variety of health care disciplines who work together on the child's total rehabilitation (ACPA, 2007; AAPD, 2005; David et al., 2006; EuroCran, 2003a; EuroCran, 2003b).

Table 2 represents a general treatment plan. Since growth is a significant factor in the ultimate outcome of treatment, the patient must be assessed thoroughly and regularly from infancy until young adulthood.

Table 2. Standard Treatment Plan for Oral Clefts

Age Range	Intervention
Prenatal	Refer to Cleft Palate or Craniofacial Team Medical diagnosis Genetic counseling Address psychosocial issues
Neonatal (0-1 month)	Same as above Provide feeding instructions Monitor growth Hearing screening Initiate pre-surgical orthodontics, if indicated (create and insert pin-retained appliance, or create and insert naso-alveolar molding: 21080)
1-4 months	Monitor feeding and growth Repair cleft lip Monitor ears and hearing
5-15 months	Monitor feeding, growth, and development Repair cleft palate (if fistula develops, then 21085: fistula closure split) Monitor ears and hearing; consider ear tubes Instructions in oral hygiene
16-24 months	Assess speech and language development Monitor ears and hearing; ear tubes if indicated Monitor development
2-5 years	Monitor speech and language development; manage velopharyngeal insufficiency Monitor ears and hearing; ear tubes if indicated Assess development and psychosocial needs Consider lip/nose revision prior to school
6-11 years	Monitor speech and language; manage velopharyngeal insufficiency Orthodontic evaluation and treatment (21110: maxillary expansion, braces, headgear) Alveolar bone graft (ortho codes 21085: alveolar bone graft splits) Monitor school and psychosocial needs
12-21 years	Monitor school and psychosocial needs Orthodontics and restorative dentistry (21085) Genetic counseling Rhinoplasty (if needed) Orthognathic surgery (if needed)

Source: Adapted from Friedman et al, 2005.

Note: Orthodontic procedures are in **bold**.

The orthodontic elements of the oral cleft repair procedure that are considered medically necessary are described below.

- Pre-surgical orthodontics are begun within the first month of life in a patient born with oral clefts. These treatments include frequent adjustments, every 1 to 2 weeks, until the cleft lip is repaired.
- Maxillary expansion and braces (with or without head gear) are essential to the preparation for the alveolar bone graft. Expansion is started once permanent molars have

erupted and continues for a variable period of time. The child is usually aged 8 or 9 years when these treatments begin. The alveolar bone graft surgery follows completion of the orthodontic treatments.

- The alveolar bone graft splint is medically necessary to protect the graft site after surgery. A fistula closure splint would be medically necessary in the event that a complication of palate surgery, an oronasal fistula, occurs. This can happen at any age (at initial palate repair, during speech surgery, or a failed alveolar bone graft).
- Though not required in all circumstances, maxillary distraction and mandibular osteogenesis are often medically necessary. Maxillary distraction preserves vision. Mandibular osteogenesis relieves upper airway obstruction. Often, mandibular osteogenesis is performed during infancy, but may be performed any time a child with a small mandible develops obstructive sleep apnea.

Cleft Palate Foundation

The Cleft Palate Foundation (CPF) is a non-profit organization founded by the American Cleft Palate-Craniofacial Association (ACPA) in 1973 to be the public service arm of the professional association (CPF, 2008). The CPF maintains a website, produces publications, and operates a toll-free service to provide information about oral clefts..

Cleft Palate or Craniofacial Teams

A cleft palate or craniofacial team is a group of interdisciplinary specialists who create and update the individual's health care plan (CPF, 2008). Depending on individual needs, the list of specialists may include:

- an audiologist (who assesses hearing);
- a surgeon (such as a plastic surgeon, an oral/maxillofacial surgeon, a craniofacial surgeon, or a neurosurgeon);
- a pediatric dentist or other dental specialist (such as a prosthodontist, who makes prosthetic devices for the mouth);
- an orthodontist (who straightens the teeth and aligns the jaws);
- a geneticist (who screens patients for craniofacial syndromes and helps parents and adult patients understand the chances of having more children with these conditions);
- a nurse (who helps with feeding problems and provides ongoing supervision of the child's health);
- an otolaryngologist (an "ear, nose, and throat" doctor, or "ENT");
- a pediatrician (to monitor overall health and development);
- a psychologist or other mental health specialist (to support the family and assess any adjustment problems);
- a speech-language pathologist (who assesses not only speech but also feeding problems); and
- other necessary specialists who treat specific aspects of complex craniofacial anomalies.

Teams identified by the Cleft Palate Foundation

The ACPA's Team Standards Committee publishes a list of cleft palate and craniofacial teams for the sole purpose of allowing professionals, patients, and families to locate such teams in their vicinity (CPF, 2008). The CPF states:

The team listings are submitted voluntarily and listing implies neither approval nor disapproval of any team on the part of the ACPA or the CPF. The CPF and ACPA do not guarantee the accuracy or veracity of the listings. Each team clinical director/leader who responded to the 2002 Team Self-Assessment Instrument was asked to sign a pledge of veracity indicating their answers were, to the best of their knowledge, truthful and correct.

MEDICAL EFFECTIVENESS

Care of persons with oral clefts proceeds according to protocols established by expert consensus panels organized by the ACPA in the U.S. (ACPA, 2007; AAPD, 2005), and analogous organizations in other nations or continents (David et al., 2006; EuroCRAN, 2003a; EuroCRAN, 2003b).

In the ACPA protocol as well as in others (ACPA, 2007; Jaques et al., 1997; Rosenstein et al., 2003; Schnitt et al., 2004; Strauss, 1998; Strauss, 1999; Tindlund and Holmefjord, 1997; Wellens and Vander Poorten, 2006), teams of professionals coordinate, plan, and implement care over the period starting at birth and proceeding into adulthood. These teams may include some or all of the following: anesthesiologists, audiologist, radiologists, genetic counselors, neurologists and neurosurgeons, nurses, ophthalmologists, oral and maxillofacial surgeons, orthodontists, otolaryngologists, pediatricians, pediatric dentists, plastic surgeons, psychiatrists, psychologists, social workers, and speech-language pathologists. The goals of treatment are to avoid problems in feeding, breathing, skeletal growth and development, hearing, speech and language, learning, and social integration. The problems associated with the conditions in question include the psychological adjustment to having a chronic disease in general as well as one that is disfiguring, at least prior to a completed treatment.

Provision of care with this team approach has been the standard since the ACPA's Parameters for Evaluation and Treatment of Patients with Cleft Lip/Palate or Other Craniofacial Anomalies was published in 1993. The guidelines came about as a result of the deliberations of the expert consensus panel, with funding from the U.S. Bureau of Maternal and Child Health (subsequent revisions have occurred in 2000 and 2007) (ACPA, 2007). Care coordination within the team addresses both the mix of services needed and the timing appropriate to the patient (Hoffman, 2008).

Under existing law, health care service plans regulated by the DMHC and health insurance products regulated by the CDI are required to reimburse the costs of surgical interventions for oral clefts. The proposed legislation, SB 1634 would require health care service plans and health insurance plans to pay for the orthodontic services deemed necessary for medical reasons by a cleft palate or craniofacial team that is identified by the CPF, in addition to the costs of surgery. Such services start potentially in the first weeks of life prior to surgery, continue through any and all surgical procedures that occur, and may persist until normal adult dental function is established.

Orthodontia in the Treatment of Oral Clefts

As outlined in greater detail in the *Introduction*, orthodontic services—coordinated with the surgeries that take place over the development of the child—are a central part of the standard of care for treatment of oral clefts. Some of these services are to prepare the patient for surgeries as an infant. However, as part of this standard of care, orthodontic services are also provided throughout the developmental period culminating in post-adolescence. Because the provision of orthodontic services has become the standard of care and has been incorporated into treatment guidelines, most, if not all of those treated receive such services.

The medical effectiveness team, working with the medical librarian, sought to identify studies that isolated the effect of adding orthodontic services to surgical care with the goal of assessing the increment of benefit in reducing the problems outlined above and in fostering improved quality of life. The team uncovered no such studies.

Team Care

The team then sought to enlarge the scope of the literature review to compare the effectiveness of team care versus that of individual professionals without explicit coordination. Although not as directly targeted on the provisions of SB 1634 as studies of the added benefit of orthodontic services beyond surgical care would be, team care studies would serve as a proxy of the benefit of adding aggregations of services to ones provided individually. The literature review uncovered no studies that addressed the added value of team care versus services of individual professionals empirically.

The literature review uncovered one small empirical study (Gluchacki et al., 2002) using a pre- and post-intervention design of primary cleft palate surgery patients that addressed the impact of using a more extensive and explicit written protocol for use of team care services (n = 33) versus a more limited protocol (n = 39), but also in the context of team care. The study referred to the protocol as “order sets,” that is, activities ordered by the team to organize care for the near-term. That study indicated that more care consistent with the protocol was provided after introduction of the more extensive protocol, with the implication that following a team care approach explicitly and thoroughly by having a more explicit order set may improve the process of care relative to a less extensive protocol. Many services were listed in the more extensive protocol, but only several were subjected to formal statistical testing. The study found no difference in the percentage returning to the plastic surgeon for postoperative care ($p = .7$). There was a statistically significant increase in the percentage receiving care from an otolaryngology clinic ($p = .0002$). The study did not address outcomes, however.

Similarly, the literature review uncovered a study (Bearn et al., 2001) that established that individual surgical teams that had high volumes of patients with oral clefts achieved better outcomes than teams with low volumes for three parameters among 5-year-olds and two among 12-year-olds. However, in the latter study, there was no direct comparison of team vs. non-team care.

Timing of Surgery

The team found no studies that addressed whether there is a delay to surgery while a prospective patient tries to secure coverage for orthodontic services, and whether the delay affects the outcomes experienced.

However, there are studies that show that delayed surgery is associated with adverse impacts on several outcomes, including speech and the persistent palatal fistula rate (a fistula closure splint would be medically necessary in the event that a complication of palate surgery, a oronasal fistula, occurs.). In a new review of treatment for oral clefts, Hoffman (2008) states:

The trend in timing of palate repair has been toward earlier repair, and there are data supporting palate repair earlier than a year of age. Both a decrease in compensatory articulations (habits that are developed to mimic a sound that cannot be produced because of the cleft), as well as a decreased need for secondary surgery for speech have been demonstrated with earlier repairs, even when compared to “later” repairs at 12–18 months of age.

It is critical to think of palate repair in relation to the child's development of speech and language. The cleft does not affect speech development but, rather, the ability to produce specific sounds. In particular, sounds requiring positive intraoral pressure will be most affected. Early palate repair, then, is carried out in children who are displaying normal development in motor skills as well as in speech (babbling is the norm at about 7–9 months of age). In contrast, in children with syndromes that are associated with developmental delay, speech development may well be delayed as well and palate repair will be a little safer at a later stage, even at 18–24 months of age.

Summary

Overall, the medical effectiveness team could find no evidence that the increment of orthodontic services over and above the provision of surgical care is effective. The team also found no evidence that team care is more effective relative to care provided by individual professionals without explicit coordination. Finally, the team found no studies that evaluated whether there is evidence of delay to surgery as a result of not having coverage for orthodontic services, and whether delay due to lack of coverage has an effect on outcomes. There is some evidence that delay itself does adversely affect outcomes.

The lack of evidence with respect to the effectiveness of adding orthodontic services to surgical care—the issue most directly addressed by SB 1634—and the relative paucity of evidence with respect to team care is in part the result of the fact that most parents would not want their children to participate in studies in which they did not receive recommended care. Team care, including the services of a wide range of professionals that is tightly and explicitly coordinated, is the standard of care.

It is important to note that the *absence of evidence*, the result of the literature search for this analysis, is not the same as *evidence of no effect*.

As noted, it is difficult to perform research on topics for which there is a strong consensus. It is also difficult in a practical sense to perform research that tests parts of a package of care against other parts (for example, the increment value of orthodontic services over the provision of surgical care), especially when the prevalence of the problem is relatively low. Or, to test the value of the entire package of services explicitly coordinated “team care” against individual services without such coordination.

UTILIZATION, COST, AND COVERAGE IMPACTS

SB 1634 would require coverage for orthodontic services related to oral clefts when deemed medically necessary by a cleft palate or craniofacial team identified by the CPF. Specifically, SB 1634 would require coverage for orthodontic services for enrollees in:

- all Knox-Keene⁹ licensed plans regulated by the DMHC, including enrollees in group (large and small) and individual markets;
- all policies regulated by the CDI, including enrollees in group (large and small) and individual markets; and
- managed care plans offered by Healthy Families and the California Public Employees' Retirement System (CalPERS). As discussed, Medi-Cal managed care beneficiaries enrolled in Knox-Keene licensed health plans are exempt from SB 1634 since the provision of the bill states that the mandate "shall not apply to contracts...between the State Department of Health Care Services and a health care service plan for enrolled Medi-Cal beneficiaries."

Health care service plans regulated by the DMHC and health insurance products regulated by the CDI are already required to provide coverage for reconstructive surgery related to oral clefts.¹⁰ However, orthodontic services are not explicitly covered by this prior legislation. Therefore, this section will look specifically at the *incremental* cost effects of *orthodontic services* in the treatment of oral clefts.

The following analysis will present first the current, or baseline, costs and coverage related to orthodontic services for oral cleft repair, and then the estimated utilization, cost, and coverage impacts of SB 1634. For further details on the underlying data sources and methods, see *Appendix D* at the end of this document.

Present Baseline Cost and Coverage

Current Coverage of the Mandated Benefit

The treatment of oral clefts is typically performed by a team of professionals who coordinate care starting at birth and continuing through adulthood. Orthodontic services related to oral clefts may include pre-surgical orthodontics (i.e., naso-alveolar molding), palate expansion, head gear, alveolar bone graft splints, osteogenesis splints, fistula closure splints, orthognathic surgery splints, and braces (see Table 2 in the *Introduction* section of this report).

There are 18,973,000 individuals in California enrolled in health plans or policies that would be affected by this legislation. DMHC-regulated plans represent about 89.6% of the privately insured market in California, while CDI-regulated plans represent 10.4%. CHBRP's methods of calculating enrollment in private and public programs that would be affected by the mandate are described in Appendix D.

⁹ Health maintenance organizations in California are licensed under the Knox-Keene Health Care Services Plan Act, which is part of the California Health and Safety Code.

¹⁰ California Health and Safety Code, Section 1367.63 and Section 10123.88 of the California Insurance Code.

A survey of the seven largest health plan and insurers in California was conducted by CHBRP to examine current coverage for orthodontic services for oral cleft repair. Responding carriers represent 75% of the privately insured enrolled in the CDI-regulated market and 85% in the DMHC-regulated market. Combined, responses to this survey represent 84% of the privately-insured market.¹¹ Based on these responses, CHBRP estimates that 76.5% (14,506,000) of individuals have coverage for orthodontic services related to oral cleft repair.¹²

The results of CHBRP's survey of health plans indicate that coverage for orthodontic services related to oral cleft repair varies by insurer, but not by plan type (e.g., DMHC-regulated large- and small-group plans have the same coverage as CDI-regulated large- and small-group plans within a single insurer). Of those health plans that cover orthodontic services related to oral cleft repair, all indicate that they authorize orthodontic services based on a determination of medical necessity after review. SB 1634 would not preclude a health plan or insurer from determining medical necessity, or conducting utilization review.

Healthy Families and other state program beneficiaries in need of orthodontia related to oral cleft repair are referred to and covered by California Children's Services (CCS). Therefore, this bill would not affect Healthy Families utilization or expenditures. On the other hand, CHBRP estimates that only 52% of members of CalPERS plans have coverage for orthodontia related to oral cleft repair subject to a determination of medical necessity.

Current Utilization Levels and Costs of the Mandated Benefit

Current utilization levels

According to the California Birth Defects Monitoring Program (CBDMP), oral clefts occur at a rate of 1.27 per 1,000 births in California (CBDMP). This translates to approximately 700 children born every year in the state with oral clefts. Of these, approximately 300 are in health plans that would be affected by this legislation.¹³ CHBRP could not identify a source that provided information on the number of individuals with oral clefts who were unable to receive orthodontic services due to prohibitive costs. Therefore, CHBRP assumed that all 300

¹¹ CHBRP analysis of the share of insured members included in CHBRP's survey of the major carriers in the state is based on "CDI Licenses with HMSR Covered Lives Greater than 100,000" as part of the Accident and Health Covered Lives Data Call, December 31, 2006 by the California Department of Insurance, Statistical Analysis Division and data retrieved from The Department of Managed Health Care's interactive web site "Health Plan Financial Summary Report," December, 2007.

¹² Carrier responses to the survey fielded by CHBRP indicate that most, but not all, plans and policies cover medically necessary orthodontic services for oral cleft repair. Coverage may be even broader than the responses indicate, as it is a standard practice among health plans for some services to undergo pre-service review with the plan medical director and specialist consultants before being deemed "medically necessary." Orthodontic services connected to oral cleft repairs might well be approved during such a process.

¹³ According to the California Department of Health Services, there were 548,700 live births in California in 2005 (CDPH, 2007). Using an oral cleft rate of 1.27 per 1,000 births, this equals 697 children born with oral clefts every year. The California Department of Health Care Services Vital Statistics reports that in 1999, 42% of births in California were covered by public insurance. Additionally, 4% of deliveries in California were not covered by any form of insurance (DHS, 2002). This leaves 54% of births covered by private insurance. Finally, because self-insured plans are exempt from this mandate, there was an additional adjustment to exclude those 2,223,000 self-insured individuals. The final calculation is as follows: Annual number of oral cleft repairs subject to the mandate = $548,700 * (1.27/1000) * 0.54 * (1 - 2,223/2,223 + 18.973) = 337$.

individuals are currently receiving orthodontic services, through coverage by their health insurance plans, through charitable organizations, or by paying out of pocket. Based on carrier survey responses, CHBRP estimates that approximately 80 of these individuals with oral clefts were in health plans that do not provide coverage for orthodontic services related to oral cleft repair.

Unit price

The total cost, in current dollars, over the child's lifetime for all orthodontic services related to oral cleft repair and management is estimated to be \$10,250.00. This cost reflects a two-phase orthodontic approach, needed by the majority of oral cleft cases, and the cost of a palate expander or splint.

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

CHBRP was unable to find sources of data on the number of individuals who seek and receive care from public programs or other private sources because of lack of health insurance coverage for orthodontic services related to oral cleft repair. However, numerous organizations including the National Association for the Craniofacially Handicapped, the March of Dimes, and the Easter Seal Society all assist individuals and families suffering from craniofacial anomalies. CHBRP assumed that privately insured individuals who do not have coverage for orthodontic services for oral clefts and who do not get assistance through charitable organizations pay for these non-covered services out of pocket.

Public Demand for Coverage

As a way to determine whether public demand exists for the proposed mandate (based on criteria specified under SB 1704 [2007]), CHBRP is to report on the extent to which collective bargaining entities negotiate for, and the extent to which self-insured plans currently have, coverage for the benefits specified under the proposed mandate. Currently, the largest public self-insured plans are those preferred provider organization (PPO) plans offered by CalPERS. From its review of the EOCs for CalPERS PPO plans, CHBRP staff was unable to determine whether orthodontic services for oral cleft repair are considered a covered benefit. Based on conversations with the largest collective bargaining agents in California, CHBRP concluded that unions currently do not include coverage for orthodontic services related to oral cleft repair in their health insurance policy negotiations. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and coinsurance levels.¹⁴ In summary, CHBRP was unable to determine the extent of public demand for coverage of these services.

Impacts of Mandated Coverage

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

Because oral cleft is a rare condition and because AB 1634 would not affect the demand for orthodontic services related to oral cleft repair, CHBRP estimates that there would be no price

¹⁴ Personal communication with the California Labor Federation and member organizations, January 2007.

pressures on the unit cost of these procedures. Therefore, no effect on per-unit cost of orthodontic services is expected as a result of this mandate.

How Will Utilization Change as a Result of the Mandate?

CHBRP assumes that all individuals affected by this mandate are currently receiving orthodontic services related to oral cleft repair, either through their current health care coverage, through charitable organizations, or by paying out of pocket. This assumption is based on input from clinical experts who have participated in oral cleft repair surgery teams.

The current number of enrollees in plans subject to the mandate in need of oral cleft repair is estimated to be approximately 300. This estimate includes approximately 80 cases of children who are not covered by their health plan for orthodontic services related to oral cleft repair. As discussed, SB 1634 would mandate that health plans and insurers directly cover these orthodontic services. Therefore, CHBRP estimates no change in *overall* utilization of orthodontic services, but rather a small shift in who pays for the orthodontic services post-mandate—from individuals or charitable sources to insurance.

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

CHBRP assumes that if health care costs covered by insurance increase as a result of increased utilization or changes in unit cost, there is a corresponding proportional increase in administrative costs. CHBRP assumes that the administrative cost *proportion of premiums* is unchanged. All health care plans and insurers include a component for administration and profit in their premiums. The main administrative costs associated with this mandate would be related to amending the Evidence of Coverage, amending other provider and patient materials, and notifying providers and patients of their new coverage.

Impact of the Mandate on Total Health Care Costs

SB 1634 is estimated to increase total annual expenditures by \$146,000, or 0.0002%. The mandate is estimated to increase premiums by \$884,000: \$552,000 for the portion of group insurance premiums paid by private employers; \$105,000 for individually purchased insurance; \$159,000 for the portion of group insurance, CalPERS, and Health Families premiums paid by enrollees; and \$68,000 for CalPERS employer expenditures. SB 1634 would decrease out-of-pocket expenditures for non-covered services by approximately \$813,000 (Table 1). Therefore, the premium increase would primarily go to relieving some of the cost burden faced by individuals in need of orthodontic services related to oral cleft repair who are not currently covered for these services by their health plans. Furthermore, while there is no expected change in the number of orthodontic services provided for oral cleft repair, there are administrative costs associated with providing insurance coverage for services that are currently paid for privately, as discussed in the previous section.

Total expenditures (including total premiums and out-of-pocket spending for copayments and non-covered benefits) would increase by between 0.0001% and 0.0008% for those markets affected by the mandate, with CDI-regulated individual plans facing the greatest increase (0.0008%) (Table 4).

Across all markets affected by the mandate, insured premiums are expected to increase by 0.0012% or \$0.0033 per member per month (PMPM). For privately insured individuals, health insurance premiums would increase by approximately 0.0005% to 0.0029%, depending on their coverage segment, with the greatest impacts falling on the CDI-regulated individual market (\$0.0047) and the CalPERS HMO market (\$0.0081).

Costs or Savings for Each Category of Insurer Resulting from the Benefit Mandate

SB 1634 would lead to an estimated increase in total expenditures of 0.0002% (Table 4). The increase in total expenditures varies by insurance market as follows:

- 0.0001% (\$0.0004) for the DMHC-regulated large-group market;
- 0.0001% (\$0.0003) for the DMHC-regulated small-group market;
- 0.0003% (\$0.0010) for the CDI-regulated large-group market;
- 0.0002% (\$0.0009) for the CDI-regulated small-group market;
- 0.0004% (\$0.0012) for the DMHC-regulated individual market;
- 0.0008% (\$0.0016) for the CDI-regulated individual market;
- 0.0003% (\$0.0012) for CalPERS HMO; and
- 0.0000% (\$0.0000) for Healthy Families Managed Care.

In addition, for affected markets, increases as measured by PMPM payments are estimated to range from \$0.0018 for CDI-regulated large group market to \$0.0081 for the CalPERS HMO market. Specifically, the increase in each market would be:

- 0.0011% (\$0.0033) for the DMHC-regulated large-group market;
- 0.0005% (\$0.0018) for the CDI-regulated large-group market;
- 0.0015% (\$0.0050) for the DMHC-regulated small-group market;
- 0.0011% (\$0.0040) for the CDI-regulated small-group market;
- 0.0013% (\$0.0039) for the DMHC-regulated individual market;
- 0.0029% (\$0.0047) for the CDI-regulated individual market;
- 0.0023% (\$0.0081) for CalPERS HMO; and
- 0.0000% (\$0.0000) for Healthy Families Managed Care.

SB 1634 would decrease the member expenses for benefits not covered by a total of \$813,000. Looking across all affected markets, this decrease is greatest for the CalPERS HMO market (-\$0.0073) and least for the CDI-regulated large group market (-\$0.0018).

Due to the relatively small increase in premiums and total expenditures, CHBRP does not expect any change in the number of uninsured as a result of this mandate.

Impact on Long-Term Costs

Though the timeline for orthodontic services related to oral cleft repair stretches from birth through early adulthood, costs are typically calculated and paid as a lump sum at the beginning of care. Therefore, while care does continue for many years and while there are long-term health consequences, there are no associated long-term costs for orthodontia for oral cleft repair.

Impact on Access and Health Service Availability

The mandate would not change access to orthodontic services for oral cleft repair. Currently, CHBRP assumed that all individuals in need of these services are receiving them, either because of coverage by their health plan, through help from charitable organizations, or by paying out of pocket for services. Additionally, continued use of utilization review to determine medical necessity would mitigate any large increase in utilization. The mandate would not have any impact on the availability or supply of orthodontists or other health care providers qualified to carry out the orthodontic portion of oral cleft repair.

Table 3. Baseline (Premandate) Per Member Per Month Premium and Expenditures by Insurance Plan Type, California, 2008

	Large Group		Small Group		Individual		CalPERS	Medi-Cal Managed Care		Healthy Families Managed Care	Total Annual
	DMHC-Regulated	CDI-Regulated	DMHC-Regulated	CDI-Regulated	DMHC-Regulated	CDI-Regulated	HMO (a)	65 and Over	Under 65		
Population Currently Covered	11,721,000	342,000	3,256,000	728,000	1,299,000	812,000	815,000	172,000	2,532,000	685,000	22,362,000
Average portion of premium paid by employer	\$238.92	\$315.18	\$245.82	\$296.00	\$0.00	\$0.00	\$300.92	\$181.00	\$120.01	\$78.35	\$54,695,911,000
Average portion of premium paid by employee	\$54.60	\$86.99	\$93.75	\$62.26	\$294.46	\$160.95	\$53.10	\$0.00	\$0.80	\$6.81	\$19,001,902,000
Total Premium	\$293.53	\$402.17	\$339.57	\$358.26	\$294.46	\$160.95	\$354.02	\$181.00	\$120.81	\$85.17	\$73,697,813,000
Member expenses for covered benefits (deductibles, copays, etc.)	\$15.78	\$45.50	\$24.95	\$95.56	\$50.61	\$39.36	\$18.26	\$0.00	\$0.56	\$2.32	\$5,602,060,000
Member expenses for benefits not covered	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.01	\$0.00	\$0.00	\$0.00	\$813,000
Total Expenditures	\$309.30	\$447.67	\$364.52	\$453.82	\$345.07	\$200.32	\$372.29	\$181.00	\$121.36	\$87.49	\$79,300,686,000

Source: California Health Benefits Review Program, 2008.

Note: The population includes individuals and dependents in California who have private insurance (group and individual) or public insurance (e.g., CalPERS, Medi-Cal, Healthy Families, AIM, MRMIP) under health plans or policies regulated by DMHC or CDI. All population figures include enrollees aged 0-64 years and enrollees 65 years or older covered by employment-based coverage. The total annual expenditures expressed in this Table vary from Table 1 in this report due to rounding. (a) Of these CalPERS members, about 60% or 489,000 are state employees whose cost is borne by the General Fund.

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

Table 4. Postmandate Impacts on Per Member Per Month and Total Expenditures by Insurance Plan Type, California, 2008

	Large Group		Small Group		Individual		CalPERS	Medi-Cal Managed Care		Healthy Families Managed Care	Total Annual
	DMHC-Regulated	CDI-Regulated	DMHC-Regulated	CDI-Regulated	DMHC-Regulated	CDI-Regulated	HMO (a)	65 and Over	Under 65		
Population Covered	11,721,000	342,000	3,256,000	728,000	1,299,000	812,000	815,000	172,000	2,532,000	685,000	22,362,000
Average portion of premium paid by employer	\$0.0027	\$0.0014	\$0.0036	\$0.0033	\$0.0000	\$0.0000	\$0.0069	\$0.0000	\$0.0000	\$0.0000	\$619,000
Average portion of premium paid by employee	\$0.0006	\$0.0004	\$0.0014	\$0.0007	\$0.0039	\$0.0047	\$0.0012	\$0.0000	\$0.0000	\$0.0000	\$265,000
Total Premium	\$0.0033	\$0.0018	\$0.0050	\$0.0040	\$0.0039	\$0.0047	\$0.0081	\$0.0000	\$0.0000	\$0.0000	\$884,000
Member expenses for covered benefits (deductibles, copays, etc.)	\$0.0002	\$0.0002	\$0.0004	\$0.0011	\$0.0007	\$0.0011	\$0.0004	\$0.0000	\$0.0000	\$0.0000	\$75,000
Member expenses for benefits not covered	-\$0.0031	-\$0.0018	-\$0.0044	-\$0.0042	-\$0.0033	-\$0.0043	-\$0.0073	\$0.0000	\$0.0000	\$0.0000	-\$813,000
Total Expenditures	\$0.0004	\$0.0003	\$0.0010	\$0.0009	\$0.0012	\$0.0016	\$0.0012	\$0.0000	\$0.0000	\$0.0000	\$146,000
Percentage Impact of Mandate											
Insured Premiums	0.0011%	0.0005%	0.0015%	0.0011%	0.0013%	0.0029%	0.0023%	0.0000%	0.0000%	0.0000%	0.0012%
Total Expenditures	0.0001%	0.0001%	0.0003%	0.0002%	0.0004%	0.0008%	0.0003%	0.0000%	0.0000%	0.0000%	0.0002%

Source: California Health Benefits Review Program, 2008.

Note: The population includes individuals and dependents in California who have private insurance (group and individual) or public insurance (e.g., CalPERS, Medi-Cal, Healthy Families, AIM, MRMIP) under health plans or policies regulated by the DMHC or CDI. All population figures include enrollees aged 0-64 years and enrollees 65 years or older covered by employment-based coverage. The total annual expenditures expressed in this Table vary from Table 1 in this report due to rounding. (a) Of these CalPERS members, about 60% or 489,000 are state employees whose cost is borne by the General Fund.

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

PUBLIC HEALTH IMPACTS

Oral clefts are one of the most common birth defects in California and occur at a rate of 1.27 per 1,000 births (CBDMP). Among the population of babies born in health plans subject to SB 1634, this translates into approximately 300 oral clefts each year. As presented in the *Utilization, Cost, and Coverage Impacts* section, it is assumed that all of these children with oral clefts currently get the needed treatment, including orthodontia, to repair their oral clefts, either through health insurance, charitable organizations, or by paying out of pocket. Therefore, SB 1634 is not expected to increase the utilization of orthodontic devices or services among children with oral clefts.

As presented in the *Medical Effectiveness* section, no evidence was found that measures the incremental benefit of orthodontic services over and above the provision of surgical care. This is in part due to the strong consensus of medical professionals working on craniofacial teams that orthodontia is an essential component to repairing oral clefts (APCA, 2007). Typically the orthodontic work is needed prior to surgery to prepare the teeth and mouth. Members of the craniofacial community are concerned that a lack of coverage for orthodontic services is resulting in delayed surgeries. This is because it can take a family a long time to file appeals with health plans or to find alternative methods to pay for the orthodontic services by soliciting national and local charitable organizations.

The intention of SB 1634 is to improve health outcomes by reducing the surgical delays due to lack of insurance for orthodontia. The medical effectiveness team did not find any studies that examined the effect of health insurance coverage on delays in surgery to repair oral clefts. They did find evidence that delays in surgery to repair oral clefts resulted in worse health outcomes in areas such as speech development. Therefore, to the extent that SB 1634 reduces delays in surgery, and reduced delays improve health outcomes, there is a potential for improvements in the health of children with oral clefts. In addition, SB 1634 would likely reduce the administrative burden and financial hardship faced by families with children with oral clefts.

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

There are differences in regard to the distribution of oral clefts by gender and race/ethnicity in California. The rates of oral clefts differ by gender and type of cleft with males having higher rates of cleft lip with or without cleft palate, and females having higher rates of cleft palate alone (CBDMP). Regardless of the type of oral cleft, non-Hispanic whites have the highest rates of both cleft lip (with or without cleft palate) and cleft palate alone compared to all other racial/ethnic groups (Table 5).

Although there is evidence of differences in rates of oral clefts by gender and race/ethnicity, CHBRP found no evidence as to disparities in utilization of orthodontia between these groups. In addition, CHBRP found no evidence of disparities in insurance coverage of orthodontia for use in the treatment of oral clefts by gender or race/ethnicity. Therefore, there is insufficient evidence to determine if SB 1634 would impact differences in gender or racial disparities in the use of orthodontia in the treatment of oral clefts.

Table 5. Rates of Cleft Lip With or Without Cleft Palate and Cleft Palate Alone, by Race/Ethnicity, California 1999-2003

	Cleft Lip +/- Cleft Palate (Rate per 1,000 births)	Cleft Palate Alone
Asian/Pacific Islander	0.89	0.39
Hispanic	0.85	0.41
Non-Hispanic black	0.88	0.44
Non-Hispanic white	1.09	0.45

Source: California Birth Defects Monitoring Program registry data, 1999-2003, livebirths and stillbirths over 20 weeks.

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

It is estimated that 15% of babies born with oral clefts die before age 1 (CBDMP). Mortality among babies born with oral clefts is generally due to other associated birth defects such as malformation of the respiratory system. Approximately 25% of babies born with cleft lip (with or without cleft palate) and 50% of babies born with cleft palate alone have additional major birth defects (CBDMP). It is estimated that the lifetime costs (in 1992 dollars) in California of cleft lip or cleft palate is \$101,000 per case (Waitzman et al., 1995). Of this, 86% of the costs (\$87,000 per case) are due to lost productivity associated with premature death and morbidity associated with reduced productivity. Morbidity calculations are based on data that show that an estimated 11.7% of those with oral clefts are unable to work and an additional 17.2% are limited in their ability work (Waitzman et al., 1994).

Since the majority of mortality associated with oral clefts is caused by co-existing birth defects, orthodontia for treating oral clefts is not expected to impact these mortality rates. The *Medical Effectiveness* section found that delaying surgery led to worse health outcomes. Thus, to the extent that insurance coverage reduces delays in getting orthodontia and the following surgery, there is a potential for a reduction in the morbidity and associated lost productivity due to oral clefts. Therefore, to the extent that SB 1634 reduces delays in surgery, there is a potential for a reduction in morbidity and lost productivity of people with oral clefts over the course of a lifetime.

APPENDICES

Appendix A: Text of Bill Analyzed

After introduction, the bill author's office submitted amended text for SB 1634 to CHBRP. At the author's request, CHBRP has focused this report on the amended language. Below is the text as introduced. Following is the amended language.

BILL NUMBER: SB 1634 INTRODUCED
BILL TEXT

INTRODUCED BY Senator Steinberg

FEBRUARY 22, 2008

An act to amend Section 1367.63 of the Health and Safety Code, and to amend Section 10123.88 of the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

SB 1634, as introduced, Steinberg. Health care coverage: cleft palates.

Existing law provides for the regulation of health care service plans by the Department of Managed Health Care. Existing law provides for the regulation of health insurers by the Insurance Commissioner. A willful violation of the provisions governing health care service plans is a crime.

Existing law requires health care service plan contracts and every policy of health insurance covering hospital, medical, or surgical expenses to cover reconstructive surgery, as defined.

On and after January 1, 2009, this bill would require specified health care service plan contracts and the above-described insurance policies to cover orthodontic services deemed necessary for medical reasons by a cleft palate or craniofacial team, as specified. Because the bill would impose new requirements on health care service plans, 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 all of the following:

(a) There are over 1,000 cleft palate procedures performed annually in California.

(b) Children with cleft palates may have special problems related to missing, malformed, or misplaced teeth that require orthodontic procedures.

(c) The orthodontic procedures for cleft palate children to correct these problems are needed for medical reasons to improve speech, eating, and the general health of a child's mouth.

(d) Currently, multiple states require health plans to cover orthodontic care needed for medical reasons as a result of a cleft palate.

SEC. 2. Section 1367.63 of the Health and Safety Code is amended to read:

1367.63. (a) Every health care service plan contract, except a specialized health care service plan contract, that is issued, amended, renewed, or delivered in this state on or after July 1, 1999, shall cover reconstructive surgery, as defined in subdivision (c), that is necessary to achieve the purposes specified in paragraphs (1) or (2) of subdivision (c). Nothing in this section shall be construed to require a plan to provide coverage for cosmetic surgery, as defined in subdivision (d).

(b) No individual, other than a licensed physician competent to evaluate the specific clinical issues involved in the care requested, may deny initial requests for authorization of coverage for treatment pursuant to this section. For a treatment authorization request submitted by a podiatrist or an oral and maxillofacial surgeon, the request may be reviewed by a similarly licensed individual, competent to evaluate the specific clinical issues involved in the care requested.

(c) "Reconstructive surgery" means surgery performed to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease to do either of the following:

(1) To improve function.

(2) To create a normal appearance, to the extent possible.

(d) "Cosmetic surgery" means surgery that is performed to alter or

reshape normal structures of the body in order to improve appearance.

(e) In interpreting the definition of reconstructive surgery, a health care service plan may utilize prior authorization and utilization review that may include, but need not be limited to, any of the following:

(1) Denial of the proposed surgery if there is another more appropriate surgical procedure that will be approved for the enrollee.

(2) Denial of the proposed surgery or surgeries if the procedure or procedures, in accordance with the standard of care as practiced by physicians specializing in reconstructive surgery, offer only a minimal improvement in the appearance of the enrollee.

(3) Denial of payment for procedures performed without prior authorization.

(4) For services provided under the Medi-Cal program (Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code), denial of the proposed surgery if the procedure offers only a minimal improvement in the appearance of the enrollee, as may be defined in any regulations that may be promulgated by the State Department of Health Care Services.

(f) (1) Every health care service plan contract that is issued, amended, renewed, or delivered in this state on or after January 1, 2009, shall cover orthodontic services deemed necessary for medical reasons by a cleft palate or craniofacial team that is identified by the Cleft Palate Foundation for cleft palate procedures.

(2) This subdivision shall not apply to contracts entered into pursuant to Chapter 7 (commencing with Section 14000) or Chapter 8 (commencing with Section 14200) of Part 3 of Division 9 of the Welfare and Institutions Code, between the State Department of Health Care Services and a health care service plan for enrolled Medi-Cal beneficiaries.

SEC. 3. Section 10123.88 of the Insurance Code is amended to read:

10123.88. (a) Every policy of ~~disability~~ health insurance covering hospital, medical, or surgical expenses that is issued, amended, renewed, or delivered in this state on or after July 1, 1999, shall cover reconstructive surgery, as defined in subdivision (c), that is necessary to achieve the purposes specified in paragraphs (1) or (2) of subdivision (c). Nothing in this section shall be construed to require a policy to provide coverage for cosmetic surgery, as defined in subdivision (d). This section shall only apply to health benefit plans, as defined in subdivision (a) of Section 10198.6, except that for accident only, specified disease, or hospital indemnity insurance, coverage for

benefits under this section shall apply to the extent that the benefits are covered under the general terms and conditions that apply to all other benefits under the policy. Nothing in this section shall be construed as imposing a new benefit mandate on accident only, specified disease, or hospital indemnity insurance.

(b) No individual, other than a licensed physician competent to evaluate the specific clinical issues involved in the care requested, may deny initial requests for authorization of coverage for treatment pursuant to this section. For a treatment authorization request submitted by a podiatrist or an oral and maxillofacial surgeon, the request may be reviewed by a similarly licensed individual, competent to evaluate the specific clinical issues involved in the care requested.

(c) "Reconstructive surgery" means surgery performed to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease to do either of the following:

- (1) To improve function.
- (2) To create a normal appearance, to the extent possible.

(d) Nothing in this section shall be construed to require an insurer to provide coverage for cosmetic surgery. "Cosmetic surgery" means surgery that is performed to alter or reshape normal structures of the body in order to improve the patient's appearance.

(e) In interpreting the definition of reconstructive surgery, an insurer may utilize prior authorization and utilization review that may include, but need not be limited to, any of the following:

- (1) Denial of the proposed surgery if there is another more appropriate surgical procedure that will be approved for the enrollee.
- (2) Denial of the proposed surgery or surgeries if the procedure or procedures, in accordance with the standard of care as practiced by physicians specializing in reconstructive surgery, offer only a minimal improvement in the appearance of the enrollee.
- (3) Denial of payment for procedures performed without prior authorization.

(f) Every policy of health insurance covering hospital, medical, or surgical expenses that is issued, amended, renewed, or delivered in this state on or after January 1, 2009, shall cover orthodontic services deemed necessary for medical reasons by a cleft palate or craniofacial team that is identified by the Cleft Palate Foundation for cleft palate procedures.

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.

SB 1634 - Amended Text, submitted to CHBRP on March 5, 2008.

Page 3:

(f) (1) Every health care service plan contract, ***except a specialized health care service plan contract***, that that is issued, amended, renewed, or delivered in this state on or after January 1, 2009, shall cover orthodontic services deemed necessary for medical reasons by a cleft palate or craniofacial team that is identified by the Cleft Palate Foundation for cleft palate procedures.

(2)The prior authorization and utilization review processes prescribed in (e) shall apply to the services provided pursuant to this subsection.

~~(2)~~ (3) This subdivision shall not apply to contracts entered into pursuant to Chapter 7 (commencing with Section 14000) or Chapter 8 (commencing with Section 14200) of Part 3 of Division 9 of the Welfare and Institutions Code, between the State Department of Health Care Services and a health care service plan for enrolled Medi-Cal beneficiaries.

Page 5:

(f)(1) Every policy of health insurance covering hospital, medical, or surgical expenses that is issued, amended, renewed, or delivered in this state on or after January 1, 2009, shall cover orthodontic services deemed necessary for medical reasons by a cleft palate or craniofacial team that is identified by the Cleft Palate Foundation for cleft palate procedures.

(2)The prior authorization and utilization review processes prescribed in (e) shall apply to the services provided pursuant to this subsection.

(3) This subsection shall not apply to Medicare supplement, short-term limited duration health insurance, vision-only, dental-only, or CHAMPUS supplement insurance, or to hospital indemnity, hospital-only, accident-only, or specified disease insurance that does not pay benefits on a fixed benefit, cash payment only basis.

Appendix B: Literature Review Methods

Appendix B describes methods used in the medical effectiveness literature review for SB 1634.

Under current law, health care service plans regulated by the California Department of Managed Health Care (DMHC) and health insurance products regulated by the California Department of Insurance (CDI) are required to reimburse the costs of surgical interventions for cleft palate or craniofacial anomalies. The proposed legislation, SB 1634, would require health care service plans and health insurance plans to pay for the orthodontic services deemed necessary for medical reasons by a cleft palate or craniofacial team that is identified by the Cleft Palate Foundation in addition to the costs of surgery.

The medical effectiveness literature review focused on studies that evaluate the added benefit of coverage for orthodontic services compared to coverage of the surgical services alone. When no such studies were uncovered, the medical effectiveness literature review was expanded to target evidence that team care resulted in better outcomes than services provided by individual professionals without explicit coordination. The literature review uncovered no empirical studies that addressed this issue either.

The review did uncover several articles describing the composition and advantages of team care and several guidelines for care that were based on expert opinion, but not empirical studies.

The search terms for the literature review for SB 1634 appear below.

PubMed and Cochrane Library

MeSH terms

Adolescent

Adult

Bone Transplantation

Child (explode)

Cleft Lip/complications/physiopathology/psychology/surgery/therapy/rehabilitation

Cleft Palate/complications/physiopathology/psychology/surgery/therapy/rehabilitation

Clinical Protocols

Comprehensive Health Care

Delivery of Health Care, Integrated

Health Status

Infant (explode)

Oral Surgical Procedures/standards

Orthodontics (explode)

Outcome Assessment (Health Care)

Patient Care Planning

Patient Care Team

Quality Assurance, Health Care

Quality of Health Care

Quality of Life
Reconstructive Surgical Procedures
Self Concept
Social Adjustment
Speech
Surgical, Oral
Surgery, Plastic
Time Factors
Treatment Outcome

Keywords

Cleft lip, cleft palate, comparative, comparison, effective*, interdisciplinary care, multidisciplinary care, orthodontics, patient care team, quality of life, surgeon*, surgery, team care, time factors, timing, treatment outcome*,

* indicates that a term was truncated to maximize the number of citations retrieved

Web Sites

[American Cleft Palate-Craniofacial Association](#)

[Cleft Palate Foundation](#)

[EuroCrane](#): European Collaboration on Cranial Facial Anomalies

[National Guidelines Clearinghouse](#)

Appendix C: Summary Findings on Medical Effectiveness

This appendix is not included in this report on SB 1634 because no studies provided empirical evidence with respect to the added value of coverage of orthodontic services beyond the value associated with coverage of surgical services for cleft lip, cleft palate, and other craniofacial anomalies.

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, 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, and it provides data and analyses per the provisions of CHBRP 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 (2005) 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 40,000 households. More information on CHIS is available at www.chis.ucla.edu/
2. The latest (2007) 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]),
 - premiums for policies regulated by the California Department of Insurance (CDI) (primarily preferred provider organizations [PPOs]), and
 - premiums for high-deductible health plans (HDHPs) for the California population covered under employment-based health insurance.

This annual survey is 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:

- The MEDSTAT MarketScan Database, which includes demographic information and claim detail data for approximately 13 million members of self-insured and insured group health plans.
- An annual survey of HMO and PPO pricing and claim experience. The most recent survey (2006 Group Health Insurance Survey) contains data from seven major California health plans regarding their 2005 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, 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 94.6% of privately insured enrollees in full-service health plans regulated by DMHC and 85.4% of those privately insured by comprehensive health insurance products regulated by CDI

Public Health Insurance

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—which is 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 available online at www.dhs.ca.gov/admin/ffdmb/mcss/RequestedData/Beneficiary%20files.htm.

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 Major 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-MRMIB 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 people with insurance and only for the first year after enactment of the proposed mandate.
- The projections do not include people covered under self-insured employer plans because those plans are not subject to state-mandated minimum benefit requirements.
- 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., 2003; Hadley, 2006; Glied and Jack, 2003). Chernew et al. estimate that a 10% increase in private premiums results in a 0.74 to 0.92 percentage point decrease in the number of insured, while Hadley (2006) and Glied and Jack (2003) estimate that a 10% increase in private premiums produces a 0.88 and 0.84 percentage point decrease in the number of insured, respectively. The price elasticity of demand for insurance can be calculated from these studies in the following way. First, take the average percentage point decrease in the number of insured reported in these studies in response to a 1% increase in premiums (about -0.088), divided by the average percentage of insured 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-percent 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

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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