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Analysis of Assembly Bill 368: Mandate to Offer Coverage of Hearing Aids for Children

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Analysis of Assembly Bill 368: Mandate to Offer Coverage for Hearing Aids for Children

A Report to the 2007–2008 California Legislature April 16, 2007

CHBRP 07-01



The California Health Benefits Review Program (CHBRP) responds to requests from the State Legislature to provide independent analyses of the medical, financial, and public health impacts of proposed health insurance benefit mandates and proposed repeals of health insurance benefit mandates. CHBRP was established in 2002, 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 of 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 Assembly Bill 368: Mandate to Offer Coverage for Hearing Aids for Children

April 16, 2007

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PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill 368, a bill to require state regulated health plans and health insurance products to offer up to \$1,000 of coverage for hearing aids for children. In response to a request from the California Assembly Committee on Health on February 15, 2007, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the provisions of Senate Bill 1704 (Chapter 684, Statutes of 2006) as chaptered in Section 127600, et seq. of the California Health and Safety Code.

Janet Coffman, MPP, PhD, Patricia Franks, BA, and Edward Yelin, PhD, all of the University of California, San Francisco, prepared the medical effectiveness analysis. Penny Coppernoll-Blach, MLIS, of the University of California, San Diego, conducted the literature search. Margaret Winter, MS, CCC-A, Coordinator of Clinical Services for the Children's Auditory Research and Evaluation Center at the House Ear Institute, provided technical assistance with the literature review and clinical expertise for the medical effectiveness analysis. Helen Halpin, MSPH, PhD, and Nicole Bellows, MPH, PhD, both of the University of California, Berkeley, prepared the public health impact analysis. Gerald Kominski, PhD, and Ying-Ying Meng, PhD, both of the University of California, Los Angeles, prepared the cost impact analysis. Robert Cosway, FSA, MAAA, of Milliman, provided actuarial analysis. Cynthia Robinson, MPP, of CHBRP staff prepared the background section and combined individual sections into a single report. Cherie Wilkerson, BA, provided editing services. In addition, a subcommittee of CHBRP's National Advisory Council (see final pages of this report) and a member of the CHBRP Faculty Task Force, Thomas Valente, PhD, of the University of Southern California School of Medicine, 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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Jeffrey Hall Acting Director

EXECUTIVE SUMMARY	5
INTRODUCTION	12
MEDICAL EFFECTIVENESS	16
Literature Review Methods	
Interventions and Outcomes Assessed	17
Study Findings	19
Summary of Findings	27
UTILIZATION, COST, AND COVERAGE IMPACTS	34
Present Baseline Cost and Coverage	34
Impacts of Mandated Coverage	38
PUBLIC HEALTH IMPACTS	45
Impact on Community Health	45
Impact on Community Health Where Gender and Racial Disparities Exist	46
Reduction of Premature Death and the Economic Loss Associated with Disease	47
APPENDICES	49
Appendix A: Text of Bill Analyzed	49
Appendix B: Literature Review Methods	52
Appendix C: Summary Findings on Medical Effectiveness	57
Appendix D: Cost Impact Analysis: Data Sources, Caveats, and Assumptions	64
Appendix E: Information Submitted by Outside Parties	
REFERENCES	70

TABLE OF CONTENTS

LIST OF TABLES

Table 1. Summary of Coverage, Utilization, and Cost Impacts of AB 368	9
Table 2. Levels of Hearing Loss	14
Table 3. Summary of Findings from Studies of the Effectiveness of Hearing Aids for Children	29
Table 4. Current Coverage Levels of Hearing Aids for Children	35
Table 5. Baseline (Premandate) Per Member Per Month Premium and Expenditures by Insurance Plan Type, California, 2007	43
Table 6. Postmandate Impacts on Per Member Per Month and Total Expenditures by Insurance Plan Type, California, 2007	44
Table 7. Population Prevalence Estimates for Hearing Impairment	45
Table 8. Gender Differences Among Children 3–17 Years Old with Hearing Trouble, United States 1990–1991.	46
Table 9. Racial and Ethnic Differences Among Children 3–17 Years Old with Hearing Trouble, United States 1990–1991.	47
Table C-1. Summary of Public Studies on the Medical Effectiveness of Intervention to Address Hearing Loss and Hearing Aids for Children.	58

EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Assembly Bill 368: Mandate to Offer Coverage for Hearing Aids for Children

The California Legislature has asked the California Health Benefits Review Program (CHBRP) to conduct an evidenced-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 368. In response to a request from the California Assembly Committee on Health on February 15, 2006, CHBRP undertook this analysis pursuant to the provisions of Senate Bill 1704 (2006) as chaptered in Section 127600, et seq., of the California Health and Safety Code.

AB 368 would add section 1367.195 to the Health and Safety Code and Section 10123.75 to the Insurance Code. AB 368 would require health plans and insurers, regulated by the Department of Managed Health Care (DMHC) and the California Department of Insurance (CDI) to *offer* groups and individuals coverage up to \$1,000 towards the cost of hearing aids to enrollees younger than 18 years. Coverage may be restricted to "one claim during a 48-month period."

The bill defines hearing aids as "any nonexperimental, wearable instrument or device designed for the ear and offered for the purpose of aiding or compensating for impaired human hearing, but excluding batteries and cords." AB 368 does not restrict plans and insurers in their contracting and reimbursement arrangements for coverage of hearing aids or in conducting managed care, medical necessity, or utilization review of these mechanisms in the same manner that plans and insurers use for other sevices and devices.

CHBRP conducted three previous analyses of legislation substantially similar to AB 368. Senate Bill (SB) 1223 (Scott) in 2006, SB 1158 (Scott) in 2004, and SB 174 (Scott) in 2003. SB 1158 and SB 174 are virtually identical to SB 1223. However, AB 368 differs from SB 1223 in three ways:

- (1) AB 368 is a mandate to *offer* coverage, whereas, SB 1223 was a mandate to *provide* coverage;
- (2) AB 368 allows the benefit to be restircted to one claim every 48 months; whereas SB 1223 allowed the benefit to be restricted to one claim every 36 months; and
- (3) AB 368 applies to both individual and group contracts regulated by the CDI and the DMHC; whereas SB 1223 applied to both group and individual insurance policies regulated by the CDI but only group contracts regulated by the DMHC.

Medical Effectiveness

Interventions to diagnose and treat hearing loss in children involve testing children to determine the type and level of hearing loss, fitting children with hearing aids, training parents and teachers how to communicate with children, and training children in the use of hearing aids and in auditory, speech, and language development. The evidence summarized below indicates that hearing aids are helpful to many children who have hearing impairments.

- Studies of children with hearing loss indicate that early diagnosis and treatment have favorable effects on ability to hear and speak, but that improvements cannot be attributed solely to hearing aids, because they are only part of a larger package of diagnostic and treatment services.
 - Children whose hearing loss is diagnosed and treated prior to 6 months of age have more intelligible speech, larger vocabularies, stronger verbal reasoning skills, and greater comprehension of other persons' speech compared to children who receive intervention after 6 months of age.
 - The speech and language development of children whose hearing loss is diagnosed and treated prior to 6 months of age is similar to that of children with normal hearing.
 - Children whose hearing loss is diagnosed and treated at an earlier age also score slightly higher on tests of non-verbal interaction than do children diagnosed and treated at later ages.
 - Evidence of the effects of early diagnosis and treatment on personal and social development is ambiguous.
 - Effects on speech, language, nonverbal interaction, and personal/social development cannot be attributed solely to hearing aids, because most children who have been studied were enrolled in educational intervention programs at the same time they were fitted with hearing aids.
- Relative to older hearing aid technologies, some newer, more sophisticated hearing aid technologies improve the hearing and speech recognition of children with hearing loss. (These technologies are described in the Medical Effectiveness section of the report.)
- Among children who have a cochlear implant, there is some evidence that wearing a hearing aid in the opposite ear is beneficial.
 - Using a hearing aid in the opposite ear from a cochlear implant is associated with better speech recognition and functional performance.
 - Evidence of the effect of using a hearing aid with a cochlear implant on ability to identify the direction from which sound comes is ambiguous.
 - There is limited evidence that bilateral cochlear implants are more effective than the combination of a hearing aid with a cochlear implant.

Utilization, Cost, and Coverage Impacts

• Approximately 118,000 children (aged 0–17 years) in California have hearing impairments and are enrolled in plans or policies subject to AB 368.

- The mandate to offer up to \$1,000 of coverage would subsidize about 25% of the average cost of a pair of hearing aids (\$4,000).
- Currently, 41.7 % of children with hearing impairments in California have more extensive coverage than proposed under AB 368. An estimated 9% of children have coverage similar to the proposed mandated offering. The remaining 49.2% of children with hearing impairments do not have any coverage for hearing aids. Coverage of hearing aids varies by market segments:
 - In the publicly insured market, including the California Public Employees' Retirement System (CalPERS), Medi-Cal, and Healthy Families, 100% of the children with hearing impairments have coverage that equals or exceeds the requirements of AB 368;
 - In the privately insured large-group market, about 34.0% of children with hearing impairments in DMHC-regulated health insurance plans and 54.2% in CDI-regulated health plans have coverage that equals or exceeds the requirements of AB 368;
 - Coverage of hearing aids is largely not available in the private small-group and individual market segments.
- Based on the data from Gallaudet Research Institute's survey, the current hearing aid utilization rate for children who have hearing impairments is 56.1% in California. CHBRP estimated the utilization rate of hearing aids by children *with coverage* to be 58%, and 54% for children *without coverage*. Utilization of hearing aids by children currently without coverage is expected to increase by approximately four percentage points to the same level of utilization by children who currently have coverage. The utilization rate among those with current coverage is expected to remain the same. CHBRP estimates that the hearing aid utilization rate for those without insurance is 2% less than the statewide average, or 54%. This estimate is based on applying a percentage for the number of hearing-impaired children for whom cost is a barrier (1,180 children) to the population subject to the mandated offering who lack coverage (58,000 children).
- When hearing aid coverage is offered as an optional rider, the coverage rates in large-group markets are estimated to increase from 34.0% to 37.1% for DMHC-regulated plans and from 54.2% to 54.4% for CDI-regulated plans, based on the current take-up rates in these markets. In the small-group and the individual market, one health plan would likely offer coverage as a part of base plan, and other health plans, in response to CHBRP's survey of coverage, expressed concerns about adverse selection if the coverage is offered as an optional rider. Therefore, CHBRP assumes that health plans in the small-group and individual markets would offer coverage as a part of their base plans, not as riders.
- The mandated offering is estimated to increase total net annual expenditures by \$2.29 million or 0.003%. The largest portion of the shift in benefit expenditures would be from privately insured individuals' out-of-pocket expenses to insurers. There is an increase in member copayments of \$11.74 million, offset by a decrease of \$14.57 million in expenditures for non-covered hearing aids, for a net reduction in out-of-pocket expenditures of \$2.83 million.

- The mandated offering is estimated to increase premiums by approximately \$5.13 million. Health insurance premiums for members enrolled in privately insured programs are estimated to increase *on average* by 0.008% or \$0.03 per member per month (PMPM). The distribution of the cost impact in different market segments are as follows:
 - Publicly insured programs (e.g., Healthy Families, Medi-Cal, and CalPERS fully-insured plans) are not projected to experience expenditure increases for the employer or state share.;
 - Total private employer premiums will increase by 0.00003% to 0.021% (or \$0.0001 to \$0.06 PMPM). Aggregating across all employers, premium expenditures by private employers will increase by \$2.57 million per year. Enrollee contributions toward premiums would increase by \$863,000.
- Total premiums for individually purchased insurance will increase by 0.025% to 0.047% (or \$0.07 PMPM), resulting in an aggregate increase of \$1.69 million annually.
- Health plans and insurers could comply with this mandated offering in one of two ways: (1) as a written agreement, or rider, that attaches to a policy to modify insurance coverage; or (2) as part of their basic benefit package. In the large group market, CHBRP assumed that health plans and insurers would offer the benefit as a rider because several carriers currently offer this benefit as a rider in this market. Although it is difficult to predict carrier behavior in the small group market, CHBRP assumed that carriers would provide coverage in the base plan to avoid adverse selection (attracting members who anticipated using this benefit). However, if carriers choose to offer this benefit as a rider, it would likely be accompanied by high premiums to compensate for the adverse selection. As a consequence, a very small percentage of small employers and individuals would choose to purchase the rider. While this percentage will probably be small and not exactly zero, the CHBRP best estimate for this scenario is that the mandate will have no material impact on hearing aid costs or utilization.

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Coverage				
Number of insured children aged 0–17 yrs	6,963,000	6,963,000	0	0%
Number of insured hearing-impaired children aged 0–17 yrs with coverage subject to the mandate Percentage of insured children aged 0–17	118,000	118,000	0	0%
yrs with coverage for hearing aids	41.70/	41.70/	0	00/
Full coverage	41.7% 9.0%	<u>41.7%</u> 31.9%	0 22.8%	0%
Coverage similar to mandated levels				
No coverage Number of insured children aged 0–17	49.2%	26.4%	-22.8%	-46.4%
yrs with coverage for hearing aids				
Full coverage	2,907,000	2,907,000	0	0.0%
Coverage similar to mandated levels	630,000	2,218,000	1,588,000	252.1%
No Coverage	3,426,000	1,838,000	(1,588,000)	-46.4%
Number of insured hearing-impaired children aged 0–17 yrs with coverage for hearing aids				
Full coverage	49,000	49,000	0	0.0%
Coverage similar to mandated levels	11,000	38,000	27,000	245.5%
No coverage	58,000	31,000	(27,000)	-46.6%
Utilization and cost	· · ·		,	
Number of children aged 0–17 yrs receiving hearing aids in a year under provisions:				
Full coverage	7,170	7,170	0	0%
Coverage similar to mandated levels	1,550	5,460	3,910	243.8%
No coverage	7,860	4,220	(3,640)	-46.8%
Total	16,580	16,850	270	1.2%
Average cost per set of hearing aids	\$4,000	\$4,000	\$0	0%
Average lifetime of hearing aids (yrs)	4	4	0	0%

Table 1. Summary of Coverage, Utilization, and Cost Impacts of AB 368

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Expenditures				
Premium expenditures by private employers for group insurance	\$43,944,936,000	\$43,947,506,000	\$2,570,000	0.01%
Premium expenditures for individually purchased insurance	\$5,515,939,000	\$5,517,634,000	\$1,695,000	0.03%
CalPERS employer expenditures	\$2,631,085,000	\$2,631,085,000		0.00%
Medi-Cal state expenditures	\$4,015,964,000	\$4,015,964,000		
Healthy Families state expenditures	\$627,766,000	\$627,766,000		
Premium expenditures by employees with group insurance	\$11,515,939,000	\$11,516,802,000	\$863,000	0.01%
Member copayments	\$5,261,095,000	\$5,272,838,000	\$11,743,000	0.22%
Expenditures for noncovered services	\$31,446,000	\$16,869,000	(\$14,577,00)	-46.36%
Total annual expenditures	\$73,544,170,000	\$73,546,464,000	\$2,294,000	0.003%

Table 1. Summary of Coverage, Utilization, and Cost Impacts of AB 368 (Cont'd)

(1) Medi-Cal state expenditures for members under 65 years include expenditures for the Major Risk Medical Insurance Program (MRMIP) and Access for Infants and Mothers (AIM) programs.

Source: California Health Benefits Review Program, 2007.

Note: The population includes individuals and dependents in California who have private insurance (group and individual) or are enrolled in public plans subject to the Health and Safety Code, including CalPERS, Medi-Cal, or Healthy Families. All population figures include enrollees aged 0–17 years covered by employment-based coverage. Employees and their dependents who receive their coverage from self-insured firms are excluded because these plans are not subject to mandates.

Key: CalPERS = California Public Employees' Retirement System

Public Health Impacts

- An estimated 1.7% of children in the United States have a hearing impairment.
- Although 118,000 children (aged 0–17 years) in California have hearing impairments and are enrolled in plans and policies subject to AB 368, it is projected that approximately 270 additional children will receive hearing aids each year as a result of AB 368. These children are new users of hearing aids and are subsequently expected to have improved hearing following the mandated offering.
- Additionally, over 15,000 children could potentially use the benefit of AB 368 to acquire hearing aids with more sophisticated technologies that could further improve speech recognition. Approximately 1,800 children with cochlear implants could potentially use the benefit to obtain a hearing aid in the opposite ear, which has also been shown to be beneficial in children
- In addition to improved hearing, the use of hearing aids in conjunction with educational interventions can also result in improved speech and language development. Although the interventions that aim to improve speech and language development have been found to be effective, they tend to include the use of hearing aids in conjunction with other educational components not specified in AB 368. Therefore, although the passage of AB 368 would likely contribute to better speech and language outcomes, improvements in these areas cannot be attributed to the acquisition of hearing aids alone.
- Male children have higher prevalence rates of hearing problems compared to female children. Additionally, Hispanic children have a higher prevalence of hearing problems compared to non-Hispanic children. The gender and ethnic differences in hearing problem prevalence among children diminish when more stringent definitions of hearing loss are used. No literature was identified that discussed racial or ethnic disparities with regard to receipt of hearing aids.
- Estimates on the lifetime costs associated with hearing loss typically focus on those with severe or profound hearing loss and vary from \$297,000 to \$417,000 per person. In addition to medical costs, lifetime cost estimates include special education costs and costs associated with reduced productivity. No literature was identified that examined economic cost savings associated with hearing aids. As such, although it is possible that AB 368 could contribute to decreased special education and productivity costs associated with hearing loss, there is no evidence in the literature to support this conclusion.

INTRODUCTION

According to the National Institute on Deafness and Other Communication Disorders (NIDCD), hearing loss affects approximately 28 million individuals across the United States. Approximately 17 in 1,000 children have a hearing impairment (NIDCD, 2006). Assembly Bill (AB) 368 would require health care service plan contracts and health insurance policies sold in the group and individual market to *offer* coverage up to \$1,000 in costs for hearing aids to all enrollees under 18 years during a 48-month period.¹ In California, approximately 118,000 children who are enrolled in plans and policies subject to the mandated offering have hearing impairments.

The California Health Benefits Review Program (CHBRP) conducted three previous analyses of legislation substantially similar to AB 368. Senate Bill 1223 (Scott) in 2006, SB 1158 (Scott) in 2004 and SB 174 (Scott) in 2003. Both SB 1158 and SB 1223 passed the California State Legislature and were vetoed by Governor Arnold Schwarzenegger in 2005 and 2006, respectively.²

SB 1158 and SB 174 are virtually identical to SB 1223. However, AB 368 differs from SB 1223 in three ways:

- (1) AB 368 is a mandate to *offer* coverage, whereas, SB 1223 was a mandate to *provide* coverage;
- (2) AB 368 allows the benefit to be restricted to one claim every 48 months; whereas SB 1223 allowed the benefit to be restricted to one claim every 36 months; and
- (3) AB 368 applies to both individual and group contracts regulated by the CDI and the DMHC; whereas SB 1223 applied to both group and individual insurance policies regulated by the CDI but only group contracts regulated by the DMHC.

Current law does not require that coverage for hearing aids be provided as part of a basic contract or offered as an optional benefit to groups or individuals. Nevertheless, about two-thirds of the children who would be affected by the mandated offering are currently offered coverage through an optional rider or as part of a basic product. In the publicly insured market, both Medi-Cal and Healthy Families Program (HFP) require participating plans to provide coverage for hearing aids. HFP will provide coverage of up to \$1,000 every 36 months; Medi-Cal does not have a benefit limit. California Public Employees' Retirement System (CalPERS) also provides coverage up to \$1,000 every 36 months for hearing aids for children in its basic health maintenance organization (HMO) plans.

¹AB 368 would add section 1367.195 to the Health and Safety Code and Section 10123.75 to the Insurance Code. Health care service plans, commonly referred to as health maintenance organizations (HMOs), are regulated and licensed by the California Department of Managed Care (DMHC), as provided in the Knox-Keene Health Care Services Plan Act of 1975. The Knox-Keene Health Care Services Plan Act is codified in the California Health and Safety Code. Health insurance policies are regulated by the California Department of Insurance and are subject to the California Insurance Code.

²Veto messages are available here: <u>http://www.governor.ca.gov/govsite/pdf/vetoes/SB_1158_veto.pdf</u>; and <u>http://gov.ca.gov/pdf/press/sb_1223_veto.pdf</u>.

The bill author's intent is "to help families with children who are hearing impaired. [This] legislation would allow parents to work with their insurance plans to ensure that their children also have the opportunity to grow and develop at the same pace as children who don't have hearing problems.... Unfortunately, at this time, only Healthy Families and Medi-Cal programs cover the cost of hearing aids for very low-income children; while the private insurers have shied away from assuming coverage costs."³

Hearing Aid Insurance Legislation

No states currently mandate that insurers *offer* coverage for hearing aids to children. Eight states—Connecticut, Kentucky, Louisiana, Maryland, Missouri, Minnesota, Oklahoma, and Rhode Island—currently mandate that insurers provide coverage for hearing aids for children or adults (HPTS, 2007). The trend for these mandate laws is to require coverage for children at a prescribed dollar limit over a specified time period. For example, Maryland mandates coverage for children limited to \$1,400 per hearing aid every 36 months. Legislation is currently pending in New Jersey, New Mexico, and New York that would require insurance companies to pay for the cost of hearing aids for children.

Hearing Loss and Early Detection

Hearing loss may be conductive or sensorineural. Conductive hearing loss (usually affecting low-frequency hearing) may be caused by a foreign body, edema of the auditory canal,⁴ or otitis media.⁵ Sensorineural hearing loss occurs when there is damage to the inner ear hair cells or a damaged hearing nerve. Sensorineural hearing loss can be caused by noise, injury, certain medications, tumors, genetic causes, jaundice, meningitis, or problems with blood circulation. The most common cause of conductive hearing loss among children is ear infections. Sensorineural hearing loss in children is most commonly congenital of unknown etiology.

Hearing loss can range from "mild" to "profound." The following table (Table 2) describes the levels of hearing loss.

³ Assembly Member Carter Introduces Legislation to Provide Hearing Aids for Children, February 16, 2007, Press Release. <u>http://democrats.assembly,ca.gov/members/a62/newsroom/20070216AD62PR02.htm</u> (accessed on March 8, 2007).

⁴ "Edema" refers to the presence of an abnormally large amount of fluid in intercellular tissue spaces, such as the auditory canal.

⁵ "Otitis media" refers to a middle ear infection or inflammation and is often accompanied by a common cold, flu, or other respiratory tract infection.

Level of Hearing	Decibel Level	Description
Loss		
Mild	15–40 dB	Cannot hear a whispered conversation in a quiet atmosphere at close range.
Moderate	40–60 dB	Cannot hear normal conversation in a quiet atmosphere at close range.
Severe	60–90 dB	Cannot hear speech; can only hear loud noises such as a vacuum cleaner or lawn mower at close range.
Profound	over 90 dB	Cannot hear speech; may only hear extremely loud noises such as a chain saw at close range or the vibrating component of loud sound.

Table 2. Levels of Hearing Loss

Source: American Academy of Otolaryngology-Head and Neck Surgery Foundation, 2006b.

In order for hearing loss to be treated, it must be detected. According to the NIDCD, approximately 33 children per day are born with significant hearing impairment, and many of these children are not identified until about age two years (NIDCD, 2006). To address this concern of undetected hearing loss in newborns, 11 states and the District of Columbia provide for the establishment of mandatory early hearing screening programs (HPTS, 2007). Beginning in January 2008, California will require a hearing screening to be offered to every newborn upon birth through licensed prenatal services.⁶

Types of Hearing Aids Available on the Market

There are four different styles of hearing aids for people with sensorineural hearing loss. The type of hearing aid that is most suitable for children is Behind-the-Ear (BTE), which is appropriate for those with mild-to-profound levels of hearing loss. BTE aids fall within the category of "traditional air conduction hearing aids" since they use the conduction of air to facilitate hearing.

- In-the-Ear (ITE) hearing aids are used for mild-to-severe hearing loss. A tough plastic case holds the components of the hearing aid. ITE aids accommodate technical mechanisms such as a telecoil, which is a small magnetic coil used in hearing aids that can improve hearing during telephone calls. ITE hearing aids can be damaged by earwax and ear drainage. Because they are small, they can also cause problems resulting from growth changes and unwanted feedback. ITE aids are not usually worn by children because the casings need to be replaced as the ear grows, and children grow rapidly.
- BTE hearing aids are worn behind the ear and are connected to a plastic mold that fits inside the ear. The hearing aid components are held in a case behind the ear. Sound travels through the mold into the ear. BTE aids are used by people of all ages for mild-to-profound hearing loss. Poorly fitting BTE ear molds may cause disturbing

⁶ Health and Safety Code Section 124116.5 (added by Stats. 2006, ch.335).

feedback, such as a whistle sound caused by the fit of the hearing aid or by build-up of earwax or fluid. BTE aids are used regularly in children.

- Canal aids fit into the ear canal and are available in two sizes. In-the-Canal (ITC) hearing aids are customized to fit the size and shape of the ear canal, and are used for mild or moderately severe hearing loss. Completely-in-Canal (CIC) hearing aids are largely concealed in the ear canal and are used for mild-to-moderately severe hearing loss. Their small size makes canal aids difficult to adjust, remove, or hold additional technical devices, such as a telecoil. Because canal aids can also be damaged by earwax and ear drainage, they are not typically recommended for children.
- Body aids are used by people with profound hearing loss. The aid is attached to a belt or a pocket and connected to the ear by a wire. Its large size enables the aid to hold additional technical devices and have other signal-processing options. Although suitable for children or adults, body aids are typically used only when other types of aids cannot be used or are not effective.

Hearing aids also vary by the type of circuitry or electronics used within. The type of circuitry or electronics, rather than the type of hearing aid, is what influences the total price of the hearing aid. There are three types of circuitry/electronics used within hearing aids:

- Analog/adjustable aids allow the audiologist to determine the volume and other specifications needed, and then a separate laboratory builds the aid according to the audiologist's specifications. The audiologist has some flexibility in making adjustments to the aid. These are the least expensive hearing aids.
- Analog/programmable aids allow the audiologist to use a computer to program the hearing aid. The mechanisms behind analog/programmable hearing aids accommodate more than one environmental setting. If the aid is equipped with a remote control device, the wearer can change the program to accommodate a given listening environment. Analog/programmable circuitry can be used in all styles of hearing aids.
- Digital/programmable aids use a microphone, receiver, battery, and computer chip. The audiologist programs digital hearing aids with a computer. The sound quality and response time can be adjusted on an individual basis. Digital hearing aids allow the audiologist to be flexible in making adjustments to the hearing aids. Digital circuitry can be used in all styles of hearing aids and are the most expensive (NIDCD, 2006).

MEDICAL EFFECTIVENESS

Interventions to treat hearing loss in children involve fitting children with hearing aids, and providing educational interventions for children and their caregivers. Hearing aids help children with hearing loss by amplifying sounds. In the United States, the federal Individuals with Disabilities Education Act (IDEA) requires local school districts to provide educational interventions to children with hearing loss. These interventions include training in the use of hearing aids and auditory, speech, and language development. Families of children with hearing loss are often given counseling and training in stimulation of speech and communication. Interventions may also include sign language if a child has profound hearing loss. Most intervention programs for hearing loss among young children provide a combination of home-and school-based services (Carney and Moeller, 1998).

The medical effectiveness review for AB 368 focuses on traditional air conduction hearing aids because they are the type of hearing aids most frequently used by children with hearing loss (Gabbard and Schryer, 2003; Palmer and Ortmann. 2005). AB 368 may also apply to bone conduction hearing aids and vibrotactile aids, wearable devices that are used by persons who are not helped by air conduction hearing aids.⁷ *The review does not assess the effects of bone-anchored hearing aids or cochlear implants because AB 368 only addresses external, wearable devices*. Both bone-anchored hearing aids and cochlear implants combine a surgical implant with an external microphone. The review also does not examine frequency modulation (FM) systems that are used in combination with hearing aids to improve children's ability to hear teachers or other speakers, because school districts typically supply these devices to children.⁸ In addition, this review does not evaluate the effectiveness of screening for hearing loss or the quality of the educational interventions provided to children with hearing loss and their families, because AB 368 only addresses coverage for hearing aids.

Literature Review Methods

Studies of the medical effectiveness of hearing aids were identified through searches of the following databases: PubMed, the Cochrane databases, BIOSIS, Compendex, Inspec, PsycInfo, Sociological Abstracts, Social Sciences Citation Index, and the Educational Resources Information Center (ERIC). Web of Science was searched for articles that cited particularly valuable older articles. The search was limited to abstracts of peer-reviewed studies of children with hearing loss, defined as subjects aged 0–18 years. The search was limited to studies of children with hearing loss because AB 368 would require health plans to cover hearings aids only for children and because characteristics of hearing loss in children and adults differ (Eisenberg et al., 2000; Pittman and Stelmachowicz, 2003; Stelmachowicz et al., 2004). These differences suggest that findings from studies of adults with hearing loss should not be

⁷ Gabbard and Schryer (2003), Gatehouse (2002), and Palmer and Ortmann (2005) provide further information about bone conduction hearing aids, bone-anchored hearing aids, and cochlear implants.

⁸ Palmer and Ortmann (2005) describe FM systems and other assistive listening devices.

generalized to children with hearing loss. A more thorough description of the methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure may be found in Appendix B: Literature Review Methods. Appendix C includes a table (Table C-1) describing the studies on effectiveness. A table (Table 3) summarizing evidence of effectiveness appears at the end of this section of the report.

It is generally accepted that the use of hearing aids improve the hearing of children with hearing loss. As a result, there have been few recent studies on the impact of hearing aids on hearing in children. The current review builds upon the review conducted for SB 1223. The review examines three major categories of recent studies on children with hearing loss: (1) studies of the relationship between age at initial diagnosis and treatment of hearing loss, and children's speech, language, and social development; (2) studies of the relative effectiveness of hearing aids that differ with respect to the type of circuitry and various other technologies; and (3) studies of the effect of wearing a hearing aid in the opposite ear from a cochlear implant.

Interventions and Outcomes Assessed

Studies of the relationship between age at diagnosis and treatment examined the following outcomes:

- Speech development outcomes
- Language development outcomes
- Non-verbal interaction outcomes
- Personal/social development outcomes

Studies of the relative effectiveness of different types of technologies used in air conduction hearing aids evaluated the following technologies. (These technologies are described on pages 22-25 in conjunction with the summary of the literature):

- Compression
- Directional microphone
- Digital feedback suppression
- Frequency transpositioning
- Spectral enhancement

Outcomes of different types of hearing aid technologies assessed include:

- Hearing outcomes
- Speech outcomes
- Satisfaction outcomes
- Parent and teacher assessment of outcomes

Studies of the effectiveness of using a hearing aid in the opposite ear from a cochlear implant evaluated effects on the following outcomes:

• Speech recognition outcomes

- Localization outcomes (i.e., ability to determine the direction from which a sound is coming)
- Functional performance outcomes

The literature review did not discover any randomized controlled trials of children with hearing loss that assess the effects of early diagnosis and treatment of hearing loss, the relative effectiveness of different hearing aid technologies, or the effectiveness of using a hearing aid in the opposite ear from a cochlear implant.

All of the studies of the effectiveness of early diagnosis and treatment were observational studies that did not include control groups of children with hearing loss who did not receive hearing aids or other interventions. Most studies examined a single group of children with hearing loss or two or more groups of children who were grouped by the age at which the children were diagnosed with hearing loss and/or fitted with hearing aids.

The studies of different hearing aid technologies were also observational studies without control groups. Some studies compared a more advanced hearing aid to children's own hearing aids. Other studies compared hearing aids with two or more different types of technologies. Two of the five studies of the use of a hearing aid in the opposite ear from a cochlear implant contained a comparison group of children who had bilateral cochlear implants, but three of the studies compared findings for a single group of children who had unilateral cochlear implants with and without hearing aids.

The lack of randomized controlled trials (RCTs) reflects challenges inherent in conducting research on treatment of hearing loss in children. Hearing aids and educational interventions have been the standard of care for children with hearing loss for so long that some researchers believe it is unethical to deny or delay access to these devices and services (Downs and Yoshinaga-Itano, 1999). Parents and other caregivers may refuse to enroll children in studies in which they might not receive standard treatments for hearing loss (Yoshinaga-Itano et al., 1998). In addition, as a result of the federal IDEA, children whose caregivers suspect hearing loss are entitled to receive a timely evaluation and intervention. This requirement has been interpreted to forbid enrollment of children with hearing loss in RCTs (Yoshinaga-Itano, 2003, 2004). The barriers to conducting RCTs of hearing loss treatments for children are formidable and perhaps insurmountable. These barriers result in a research base that is not as rigorous as that available for many other diseases and conditions, which limits the certainty of conclusions drawn from this literature.

The methodological weaknesses of studies of the use of hearing aids in children preclude CHBRP from awarding its highest grade, "clear and convincing evidence," to evidence of the impact of hearing aids on any of the outcomes these studies assessed. In the remainder of this section, the evidence for an outcome is graded as "preponderance of evidence" if the majority of observational studies that examined the outcome report statistically and clinically significant findings that favor use of hearing aids. The evidence is graded as "ambiguous" if findings differ dramatically across studies that address an outcome.

Study Findings

Studies of the Relationship Between Age at Intervention to Address Hearing Loss and Child Development

Fourteen studies have examined the relationship between age at intervention and outcomes for children with hearing loss. The results of these studies are relevant to assessing the potential benefits of AB 368 because obtaining coverage for hearing aids may make it easier for caregivers (usually parents) to purchase hearing aids for children as soon as hearing loss is diagnosed. However, these studies do not enable one to separate the effects of early receipt of hearing aids from the effects of early receipt of educational interventions. In most of the studies reviewed, children were enrolled in educational intervention programs at the same time that they were fitted with hearing aids, because the standard of care for treatment of children with hearing loss calls for children to receive both hearing aids and educational interventions. One cannot determine whether the outcomes would be the same if the children studied had only received hearing aids.

Speech outcomes

Three studies have examined the effects of age at intervention to treat hearing loss on speech outcomes. Eilers and Oller (1994) investigated the relationship between the age at which infants with severe or profound hearing loss were first fitted with hearing aids and the age at which they began to produce well-formed syllables during vocalization (e.g., "dada," "ma"). There was a statistically significant and negative relationship between age at fitting with hearing aids and age at which children began producing well-formed syllables. The younger a child was when fitted with hearing aids, the younger the age at which he or she began to speak in well-formed syllables.

Calderon and Naidu (2000) assessed speech production by pre-school children who had participated in an intervention program that included hearing aids and speech and language training. They compared children who enrolled in the intervention by age 12 months to children enrolled between ages 13 and 36 months. The relationship between age at intervention and speech production was negative and statistically significant in a multivariate regression that controlled for level of hearing loss, another variable that affects speech production. Thus, the authors found that when level of hearing loss was taken into account, children who enrolled in the intervention at a younger age had better speech production.

Markides (1986) examined teachers' ratings of speech produced by school-aged children with hearing loss. The children were divided into four groups according to the age at which they were first fitted with hearing aids: 6 months or younger, 7 to 12 months, 1 to 2 years, and 2 to 3 years. Teachers rated a significantly higher proportion of children who were first fitted with hearing aids within the first 6 months of life as having speech that was very easy or fairly easy to understand compared with children who were first fitted with hearing aids after they were 6 months old.

Overall, the preponderance of evidence suggests that early diagnosis and treatment of hearing loss decreases the age at which children begin to form syllables and improves the intelligibility of their speech.

Language development outcomes

Eleven studies have assessed the effects of age at intervention to treat hearing loss on language development. Nine studies assessed the impact of age at intervention on children's receptive vocabularies (i.e., comprehension of spoken words and sentences). Six of these studies found that children who were treated for hearing loss at a younger age had better scores on tests of receptive vocabulary and that the differences were statistically significant (Calderon and Naidu, 2000; Friedmann and Sztermann, 2005; Moeller, 2000; Yoshinaga-Itano and Apuzzo, 1998a,b; Yoshinaga-Itano et al., 1998).⁹ Another study found that children whose hearing loss was diagnosed by age 2 months had better scores on a test of receptive vocabulary than did children diagnosed after age 2 months, but the difference was not statistically significant (Apuzzo and Yoshinaga-Itano, 1995). A study of children with severe-to-profound hearing loss, who were tested at ages 3 to 5 years, found that children whose hearing loss was diagnosed and treated at a younger age had a larger receptive vocabulary at initial testing. However, there was no significant association between age at intervention and receptive vocabulary when children were retested 3 to 4 years later (Musselman et al., 1988). Pittman and colleagues' (2005) study of children aged 5 to 13 years found that age at intervention was not associated with receptive language.

The results of the last two studies suggest that the effects of early intervention do not persist over time. Most of the children enrolled in the studies that found that early intervention increased receptive vocabulary were 2 to 3 years old at the time of testing, whereas the children evaluated in the studies that found no difference were aged 5 to 13 years. Other explanations for the difference in findings concern age at intervention, characteristics of interventions, and instruments used to measure receptive vocabulary. In the studies that found that younger age at intervention was associated with a larger receptive vocabulary, most children in the younger group received hearing aids and education during the first 12 months of life. In contrast, two-thirds of the children enrolled in the study that reported that age at intervention had no impact on receptive vocabulary did not receive hearing aids and education are provided during infancy, an especially critical period for development of language. Thus, despite a few nonsignificant findings, the preponderance of evidence suggests that early diagnosis and treatment of hearing loss improve receptive language.

Seven studies examined the effects of age at intervention on children's expressive vocabularies (i.e., the vocabularies they use when communicating with others). Four studies reported that children whose hearing loss was diagnosed by age 6 months had better scores on tests of expressive vocabulary than children whose hearing loss was diagnosed after age 6 months and

⁹ The four studies by Yoshinaga-Itano and colleagues (Apuzzo and Yoshinaga-Itano, 1995; Yoshinaga-Itano and Apuzzo, 1998a,b; Yoshinaga-Itano et al., 1998) analyzed existing data regarding children with hearing loss who were enrolled in the Colorado Home Intervention Program. The samples of children analyzed in these studies may overlap.

that the difference was statistically significant (Apuzzo and Yoshinaga-Itano, 1995; Yoshinaga-Itano and Apuzzo, 1998a,b; Yoshinaga-Itano et al., 1998). Calderon and Naidu (2000) reported that children with a mean age of 3 years whose hearing loss was diagnosed and treated by age 12 months had better scores on a test of expressive vocabulary than did children whose hearing loss was diagnosed and treated between ages 13 and 36 months. They obtained similar results when analyzing a group of children with a mean age of 5 1/2 years. However, one study found no statistically significant relationship between age at intervention and scores on two tests of expressive vocabulary (Musselman et al., 1988). Another study reported that children whose hearing loss was diagnosed after age 31 months had better scores on tests of expressive language than children diagnosed at a younger age and also scored within the low-normal range for children with normal hearing (Kiese-Himmel and Reeh, 2006).

The differences in findings regarding the effect of age at intervention on expressive vocabulary may be due to differences in the ages of the children studied at the time they received hearing aids and education. In the studies that found that younger age at intervention was associated with a larger expressive vocabulary, most children in the younger group received intervention during the first 12 months of life. In contrast, in one of the studies that reached the opposite conclusion, the median age at diagnosis was 28 months, and no children received hearing aids before age 14 months (Kiese-Himmel and Reeh 2006). As with receptive vocabulary, the benefits of early intervention may only accrue if hearing aids and education are provided during infancy. Differences in the instruments used to measure expressive language or the educational interventions provided in conjunction with hearing aids may also have contributed to the differences in findings. Nevertheless, the preponderance of evidence suggests that diagnosis and treatment of hearing loss during infancy improves expressive language.

Two studies analyzed other language outcomes. Moeller (2000) found that 5-year-old children whose hearing loss was treated at an earlier age had better scores on a test of verbal reasoning. Ramkalawan and Davis (1992) assessed measures of syntactic complexity, rate of verbal interaction, and clarity of communication for children with bilateral hearing loss who had a mean age of 57 months (4.75 years). Children who were fitted with hearing aids at a younger age had significantly larger vocabularies, asked a significantly higher proportion of questions in conversation, and spoke significantly more words per minute as measured by one of two instruments. Children who were fitted with hearing aids at a younger age also had greater mean length of utterance in morphemes in words (i.e., grammatically meaningful combinations of sounds), total utterance attempts per minute, and proportions of nonverbal utterances, and spoke more words per minute as measured by a second instrument, but the differences were not statistically significant.

The results of two studies suggest that early diagnosis and treatment may enable children with hearing loss to develop language skills that are equal to those of many children with normal hearing. Yoshinaga-Itano and Apuzzo (1998b) found that children with normal cognitive function whose hearing loss was diagnosed and treated by age 6 months had receptive and expressive vocabularies that were similar to those of children the same age with normal hearing. Similarly, Moeller (2000) reported that 5-year old children whose hearing loss was diagnosed and treated by age 11 months had receptive vocabularies within the average range for 5-year-old children with normal hearing.

Nonverbal interaction outcomes

Three studies examined the effect of age at intervention on nonverbal understanding and interactions. Examples of nonverbal interaction include observation, imitation, discrimination among objects, and motor behavior (Apuzzo and Yoshinaga-Itano, 1995). Yoshinaga-Itano and Apuzzo (1998a) found that children whose hearing loss was diagnosed by age 6 months displayed significantly more advanced -nonverbal comprehension and interaction than children whose hearing loss was diagnosed after age 6 months. Apuzzo and Yoshinaga-Itano (1995) reported that children diagnosed after age 6 months. Apuzzo and Yoshinaga-Itano (1995) reported that children diagnosed with hearing loss by age 2 months had more advanced nonverbal comprehension and interaction than children diagnosed after age 2 months, but the difference was not statistically significant. A study that compared children diagnosed with hearing loss by age 6 months to children diagnosed after age 18 months reported the same finding (Yoshinaga-Itano and Apuzzo, 1998b).

Thus, the preponderance of evidence suggests that early diagnosis and treatment are associated with small, nonsignificant gains in nonverbal understanding and interaction.

Personal/social development outcomes

Five studies investigated the effects of age at intervention to treat hearing loss on children's personal and social development. One study found that children whose hearing loss was diagnosed by age 6 months had significantly higher levels of personal/social development than did children diagnosed after they were 6 months old (Yoshinaga-Itano and Apuzzo, 1998a). Apuzzo and Yoshinaga-Itano (1995) found that children whose hearing loss was identified by age 2 months had higher levels of personal/social development than did children whose hearing loss was identified after age 2 months, but the difference was not statistically significant. A study that compared children diagnosed with hearing loss by age 6 months to children diagnosed after age 18 months reported the same finding (Yoshinaga-Itano and Apuzzo, 1998b). Musselman and colleagues (1988) study found that age at intervention did not have a significant effect on social development. Calderon and Naidu's (2000) study reported mixed results. Children whose hearing loss was diagnosed and treated by age 13 months had better scores on one instrument that measures social development than did children diagnosed and treated later, but worse scores on another instrument. The results were not statistically significant for either instrument.

The lack of consistent and significant findings indicates that the evidence of effects of early diagnosis and treatment of hearing loss on personal/social development is ambiguous.

Studies of the Relative Effectiveness of Technologies Used in Air Conduction Hearing Aids

This part of the Medical Effectiveness section summarizes the literature on the relative effectiveness of five technologies used in air conduction hearing aids. Originally, hearing aids used analog technology to transmit sound as a continuous signal. A major limitation of analog hearing aids is that they amplify all sounds equally. For example, persons who use analog hearing aids may have difficulty hearing conversations in environments with a lot of background noise, because the noise is amplified at the same level as the voices of persons to whom they are listening or talking. As digital technology matured, hearing aid manufacturers began producing hearing aids with digital components that manipulate sound to improve users' ability to hear the sounds that are most important to them.

Compression amplification

Traditionally, analog hearing aids have used a linear amplification technology that provides the same amount of amplification regardless of the loudness of the sound to which a person is listening. As a consequence, amplification may not be adequate to enable a person to hear soft sounds or may amplify loud sounds to the point that they are uncomfortable and distorted (Kopun, 1995). For many persons with sensorineural hearing loss, this problem is exacerbated because they have a narrower range "between the threshold of audibility and the loudness discomfort level" than persons with normal hearing (Palmer and Ortmann, 2005). Although this problem can be addressed by changing the hearing aid's volume, children often have difficulty adjusting volume or may forget to readjust the volume when sound levels change.

Several technologies have been developed to ensure that hearing aids amplify all sounds at adequate and comfortable levels. Peak clipping is a process by which the hearing aid cuts off signals that are uncomfortably loud. Although peak clipping prevents exposure to uncomfortably loud sounds, it can distort loud speech (Gabbard and Schryer, 2003; Kopun. 1995). Output limiting applies less amplification when an amplified signal reaches a certain level (Gatehouse, 2002; Kopun, 1995). Multichannel hearing aids amplify sounds differently depending on their frequency (Kopun, 1995). Compression amplification automatically reduces volume when an amplified signal reaches a fixed level and then returns the volume to a normal level as soon as the intense sound is over. Compression amplification can help persons hear high- and low-intensity sounds within a word or syllable more clearly (Boothroyd et al., 1988). Hearing aids with wide dynamic range compression automatically adjust the level of gain in hearing depending on the level of sound, increasing the gain for soft sounds and decreasing it for loud sounds (Gabbard and Schryer, 2003; Palmer and Ortmann, 2005). Use of digital signal procession than is possible with analog technology (Gabbard and Schryer, 2003).

Six studies have examined the effects of hearing aids with compression amplification on children with hearing loss. Dreschler (1988) assessed peak clipping and single-channel compression amplification. Single-channel compression was associated with a 15-percentage point increase in speech intelligibility relative to peak clipping, but the authors do not report results of tests of statistical significance. Boothroyd and colleagues (1988) compared the effects of a combination of output limiting and compression amplification to output limiting alone. They found that combining output limiting and compression led to a statistically significant decrease in speech recognition relative to output limiting alone. Bamford and colleagues (1999) examined twochannel hearing aids with low-frequency compression amplification and high-frequency linear amplification. The two-channel hearing aids were associated with a statistically significant increase in speech recognition in a noisy environment relative to the children's own singlechannel hearing aids. The two-channel hearing aids were also associated with an increase in speech recognition in a quiet environment, but the increase was not statistically significant. The children were also significantly more satisfied with the two-channel hearing aids. Flynn and colleagues (2004) compared digital hearing aids with multichannel nonlinear compression amplification to children's own analog hearing aids. The children in their study had significantly lower audibility thresholds and significantly better scores on speech recognition tests when using the digital multichannel hearing aids than with their own analog hearing aids. Children rated the

digital multichannel hearing aids more highly in seven out of eight types of listening situations and in four situations the differences were statistically significant (i.e., listening in noise, outdoors, to television, and to music). Parents rated the digital multichannel hearing aids more highly in all eight listening situations; and in six situations, the differences were statistically significant (i.e., listening in quiet, in noise, at a distance, to television, to music, and to vehicles approaching).

Marriage and Moore (2003) compared linear amplification to wide dynamic range compression amplification. They found that children scored higher on a test in which they were asked to select a picture that corresponded to a spoken word when using wide dynamic range compression than when using linear amplification, and that the difference was statistically significant for all children studied regardless of their level of hearing loss. Children also scored higher on a test in which they were asked to repeat spoken words, but the difference was statistically significant only for children with severe hearing loss. Another study by Marriage and colleagues (2005) evaluated the use of three amplification strategies with digital hearing aids: peak clipping, output limiting, and wide dynamic range compression. For children with profound hearing loss, widedynamic range compression was associated with significantly higher scores on one test of speech recognition than those obtained when using peak clipping or output limiting. Children with severe hearing loss did not score as well on this test when using wide-dynamic range compression, but the difference was not statistically significant. Children with profound hearing loss also achieved higher scores on three other speech recognition tests when using hearing aids with wide-dynamic range compression, but the differences were not statistically significant.

Overall, a preponderance of the evidence suggests that compression amplification improves speech recognition and children's satisfaction with hearing aids.

Dual microphones

Traditionally, hearing aids had omnidirectional microphones that amplified sounds from all directions at the same level. Amplifying all sounds at the same level may make it difficult for a person wearing a hearing aid to focus on any single voice, which can frustrate attempts at conversation. Some hearing aids have two or more directional microphones. Hearing aids with dual microphones reduce the volume of signals that come from the rear of a person wearing a hearing aid relative to the volume of signals from the front, enabling the hearing aid user to hear the person in front of him or her more clearly (Gabbard and Schryer, 2003; Gatehouse, 2002; Palmer and Ortmann 2005).

Two studies have compared outcomes of hearing aids with dual microphones and omnidirectional microphones for children with hearing loss. Gravel and colleagues (1999) assessed children with bilateral cochlear hearing loss. The children who participated in the study experienced a statistically significant improvement in hearing of words and sentences when using dual microphone hearing aids. Kuk and colleagues (1999) examined school-aged children with mild-to-profound hearing loss and found a statistically significant improvement in children's ability to hear words. The children also reported less difficulty in listening, but the difference was not statistically significant. The majority of teachers and parents reported that the hearing aids improved listening, comprehension of speech, and intelligibility of children's speech. The results of these studies suggest that dual microphones improve speech recognition.

Digital feedback suppression

"Acoustic feedback occurs when sound that has been amplified by a hearing aid escapes from the ear and is reamplified" (Kopun, 1995). Feedback is distracting for both the person with a hearing aid and other persons in close proximity. Many hearing aids have automatic feedback control features (Gabbard and Schryer, 2003; Gatehouse, 2002).

One study compared the effects of digital feedback suppression hearing aids on children with profound hearing loss to the children's own hearing aids (Henningsen et al., 1994). The children experienced statistically significant increases in gain in hearing in their left ears at all three high frequencies tested (1.5 kHz, 2 kHz, and 3 kHz) relative to their own hearing aids. Hearing also increased in children's right ears, but the increase in gain was statistically significant only at 2 kHz. There were no statistically significant differences in hearing gain at low frequencies.

Thus, this single study provides insufficient evidence that digital feedback suppression improves children's hearing.

Frequency transpositioning

Many children with severe-to-profound hearing loss are not helped by traditional amplification because they have such limited residual hearing at high frequencies that traditional amplification cannot make these sounds audible to them. Frequency transpositioning hearing aids are intended to help these children by converting high-frequency sounds to lower-frequency sounds (Kopun, 1995). One study (Miller-Hansen et al., 2003) examined use of frequency transpositioning hearing aids by children with hearing loss. The authors found that use of a frequency transpositioning hearing aid yielded a statistically significant improvement in children's' ability to detect sound relative to their own hearing aids. There was also a statistically significant and positive association between use of a frequency transpositioning hearing aid and children's scores on a word recognition test.

Thus, this single study suggests that frequency transpositioning hearing aids improve children's hearing and speech recognition.

Spectral enhancement

One study (Franck et al., 1999) examined the effects of spectral enhancement on children with hearing loss. Spectral enhancement modifies the speech signal by altering the time structure or the frequency spectrum of signals. The authors made three comparisons: hearing aids that do not process speech to hearing aids with spectral enhancement and multichannel compression, spectral enhancement alone to spectral enhancement and multichannel compression, and spectral enhancement with multichannel compression to spectral enhancement with single-channel compression. Children's speech was significantly less intelligible when using hearing aids with spectral enhancement and multichannel compression also yielded speech that was significantly less intelligible than speech produced when children wore hearing aids with spectral enhancement alone. There was no statistically significant difference in speech intelligibility when children wore hearing aids with spectral enhancement and multichannel compression versus hearing aids with spectral enhancement and single-channel compression or between spectral enhancement and unprocessed speech.

Thus, this study suggests that the combination of spectral enhancement and multichannel compression has unfavorable effects on the intelligibility of children's speech relative to unprocessed speech or spectral enhancement alone.

Studies of the Effects of Using a Hearing Aid in the Opposite Ear From a Cochlear Implant

Five studies have assessed the impact of using a hearing aid in the opposite ear from a cochlear implant. These implants are used by children with severe or profound sensorineural hearing loss who have one or more ears in which hearing is too poor to derive benefit from a hearing aid. Whereas a hearing aid amplifies sounds to improve the ear's ability to hear them, a cochlear implant bypasses the damaged portions of the ear and directly stimulates the auditory nerve. Cochlear implants consist of an implanted electrode array that is attached to an external device that amplifies sound, processes speech, stimulates the auditory nerve, and transmits signals to the implanted electrode array. Children who receive cochlear implants must undergo extensive speech therapy because the process of hearing with a cochlear implant differs from normal hearing or using a hearing aid (NIDCD, 2006).

When cochlear implants first became available, children typically received an implant in the most damaged ear and did not use a hearing aid or any device in the opposite ear. Audiologists and otolaryngologists were concerned that using a hearing aid in the opposite ear would impede speech recognition and localization (i.e., the ability to determine the direction from which a sound comes) because a sound may elicit a different pitch when processed by a hearing aid and a cochlear implant (Ching et al., 2001; Holt et al., 2005). However, studies of unilateral versus bilateral hearing aids suggest that bilateral amplification reduces neural degeneration and improves localization and speech recognition, especially in noise (Ching et al., 2001; Holt et al., 2005). In addition, the criteria for receipt of cochlear implants has changed. Whereas, cochlear implants were initially approved only for children with profound hearing loss, they are now used in children with severe-to-profound hearing loss, many of whom have some residual hearing in the opposite ear (Holt et al., 2005).

In recent years, several teams of researchers have conducted studies to assess whether using a hearing aid in the opposite ear compromises or improves hearing in children with cochlear implants, and whether bilateral cochlear implants are more effective than the combination of a cochlear implant and hearing aid. Four studies have examined the effect of using a hearing aid with a cochlear implant on speech recognition. Three studies found that using a hearing aid with a cochlear implant was associated with a statistically significant improvement in speech recognition (Ching et al., 2001; Ching et al., 2005; Holt et al., 2005). One study reported that using a hearing aid with a cochlear implant had no effect on speech recognition (Litovsky et al., 2006a). That study also found that bilateral cochlear implants were associated with better speech recognition than were unilateral cochlear implants.

One possible explanation for the difference in findings concerns the tuning of the hearing aids. In two of the studies that found improvements in speech recognition, a staff member at the research center fine-tuned the children's hearing aids to complement their cochlear implants (Ching et al., 2001; Ching et al., 2005). In contrast, the hearing aids used by the children in the study that

found no difference in speech recognition were tuned by the children's own clinicians who may not have been as adept at calibrating hearing aids for use with cochlear implants (Litovsky et al., 2006a).

Overall, the preponderance of the evidence suggests that using a hearing aid with a cochlear implant improves speech recognition, but may not be as effective as bilateral cochlear implants.

Four studies assessed the effect of using a hearing aid in conjunction with a cochlear implant on localization of sound. Localization is an important outcome because it enables a person to determine the direction from which a sound is coming. Knowing the direction of a sound can help a person know where to find a person who is talking to them and turn toward the person or approach to hear him or her more clearly. Localization can also help people avoid accidents because it can enable them to identify the direction from which a harmful sound is coming and move away from it. This can be especially important for children who may be too absorbed in play or conversation to see a vehicle approaching them.

Two studies reported that using a hearing aid with a cochlear implant was associated with a statistically significant improvement in localization (Ching et al., 2001; Ching et al., 2005). Two studies found that using a hearing aid did not affect localization (Litovsky et al., 2006a,b), and one found that the combination of a hearing aid and cochlear implant was worse than bilateral cochlear implants (Litovsky et al., 2006b). As with speech recognition, differences in the tuning of the hearing aids may have contributed to the difference in outcomes.

These conflicting findings suggest that the evidence of the effect of using a hearing aid in the opposite ear from a cochlear implant on localization of sound is ambiguous.

Two studies investigated the impact of using a hearing aid in conjunction with a cochlear implant on parents' assessment of the child's functional performance during activities of daily living. Both studies found that using a hearing aid with a cochlear implant was associated with statistically significant improvements in functional performance, such as answering questions, engaging in conversation, and playing with other children (Ching et al., 2001; Ching et al., 2005).

Summary of Findings

The findings of this review of the literature on the effects of hearing aids on children with hearing loss may be summarized as follows.

Studies of the Effects of Early Diagnosis and Intervention

- Studies of children with hearing loss indicate that early diagnosis and treatment have favorable effects, but improvements cannot be attributed solely to hearing aids because they are only part of a larger package of diagnostic and treatment services.
 - Children whose hearing loss is diagnosed and treated prior to 6 months of age have more intelligible speech, larger vocabularies, stronger verbal reasoning skills, and greater

comprehension of other persons' speech compared to children who receive intervention after 6 months of age.

- The speech and language development of children whose hearing loss is diagnosed and treated prior to 6 months of age is similar to that of children with normal hearing.
- Children whose hearing loss is diagnosed and treated at an earlier age also score slightly higher on tests of nonverbal interaction than do children diagnosed and treated at a later age.
- Evidence of the effects of early diagnosis and treatment on personal and social development is ambiguous.
- Effects on speech, language, nonverbal interaction, and personal/social development cannot be attributed solely to hearing aids, because most children who have been studied were enrolled in educational intervention programs at the same time they were fitted with hearing aids.

Studies of the Relative Effectiveness of Different Hearing Aid Technologies

- Some more sophisticated hearing aid technologies improve outcomes for children with hearing loss.
 - Compression amplification, multidirectional microphones, and frequency transpositioning improve speech recognition.
 - There is insufficient evidence that digital feedback suppression improves children's hearing.
 - Spectral enhancement of speech has unfavorable effects on the intelligibility of children's speech.

Studies of the Use of a Hearing Aid in Conjunction with a Cochlear Implant

- Among children who have a cochlear implant, there is some evidence that wearing a hearing aid in the opposite ear is beneficial.
 - Using a hearing aid in the opposite ear from a cochlear implant is associated with better speech recognition and functional performance.
 - Evidence of the effect of using a hearing aid in the opposite ear from a cochlear implant on ability to identify the direction from which sound comes is ambiguous.
 - There is some evidence that bilateral cochlear implants are more effective than the combination of a hearing aid with a cochlear implant.

Table 3. Summary of Findings from Studies of the Effectiveness of Hearing Aids for Children

Outcome	Research Design ⁽¹⁾	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Speech outcomes (3 studies)	• Level III: 3 studies	 Statistically significant: 3 of 3 studies Not statistically significant: 0 studies Not reported: 0 studies 	 Better for children who were younger at intervention: 3 of 3 studies No effect: 0 studies Worse: 0 studies 	• Difficult to generalize across studies because each study used a different measure of speech intelligibility	• Highly generalizable = 3 of 3 studies	• Preponderance of evidence suggests that early intervention to provide hearing aids and education improves speech outcomes
Language outcomes (11 studies)	• Level III: 11 studies	 Statistically significant: 9 of 11 studies for one or more outcomes Not statistically significant: 2 of 11 studies Not reported: 0 studies 	 Better for children who were younger at intervention: 9 of 11 studies No effect: 2 of 11 studies Worse: 0 studies 	 In 7 studies, children who were younger at intervention scored 11%– 131% higher and, in some cases, scored within the range for children with normal hearing No effect: 2 of 11 studies Size of effect not reported: 2 of 11 studies 	• Highly generalizable = 11 of 11 studies	• Preponderance of evidence suggests that early intervention to provide hearing aids and education improves language outcomes

Part 1—Age at Which Fitted with Hearing Aids and Received Education

(1) Note: Level I = Well-implemented randomized controlled trials (RCTs) and cluster RCTs; Level II = RCTs and cluster RCTs with major weaknesses; Level III = Nonrandomized studies that include an intervention group and one or more comparison groups and time series analyses; Level IV = Case series and case reports; and Level V = Clinical/practice guidelines based on consensus or opinion.

Outcome	Research Design ⁽¹⁾	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Nonverbal understandin g and interaction outcomes (3 studies)	• Level III: 3 studies	 Statistically significant: 1 of 3 studies Not statistically significant: 2 of 3 studies Not reported: 0 studies 	 Better for children who were younger at intervention: 3 of 3 studies No effect: 0 studies Worse: 0 studies 	 Children aged ≤ 2 months at intervention scored 3%–15% higher on tests than children who were older at intervention and children aged ≤ 6 months at intervention scored 5%–14% higher 	• Highly generalizable = 3 of 3 studies	• Preponderance of evidence suggests that early intervention to provide hearing aids and education is associated with a small, nonsignificant increase in nonverbal understanding
Personal/ social development outcomes (5 studies)	• Level III: 5 studies	 Statistically significant: 1 of 5 studies Not statistically significant: 4 of 5 studies Not reported: 0 studies 	 Better for children who were younger at intervention: 4 of 5 studies No effect: 0 studies Worse: 0 studies Not reported: 1 of 5 studies 	• Children who were younger at intervention scored 4%–23% higher on tests depending on the age groups compared and the test used	• Highly generalizable = 5 of 5 studies	• Ambiguous/ conflicting evidence that early intervention to provide hearing aids and education is associated with personal/social development

(1) Note: Level I = Well-implemented randomized controlled trials (RCTs) and cluster RCTs; Level II = RCTs and cluster RCTs with major weaknesses; Level III = Nonrandomized studies that include an intervention group and one or more comparison groups and time series analyses; Level IV = Case series and case reports; and Level V = Clinical/practice guidelines based on consensus or opinion.

Technology/	Research	Statistical	Direction of Effect	Size of Effect	Generalizability	Conclusion
Outcome	Design	Significance				0 0110100000
Compression amplification —effect on speech recognition (6 studies)	• Level IV: 6 of 6 studies	 Statistically significant: 4 of 6 studies Not statistically significant: 1 of 6 studies Not reported: 1 of 6 studies 	 Better: 5 of 6 studies No effect: 0 studies Worse: 1 of 6 studies 	 Scored 3%– 28% higher: 4 of 6 studies Lower score: 1 of 6 studies Size of effect not reported: 1 of 6 	• Highly generalizable = 6 of 6 studies	• Preponderance of evidence suggests that compression amplification improves speech recognition
Multidirection al microphone/ signal-to-noise ratio and speech recognition (2 studies)	• Level IV: 2 of 2 studies	 Statistically significant: 2 of 2 studies Not statistically significant: 0 studies Not reported: 0 studies 	 Better: 2 of 2 studies No effect: 0 studies Worse: 0 studies 	• Improvement of 5.5 to 8 decibels: 2 of 2 studies	• Highly generalizable = 2 of 2 studies	• Preponderance of evidence suggests that multidirectional microphones lower signal-to- noise ratios and improve speech recognition
Digital feedback suppression/ gain in hearing (1 study)	• Level IV: 1 of 1 study	 Statistically significant for gain at high frequencies: 1 of 1 study Not statistically significant for gain at low frequencies: 1 of 1 study Not reported: 0 studies 	 Better at high frequencies: 1 of 1 study No effect or worse effect at low frequencies: 1 of 1 study 	• Size of effect ranged from 1.5-decibel reduction to 15-decibel improvement	• Highly generalizable = 1 of 1 study	• Single study provides insufficient evidence to determine whether digital feedback suppression improves hearing

Part 2—New Hearing Aid Technologies

Technology/ Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Frequency transpositionin g/ speech recognition (1 study)	• Level IV: 1 of 1 study	 Statistically significant: 1 of 1 study Not statistically significant: 0 studies Not reported: 0 studies 	 Better: 1 of 1 study No effect: 0 studies Worse effect: 0 studies 	• Scored 12.5% higher	• Highly generalizable = 1 of 1 study	• Single study suggests that frequency trans- positioning improves speech recognition
Spectral enhancement/ speech recognition (1 study)	• Level IV: 1 of 1 study	 Statistically significant: 2 of 6 comparisons in 1 study Not statistically significant: 4 of 6 comparisons in 1 study Not reported: 0 studies 	 Better: 0 studies No effect: 2 of 6 comparisons in 1 study Worse effect: 4 of 6 comparisons in 1 study 	• Not reported	• Highly generalizable = 1 of 1 study	• Single study suggests that spectral enhancement does not improve speech recognition alone or in combination with compression amplification

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Speech recognition (4 studies)	 Level III: 1 of 4 studies Level IV: 3 of 4 studies 	 Statistically significant: 3 of 4 studies Not statistically significant: 1 of 4 studies Not reported: 0 studies 	 Better: 3 of 4 studies No effect: 1 of 4 studies Worse: 0 studies 	 Scored 50% higher: 1 of 4 studies No difference: 1 of 4 studies Size of effect not reported: 1 of 4 	• Highly generalizable = 4 of 4 studies	• Preponderance of evidence suggests that using a hearing aid in the opposite ear from a cochlear implant improves speech recognition
Localization (i.e., ability to ascertain the direction from which sound is coming) (4 studies)	 Level III: 2 of 4 studies Level IV: 2 of 4 studies 	 Statistically significant: 2 of 4 studies Not statistically significant: 1 of 4 studies Not reported: 1 of 4 studies 	 Better: 2 of 4 studies No effect: 2 of 4 studies Worse: 0 studies 	• Difficult to generalize across studies because most did not report the mean effect size across subjects	• Highly generalizable = 4 of 4 studies	• Ambiguous/ conflicting evidence that using a hearing aid in the opposite ear from a cochlear implant improves localization
Functional performance reported by parent (2 studies)	• Level IV: 2 of 2 studies	 Statistically significant: 2 of 2 studies Not statistically significant: 0 studies Not reported: 0 studies 	 Better: 2 of 2 studies No effect: 0 studies Worse: 0 studies 	• Not reported	• Highly generalizable = 2 of 2 studies	• Preponderance of evidence suggests that using a hearing aid in the opposite ear from a cochlear implant improves functional performance

Part 3—Use of Hearing Aid in Opposite Ear from Cochlear Implant

UTILIZATION, COST, AND COVERAGE IMPACTS

AB 368 would require Knox-Keene licensed health care service plan contracts and insurance policies sold in the group and individual market to *offer* coverage up to \$1,000 for hearing aids to all enrollees and subscribers under 18 years of age. This benefit may be restricted to "one claim during a 48-month period." This section will initially present the current, or baseline, costs and coverage related to hearing aids for children, and then detail the estimated utilization, cost, and coverage impacts of AB 368.

For further details on the underlying data sources and methods, please see Appendix D at the end of this document. A discussion of the current or baseline levels precedes presentation of the impact estimates.

Present Baseline Cost and Coverage

Current Coverage of the Mandated Benefit

The NIDCD estimates that approximately 1.7% of children in the United States have a hearing impairment (NIDCD, 2006). Approximately 118,000 children (ages 0–17 years) in California have hearing impairments and are enrolled in plans or policies that would be subject to the mandated offering (Table 1). Children with hearing impairments who may benefit from the use of a hearing aid includes those children with a cochlear implant in one ear. The population subject to the mandated offering includes children covered by employer sponsored insurance (including CalPERS), individually purchased insurance, or publicly sponsored insurance subject to the requirements of the Knox-Keene Health Care Service Plan Act of 1975 (e.g., Medi-Cal Managed Care, Healthy Families Program) that are regulated by the California DMHC or the CDI. Children covered by self-insured products would not be subject to the mandated offering.

Current law does not require that coverage for hearing aids be provided as part of a basic contract or offered as an optional benefit to groups or individuals. CHBRP estimated the current coverage levels of hearing aids for children in the private market by surveying the seven largest providers of health insurance in California. Based on the responses of six health plans and insurers in California,¹⁰ almost 70.6% of children in the private market who would be affected by the mandated offering are currently offered coverage through an optional rider or as part of a standard or basic product, mainly in the large-group market. Coverage of hearing aids is largely not available in the small-group and the individual market segments.

Based on CHBRP's survey of the seven largest health plans and insurers in California, about 51% of children with hearing impairments in California currently have coverage for hearing aids

¹⁰ The six that responded represent 74.9% of enrollees in the privately insured market.

(Table 4). In the publicly insured market, including CalPERS, Medi-Cal, and Healthy Families, 100% of the children with hearing impairments have coverage that equals or exceeds the requirements of AB 368. Both CalPERS and HFP provide coverage of up to \$1,000 every 36 months. Medi-Cal, which covers 24% of children subject to the mandated offering, includes hearing aids as a covered benefit.

In DMHC-regulated plans purchased by large groups, the take-up rate is typically 22% for an optional rider, resulting in coverage for about 34% of children. In CDI-regulated health insurance products purchased by large groups, the take-up rate is typically 7% for an optional rider, resulting in coverage for about 54.2% of children. One health plan in California covers hearing aids under their durable medical equipment benefit subject to a \$5,000 benefit limit for all large-group medical plans.

Insurance Plan Type	Percentage with Coverage More Than Mandated Offering	Percentage with Coverage Similar to Mandated Offering	Percentage with No Coverage	Total
Privately insured market	8	0	8	
DMHC-regulated health plans				
Large group	20%	14%	66%	100%
Small group	0%	0%	100%	100%
Individual	0%	0%	100%	100%
CDI-regulated health insurance p	roducts			
Large group	51%	3%	46%	100%
Small group	0%	0%	100%	100%
Individual	0%	0%	100%	100%
Publicly insured market				
CalPERS	0%	100%	0%	100%
Medi-Cal	100%	0%	0%	100%
Healthy Families	100%	0%	0%	100%

Table 4. Current Coverage Levels of Hearing Aids for Children

Source: California Health Benefits Review Program, 2007. Analysis of health plan and insurers responses to CHBRP questionnaire on current coverage for AB 368.

Current Utilization Levels and Costs of the Mandated Benefit

Children with hearing impairments have been remediated with hearing amplification devices for decades. Based on the data from Gallaudet Research Institute's *State Summary Report of Data from the 2004–2005 Annual Survey of Deaf and Hard of Hearing Children and Youth,* the current hearing aid utilization rates for children who have hearing impairments are 59.2% for the nation and 56.1% for California (GRI, 2005). This rate includes children with and without insurance coverage for hearing aids. The utilization rates of less than 100% are partially due to

the fact that not all children with hearing impairment use hearing aid devices. Reasons for this include the following:

- Not everyone can be helped with hearing aids. Some children with profound levels of hearing loss will not be helped by the use of a hearing aid. For a portion of this population, cochlear implantation surgery may be a more effective vehicle to improve hearing-loss symptoms. However, as mentioned in the Medical Effectiveness section of this report, there is some evidence that children who have a cochlear implant in one ear will also benefit from wearing a hearing aid in the opposite ear. Additionally, children who experience mild symptoms may have their hearing loss either go undetected or choose to go without a hearing aid.
- Cultural reasons for not using hearing aids. Another potential reason for not using hearing aids is that the deaf community at large views deafness as a characteristic of cultural identity rather than a disability (DANZ, 2001; Kudlick, 2004). Deaf parents who do not interpret deafness as a disability may not want their children to have hearing aids. However, Gallaudet Research Institute's Annual Survey indicates that only 5.6% of deaf or hard-of-hearing children have both parents who are deaf or hard-of-hearing, and another 3.2% children have one parent with hearing problems (GRI, 2005), and so the projected likelihood of this reason for not using hearing aids is assumed to be similarly low.
- Hearing aids take patience and time to learn. Using a hearing aid takes time and adjustment; for example, the molding may be uncomfortable at first. It also takes time for the user to become accustomed to new sounds and environments not previously perceived. There is also a stigma attached to needing hearing aids, and children may not use their hearing aids even if they have them.

CHBRP estimated the hearing aid utilization rates for those with and without insurance coverage for hearing aids because CHBRP did not identify a source that provided this information. The calculation uses as its starting point the current hearing aid utilization rate for children who have hearing impairments, equal to 56.1% in California. CHBRP estimates that the hearing aid utilization rate for those without insurance was 2% less, or 54%. This estimate is based on applying a percentage for the number of hearing-impaired children for whom cost is a barrier to the population subject to the mandated offering who lack coverage. Specifically, a survey conducted by the Listen Up organization found that approximately 1% of respondents cited cost as a barrier to obtaining a hearing aid for a hearing-impaired child (Bender et al., 2003). Using this figure, CHBRP estimates that currently about 1,180 children with hearing impairments may experience cost as a barrier in obtaining hearing aids. Because cost barriers are more likely to affect individuals without coverage, and because those individuals will face higher out-of-pocket payments, CHBRP estimated a utilization rate 2% less for those who lack coverage (1,180/58,000 children who lack coverage = 2%). Given that the average utilization rate of hearing aids for both the insured and uninsured population statewide is 56.1%, the resulting hearing aid utilization rate for those with insurance coverage would be 58% ([(0.54 + 0.58)/2] = 56%). As a result, CHBRP estimates a 58% rate of utilization for children with coverage for hearing aids and a 54% rate for children without coverage for the purposes of this analysis.

Per-unit cost of hearing aids

Behind-the-ear (BTE) hearing aids are the style of choice for most children. The price of hearing aids ranges from a few hundred dollars to more than \$2,500, with linear analog hearing aids costing the least (AAO, 2006a). Due to technical advancements, analog hearing aids are currently being phased out. Based on the 2006 Hearing Review Dispenser Survey, economy BTE digital aids averaged \$1,339, whereas the cost of the premium BTE digital aids averaged \$2,588 (Strom, 2006). The average price of a hearing aid in 2005 was \$1,904.¹¹ Therefore, for the purposes of this analysis, the estimated average cost of a hearing aid is \$4,000 per pair (one for each ear).¹²

The average lifetime of a hearing aid was 4.5 years in 2004 (Kochkin, 2005). The need for new hearing aids may occur more frequently if a child's hearing status changes, but with the availability of programmable and digital hearing aids, these adjustments can be made in the audiologist's office without ordering new devices. Wear and tear caused by earwax and general use will affect the life span of a hearing aid. For the purpose of this analysis, we expect families will get a new pair of hearing aids for their child with hearing impairment every 48 months.

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

CHBRP estimates no shift in costs among private or public payers as a result of current coverage. Though many privately insured hearing-impaired children do not have coverage for hearing aids, many of them still obtain hearing aids:

- Families make other sacrifices to obtain hearing aids for children. A general supposition is that families forgo expenditures on other items to obtain hearing aids for their hearing-impaired children. In addition, there is anecdotal evidence to suggest that individuals without coverage may purchase hearing aids but will opt for the less expensive versions using older technology (NAAS, 1999).
- Charities exist. There are organizations that provide hearing aids for free or at a drastic discount, based on specified qualifications. The Miracle-Ear Children's Foundation provides hearing aids to children 16 years or younger whose families are low income but do not qualify for public support (Miracle-Ear Children's Foundation, 2004). A national hearing aid bank, called HEAR NOW, provides new and reconditioned hearing aids for people who meet financial and medical qualifications (Starkey Hearing Foundation, 2005).
- Health plans and insurers provide discounts to members or subscribers. Although health plans and insurers generally do not cover hearing aids, some have relationships with vendors to provide a discount to their members or subscribers.

¹¹ 2005 was the last full year for which these data are available.

¹² As discussed, per AB 368, hearing aids are defined as "any nonexperimental, wearable instrument or device designed for the ear and offered for the purpose of aiding or compensating for impaired human hearing, but excluding batteries and cords." Therefore, this analysis does not include bone-anchored hearing aids or cochlear implants.

Public Demand for Coverage

As a way to determine whether public demand exists for the proposed mandated offering (based on criteria specified under SB 1704 (2006)), 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 mandated offering. Currently, the largest public self-insured plans are CalPERS' PERSCare and PERS Choice preferred provider organization (PPO) plans. These plans include coverage for hearing aids for children, up to \$1,000 per member, every 36 months. The Self-Insured Schools of California, one of the largest purchasing pools in California covering 200,000 subscribers statewide, also provides coverage benefit levels identical to CalPERS.

Based on conversations with the largest collective bargaining agents in California, no evidence exists that unions currently include such detailed provisions (specific to medical devices such as hearing aids) during the negotiations of their health insurance policies. In general, unions tend to negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and coinsurance levels.¹³ In order to determine whether any local unions engage in negotiations at such detail, they would need to be surveyed individually.

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?

Large-group market

CHBRP surveyed the seven largest health plans and insurers in California to predict their response to the mandated offering. Based on the six respondents, representing 74.9% of enrollees in the privately insured market, CHBRP estimates that the percentage of children covered as part of a base product in the large-group market would stay the same after AB 368 was enacted, whereas the rest of children in the large market would be covered either in the base product or through an optional rider. It is very likely some children in the large-group market would still have no coverage after AB 368 was enacted if their employers choose not to purchase a newly offered rider. Based on the current take-up rates of 22% in DMHC-regulated plans and 7% in CDI-regulated plans, the coverage for hearing aids would increase to 37.1% in large-group markets of DMHC-regulated plans and 54.4% in CDI-regulated plans.

Small-group and individual markets

No commercial carriers currently cover or offer coverage for hearing aids in either the smallgroup or individual market. In response to CHBRP's carrier survey, one carrier stated they would likely offer coverage as a part of the base plan. No carrier suggested they would offer coverage as a rider. Several carriers responded that they were unable to predict the manner in which they would offer coverage if the bill was enacted into law. Carriers expressed concern with offering hearing aids as a rider due to the potential for "adverse selection." Adverse selection occurs when individuals self-select into plans with hearing aid coverage because of their anticipated

¹³ Personal communication with the California Labor Federation and member organizations on January 29, 2007.

utilization of these services. For example, in the individual market, only families with children that need hearing aids would be likely to purchase a hearing aid rider. As a result, the price for a family to add this rider might be close to the \$1,000 benefit. In modeling the impact of this bill in these market segments, CHBRP considered the possibility that carriers would offer coverage as a rider, but charge extremely high prices to adjust for potential adverse selection. Since the rider premiums would be very high, it is likely that a very small percentage of small employers would choose to purchase the rider. In the individual market, families electing the rider for their children would essentially pay for the full cost of the benefit received. Consequently, a high-priced optional rider would result in no increase in coverage for those children with hearing impairments.

The alternative scenario, which is the assumption reflected in the cost estimates, assumes that carriers would avoid the adverse selection issue by including this benefit in the base plan for products offered in the individual and small-group market. In other words, even though the bill only requires carriers to *offer* coverage, CHBRP assumed carriers would actually *provide* coverage to all insured in the individual and small-group market. The method CHBRP chose produces a conservative estimate for the costs, since all individuals and small groups who purchase insurance are assumed to get hearing aid coverage. However, if carriers choose to offer this benefit as a rider with extremely high premiums, the true cost may actually be closer to zero, and the number of children in small groups and individual plans having this coverage may also be close to zero.

Per-unit cost changes

The per-unit cost of hearing aids is expected to remain the same after the mandated offering. The \$1,000 annual benefit acts as a subsidy. Although such a subsidy may put some inflationary pressures on the per-unit cost, health plans and insurers may obtain discounts from manufacturers and wholesale distributors in the same way they obtain discounts on other medical devices.

How Will Utilization Change as a Result of the Mandate?

The utilization rate for children who are not currently covered for hearing aids is estimated to increase from a current rate of 54% to 58%. This increase will put the utilization for these newly covered children on par with the rate for those who already have coverage. The utilization rates for those with coverage will stay the same (58%). As mentioned above, the estimated utilization rate increase is limited because of the following:

- Some children who are profoundly hearing impaired may not receive significant benefits from using a hearing aid.
- Some children may have hearing loss that is so mild that their hearing loss goes undetected, or they choose not to use a hearing aid.
- Cost does not appear to be a strong access barrier.

As previously discussed, the average lifetime of a child's hearing aid is expected to be around 4 years. Due to the availability of programmable and digital hearing aids, the adjustments can be made in the audiologist's office if a child's hearing status changes. Thus, the hearing aid benefit is expected to be used once every 4 years per affected child. This is an average, as some children

may need to replace their hearing aid(s) more frequently and others less frequently. After the mandated offering was enacted, we would expect 270 additional children to obtain hearing aids annually who would otherwise not be able to obtain hearing aids by other means (e.g., out-of-pocket expenses, charity services, etc.).¹⁴

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

Administrative expenses may include the cost of setting up contracts with hearing aid dispensers, or building financial arrangements for currently contracted hearing aid dispensers.

Because AB 368 would mandate that health plans and insurers offer the benefit once every 48 months, there may be some administrative expenses associated with setting up systems that track utilization over that time period. Typically, benefits are tracked and provided over the members' or policyholders' contract or 12-month period.¹⁵

Health care plans include a component for administration and profit in their premiums. In estimating the impact of this mandated offering on premiums, actuarial analysis (see Appendix D) assumes that health plans will apply their existing administration and profit loads to the increase in health care costs produced by the mandated offering. Therefore, although there may be administrative costs associated with the mandated offering, administrative costs *as a percentage of premiums* would not change.

Impact of the Mandate on Total Health Care Costs

The mandated offering is estimated to increase total net annual expenditures by \$2.29 million or 0.003%. The mandated offering will increase premiums by \$5.13 million (\$2.57 million for the portion of group insurance premiums paid by private employers, \$1.69 million for individually purchased insurance, and \$863,000 for the portion of group insurance, CalPERS, and Healthy Families premiums paid by enrollees). At the same time, there is an increase in member copayments of \$11.74 million, offset by a decrease of \$14.57 million in out-of-pocket expenditures for noncovered hearing aids, for a net reduction in out-of-pocket expenditures of \$2.83 million. In addition to providing access to hearing aids for about 270 children, the premium increase will mainly go to relieve some of the cost burden for those children who need to replace their hearing aids, but are not currently covered by their insurers.

Actuarial analysis for AB 368 shows that the total expenditure for hearing aids in California (including total premiums and out-of-pocket spending for copayments and noncovered benefits) would increase by between 0.00001% and 0.019% for those markets affected by the mandated offering. For those markets, health insurance premiums are estimated to increase *on average* by 0.008% or \$0.03 per member per month (PMPM). These estimates should be viewed as an upper

¹⁴ See Appendix D under Mandate-Specific Caveats and Assumptions for how this was calculated.

¹⁵ It is possible that a member may switch plans with the same carrier during a 4-year benefit period. To the extent to which this information is tracked among the same carrier, the benefit may be reset to the start of a 48-month period or continued. This analysis assumes no change in enrollment status. See Appendix D for caveats and assumptions related to this analysis.

bound, given that they are based on a pair of hearing aids, at a cost of \$4,000 per pair, although some children may only need one hearing aid or may go with a less expensive model.¹⁶

These estimates represent the overall cost for those markets affected by the mandated offering. It is possible that since the benefit only affects children, premiums associated with family or parent-child policies may face an increase in premiums, whereas single (no child) policies face no premium increases for group contracts, especially in the small-group market. However, because the impact of AB 368 represents a small premium percentage increase, it is estimated that the impact would, in practice, be spread over all members in the group market. In the individual market for CDI-regulated plans, it is likely that increases in premiums would be smaller for adult contracts and larger for policies that cover children, specifically children with hearing loss.

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

Increases in insurance premiums vary by market segment. Increases as measured by percentage changes in premiums are estimated to range from 0.0003% to 0.047% in the affected market segments. Increases as measured by PMPM premiums are estimated to range from \$0.0001 to \$0.07. The greatest impact on premiums would be on the small-group and individual markets. A substantial portion of the increase in insurance premiums would be due to insurance absorbing a portion of the benefit's cost previously paid for by the insured. This transfer effect is discussed below.

In the large-group market, the coverage rates would increase to 37.1% in DMHC-regulated plans with a 22% take-up rate and 54.4% with a 7% of take-up rates in CDI-regulated market among those newly offered as optional riders, and the resulting premium impact would range from 0.00003% to 0.001%. In terms of PMPM, the increase in premiums for the large-group market is estimated to range from \$0.0001 to \$0.002. For members with small-group insurance policies, health insurance premiums are estimated to increase by approximately 0.02% (see Table 6). Given that the small-group market is largely not offering the option to purchase hearing aid coverage as a benefit, this impact may be explained by the effects of increased coverage rates (from 0% coverage to 100% coverage).

In the individual market, the health insurance premiums are estimated to increase by 0.025% in DMHC-regulated market and by 0.047% in CDI-regulated market with an increase of \$0.07 PMPM. Given that insurers may underwrite to reflect risk, increases in premiums would be smaller for adult contracts and larger for policies that cover children.

CalPERS currently includes hearing aids as a covered benefit to subscribers and their dependents, limited to \$1,000 every 36 months. CalPERS coverage exceeds the mandated

¹⁶ Based on the 1990–1991 Vital Health Statistics report, among children 3–17 years with hearing loss, 47% had bilateral hearing loss, 38% had unilateral, and the status of 15% was unknown. These data do not indicate what proportion of each category are hearing aid users. Children with either bilateral or unilateral hearing loss, especially those with bilateral loss, may get two hearing aids.

offering required by AB 368, therefore, CalPERS is expected to face no impact if AB 368 was enacted.

Medi-Cal and Healthy Families Program (HFP) also provide coverage for children's hearing aids at more than the mandated offering level. Because enrollees in these public programs have coverage that exceeds that of private insurers, no cost shifting is expected to occur from the public programs to the privately insured market nor would these programs incur a cost as a result of the mandated offering. The HFP already provides a \$1,000 subsidy every three years. Medi-Cal covers the total cost of hearing aids and ancillary items, following a hearing assessment, at no cost every year.

The largest portion of the shift in benefit expenditures would be from privately insured individuals' out-of-pocket expenses to third parties. For example, in the large-group HMO market, \$0.001of the out-of-pocket expenses (measured as PMPM costs) would be expected to shift to the health plan or insurer.

Because the benefit mandated offering is limited to \$1,000 and does not cover the entire cost of a pair of hearing aids, or the ancillary costs, including batteries and cords, the user would continue to incur cost at the point of purchase. In addition, any out-of-pocket costs related to adjusting the hearing aid—for example, molds to adjust the aid to the ear as the child grows—would also be incurred.

Impact on Access and Health Service Availability

As previously discussed, the mandated offering would increase access for individuals for whom the cost of a hearing aid was a barrier to access and for whom \$1,000 every 48 months would help eliminate that barrier. Based on the expected changes in utilization, the mandate would increase access for approximately 4% of children with hearing impairments among those children without coverage.

Another possible scenario may occur if some members relied on charity-based organizations to obtain hearing aids for children prior to the mandate. These organizations typically require the child *not* be covered for hearing aids by some other means (e.g., private or public insurance). Additionally, these agencies usually require family income to be no more than 100%–250% of the federal poverty level. Because the number of privately insured children with hearing impairments at this income category is limited, we do not expect the mandated offering to affect many families currently receiving charity care.

	Large	Group	Small	Group	Indiv	idual	CalPERS		diCal ged Care	Healthy Families	
	DMHC Regulated	CDI Regulated	DMHC Regulated	CDI Regulated	DMHC Regulated	CDI Regulated	НМО	65 and Over	Under 65	Managed Care	Total Annual
Population currently covered	10,354,000	363,000	3,086,000	679,000	1,268,000	794,000	791,000	165,000	2,513,000	681,000	20,694,000
Average portion of premium paid by employer	\$249.51	\$323.69	\$249.52	\$281.52	\$0.00	\$0.00	\$277.19	\$181.00	\$120.43	\$76.82	\$51,194,004,000
Average portion of premium paid by employee	\$53.66	\$74.60	\$94.73	\$61.82	\$269.42	\$148.66	\$48.92	\$0.00	\$0.85	\$5.78	\$17,057,625,000
Total premium	\$303.17	\$398.28	\$344.26	\$343.34	\$269.42	\$148.66	\$326.11	\$181.00	\$121.29	\$82.60	\$68,251,629,000
Member expenses for covered benefits (deductibles, copays, etc)	\$16.69	\$41.50	\$25.59	\$102.13	\$45.45	\$35.38	\$17.17	\$0.00	\$0.56	\$2.25	\$5,261,095,000
Member expenses for benefits not covered	\$0.14	\$0.10	\$0.21	\$0.21	\$0.17	\$0.17	\$0.00	\$0.00	\$0.00	\$0.00	\$31,446,000
Total expenditures	\$320.00	\$439.88	\$370.06	\$445.68	\$315.04	\$184.21	\$343.27	\$181.00	\$121.85	\$84.85	\$73,544,171,000

Table 5. Baseline (Premandate) PMPM Premium and Expenditures by Insurance Plan Type, California, 2007

Source: California Health Benefits Review Program, 2007.

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, Access for Infants and Mothers [AIM], Major Risk Medical Insurance Program [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. Numbers may not add due to rounding.

Key: CalPERS = California Public Employees' Retirement System; CDI, California Department of Insurance; DMHC = Department of Managed Health Care; HMO = health maintenance organization and point of service plans.

	Large	Group	Small	Group	Indiv	idual	CalPERS		l Managed are	Healthy Families	
	DMHC Regulated	CDI Regulated	DMHC Regulated	CDI Regulated	DMHC Regulated	CDI Regulated	НМО	65 and Over	Under 65	Managed Care	Total Annual
Population currently covered	10,354,000	363,000	3,086,000	679,000	1,268,000	794,000	791,000	165,000	2,513,000	681,000	20,694,000
Average portion of premium paid by employer	\$0.00	\$0.00	\$0.05	\$0.06	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$2,570,000
Average portion of premium paid by employee	\$0.00	\$0.00	\$0.02	\$0.01	\$0.07	\$0.07	\$0.00	\$0.00	\$0.00	\$0.00	\$2,558,000
Total premium	\$0.002	\$0.0001	\$0.07	\$0.07	\$0.07	\$0.07	\$0.00	\$0.00	\$0.00	\$0.00	\$5,128,000
Member expenses for covered benefits (deductibles,											
copays, etc) Member expenses for benefits not covered	\$0.01 -\$0.01	\$0.00 \$0.00	\$0.17 -\$0.21	\$0.17 -\$0.21	\$0.14 -\$0.17	\$0.14 -\$0.17	\$0.00 \$0.00	\$0.00 \$0.00	\$0.00 \$0.00	\$0.00 \$0.00	\$11,743,000 -\$14,577,000
Total member expenditures	\$0.00	\$0.00	\$0.03	\$0.03	\$0.03	\$0.03	\$0.00	\$0.00	\$0.00	\$0.00	\$2,293,000
Percentage impact of mandate											
Insured premiums	0.001%	0.00003%	0.020%	0.021%	0.025%	0.047%	0.000%	0.000%	0.000%	0.000%	0.008%
Total expenditures	0.0002%	0.00001%	0.008%	0.007%	0.011%	0.019%	0.000%	0.000%	0.000%	0.000%	0.003%

Table 6. Postmandate Impacts on PMPM and Total Expenditures by Insurance Plan Type, California, 2007

Source: California Health Benefits Review Program, 2007.

Note: MediCal DMHC-Regulated Under 65 includes the Major Risk Medical Insurance Program (MRMIP) and Access for Infants and Mothers (AIM) programs. Numbers may not add due to rounding.

Key: CalPERS = California Public Employees' Retirement System; CDI, California Department of Insurance; DMHC = Department of Managed Heakth Care; HMO = health maintenance organization and point of service plans.

PUBLIC HEALTH IMPACTS

This analysis uses a prevalence of 1.7% of children in the United States under 18 years old who are affected by hearing loss (NIDCD, 2007)¹⁷. Other estimates on the prevalence of children with hearing loss in the United States exist, with most estimates in the range of 1% to 2% of the pediatric population. Table 7 describes five different prevalence estimates that vary according to population and hearing-loss criteria. The NIDCD prevalence estimate of 1.7% applies to the most relevant population for AB 368.

Source	Population	Criteria	Estimate
Mitchell, 2006 Survey of Income and Program Participation	Children 6–17 yrs	Difficulty understanding human speech	0.6%
Van Naarden et al., 1999 Metropolitan Atlanta Developmental Disabilities Surveillance Program	Metro Atlanta children 3–10 yrs	Serious hearing impairment	1.1%
National Institute on Deafness and Other Communication Disorders (NIDCD, 2007)	Children under 18 yrs	Affected by hearing loss	1.7%
Ries, 1994 Vital and Health Statistics 1990– 1991	Children 3–17 yrs	All levels of hearing trouble	1.8%
Niskar et al., 1998 NHANES III	Children 6–19 yrs	Self-reported hearing difficulty	3.4%

Table 7: Population Prevalence Estimates for Hearing Impairment

Impact on Community Health

The provision of hearing aids is one important component in achieving improved health outcomes for children. Other important factors include early detection of hearing loss and education interventions to assist children in developing and improving language abilities with the help of hearing aids and other hearing assistance technologies.

When they are used correctly, it is generally accepted that hearing aids improve hearing in children. As such, it is expected that hearing will improve substantially for the 270 projected new users of hearing aids who previously did not use any hearing technologies. These 270 new users of hearing aids are most likely children of low-income families since low-income individuals reported much higher rates of delaying or not getting medical treatment due to financial reasons (CHIS, 2001).

AB 368 could also be used to assist children who already use hearing technologies. AB 368 applies to more than 15,000 children who are estimated to currently have hearing aids and could therefore potentially use the hearing aids benefit of AB 368 to acquire hearing aids with more sophisticated technology, such as compression amplification and multidirectional microphones

¹⁷ National data were used because reliable estimates on the number of Californian children under 18 years that have hearing impairments or are affected by hearing loss were not identified.

that have been found to improve speech recognition in children.¹⁸ Approximately 1,800 children, enrolled in plans subject to AB 368, are estimated to currently have with cochlear implants and could also potentially use the benefit to obtain a hearing aid in the opposite ear, which has also been shown to be beneficial in children.¹⁹

Another potential benefit of AB 368 is that it could prevent delays in the fitting of hearing aids in low-income children while their families apply for and are approved for public assistance programs for hearing aids. Researchers have found that the earlier hearing loss is identified and treated, the better the outcomes are for speech and language development (Eilers and Oller, 1994; Markides, 1986; Yoshinaga-Itano and Apuzzo, 1998a; Yoshinaga-Itano et al., 1998). However, although the interventions that aim to improve speech and language development have been found to be effective, they tend to include the use of hearing aids in conjunction with other educational components not specified in AB 368. Therefore, although the passage of AB 368 would likely contribute to better speech and language outcomes, improvements in these areas cannot be attributed to the acquisition of hearing aids alone.

Impact on Community Health Where Gender and Racial Disparities Exist

A literature review was conducted to determine whether there are gender or racial disparities associated with the prevalence, treatment, and outcomes for pediatric hearing loss documented in the academic literature.

Table 8 details data from 1990–1991 that show gender differences in prevalence rates for hearing loss in children. Males have higher prevalence rates of hearing trouble; however, for more-severe hearing loss, the gender disparities appear to lessen (Ries, 1994). Among non-Hispanic white children, Lee et al. (1996) also found higher levels of hearing loss in males compared to females.

Beyond prevalence, a couple of studies have found that among children with hearing impairments, females have better language performance and make better use of their hearing aids compared with males (Easterbrooks and O'Rourke, 2001; Markides, 1989).

Gender	All Levels of Hearing Trouble (per 1,000)	Affects Speech Comprehension (per 1,000)	At Best, Can Hear Shouted Words (per 1,000)
Males	19.8	9.1	2.8
Females	16.4	8.0	2.6
Total	18.2	8.6	2.7

Table 8: Gender Differences Among Children 3–17 Years Old with Hearing Trouble, United States 1990–1991

Source: Ries, 1994

¹⁸ The more than 15,000 children with hearing aids who could potentially use the benefit to improve outcomes was calculated based on the estimate that AB 368 would result in an increase in 27,000 children with hearing impairments who would have coverage at the mandate level and the estimate that 56.1% of children with hearing impairments in California use hearing aids (GRI, 2005).

¹⁹ The more than 1,600 children with cochlear implants who could potentially use the benefit to improve outcomes was calculated based on the estimate that 6.6% of children with hearing impairments in California have cochlear implants (GRI, 2005).

Ries (1994) also provides information on different prevalence rates by racial and ethnic categories. The most noticeable disparity in Table 9 is that Hispanic children have a higher prevalence of hearing trouble compared to non-Hispanic children. Other researchers have also found that Hispanics have higher rates of hearing impairment, particularly among Cuban-Americans and Puerto Ricans (Lee et al., 1996; Niskar et al., 1998).

Although not evident in the national Vital Health Statistics data, studies based on the Metropolitan Atlanta population have found elevated prevalence rates of hearing loss for black children (Van Naarden and Decoufle, 1999; Van Naarden et al., 1999). As with gender disparities, the racial and ethnic differences in prevalence diminish when more stringent definitions of hearing loss are used (Lee et al., 1996; Ries, 1994).

Table 9: Racial and Ethnic Differences Among Children 3-17 Years Old with Hearing Trouble,	,
United States 1990–1991	

Race or Ethnicity	All Levels of Hearing Trouble (per 1,000)	Affects Speech Comprehension (per 1,000)	At Best, Can Hear Shouted Words (per 1,000)
Race			
White	19.4	9.3	2.8
Black	12.2	4.8	NS
Other	15.3	NS	NS
Hispanic ethnicity			•
Non-Hispanic	17.9	8.5	2.6
Hispanic	20.3	9.4	3.4
All races and ethnicities	18.2	8.6	2.7

Source: Ries, 1994

In addition to prevalence differences, the literature search also showed racial and ethnic disparities with regards to treatment for children with hearing loss. Kittrell and Arjmand (1997) found that white children are diagnosed with sensorineural hearing impairment earlier compared to black and Hispanic children, and this difference is independent of socioeconomic status. These findings have important implications because earlier diagnosis and intervention lead to better language abilities (Yoshinaga-Itano et al., 1998). Stern et al. (2005) also found disparities in receipt of cochlear implants, with white and Asian children receiving implants at significantly higher rates than black and Hispanic children.

No literature was identified that discussed racial or ethnic disparities with regard to receipt of hearing aids or access to a hearing aids benefit.

Reduction of Premature Death and the Economic Loss Associated with Disease

A literature review was conducted to determine the extent to which pediatric hearing loss results in premature death and economic loss to California, and whether AB 368 might have an impact on these outcomes.

Premature death is not a health outcome associated with hearing loss as described in the academic literature. Barnett and Franks (1999) found that after controlling for health status, adults with hearing impairments did not have different mortality rates than non-hearing-impaired adults. Based on this information, AB 368 will not likely have any impact on premature death associated with pediatric hearing loss.

Estimates of the lifetime costs associated with hearing loss typically focus on those with severe or profound hearing loss, and costs vary from one estimate at \$297,000 per person (Mohr et al., 2000) to another at \$417,000 per person (CDC, 2004). These cost estimates include both direct and indirect costs. The direct costs can be broken down into medical and nonmedical costs. The medical costs associated with AB 368 are specified in the Utilization, Cost, and Coverage Impacts section of this report. Nonmedical direct costs for children with hearing loss primarily consist of special education costs. One estimate from the Centers for Disease Control and Prevention (CDC) indicates that 83% of direct costs and 30% of total lifetime costs associated with hearing loss for those under 18 years are attributed to non-medical direct costs (CDC, 2004).

Effective treatment of hearing loss potentially can reduce the economic costs associated with hearing loss. Cost-benefit and cost-utility analyses have found economic benefits associated with cochlear implants due to reduced productivity costs and education costs (Cheng et al., 2000; Francis et al., 1999). However, no such analyses were identified that examined economic cost savings associated with hearing aids. As such, although it is possible that AB 368 could contribute to decreased special education and productivity costs associated with hearing loss, there is no evidence in the literature to support this conclusion.

APPENDICES

Appendix A: Text of Bill Analyzed

BILL NUMBER: AB 368 INTRODUCED BILL TEXT

INTRODUCED BY Assembly Member Carter

FEBRUARY 14, 2007

An act to add Section 1367.195 to the Health and Safety Code, and to add Section 10123.75 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 368, as introduced, Carter. Hearing aids.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the regulation of health care service plans by the Department of Managed Health Care. Existing law requires a health care service plan to provide specified coverage to its enrollees and subscribers. Existing law provides that a willful violation of the act is a crime.

Existing law provides for the regulation of health insurers by the Department of Insurance. Existing law requires a health insurance policy to provide specified coverage to insureds.

This bill would require health care service plans and health insurers, on or after January 1, 2009, to offer, at minimal cost, coverage up to \$1,000 for hearing aids, as defined, to all enrollees, subscribers, and insureds under 18 years of age. The bill would provide that the requirement to provide this coverage would not apply to certain types of insurance.

Because this bill would place additional requirements on health care service plans, the violation of which would be a crime, the bill 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. Section 1367.195 is added to the Health and Safety Code, to read:

1367.195. (a) On or after January 1, 2009, every health care service plan contract that covers hospital, medical, or surgical expenses on an individual or group basis, that is issued, amended, or renewed shall offer coverage for hearing aids, up to one thousand dollars (\$1,000), to all enrollees and subscribers under 18 years of age. This benefit may be restricted to one claim during a 48-month period. The increase in premium for the enrollee or subscriber in need of this benefit shall be minimal.

(b) For purposes of this section, "hearing aid" means any nonexperimental, wearable instrument or device designed for the ear and offered for the purpose of aiding or compensating for impaired human hearing, but excluding batteries and cords.

(c) It shall remain within the sole discretion of the health care service plan as to the provider of hearing aids with which it chooses to contract. Reimbursement shall be provided according to the respective principles and policies of the health care service plan. Nothing contained in this section shall preclude a health care service plan from conducting managed care, medical necessity, or utilization review.

SEC. 2. Section 10123.75 is added to the Insurance Code, to read:

10123.75. (a) On or after January 1, 2009, every insurer that issues, amends, or renews an individual or group policy of health insurance that covers hospital, medical, or surgical expenses shall offer coverage for hearing aids, up to one thousand dollars (\$1,000), to all insureds under 18 years of age. This benefit may be restricted to one claim during a 48-month period. The increase in premium for the insured in need of this benefit shall be minimal.

(b) For purposes of this section, "hearing aid" means any nonexperimental, wearable instrument or device designed for the ear and offered for the purpose of aiding or compensating for impaired human hearing, but excluding batteries and cords.

(c) It shall remain within the sole discretion of the health insurer as to the provider of hearing aids with which it chooses to contract. Reimbursement shall be provided according to the respective principles and policies of the health insurer. Nothing contained in this section shall preclude a health insurer from conducting managed care, medical necessity, or utilization review.

(d) This section shall not apply to Medicare supplement,

vision-only, dental-only, Champus-supplement insurance, or to insurance excluded from the definition of health insurance pursuant to subdivision (b) of Section 106.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Appendix B: Literature Review Methods

Appendix B describes methods used in the medical effectiveness literature review for AB 368. This literature review updates the review CHBRP staff conducted for SB 1223 in 2006.

This literature search included meta-analyses, systematic reviews, randomized controlled trials, controlled clinical trials, and observational studies. PubMed and Cochrane databases were searched. In addition, the following educational, engineering, scientific, and social sciences databases were searched: BIOSIS, Compendex, Inspec, PsycInfo, Sociological Abstracts, Social Sciences Citation Index, the Cumulative Index of Nursing and Allied Health Literature (CINAHL), and the Educational Resources Information Center (ERIC). Three business databases, Business Source Premier, Factiva, and Investext, were searched for current information on costs and prices of hearing aids. Web of Science was searched for recent articles that cited particularly valuable older articles.

The search for medical effectiveness literature was limited to articles with publication dates from 1980 to present, written in English, and reporting studies of children, defined as subjects aged 0–18 years. The search was limited to studies of children because differences in the characteristics of hearing loss in children and adults make it difficult to generalize findings from studies of adults to children (Pittman and Stelmachowicz, 2003; Stelmachowicz et al., 2004).

The review focused on three major categories of studies of children with hearing loss: (1) studies of the relationship between age at initial diagnosis and treatment of hearing loss, and children's speech, language, and personal/social development; (2) studies of the relative effectiveness of hearing aids with different types of circuitry and other technologies; and (3) studies of the impact of using a hearing aid in the opposite ear from a cochlear implant. Attempts were made to locate studies of the effects of hearing aids on hearing, but no studies of this research question were found. This lack of studies is probably due to the age of this technology and its widespread acceptance. Hearing aids and educational interventions have been the standard of care for hearing loss for so long that researchers who study children with hearing loss believe that it is unethical to enroll children in randomized trials in which some participants do not receive hearing aids and/or education (Downs and Yoshinaga-Itano, 1999).

The medical effectiveness review focused on traditional air conduction hearing aids because they are the type of hearing aids most frequently used by children with hearing loss (Gabbard and Schryer, 2003; Palmer and Ortmann, 2005). AB 368 may also apply to bone conduction hearing aids and vibrotactile aids, wearable devices that are used by persons who are not helped by air conduction hearing aids.²⁰ The review did not assess the effects of bone-anchored hearing aids or cochlear implants because AB 368 only addresses external, wearable devices. Both bone-anchored hearing aids and cochlear implants are surgically implanted. The review also did not examine FM systems that are used in combination with hearing aids to improve children's ability to hear teachers or other speakers, because school districts typically supply these devices to

²⁰ Gabbard and Schryer (2003), Gatehouse (2002), and Palmer and Ortmann (2005) provide further information about bone conduction hearing aids, bone-anchored hearing aids, and cochlear implants.

children.²¹ In addition, this review did not evaluate the effectiveness of screening for hearing loss or the quality of the educational interventions provided to children with hearing loss and their families, because AB 368 only addresses coverage for hearing aids.

At least two reviewers screened the title and abstract of each citation returned by the literature search to determine eligibility for inclusion. Full-text articles were obtained, and reviewers reapplied the initial eligibility criteria.

Three hundred five abstracts were reviewed for the literature review for SB 1223 in 2006 Two hundred seventy-two articles were not included in the analysis of SB 1223 because the articles: (1) included subjects who were adults, (2) compared hearing aids to cochlear implants, (3) addressed devices other than hearing aids (e.g., cochlear implants, FM systems, tactile aids), (4) concerned the accuracy of tests of hearing loss or benefits of hearing aids, (5) discussed protocols for fitting hearing aids, or (6) examined topics other than the effectiveness of hearing aids (e.g., anatomy and physiology of the ear, characteristics of hearing loss, consequences of hearing loss, attitudes toward children with hearing loss, stress experienced by parents of children with hearing loss and the effectiveness of educational interventions for children with hearing loss and their caregivers).

An additional 232 abstracts were reviewed for the literature review for AB 368. Two hundred twenty-four abstracts were not included in the analysis for reasons similar to those described previously. In addition, studies of new hearing aid technologies that presented results of experimental studies in which hearing aid prototypes were mounted on mannequins were excluded, because AB 368 would only apply to commercially available hearing aids.

A total of 29 studies were included in the current review, consisting of 21 studies from the SB 1223 review and 8 additional studies. These studies included 13 studies of the effects of early diagnosis and intervention, 11 studies of the relative effectiveness of different types of hearing aids, and 5 studies of the impact of using a hearing aid in the opposite ear from a cochlear implant. Additional information was obtained from 12 articles on hearing loss in children, hearing aid technologies, and other types of devices and interventions used by children with hearing loss.

The literature review did not uncover any randomized controlled trials of the effects of early diagnosis and treatment of hearing loss or of the relative effectiveness of different hearing aid technologies for children with hearing loss. All of the studies of the effectiveness of early diagnosis and treatment were observational studies that did not include control groups composed of children with hearing loss who did not receive hearing aids or other interventions. Most studies examined a single group of children with hearing loss or two or more groups of children who were grouped by the age at which the children were diagnosed with hearing loss and/or fitted with hearing aids. The studies of different hearing aid technologies were also observational studies without control groups. Some studies compared a more advanced hearing aid to children's own hearing aids. Other studies compared hearing aids with two or more different types of technologies. Among studies of the impact of using a hearing aid in the opposite ear from a cochlear implant, two studies had a comparison group composed of children with bilateral

²¹ Palmer and Ortmann (2005) describe FM systems and other assistive listening devices.

cochlear implants. Three of these studies did not have a comparison group and instead tested the same group of children with their cochlear implants alone and with both their cochlear implants and hearing aids.

One important limitation of the literature on the effects of early diagnosis and treatment of hearing loss is an inability to separate the effects of early receipt of hearing aids from the effects of early receipt of training in the use of hearing aids and auditory, speech, and language development. In most of the studies reviewed, children were enrolled in educational programs at the time that they were fitted with hearing aids, because providing both hearing aids and education is the standard of care for hearing loss. One cannot determine whether the outcomes reported by the authors of these studies would be similar if the children they studied had only received hearing aids.

In making a "call" for each outcome measure, the team and the content expert consider the number of studies as well the strength of the evidence. To grade the evidence for each outcome measured, the team uses a grading system that has the following categories:

- Research design
- Statistical significance
- Direction of effect
- Size of effect
- Generalizability of findings

The grading system also contains an overall conclusion that encompasses findings in the five domains of research design, statistical significance, direction of effect, size of effect, and generalizability of findings. The conclusion is a statement that captures the strength and consistency of the evidence of an intervention's effect on an outcome. The following terms are used to characterize the body of evidence regarding an outcome.

- Clear and convincing evidence
- Preponderance of evidence
- Ambiguous/conflicting evidence
- Insufficient evidence

The conclusion states that there is "clear and convincing" evidence that an intervention has a favorable effect on an outcome, if most of the studies included in a review have strong research designs and report statistically significant and clinically meaningful findings that favor the intervention.

The conclusion characterizes the evidence as "preponderance of evidence" that an intervention has a favorable effect if most, but not all, of the five criteria are met. For example, for some interventions, the only evidence available is from nonrandomized studies. If most such studies that assess an outcome have statistically and clinically significant findings that are in a favorable direction and enroll populations similar to those covered by a mandate, the evidence would be classified as a "preponderance of evidence favoring the intervention." In some cases, the

preponderance of evidence may indicate that an intervention has no effect or an unfavorable effect.

The evidence is presented as "ambiguous/conflicting" if none of the studies of an outcome have strong research designs and/or their findings vary widely with regard to the direction, statistical significance, and clinical significance/size of the effect.

The category "insufficient evidence" of an intervention's effect is used when there is little, if any, evidence of an intervention's effect.

The search terms used to locate studies relevant to the AB 368 are as follows:

Medical Subject Headings (MeSH) for Searching PubMed and Cochrane:

Hearing Aids [MeSH descriptor] AND All Children Age tags for 0–18 years, Entry dates from 2005 to present, English

Hearing Aids [MeSH] AND (multidirectional OR multi channel OR multichannel OR frequency transpositioning OR spectral enhancement OR compression amplification OR feedback suppression)

Hearing Aids [text words], Entry dates from last 90 days

PubMed was also searched using the Related Articles feature for articles that had been identified as particularly valuable.

Search Terms Used in BIOSIS, CINAHL, ERIC, Sociological Abstracts, and Social Sciences Citation Index:

Hearing Aid* or Deaf or Deafness Infant* or Child* or Adolescen* or Teenag*

Publication Dates from 1980 to present

* = truncation

Search Terms Used in PsycInfo:

Hearing Aid* [Keyword], Age categories 1-17 years, English, 2005 to present

* = truncation

Search Terms Used in Compendex and Inspec:

Hearing Aid* AND (multidirectional OR multi channel OR multichannel OR frequency transpositioning OR spectral enhancement OR compression amplification OR feedback suppression)

* = truncation

Search Terms Used in Business Source Premier, Factiva, and Investext

Hearing Aid* AND (cost OR costs OR utiliz* OR digital OR life span OR price OR pricing)

Publication Dates from 2004 to present

* = truncation

Web of Science Cited Reference Search

Web of Science database was searched for newer articles that cited 12 earlier articles that had been identified as particularly valuable.

Appendix C: Summary Findings on Medical Effectiveness

Appendix C presents detailed information on medical effectiveness findings regarding the use of hearing aids for children.

Table C-1 is a summary of the published studies on three topics pertinent to AB 368. Part 1 of the table describes studies of the relationship between age at initial diagnosis and treatment of hearing loss and children's speech, language, and social development. Part 2 describes studies of the relative effectiveness of hearing aids with different types of circuitry and other features. Part 3 describes studies of the effects of using a hearing aid in conjunction with a cochlear implant. The table includes citations and descriptions of the types of studies, intervention and control groups, populations studied, and locations in which studies were conducted.

Full bibliographic information can be found in the list of references at the end of this report.

Table C-1. Summary of Published Studies on the Medical Effectiveness of Intervention to Address Hearing Loss and Hearing Aids for Children

<u><u> </u></u>				T (•
Citation	Type of Study	Intervention vs. Control Group	Population Studied	Location
Apuzzo and	Level III—	Assessed impact of age at intervention	69 children with a mean age of 40	United
Yoshinaga-	nonrandomized	on children fitted with hearing aids who	months (3.5 yrs), who had mild-to-	States—
Itano, 1995 ²²	study with	participated in a home-based	profound hearing loss, and who did	Colorado
	comparison group	educational intervention program and	not have severe cognitive disabilities	
		whose hearing loss was identified		
		through a newborn high-risk registry		
Calderon and	Level III—	Assessed impact of age at intervention	Two groups of children:	United
Naidu, 2000	nonrandomized	on children fitted with hearing aids who		States—
	study with	participated in a home-based program	80 children with bilateral hearing loss	Washington
	comparison group	that provided audiological, educational,	and a mean age of 36 months (3 yrs)	State
		and related support services		
			28 children with moderately severe to	
			profound sensorineural hearing loss	
			and a mean age of 67 months (5.5 yrs)	
Eilers and	Level III—	Assessed impact of age at intervention	28 infants with severe or profound	United
Oller, 1994	nonrandomized	on children fitted with hearing aids	hearing loss	States—
,	study with			Florida
	comparison group			
Friedmann	Level III—	Assessed impact of age at intervention	14 Hebrew-speaking children with	Israel
and	nonrandomized	on children fitted with hearing aids who	prelingual moderate-to-profound	
Szterman,	study with	participated in a school-based	hearing loss, who did not have other	
2005	comparison group	educational intervention	disabilities, and had hearing parents	

Part 1—Studies of the Relationship Between Age at Intervention to Address Hearing Loss and Children's Speech, Language, and Social Development

²² Four studies published by Yoshinaga-Itano and colleagues analyzed data regarding children with hearing loss who were enrolled in the Colorado Home Intervention Program (Apuzzo and Yoshinaga-Itano, 1995; Yoshinaga-Itano and Apuzzo, 1998a,b; Yoshinaga-Itano et al., 1998). The populations of children examined in these four studies may overlap.

Citation	Type of Study	Intervention vs. Control Group	Population Studied	Location
Kiese- Himmel and Reeh, 2006 Markides,	Level III— nonrandomized study with comparison group Level III—	Assessed impact of age at intervention on children fitted with hearing aids who participated in educational programs	27 children aged 14–52 months (mean = 31.4 months), with mild-to-profound hearing loss, who had no major comorbidities	Germany United
1986	nonrandomized study with comparison group	Assessed impact of age at intervention on four groups of children fitted with hearing aids (by age 6 months, by age 7–12 months, by age 1–2 yrs, and by age 2–3 yrs)	153 children aged 8–12 yrs, who attended schools for the deaf or school units for children with partial hearing, and who had no other disabilities	Kingdom
Moeller, 2000	Level III— nonrandomized study with comparison group	Assessed impact of age at intervention on children fitted with hearing aids who participated in a program that provided audiological, educational, and related support services	112 children with mild-to-profound prelingual-onset bilateral sensorineural hearing loss, who had no other major disabilities, had hearing parents, and spoke English at home; some analyses conducted for a subgroup of 80 children	United States— Nebraska
Musselman et al., 1988	Level III— nonrandomized study with comparison group	Assessed impact of age at intervention on children fitted with hearing aids who participated in a program that provided audiological, educational, and related support services	118 children aged 3–5 yrs at enrollment in the study, who had severe or profound hearing loss and were enrolled in preschool programs for hearing-impaired children	Canada
Pittman et al., 2005	Level III— nonrandomized study with comparison group	Assessed impact of age at amplification on children fitted with hearing aids	37 children aged 5–14 yrs (mean = 9 yrs), with mild-to-moderately severe sensorineural hearing loss	United States— Nebraska
Ramkalawan and Davis, 1992	Level III— nonrandomized study with comparison group	Assessed impact of age at intervention on children fitted with hearing aids	16 children aged 27 to 80 months (mean = 57 months), with bilateral hearing loss, who had no other severe disability, had hearing parents, whose primary language was English, and who received services from a hospital- based hearing assessment center	United Kingdom

Citation	Type of Study	Intervention vs. Control Group	Population Studied	Location
Yoshinaga-	Level III—	Compared children who were fitted with	82 children with a mean age of 26	United
Itano and	nonrandomized	hearing aids and participated in a home-	months (2.2 yrs), who had mild-to-	States—
Apuzzo,	study with	based educational program whose	profound hearing loss	Colorado
1998a	comparison group	hearing losses were identified by 6		
		months of age vs. children whose		
		hearing losses were identified from 7 to		
		18 months of age		
Yoshinaga-	Level III—	Compared children who were fitted with	40 children with a mean age of 40	United
Itano and	nonrandomized	hearing aids and participated in a home-	months (3.3 yrs), who had mild-to-	States—
Apuzzo,	study with	based educational program whose	profound hearing loss and did not	Colorado
1998b	comparison group	hearing losses were identified by 6	have severe cognitive disabilities;	
		months of age vs. children whose	66% from low-income families	
		hearing losses were identified at 18		
		months of age		
Yoshinaga-	Level III—	Compared children who participated in	150 children who are deaf or hard of	United
Itano et al.,	nonrandomized	a home-based educational program	hearing, with a mean age of 26 months	States—
1998	study with	whose hearing losses were identified by	(2.2 yrs);	Colorado
	comparison group	6 months of age vs. children whose	45% enrolled in Medicaid;	
		hearing losses were identified after 6	25% nonwhite, primarily Hispanic	
		months of age		

Citation	Type of Study	Intervention vs. Control Group	Characteristics	Location
Bamford et	Level IV—	Two-channel hearing aid with low-	25 children aged 6–15 yrs, who had	United
al., 1999	nonrandomized	frequency compression and high-	hearing loss	Kingdom
	study without	frequency linear amplification vs.		
	comparison group	single-channel hearing aid—no control		
		group		
Boothroyd et	Level IV—	Adjustment of high- and low-frequency	9 adolescents aged 11–16 yrs, with	United
al., 1988	nonrandomized	outputs plus compression of input range	severe or profound prelingually	States—
	study without	vs. adjustment of high- and low-	acquired sensorineural hearing loss,	New York
	comparison group	frequency outputs—no control group	who attended a school for children	
			with hearing impairment	
Dreschler,	Level IV—	Peak clipping vs. single-channel	16 adolescents aged 13–18 yrs, with	Netherlands
1988	nonrandomized	compression—no control group	sensorineural or conductive hearing	
	study without		loss, who attended a high school for	
	comparison group		adolescents with hearing impairment	
Flynn et al.,	Level IV—	Digital hearing aid with multiple-	21 children aged 6–12.25 yrs (mean =	United
2004	nonrandomized	channel, non-linear compression vs.	9 yrs), who had severe sensorineural	States—
	study without	analog hearing aid—no control group	hearing loss with no conductive	study does
	comparison group		overlay, whose primary form of	not report
			communication is oral, who attended	state or city
			"mainstream" schools, and who were	
D	× 1 × ×		recruited from clinics	
Franck et al.,	Level IV—	Compression vs. spectral enhancement	8 adolescents aged 16–18 yrs, with	Netherlands
1999	nonrandomized	vs. compression and spectral	cochlear or mixed hearing loss, who	
	study without	enhancement—no control group	attended a school for children with	
	comparison group		hearing impairment	TT 1
Gravel et al.,	Level IV—	Dual microphone hearing aid vs.	20 children aged 4–11 yrs, with	United
1999	nonrandomized	omnidirectional microphone hearing	bilateral cochlear hearing loss, who	States—
	study without	aid—no control group	were recruited through a medical	New York
	comparison group		school-based program for persons	
			with hearing loss	

Part 2—Studies of the Relative Effectiveness of Different Types of Hearing Aids for Children

Citation	Type of Study	Intervention vs. Control Group	Characteristics	Location
Henningsen et al., 1994	Level IV— nonrandomized study without comparison group	Behind-the-ear hearing aid with digital feedback suppression—no control group	10 children aged 7–16 yrs (mean = 13.2 yrs), who had profound hearing loss, and who attended a school for children who were profoundly hard of hearing	Denmark
Kuk et al., 1999	Level IV— nonrandomized study without comparison group	Digital hearing aid with a directional microphone, wide–dynamic range compression, and low compression threshold vs. analog hearing aid with an omnidirectional microphone—no control group	20 children aged 7.5–13.67 yrs (mean = 11.3 yrs), with mild-to-profound sensorineural hearing loss, who were recruited from elementary schools	United States— Oregon
Marriage et al., 2005	Level IV— nonrandomized study without comparison group	Assessed three amplification strategies used with digital hearing aids: (1) linear amplification with peak clipping, (2) linear amplification with output limiting, and (3) wide dynamic range compression amplification—no control group	15 children aged 7–15 yrs, with severe and profound sensorineural hearing loss, recruited from National Health Service audiology departments	United Kingdom
Marriage and Moore, 2003	Level IV— nonrandomized study without comparison group	Wide dynamic range compression vs. linear amplification—no control group	14 children aged 4–14 yrs, with moderate-to-profound hearing loss	United Kingdom
Miller- Hansen et al., 2003	Level IV— nonrandomized study without comparison group	Dynamic speech recoding hearing aids (also known as frequency transposition hearing aids) vs. child's own hearing aid—no control group	19 children aged 1.3–21.6 yrs (mean = 12.5 yrs), with mild-to-profound bilateral sensorineural hearing loss, who had previously worn hearing aids, and who were recruited from the hearing and speech department of a children's hospital	United States— Missouri

Citation	Type of Study	Intervention vs. Control Group	Characteristics	Location
Ching et al.,	Level IV—	Cochlear implant plus hearing aid vs.	11 children aged $6-18$ yrs (mean = 11	Australia
2001	nonrandomized	cochlear implant—no comparison group	yrs) with congenital hearing	
	study without	(same children tested with and without	impairment	
	comparison group	hearing aid)		
Ching et al.,	Level IV—	Cochlear implant plus hearing aid vs.	18 children aged 7–18 yrs, with	Australia
2005	nonrandomized	cochlear implant—no comparison group	hearing loss	
	study without	(same children tested with and without		
	comparison group	hearing aid)		
Holt et al.,	Level III—	Cochlear implant plus hearing aid vs.	22 children with onset of hearing loss	United
2005	nonrandomized	cochlear implant	by age 3 yrs due to a cause other than	States
	study with		auditory neuropathy/dyssynchrony	
	comparison group		and no other disability	
Litovsky et	Level III—	Cochlear implant plus hearing aid vs.	20 children aged 3–14 yrs, who	United
al., 2006a	nonrandomized	bilateral cochlear implants	received educational interventions to	States—
	study with		address hearing impairment	Wisconsin
	comparison group			
Litovsky et	Level III—	Cochlear implant plus hearing aid vs.	19 children aged 3–16 yrs, with no	United
al., 2006b	nonrandomized	bilateral cochlear implants	cognitive disabilities, who received	States—
	study with	_	educational interventions to address	Wisconsin
	comparison group		hearing impairment	

Part 3—Studies of the Effectiveness of Using Hearing Aids in Conjunction with Cochlear Implants

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

This appendix describes data sources, and 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 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 utilized 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 (2006) California Employer Health Benefits Survey is utilized to estimate:
 - size of firm,
 - percentage of firms that are purchased/underwritten (versus self-insured),
 - premiums for plans regulated by the DMHC (primarily HMOs),
 - premiums for policies regulated by the CDI (primarily PPOs), and
 - premiums for high-deductible health plans (HDHP) for the California population covered under employment-based health insurance.

This annual survey is released by the California Health Care Foundation/Center for Studying Health System Change (CHCF/HSC) and is similar to the national employer survey released annually by the Kaiser Family Foundation and HSC. More information on the CHCF/HSC is available at:

www.chcf.org/topics/healthinsurance/index.cfm?itemID=127480

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/tools_products/healthcare/Health_Cost_Guidelines.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 six major California health plans regarding their 2005 experience.
- Ingenix MDR Charge Payment System, which includes information about professional fees paid for health care services, based upon approximately 800 million claims from commercial insurance companies HMOs and self-insured health plans.
- These data are reviewed for generalizability 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 82% of enrollees in full-service health plans regulated by DMHC and 85% of lives covered 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—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 Services (DHS). DHS supplies CHBRP with the statewide average premiums negotiated for the Two-Plan Model, as well as generic contracts which summarize the current scope of benefits. CHBRP assesses enrollment information 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-MRMIP Guaranteed-Issue Coverage Products because 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. The 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 as follows:

- Cost impacts are shown only for people with insurance.
- 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 1 year. Potential longterm 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

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 the following:

• Population shifts by type of health insurance coverage. If a mandate increases health insurance costs, then some employer groups or 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, members or insured 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 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.

Mandate-specific caveats and assumptions

- An estimated 118,000 children with hearing loss are in plans and insurance policies that are subject to this mandate.
- The coverage rates in large-group markets are estimated to increase from 34.0% to 37.1% for DMHC regulated plans and from 54.2% to 54.4% for CDI-regulated plans, based on the current take-up rates in these markets. In the small-group and the individual market, CHBRP assumes that health plans in the small-group and individual markets would offer coverage as a part of their base plans, not as riders.
- The unit cost for hearing aids is estimated to be \$4,000 per pair. This assumes that most children would benefit from an aid for each ear. This estimate is an upper bound.
- The increase in the utilization of hearing aids was estimated to be 4 percentage points (from 54% to 58%). The basis for this assumption is discussed in the Utilization, Coverage, and Cost Impacts section

- The life span of a hearing aid is estimated to be 4.5 years. The basis for this assumption is discussed in the Utilization, Coverage, and Cost Impacts section
- We assume that the member would replace the child's hearing aid once every 4 years, since they would incur out-of-pocket costs beyond the \$1,000 benefit limit at the point of purchase. The basis for this assumption is discussed in the Utilization, Coverage, and Cost Impacts section.
- Postmandate, we would expect 270 additional children to obtain hearing aids annually who would otherwise not obtain them due to lack of insurance coverage. This is calculated as follows:
 - 1) Premandate, there are 58,000 children with hearing loss but no coverage for hearing aids. Of these 54% are assumed to use hearing aids even without coverage (31,000).
 - 2) Postmandate there are an additional 27, 000 children with hearing loss with coverage. Among those newly covered children, the utilization will increase by 4 percentage points.
 - 3) 27,000 children x 4% = 1,080 children, who will newly use hearing aids.
 - 4) 1,080 children/4 years of the expected life span of a hearing aid = 270 children who will newly use hearing aids annually.

Appendix E: Information Submitted by Outside Parties

In accordance with CHBRP policy to analyze information submitted by outside parties during the first 2 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: <u>www.chbrp.org/requests.html</u>.

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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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