

## Coverage of Prosthetic Devices

As presented, SB 98 (2008), the Prosthetic Parity Act, would revise the requirements that a health insurer, a nonprofit health service plan, or an HMO (further referred to as “carriers”) would need to meet in providing coverage for prosthetic devices and orthopedic braces. The proposed changes are as follows:

- Section 15–820, Insurance Article, Annotated Code of Maryland, would be revised to mandate nonprofit health service plans that provide hospital benefits to provide benefits for orthopedic braces only. (Currently, Section 15–820 mandates nonprofit health service plans to provide benefits for both prosthetic devices and orthopedic braces).
- Section 15–843, Insurance Article, Annotated Code of Maryland, would be added as a new mandate. This would require carriers to provide the following:
  - For prosthetic devices, coverage and payment at least equal to that provided under federal laws and regulations for the aged and disabled
  - Coverage for the prosthetic device determined to be the most appropriate model that adequately meets the insured’s medical needs
  - Coverage for repair or replacement of a prosthetic device because of a change in the insured’s physical condition.

While SB 98 does address benefits for orthopedic braces, the mandated benefit that needs to be offered by nonprofit health service plans is not changing. This report will focus on the impact of mandating prosthetic devices by carriers.

Following is a discussion of the medical, social, and financial impacts of this proposal.

### ***Medical Impact***

In this section, we address questions regarding the medical impact of requiring coverage and payment at least equal to Medicare’s for prosthetic devices.

- **Does the medical community recognize prosthetic devices as being effective in treating patients?**
- **Are prosthetic devices generally recognized by the medical community, as demonstrated by a scientific and peer review of literature?**
- **Are prosthetic devices available and utilized by treating physicians?**

Amputation of a limb can be caused by congenital limb deficiency, vascular disease, cancer, or trauma. The ability to return to normal activities (or, in the case of individuals with congenital physical disabilities, the ability to learn normal activities) is critical to maximizing the physical and psychological functioning of this population. Properly fitted

prosthetic devices facilitate this development by enabling individuals to continue to exercise, perform the activities of daily life that most of us take for granted, return to work, and contribute to society.<sup>1</sup>

According to the Amputee Coalition of America, the prevalence rate for individuals with one or more missing limbs was roughly 2.8 per 1,000 for the non-elderly population.<sup>2</sup> Maryland’s non-elderly population in 2007 was roughly 5 million people. Assuming a prevalence rate of 2.8 per 1,000, there are roughly 14,000 non-elderly people living with limb loss in Maryland. The location of the amputation varies significantly among the causes listed below.

	<u><b>Lower-Limb Amputation</b></u>	<u><b>Upper-Limb Amputation</b></u>
Congenital-Related Incidences	41.5%	58.5%
Dysvascular-Related Amputations	97.0%	3.0%
Cancer-Related Amputations	76.1%	23.9%
Trauma-Related Amputations	31.4%	68.6%

From 1988 to 1996, on average, 82% of amputations were caused by vascular disease.<sup>3</sup>

It is extremely important for individuals with lower extremity (LE) amputations to exercise. Studies have shown that non-vascular LE amputees have higher rates of cardiovascular disease, hypertension and adult-onset diabetes when compared to the non-disabled population.<sup>4</sup> Ken Pitetti, PhD, a professor at Wichita State University, says that it is important for an LE amputee to have a comfortable prosthetic limb (or limbs) suited for exercise. Having prosthetics that fit should reduce medical costs for the treatment of cardiovascular disease, hypertension, and adult-onset diabetes for LE amputees.

It has been shown that 70% to 90% of amputees return to work sometime after their injury, and that those who have access to prosthetic devices show a reduction in secondary conditions caused by their disability.<sup>5</sup> In the report, “Analysis of Assembly Bill 2012 – Amended: Orthotic and Prosthetic Devices,” the California Health Benefits Review Program (CHBRP) states: “Conventional prosthetic devices have been

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<sup>1</sup> Bender, Karen, et al., “Review and Evaluation of LD 125: An Act to Promote Fairness and Opportunity for Working Amputees.” Maine Bureau of Insurance, 2003.  
<http://www.maine.gov/pfr/legislative/documents/ld125final.pdf>

<sup>2</sup> Amputee Coalition of America, Frequently Asked Questions, 1996 statistic (the most recent available)  
[http://www.amputee-coalition.org/nllic\\_faqs.html](http://www.amputee-coalition.org/nllic_faqs.html)

<sup>3</sup> Dillingham, Timothy R., MD, et al., “Limb Amputation and Limb Deficiency: Epidemiology and Recent Trends in the United States.” *Southern Medical Journal* 95 (2002): 875-83.  
[http://www.amputee-coalition.org/fact\\_sheets/amp\\_stats\\_cause.html](http://www.amputee-coalition.org/fact_sheets/amp_stats_cause.html)

<sup>4</sup> Pitetti, Ken, PhD, Professor, College of Health Professions, Wichita State University. “Epidemiology and Pathophysiology of Amputation.”  
[http://www.ncpad.org/disability/fact\\_sheet.php?sheet=58&view=all](http://www.ncpad.org/disability/fact_sheet.php?sheet=58&view=all)

<sup>5</sup> Cost Savings Analysis of the Prosthetic Parity Bill from Five States, Division of Health Care Finance and Policy, Commonwealth of Massachusetts, “Review and Evaluation of Proposed Legislation to Mandate Coverage for Certain Prosthetic Devices: H. 837. April 2005.

established as the standard of care for improving physical and psychological functioning of persons with amputations and congenital limb deformities.”

## Medicare Standards

Medicare is the largest financial resource for prosthetic care.<sup>6</sup> Coverage is provided under Medicare’s durable medical equipment, prosthetics and orthotics (DMEPOS) benefit. To qualify for any type of DMEPOS, an individual’s equipment must be necessary and reasonable to treat an illness or injury, or to improve the function of a malformed body member. In addition, to be covered under the Medicare Part B program, the equipment must be rented or purchased by a beneficiary for home use. A physician’s prescription is required for all DMEPOS and, for prosthetics, a physician must complete a Certificate of Medical Necessity.

Accessories for prosthetics are also covered when these appliances aid in or are essential to the effective use of the artificial limb.

Congress passed a provision, Section 427 of BIPA (Section 1834 (h)(1)(F) of the Social Security Act), stating that no payment shall be made for prosthetics or certain custom fabricated orthotics unless such items are furnished by a “qualified practitioner.” The provision defines a “qualified practitioner” as “a qualified physical therapist or qualified occupational therapist,” an ABC-certified orthotist/prosthetist, or a BOC-certified orthotist/prosthetist. The Centers for Medicare and Medicaid Services (CMS) is developing a rule that will further define which items will be covered under this provision and what the terms “qualified physical therapist” and “qualified occupational therapist” mean.<sup>7</sup>

Medicare has established Level II modifiers, or “K-Modifiers,” that classify the patient’s rehabilitation potential as determined by the prosthetist and ordering physician. Criteria considered for assessing the functional level include the patient’s history, current condition (including the status of the residual limb and the nature of other medical problems), and desire to ambulate. Classification levels are<sup>8</sup>.

- K0 (Level 0) – Does not have the ability or potential to ambulate or transfer safely with or without assistance, and a prosthesis does not enhance the quality of life or mobility.
- K1 (Level 1) – Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence – typical of the limited and unlimited household walker.

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<sup>6</sup> Amputee Coalition of America. Fact Sheet: “Financial Assistance for Prosthetic Services, Durable Medical Equipment and Other Assistive Devices.” Revised 2008.  
[http://www.amputee-coalition.org/fact\\_sheets/assist\\_orgs.html](http://www.amputee-coalition.org/fact_sheets/assist_orgs.html).

<sup>7</sup> American Physical Therapy Association, “FAQs Regarding Billing for DME, Orthotics, and Prosthetics.”  
<http://www.apta.org/AM/Template.cfm?Section=Home&CONTENTID=30021&TEMPLATE=/CM/ContentDisplay.cfm>

<sup>8</sup> See note 6 above.

- K2 (Level 2) – Has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces – typical of the limited community walker.
- K3 (Level 3) – Has the ability or potential for walking with variable cadence – typical of the community walker who is able to traverse most environmental barriers and may have vocational, therapeutic or exercise activity that demands prosthetic use beyond simple walking.
- K4 (Level 4) – Has the ability or potential for prosthetic use that exceeds basic walking skills, exhibiting high impact, stress or energy levels – typical of the prosthetic demands of the child, active adult, or athlete.

The following list is provided on the Amputee Coalition of America’s website:

The following determination of coverage for selected prostheses and components with respect to potential functional levels represents the usual case. Exceptions are considered in individual cases if additional documentation is included that justifies the medical necessity. Prostheses are denied as not medically necessary if the patient's potential functional level is "0."<sup>9</sup>

Feet:

- Basic lower-extremity prostheses include a solid-ankle cushion-heel (SACH) foot.
- External keel, SACH foot or single-axis ankle/foot are covered for patients with a functional Level 1 or above.
- Flexible keel foot and multiaxial ankle/foot candidates are expected to demonstrate a functional Level 2 or greater functional needs.
- Flex-foot system, energy-storing foot, multiaxial ankle/foot, dynamic response, or flex-walk system or equal are covered for patients with a functional Level 3 or above.

Knees:

- Basic lower-extremity prostheses include a single-axis, constant friction knee.
- Fluid and pneumatic knees are covered for patients with a functional Level 3 or above.
- Other knee systems are covered for patients with a functional Level 1 or above.

Ankles:

- Axial rotation units are covered for patients with a functional Level 2 or above.

The following are general policies regarding coverage of prosthetic sockets:

- Test (diagnostic) sockets for “immediate prostheses” are not medically necessary.
- No more than two test sockets for an individual prosthesis are medically necessary without additional documentation.
- No more than two of the same socket inserts are allowed per individual prosthesis at the same time.
- Socket replacements are considered medically necessary if there is adequate documentation of functional or physiological need. The Durable Medical Equipment Regional Carrier (DMERC) recognizes that there are situations where the explanation includes but is not

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<sup>9</sup> See note 6 above.

limited to changes in the residual limb, functional need changes, or irreparable damage or wear/tear due to excessive patient weight or prosthetic demands of very active amputees.

## **Non-Medicare Standards**

The focus of prosthetic devices is to restore function in the area of limb loss. Technology advancements in prosthetics are geared toward improving mobility and functional capability. Major advancements – to name a few – include microprocessors, lithium-polymer battery technology, improved silicone suction suspension, and body-powered designs.<sup>10</sup>

Few studies concerning the relative effectiveness of prosthetic technologies have rigorous research designs. Most studies compare outcomes for the same group of subjects using conventional prosthetic devices and technologically advanced studies. This scarcity of rigorous analysis with large randomized controlled trials may be due to the small number of individuals who have lost a limb.

Many amputees – especially those losing upper limbs – have very high expectations for what a prosthesis can accomplish. These expectations may be reinforced by movies and TV shows (such as “The Six Million Dollar Man” and “The Bionic Woman.”). While technology is improving, it may not be able to match all pre-amputation physical abilities and functionality. The rehabilitation team should encourage patients to become informed regarding the different prosthetic options and research, and should also encourage them to have realistic expectations.<sup>11</sup>

That said, there is also a tremendous opportunity to assist upper-limb amputees, especially if the process begins early (after the patient is fully healed from the surgery) and the patient undergoes consistent occupational therapy. This enables clinicians to better help the patient choose the best prosthetic for his or her lifestyle. It also reduces patient frustration (as problems are identified quickly), and encourages an amputee to regain some level of “normalcy” as quickly as possible.

Patients fitted within 30 days of the date of amputation return to work earlier and reported less pain from their amputation.<sup>12</sup> In their 2006 article, Chris Lake and Robert Dodson quoted a study by S. Fletchall, evaluating “the value of specialized rehabilitation of trauma and amputation” and found similar trends, indicating an approximate 96% success rate for patients who were seen immediately after their trauma versus a 56% success rate for those who were delayed from starting a specialized rehabilitation program. Additionally, 84% of those patients seen immediately by a specialized rehabilitation group remained in contact with their prosthetist/therapist, as compared with

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<sup>10</sup> O&P Digital Technologies website, [http://www.oandp.com/edge/issues/articles/2003-01\\_01.asp](http://www.oandp.com/edge/issues/articles/2003-01_01.asp)

<sup>11</sup> Lake, C., Dodson, R. “Progressive Upper Limb Prosthetics.” *Physical Medicine and Rehabilitation Clinics of North America*. 2006. [http://www.armdynamics.com/PMR\\_Clinics\\_NA\\_Feb06.pdf](http://www.armdynamics.com/PMR_Clinics_NA_Feb06.pdf)

<sup>12</sup> O&P Digital Technologies website.

[http://www.oandp.com/edge/issues/articles/2003-01\\_01.asp](http://www.oandp.com/edge/issues/articles/2003-01_01.asp)

only 41% of those patients who were delayed from starting a specialized rehabilitation program.

There are five major categories of upper-limb prostheses: cosmetic, body-powered, battery-powered, hybrid, and microprocessor-controlled. Each of these devices has pros and cons. Cosmetic devices are the lightest-weight and require minimal harnessing to wear. However, cosmetic devices are the least functioning and may have a large price tag if custom made. Body-powered prostheses are moderately priced, lightweight, and durable, and have high sensory feedback. They also require the most harnessing and need the most body movement to operate. Battery-powered prostheses require the least amount of body movement to operate and provide more functional capabilities than body-powered devices; however, battery-powered devices are also the heaviest and the most expensive. They require the most maintenance, and users must undergo extended training to operate them. Hybrid prosthetics use a combination of body power and battery power, and as a result share the pros and cons of each type of prosthetic.<sup>13</sup> Microprocessor-controlled prosthetic devices are still evolving and are much more common with lower-limb prosthetics. The technologically advanced device automatically adjusts the movement of the wrist and/or elbow joint based on data it collects.<sup>14</sup>

A long-term study conducted by R.C. Crandall and W. Tomhave compared below-elbow pediatric amputees from the Shriners Hospital for Children/Twin Cities regarding the use of a variety of prosthetic options. All the patients were considered “consistent” prosthetic users by the clinic team. The average follow-up was 14 years, with some children being followed through to adulthood. The patients were sent questionnaires, and the authors conducted patient and chart reviews. Final analysis indicated that 15 patients (44%) selected a simple cosmetic “passive hand” as their prosthesis of choice. In long-term follow-up, 14 patients (41%) continued as multiple users. Fourteen patients (41%) selected the conventional prosthesis using a voluntary closing terminal device as the prosthesis of choice. Only five patients (15%) selected the myoelectric device as their primary prosthesis. The authors conclude that successful unilateral pediatric amputees may choose multiple prostheses on the basis of function and that, frequently, the most functional prosthesis selected in the long-term is the simplest in design. The authors believe strongly that unilateral pediatric amputees should be offered a variety of prosthetic options to help with normal activities of daily living.<sup>15</sup>

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<sup>13</sup> E Medicine website.

<http://www.emedicine.com/pmr/topic174.htm#ref1>

<sup>14</sup> California Health Benefits Review Program (CHBRP), “Analysis of Assembly Bill 2012 - Amended: Orthotic and Prosthetic Devices” (June 15, 2006). California Health Benefits Review Program. CHBRP Report to California Legislature. Paper 30.

<http://repositories.cdlib.org/chbrp/crcl/30>

<sup>15</sup> Crandall, R.C. and Tomhave, W. “Pediatric Unilateral Below-Elbow Amputees: Retrospective Analysis of 34 Patients Given Multiple Prosthetic Options.” *Journal of Pediatric Orthopedics*. 2002; 22(3): 380-383. abstract can be found at:

<http://www.ncbi.nlm.nih.gov/pubmed/11961460>

Lower-limb amputations are more common than upper-limb amputations. This is largely due to dysvascular amputations associated with diabetes. There are two types of lower-limb prosthesis: below-knee (transtibular) and above-knee (transradial) prosthesis. As expected, transradial amputations require more complex prostheses in order to restore function in the amputated leg. Currently, over 100 prosthetic knee designs are available.<sup>16</sup> Each prosthetic knee can be categorized as either mechanical, hydraulic, pneumatic, or microprocessor.

“Microprocessor-controlled prosthetic knees may provide increased safety, stability, and function: for example, sensors are designed to recognize a stumble and stiffen the knee, thus avoiding a fall.”<sup>17</sup> Another example of a microprocessor-controlled prosthetic is the bionic foot. The bionic foot ranges in cost from \$15,000 to \$20,000 and has the following abilities:<sup>18</sup>

- “Senses an incline or decline and adjusts angle of foot to handle the slope with minimum effort.”
- “Senses when it’s in mid-stride and lifts the toe slightly to avoid setting down at a toe-stubbing angle. Scuffing the toe is a leading cause of falls by amputees.”
- Senses when the individual is sitting down or wants to stand up.
- Can be programmed to work with different footwear, from sneakers to two-inch heels.
- Expected to lead to decreased pain and immobility.

In March 2000, the Veterans Administration (VA) issued a short report on computerized lower-limb prosthesis. In that report, the VA combined research results from three sources:

- Peer-reviewed medical literature
- Findings from an assessment of a similar prosthesis conducted in the UK
- Selected information provided by the manufacturer of the microprocessor-controlled lower-limb prosthesis (the C-LEG®), which was new to the US at the time.

The VA found that studies published at that time enrolled “highly selected samples of amputees” who did not have additional medical problems, whose amputations were a result of trauma or congenital defects, and who were fit and active. These are characteristics of amputees who have been shown to be independently predictive of successful rehabilitation or return to normal living following amputation and may skew the results.

Given that qualifier, the VA found that:

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<sup>16</sup> Virginia General Assembly, Joint Legislative Audit and Review Commission.  
<http://jlarc.state.va.us/Reports/Rpt358.pdf>

<sup>17</sup> Ibid.

<sup>18</sup> America’s Health Insurance Plans website.  
[http://www.ahiphewire.org/News/Default.aspx?doc\\_id=186144](http://www.ahiphewire.org/News/Default.aspx?doc_id=186144)

- Compared to requirements with conventional prostheses, energy requirements of ambulation are decreased at walking speeds slower or faster than the amputee's customary speed, but do not differ significantly at customary speeds.
- Results on the potentially improved ability to negotiate uneven terrain, stairs, or inclines are mixed. Such benefits, however, could be particularly important to meeting existing deficits in the reintegration of amputees to normal living – particularly those related to decreased recreation options.
- Users' perceptions of the microprocessor-controlled prosthesis are favorable. Where such decisions are recorded or reported, the vast majority of study participants choose not to return to their conventional prostheses or keep these only as back-ups to acute problems with the computerized prosthesis.
- Users' perceptions may be particularly important for evaluating a lower-limb prosthesis, given the magnitude of the loss involved, along with the associated difficulty of designing and collecting objective measures of recovery or rehabilitation. However resilient the human organism or psyche, loss of a limb is unlikely to be fully compensated. An amputee's positive perception of certain prosthesis may make the difference between coping and achieving a functional level that more closely resembles the pre-amputation level.
- Mechanical failure is recorded in some of the studies, but seems to be rare. The manufacturer indicates that some C-LEGS® have been used for extended periods (up to 5 years) without mechanical or electrical problems.
- The UK Medical Devices Agency has evaluated the Endolite® Intelligent Prosthesis, with generally favorable results. Recognizing constraints related to the substantial cost of the prosthesis, the UK National Health Service (NHS) makes it available to a wide range of patients, and has arranged with the manufacturer for a program to lend critical components, should these components of the prosthesis require factory repair.<sup>19</sup>

In October 2007, the VA released a statement that the Center for Restorative and Regenerative Medicine at the VA medical center and Brown University in Providence, R.I., are at the leading edge of a movement to create artificial limbs that function almost like natural ones. The VA is approving C-LEG and other similar types of prosthetics when medically warranted.<sup>20</sup>

A comprehensive review of literature completed by the University of California, San Francisco and prepared for the California Health Benefits Review Program in 2006 found there was “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

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<sup>19</sup> Veterans Administration, VA Technology Assessment Program, Short Report Computerized Lower Limb Prostheses, March 2000.

[www.va.gov/vatap/pubs/ta\\_short\\_3\\_00.pdf](http://www.va.gov/vatap/pubs/ta_short_3_00.pdf).

<sup>20</sup> Department of Veteran's Affairs. Fact Sheet. “VA's Prosthetics and Sensory Aids.” October 2007. <http://www.va.gov/OPA/fact/docs/pros-sensory.doc>



sedentary lifestyle and/or major co-morbidities.” There was also “insufficient evidence regarding the effects of new technologies used in upper limb prostheses.”<sup>21</sup>

The same report indicated that eight studies comparing microprocessor-controlled versus conventional prostheses for lower-limb amputees showed “a pattern toward favorable effects of the microprocessor-controlled prosthesis on patient satisfaction, walking speed, amount of oxygen consumed and step length,” and no difference between the two in step time, daily activity level, duration of activity, and cognitive effort to walk, and mixed results for impact on gait and level of muscular activity. While microprocessor-controlled prostheses improve certain aspects of an amputee’s experience with prostheses, the improvement did occur in all of the dimensions measured in these studies.

Three studies comparing energy-storing prosthetic feet to solid-ankle, cushion-heel prosthetic feet found a “statistically significant association between energy-restoring feet and lower heart rate, less exertion, longer stride length, greater stability, momentum and speed;” a pattern toward favorable results with regard to steps walked per day and stability on unstable surfaces, and mixed results on consumption of oxygen, gait efficiency, and consumer satisfaction.

A prosthetic device’s appropriateness and medical necessity are determined by a physician’s assessment of an individual’s potential for rehabilitation or achievement of a functional level. Therefore, carriers consider appropriateness and medical necessity when determining access to prosthetic devices. For example, if a prosthetic device does not enhance an individual’s quality of life or mobility, the device would not be considered medically necessary and would not be covered.

## **SB 98 Standards**

The way SB 98 is currently written, carriers will be required to cover (as determined by the health care provider) the most appropriate prosthetic device that adequately meets the medical needs of the insured. The carrier may require prior authorization for coverage just as it requires prior authorization for any other covered benefit.

However, SB 98 does not thoroughly explain the phrase “adequately meets the medical needs of the insured.” Is it adequate that the prosthetic will restore enough functional capability to go back to work, or will an insured be able to petition to receive the most technologically advanced prosthetic to gain marginal capabilities? Is a body-powered upper-limb prosthetic more or less adequate than a battery-powered one? The subjectivity of the language in the bill may require carriers to cover extremely expensive prostheses (currently up to \$100,000)<sup>22</sup> which, according to carriers surveyed, would not be considered “medically necessary” under current standards.

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<sup>21</sup> California Health Benefits Review Program, A Report to the 2005-2006 California State Legislature, “Analysis of Assembly Bill 2012 – Amended: Orthotic and Prosthetic Devices.”

<sup>22</sup> Garibaldi, Matthew. Orthopaedic Surgery News, Myoelectric Prostheses Offer Advantage, Winter 2006. <http://www.ucsfhealth.org/common/pubs/ortho/winter2006/myoelectric/index.html>

While Mercer does not anticipate that the incidence of amputations will increase as a result of SB 98, the proposed mandate could increase the demand for more sophisticated devices by allowing the affected populations access to the newest technology, even if it is beyond what is required to restore enough functional capability to return to work, or perform the basic activities of daily living (ADL).

While not every city in Maryland will have a physician specializing in prosthetic devices, we find that care is widely available. We were able to locate over 100 prosthetic device suppliers within 100 miles of Baltimore, and over 30 suppliers in Baltimore.<sup>23</sup>

## ***Social Impact***

In this section, we address the following:

- **To what extent are prosthetic devices generally utilized by a significant portion of the population?**
- **To what extent is insurance coverage already generally available for prosthetic devices?**
- **To what extent does lack of coverage result in individuals' avoiding necessary coverage?**
- **To what extent does lack of coverage for prosthetic devices result in unreasonable financial hardship?**
- **What is the level of public demand for prosthetic devices?**
- **How interested are collective bargaining agents in negotiating privately for including this coverage in group contracts?**
- **To what extent is the service covered by self-funded employers in Maryland with at least 500 employees?**

As indicated previously, we estimate that the number of non-elderly individuals in Maryland living with the loss of a limb to be about 14,000. Therefore, SB 98 would only affect a limited portion of the population.

SB 98 requires that carriers provide prosthetics coverage that is “at least equivalent to the coverage and payment provided under federal laws and regulations for the aged and disabled.” Medicare is the federal program that provides health benefits for the aged and

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<sup>23</sup> California Health Benefits Review Program, A Report to the 2005-2006 California State Legislature, “Analysis of Assembly Bill 2012 – Amended: Orthotic and Prosthetic Devices.”  
<http://www.medicare.gov/Supplier/Include/DataSection/Questions/Results.asp>

disabled. Currently, the federal government provides coverage for prosthetics when medically necessary for those individuals enrolled in Medicare Part B . Benefits are payable at a rate of 80% of the Medicare allowable fees after satisfaction of an aggregate annual deductible that is applicable to all Medicare Part B services. The majority of Medicare Part B benefits are for physician-related services. The Part B deductible for 2009 is \$135. This deductible is subject to change every year. There are no annual maximum benefits for Medicare Part B, and no out-of-pocket limits.

It is unclear whether SB 98 intends for prosthetics to be provided at the Medicare coinsurance level, or through a combination of the Medicare-allowable fee schedule and coinsurance, or according to the rules for other medical benefits (which was the ultimate interpretation of similar legislation in New Jersey.)<sup>24</sup> It appears that the legislation leans toward the use of the well defined Medicare guidelines.

According to a recent bulletin published by the Indiana Department of Insurance,<sup>25</sup> Indiana recently enacted coverage for prosthetic and orthotic devices (for arms and legs only) whereby carriers must provide the same dollar amount coverage provided for the same device, repair, or placement under the federal Medicare program. Such coverage, subject to utilization review, must be provided when the physician determines that a prosthetic and/or orthotic device is necessary to maintain or restore the ability to perform activities of daily living or essential job related activities, rather than solely for the comfort and convenience of the individual. Moreover, carriers must follow the federal Medicare reimbursement schedule unless a different reimbursement rate is negotiated. Coverage may not be subject to a cost-sharing provision that is less favorable than that which applies generally to other items and services. Prosthetics are considered durable medical equipment and therefore are subject to separate DME cost sharing provisions and limits. Finally, any lifetime maximum coverage limitation that applies to these devices must be equal to and separate from the lifetime maximum coverage limitation that applies to all other items and services. It would seem more appropriate in Maryland to mandate that inside limits on prosthetics be prohibited, rather than impose a lifetime maximum coverage limitation.

In the following table, we show the mandates in place in other states.<sup>26</sup>

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<sup>24</sup> Bulletin 8-10, P. L. 2007c-345. "Health Benefits Coverage for Orthotic and Prosthetic Appliances, May 29, 2008. [http://www.state.nj.us/dobi/bulletins/blt08\\_10.pdf](http://www.state.nj.us/dobi/bulletins/blt08_10.pdf)

<sup>25</sup> Bulletin 167, "Coverage for Prosthetic and Orthotic Devices," Indiana Department of Insurance, October 28, 2008.

<sup>26</sup> Novak, Donna. "Review and Evaluation of Required Coverage for Prosthetics" NovaRest Consulting. 2008

<b>State Mandates in Other States</b>				
<b>State</b>	<b>Allowable deductibles and coinsurance</b>	<b>Reimbursement limits</b>	<b>Definition of Prosthetic</b>	<b>Coverage of Repair or Replacement</b>
New Jersey	Medicare (\$100, 20%)	Medicare	Limbs, hands, fingers, feet, and toes	Not explicitly
Massachusetts	Medicare (\$100, 20%)	Medicare	Whole or part of an arm or leg	Yes
California	No more than the most common amounts applied to the basic health care services.			Yes
Colorado	Medicare (\$100, 20%)	Medicare	Whole or part of an arm or leg	Unless required due to misuse or loss
New Hampshire	Medicare (\$100, 20%)	Medicare	Whole or part of an arm or leg	Not explicitly
Maine	Medicare (\$100, 20%)	Medicare	Whole or part of an arm or leg	Not explicitly
Rhode Island	Medicare (\$100, 20%)	Medicare	Limb, appendage, or external body part including hand or foot	Yes, unless required due to misuse or loss
Louisiana	Shall not be greater than the co-payments that apply to their benefits under the plan.		An artificial medical device that is not surgically implanted and that is used to replace a missing limb	Yes
Vermont	May not be subject to provisions that are more restrictive than those that apply generally to other non-primary care items and service under the health plan.	Medicare	Means an artificial limb device to replace, in whole or in part, an arm or a leg	Yes
Indiana	Must be comparable to other coverage generally under the state employee health benefit plan.	Medicare	leg or arm	Yes
Oregon			An artificial limb device or appliance designed to replace in whole or in part an arm or a leg	If medically necessary to restore or maintain the ability to complete activities of daily living or essential job-related activities

Mercer surveyed six carriers representing the vast majority of insured medical lives in Maryland regarding their current coverage provisions for prosthetics. All six carriers indicated that coverage was available for prosthetics, although most offered groups the option of purchasing policies that had internal annual limits. Aetna was the only company

that indicated it was “not aware of any insured plans that limit coverage.” The majority of the carriers indicated that they believed they were already providing benefits consistent with Medicare levels, with the exception that there are annual limitations for these types of services – some as low as \$2,500 or \$5,000 for all types of durable medical equipment (DME).

All six carriers indicated that benefits would be provided only if they were “medically necessary.” Some also required that benefits be limited to the least expensive medically necessary device that is adequate to meet the patient’s medical need. In addition, many carriers limited the number of pieces of equipment or devices for the same body part, or the frequency of replacements to assure that such devices and equipment are being used responsibly, and to limit abuse.

In conferring with the medical directors of some of the major health plans in Maryland, concern was expressed regarding how the mandate would define the level of function that should be restored by the prosthesis. It was expressed that, while activities of daily living (ADLs) should certainly be part of the evaluation, the functional level to be attained should also vary based on physical or cognitive limitations, and perhaps age. Concern was also voiced regarding how employment-related needs will be measured, and how continued employability and change of employment will be defined and addressed.

The carriers suggested that MHCC and/or the Legislature consider allowing coverage for prosthetics to be tiered – similarly to tiered copays for prescription drugs. Medicare has a tier for intra-ocular implants and for movable implants. The patient pays the difference for a device that exceeds medical necessity.

The carriers also thought that the legislation and/or regulations need to address criteria for replacement of the devices – for what reasons and how often. They suggested that coverage should exclude replacement of abused devices.

Some of the carriers are concerned that a benefit with no annual maximum for a technology that continues to change and become more expensive to maintain will increase the costs for employers and individuals who are subject to state mandates.

A survey of carriers acting as third-party administrators (TPAs) for self-funded groups – as well as a survey of large self-funded plans in Maryland – yield results similar to those for the fully insured plans. Prosthetic benefits are almost universally included, but many have inside annual dollar limitations. All plans require that the prosthetic be medically necessary.

Collective bargaining units, operating self-insured health plans, indicated that they cover prosthetics. The units with internal limitations indicated a “low” interest in incorporating this benefit into their plan. We attribute this lack of interest more to major issues facing collective bargaining units in general.

Lack of coverage can mean one of two things: the individual has no coverage (which does not appear to be the case in Maryland) or coverage is limited to the point of financial strain. Some employer groups are choosing policies that limit the annual benefit for prosthetics; annual limits between \$2,500 and \$5,000 are not uncommon. The cost of prosthetic devices generally ranges from \$2,000 to \$40,000. Clearly the low limits that some employers are choosing mean that some covered members are facing large out-of-pocket costs to obtain certain prosthetic devices. Below are cost estimates by type of prostheses.

### **Device Cost Estimates<sup>27</sup>**

Ocular Prostheses	\$2,000 - \$3,000
Below-Knee Prostheses	\$5,000 - \$7,000
Above-Knee Prostheses	\$10,000 - \$30,000
Below-Elbow Prostheses	\$3,000 - \$10,000
Above-Elbow Prostheses	\$10,000 - \$30,000

We note that some of the more advanced prostheses can cost as much as \$100,000.<sup>28</sup>

Under current product offerings, people requiring prostheses to return to an independent and functional state may have to cover significant out of pocket costs, and in some cases may forgo treatment.

There are payment sources other than health plans that may be available to people who need help paying for prosthetic devices. This would include Medicare, the Federal program providing benefits to the aged and certain disabled individuals, the Veterans Administration covering veterans who meet certain additional criteria, TRICARE, the program for active and certain retired military personnel, the Maryland Department of Rehabilitative Services providing benefits for prosthetics for individuals who are eligible, typically individuals with low incomes or severe disabilities, and finally, non-profit organizations such as the Barr Foundation, the Bowman Sicilian Limb Bank Foundation, the Life without Limbation Foundation, Limbs for Life Foundation, Limbs of Hope Foundation, Limbs of Love, and the National Amputation Foundation.

In spite of these additional payment sources, amputees and others do have significant difficulties paying for prosthetics. A proponent of the SB 98 and the Federal Prosthetics Parity Act of 2008, referenced below, the Amputee Coalition of America, cites numerous examples of people with amputations who need to take out a loan from retirement savings, college savings, or a bank in order to cover the cost of a prosthetic device.<sup>29</sup>

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<sup>27</sup> Virginia General Assembly, Joint Legislative Audit and Review Commission.  
<http://jlarc.state.va.us/Meetings/Other/prosthet.pdf>

<sup>28</sup> Long, Frank. "Work with What You've Got." Rehab Management –December 2007.  
[http://www.rehabpub.com/issues/articles/2007-12\\_02.asp](http://www.rehabpub.com/issues/articles/2007-12_02.asp)

<sup>29</sup> <https://www.amputee-coalition.org/advocacy/stories.html>

On September 19, 2008, the Prosthetics Parity Act of 2008 was introduced in the US Senate. This bill would require health plans to treat coverage of prosthetic devices on par with other essential medical care covered by health insurance. Given the existing verbiage in SB 98, passage of this bill at the federal level would necessitate parity of prosthetic devices in Maryland as well.

## ***Financial Impact***

In this section, we estimate the cost of enacting the mandated benefit and compare the results of our analysis with those of other publicly available sources.

Mercer surveyed six major carriers in Maryland to obtain information on current practices regarding prosthetic devices. Mercer also asked these carriers to provide financial estimates as to how rates would be affected if coverage were mandated for prosthetic devices at levels equivalent to Medicare.

All six carriers provide coverage for prosthetic devices, with three carriers reporting that the majority of their plans cover prosthetic devices at least equivalent to Medicare. The remaining three carriers stated that they provide coverage that is subject to copayments, coinsurance, deductibles, and annual benefit maximums.

The following table summarizes the financial impact estimates provided by the carriers.

<b>Number of Carriers</b>	<b>Financial Impact</b>
1	no estimate provided
3	zero
1	\$0.17 PMPM
1	0.5% of premium

The carrier that did not provide a financial impact estimate submitted the following comments:

“Our Prosthetic benefit rider is similar to the Medicare benefit in terms of types of devices covered. However, employers are provided coverage options (annual maximums) when purchasing the prosthetic rider. As we understand the Medicare benefit, an annual ‘cap’ is not available. If mandated to purchase a prosthetic benefit equal to the existing Medicare benefit, employers’ costs will increase to the extent they currently provide no benefit or a benefit with an annual maximum. A benefit with no annual maximum for a technology that continues to change and becomes more expensive to purchase and maintain undoubtedly will increase costs for employers and employees subject to a state mandate.”

As indicated previously, there is a very broad range for the cost and repair of prosthetic devices. Thus, the actual cost for any single health plan may vary significantly from the

average, depending on the concentration of high-cost/low-cost devices provided/maintained in any one year.

As examples, the CHBRP reported that the average cost for a prosthetic device in 2006 was \$965.40.<sup>30</sup> The Division of Health Care Finance and Policy in Massachusetts has estimated the per-patient cost of a prosthesis to be \$1,669 in 2010.<sup>31</sup> Assuming that 2.8 per 1,000 people in Maryland are living with limb loss and all amputees use prosthetic devices, the expected allowed PMPM cost would be between \$0.23 and \$0.39. The plan liability PMPM, or full cost of the mandate, would be roughly 80% of the allowed PMPM, or between \$0.18 and \$0.31. We define the marginal cost of implementing the mandated benefit as the additional cost the carriers will incur if required to provide the service (or device, in this case) at a minimal level.

The six Maryland carriers surveyed did not provide Mercer with sufficient information as to the level at which prosthetic devices are currently covered. Three of the carriers responded that coverage is currently provided at Medicare levels. The other three carriers reported that prosthetic devices are subject to copayments, coinsurance, deductibles, and possibly an annual maximum. In the case that coverage is already at Medicare levels, the marginal cost would be \$0.00. The marginal cost for plans subject to deductibles and copayments/coinsurance will vary. To provide a conservative estimate, Mercer has assumed the marginal cost will be the same as the full cost for these carriers. We estimate the marginal cost to be roughly 50% of the full cost, or \$0.09 and \$0.16.

In the table below, we summarize the potential cost of SB 98.

	Full Cost	Marginal Cost
Estimated cost as a percentage of average cost per group policy	0.08%	0.04%
Estimated cost as a percentage of average wage	0.00%	0.00%
Estimated annual per member cost	\$0.25	\$0.13

Several other states have completed analysis for similar benefits.

State	Range
Massachusetts (2007)	\$0.27 PMPM to \$0.48 PMPM
California (2005)	\$0.10 PMPM to \$0.26 PMPM
New Jersey (2006)	0.08% of premium
Virginia ( <i>mandated, not an optional benefit</i> )	\$0.11 PMPM to \$1.73

<sup>30</sup> California Health Benefits Review Program (CHBRP), “Analysis of Assembly Bill 2012 - Amended: Orthotic and Prosthetic Devices” (June 15, 2006). California Health Benefits Review Program. CHBRP Report to California Legislature. Paper 30.  
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<sup>31</sup> See note 5 above.



Virginia's median estimates for prosthetics coverage as a mandated benefit (rather than as an optional rider) varied between \$0.11 PMPM and \$0.24 PMPM. These estimates were provided by insurance companies operating in Virginia. Our independent estimate is within the range calculated by other states considering this type of mandate.

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