CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Analysis of Assembly Bill 2012: Orthotic and Prosthetic Devices

A Report to the 2006–2007 California Legislature
April 11, 2006

CHBRP 06-06

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 sound scientific evidence relevant to the proposed mandate, but does not make recommendations, deferring policy decision making to the Legislature. The State funds this work though 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 CHBRP's Web site, www.chbrp.org.

A Report to the 2006–2007 California State Legislature

Analysis of Assembly Bill 2012:
Orthotic and Prosthetic Devices

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PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill 2012, a bill that would require health care service plans and health insurance policies that offer coverage on a group basis for orthotic and prosthetic devices and services to (1) cover these devices when they are prescribed by surgeons and doctors of podiatric medicine, (2) cover these devices when they are furnished by physicians, surgeons, certified orthotists and prosthetists, or licensed health care providers acting within the scope of their license, and (3) eliminate a requirement that plans and insurers provide coverage "under terms and conditions that may be agreed upon between the subscriber and plan or policyholder and insurer." In response to a request from the California Assembly Committee on Health on February 10, 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.

Wade Aubry, MD, Janet Coffman, PhD, Patricia Franks, BA, Witney McKiernan, RN, Harold Luft, PhD, and Edward Yelin, PhD, all of the University of California, San Francisco, prepared the medical effectiveness analysis. Patricia Sinnott, PT, PhD, MPH, and Henry (Hank) Chambers, MD, provided technical assistance with the literature review and clinical expertise for the medical effectiveness analysis. Min-Lin Fang, MLIS of the University of California, San Francisco, conducted the literature search. Helen Halpin, PhD, Nicole Bellows, MHSA, of the University of California, Berkeley, prepared the public health impact analysis. Meghan Cameron, MPH, and Gerald Kominski, PhD, of the University of California, Los Angeles, prepared the cost impact analysis. Robert Cosway, FSA, MAAA, of Milliman, provided actuarial analysis. Cynthia Robinson, MPP, of CHBRP staff prepared the background section and synthesized individual sections into a single report. Sarah Ordody, BA, provided editing services. In addition, a subcommittee of CHBRP's National Advisory Council (see final pages of this report) 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 CHBRP:

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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Assembly Bill 2012: 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. In response to a request from the California Assembly Committee on Health on February 10, 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.

AB 2012 would amend section 1367.18 of the Health and Safety Code and Section 10123.7 of the Insurance Code. AB 2012 would mandate that health care service plans licensed under the Knox-Keene Act[1] and health insurance policies regulated under the California Insurance Code that offer coverage on a group basis for orthotic and prosthetic (O&P) devices to (1) cover these devices when they are prescribed by surgeons and doctors of podiatric medicine, (2) cover these devices when they are furnished by physicians, surgeons, certified orthotists and prosthetists, or licensed health care providers acting within the scope of their license, and (3) eliminate a requirement that plans and insurers provide coverage "under terms and conditions that may be agreed upon between the subscriber and plan or policyholder and insurer."

I. Medical Effectiveness

- O&P devices can help improve physical and psychological functioning of persons with amputations and injuries by enabling them to exercise, work, and perform other activities of daily living and, thus, reduce their dependence on caretakers.

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

II. Utilization, Cost, and Coverage Impacts

- Currently, there are 14,049,893 individuals under age 65 with coverage for O&P devices in health plans affected by the mandate—those enrolled in group insurance plans or policies.

- The total per member per month (PMPM) cost of O&P devices is $0.65 for a typical insured population. This is based Milliman national claims data which indicates a

[1] Knox-Keene licensed health plan are regulated by the Department of Managed Health Care. The Knox-Keene Health Care Services Plan Act of 1975 regulated all California health maintenance organizations, as well as Blue Cross and Blue Shield PPOs. PPOs (except Blue Cross and Blue Shield PPOs) and other non-HMO insurers are regulated by the California Department of Insurance (CDI). Knox-Keene Act is part of the Health and Safety Code.

utilization rate of 40.4 procedures per 1,000 members and an average allowed cost of $193 per procedure.

- This bill is not estimated to impact the utilization or total cost for O&P devices because (1) AB 2012 would not change O&P benefits for enrollees, and (2) the majority of health plans who use orthotists and prosthetists already contract with those who are certified.

- Total medical costs are not projected to change as a result of this mandate.

- Premiums are not projected to change.

III. Public Health Impacts

- A broad range of health conditions are associated with the use of O&P devices ranging 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.

- Because there is no evidence to suggest that AB 2012 would have an impact on health outcomes or utilization, there is also no evidence to project that AB 2012 would have an impact on the public's health.

- Because there is no evidence to suggest that AB 2012 would have an impact on health outcomes or utilization, there is also no evidence to project that AB 2012 would have an impact on health disparities.

- Because there is no evidence to suggest that AB 2012 would have an impact on health outcomes or utilization, there is also no evidence to project that AB 2012 would have an impact on premature death or economic loss associated with the conditions related to the use of O&P devices.

INTRODUCTION

Assembly Bill 2012 (AB 2012) would mandate that health care service plans licensed under the Knox-Keene Act[2] and health insurance policies regulated under the California Insurance Code that offer coverage on a group basis for orthotic and prosthetic (O&P) devices and services cover these devices when they are prescribed, ordered, and furnished by specific providers. In addition, AB 2012 would eliminate a requirement that plans and insurers provide coverage "under terms and conditions that may be agreed upon between the subscriber and plan or policyholder and insurer."

A prosthesis is an artificial limb 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. Nationally, about 4.5 million people rely on an O&P device, such as an artificial limb or back brace, to function more independently and improve their quality of life (NCHS, 1994).

Current law does not mandate that plans and insurers *cover* O&P devices and services but does mandate that coverage be *offered* for purchase by a group, including large or small employer groups. AB 2012 would not alter this requirement. AB 2012 would also not affect current mandates on Knox-Keene licensed plans to cover prosthetic devices following a mastectomy or laryngectomy, or the requirement that plans offer coverage for special footwear needed by persons who suffer from foot disfigurement.

Under current laws that govern group health plan and insurer policies, prosthetic devices are only covered if physicians prescribe them. Orthotic devices are only covered if physicians prescribe them *and* they are ordered by a licensed health care provider acting within the scope of his or her license.[3] AB 2012 would amend these statutes to:

- Add coverage for O&P devices prescribed by surgeons and podiatrists.
- Add coverage for orthotic devices furnished by physicians, surgeons, licensed health care providers acting within the scope of their license, and orthotists and prosthetists certified pursuant to Section 14132.63 of the Welfare and Institutions Code. (Welf. & Inst. Code §14132.63 requires orthotists and prosthetists participating in Medi-Cal to be certified by either the American Board for Certification in Orthotics and Prosthetics [ABC] or the Board for Orthotist/Prosthetist Certification [BOC]).
- Eliminate a requirement that plans and insurers provide coverage "under terms and conditions that may be agreed upon between the subscriber and plan or policyholder and insurer."

[2] Knox-Keene licensed health plan are regulated by the Department of Managed Health Care. The Knox-Keene Health Care Services Plan Act of 1975 regulated all California health maintenance organizations, as well as Blue Cross and Blue Shield PPOs. PPOs (except Blue Cross and Blue Shield PPOs) and other non-HMO insurers are regulated by the California Department of Insurance (CDI). Knox-Keene Act is part of the Health and Safety Code.
[3] See Health and Safety Code Section 1367.18 and Insurance Code Section 10123.7.

Linking coverage for O&P devices to specific practitioners

Prescribing O&P devices
The portion of AB 2012 that addresses the professionals who can *prescribe* O&P devices reiterates in statute the provisions found in the Business and Professions Code. AB 2012 does not change current practice with respect to those providers who can prescribe medical devices; AB 2012 updates the laws governing health plan and insurer health policies to reflect existing authority granted under their license for physicians and podiatrists to prescribe medical devices. Under the Business and Professions Code, podiatrists and surgeons (under their physician's license) are currently permitted to prescribe and furnish any medical device.[4] There is nothing in current law that would preclude these professions from coverage; although some health plans may have contract limitations on coverage for O&P devices.

Furnishing O&P devices
The portion of AB 2012 that addresses the professions who can *furnish* orthotic devices is a new requirement. Current laws that govern health plan and insurer health policies do not specify the types of providers who may be reimbursed for furnishing orthotic devices. Unless health plans and insurers have contract limitations, there nothing in current law to preclude a variety of health care providers from furnishing orthotic devices. Providers who currently furnish orthoses include podiatrists, physical and occupational therapists, and orthotists and prosthetists.

For those health plans and insurers who contract with orthotists and prosthetists to furnish orthotic devices, AB 2012 would limit coverage to orthotists and prosthetists who are certified by either of two national private certifying organizations—the American Board for Certification in Orthotics and Prosthetics (ABC) or the Board for Orthotist/Prosthetist Certification (BOC). Other public programs maintain similar certification requirements. In California, Medi-Cal and California Children's Services require orthotists and prosthetists to be certified by the ABC or the BOC.[5] Nationally, Medicare regulations specify that payment for custom-fabricated orthoses and prostheses are to be furnished only by qualified providers. If the qualified provider is an orthotist or prosthetist, he or she must meet the certification standards of the ABC, or BOC, or a program with essentially equivalent standards.[6]

Currently, 11 states have licensure requirements in place for O&P practitioners (ABC, 2006). California does not require licensing of orthotists or prosthetists. According to the bill sponsor, the California Orthotics and Prosthics Association (COPA) the intent of this provision—mandatory certification for O&P practitioners who furnish orthotic devices—is to "reduce chronic and life threatening health problems due to unskilled O&P practitioners" (COPA, 2006).

Eliminate "terms and conditions" language

AB 2012 would also eliminate the requirement that plans and insurers provide coverage "under terms and conditions that may be agreed upon between the subscriber and plan or policyholder and insurer."

[4] Business and Professions Code, Sections 4070 et seq. and 2477.
[5] Section 14132.63 of the Welfare and Institutions Code for Medi-Cal; CCS, Program Provider Paneling, June 2004.
[6] Social Security Act, 42 U.S.C. Section 1834(h). Other providers include physical and occupational therapists.

Only California and Florida and 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. In contrast, Colorado, Connecticut, Maine, Maryland, Michigan, New Hampshire, and Oregon have laws mandating some level of coverage for orthotic or prosthetic device. 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).[7] These "parity" laws 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 insurance (ACA, 2006).

In materials provided to CHBRP, COPA maintains that the "terms and conditions" in group contracts have been used by health plans and insurers to "lessen their commitment to covered patients who need these devices and services." COPA intends that the elimination of this provision would remedy the problem of plans or insurers offering coverage that is not "reasonably covered consistent with other benefits" (COPA, 2006).

CHBRP discussions with state regulatory agencies indicate that removal of the "terms and conditions" language for a mandated offering would not change current benefit structure requirements (e.g. cost-sharing, benefits limitations, etc) for plans and insurers. In other words, plans and insurers may continue to offer the same level of coverage to groups that have opted to purchase the O&P benefit. As a result, this analysis focuses exclusively on the impact of linking coverage for O&P devices to specific types of providers who prescribe, order, or furnish them.

Factors to consider if AB 2012 were to mandate "parity"

Because the language of the bill does not require that plans offer coverage for O&P devices at the same level as other types of insurance, CHBRP does not view the bill as mandating parity for O&P benefit offerings. However, if the bill is intended by the legislature as a vehicle for mandating parity, it would require CHBRP to revisit the analysis, particularly in regard to cost estimates presented in this report. Clarity in regard to the bill's intent might be achieved if the bill were to establish whether parity was sought for both orthotic and prosthetic devices and specify the benefit level to be used as the benchmark (e.g., other covered health benefits, with Medicare, or with a typical durable medical equipment benefit). To perform this analysis, CHBRP would need to estimate the following:

- The rate at which employer groups currently purchase O&P benefits.
- The rate at which employer groups would continue to purchase O&P benefits in response to the premiums changes for O&P coverage that may result from a parity mandate.

[7] 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.

- Current expenditures per enrollee for O&P benefits.
- Percentage of expenditures currently covered by the health plan
- The impacts of eliminating or raising annual benefit maximums (or caps) for enrollees in plans and policies with such benefit maximums. The impacts of changing the cost sharing structure (e.g. copayment or coinsurance levels) for the O&P benefit. These impacts will depend on the specified benchmark the O&P benefit would require to
- The corresponding changes in utilization of the O&P benefit as result of changes in cost sharing structure.
- The cost shift from out-of-pocket expenditures to private insurance. Since charitable organizations are involved in providing O&P services, this shift could be significant.

In addition, the medical effectiveness and public health impact analysis would need to assess the extent to which altering cost sharing arrangements for O&P benefits might impact the quality of patient care and the health status of the population.

I. MEDICAL EFFECTIVENESS

O&P devices can help improve the physical and psychological functioning of persons with amputations, injuries, musculoskeletal disorders, and congenital physical disabilities by enabling them to exercise, work, and perform other activities of daily life and thus, reduce their dependence on caretakers (Division of Health Care Finance and Policy, Commonwealth of Massachusetts, 2005, p. 2; Maine Bureau of Insurance, 2003, p. 31). 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). Improving the ability of persons with lower extremity amputations to exercise may reduce costs associated with treating them for these chronic illnesses (Maine Bureau of Insurance, 2003, p. 31). Ability to exercise is enhanced by a well-fitting O&P device that is appropriate for a person's exercise activity of choice (Pitetti, 2005).

The review of the medical effectiveness literature for AB 2012 focuses on whether there is evidence that quality of care differs if O&P devices are 1) prescribed by physicians versus podiatrists, and 2) furnished by certified versus uncertified orthotists and prosthetists. *The literature search did not address the medical effectiveness of O&P devices, because, as discussed in the Introduction, the bill would not require health plans to provide coverage for orthoses and prostheses to all enrollees.* Rather, the bill would link coverage for O&P devices to specified practitioners, and require orthotists and prosthetists who furnish orthotic devices to be certified.

The literature review encompassed meta-analyses, systematic reviews, randomized controlled trials, controlled clinical trials, and observational studies. The PubMed, Cochrane, and CINAHL databases were searched. In addition, the following specialized databases on prosthetics, orthotics, disabilities, rehabilitation, and sports medicine were searched: ABLEDATA, RECAL, REHABDATA, and SPORTDiscus. A web search was also conducted to identify relevant materials that were not published in peer-review journals. The search was limited to articles

published in English.

The literature review yielded no peer-reviewed studies of the relative effectiveness of the prescribing of O&P devices by physicians versus podiatrists or the furnishing of such devices by certified versus uncertified orthotists and prosthetists. One study compared the quality of care furnished by physicians and podiatrists for foot disorders and injuries, but did not specifically address the quality of orthotic and prosthetic services (Glenn, 1995). Reports issued by other states in which bills regarding coverage for O&P devices have been introduced 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). None of these reports addressed the relative effectiveness of physicians versus podiatrists or of certified versus uncertified orthotists and prosthetists.

One reason for the lack of pertinent peer-reviewed studies may be that orthotists and prosthetists have only recently launched new initiatives to increase the amount of research conducted on O&P services and to improve the synthesis and dissemination of findings (Jerrell, 2006). However, to date most initiatives have focused on the effectiveness of O&P devices and instruments for assessing patients' needs and preferences, and not on the relative effectiveness of health professionals with different types and levels of training. Studies have examined whether outcomes differ when services are provided by other types of health professionals, such as physicians versus nurse practitioners[8], but none have specifically evaluated whether outcomes of O&P services differ when they are prescribed or furnished by one type of health professional versus another. Little research has been conducted on the effectiveness of certification for any health profession.

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 and with the furnishing of such devices by certified versus uncertified orthotists and prosthetists. Therefore, the impact of AB 2012 on the medical effectiveness of O&P services cannot be assessed and is inconclusive.

II. UTILIZATION, COST, AND COVERAGE IMPACTS

CHBRP estimates that AB 2012 would have no impact on the utilization or cost of O&P devices. This assessment was based on the fact that the bill does not change the providers who can *prescribe* O&P devices; this is already dictated by current law.[9] The bill does, however, specify who can *furnish* orthotic devices and eliminates orthotists and prosthetists who are not certified pursuant to Section 14132.63 of the Welfare and Institutions Code. However, because CHBRP was unable to identify the percentage of total orthotic devices currently provided by noncertified orthotists and prosthetists, it was not possible to estimate the impact of this provision on utilization or costs. CHBRP's survey of health plans indicated that many plans currently

[8] See, for example, Mundinger et al. (2000), and Lenz et al.(2004).
[9] Business and Professions Code, Sections 4070 et seq. and 2477.

contract with certified providers, so the impact of this provision of the bill is likely to be negligible.

Present Baseline Cost and Coverage

Current coverage of the mandated benefit

AB 2012 would require all Knox-Keene licensed health plans and group policies regulated under the California Department of Insurance that offer coverage on a group basis for O&P devices to provide coverage for O&P devices when prescribed by surgeons and podiatrists and provide coverage for orthotic devices when furnished by physicians, surgeons, licensed health care providers acting within the scope of their license, and orthotists and prosthetists certified pursuant to Welf. & Inst.Code §14132.63.

This bill would not change current benefits for enrollees related to O&P devices. Benefits offered vary by plan. Some plans offer benefits as part of their basic benefit package, while others offer benefits as a rider. Plans which offer benefits as part of their basic benefit package often include coverage as part of their Durable Medical Equipment (DME) benefit. All plans offer benefit subject to calendar years limits, copayments or coinsurance (See Table 1). Currently, there are 14,049,893 individuals under age 65 with O&P coverage in group insurance plans or policies who would be affected by the mandate.

CHBRP surveyed the seven largest health plans and insurers in California regarding their coverage levels and contracting arrangements for those who prescribe and furnish O&P devices. Of the five plans responding to the survey, all currently contract with physicians, surgeons and podiatrists to prescribe O&P devices. Some also contract with physical therapists, certified orthotists and prosthetists, or other health care providers to furnish orthotic devices. Only one indicated that certification was not a contract requirement for orthotists and prosthetists. Overall, two-thirds of the plans surveyed already use certified O&P providers in their networks.

Current utilization levels and costs of the mandated benefit

According to Milliman's claims data, the utilization rate for O&P devices was 40.4 procedures per 1,000 covered lives. Because available data sources do not provide sufficient information to determine utilization rates by provider type or certification level, and no information on the cost of O&P devices by provider type could be found, CHBRP estimates that utilization does not vary by type of practitioner.

Because this bill was determined by CHBRP not to have an impact on the utilization or cost of O&P devices, CHBRP did not estimate current utilization and costs for all populations that would be affected by the mandate. The following information is intended to provide a general sense of the amount of these costs typically found in a commercially insured population.

Based on Milliman claims data, CHBRP estimates that for a typical insured population, orthotic

and prosthetic devices have a total per member per month (PMPM) cost of $0.65. This is based on a utilization rate of 40.4 procedures per 1,000 members, and an average allowed cost of $193 per procedure. This is the total amount paid for these services. The portion paid by the member through cost sharing varies by plan type, but on average, CHBRP estimates 82% is paid by the plan and 18% is paid by the member.

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

Many public programs, including Medi-Cal, California Children's Services, and Medicare, require all orthotists and prosthetists to be certified. Thus, AB 2012 would bring health plans in line with requirements already in place for many public plans. CHBRP therefore estimates no cost shifting among payers due to AB 2012. After the mandate is enacted, these costs would continue to be borne by the same plan with the same distribution between the private and public market.

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 insured population. Based on conversations with the largest collective bargaining agents in California, CHBRP concluded that unions currently do not include such detailed provisions regarding types of providers who can prescribe and supply O&P devices in their health insurance policy negotiations. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductible, 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?

No effect on per-unit cost of O&P devices is expected. This legislation does not propose an increase in the number of people who have coverage for O&P devices or an increase in the benefit level for those who already have such coverage, but rather links coverage for O&P devices to specific providers who furnish these devices. With the exception of eliminating noncertified orthotists and prosthetists, health plans may continue to contract with a range of providers. Because the majority of health plans in the state already contract with certified O&P practitioners, the requirement that orthotists and prosthetists be certified is not expected to change costs because certification is factored into existing reimbursement rates.

How would utilization change as a result of the mandate?

Utilization is not expected to change as a result of the mandate. Available literature does not provide sufficient evidence to distinguish patients' demand for various O&P providers who prescribe or furnish devices. Though overall utilization rates for O&P devices is not predicted to change, the mix of providers furnishing these devices may change. This is due to some plans having to drop noncertified providers from their current networks. However, as mentioned previously, since the majority of plans currently have certified providers in their networks, this is not expected to affect reimbursement rates or health care costs.

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

With no change estimated in premium rates, reimbursement rates, or per-unit cost of O&P devices, CHBRP does not expect any effect on administrative or other expenses. While a minority of plans may have to shift some providers from noncertified to certified, this change would be a one-time, absorbable and negligible expense.

Impact of the mandate on total health care costs

Based on the discussion above, no overall increase or decrease in health care costs is estimated as a result of implementing AB 2012.

Costs or savings for each category of insurer resulting from the benefit mandate

Because no increase or decrease in overall health care costs is anticipated to result from AB 2012, the actuarial analysis does not project a change in health care costs for any specific category of insurers.

Impact on access and health service availability

No impact on access and health service availability is predicted. Since the majority of O&P providers in health plan networks are already certified, there is expected to be minimal effects on provider availability and, thus, the supply of O&P devices.

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 claims data, approximately 6.8 million O&P devices were used by the insured population nationally, for a utilization rate of 40.4 procedures per 1,000 persons. The ten 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

Table 2 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 utilization of any anatomical device listed in Table 2 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).

The *Medical Effectiveness* review did not identify any literature to indicate that requiring that O&P devices be provided by certified orthotists and prosthetists results in improved outcomes. Additionally, the *Utilization, Cost, and Coverage* section did not project any utilization changes

associated with AB 2012. As a result, there is no evidence to suggest that AB 2012 will have an impact on public health.

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 regards 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).

Another example is the use of breast prostheses such as a mastectomy bra. Utilization of breast prostheses is typically the result of breast cancer, which occurs predominately in females. A substantial amount of literature has examined racial disparities with regards to breast cancer in which black women have been found to be diagnosed at a later stage of disease and have poorer survival rates compared to white women (Campbell, 2002; Chu et al., 2003; Clarke et al., 2003; Ghafoor et al., 2003).

Research has also found that amputations and limb deficiency are more common in males than females and more common in blacks compared to whites (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.

Table 3 details utilization data of all O&P devices from Milliman's national database of insurance claims. 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 there is no evidence to suggest that AB 2012 will have an impact on health outcomes or utilization, there is also no evidence to project that AB 2012 will have an impact on health 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 or economic loss associated with the entire range of conditions associated with utilization of such devices.

Looking at health conditions individually, some are associated with premature death and economic loss associated with disease. 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, breast cancer, and congenital abnormalities. In addition to lost productivity due to disability, breast cancer and diabetes also result in premature death (McKenna et al., 2005).

Since there is no evidence to suggest that AB 2012 will have an impact on health outcomes or utilization, there is also no evidence to project that AB 2012 will have an impact on premature death or economic loss associated with the conditions related to the use of O&P devices.

TABLES

TABLE 1: Summary of Coverage Levels for the Orthotics and Prosthetics Benefit

Benefit	**General Description**
Coverage is part of durable medical equipment benefit?	Varies across plans or policies
Is there an annual dollar limit?	Varies across plans or policies; If the plan does not have an annual limit, they tend to be large group plans; for those with annual limits, typical benefit limit is approximately $2,000
What are the average copayments or coinsurance?	Varies across plans; Can range from 20%-50% of allowable charge for HMOs and PPOs. Deductibles may also apply. Some large groups purchase the O&P benefit with zero copayments or coinsurances.

Source: CHBRP Coverage Questionnaire. February 2006.
Note: Coverage levels for insured enrollees under age 65 in group plans and policies in which subscribers/insured opt to purchase O&P coverage.

Table 2. Utilization of Anatomical Devices–United States, 1994

Anatomical Device	Number in Thousands (Under 65)
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*
Any anatomical device	**3,816**

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

Table 3. Utilization of Orthoses/Prostheses per 1,000 Members

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

Source: Milliman national claims database, 2003.

APPENDICES

Appendix A: Literature Review Methods

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) devices and services (1) provide coverage for orthotists and prosthetists who furnish O&P devices as long as they meet specific certification standards, and (2) eliminate a requirement that plans and insurers provide coverage "under terms and conditions that may be agreed upon between the subscribe and plan or policyholder and insurer."

A prosthesis is an artificial limb 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 large numbers of congenital and acquired physically disabling conditions.

Appendix A describes the methods used in the medical effectiveness literature review for AB 2012. *The literature search did not address the medical effectiveness of O&P devices, because the bill would not require health plans to offer coverage for such devices.* Rather, the bill would change the manner in which decisions about terms and conditions of coverage are made, link coverage for O&P devices to specified practitioners, and require orthotists and prosthetists who furnish orthotic devices to be certified.

The literature review encompassed meta-analyses, systematic reviews, randomized controlled trials, controlled clinical trials, and observational studies. The PubMed, Cochrane, and CINAHL databases were searched. In addition, the following specialized databases on prosthetics, orthotics, disabilities, rehabilitation, and sports medicine were searched: ABLEDATA, RECAL, REHABDATA, and SPORTDiscus. A web search was also conducted to identify relevant materials that were not published in peer-review journals. The search was limited to articles written in English.

The literature search yielded no peer-reviewed studies of the relative effectiveness of the prescribing of O&P devices by physicians versus podiatrists, or of the furnishing of such devices by certified versus uncertified orthotists and prosthetists. One study (Glenn, 1995) compared the quality of care furnished by physicians and podiatrists but did not specifically address the quality of O&P services. Several articles and reports that described O&P devices and their impact on the lives of persons with disabilities were used as sources of background information for this report.

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

PubMed, Cochrane Library

MeSH terms:

Activities of Daily Living
Exp[10] Amputation
Amputation, Traumatic
Amputees
Certification
Clinical Competence
Comparative Study
Costs and Cost Analysis
Evaluation Studies
Health Care Costs
Health Plan Implementation/legislation and jurisprudence
Health Status
Legislation
Exp Lower Extremity (including Foot, Ankle, Heel, Hip, Knee, Leg, Thigh)
Lumbosacral Region
Exp Orthotic Devices (including Braces)
Outcome Assessment (Health Care)
Parity
Patient Satisfaction
Physicians
Podiatry
Prostheses and Implants
Prosthesis Fitting
Quality of Life
Specialism
Exp Spine (including Cervical Vertebrae, Lumbar Vertebrae)
Treatment Outcome
Exp Upper Extremity (including Arm, Elbow, Hand, Fingers, Wrist, Shoulder)

[10] Exp means PubMed will retrieve citations with all narrower MeSH terms underneath of the broader MeSH terms.

Keywords:

Podiatrist*[11], podiatry, physician*, surgeon*, effect*, impact*, cost*, efficacy, effective*, certified, uncertified, certification, prosthetist*, orthotist*, prostheses, prosthesis, orthosis, orthoses, (brace or braces or bracing), (prosthetic or orthotic) device*, fitting, prosthesis fitting, furnished, prescri*, treatment outcome*, patient satisfaction, comparison, comparative, clinical competence, clinical proficiency, health status, quality of life, evaluation, prosthetic parity, implementation, legislation, activities of daily living, daily activit*, amputation, amputee*, lower extremity, foot, ankle, heel, hip, knee, leg, thigh, upper extremity, arm, elbow, finger*, shoulder, wrist, hand, spine, cervical, lumbar, lumboscral regions

CINAHL

CINAHL thesaurus

Activities of Daily Living
Exp Amputation
Amputation, Traumatic
Amputees
Certification
Clinical Competence
Comparative Studies
Costs and Cost Analysis
Evaluation
Program Implementation
Health Care Costs
Health Status
Legislation
Limb Prosthesis
Exp Lower Extremity (including Foot, Hip, Knee, Leg, Thigh)
Lumbosacral Plexus
Orthopedic Prosthesis
Exp Orthoses (including Foot Orthoses, Orthoses Fitting)
Outcomes (Health Care)
Parity
Patient Satisfaction
Physicians
Podiatrists
Prostheses and Implants
Prosthetic Fitting
Orthoses
Quality of Life

[11] * indicates that a word was truncated to retrieve all studies in which the root portion of the keyword appeared (e.g., physician* retrieves studies in which either “physician” or “physicians” appears, effective* retrieves studies in which either “effective” or “effectiveness” appears.

Specialization
Exp Spine (including Cervical Vertebrae, Lumbar Vertebrae)
Surgeons
Treatment Outcomes
Exp Upper Extremity (including Arm, Elbow, Hand, Fingers, Wrist, Shoulder)

Keywords:

Podiatrist*, podiatry, physician*, surgeon*, effect*, impact*, cost*, efficacy, effective*, certified, uncertified, certification, prosthetist*, orthotist*, prostheses, prosthesis, orthosis, orthoses, (brace or braces or bracing), (prosthetic or orthotic) device*, fitting, prosthesis fitting, furnished, prescri*, treatment outcome*, patient satisfaction, comparison, comparative, clinical competence, clinical proficiency, health status, quality of life, evaluation, prosthetic parity, implementation, legislation, activities of daily living, daily activit*, amputation, amputee*, lower extremity, foot, ankle, heel, hip, knee, leg, thigh, upper extremity, arm, elbow, finger*, shoulder, wrist, hand, spine, cervical, lumbar, lumboscral regions

ABLEDATA, RECAL, REHABDATA, SPORTDiscus, Web

Keywords:

Podiatrist*, podiatry, physician*, surgeon*, effect*, impact*, cost*, efficacy, effective*, certified, uncertified, certification, prosthetist*, orthotist*, prostheses, prosthesis, orthosis, orthoses, (brace or braces or bracing), (prosthetic or orthotic) device*, fitting, prosthesis fitting, furnished, prescri*, treatment outcome*, patient satisfaction, comparison, comparative, clinical competence, clinical proficiency, health status, quality of life, evaluation, prosthetic parity, implementation, legislation, activities of daily living, daily activit*, amputation, amputee*, lower extremity, foot, ankle, heel, hip, knee, leg, thigh, upper extremity, arm, elbow, finger*, shoulder, wrist, hand, spine, cervical, lumbar, lumboscral regions

Please note: CHBRP's standard "Appendix B" was not prepared for this report because no peer-reviewed studies could be found that assessed whether the quality of orthotic and prosthetic (O&P) services differs if O&P devices are prescribed by physicians versus podiatrists, or if these devices are furnished by certified versus uncertified orthotists and prosthetists.

Appendix B: Information Submitted by Outside Parties for Consideration for CHBRP Analysis

CHBRP policy includes analysis of information submitted by outside parties, and places an open call to all parties who want to submit information during the first two weeks of the CHBRP review.

Personal Communication, Bryce Docherty, Docherty Group, Legislative Advocate for the California Orthotics & Prosthetics Association, February 22, 2006.

> *Fact Sheet on AB 2012, California Orthotics & Prosthetics Association, February 22, 2006;*
>
> *Amendments that may be taken prior to Assembly Health Committee hearing to clarify the intent;*
>
> *Ops. Cal. Legis. Counsel, No. 8942 (May, 18, 1993);*
>
> Division of Health Care Finance and Policy, Commonwealth of Massachusetts. *Commonwealth of Massachusetts Mandated Benefit Review: Review and Evaluation of Proposed Legislation to Mandate Coverage for Certain Prosthetic Devices: H. 837. Provided for the Joint Committee on Financial Services.* April 2005.
>
> *Excel spreadsheet of Federal CMS codes for Durable Medical Equipment and O&P by state, provided by Bryce Docherty, Docherty Group, February 22, 2006.*

Personal Communication, Rick Chavez, President COPA, February 22, 2006

> *Background letter from the California Orthotics and Prosthetics Association, California Orthotics and Prosthetics Association, February 22, 2006.*

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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 CHBRP's 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 CHBRP's authorizing legislation, UC contracts with a certified actuary, Milliman, to assist in assessing the financial impact of each benefit mandate bill. Milliman also helped with the initial development of CHBRP's 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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The California Health Benefits Review Program is administered by the Division of Health Affairs at the University of California, Office of the President, under Wyatt R. Hume, DDS, PhD, Acting Provost and Senior Vice President for Academic Affairs.

*Professor Laugesen recused herself from participation or review of this analysis.