



CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

EXECUTIVE SUMMARY
Analysis of Senate Bill 1634
Health Care Coverage: Cleft Palates

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

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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Senate Bill 1634 Health Care Coverage: Cleft Palates

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.

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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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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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