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## **Report to California Legislature**

### **Title**

Analysis of Assembly Bill 2012: Orthotic and Prosthetic Devices

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**CALIFORNIA**  
HEALTH BENEFITS REVIEW PROGRAM

## Analysis of Assembly Bill 2012-Amended: Orthotic and Prosthetic Devices

A Report to the 2005–2006 California Legislature  
June 15, 2006



Established in 2002 to implement the provisions of Assembly Bill 1996 (*California Health and Safety Code*, Section 127660, et seq.), the California Health Benefits Review Program (CHBRP) responds to requests from the State Legislature to provide independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit mandates. The statute defines a health insurance benefit mandate as a requirement that a health insurer and/or managed care health plan (1) permit covered individuals to receive 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, made up of 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 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](http://www.chbrp.org).

# **A Report to the 2005-2006 California State Legislature**

## **Analysis of Assembly Bill 2012-Amended: Orthotic and Prosthetic Devices**

**June 15, 2006**

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## PREFACE

This report provides an analysis of the medical, financial, and public health impacts of AB 2012, as amended on June 1, 2006. This bill would mandate that any offering of coverage for orthotic and prosthetic devices, on a group basis, provide benefits under the same cost-sharing arrangements as other benefits of the health plan or insurance policy. In response to a request from the California Assembly Committee on Health on May 2, 2006, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the provisions of Assembly Bill 1996 (2002) as chaptered in Section 127600, et seq., of the California Health and Safety Code. An analysis of the version of AB 2012 introduced on February 9, 2006, was submitted to the Legislature on April 11, 2006.

Wade Aubry, MD, Harold Luft, PhD, Edward Yelin, PhD, Janet Coffman, MPP, PhD, Patricia Franks, BA, all of the University of California, San Francisco, prepared the medical effectiveness analysis. Min-Lin Fan, MLIS, of UCSF conducted the literature search. Patricia Sinnott, PT, PhD, MPH, of the VA Palo Alto Health Care System, and Henry (Hank) Chambers, MD, of the University of California, San Diego, provided technical assistance with the literature review and clinical expertise for the medical effectiveness analysis. Helen Halpin, PhD, and Nicole Bellows, MHA, of the University of California, Berkeley, prepared the public health impact analysis. Gerald Kominski, PhD, and Meghan Cameron, MPH, of the University of California, Los Angeles, prepared the analysis of the cost impact. Robert Cosway, FSA, MAAA, and Jay Ripps, FSA, MAAA, of Milliman, provided actuarial analysis. Cynthia Robinson, MPP, Susan Philip, MPP, and Joshua Dunsby, PhD, of CHBRP staff prepared the background section and integrated the individual sections into a single report. Sarah Ordódy, 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 MaCurdy, PhD, of Stanford University reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

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

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## EXECUTIVE SUMMARY

### **California Health Benefits Review Program Analysis of Assembly Bill 2012 (Amended): Orthotic and Prosthetic Devices**

The California Legislature has asked the California Health Benefits Review Program to conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill 2012, as amended on June 1, 2006. In response to a request from the California Senate Committee on Banking, Finance and Insurance on May 2, 2006, CHBRP undertook this analysis pursuant to the provisions of Assembly Bill 1996 (2002) as chaptered in Section 127600, et seq., of the California Health and Safety Code.<sup>1</sup> An analysis of the version of AB 2012 introduced on February 9, 2006, was submitted to the Legislature on April 11, 2006.

AB 2012, as amended, would mandate that health care service plans licensed under the Knox-Keene Act<sup>2</sup> and health insurance policies regulated under the California Insurance Code that offer coverage on a group basis for orthotic and prosthetic (O&P) benefits, offer these benefits under the same cost-sharing arrangements as other benefits. Analysis of this newly proposed “parity” requirement for the O&P mandated offering distinguishes this report from CHBRP’s previous analysis. Specifically, AB 2012 (as amended) would require that cost sharing be comparable to cost sharing for other benefits offered in terms of the annual and lifetime benefit maximums, copayments, coinsurance, deductibles, and maximum out-of-pocket amounts. AB 2012 would only apply to group plans and insurance policies. It would not apply to individual insurance or contracts between a health care service plan and the State Department of Health Services for Medi-Cal enrollees or the Major Risk Medical Insurance Board for Healthy Families Program enrollees.

Both the current and the previous versions of AB 2012 would require health plans and insurers to allow contracting surgeons and doctors of podiatry to prescribe O&P devices. Under current laws that govern group health plan and insurer policies, O&P devices are only covered if physicians prescribe them. Because surgeons (under their physician’s license) and podiatrists are permitted to prescribe any medical device under the professions’ scope of practice, this provision of AB 2012 would update the laws governing health plan and insurer health policies to reflect already existing authority granted to surgeons and podiatrists in the California Business and Professions Code.

A prosthesis is an artificial device that replaces a missing body part. An orthosis corrects a physical deformity or malfunction, or supports a weak or deformed portion of the body. O&P devices are used by people with amputations, musculoskeletal conditions, neurological disorders, stroke, and congenital or acquired physically disabling conditions.

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<sup>1</sup> The proposed AB 2012 amended bill text was sent to CHBRP on May 11, 2006. These amendments were made by the Senate on June 1, 2006. The bill language can be found on the Legislative Counsel Web site at [http://www.leginfo.ca.gov/pub/bill/asm/ab\\_2001-2050/ab\\_2012\\_bill\\_20060601\\_amended\\_sen.html](http://www.leginfo.ca.gov/pub/bill/asm/ab_2001-2050/ab_2012_bill_20060601_amended_sen.html)

<sup>2</sup> Health maintenance organizations in California are licensed under the Knox-Keene Health Care Services Plan Act, which is part of the California Health and Safety Code.



## **I. Medical Effectiveness**

The literature review for AB 2012, as amended, addressed three topics: (1) the impact of cost sharing on use of O&P devices; (2) evidence of quality of care differences if O&P devices are prescribed by physicians versus podiatrists; and (3) the effectiveness of newer, more expensive technologies used in O&P devices relative to those traditionally used. The review of new technologies focused on three types of O&P devices, which were selected because they are among the most expensive (lower and upper limb prostheses) or the most frequently utilized devices (spinal orthoses). *The effectiveness of O&P devices relative to no treatment was not evaluated because use of conventional prosthetic devices has been established as the standard of care for improving physical and psychological functioning of persons with amputations and congenital limb deformities.* The effects of cost sharing were assessed because the amendments to AB 2012 would require that cost-sharing arrangements for O&P devices be the same as cost sharing for other benefits offered by a health plan or insurance policy. New technologies were assessed to determine if there is compelling evidence that more technologically advanced O&P devices provide greater benefits than conventional O&P devices.

- **Quality of Evidence Regarding Professions that Prescribe O&P Devices**

- There is a lack of information about the quality-of-care differentials associated with the prescribing of O&P devices by physicians versus podiatrists. Therefore, the impact of AB 2012 on the medical effectiveness of orthotic and prosthetic services cannot be assessed and is inconclusive.

- **Impact of Cost Sharing on Use of O&P Devices**

- No peer-reviewed studies were found that evaluated the impact of cost sharing on the use of O&P devices. Thus, there is no evidence to assess the effects of provisions of the amendments to AB 2012 on numbers of consumers using O&P devices.

- **Quality of the Evidence Regarding New Technologies for O&P Devices**

- Most studies of the effectiveness of new O&P technologies are small observational studies that do not have control groups and do not adjust for other factors that may affect the results, such as age, co-morbidities, and level of physical activity. Thus, the evidence of the effectiveness of these technologies is not based on studies with rigorous research designs.
- Most studies have assessed young and middle-aged adults who are physically active and in good health aside from their amputations. The results of these studies, therefore, may not be generalizable to children and to older adults who have a sedentary lifestyle and/or major co-morbidities, such as diabetes.
- There is weak evidence that newer technologies for lower limb prostheses benefit young and middle-aged adults who are healthy and active. There is also insufficient evidence





regarding the effects of new technologies used in upper limb prostheses and spinal orthoses.

- **New Technologies for Upper Limb Prostheses**

- Microprocessors are the most recent technological advance in prostheses. To date, no research studies that compare upper limb prostheses with microprocessors to upper limb prostheses that use older technologies have been published.
- One recent study found that children and adolescents rated body-powered prostheses as more functional than myoelectric and passive prostheses for a wide range of commonly performed activities (e.g., steering a bicycle), and rated myoelectric prostheses as more functional than passive prostheses.<sup>3</sup>

- **New Technologies for Lower Limb Prostheses**

- Eight studies that compared microprocessor-controlled and conventional prostheses<sup>4</sup> for persons with transfemoral (above the knee) amputation suggest a pattern toward favorable effects of microprocessor-controlled prostheses on oxygen consumption at slow speeds, step length and cadence at a person's customary speed, and satisfaction. However, the evidence is ambiguous with regard to effects on gait and oxygen consumption at customary speed. Microprocessor-controlled prostheses do not affect amount of physical activity or cognitive effort required to walk.
- Three studies that compared energy-storing prosthetic feet to solid ankle cushion heel (SACH) prosthetic feet<sup>5</sup> suggest that energy-storing feet reduce exertion and improve stability, speed, and ability to walk on inclines and declines. However, the evidence is ambiguous with regard to effects on oxygen consumption, gait, and satisfaction.

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<sup>3</sup> A passive upper limb prosthesis resembles a human arm and hand but does not contain a mechanism for grasping objects. A body-powered prosthesis has a hook at the end of the arm that the wearer operates by moving the muscles of the residual limb. A myoelectric prosthesis contains electrodes that are attached to the residual limb. When a person moves the muscles of the residual limb, the electrodes generate energy that powers an electric motor that moves the prosthetic arm (Lake and Dodson, 2006, p.57-58).

<sup>4</sup> Conventional lower limb prostheses for persons with amputations above the knee have a pneumatic or hydraulic valve, which is adjusted to provide optimum knee extension and flexion at a person's customary walking speed, but which may not perform optimally at other speeds, on stairs, or on uneven terrain. Prostheses with microprocessor-controlled knees contain a microcomputer that automatically adjusts knee extension and flexion based on data regarding speed, cadence, terrain, and other factors. Newer types of microprocessor-controlled knees also provide greater stability during the stance phase of walking and when bending or lifting and carrying items (Berry, 2006, p., 91-93; Flynn et al., 2000, p. 3; Johansson et al., 2005, p. 565; Klute et al., 2006, p. 717).

<sup>5</sup> The solid ankle cushion heel foot is a frequently prescribed type of prosthetic foot that provides stability but does not enable a person to use the prosthetic foot in the same way he or she would use a human foot to move the body forward (Underwood et al., 2004, p. 609-610). The energy-storing foot (also known as the dynamic response foot) contains springs and an internal plate that stores energy when the heel of the foot strikes the surface on which a person is walking and releases energy when the person pushes off the toes for his or her next step (Hsu et al., 2006, p. 123; Marks and Michael, p. 733).



- Two studies that compared total surface-bearing (TSB) sockets and patellar tendon-bearing (PTB) sockets<sup>6</sup> suggest that TSB sockets improve mobility and comfort, but have no effect gait or satisfaction and have unfavorable effects on skin problems and time engaged in physical activities that involve use of lower limbs.

- **New Technologies for Spinal Orthoses**

- No peer-reviewed studies have explicitly compared the effects of more technologically advanced spinal orthoses to conventional spinal orthoses. Thus, there is no evidence that more technologically advanced spinal orthoses provide greater benefits than conventional spinal orthoses.

## II. Utilization, Cost, and Coverage Impacts

- Utilization of O&P devices and services is not expected to change as a result of the mandate. Utilization is not expected to increase because: (1) AB 2012 would not increase the number of members who have coverage for O&P benefits as the proposed law maintains the current provision to require plans and insurers to *offer* coverage as opposed to *mandating* coverage; (2) prescribing practices are unlikely to change, because there is a lack of compelling evidence that more technologically advanced O&P devices provide greater benefits than conventional devices; and (3) health plans and insurers still influence the choice of O&P devices through their determination of medical necessity during the utilization review process.
- The number of members who are covered for O&P benefits is expected to remain the same after enactment of AB 2012. For the large group market, plans and insurers would likely continue offering the O&P benefits under a “base” (or standard) benefit package. For the small group market, it is likely that plans and insurers would offer the O&P benefit exclusively under a rider if AB 2012 were to be enacted. In either case, CHBRP estimates that the increase in premiums associated with AB 2012 would not result in large or small groups dropping the O&P benefit from the package of benefits they purchase. Furthermore, because AB 2012 will not place limits on health plans’ utilization review of more expensive and technologically advanced devices, CHBRP estimates that per-unit costs by user of O&P benefits would remain constant.
- At present, CHBRP estimates that for a typical insured population, O&P devices and services have a total per member per month (PMPM) cost of \$0.74, of which \$0.16 is for prosthetic devices and \$0.57 is for orthotic devices. The estimated average annual cost per prosthetic user is considerably more than per orthotic user (\$965.40 vs. \$291.31), but there are far fewer prosthetic users per year (2.0 users per 1,000 members) than orthotic users (23.7 users per

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<sup>6</sup> Total surface-bearing (TSB) sockets use silicon liners that provide a close fit between the prosthesis and the residual limb and permit body weight to be distributed over the total surface area of the residual limb. The patellar-tendon-bearing socket is an older type of socket that distributes body weight such that most weight is borne by the patellar tendon, which may put excessive stress on the tendon (Selles et al., 2005, p. 154).



1,000 members). Although orthotic devices represent approximately three-quarters of the PMPM cost for a combined O&P benefit, costs are not reduced proportionately by eliminating annual benefit limits across the O&P benefit since prosthetic devices typically cost more than orthotic devices.

- Total net expenditures (including total premiums and out-of-pocket expenditures) would increase by 0.01% for those groups purchasing an O&P benefit.
- Premiums are expected to increase by 0.054%, or \$0.152 PMPM. Increases in insurance premiums vary by market segment, ranging from approximately 0.034% to 0.098%. Increases as measured by PMPM payments are estimated to range from approximately \$0.097 to \$0.258. The greatest impact on premiums will be in the small-group HMO market. These premium increases will be largely offset by reductions in out-of-pocket expenditures. Thus, CHBRP estimates that most of the impact of AB 2012 will be in shifting expenditures from users of O&P services to the broader pool of all insured members.
- Some plans exclude prosthetic and orthotic benefits from the total amount that can be applied to the member's maximum out-of-pocket expenses. AB 2012 would prohibit this practice. The impact of this provision is included in the cost estimates presented in this analysis, although the impact is estimated to be negligible.
- A substantial portion of the increase in insurance premiums resulting from AB 2012 can be explained by insurance absorbing a portion of the benefit cost previously paid for out of pocket by insured members—specifically in terms of coinsurance rates and expenses after the current annual benefit limits have been reached.



**Table 1. Summary of Coverage, Utilization, and Cost Effects of AB 2012-Amended**

	<b>Before Mandate</b>	<b>After Mandate</b>	<b>Increase/ Decrease</b>	<b>% Change After Mandate</b>
<b>Coverage (%)</b>				
Total percentage of insured individuals with coverage for Orthotic and Prosthetic Devices in Base Plan Only	48.0%	37.2%	-10.8	-22.5%
In AB 2012 Compliant Plans	15.9%	37.2%	21.3	134.0%
In AB 2012 Non-Compliant Plans	32.1%	0.0%	-32.1	-100.0%
Total percentage of insured individuals with coverage for Orthotic and Prosthetic Devices in Base Plan/Rider Combinations	45.4%	56.3%	10.9	24.0%
In AB 2012 Compliant Plans	19.9%	56.3%	36.4	183.0%
In AB 2012 Non-Compliant Plans	25.5%	0.0%	-25.5	-100.0%
Total percentage of insured individuals with no coverage for Orthotic and Prosthetic Devices	6.6%	6.6%	0.0	0.0%
<b>Coverage (Number)</b>				
Total number of insured individuals with coverage for Orthotic and Prosthetic Devices in Base Plan Only	7,040,154	5,444,169	-1,595,985	-22.7%
In AB 2012 Compliant Plans	2,330,076	5,444,169	3,114,093	133.6%
In AB 2012 Non-Compliant Plans	4,710,078	0	-4,710,078	-100.0%
Total number of insured individuals with coverage for Orthotic and Prosthetic Devices in Base Plan/Rider Combinations	6,652,167	8,248,152	1,595,985	24.0%
In AB 2012 Compliant Plans	2,914,786	8,248,152	5,333,366	183.0%
In AB 2012 Non-Compliant Plans	3,737,381	0	-3,737,381	-100.0%
Total number of insured individuals with no coverage for Orthotic and Prosthetic Devices	961,680	961,680	0	0.0%
<b>Total number of affected population</b>				
Total number of affected population	14,654,000	14,654,000	0	0.0%
Total number of insured individuals in Compliant O&P plans	5,244,862	13,692,321	8,447,459	161.2%
Total number in insured individuals in Non-Compliant O&P plans	8,447,459	0	-8,447,459	-100.0%
<b>Utilization and Cost</b>				
<i>Prosthetics</i>				
Estimated Prosthesis Users per year per 1000 members	2.0	2.0	0	0.0%
Estimated Average Cost per Prosthetics User	\$965.40	\$965.40	0	0.0%



**Table 1. Summary of Coverage, Utilization, and Cost Effects of AB 2012-Amended (cont'd.)**

	<b>Before Mandate</b>	<b>After Mandate</b>	<b>Increase/ Decrease</b>	<b>% Change After Mandate</b>
<b>Utilization and Cost (cont'd.)</b>				
<i>Orthotics</i>				
Estimated Orthosis Users per year per 1000 members	23.7	23.7	0	0.0%
Estimated Average Cost per Orthotic User	\$291.31	\$291.31	0	0.0%
<i>Orthotics and Prosthetics</i>				
Estimated Orthosis and Prosthesis Users per year per 1000 members	25.7	25.7	0	0.0%
Estimated Average Cost per Orthosis and Prosthesis User	\$344.04	\$344.04	0	0.0%
<b>Orthotics and Prosthetics Benefit Provisions Subject to AB 2012 (1)</b>				
Average Orthosis and Prosthesis Coinsurance Rate	18.5%	7.7%	-10.8	-58.4%
Percentage of Members with coverage for Orthosis and Prosthesis subject to Orthosis and Prosthesis Annual Benefit Limit	78.1%	0.0%	-78.1	-100.0%
Average Orthosis and Prosthesis Annual Benefit Limit, for plans with limits	\$1,971	N/A	—	—
<b>Expenditures</b>				
Premium expenditures by private employers for group insurance	\$35,792,975,000	\$35,813,185,000	\$20,210,000	0.06%
Premium expenditures for individually purchased insurance	—	—	—	N/A
CalPERS employer expenditures	\$2,330,367,000	\$2,330,367,000	0	0.00%
Medi-Cal state expenditures	—	—	—	N/A
Healthy Families state expenditures	—	—	—	N/A
Premium expenditures by employees with group insurance or CalPERS, and by individuals with Healthy Families	\$11,337,458,000	\$11,343,960,000	\$6,502,000	0.06%
Member Cost Sharing (Deductible, Coinsurance, Amounts over Annual Maximums)	\$3,236,437,000	\$3,214,295,000	-22,142,000	-0.68%
Expenditures for non-covered services	\$8,496,000	\$8,496,000	0	0.00%
<b>Total annual expenditures</b>	<b>\$52,705,733,000</b>	<b>\$52,710,303,000</b>	<b>\$4,570,000</b>	<b>0.01%</b>

Source: California Health Benefits Review Program, 2006.

Notes: The population includes individuals and dependents who are enrolled in group Knox-Keene licensed plans and group insurance policies regulated under the Insurance Code or are enrolled in CalPERS.

Medi-Cal or Healthy Families enrollees and those enrolled in individual plans or policies are not subject to AB 2012. All population figures include enrollees aged 0–64 years and enrollees 65 years or older 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.

For Knox-Keene licensed plans, “compliant” means that the amount of the benefit for orthotic and prosthetic devices and services is no less than the annual and lifetime benefit maximums applicable to basic health care services as defined under Section 1376 of the Health and Safety Code. Any copayment, coinsurance, deductible, and maximum out-of-pocket amount applied to the benefit for orthotic and prosthetic devices and services is no more than the most common amounts applied to the basic health care services. For policies regulated under the Insurance Code, the amount of the benefit for orthotic and prosthetic devices and services is no less than the annual and lifetime benefit maximums applicable to all benefits in the policy. Any copayment, coinsurance, deductible, and maximum out-of-pocket amount applied to the benefit for orthotic and prosthetic devices and services is no more than the most common amounts contained in the policy.

(1) Some plans exclude prosthetic and orthotic benefits from the total amount that can be applied to the maximum out-of-pocket expenses. AB 2012 would prohibit this practice. The impact of this provision is included in the cost estimates presented in this analysis, although the impact is estimated to be negligible.

Key: CalPERS = California Public Employees’ Retirement System.



### **III. Public Health Impacts**

- A broad range of health conditions are associated with the use of O&P devices, from relatively rare diseases to more common conditions. According to Milliman national claims data, these include disorders of the muscle, ligament, and fascia; peripheral enthesopathies and allied syndromes; and sprains and strains.
- The health outcomes associated with the use of O&P devices include reduced pain and disability; increased functionality; prevention and correction of deformity; and increased quality of life.
- Because AB 2012 is not expected to result in increased utilization of O&P devices, AB 2012 is not expected to have a substantial impact on the health of the community.
- Because AB 2012 is not expected to result in increased utilization of O&P devices, AB 2012 is not expected to have an impact on gender or racial disparities.
- Because AB 2012 is not expected to result in increased utilization of O&P devices, AB 2012 is not expected to have an impact on premature death or the economic loss associated with O&P-related diseases.



## INTRODUCTION

Assembly Bill 2012 (AB 2012), a bill related to orthotic and prosthetic devices, was introduced on February 9, 2006. On April 11, 2006, The California Health Benefit Review Program (CHBRP) submitted an analysis of the bill as originally introduced upon the request of the Assembly Health Committee. Subsequently, the bill was amended on April 19, 2006 and passed out of the Assembly. On May 2, 2006, the Senate Banking, Finance and Insurance Committee requested CHBRP to conduct an evidence-based assessment of the medical, financial, and public health impacts of AB 2012, as amended on June 1, 2006.<sup>7</sup> This analysis responds to that request.

The primary difference between the introduced version of AB 2012 and the June 1, 2006, amended version is that the cost-sharing arrangements and benefit maximums for orthotic and prosthetic (O&P) devices are required to be comparable to the cost-sharing arrangements for other benefits offered by a health plan or insurance policy.

A prosthesis is an artificial device that replaces a missing body part. An orthosis corrects a physical deformity or malfunction, or supports a weak or deformed portion of the body. O&P devices are used by people with amputations, musculoskeletal conditions, neurological disorders, stroke, and congenital or acquired physically disabling conditions.

Under current law, the O&P benefit is a mandated offering for group contracts.<sup>8</sup> Plans and insurers are not required to cover O&P benefits. As a mandated offering, health plans and insurance carriers are required to offer groups, including small and large employer groups, the option of a policy with coverage for O&P devices; the group can choose to purchase coverage or not. Current law also requires Knox-Keene licensed health care service plans to cover prosthetic devices following a mastectomy or laryngectomy. These mandates are not affected by this bill.<sup>9</sup>

### Parity for O&P Benefits with Other Benefits

Analysis of this newly proposed “parity” requirement for the O&P mandated offering distinguishes this report from CHBRP’s previous analysis. Specifically, the amendments would require the cost sharing to be comparable to other benefits offered in terms of the annual and lifetime benefit maximums, copayments, coinsurances, deductibles, and maximum out-of-pocket amounts.

- For health care service plans, the amount of annual and lifetime benefit maximums are to be no less than those associated with required basic health care services.<sup>10</sup>

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<sup>7</sup> The proposed AB 2012 amended bill text was sent to CHBRP on May 11, 2006. These amendments were made by the Senate on June 1, 2006. The bill language can be found on the Legislative Counsel Web site at [http://www.leginfo.ca.gov/pub/bill/asm/ab\\_2001-2050/ab\\_2012\\_bill\\_20060601\\_amended\\_sen.html](http://www.leginfo.ca.gov/pub/bill/asm/ab_2001-2050/ab_2012_bill_20060601_amended_sen.html)

<sup>8</sup> See Health and Safety Code Section 1367.18 for requirement on Knox-Keene licensed health care service plans, and California Insurance Code Section 10123.7 for requirement on insurance policies regulated by the California Department of Insurance.

<sup>9</sup> Prosthetic devices following a mastectomy (Health & Safety Code §1367.6); prosthetic devices following a laryngectomy (Health & Safety Code, §1367.61).

<sup>10</sup> For Knox-Keene licensed health plans, the proposed amendments would require that the annual and lifetime benefit maximums applicable to O&P be no less than those applicable to the basic health care services required to be



- For insurance policies, the amount of annual and lifetime benefit maximums are to be no less than those associated with “all benefits” in the policy.
- Any copayment, coinsurance, deductible, and maximum out-of-pocket amount applied to O&P devices and services shall be no more than the most common amounts applied to the required basic health care services (for Knox-Keene plans) or to the most common amounts contained in the policy (for insurance policies).

The intent of the legislation is to eliminate restrictive coverage of orthotic and prosthetic devices by requiring the O&P benefit offering to be consistent with other types of health insurance benefits.<sup>11</sup> The author has made multiple attempts to redress the “financial hardship” borne by patients due to insurance policies that impose both annual and lifetime limits on reimbursement that are typically lower than those for other benefits.<sup>12</sup> According to the author, “limitations in coverage of O&P services have the potential to cause substantial and lasting disabilities,” and “patients will struggle to achieve proper use and maintenance of worn out and defective O&P devices, increasing the likelihood of chronic disability and injury.”<sup>13</sup>

Only California and Florida have so-called mandated “offering laws,” in which plans and insurers that cover health benefits on a group basis are required to offer coverage for O&P devices for group purchase (BCBSA, 2005).<sup>14</sup> In contrast, Colorado, Connecticut, Maine, Maryland, Michigan, New Hampshire, and Oregon have laws mandating some level of coverage for orthotic or prosthetic benefits. Three of these states—Colorado, New Hampshire and Maine—have enacted laws that require plans to cover prosthetic devices at the same level as Medicare (Maine and Colorado) or under the same terms and conditions that apply to other durable medical equipment (New Hampshire).<sup>15</sup> These “parity” laws for prosthetic services eliminate differential cost-sharing arrangements, such as coinsurance rates or annual benefit maximums, between benefits for prosthetic devices and benefits for these other types of services (ACA, 2006). No state has enacted a “parity” law for orthotic services.

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provided under the Health and Safety Code Section 1367 (Requirements for Health Care Service Plans). Health and Safety Code §1367 requires plans to provide “all of the basic health care services included in subdivision (b) of Section 1345.” Section 1345 defines “basic health care services” to mean all of the following: physician services, including consultation and referral; hospital inpatient services and ambulatory care services; diagnostic laboratory and diagnostic and therapeutic radiologic services; home health services; preventive health services; emergency health care services, including ambulance and ambulance transport services and out-of-area coverage; and hospice care pursuant to Section 1368.2.

<sup>11</sup> Personal communication, C. Ginno, Office of Assemblymember Bill Emmerson, February 2006.

<sup>12</sup> Assemblymember Bill Emmerson’s Web site. Available at <http://republican.assembly.ca.gov/members/index.asp?Dist=63&Lang=1>. Accessed June 9, 2006.

<sup>13</sup> AB 2012 fact sheet received from C. Ginno, Office of Assemblymember Bill Emmerson, June 2006.

<sup>14</sup> Florida has a mandated offering for breast reconstruction that includes coverage for prosthetic devices incident to a mastectomy.

<sup>15</sup> Under Part B, Medicare covers “prosthetic and orthotic devices (other than dental) to replace all or part of an internal body organ, including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens; leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient’s physical condition.” Beneficiaries pay 20% coinsurance rate. Available at <http://www.cms.hhs.gov/manuals/downloads/ge101c01.pdf>. Accessed April 6, 2006.





## Professions Permitted to Prescribe O&P Devices

Both the current and the prior versions of AB 2012 amend statutes governing health plans and insurance policies to include surgeons and doctors of podiatric medicine among those professionals who can prescribe O&P devices. Currently, these statutes only require coverage for physicians. Under the Business and Professions Code, podiatrists and surgeons (under their physician's license) are permitted to prescribe any medical device.<sup>16</sup> This provision of AB 2012 would update the laws governing health plan and insurer health policies to reflect already existing authority granted to surgeons and podiatrists to prescribe medical devices under regulations defining their scope of practice.

## Analytic Approach to AB 2012-Amended

CHBRP assumes certain market reactions if AB 2012, as currently amended were to become law. First, CHBRP assumes that any offering, no matter how the O&P benefit was designed, would have to be comparable to other benefits in order to meet the requirements of AB 2012. In California, the current practice of health plans and insurance carriers is to offer an O&P benefit either: (1) as part of their basic benefit package; (2) as a written agreement, or rider, that attaches to a policy to modify insurance coverage; or (3) as a combination of both. For example, some carriers offer coverage for more devices and items through riders with higher cost sharing. These riders would no longer be permitted under AB 2012.

CHBRP analysis also assumes that health plans and insurance carriers' utilization review process for O&P devices would remain in place as for any other medical condition. The bill does not alter current law that grants every health plan "the right to conduct a utilization review to determine medical necessity prior to authorizing these (O&P) services."<sup>17</sup>

This analysis does not include in-depth discussion on the impacts of the provision related to professions permitted to prescribe O&P devices. CHBRP estimates these provisions to have no tangible impact on the medical effectiveness, cost, or public health because (1) the current scope of practice of these professions would not change, and (2) health plans and insurers reimbursement would not likely change because they currently contract with these professions to prescribe devices.

CHBRP's analysis of AB 2012, as amended, is designed to:

- Review evidence from the medical effectiveness literature on (1) the impact of cost sharing on the use of O&P devices; and (2) the effectiveness of newer, more expensive technologies relative to those traditionally used to determine if there is compelling evidence that more technologically advanced O&P devices provide greater benefits than conventional O&P devices, which would increase demand for these devices.
- Analyze utilization, cost, and coverage impacts of requiring the mandated offering have similar cost-sharing arrangements as other benefits offered by a health plan or insurance policy.
- Evaluate the potential public health impacts of AB 2012.

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<sup>16</sup> Business and Professions Code, Sections 4070 et seq. and 2477.

<sup>17</sup> See Health and Safety Code, Section 1367.18.



## I. MEDICAL EFFECTIVENESS

O&P devices can improve the physical and psychological functioning of persons with amputations, injuries, and congenital physical disabilities by enabling them to exercise, work, and perform other activities of daily life and, thus, reduce their dependence on caretakers (Maine Bureau of Insurance 2003, p. 31, and Massachusetts Division of Health Care Finance and Policy 2005, p. 2). Exercise is especially important for persons whose lower extremities have been amputated because they tend to have a sedentary lifestyle, which increases their risk of cardiovascular disease, hypertension, and adult-onset diabetes relative to persons who are not physically disabled (Pitetti, 2005). Ability to exercise is enhanced by a well-fitting orthotic or prosthetic device that is appropriate for a person's exercise activity of choice (Pitetti, 2005).

The literature review for AB 2012, as amended, focused on three topics: (1) the impact of cost sharing on use of O&P devices; (2) whether there is evidence that quality of care differs if O&P devices are prescribed by physicians versus podiatrists; and (3) the effectiveness of newer, more expensive technologies used in O&P devices relative to those traditionally used. The effectiveness of O&P devices relative to no treatment was not evaluated, because the amendments to AB 2012 would change the amount of coverage offered for O&P devices rather than establish a new requirement for coverage of these devices. In addition, the use of conventional prosthetic devices has been the standard of care for amputations and congenital limb deformities for so long that their benefits are widely established. CHBRP could not review newer technologies for all O&P devices during the time frame for this report. Therefore, three types of O&P devices were selected for review. These devices were chosen because they are among the most expensive devices (lower and upper limb prostheses) or the most frequently utilized devices (spinal orthoses).

The literature review encompassed meta-analyses, systematic reviews, randomized controlled trials, controlled clinical trials, and observational studies. The PubMed and Cochrane databases were searched. Web sites were also searched to identify relevant materials that were not published in peer-reviewed journals. The search was limited to articles written in English. For studies of new technologies, the search was limited to articles published from 2000 to present. This short time span was chosen to ensure that only studies of recently commercialized O&P technologies were retrieved.

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 A: Literature Review Methods. Tables presenting detailed findings for each outcome measure may be found in Appendix B: Summary of Findings on the Effects of Technological Innovations in Prosthetic Devices.

The literature search yielded no peer-reviewed studies of the effects of cost sharing on use of O&P devices. Thus, there is no evidence to assess the effects of provisions of AB 2012, as amended, that would require health plans that offer coverage on a group basis to offer benefits for O&P devices under the same cost-sharing arrangements as other benefits.



The literature review yielded no peer-reviewed studies of the relative effectiveness of the prescribing of O&P devices by physicians versus podiatrists. One study compared the quality of care furnished by physicians and podiatrists for foot disorders and injuries, but it did not specifically address the quality of orthotic and prosthetic services (Glenn, 1995). Reports issued by other states about legislation regarding coverage for O&P devices were reviewed (Department of Health Care Policy and Financing Medical Policy and Benefits, Colorado, 1999; Division of Health Care Finance and Policy, Commonwealth of Massachusetts, 2005; Maine Bureau of Insurance, 2003; Mandated Health Benefits Advisory Commission, New Jersey, 2005). None of these reports addressed the relative effectiveness of physicians versus podiatrists.

Thus, there is a lack of information about the quality-of-care differentials associated with the prescribing of O&P devices by physicians versus podiatrists. Therefore, the impact of the requirement for health plans and insurers to cover devices prescribed by surgeons (under their physician's license) and podiatrists on the medical effectiveness of O&P services cannot be assessed and is inconclusive.

Fourteen studies of the relative effectiveness of prosthetic technologies were identified. One study concerned upper limb prostheses and the other thirteen studies addressed lower limb prostheses. One study of pneumatic spinal orthoses and four studies of lower limb prostheses were not received in time to be included in this review. One meta-analysis and three systematic reviews of literature on technological advances in lower limb prostheses were identified. Results from the meta-analysis and systematic reviews were given substantial weight in decisions about the effectiveness of new technologies because the authors applied rigorous methodological criteria prior to the inclusion of each article in their analyses. Additional background information on technological advances in O&P devices was gleaned from seven descriptive articles published in peer-reviewed and trade journals.

The studies obtained for the review did not use the most rigorous research designs. The ten individual studies identified had small sample sizes ranging from 1 to 26 persons. Only one of the ten individual studies was a randomized controlled trial. The other nine studies were observational studies that did not include control groups. Most studies involved repeated measurement of outcomes for the same group of subjects when using technologically advanced and conventional prosthetic devices. The research designs of the studies evaluated in the meta-analyses and systematic reviews were similar. The lack of large randomized controlled trials of prosthetic devices may be due to the small number of persons eligible to participate in studies of these devices. Far fewer persons have amputations or congenital limb deformities than have common conditions such as heart disease and cancer. Nevertheless, the lack of large studies with rigorous designs limits the certainty of conclusions drawn from this literature.

Additional methodological problems concern causality and generalizability of findings to all persons who use prosthetic devices. The effects reported in these studies may not have been due to the more technologically advanced prosthetic devices that were assessed, because the authors did not adjust for other factors that might affect the results, such as age, presence of comorbidities, and level of physical activity. Most studies enrolled young and middle-aged adults who were physically active and in good health aside from their amputations or congenital problems. The results may not generalize to older adults who have a sedentary lifestyle or have



major co-morbidities such as diabetes. The potential lack of generalization to persons with major co-morbidities is important because vascular disease is the most common indication for amputation among older adults.

The findings from the literature review follow. The findings are organized by type of O&P device. As stated previously, literature on technological advances in three types of O&P devices was reviewed:

- prosthetic upper limbs
- prosthetic lower limbs
- spinal orthoses (back braces)

The literature on prosthetic lower limbs is further subdivided by type of component:

- knees
- ankle-foot mechanisms
- sockets

*The literature review on prosthetic knees addresses only studies of external devices used by persons with congenital deformities or transfemoral (above the knee) or hip amputations. It does not address devices that are implanted during hip replacement, knee replacement, or other types of surgery.*

## **Findings**

### Upper limb prostheses

Upper limb prostheses replace a person's hand and arm. There are five major types of upper limb prostheses. A passive upper limb prosthesis resembles a human arm and hand but does not contain a mechanism for grasping objects. A body-powered prosthesis has a hook at the end of the arm that the wearer operates by moving the muscles of the residual limb. A myoelectric prosthesis contains myoelectrodes that convert signals generated by movement of the muscles of the residual limb into energy that powers an electrical motor. Activity-specific prostheses are designed to perform a specific activity, such as gardening or catching a ball, better than a typical prosthetic device. A microprocessor-controlled upper limb prosthesis contains a microprocessor that automatically adjusts the movement of the wrist and/or elbow joint based on data it collects (Lake and Dodson, 2006, p.57-58, 62, 68-70).

To date, no research studies have been published that compare upper limb prostheses with microprocessors to upper limb prostheses that use older technologies. One recent study examined the functionality of passive, body-powered, and myoelectric upper limb prostheses. The researchers asked 26 children and adolescents with unilateral below-elbow limb loss to rate the



functionality of the three types of upper limb prostheses for performing 22 common activities, such as tying shoelaces or steering a bicycle. The children and adolescents rated body-powered prostheses as more functional than myoelectric and passive prostheses for all 22 activities. They also rated myoelectric prostheses as more functional than passive prostheses (Crandall and Tomhave, 2002). The value of this study is limited by its reliance on self-reported data on functionality, which may be biased by the subjects' perceptions. The authors did not collect data on objective measures of the functionality of the three types of upper limb prostheses.

## Lower limb prostheses

### *Knees*

Conventional lower limb prostheses for persons with transfemoral (above the knee) amputations have a pneumatic or hydraulic valve that serves the function of a knee joint. The valve is adjusted by a prosthetist to provide optimum knee extension and flexion at a person's customary walking speed, but may not perform optimally at other speeds. Extension and flexion may also be sub-optimal on stairs or uneven terrain, which may compel a person to move unnaturally to ensure that the prosthetic limb is at the right place. As a consequence, a person may put greater stress on other parts of the body and be at greater risk for falls. Microprocessor-controlled prosthetic limbs have been developed to address these problems. These prostheses contain a microcomputer that automatically adjusts knee extension and flexion based on data regarding speed, cadence, terrain, and other factors. Newer types of microprocessor-controlled knees are also designed to provide greater stability during the stance phase of walking and when bending or lifting and carrying items (Berry, 2006, p., 91-93; Flynn et al., 2000, p. 3; Johansson et al., 2005, p. 565; Klute et al., 2006, p. 717). Most prostheses with microprocessor-controlled knees use a hydraulic valve to adjust knee extension and flexion, although one of the newest models use magnetic fluid and steel rotary blades (Berry 2006, p. 108-109).

The literature review identified two systematic reviews published by the U.S. Department of Veterans Affairs and the British Columbia Workers Compensation Board that synthesized studies of microprocessor-controlled prosthetic knees published from 1996 through 2003 (Flynn et al., 2000; Martin et al., 2003). Five individual studies published from 2004 through 2006 were also obtained (Chin et al., 2005; Datta et al., 2005; Johansson et al., 2005; Klute et al., 2006; Perry et al., 2004). The studies measured six major types of outcomes: (1) energy expenditure; (2) gait (i.e., the manner in which a person walks); (3) ability to ambulate on various surfaces, such as stairs and uneven terrain; (4) cognitive effort required to walk; (5) level of activity; and (6) consumer satisfaction. Energy expenditure is usually measured as level of oxygen consumption or efficiency of gait. This outcome is important because persons with prosthetic lower limbs expend considerably more energy than persons with intact lower limbs when ambulating. When walking with a conventional lower limb prosthesis, a person with a unilateral transfemoral amputation expends 45% more energy than a person with two intact limbs (Perry et al., 2004, p. 1711). Persons with transtibial amputations also expend more energy than persons with intact limbs, although the difference is not quite as dramatic.

Both of the systematic reviews evaluated studies of persons with unilateral transfemoral amputations. Neither conducted a formal meta-analysis and, thus, neither reported results of tests



of statistical significance. One systematic review found that microprocessor-controlled knees were associated with less energy expenditure at speeds faster or slower than a person's customary walking speed, but found no difference at customary speed (Flynn et al., 2000). The other systematic review reported that microprocessor-controlled knees were associated with lower oxygen consumption at slower speeds, but reported ambiguous evidence of effects at customary and high speeds (Martin et al., 2003).

Four studies published after those included in the meta-analyses examined energy expenditure. Datta and colleagues (2005) and Johansson and colleagues (2005) studied persons with unilateral transfemoral amputations. Datta and colleagues (2005) found that microprocessor-controlled knees were associated with a statistically significant reduction in oxygen consumption at speeds slower than a person's customary speed, but found no difference at customary speed. Johansson and colleagues (2005) compared conventional lower limb prostheses to two types of microprocessor controlled prostheses, one that used a hydraulic mechanism and one that used magnetic fluid. There was a statistically significant reduction in oxygen consumption at customary walking speed when participants used the microprocessor-controlled knees with magnetic fluid, but no difference for microprocessor-controlled knees that used hydraulic valves. Chin and colleagues (2005) reported that microprocessor-controlled knees were associated with consumption of less oxygen among persons with unilateral hip disarticulation amputations, but did not conduct tests of statistical significance. Perry and colleagues' (2004) case study of a man with bilateral transfemoral amputation found that the man consumed less oxygen when using microprocessor-controlled knees. Overall, these studies suggest that microprocessor-controlled knees reduce oxygen consumption when people walk at speeds slower than their customary speed. The evidence is ambiguous with regard to effects on oxygen consumption at customary and faster speeds.

With regard to gait, one systematic review found that microprocessor-controlled knees were associated with increases in cadence and step length at a person's customary speed and at higher speeds (Martin et al., 2003). Datta and colleagues (2005) found no difference in objective and subjective measures of gait. Johansson and colleagues (2005) reported a statistically significant and positive association between microprocessor-controlled knees with magnetic fluid and time required to take a step and smoothness of gait. Microprocessor-controlled knees with magnetic fluid also had a statistically significant and negative association with muscular activity and shank and thigh jerk during walking. For microprocessor-controlled knees with hydraulic valves, findings for smoothness of gait and shank and thigh jerk were similar. However, no differences were reported for level of muscular activity and time required to take a step. Perry and colleagues' (2004) case study found that microprocessor-controlled knees were associated with faster speed and longer stride when walking. Overall, the evidence of effects of microprocessor-controlled knees on gait is ambiguous. Most studies report favorable findings for some measures of gait but no difference for other measures.

Other outcomes were assessed by only a small number of studies. Both systematic reviews reported that the evidence was ambiguous with regard to effects of microprocessor-controlled knees on ability to walk on inclines, stairs, and uneven terrain (Flynn et al., 2000; Martin et al., 2003). One systematic review reported no difference in cognitive effort required to walk when using microprocessor-controlled or mechanical knees (Martin et al., 2003). Klute and colleagues



(2006) reported that level of daily activity and duration of activity did not differ. Both systematic reviews found that microprocessor-controlled knees were associated with greater consumer satisfaction (Flynn et al., 2000; Martin et al., 2003).

Overall, studies of microprocessor-controlled prosthetic knees suggest that they may reduce oxygen consumption at slow speeds, but the evidence is ambiguous with regard to effects on oxygen consumption at customary speed, gait, and ability to walk on inclines, stairs, and uneven terrain. In addition, the evidence is not very strong because all of the studies were observational studies that had small samples and did not include control groups. Moreover, most subjects were young and middle-aged adults who were active and healthy aside from their amputations (Flynn et al., 2000, p. 1). As discussed previously, the results may not generalize to older adults or persons with vascular disease or other co-morbidities.

### *Ankle-Foot Mechanisms*

Technological advances in prosthetic ankle-foot mechanisms have focused on developing devices that function more like a human ankle and foot. Conventional prosthetic feet have a solid ankle cushion heel (SACH) design. SACH feet have a heel made from molded polyurethane foam and a rigid keel (top of the foot and arch) that restricts lateral movement (Underwood et al., 610-611). They provide good stability but cannot be flexed and extended to propel forward motion. The stationary attachment flexible endoskeletal or stable ankle, flexible endoskeleton (SAFE) foot was developed subsequent to the SACH foot. The SAFE foot has a flexible keel, which permits a wider range of motion than the SACH foot (Underwood et al., p. 611). The most notable technological advance in prosthetic ankle-foot mechanisms has been the development of energy-storing feet, also known as dynamic response feet. Energy-storing prosthetic feet contain a spring that mimics the action of a human foot. The spring contracts when a person's heel strikes the surface he or she is traversing, storing energy. The spring releases when the person lifts the heel and pushes off the toes for his or her next step, providing forward momentum in much the same manner as a human foot (Hsu et al., 2006, p. 123; Marks and Michael 2001, p. 733; Underwood et al., 2004, p. 609).

A meta-analysis published by the Cochrane Collaboration synthesized 23 studies of 18 types of prosthetic ankle-feet mechanisms published from 1983 through 2002 (Hofstad et al., 2006). Two additional studies have been published since the studies included in the meta-analysis (Hsu et al., 2006; Underwood et al., 2004). Most studies evaluated in the meta-analysis compared various brands of energy-storing feet to SACH feet (Hofstad et al., 2006). Energy-storing feet were associated with statistically significant improvements in dorsiflexion<sup>18</sup> during the late stance phase of walking, stride length, meters walked per minute, and performance when running, walking briskly, or walking on inclines and declines. The evidence concerning effects on oxygen consumption when walking on a flat surface at normal speed was ambiguous, as was evidence regarding gait efficiency<sup>19</sup> and consumer satisfaction. Some studies reported outcomes for oxygen consumption and gait efficiency that were statistically significant and favorable to

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<sup>18</sup> Dorsiflexion refers to upward movement of the foot or toes.

<sup>19</sup> Gait efficiency refers to the energy expended when ambulating. Gait efficiency increases as energy expenditure decreases.



energy-storing feet, whereas others reported no difference or unfavorable outcomes. The studies found no difference in cadence.

The two studies published after the studies included in the meta-analysis reported additional favorable findings. Underwood and colleagues (2004) compared energy-storing feet to SAFE feet and reported statistically significant and positive associations between energy-storing feet and stability during walking, power absorption during the weight acceptance phase of walking, and power during the push-off phase of walking. Subjects also reported that energy-storing feet enabled them to walk faster and have greater stability on unstable surfaces, but these differences were not statistically significant. Hsu and colleagues (2006) reported that energy-storing feet were associated with statistically significant reductions in heart rate and perceived exertion and a nonsignificant increase in steps walked per day. Their study found no difference in oxygen consumption or gait efficiency.

Overall, studies of energy-storing prosthetic feet suggest that they enable persons with a prosthetic lower limb to walk in a manner more similar to persons with intact limbs, to walk farther, and move more confidently when running, walking briskly, or on inclines or declines. However, evidence of effects on oxygen consumption and gait efficiency is ambiguous. In addition, most evidence comes from small, uncontrolled studies.

### *Sockets*

The socket is the part of a prosthesis that fits over a person's residual limb (Marks and Michael 2001, p. 732). The role of the socket is to support upper body weight that a leg bears when a person is upright. The patellar tendon-bearing (PTB) socket was developed in the 1950s and continues to be widely used. This type of socket distributes body weight such that most weight is borne by the patellar tendon, the area of the residual limb that is best able to bear weight (Selles et al., 2005, p. 154). The most significant advance in socket technology since the PTB socket has been the total surface-bearing (TSB) socket, which uses a silicon liner to attach the prosthesis to the residual limb. The silicon liner provides a closer fit between the prosthesis and the residual limb and permits body weight to be distributed over the total surface area of the residual limb (Selles et al., 2005, p. 154). The closer fit and more even distribution of weight are intended to reduce skin problems and improve ambulation.

Two studies that compared TSB and PTB sockets were identified. Baars and Geertzen (2005) conducted a systematic review of studies of TSB and PTB sockets completed from 1994 through 2002. The six studies they reviewed reported that TSB sockets were associated with a statistically significant improvement in comfort, distance walked, ability to climb stairs, and ability to walk on even and uneven terrain. The studies also reported statistically significant decreases in pain and use of walking aids (e.g., walkers, canes). However, contrary to expectations, TSB sockets were associated with a statistically significant increase in skin problems rather than a decrease. Findings from a more recent study of TSB and PTB sockets by Selles and colleagues (2005) were less positive overall. This study found no difference in gait, motility, and consumer satisfaction. The authors also found that persons who used TSB sockets spent less time standing, walking, or climbing stairs than persons who used PTB sockets and that the difference was statistically significant.





The difference between Selles and colleagues' findings and the findings reported by the studies discussed in Baars and Geertzen's systematic review may reflect both differences in the outcomes measured and the manner in which they were measured. The earlier studies primarily analyzed self-report data from questionnaires administered to subjects, whereas Selles and colleagues measured actual levels of activity and quality of gait. Subjects' expectations may have biased the results of the earlier studies. Alternately, Selles and colleagues' findings may be due to baseline differences between subjects using the TSB and PTB sockets for which they did not adjust when analyzing their follow-up data. Overall, there is some evidence that TSB sockets improve ambulation relative to PTB sockets, but this evidence is not very compelling.

### Spinal orthoses

Back pain is a very common health problem with many different etiologies. Many persons with back pain experience recurrent or chronic pain. Spinal orthoses, commonly referred to as "back braces," are used to immobilize the back following back surgery and to treat and prevent back injuries (Jellema et al., 2001, p. 377). No studies have explicitly compared more technologically advanced spinal orthoses to conventional spinal orthoses. Two studies of more technologically advanced spinal orthoses were not included in the literature review, because the authors only assessed more technologically advanced devices (Dallolio, 2005; Pfeifer et al., 2004). The studies did not use control groups. Nor did they compare data collected on the same group of subjects when using a conventional orthosis and a technologically advanced orthosis to determine whether outcomes improved when subjects used the technologically advanced orthosis. Thus, there is no evidence as to whether more technologically advanced spinal orthoses provide greater benefits than conventional spinal orthoses.

### **Conclusions**

- **Impact of Cost Sharing on Use of O&P Devices**
  - No studies were available that evaluated the impact of cost sharing on use of O&P devices. Thus, there is no evidence to assess the effects of provisions of the amendments to AB 2012 that would require that cost-sharing arrangements for O&P devices be the same as cost sharing for other benefits offered by a health plan or insurance policy.
- **Quality of the Evidence Regarding New Technologies for O&P Devices**
  - Most studies of the effectiveness of new O&P technologies are small observational studies that do not have control groups and do not adjust for other factors that may affect the results. Thus, the evidence of the effectiveness of these technologies is not based on studies with rigorous research designs.
  - Most studies have assessed young and middle-aged adults who are physically active and in good health aside from their amputations. The results of these studies may not be generalizable to older adults who have a sedentary lifestyle and major co-morbidities such as diabetes.



- There is weak evidence that newer technologies for lower limb prostheses benefit young and middle-aged adults who are healthy and active, but insufficient evidence to determine whether these technologies benefit children or older adults who have a sedentary lifestyle and/or major co-morbidities. There is also insufficient evidence regarding the effects of new technologies used in upper limb prostheses and spinal orthoses.
- **New Technologies for Upper Limb Prostheses**
  - To date, no research studies have been published that compare upper limb prostheses with microprocessors to upper limb prostheses that use older technologies.
  - One recent study found that children and adolescents rated body-powered prostheses as more functional than myoelectric and passive prostheses for a wide range of commonly performed activities, and rated myoelectric prostheses as more functional than passive prostheses.
- **New Technologies for Lower Limb Prostheses**
  - Eight studies that compared microprocessor-controlled and conventional prostheses for persons with transfemoral (above the knee) amputation suggest:
    - a pattern toward favorable effects of microprocessor-controlled prostheses on patient satisfaction, walking speed, amount of oxygen consumed when walking at speeds slower than a person's customary speed, and step length and cadence at customary speed;
    - ambiguous evidence regarding their impact on gait, level of muscular activity, amount of oxygen consumed when walking at customary speed and at faster speeds, and ability to walk on inclines, stairs, and uneven terrain; and
    - no differences in step time, daily activity level, duration of activity, and cognitive effort required to walk.
  - Three studies that compared energy-storing prosthetic feet to solid ankle cushion heel (SACH) prosthetic feet suggest:
    - a statistically significant association between energy-storing feet and lower heart rate, less exertion, longer stride length, greater stability, momentum, and speed, as well as better performance when running or walking on inclines and declines;
    - a pattern toward favorable with regard to steps walked per day and stability on unstable surfaces; and
    - ambiguous evidence regarding effects on consumption of oxygen, gait efficiency, and consumer satisfaction.



- Two studies that compared total surface-bearing (TSB) sockets and patellar tendon-bearing (PTB) socket suggest:
  - favorable effects for TSB sockets on distance walked, ability to walk under specific conditions, use of walking aids, suspension, comfort, and amount of pain experienced when walking;
  - unfavorable effects for TSB sockets on skin problems and time spent standing, walking, or climbing stairs; and
  - no differences in gait and consumer satisfaction.

- **New Technologies for Spinal Orthoses**

- No studies have explicitly compared the effects of more technologically advanced spinal orthoses to conventional spinal orthoses. Thus, there is no evidence as to whether more technologically advanced spinal orthoses provide greater benefits than conventional spinal orthoses.

## II. UTILIZATION, COST, AND COVERAGE IMPACTS

This section details the estimated impacts on utilization, cost, and coverage of AB 2012. 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

AB 2012 would require all plans and policies offered on a group basis by Knox-Keene licensed health plans and insurance carriers to offer coverage for O&P devices and services that are no less than other medical benefits under the contract. AB 2012 would not require plans and insurance carriers to *cover* O&P benefits. The current practice of health plans and insurance carriers is to offer an O&P benefit either: (1) as part of a “base” benefit package (a standard set of benefits that is the minimum level of benefits a group may purchase); (2) as a written agreement or rider (an additional set of benefits available for purchase) that attaches to a policy to modify insurance coverage; or (3) as a combination of the two.

For Knox-Keene licensed plans, AB 2012 would require that the amount of the benefit for O&P devices and services be no less than the annual and lifetime benefit maximums applicable to basic health care services. Any copayment, coinsurance, deductible, and maximum out-of-pocket amount applied to the benefit for O&P devices and services can be no more than the most common amounts applied to the basic health care services. For policies regulated under the California Insurance Code, AB 2012 would require the amount of the benefit for O&P devices



and services be no less than the annual and lifetime benefit maximums applicable to all benefits in the policy. Any copayment, coinsurance, deductible, and maximum out-of-pocket amount applied to the benefit for O&P devices and services can be no more than the most common amounts contained in the policy. Some plans exclude prosthetic and orthotic benefits from the total amount that can be applied to the enrollee's maximum out-of-pocket expenses. AB 2012 would prohibit this practice. The impact of this provision is included in the cost estimates presented in this analysis, although the impact is estimated to be negligible.

There are 14,654,000<sup>20</sup> individuals in California under age 65 with O&P coverage in group insurance plans or policies who would be affected by the mandate (Table 1).

CHBRP surveyed the seven largest health plans and insurers in California regarding their offered coverage and benefit levels for O&P devices and services. CHBRP determined that members could fall into one of five different categories for O&P devices and services:

- covered by an AB 2012 compliant base plan;
- covered by an AB 2012 non-compliant base plan;
- covered by an AB 2012 compliant base plan/rider (or rider only) plan;
- covered by an AB 2012 non-compliant base plan/rider (or rider only) plan;
- no coverage.

Using the responses of the six carriers that replied to the survey, CHBRP determined that 13,692,000 (93.4%) individuals have some coverage for O&P and 962,000 (6.6%) have no coverage (Table 2). In the large-group HMO market, 32.8% (2,701,000) of those with O&P coverage have it only as part of their base plan and 62.9% (5,180,000) are covered under a base plan/rider arrangement. In the large group PPO/FFS market, 75.6% (1,381,000) are covered solely as part of their base plan and 14.9% (272,000) in a base plan/rider arrangement. In the small-group HMO market, 53.5% (1,387,000) of those with O&P coverage have it as part of the base plan, and 35.3% (915,000) as part of a base plan/rider arrangement. In the small-group PPO/FFS market, 64.9% (788,000) have O&P coverage in their base plan and 23.5% (286,000) in a base plan/rider arrangement. Of the 13,692,000 individuals with O&P coverage, 57.6% (8,447,000) have a plan that is not compliant with AB 2012 because they face higher coinsurance for O&P devices and services than for other medical benefits, or because they face annual benefit limits, or both.

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<sup>20</sup> This figure is different from the 14,049,893 reported in the previous analysis of AB 2012 because of more precise numbers on groups with O&P coverage collected during a second CHBRP survey of health plans.



**Table 2: Member Coverage of O&P Benefits by Market Segment, California, 2006**

	Large Group		Small Group		CalPERS	
	HMO/POS	PPO/FFS	HMO/POS	PPO/FFS		
<b>Percentage of Members Having Coverage for O&amp;P</b>						<b>Percentage of Total Members</b>
In Base Plan Only	32.80%	75.60%	53.50%	64.90%	100.00%	48.00%
In Base Plan and Rider (or Rider Only)	62.90%	14.90%	35.30%	23.50%	0.00%	45.40%
Total	95.70%	90.50%	88.80%	88.40%	100.00%	93.40%
<b>Number of Members Having Coverage for O&amp;P</b>						<b>Members in all Plans</b>
In Base Plan Only	2,701,000	1,381,000	1,387,000	788,000	782,000	7,040,000
In Base Plan and Rider (or Rider Only)	5,180,000	272,000	915,000	286,000	-	6,652,000
Total	7,882,000	1,653,000	2,302,000	1,074,000	782,000	13,692,000
<b>Number of Members Not Covered for O&amp;P</b>	355,000	174,000	291,000	141,000	-	962,000
<b>Total Members</b>	8,237,000	1,827,000	2,593,000	1,215,000	782,000	14,654,000

Source: California Health Benefits Review Program, 2006

Note: Figures may exceed 100% due to rounding error.

The California Public Employees' Retirement System (CalPERS) is already in compliance with the provisions of AB 2012. CalPERS covers O&P devices and services with no cost sharing and no annual benefit limits. Medi-Cal and Healthy Families were not included in this analysis because AB 2012 only applies to policies offered on a group basis, which CHBRP interpreted to include only employment-based coverage.

#### Current utilization levels and costs of the mandated benefit

CHBRP estimates that there are 25.7 orthotic and prosthetic device users per year per 1,000 members. The estimated average annual cost per O&P user is \$344.04 (Table 1). Overall, 95.16% of O&P patients have annual claims from \$0 to \$1,000, 4.18% have annual claims between \$1,001 and \$5,000, and 0.66% have annual claims over \$5,000 (Table 4). CHBRP estimates that for a typical insured population, O&P devices and services have a total per member per month (PMPM) cost of \$0.74. This is the total amount paid for these services. The estimated average annual cost per prosthetic user is considerably more than per orthotic user (\$965.40 vs. \$291.31), but there are far fewer prosthetic users per year per 1,000 members than orthotic users (2.0 vs. 23.7) (Table 1). As a result, total PMPM cost for prostheses is \$0.16 and for orthoses is \$0.57. Although orthotic devices represent approximately three-quarters of the PMPM cost for a combined O&P benefit, costs are not reduced proportionately by eliminating annual benefit limits across the O&P benefit. Eliminating annual benefit limits has a disproportionate effect on prosthetic services because they typically cost more than orthotic devices.

The portion paid by members through cost sharing, including the portion over any annual benefit limit, ranges from \$0.15 to \$0.25 PMPM. The portion paid through cost sharing for large-group



HMO/POS, large-group PPO/FFS, small-group HMO/POS, and small-group PPO/FFS is \$0.15, \$0.25, \$0.25, and \$0.21 PMPM, respectively. Plans pay \$0.56, \$0.41, \$0.40, and \$0.45 PMPM, respectively. Group members lacking coverage for O&P benefits, who pay the entire amount out of pocket, pay the remainder of the \$0.74 PMPM.

An example of the ten highest-cost orthotic devices and the nine highest-cost prosthetic devices and services are shown in Table 3. Eleven of the nineteen devices and services shown in this Table exceed the \$2,000 maximum benefit for O&P devices found in many current insurance plans. Table 4 shows the distribution of claims for O&P based on Milliman analysis of national claims data. The vast majority of claims per user for O&P devices and services (98.25%) fall below \$2,000. The costs associated with these claims equal about three-quarters of total claim costs (72.7%). As a result, the impact of increasing the annual and lifetime expenditure limits is likely to affect less than 2% of total claimants, and thus have a small overall impact on utilization, as discussed further below.

#### The extent to which costs resulting from lack of coverage are shifted to other payers, including both public and private entities

Two types of cost transfer to private insurance programs could arise as a result of the current limitations on coverage: first, people taking up employer-based insurance for O&P coverage instead of public insurance; and second, people who use their employer-based insurance rather than rely on services in the nonprofit sector. No cost shifting is expected to occur from public programs for the uninsured (i.e., Medi-Cal and Healthy Families) to the privately insured market because the publicly insured are unlikely to have access to employment-based coverage to purchase private insurance for the O&P benefit. There are large nonprofits (e.g., Shriner's Childrens Hospitals) that provide O&P devices for insured and uninsured children under 18 at no cost. CHBRP recognizes that there may be some shift in costs from these charitable organizations to carriers as a result of coverage, but it was not possible to quantify this effect.<sup>21</sup>

#### Public demand for coverage

As a way to determine whether public demand exists for the proposed mandate (based on criteria specified under AB 1996 [2002]), CHBRP is to report on the extent to which collective bargaining entities negotiate for, and the extent to which self-insured plans currently have, coverage for the benefits specified under the proposed mandate. Currently, the largest public self-insured plans are CalPERS' PERSCare and PERS Choice preferred provider organization (PPO) plans. These plans include coverage similar to that of the privately self-insured plans. Based on conversations with the largest collective bargaining agents in California, CHBRP concluded that unions currently do not include cost-sharing arrangements and out-of-pocket maximums for the O&P benefit in their health insurance policy negotiations. In general, unions

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<sup>21</sup> CHBRP contacted a number of nonprofits and charitable organizations to better characterize the extent to which orthotic and prosthetic services are received on a charitable basis. CHBRP believed charitable care might substitute for privately insured services especially for children. For example, the Shriner's Hospital for Children, Northern California reported that in 2005 they prescribed 132 prosthetic devices and 2,351 orthotic devices. About 90 to 95% of these were prescribed to children under the age of 18. About 70% were believed to have private insurance and 30% to have public insurance of some kind. Patients receiving the services pay no cost.



negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and coinsurance levels.

## **Impacts of Mandated Coverage**

How would changes in coverage related to the mandate affect the benefit of the newly covered service and the per-unit cost?

### *Impact on per-unit cost*

CHBRP estimates no effect on per-unit cost of O&P devices. While it is true that a decrease in the amount of coinsurance and removal of annual benefit limits could cause a shift to more expensive, higher-technology devices, the bill continues to allow “every plan . . . the right to conduct a utilization review to determine medical necessity prior to authorizing these services.” CHBRP estimates that health plans’ and insurers’ utilization review and medical management processes after the enactment of AB 2012 would continue to limit coverage of more expensive devices based on:

- the lack of compelling evidence that more technologically advanced O&P devices provide greater benefits than conventional devices (as described in the Medical Effectiveness section of this report), and
- the experience with medical management in other states and at the federal level that enacted parity-type legislation, for example, for mental health benefits

### *Postmandate coverage*

As mentioned, there are 14,654,000 individuals in California under age 65 with O&P coverage in group insurance plans or group policies who would be affected by the mandate.

Coverage for O&P services after the mandate could fall into the following categories:

- covered by an AB 2012 compliant base plan;
- covered by an AB 2012 compliant base plan/rider (or rider only) plan;
- no coverage.<sup>22</sup>

For this analysis, CHBRP assumed that large-group employers with non-compliant base plans would expand their base plans to bring them into compliance with AB 2012, resulting in no change in the number of enrollees having coverage for O&P benefits. Because plans and insurers would likely wish to retain some flexibility to meet the purchasing requirements of small group employers, plans would likely almost exclusively offer the O&P benefit through a rider (i.e., pull O&P coverage out of the base plan and offer it instead as a compliant rider).

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<sup>22</sup> Plan and insurers that currently bundle the O&P benefit may move to offer the orthotics and prosthetics as separate benefits—either under base benefits and/or as separate riders. For example, specialized footwear may be provided as a separate rider.



### *Changes in coverage as a result of premium increases*

When benefits are offered for purchase, groups have the *option* to purchase them. For the large-group market, plans and insurers would likely continue offering the O&P benefits under a “base” (or standard) benefit package, thus the number of enrollees in the large-group market that have O&P coverage is estimated to remain the same.

It is possible that AB 2012 will have the unintended consequence of causing small-group employers to drop coverage because they would no longer have a low-cost option for covering O&P devices and services. However, because the estimated increase in premiums (see Total Health Care Costs section below) is less than 1% for the small-group market, CHBRP estimates that these groups would continue to purchase the rider. CHBRP estimates that dropping O&P coverage from the total benefit package they purchase would result in a savings of \$0.74 PMPM, or \$8.88 per member per year. Because these savings are less than 0.01% of total premiums in the small-group market, we assume that employers would not respond to such a small potential savings (Gabel et al., 2003).

### How would utilization change as a result of the mandate?

Although AB 2012 expands coverage of O&P benefits to parity levels for members with O&P coverage, overall utilization rates are not expected to change as a result of the mandate. As with other health benefits, CHBRP recognizes that a decrease in cost sharing may cause patients to demand more expensive devices regardless of their medical effectiveness. However, due to other mitigating factors discussed below, CHBRP model assumes increased utilization is unlikely for O&P devices in response to reduced cost sharing and lifting of annual and lifetime expenditure limits. Utilization is not expected to increase in terms of the type of device or item (e.g., more expensive items) or in terms of quantity.

CHBRP’s assumption of zero utilization increase is supported by the following evidence.

- **No increase in the number of newly covered members:** AB 2012 would not increase the number of members who have coverage for O&P benefits as the proposed law maintains the current provision to require plans and insurers to *offer* coverage as opposed to *mandating* coverage.
- **Prescribing practices are unlikely to change:** Prescribing practices are unlikely to change, because there is a lack of compelling evidence that more technologically advanced O&P devices provide greater benefits than conventional devices.
- **No estimated increase in utilization due to removal of the annual benefit limit:** The majority of devices purchased by enrollees fall under typical annual benefit limits. Only 4.84% of O&P users have annual claims that exceed \$1,000, and only 1.75% of all claims currently exceed \$2,000 (See Table 4). Most of these high-cost claims can be attributed to prosthetic devices (i.e., 8.69% of prosthetic users have claims over \$2,000 in a given year). Users of prosthetic devices with claims over \$2,000 represent a small proportion of total O&P devices users (0.68%).





Disputes over the O&P benefit are related to complaints over lack of coverage for the benefit rather than disputes over benefit limits or cost-sharing arrangements. According to the DMHC, complaints received are primarily over the lack of benefits for orthotic devices rather than the O&P benefit offering being too restrictive.<sup>23</sup>

The potential change in benefit structure from one with an annual benefit limit to a benefit with no limit but a coinsurance rate (such as 20%) or deductible might also create a disincentive for an enrollee to upgrade an O&P device.

- **Utilization review process controls the type of O&P devices members can obtain:** Health plans and insurers still influence the choice of O&P devices through their determination of medical necessity during the utilization review process.

Data from DMHC's Independent Medical Review (IMR) process indicate that there are few appeals of health plan denials for O&P devices. Since January 2001, there have been 12 appeals for external prosthetic or orthotic devices using the IMR process. Of those appeals, a majority of health plan denials were upheld on review. Some of the reasons given for upholding health plans' denials include the requested device being deemed "investigational," the requested device being no more effective than a current device, the lack of scientific evidence regarding the efficacy of the device, and the requested device being not medically necessary for the treatment of a given condition.<sup>24</sup> Although AB 2012 does not change a health plan's ability to conduct utilization review, it is reasonable to assume that health plans and insurers will continue to limit demand for new devices to those deemed medically necessary for the patient's medical condition. And, that health plans' decisions will not be significantly overturned during the IMR process.

Studies looking at the implementation of mental health parity have found little or no increase in utilization of services. In one article on the Federal Employee Health Benefit Program's (FEHBP), the authors found that parity did not increase the overall rate of use of mental health or substance abuse services and did not increase spending for these services, but did decrease out-of-pocket spending for beneficiaries (Goldman et al., 2006). The authors conclude, "When coupled with management of care, implementation of parity in insurance benefits for behavioral health care can improve insurance protection without increasing total costs." A *Health Affairs* article from 2006 similarly concludes that when mental health parity is instituted in the context of managed care, there is minimal effect on total spending (Barry et al., 2006).

### To what extent does the mandate affect administrative and other expenses?

Health care plans include a component for administration and profit in their premiums. In estimating the impact of this mandate on premiums, actuarial analysis assumes that health plans

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<sup>23</sup> Personal Communication with S. Lowenstein, DMHC, June 2006.

<sup>24</sup> Independent Medical Review Database January 2001 to present. Available at <http://wp.dmhc.ca.gov/imr/>. Accessed June 1, 2006



will apply their existing administration and profit loads to the increase in health care costs produced by the mandate. Therefore, although there may be administrative costs associated with the mandate, administrative costs as a portion of premium would not change. For example, health plans and insurers may implement administrative changes as to how the O&P benefit is offered—moving it from the base plan to a rider. These administrative changes would be absorbed in the standard administrative cost load associated with premiums.

#### Impact of the mandate on total health care costs, including costs or savings for each category of insurer

CHBRP estimates that total net expenditures (including total premiums and out-of-pocket expenditures) for O&P devices and services are estimated to increase by 0.01% as a result of AB 2012 (Table 6). The impact varies by market segment:

- 0.008% for the large-group HMO/POS market;
- 0.006% for the large-group PPO/FFS market;
- 0.018% for the small-group HMO/POS market; and
- 0.006% for the small-group PPO/FFS market.

These percentage increases result in a \$4,570,000 annual increase in total health care costs in California. For affected markets, premiums are expected to increase by 0.054% or \$0.15 PMPM. The increases in premiums vary by market segment:

- \$0.14 PMPM in the large-group HMO and PPO/FFS markets;
- \$0.26 PMPM in the small-group HMO market; and
- \$0.10 PMPM in the small-group PPO/FFS market.

Though AB 2012 is expected to increase the premiums paid by both employer and employee, it would cause a decrease in the cost of the covered benefits paid by the member (deductibles, copayments, etc.). The average portion of the premium paid by the employer would increase between \$0.08 and \$0.19 (\$0.11 across all plans) and the average portion of the premium paid by employees would increase between \$0.02 and \$0.07 (\$0.04 across all plans). However, the covered benefits paid by members (deductibles, copayments, etc.) would decrease between \$0.08 and \$0.21 (\$0.13 across all plans). Thus, total premiums would increase by \$26,712,000, but covered benefits paid for by members out of pocket would decrease by \$22,142,000.

CalPERS currently provides full coverage for O&P devices with no cost sharing and no annual limits, which is aligned with the mandated benefit offering required under AB 2012. Therefore, CalPERS is expected to face no impact if AB 2012 were to be enacted.

#### Impact on access and health service availability

CHBRP expects that there will be minimal impacts on the access and availability of O&P devices and services as a result of AB 2012 because neither utilization nor costs are projected to increase. To the extent that cost sharing will be reduced and limits will be removed, access would be expected to increase for the small number of individuals who seek devices in excess of the annual benefit limit. Nonetheless, utilization review and medical management are expected to



mediate the response of the health plans and insurers to this increase in demand. Some health plans and insurers that offer a non-compliant O&P devices benefit in their base plan may shift the benefit to a compliant O&P rider. As an unintended consequence, small employers may drop O&P coverage altogether because they lack a “low-cost” O&P option, consequently decreasing health service availability and access for some employees. CHBRP is unable to estimate these effects quantitatively, but expects the magnitude of these effects to be negligible.

### **III. PUBLIC HEALTH IMPACTS**

#### **Present Baseline Health Outcomes**

A number of health conditions are associated with the use of O&P devices. Prostheses can be used to replace body parts that are lost due to amputation or congenital deformity. Limb-loss can be related to trauma, congenital deficiency, cancer, and dysvascular diseases such as diabetes (Dillingham et al., 2002; MMWR, 2001). Besides artificial limbs, other types of prostheses include prosthetic breasts and prosthetic eyes.

A broad range of health conditions are associated with the use of orthoses, ranging from relatively rare diseases like peroneal muscular atrophy to much more common conditions like ankle sprains and osteoarthritis (Birch, 1998; Defrin et al., 2005; Krohn, 2005).

According to Milliman analysis of national claims data, approximately 6.8 million O&P devices were used by the insured population nationally in 2004, for a utilization rate of 40.4 procedures per 1,000 persons. The 10 most common diagnoses associated with their use are:

1. Disorders of the muscle, ligament, and fascia (connective tissue)
2. Peripheral enthesopathies and allied syndromes (inflammation at site of attachment of ligament or tendon to bone)
3. Sprains and strains of the ankle and foot
4. Other and unspecified disorders of the joint
5. Mononeuritis of the upper limb and mononeuritis multiplex (painful nerve damage)
6. Traumatic amputation of leg(s)
7. Other disorders of the synovium (lining or membrane of the joints), tendon, and bursa (fluid sac between tendon and bone)
8. Sprains and strains of the knee and leg
9. Malignant neoplasm of the female breast



## 10. Osteoarthritis and allied disorders

AB 2012 is relevant to the O&P device needs related to these diagnoses. Exceptions include coverage of breast prostheses related to breast cancer and prosthetic devices related to a laryngectomy, which are already mandated benefits for Knox-Keene plans.

Table 7 provides utilization information for a subset of O&P devices. In 1994, approximately 3.8 million persons in the United States under the age of 65 years used at least one of the listed anatomical devices, consisting of braces and artificial limbs. Of the anatomical devices examined, the back brace was the most commonly used device by persons under the age of 65 years, and all braces were more common than artificial limbs. Overall, the 1994 utilization of any anatomical device listed in Table 7 was 14.0 per 1,000 persons under the age of 44 years and 26.3 per 1,000 persons aged 45 to 64 years.

### **Impact of the Proposed Mandate on Public Health**

#### Impact on community health

The health outcomes associated with the use of O&P devices include reduced pain and disability; increased functionality; prevention and correction of deformity; and increased quality of life (Defrin et al., 2005; Krohn, 2005; Lin et al., 2000; Pfeifer et al., 2004). As stated in the *Medical Effectiveness* section, reviewing the effectiveness of every O&P device was not possible within the time frame of this analysis. Instead, this analysis has focused on three specific O&P devices (upper limb prostheses, lower limb prostheses, and back braces) to illustrate the potential for improved health outcomes as a result of AB 2012. Most of the research identified in the medical effectiveness review relates to lower limb prosthetic technologies, such as microprocessor-controlled prostheses. The literature indicates that there is some evidence that these technologies improve functionality for some individuals, particularly younger and healthier adults.

In addition to the effectiveness of the O&P devices, the extent that AB 2012 will influence health outcomes is based on the change in utilization of O&P devices due to AB 2012. Based on estimates from the *Cost* section, AB 2012 will not have a substantial effect on 35.8% of insured Californians (approximately 5.2 million enrollees) because they are currently enrolled in health plans where coverage for O&P devices is already compliant with the mandate legislation. An additional 6.6% of enrollees (approximately 960,000) are not expected to be affected by AB 2012 because their employers currently do not purchase O&P coverage and are not expected to purchase the O&P rider option if AB 2012 were enacted. For the remaining 57.6%, or approximately 8.4 million enrollees, O&P insurance coverage is expected to increase (due to lower coinsurance amounts and/or higher dollar limits).

Although these 8.4 million enrollees are expected to have better coverage for O&P devices, utilization of O&P devices is not expected to change but rather some of the costs of O&P devices will be shifted from the patient's out-of-pocket expenditures to the insurer. Any increased incentive to obtain O&P devices is expected to be minimized by increased management and review of the O&P benefit by insurers. As a result, AB 2012 is not expected to result in a



substantial impact on the health of the community.

### 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 conditions related to the utilization of O&P devices. No literature was identified that discussed gender or racial disparities with regard to overall utilization of such devices.

There is some information, however, on disparities associated with the myriad of health conditions that necessitate the use of prostheses and orthoses. For example, males have been found to have higher rates of sprains and strains compared to females, and whites have higher rates compared to blacks (Collins, 1990). Research has also found that amputations and limb deficiency are more common in males than females (both adults and children) and more common in blacks compared to whites (Yigiter et al., 2005; Dillingham et al., 2002; MMWR, 2001). Additionally, Pezzin et al. (2004) found that male and black amputees reported less favorable provider quality compared to their female and white counterparts.

In contrast, female adolescents have been found to have a higher prevalence of idiopathic scoliosis compared to males, which often results in use of a back brace for corrective treatment (Reamy and Slakey, 2001). Among adults aged 25-74, females also have a higher prevalence of scoliosis (Carter and Haynes 1987).

Table 8 details utilization data of all O&P devices from Milliman's national database of insurance claims from 2004. Males younger than 18 years appear to have a slightly higher utilization rate than females in the same age group. However, females aged 18 years and older have a substantially higher utilization rate. Utilization data by race and ethnicity are not available.

Since AB 2012 is not expected to result in increased utilization of O&P devices, it is not expected to have an impact on gender or racial disparities.

### Reduction of premature death and the economic loss associated with the disease

A literature review was conducted to determine whether the conditions related to the utilization of O&P devices result in premature death and economic loss. No literature was identified that examined premature death and economic loss across the entire range of conditions associated with utilization of O&P devices.

Looking at health conditions associated with O&P utilization individually, some are associated with premature death and economic loss. McKenna et al. (2005) ranked the top 20 leading causes of disability adjusted life years (DALYs) for males and females in the United States and a number of conditions that can result in the use of O&P devices were in the top 20, including diabetes mellitus, osteoarthritis, cancer, and congenital abnormalities. In addition to lost



productivity due to disability, cancer and diabetes can also result in premature death (McKenna et al., 2005). A reduction in premature death, however, is not an outcome typically associated with the utilization of O&P devices.

O&P devices can result in improved functionality that can potentially increase productivity and thus reduce the economic loss associated with the diseases and conditions that require O&P use. Little research was identified, however, with regard to the relationship between O&P utilization and productivity or economic costs. One study of warehouse workers found that the use of lumbar supports for the back resulted in less lost time from work, although the orthoses did not prevent injury (Walsh and Schwartz 1990). Overall, systematic reviews of the effectiveness of lumbar supports in the workplace have not found them to be particularly effective in preventing injury or back pain (Jellema et al., 2001; van Poppel et al., 2004).

Since AB 2012 is not expected to result in increased utilization of O&P devices, AB 2012 is not expected to have an impact on premature death or the economic loss associated with O&P-related diseases.



## TABLES

**Table 3.** Per-Unit Cost of High-Cost Prosthetic and Orthotic Devices by Procedure Code, 2006

<b>CPT</b>	<b>Category</b>	<b>Description</b>	<b>Average Allowed Cost (2004)</b>
L5987	Prosthesis	All lower extremity prosthesis, shank foot system with vertical loading pylon	\$5,942
L5846	Prosthesis	Addition, endoskeletal knee-shin system, microprocessor control feature, swing phase only	\$4,467
L5980	Prosthesis	All lower extremity prostheses, flex-foot system	\$2,971
L5814	Prosthesis	Addition, endoskeletal knee-shin system, polycentric, hydraulic swing phase control, mechanical stance phase lock	\$2,901
L5701	Prosthesis	Replacement, socket, above knee/knee disarticulation, including attachment plate, molded to patient model	\$2,867
L5321	Prosthesis	Above knee, molded socket, open end, SACH foot, endoskeletal system, single axis knee	\$2,812
L5930	Prosthesis	Addition, endoskeletal system, high activity knee control frame	\$2,569
L5981	Prosthesis	All lower extremity prostheses, flex-walk system or equal	\$2,416
L5828	Prosthesis	Addition, endoskeletal knee-shin system, single axis, fluid swing and stance phase control	\$2,407
L5700	Orthosis	Replacement, socket, below knee, molded to patient model	\$2,586
L5301	Orthosis	Below knee, molded socket, shin, SACH foot, endoskeletal system	\$2,362
L5979	Orthosis	All lower extremity prostheses, multi-axial ankle, dynamic response foot, one piece system	\$1,978
L5649	Orthosis	Addition to lower extremity, ischial containment/narrow M-L socket	\$1,813
L2036	Orthosis	KAFO, full plastic, double upright, free knee, custom fabricated	\$1,798
L5845	Orthosis	Addition, endoskeletal knee-shin system, stance flexion feature, adjustable	\$1,491
L1300	Orthosis	Other scoliosis procedure, body jacket molded to patient model	\$1,332
L1200	Orthosis	TLSO, inclusive of furnishing initial orthosis only	\$1,286
L1844	Orthosis	KO, single upright, thigh and calf, with adjustable flexion and extension joint, medial-lateral and rotation control, custom fabricated	\$1,194
L0560	Orthosis	LSO, anterior-posterior-lateral control, molded to patient model, with interface material	\$1,120

*Source:* Milliman analysis of national claims data, 2004.

*Note:* High cost prosthetic /orthotic codes that occurred multiple times.



**Table 4.** Distribution of Claims per User for Prosthetic and Orthotic Devices, 2006

Claim Cost	Prosthetic and Orthotic Devices		Prosthetic Devices		Orthotic Devices	
	Annual Claims Per User	Allowed Charges For Annual Claims Per User	Annual Claims Per User	Allowed Charges For Annual Claims Per User	Annual Claims Per User	Allowed Charges For Annual Claims Per User
<\$1000	95.16%	59.4%	86.41%	20.7%	95.90%	62.7%
\$1,000-2,000	3.09%	13.3%	4.90%	7.2%	2.94%	13.8%
\$2,000-3,000	0.71%	4.7%	2.51%	6.2%	0.56%	4.6%
\$3,000-4,000	0.25%	2.2%	1.24%	4.4%	0.17%	2.0%
\$4,000-5,000	0.13%	1.4%	0.72%	3.3%	0.08%	1.2%
\$5,000-6,000	0.11%	1.3%	0.73%	4.2%	0.06%	1.1%
\$6,000-7,000	0.07%	1.0%	0.40%	2.7%	0.04%	0.8%
\$7,000-8,000	0.07%	1.1%	0.50%	3.9%	0.03%	0.8%
\$8,000-9,000	0.05%	1.0%	0.30%	2.6%	0.03%	0.8%
\$9,000-10,000	0.05%	1.1%	0.29%	2.8%	0.03%	0.9%
\$10,000+	0.32%	13.7%	2.01%	41.9%	0.17%	11.3%
<b>Totals</b>	100.00%	100.0%	100.00%	100.0%	100.00%	100.0%

Source: Milliman analysis of national claims data, 2004.

Note: "Allowed Charge" is the charge providers are allowed to bill based on their contract with the health plan. In this analysis, claim costs refer to allowed charges.





**Table 5. Baseline (Premandate) Per Member Per Month Premium and Expenditures by Insurance Plan Type, California, 2006**

	Large Group		Small Group		Individual		Cal-PERS HMO	Medi-Cal HMO 65 and Over	Medi-Cal HMO Under 65	Healthy Families HMO	Total Annual
	HMO	PPO	HMO	PPO	HMO	PPO					
<b>Population Currently Covered</b>	8,237,000	1,827,000	2,593,000	1,215,000	-	-	782,000	-	-	-	14,654,000
Average Portion of Premium Paid by Employer	\$202.76	\$292.75	\$189.45	\$235.81	\$0.00	\$0.00	\$248.33	\$0.00	\$0.00	\$0.00	\$38,123,342,000
Average Portion of Premium Paid by Employee	\$62.47	\$77.87	\$74.62	\$49.58	\$0.00	\$0.00	\$43.82	\$0.00	\$0.00	\$0.00	\$11,337,458,000
Total Premium	\$265.23	\$370.62	\$264.07	\$285.39	\$0.00	\$0.00	\$292.16	\$0.00	\$0.00	\$0.00	\$49,460,800,000
Covered Benefits Paid by Member (Deductibles, copays, etc)	\$9.39	\$50.08	\$15.90	\$42.40	\$0.00	\$0.00	\$10.35	\$0.00	\$0.00	\$0.00	\$3,236,437,000
Benefits Not Covered	\$0.03	\$0.07	\$0.08	\$0.09	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0
<b>Total Expenditures</b>	\$274.65	\$420.77	\$280.05	\$327.87	\$0.00	\$0.00	\$302.51	\$0.00	\$0.00	\$0.00	\$52,705,733,000

Source: California Health Benefits Review Program, 2006.

Notes: The population includes individuals and dependents who are enrolled in group Knox-Keene licensed plans and group insurance policies regulated under the Insurance Code or are enrolled in CalPERS.

Medi-Cal, or Healthy Families enrollees and those enrolled in individual plans or policies are not subject to AB 2012.

All population figures include enrollees aged 0–64 years and enrollees 65 years or older 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.

For Knox-Keene licensed plans, “compliant” means that the amount of the benefit for orthotic and prosthetic devices and services is no less than the annual and lifetime benefit maximums applicable to basic health care services as defined under Section 1376 of the Health and Safety Code. Any copayment, coinsurance, deductible, and maximum out-of-pocket amount applied to the benefit for orthotic and prosthetic devices and services is no more than the most common amounts applied to the basic health care services. For policies regulated under the Insurance Code, the amount of the benefit for orthotic and prosthetic devices and services is no less than the annual and lifetime benefit maximums applicable to all benefits in the policy. Any copayment, coinsurance, deductible and maximum out-of-pocket amount applied to the benefit for orthotic and prosthetic devices and services is no more than the most common amounts contained in the policy.

Key: CalPERS = California Public Employees’ Retirement System; HMO = health maintenance organization and point of service plans; PPO = preferred provider organization and fee-for-service plans.



**Table 6.** Postmandate Impacts on Per Member Per Month and Total Expenditures by Insurance Plan Type, California, 2006

	Large Group		Small Group		Individual		Cal-PERS HMO	Medi-Cal HMO 65 and Over	Medi-Cal HMO Under 65	Healthy Families HMO	All Plans	Total Annual
	HMO	PPO	HMO	PPO	HMO	PPO						
<b>Population Currently Covered</b>	8,237,000	1,827,000	2,593,000	1,215,000	-	-	782,000	-	-	-	14,654,000	14,654,000
Average Portion of Premium Paid by Employer	\$0.11	\$0.11	\$0.19	\$0.08	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.11	\$20,210,000
Average Portion of Premium Paid by Employee	\$0.03	\$0.03	\$0.07	\$0.02	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.04	\$6,502,000
Total Premium	\$0.14	\$0.14	\$0.26	\$0.10	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.15	\$26,712,000
Covered Benefits Paid by Member (Deductibles, copays, etc)	-\$0.12	-\$0.19	-\$0.21	-\$0.08	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	-\$0.13	\$22,142,000
Benefits Not Covered	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.0000	\$ -
Total Expenditures	\$0.022	\$0.024	\$0.0516	\$0.02	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.03	\$4,570,000
<b>Percentage Impact of Mandate</b>												
Insured Premiums	0.054%	0.039%	0.098%	0.034%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.054%	0.054%
Total Expenditures	0.008%	0.006%	0.018%	0.006%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.009%	0.009%

Source: California Health Benefits Review Program, 2006.

Notes: The population includes individuals and dependents who are enrolled in group Knox-Keene licensed plans and group insurance policies regulated under the Insurance Code or are enrolled in CalPERS.

Medi-Cal, or Healthy Families enrollees and those enrolled in individual plans or policies are not subject to AB 2012.

All population figures include enrollees aged 0–64 years and enrollees 65 years or older 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.

For Knox-Keene licensed plans, “compliant” means that the amount of the benefit for orthotic and prosthetic devices and services is no less than the annual and lifetime benefit maximums applicable to basic health care services as defined under Section 1376 of the Health and Safety Code. Any copayment, coinsurance, deductible and maximum out-of-pocket amount applied to the benefit for orthotic and prosthetic devices and services is no more than the most common amounts applied to the basic health care services. For policies regulated under the Insurance Code, the amount of the benefit for orthotic and prosthetic devices and services is no less than the annual and lifetime benefit maximums applicable to all benefits in the policy. Any copayment, coinsurance, deductible and maximum out-of-pocket amount applied to the benefit for orthotic and prosthetic devices and services is no more than the most common amounts contained in the policy. Key: CalPERS = California Public Employees’ Retirement System; HMO = health maintenance organization and point of service plans; PPO = preferred provider organization and fee-for-service plans.



**Table 7.** Utilization of Anatomical Devices, United States, 1994

<b>Anatomical Device</b>	<b>Number in Thousands (Under 65)</b>
Back brace	1,409
Knee brace	893
Leg brace	404
Other brace	343
Arm brace	295
Hand brace	290
Foot brace	250
Neck brace	154
Any artificial limb	128
Artificial leg or foot	108
Artificial arm or hand	15*
<b>Any anatomical device</b>	<b>3,816</b>

\*Figure does not meet standard of reliability or precision  
*Source:* Russell et al. (1997) *Vital Health Statistics*

**Table 8.** Utilization of Orthoses/Prostheses per 1,000 Members

<b>Age Range</b>	<b>Males</b>	<b>Females</b>	<b>Total</b>
<b>Under 18</b>	28.0	25.4	26.7
<b>18 and over</b>	37.2	51.4	44.8
<b>Total</b>	34.7	45.4	40.4

*Source:* Milliman analysis of national claims data, 2004.

## APPENDICES

### Appendix A: Literature Review Methods

As amended, Assembly Bill 2012 (AB 2012) would mandate that health care service plans licensed under the Knox-Keene Act and health insurance policies regulated under the California Insurance Code, that offer coverage on a group basis for orthotic and prosthetic (O&P) benefits, offer these benefits under the same cost-sharing arrangements that apply to other benefits, and include surgeons and doctors of podiatric medicine among the health professionals permitted to prescribe O&P devices. (The Introduction presents more detailed information about this legislation.)

A prosthesis is an artificial device that replaces a missing body part. An orthotic device corrects a physical deformity or malfunction, or supports a weak or deformed portion of the body. O&P devices are used by people with amputations, musculoskeletal conditions, neurological disorders, stroke, and congenital or acquired physically disabling conditions.

Appendix A describes the methods used to review the medical effectiveness literature pertinent to AB 2012 as amended. The literature review focuses on two topics: (1) the impact of cost sharing on use of orthotic and prosthetic (O&P) devices; and (2) the effectiveness of newer, more expensive technologies used in O&P devices. The review of new technologies focuses on three types of O&P devices that were selected because they are among the most expensive devices (lower and upper limb prosthetics) or the most frequently utilized devices (spinal orthoses).

The literature review encompasses meta-analyses, systematic reviews, randomized controlled trials, controlled clinical trials, and observational studies. The PubMed and Cochrane databases were searched. Web sites were also searched to identify relevant materials that were not published in peer-review journals. The search was limited to articles written in English. For studies of new technologies, the search was limited to articles published from 2000 to present. This short time horizon was chosen to ensure that only studies of recently commercialized O&P technologies were retrieved.

Abstracts of 79 articles were obtained and reviewed. 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.

The literature search yielded no peer-reviewed studies of effects of cost sharing on use of O&P devices. Fourteen studies of the relative effectiveness of prosthetic technologies were identified. One study concerned upper limb prostheses and the other thirteen studies addressed lower limb prostheses. Additional background information on technological advances in O&P devices was gleaned from seven descriptive articles published in peer-reviewed and trade journals. Fifty-three articles were not included in the analysis for the following reasons: abstract written in English but text in another language, did not address O&P devices, assessed an O&P device other than the three devices selected for review, did not examine a device currently on the market (i.e., examined a prototype), addressed selected O&P devices but did not evaluate the relative effectiveness of new technologies (e.g., did not compare technologically advanced O&P devices

to conventional O&P devices, compared O&P device to other types of treatment and/or no treatment, were conducted to validate instruments for measuring effectiveness, or described use of computer-assisted design and manufacturing).

One meta-analysis and three systematic reviews of literature on technological advances in lower limb prostheses were identified. A meta-analysis published in the Cochrane Database of Systematic Reviews synthesized the results of 23 studies of 18 different types of prosthetic ankle-foot mechanisms published from 1983 through 2002. Systematic reviews produced by the US Department of Veterans Affairs and the British Columbia Workers Compensation Board evaluated studies of microprocessor-controlled prosthetic knees for persons with transfemoral (above the knee) amputations published from 1996 through 2003. A systematic review published in a peer-reviewed journal analyzed studies published from 1994 through 2002 that compared total surface-bearing (TSB) prosthetic sockets to older types of prosthetic sockets. Results from the meta-analysis and systematic reviews were given substantial weight in decisions about the effectiveness of new technologies because the authors applied rigorous methodological criteria prior to the inclusion of each article in their analyses.

The ten individual studies of prosthetic devices had small sample sizes ranging from 1 to 26 persons. Only one of the ten individual studies was a randomized controlled trial. The other nine studies were observational studies that did not incorporate control groups. Most studies involved repeated measurement of outcomes for the same group of subjects when using technologically advanced and conventional prosthetic devices. The studies' authors also did not adjust for other factors that might affect the results, such as age, presence of co-morbidities, and level of physical activity.

In addition, the findings of these studies may not be generalizable to all persons who use prosthetic devices. Most studies enrolled young and middle-aged adults who were physically active and in good health aside from their amputation or congenital problem. The results may not generalize to older adults who have a sedentary lifestyle or have major co-morbidities such as diabetes.

To “grade” the evidence for all outcome measures, the CHBRP effectiveness team uses a system<sup>25</sup> with the following categories:

1. Favorable (statistically significant effect): Findings are uniformly favorable, and many or all are statistically significant.
2. Pattern<sup>26</sup> toward favorable (but not statistically significant): Findings are generally favorable, but there may be none that are statistically significant.
3. Ambiguous/mixed evidence: Some findings are significantly favorable, and some findings with sufficient statistical power show no effect.

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<sup>25</sup> The foregoing system was adapted from the system used by the U.S. Preventive Services Task Force (available at <http://www.ahcpr.gov/clinic/3rduspstf/ratings.htm>.) The medical effectiveness team also considered guidelines from the Centers for Medicare & Medicaid Services (available at <http://www.cms.hhs.gov/FACA/downloads/recommendations.pdf>) and guidelines from the Blue Cross and Blue Shield Association (available at <http://www.bcbs.com/tec/teccriteria.html>).

<sup>26</sup> In this report, the word “trend” may be used synonymously with “pattern.”

4. Pattern toward no effect/weak evidence: Studies generally find no effect, but this may be due to a lack of statistical power.
5. No effect: There is statistical evidence of no clinical effect in the literature with sufficient statistical power to make this assessment.
6. Unfavorable: No findings show a statistically significant benefit, and some show significant harms.
7. Insufficient evidence to make a “call”: There are very few relevant findings, so that it is difficult to discern a pattern.

The search terms used to retrieve studies relevant to the amendments to AB 2012 were as follows:

**MeSH terms used to search PubMed and Cochrane Library:**

Explode indicates that the broader term and all narrower terms underneath it were searched.

Abnormalities  
 Alcoholism  
 Amputation  
 Amputation/rehabilitation  
 Amputation, Traumatic  
 Artificial Limbs  
 Artificial Limbs/\*economics  
 Exp Back Pain (including low back pain)  
 Comparative Study  
 Contraceptives, Oral  
 Exp Costs and Cost Analysis (including Cost-Benefit Analysis, Cost Control, Cost Saving, Cost Sharing, Deductibles and Coinsurance, etc.)  
 Health Benefit Plans, Employee/ economics/trends  
 Insurance Coverage  
 Knee Prosthesis  
 Lower Extremity  
 Microcomputers  
 Obesity  
 Orthotic Devices (including Braces)  
 Patient Satisfaction  
 Prostheses and Implants  
 Prosthesis Design  
 Prosthesis Fitting  
 Prosthesis Implantation  
 Recovery of Function  
 Shoes  
 Surface Properties  
 Tendons, Para-Articular  
 Treatment Outcome  
 Upper Extremity  
 Weight-Bearing

**Publication Types:**

Clinical Trial  
Meta Analysis  
Randomized Controlled Trial  
Review

**Keywords used to search PubMed, Cochrane Library and Web sites:**

\* indicates truncation

abnormalities, alcoholism, amputation, artificial limb\*, back pain, body powered prosthesis, brace\*, c-leg, clinical trial\*, coinsurance, comparative stud\*, computerized controlled, congenital disability\*, copayment, cost benefit analysis, cost control, cost sharing, cost\*, costs and cost analysis, deductibles and coinsurance, effective\*, employer\*, endolite prosthetics, functional outcome, health benefit\*, health benefit plan\*, health insurance, ICEX, insurance coverage, intelligent prosthetics, lower limb\*, lower extremity, knee prosthesis, meta analysis, microcomputer\*, microprocessor\*, obesity, offer rate, oral contraceptive\*, orthotic device\*, otto bock, premium\*, prostheses or prosthese or prosthesis or prosthetics, patient satisfaction, PTB, meta analysis, myoelectric prosthesis, randomized controlled trial\*, recovery of function, shoe\*, socket\*, surface properties, systematic review, total surface bearing socket, touch EMAS limb system, treatment outcome\*, TSB, upper limb\*, upper extremity, total surface bearing socket, treatment outcome\*, vaccum assisted socket\*, weight bearing

**Thesaurus used to search Business Source Premier:**

Cost Shifting  
Employer-sponsored Health Insurance  
Insurance, Health  
Insurance Premiums  
Insurance Surveys

**Keywords used to search Business Source Premier and EconLit:**

alcoholism, cost sharing, employer\*, employer health benefit\*, employer health benefit survey, health benefit\*, health benefit plan\*, health insurance, insurance coverage, insurance premiums, obesity, offer rate, oral contraceptive\*, premium\*

**Thesaurus used to search EconLit**

Cost Sharing  
Benefit  
Benefit Cost  
Employers  
Health Insurance  
Survey  
Wage and Fringe Benefit Studies

## **Appendix B: Summary of Findings on the Effects of Technological Innovations in Prosthetic Devices**

Appendix B presents detailed information on findings regarding the impact of technological innovations in prosthetic devices.

Table B-1 is a summary of the published studies on these topics. The table includes study citations and descriptions of the types of studies, intervention and control groups, populations studied, locations in which studies were conducted, and principal findings.

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



**Table B-1.** Summary of Published Studies on the Effects of Technological Innovations in Prosthetic Devices

Citation	Type of Prosthesis	Type of Study	Intervention vs. Control Group	Population Studied	Location	Findings
Crandall and Tomhave, 2002	Upper Limb	Observational — retrospective cohort (no control group)	Compares perceived functionality of three types of upper limb prostheses for performing 22 common activities (e.g., tying shoelaces, steering a bicycle): (1) passive prosthesis; (2) body-powered prosthesis; (3) myoelectric prosthesis <sup>27</sup> (no control group)	26 children and adolescents with unilateral below-elbow limb loss who used multiple prostheses; mean age 15.7 years; recruited at a Shriner’s Hospital	United States: Minnesota	NS, fav—body-powered prosthesis had greater functional response than myoelectric and passive prostheses for all 22 activities  NS, fav—myoelectric prosthesis had greater functional response than passive prosthesis for most activities

<sup>27</sup> A passive upper limb prosthesis resembles a human arm and hand but does not contain a mechanism for grasping objects. A body-powered prosthesis has a hook at the end of the arm that the wearer operates by moving the muscles of the residual limb. A myoelectric prosthesis contains myoelectrodes that convert signals generated by movement of the muscles of the residual limb into energy that powers an electrical motor (Lake and Dodson, 2006).

Citation	Type of Prosthesis	Type of Study	Intervention vs. Control Group	Population Studied	Location	Findings
Flynn et al., 2000 (US Dept. Veterans Affairs Report)	Lower Limb: knee	Systematic review	Microprocessor-controlled prosthetic knees vs. mechanically controlled prosthetic knees <sup>28</sup>	Four studies of persons with unilateral transfemoral amputations (i.e., amputation of one leg above the knee)	Not stated	<p><b>Note: statistical significance not reported.</b></p> <p>Fav—microprocessor-controlled knees: oxygen consumption when walking at speeds faster or slower than customary speed, gait, patient satisfaction</p> <p>Mixed evidence<sup>29</sup>—ability to walk on inclines, stairs, and uneven terrain</p> <p>No difference<sup>30</sup>—oxygen consumption when at customary speed</p>

<sup>28</sup> Conventional lower limb prostheses for persons with amputations above the knee have a pneumatic or hydraulic valve that performs the functions of the knee. A prosthetist adjusts the valve to provide optimum knee extension and flexion at a person’s customary walking speed. If a person walks at a different speed, he or she must alter his or her movements to ensure the prosthetic limb is at the appropriate place for the next step. Prostheses with microprocessor-controlled knees contain a microcomputer that collects data on factors such as walking speed, cadence, and terrain, and automatically adjusts knee extension and flexion based on these data. Newer types of microprocessor-controlled knees also provide greater stability during the stance phase of walking and when bending or lifting and carrying items (Berry, 2006, p., 91-93; Flynn et al., 2000, p. 3; Johansson et al., 2005, p. 565; Klute et al., 2006, p. 717).

<sup>29</sup> A finding of “mixed evidence” indicates that for the outcome(s) listed some studies reported findings favorable to the intervention (in this case microprocessor-controlled knees), but that other studies reported unfavorable findings or no difference between the intervention and control groups.

<sup>30</sup> A finding of “no difference” indicates that none of the studies found a difference between the intervention and control groups for the outcome(s) listed.

Citation	Type of Prosthesis	Type of Study	Intervention vs. Control Group	Population Studied	Location	Findings
Martin et al., 2003 (British Columbia Workers Compensation Board Report)	Lower Limb: knee	Systematic review	Microprocessor-controlled prosthetic knees vs. mechanically controlled prosthetic knees	Two systematic reviews, one unsystematic review, and four individual studies of persons with unilateral transfemoral amputations	Not stated	<p><b>Note: statistical significance not reported.</b></p> <p>Fav—microprocessor-controlled knees: oxygen consumption at low walking speeds, heart rate at steady speed, step length at regular speed, cadence at regular and high speeds, patient satisfaction</p> <p>Mixed evidence—ability to walk on inclines, stairs, and uneven terrain, oxygen consumption at customary and faster walking speeds</p> <p>No difference—cognitive effort required to walk</p>
Chin et al., 2005	Lower Limb: knee	Observational study—repeated measures on the same group of subjects (no control group)	Intelligent Prosthesis brand <sup>31</sup> microprocessor-controlled prosthetic knees vs. mechanically controlled prosthetic knees	Three persons with unilateral hip disarticulation amputations (i.e., amputation of one leg at the hip joint); aged 51-55 years	Japan	Fav—microprocessor controlled knees: oxygen consumption

<sup>31</sup> The Intelligent Prosthesis was one of the first prostheses with microprocessor-controlled prosthetic knees. It has a hydraulic cylinder and was designed to adjust knee extension to walking speed (Flynn et al., 2000).

Citation	Type of Prosthesis	Type of Study	Intervention vs. Control Group	Population Studied	Location	Findings
Datta et al., 2005	Lower Limb: knee	Observational study—repeated measures on the same group of subjects (no control group)	Intelligent Prosthesis brand microprocessor-controlled prosthetic knees vs. mechanically-controlled prosthetic knees	Ten persons with unilateral transfemoral amputations; mean age 38 years; recruited from rehabilitation center of a teaching hospital	United Kingdom	Fav—microprocessor controlled knees: oxygen consumption when walking at slow speeds;  No difference—oxygen consumption when walking at subject's normal speed, gait
Klute et al., 2006	Lower Limb: knee	Observational study—repeated measures on the same group of subjects (no control group)	C-Leg <sup>32</sup> microprocessor-controlled prosthetic knees vs. mechanically controlled prosthetic knees	Five persons with unilateral amputations who were long-term users of prostheses with mechanically controlled knees, who wore a prosthesis at least eight hours per day, who could walk without upper extremity aids (e.g., cane), and had no significant musculoskeletal or neurological disorders; mean age 48 years.	United States: Washington State	No difference—daily activity level, duration of activity
Perry et al., 2004	Lower Limb: knee	Observational study—case study (no control group)	C-Leg microprocessor-controlled prosthetic knees vs. mechanically-controlled prosthetic knees	One man with bilateral amputation (i.e., both legs) due to meningococemia with purpura fulminans; recruited from rehabilitation center	United States: California	<b>Note: statistical significance not reported.</b>  Fav—within individual for C-Leg microprocessor-controlled knees: walking speed, stride length, oxygen consumption, respiratory exchange ratio  No difference—cadence

<sup>32</sup> The C-Leg is a prosthetic lower limb that has microprocessor-controlled, hydraulic cylinders that optimize knee extension as well as stability during the stance phase of walking (Flynn et al., 2000, pg. 3).

Citation	Type of Prosthesis	Type of Study	Intervention vs. Control Group	Population Studied	Location	Findings
Johansson et al., 2005	Lower Limb: knee	Observational study—repeated measures on the same group of subjects (no control group)	Compared three types of lower limb prostheses: (1) magnetorheological-based microprocessor-controlled; <sup>33</sup> (2) hydraulic-based microprocessor-controlled; and (3) hydraulic-based mechanically controlled	Eight persons with unilateral transfemoral amputations; aged 29-54 years; able to walk at variable cadence; no other musculoskeletal, cardiovascular, pulmonary, or neurological disorders	United States: Massachusetts	<p><b>Magnetorheological-based, microprocessor controlled knees vs. hydraulic-based, mechanically-controlled knees:</b></p> <p>Sig, fav—oxygen consumption at self-selected walking speed, step time, smoothness of gait, level of muscular activity, shank jerk about toe-off, thigh jerk in terminal swing</p> <p>No difference—step length, thigh jerk about toe-off, shank jerk in terminal swing</p> <p><b>Hydraulic-based, microprocessor-controlled knees vs. hydraulic-based, mechanically controlled knees:</b></p> <p>Sig, fav—smoothness of gait, thigh jerk in terminal swing</p> <p>NS, fav—shank jerk about toe-off (p=0.057)</p> <p>No difference—oxygen consumption at self-selected walking speed, step time, step length, level of muscular activity, thigh jerk about toe-off, shank jerk in terminal swing</p>

<sup>33</sup> In lower limb prostheses with magnetorheological fluid, the axis of the knee incorporates a magnetic fluid and steel rotary blades. Knee extension and flexion are adjusted through changes in the viscosity of the magnetic fluid, which is controlled by a microprocessor (Berry, 2006, p. 108-109).

Citation	Type of Prosthesis	Type of Study	Intervention vs. Control Group	Population Studied	Location	Findings
Johansson et al., 2005	Lower Limb: knee	Observational study—repeated measures on the same group of subjects (no control group)	Compared three types of lower limb prostheses: (1) magneto-rheological-based microprocessor-controlled; (2) hydraulic-based microprocessor-controlled; and (3) hydraulic-based mechanically controlled	Eight persons with unilateral transfemoral amputations; Aged 29-54 years; Able to walk at variable cadence; No other musculoskeletal, cardiovascular, pulmonary, or neurological disorders	United States: Massachusetts	<b>Magnetorheological-based, microprocessor controlled knees vs. hydraulic-based, microprocessor-controlled knees:</b>  Sig, fav—walking speed, step time  NS, fav—oxygen consumption at self-selected walking speed (p=0.092)  No difference—step length, level of muscular activity, shank and thigh jerk about toe-off, shank and thigh jerk in terminal swing

Citation	Type of Prosthesis	Type of Study	Intervention vs. Control Group	Population Studied	Location	Findings
Hofstad et al., 2006	Lower Limb: ankle-foot	Meta-analysis—all studies analyzed repeated measures on the same group of subjects (no control group)	Studies made one of two types of comparisons between 18 different types of prosthetic ankle-foot mechanisms: (1) one or more types of energy-storing feet to one or more types of solid ankle cushion heel feet (SACH) <sup>34</sup> ; (2) two different types of energy-storing feet	23 studies of adults with transfemoral, through-knee, or transtibial (below the knee) amputations	Canada, Germany, Netherlands, Spain, Taiwan, United Kingdom, United States.	<p><b>Energy-storing foot vs. SACH foot:</b></p> <p>Sig, fav—walking on level surfaces, inclines, or declines (1 study), running or walking briskly (3 studies), late stance dorsiflexion (5 studies);</p> <p>Mixed evidence—oxygen consumption when walking (8 studies), gait efficiency (8 studies), meters walked per minute (2 studies), stride length (2 studies), patient satisfaction (3 studies)</p> <p><b>Different types of energy-storing feet:</b></p> <p>Sig, fav—Re-Flex VSP foot vs. Flex-Foot: energy cost while running (1 study), gait efficiency when running (2 studies)</p> <p>Sig, fav—Flex-Foot vs. Seattle foot: stride length</p> <p>No difference—Flex-Foot<sup>35</sup> vs. Seattle Foot: gait efficiency (1 study)</p> <p><b>All types of prosthetic feet:</b></p> <p>No difference—cadence</p>

<sup>34</sup> The solid ankle cushion heel foot is a frequently prescribed type of prosthetic foot that provides stability but does not enable a person to use the prosthetic foot to propel forward motion (Underwood et al., 2004). The energy-storing foot (also known as the dynamic response foot) contains springs and internal plate that stores energy when the heel of the foot strikes the surface on which a person is walking and releases energy when the person pushes off the toe for his or her next step (Hsu et al., 2006; Marks and Michael, p. 733).

<sup>35</sup> The Flex-Foot, Proteor, Re-Flex VSP, and Seattle Foot are four different types of energy-storing prosthetic feet.

Citation	Type of Prosthesis	Type of Study	Intervention vs. Control Group	Population Studied	Location	Findings
Hsu et al., 2006	Lower Limb: ankle-foot	Observational study—repeated measures on the same group of subjects (no control group)	Compares the effectiveness of three types of prosthetic feet: (1) C-Walk foot; <sup>36</sup> (2) Flex-Walk foot; and (3) SACH foot	Eight men with unilateral transtibial amputations who had used a prosthesis for at least one year, could walk at least 107.28 meters per minute on a treadmill, and had no major medical problems aside from amputation; mean age 36 years	Not stated	<p><b>C-Walk foot vs. SACH foot:</b></p> <p>No difference: oxygen consumption, % age-predicted maximum heart rate, rating of perceived exertion, gait efficiency, steps per day;</p> <p><b>Flex-Foot foot vs. SACH foot:</b></p> <p>Sig, fav—Flex-Foot: % age-predicted maximum heart rate, rating of perceived exertion;</p> <p>NS, fav—Flex-Foot: steps per day (p=0.06);</p> <p>No difference: oxygen consumption, gait efficiency</p>
Underwood et al., 2004	Lower Limb: ankle-foot	Observational study—repeated measures on the same group of subjects (no control group)	Energy-storing Flex-Foot foot vs. SAFE II <sup>37</sup> foot	Eleven persons with unilateral transtibial amputations due to trauma, who could ambulate without assistive devices, and did not have a cardiovascular, musculoskeletal, or neurological condition; mean age 42.5 years; mean years since amputation 11.08 years	Canada	<p>Sig, fav—Flex-Foot: greater power during the push-off phase of walking, greater power absorption during weight acceptance, and greater stability during walking;</p> <p>NS, fav—Flex-Foot: perceived ability to walk more quickly and stability on a foam surface.</p>

<sup>36</sup> The C-Walk foot and the Flex-Walk foot are two types of energy-storing prosthetic feet that have different types of springs (Hsu et al., 2006). See footnote 24 for a definition of energy-storing feet.

<sup>37</sup> The SAFE II foot has a solid ankle cushion heel and a flexible keel (top part of the foot) that provides a greater range of movement than the SACH foot (Underwood et al., 2004).



Citation	Type of Prosthesis	Type of Study	Intervention vs. Control Group	Population Studied	Location	Findings
Baars and Geertzen, 2005	Lower Limb: socket <sup>38</sup>	Systematic review	Total surface-bearing (TSB) socket <sup>39</sup> with silicon liner vs. older types of sockets	6 studies of persons with transtibial amputations; 5 of 6 studies enrolled only adults	Article does not state	<p><b>Note: statistical significance not reported.</b></p> <p>Fav—TSB sockets: distance walked, ability to walk on even and uneven terrain, ability to climb stairs, ability to walk on inclines and declines, use of walking aids (5 studies), suspension (4 studies), comfort (3 studies), amount of pain (3 studies).</p> <p>Not fav—TSB socket: skin problems (3 studies)</p>
Selles et al., 2005	Lower Limb: socket	Randomized controlled trial	Total surface-bearing socket (TSB) vs. patellar tendon-bearing (PTB) socket <sup>40</sup>	26 adults who had unilateral transtibial amputations and who had used a prosthesis for at least one year; mean age 60 years; recruited from two hospitals.	Netherlands	<p>Sig, not fav—TSB socket: time standing, walking, and climbing stairs;</p> <p>No difference—other measures of activity and motility, gait, and patient satisfaction.</p>

<sup>38</sup> The socket is the part of a prosthesis that fits over a person's residual limb (Marks and Michael 2001, p. 732).

<sup>39</sup> Total surface-bearing (TSB) sockets use silicon liners to attach the prosthesis to the residual limb. The silicon liner provides a closer fit between the prosthesis and the residual limb than older types of sockets, and permits body weight to be distributed over the total surface area of the residual limb (Selles et al., 2005).

<sup>40</sup> The patellar tendon-bearing socket was developed in the 1950s and continues to be widely used. This type of socket distributes body weight such that most weight is borne by the patellar tendon, the area of the residual limb best able to bear weight (Selles et al., 2005).

## Appendix C: Cost Impact Analysis: General Caveats and Assumptions

This appendix describes general 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, <http://www.chbrp.org/costimpact.html>.

The cost analysis in this report was prepared by Milliman Inc. (Milliman) and University of California, Los Angeles, with the assistance of CHBRP staff. Per the provisions of AB 1996 (California Health and Safety Code, Section 127660, et seq.), the analysis includes input and data from an independent actuarial firm, Milliman. In preparing cost estimates, Milliman and UCLA relied on a variety of external data sources. The *Milliman Health Cost Guidelines* (HCG) were used to augment the specific data gathered for this mandate. The HCGs are updated annually and are widely used in the health insurance industry to estimate the impact of plan changes on health care costs. Although this data was reviewed for reasonableness, it was used without independent audit.

### General Caveats and Assumptions

The expected costs in this report are not predictions of future costs. Instead, they 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 different from our assumptions.
- Utilization of mandated services before and after the mandate different from our assumptions.
- Random fluctuations in the utilization and cost of health care services.

Additional assumptions that underlie the cost estimates presented here are:

- Cost impacts are only shown for people with insurance.
- The projections do not include people covered under self-insurance employer plans because those employee benefit 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.

There are other variables that may affect costs, but which Milliman did not consider in the cost projections presented in this report. Such variables include, but are not limited to:

- Population shifts by type of health insurance coverage. If a mandate increases health insurance costs, then some employer groups 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). Milliman 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 our cost estimates. The dampening would be more pronounced on the plan types that previously had the least effective medical management (i.e., FFS and 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 we modeled (HMO, PPO, POS, and FFS), there are variations in utilization and costs within California. One source of difference is geographic. Utilization 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, we have estimated the impact on a statewide level.

#### Mandate Specific Assumptions

- Throughout the analysis, CHBRP assumes that compliance with AB 2012 means parity in cost sharing and out-of-pocket maximums with other benefits, and no separate O&P annual benefit maximum.
  - Specifically, for Knox-Keene licensed plans, “compliant” means that the amount of the benefit for orthotic and prosthetic devices and services is no less than the annual and lifetime benefit maximums applicable to basic health care services as defined under Section 1376 of the Health and Safety Code. Any copayment, coinsurance, deductible, and maximum out-of-pocket amount applied to the benefit for orthotic and prosthetic devices and services is no more than the most common amount applied to the basic health care services.
  - For policies regulated under the Insurance Code, the amount of the benefit for orthotic and prosthetic devices and services is no less than the annual and lifetime benefit maximums applicable to all benefits in the policy. Any copayment, coinsurance, deductible, and maximum out-of-pocket amount applied to the benefit for orthotic and prosthetic devices and services is no more than the most common amount contained in the policy.
- Some plans exclude prosthetic and orthotic benefits from the total amount that can be applied to the maximum out-of-pocket expenses. Because few individuals reach the maximum out-of-pocket expense limit, this provision would have negligible impacts on the cost estimates presented in this analysis.

- The costs associated with surgically implanted prosthetic devices (e.g., hip joints and heart pacemakers) were excluded from the analysis because these devices, if FDA approved, are typically covered at benefit levels similar to those for other medical conditions requiring hospitalization.
- Knox-Keene licensed health plans are required to cover prosthetic devices used to restore a method of speaking following laryngectomy and prosthetic devices used to restore and achieve symmetry incident to a mastectomy. These costs were not excluded from the premandate or postmandate costs. CHBRP estimated that these expenditures were a negligible amount of total O&P expenditures and that they would not affect the marginal increase in costs because coverage is mandated before and after the passage of AB 2012.
- Knox-Keene licensed plans are required to offer coverage in their group policies for special footwear for persons who suffer from foot disfigurement. (As used in Health and Safety Code, Section 1367.19, foot disfigurement includes disfigurement from cerebral palsy, arthritis, polio, spinabifida, diabetes, and foot disfigurement caused by accident or developmental disability.) CHBRP analysis assumes that this product offering would be subject to the requirements of AB 2012. Therefore, product offerings for foot orthotics are included in the cost model.
- Plans and insurers generally exclude devices for enrollees' participation in sports or recreational activities (i.e., athletic devices) from O&P benefits and, therefore, these are excluded from premandate and postmandate cost analysis.
- Estimates of the number of insured and their distribution by employment-based, privately purchased, or publicly financed plans and HMO membership were based on the California Health Interview Survey, 2003.
- For the purposes of analysis, CHBRP assumes that member coinsurance is applied first and then any applicable annual benefit limit. CHBRP also assumes that the annual benefit limit applies to the health plans' payment for the benefit and not the cost of the devices. Thus, for example, if a policy currently has 50% coinsurance for O&P benefits and a \$2,000 annual benefit limit, then for a \$5,000 device:
  - The plans' payment should be 50% of the benefit being used, in this case 50% of \$5,000 or \$2,500.
  - The members' payment should be 50% of the benefit being used, in this case 50% of \$5,000 or \$2,500.
  - However, because the benefit has an annual benefit limit of \$2,000, the plan would pay no more than \$2,000
  - The final member out-of-pocket expense for the benefit would be the original coinsurance amount (\$2,500) plus the difference between the plan's share of payment for the benefit and the plan's annual benefit limit ( $\$2,500 - \$2,000 = \$500$ ) or \$3,000.
- If a plan or policy currently includes an annual out-of-pocket maximum *and* an annual benefit limit for O&P benefits, CHBRP assumes that the plans' payments for O&P benefits would stop at the amount specified by the annual benefit limit.
- CHBRP estimates the postmandate cost-sharing levels for HMO enrollee based on the average share of cost of basic health care services that are reflected in typical copayments. For example, average copayments for doctors' office visits, other outpatient services and hospitalizations reflect approximately 4% of cost of services under large group plans and 7% for small group plans.

- CHBRP estimate for average annual benefit limits was based on plans that had such benefit limits. In general, a majority of small group plans or policies have annual benefit limits; whereas, fewer large group plans or policies have such limits.
- A reference to health plan utilization review process includes both determinations of medical necessity and determinations of treatment that is experimental or investigational. Plans and insurers commonly limit their obligation for P&O benefits to cost effective devices as recognized by professional standards.

## **Appendix D: Information Submitted by Outside Parties for Consideration for CHBRP Analysis**

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

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

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

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

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

The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance and thoughtful critiques provided by the members of the National Advisory Council. However, the Council does not necessarily approve or disapprove of or endorse this report. CHBRP assumes full responsibility for the report and the accuracy of its contents.

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