

REPORT OF THE  
SPECIAL ADVISORY COMMISSION ON MANDATED  
HEALTH INSURANCE BENEFITS

**MANDATED COVERAGE FOR PROSTHETIC  
DEVICES AND COMPONENTS**  
**Senate Bill 931**

TO THE GOVERNOR AND  
THE GENERAL ASSEMBLY OF VIRGINIA

COMMONWEALTH OF VIRGINIA  
RICHMOND  
2008

January 4, 2008

To: The Honorable Timothy M. Kaine  
Governor of Virginia  
and  
The General Assembly of Virginia

The report contained herein has been prepared pursuant to § 2.2-2504 and § 2.2-2505 of the Code of Virginia.

This report documents a study conducted by the Special Advisory Commission on Mandated Health Insurance Benefits to assess the social and financial impact and the medical efficacy of Senate Bill 931 regarding coverage for prosthetic devices and components.

Respectfully submitted,

R. Lee Ware  
Chairman  
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## **INTRODUCTION**

During the 2007 session of the General Assembly, the Senate Committee on Commerce and Labor referred Senate Bill 931 to the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission). Senate Bill 931 was introduced by Senator Patricia Ticer.

The Advisory Commission held a public hearing on September 20, 2007 in Richmond to receive public comment on Senate Bill 931. In addition to the patron, Senator Patricia Ticer, a representative of Virginia Prosthetics, Roanoke, Virginia and a national spokesperson from the Amputee Coalition of America (ACA) addressed the Advisory Commission. Thirty amputees and family members also commented on Senate Bill 931. Over one hundred concerned citizens attended the public hearing in support of Senate Bill 931. Written comments in support of the bill were received from three orthotic and prosthetic companies and from seventeen concerned citizens. More than 250 signatures was submitted in support of Senate Bill 931. Representatives from the Virginia Association of Health Plans (VAHP) and the Virginia Chamber of Commerce (VCC) spoke against Senate Bill 931. The VAHP submitted written comments in opposition to the bill.

The Joint Legislative Audit and Review Commission (JLARC) staff of the Virginia General Assembly prepared an "Evaluation of Senate Bill 931, Mandated Coverage of Prosthetic Devices" pursuant to §§ 2.2-2503 and 30-58.1 of the Code of Virginia. A copy of the evaluation is available on the JLARC website at <http://jlarc.state.va.us>.

## **SUMMARY OF PROPOSED LEGISLATION**

Senate Bill 931 adds § 38.2-3418.15 to the mandated benefits article and amends §38.2-4319 to make it applicable to HMOs.

The bill requires insurers to provide coverage for the cost of prosthetic devices and components, if the treating physician certifies that the medical necessity of the prosthetic device and component as a proposed course of treatment, at a minimum, equals the coverage provided under the federal Medicare program. The bill is applicable to insurers proposing to issue individual or group accident and sickness policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; corporations providing individual or group subscription contracts; and health maintenance organizations (HMOs) providing health care plans.

The bill defines "component" as the materials and equipment needed to ensure the comfort and functioning of a prosthetic device. "Limb" is defined as an arm, hand, leg, foot, or any portion of an arm, hand, leg, or foot. "Prosthetic device" is defined as an artificial device to replace a limb in whole or in part, or to replace an eye, if required because of a change in the patient's physical condition, as set forth in 42 U.S.C. §1395x(s)(9).

The insurer, corporation or HMO may require preauthorization to determine medical necessity and the eligibility of benefits for prosthetic devices and components, in the same manner that prior authorization is required for any other covered benefit. The insurer, corporation or HMO may require that prosthetic services be rendered by a provider who contracts with the carrier and that a prosthetic device or component be provided by a vendor designated by that insurer. The bill proposes coverage that would include the fitting, repair, or replacement of a prosthetic device or components, or both, if the fitting, repair, or replacement is determined to be medically necessary. A fitting, repair, or replacement necessitated by the negligence of proper care and maintenance or by an abusive act committed by the individual having the prosthetic device shall not be covered. Also, coverage shall not be required for a prosthetic device that is designed exclusively for athletic purposes.

The bill prohibits insurers, corporations, or HMOs from imposing any copayment, coinsurance, or deductible amounts, or any policy year or calendar year or lifetime, or other durational limit or maximum for benefits or services that is not equally imposed on terms and services covered under the policy, contract or class. The bill applies to policies, contracts or plans delivered, issued for delivery, reissued, or extended on or after January 1, 2008, or at any time thereafter when any term of the policy, contract or plan is changed or premium adjustments are made. The bill does not apply to short-term travel, accident only, limited or specified disease, or individual conversion policies or contracts, or policies or contracts designed for issuance to persons eligible for Medicare, or similar coverage under government plans.

Current insurance law does not have specific requirements for prosthetic and orthotic coverage as required in Senate Bill 931. The Rules Governing The Implementation of The Individual Accident and Sickness Minimum Standards for Individual Accident and Sickness Policies [14 VAC 5-140-70] require major medical expense coverage to include at least three additional benefits, of which two may be (1) rental of special equipment, as defined by the insurer in the policy, and (2) artificial limbs or eyes, casts, splints, trusses or braces, and up to \$2,000 for such covered charges. In most insurance plans, orthotic and prosthetic services and equipment may be subject to separate service levels, limits, and other variables. Generally, orthotic and prosthetic (O&P) services and equipment are not defined as basic health care.

## **PRIOR LEGISLATION**

House Bill 2552 was referred to the Advisory Commission for review by the House Committee on Commerce and Labor during the 2003 Session of the General Assembly of Virginia. House Bill 2552 was introduced by Delegate R. Steven Landes. The bill, as introduced, would have added § 38.2-3418.14 to the Code of Virginia to require insurers to provide coverage for artificial limbs (arms and legs). These provisions would have applied to all insurers proposing to issue individual or group accident and sickness policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; corporations providing subscription contracts; and HMOs providing health care plans.

“Artificial limb” was defined as a medically necessary prosthetic appliance prescribed as the result of the amputation of an arm or leg. The benefit was required to include coverage for the replacement of an artificial limb when medically appropriate, including, but not limited to, replacements required as a result of the insured's growth and normal wear and tear on an artificial limb. The benefit did not include replacement more frequently than once in a 12-month period. Subsection C required that artificial limbs were not to be considered durable medical equipment for the purpose of coverage limits, coinsurance, or co-payments and deductibles.

At the September 15, 2003 hearing Delegate Landes amended House Bill 2552 to limit coverage to prostheses for artificial legs. “Artificial leg” was defined as a medically necessary prosthetic appliance prescribed as the result of an above-the-knee amputation of a leg. The frequency with which an artificial leg could be replaced remained the same at one replacement in a 12-month period and the requirement that artificial limbs not be considered durable medical equipment for the purpose of coverage limits, coinsurance, or co-payments and deductibles did not change.

The Advisory Commission voted unanimously (11 to 0) on September 15, 2003 to recommend against the enactment of House Bill 2552. The Advisory Commission discussed the disparity of mandating coverage for a specific limb. The Advisory Commission concluded that coverage for artificial legs alone would impact a very small population and that a mandate was not warranted at that time.

## **MEDICARE COVERAGE (abridged)**

Medicare Part B requires a \$100 deductible and will reimburse 80% of its allowed charges for prosthetic devices and other benefits. Beneficiaries pay the remaining 20% coinsurance rate and any difference in charges between the provider's charges and the Medicare allowed charges. The Medicare Part B reimbursement is based on fixed fees or allowable or approved charges. Also, coverage and reimbursement is based on medical necessity and the physician's orders. The amount reimbursed may be less than the physician's actual charges.<sup>1</sup>

Prosthetics and orthotics are covered as durable medical equipment (DME) under Part B as a medical or other health service (§1861(s)(6) of the Social Security Act), and is defined as equipment that (a) can withstand repeated use; (b) is primarily and customarily used to serve a medical purpose; (c) generally is not useful to a person in the absence of an illness or injury; and (d) is appropriate for use in the home. All requirements of the definition must be met before an item can be considered DME.<sup>2</sup>

Under Part B, Medicare covers prosthetic and orthotic devices (other than dental) to replace all or part of a body organ, including replacement of such devices. The coverage includes 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." Replacements or repairs of such devices are covered when furnished incident to physicians' services or on a physician's orders. Beneficiaries pay a \$100 deductible and a 20% coinsurance fee.<sup>3</sup>

Prosthetics and orthotics include coverage for leg, arm, back, and neck braces, trusses, and artificial legs, arms, and eyes. A brace includes rigid and semi-rigid devices that are used for the purpose of supporting a weak or deformed body part or restricting or eliminating motion in a diseased or injured part of the body. "Replacement of Prosthetic Devices and Parts," refers to prosthetic devices that are artificial limbs, (Section 1834(h)(1)(G) of the Act. , Section 1861(s) of the Act).

Medicare categorizes Durable Medical Equipment Prosthetic and Orthotic Supplies (DMEPOS) into one of the following payment classes:

<p>Inexpensive or other routinely purchased DME</p>	<p>Equipment whose purchase price does not exceed \$150; contractors pay for rentals or lump-sum purchases. However, with the exception of Transcutaneous Electrical Nerve Stimulator (TENS), the total payment amount may not exceed the actual charge or the fee schedule amount for purchase.</p> <p>Other routinely purchased DME is defined as equipment that is acquired at least 75 percent of the time by purchase and includes equipment that is an accessory used in conjunction with a nebulizer, aspirator, or ventilators that are either continuous airway pressure devices or intermittent assist devices with continuous airway pressure devices. Includes used equipment; and circumstances where there has been no commercial transaction (e.g., equipment used for trial periods or as a demonstrator).</p>
<p>Items requiring frequent and substantial servicing</p>	<p>Contractors pay the fee schedule amounts on a rental basis until medical necessity ends. Contractors cannot pay for purchase of this type of equipment. Contractors make payment for each day that the device is used in the patient's home. No payment can be made for the device when the device is not used in the patient's home or once the 21 day period has elapsed (e.g., continuous passive motion (CPM) devices are covered for patients who have received a total knee replacement. To qualify for coverage, use of the</p>



	device must commence within 2 days following surgery. In addition, coverage is limited to that portion of the 3 week period following surgery during which the device is used in the patient's home).
Certain customized items	Items that require custom fabrication are unsuitable for grouping together for profiling purposes. Therefore there are neither customary and prevailing charges or fee schedules established. Contractors make payment for customized items without appropriate Healthcare Common Procedure Coding System (HCPCS) codes in a lump-sum based upon individual consideration for each item. For Part A providers, this is a final payment and is not reflected as a Medicare cost in provider cost reports.
Other prosthetic and orthotic devices	For payment purposes, these items consist of all prosthetic and orthotic devices excluding: items requiring frequent and substantial servicing; customized items; parenteral/enteral nutritional supplies and equipment; and intraocular lenses. Other than these exceptions, contractors pay the fee schedule amounts for prosthetic and orthotic devices on a lump-sum purchase basis.
Capped rental items	Contractors pay the fee schedule amounts on a monthly rental basis not to exceed a period of continuous use of 15 months. In the tenth month of rental, the beneficiary is given a purchase option. If the purchase option is exercised, contractors continue to pay rental fees not to exceed a period of continuous use of 13 months and ownership of the equipment passes to the beneficiary. If the purchase option is not exercised, contractors continue to pay rental fees until the 15 month cap is reached and ownership of the equipment remains with the supplier. In the case of electric wheelchairs only, the beneficiary must be given a purchase option at the time the equipment is first provided.  Suppliers must give beneficiaries the option of converting their capped rental equipment to purchased equipment during their 10th continuous rental month. Contractors make no further rental payments after the 11th rental month for capped rental items until the supplier notifies the contractor

	<p>that it has contacted the beneficiary and furnished him/her with the option of either purchase or continued rental.</p> <p>Beneficiaries have one month from the date the supplier makes the offer to accept this option. If the beneficiary declines or fails to respond to the purchase option, the contractor continues to make rental payments until the 15-month rental cap is reached. If the beneficiary accepts the purchase option, the contractor continues making rental payments until a total of 13 continuous rental months have been paid. The contractor will not make any additional rental payments beyond the 13th rental month. On the first day after 13 continuous rental months have been paid, the supplier must transfer title to the equipment to the beneficiary.</p>
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<sup>4</sup>Source: (Medicare Claims Processing Manual, Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); Rev. 1142, 12-22-06; retrieved May 23, 2007 from <http://www.cms.hhs.gov/manuals/downloads/clm104c20pdf>.)

The Centers for Medicare & Medicaid Services (CMS) determines the category that applies to each HCPCS code and issues instructions when changes are appropriate. DME, including DME furnished under the home health benefit and Part B DME benefit, is paid on the basis of the fee schedule. The definition of DME provides that DME is covered by Part B only when intended for use in the home, which explicitly does not include a skilled nursing facility (SNF) or hospital.

Clinical assessments of a client's rehabilitation potential, or functional ability, are used in determining medical necessity and the potential for successful use of prostheses are based on the following classification levels:

- Level 0: Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.
- 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 ambulator.
- 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 ambulatory.

- Level 3: Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
- Level 4: Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

## **BACKGROUND**

In the United States, there are approximately 1.9 million people living with limb loss. It is estimated that one out of every 200 people in the U.S. has had an amputation. Approximately 185,000 amputations take place each year in the United States. Limb deficiency occurs 1 in 3,846 live births in the United States (or at a rate of 2.6 per 10,000 live births). Congenital upper limb deficiency occurs 1.6 times more often than lower limb deficiency. Upper-limb deficiencies accounted for 58.5 percent of newborn, congenital limb anomalies.<sup>5</sup>

According to the American Academy of Orthotists and Prosthetists, amputation is a reconstructive operation, part of a process to replace an irrevocably diseased or damaged limb with a functional, artificial one. Coverage for treatment relating to prosthetic devices and components can vary. The current practice of health maintenance organizations and insurance carriers is to provide orthotic and prosthetic (O&P) benefits as a part of a standard benefit package or by rider. Also, there is no requirement that insurers must provide coverage for prosthetics devices, except in connection with the mandate for coverage for reconstructive breast surgery. Some policies provide coverage for prosthetic devices under the Durable Medical Equipment (DME) benefit and impose an annual dollar limitation.<sup>6</sup>

Other policies may provide coverage for the initial prosthesis but not for ongoing repairs beyond the warranty period, or they may place an annual dollar limit for repairs. Coverage for prosthetic devices may be limited to one prosthesis per lifetime or require that an extended period of time pass before benefits are available for a new prosthesis, regardless of the degree of changes in the residual limb or person's functional ability.<sup>7</sup>

According to proponents, the intent of Senate Bill 931 is to ensure that amputees who do require prosthetic care are not treated differently by different insurers. An amputee who needs a prosthesis should be able to receive a prosthesis that meets his needs. Proponents believe reimbursement rates should be driven by the market and Medicare should only be the lower limit or floor in Virginia. Insurance companies should no longer be allowed to set reimbursement rates, particularly at levels less than Medicare reimbursement. A patient receiving Medicare benefits should not be able to

receive a more suitable prosthesis than a patient who has insurance but needs the same prosthesis.<sup>8</sup>

Proponents support mandating orthotic and prosthetic insurance coverage consistent with Medicare coverage because they believe insurance policies that impose both annual and lifetime limits on reimbursements inflict a financial hardship on those patients due to typically lowered reimbursements. The California Health Benefits Review Program (CHBRP) which conducted an analysis of a proposal to mandate orthotic and prosthetic devices in California in 2006, provided evidence indicating that limiting O&P services has the potential to cause substantial and lasting disabilities. Evidence indicates that patients will struggle to achieve proper use and maintenance of worn out and defective O&P devices, which would increase the likelihood of chronic disability and injury.<sup>9</sup>

Opponents are concerned with the costs of mandated benefits, the potential for some individuals to lose coverage because of increased costs, and inconsistencies in prescription determinations between physician and payor as more technologically advanced devices become available. Opponents are particularly concerned that medically advanced and technologically advanced devices have a tendency to increase the overall cost to the health care system.<sup>10</sup>

## **SOCIAL IMPACT**

The prevalence rate for amputation in Virginia is 4.9 per 1,000. Approximately 37,450 amputees reside in of Virginia. The Amputee Coalition of America (ACA) reports that about 24,717 amputees have private health insurance in Virginia.<sup>11</sup>

Proponents believe that amputees have poor access to private health insurance coverage due to exemptions and limitations imposed by insurance companies related to prosthetic care. The observation of the ACA is that persons with prosthetic and orthotic needs may be excluded from coverage as a result of underwriting practices of private insurance companies.<sup>12</sup> Written testimony indicates the proposed legislation would make an improvement in the lives of individual amputees.

According to ACA, studies provide evidence that the working population and middle class who do have insurance are typically underinsured with coverage that is geared more toward acute care and will not meet their specific chronic and long-term care needs. These needs can include assistive or rehabilitation technology devices and related services such as training, therapy, or maintenance required for persons to be able to use the devices that provide the greatest benefit. Some benefits derived from prostheses affect one's quality of life, and are less measurable.<sup>13</sup>

ACA points out that once it is established that prosthetic care is not a covered benefit, individuals may become compelled to use other resources to obtain prostheses. Some financial alternatives used to obtain prostheses include retirement benefits, children's college savings, bank loans, home mortgages, or credit cards. Some

individuals may seek public insurance to receive prosthetic care. The shift to public programs, such as the state Medicaid program or the state vocational rehabilitation program, would mean additional expense to the Commonwealth. In addition to this specific cost, the Commonwealth may incur other expenses related to individual loss of employment and associated expenses.<sup>14</sup>

The Virginia Department of Medical Assistance Services (DMAS) provides coverage for prosthetic services for qualifying individuals. The coverage provision requires prior approval for medically necessary artificial arms, legs, their necessary supportive devices and breast prostheses when prescribed by a physician or other licensed practitioner of the healing arts within the scope of their professional license as defined by state law. Coverage also includes prosthetic services, which means the replacement of missing arms, legs, eyes, and breasts and the provision of an internal (implant) body part. The service must be pre-authorized for the minimum applicable component necessary for the activities of daily living (ADLs). Coverage does not include orthotic services or devices or organ transplantation services.<sup>15</sup>

The Virginia Department of Rehabilitative Services (DRS) provides coverage for prosthetic services and physical restorations to individuals with disabilities through services which will assist them in becoming employed and living more independently. Funds from this agency are used in pre- and post operative phases, and are utilized for the purchase of the actual prosthesis. The DRS fee schedule is based on Medicare rates. DRS report that between FY 2002 and FY 2007, it has assisted approximately 1,300 clients with limb amputations.<sup>16</sup>

The Veterans Health Administration (VHA) reported 60,324 discharges with amputation from VHA facilities between 1989 and 1998. The VHA assessed trends in lower-limb amputation numbers, re-operation rates and age-specific amputation rates. The study utilized Patient Treatment Files from all VHA hospitals. The file contained up to 5 codes for each operation and up to 10 diagnoses codes for the hospitalization.<sup>17</sup>

Medicare data shows that in 2002, 1.9 million Medicare beneficiaries (or 5.8% of all Medicare patients) submitted claims for orthotic or prosthetic care. This was up from 1.4 million beneficiaries or 4.4% of all Medicare patients in 1999. The 40 percent increase in orthotic and prosthetic utilization contrasts with a 7.1 percent increase in Medicare beneficiaries over this same time period. According to the Orthotic and Prosthetic Alliance, Medicare data also suggests greater demand for O&P care in the younger age groups than in older beneficiaries, suggesting that quality O&P care will be pivotal in enabling people with disabilities to return to work, live independently, and improve the quality of their lives.<sup>18</sup>

In Virginia, support for Senate Bill 931 comes from a cross section of professional groups and interested parties. According to the ACA, the American Academy of Family Physicians, the American Diabetes Association and the American Congress of Rehabilitation Medicine support this bill. Also, the three organizations representing prosthetists, as well as the organization responsible for accrediting

prosthetists, support this bill: The American Academy of Orthotists and Prosthetists (AAOP); The American Orthotic and Prosthetic Association (AOPA); The Orthotic and Prosthetic Alliance; and The American Board for Certification in Orthotics, Prosthetics, and Pedorthics (ABC).

Written comments in support of Senate Bill 931 were received from seven concerned citizens and ACA, who also presented 251 signatures on behalf of Virginia residents; several representatives within Powell Orthotics & Prosthetics (Richmond); Lawrence Rehabilitation and Virginia Prosthetics (Roanoke) also provided written comments.

## **FINANCIAL IMPACT**

Depending on the amputee's level of activity and type of amputation, prostheses can range in cost from \$5,000 to \$40,000. Some insurance plans provide their insureds with one limb per lifetime, or a \$2,500 maximum lifetime benefit or a \$500 limit on treatment per year.<sup>19</sup> The expense of artificial limbs does include additional maintenance costs because artificial limbs are usually replaced every 3 to 4 years as a result of normal wear and tear, weight loss or gain, significant changes in the residual limb or patient's functional ability.<sup>20</sup> DMAS provided information of cases in 2005 and 2006 indicating that the cost of ocular implants ranged from \$369 to \$595.<sup>21</sup>

According to the ACA, the inability to obtain private health insurance coverage for O&P care can financially impact individuals, and the general population in many aspects. Cost data seems to support a direct relationship between not having O&P health insurance coverage and other more costly, secondary conditions. The ACA believes that insurance companies are failing to view the long-term financial costs. Subsequent costs to the healthcare system would exceed the cost of providing prosthetic care, while the lack of productivity would place a burden on the society at large.<sup>22</sup>

For uninsured and underinsured O&P patients, necessary medications for increased diabetes-related care could cost up to \$100 per month (\$240,000 for 20 years). An individual suffering a heart attack due to peripheral vascular disease might incur costs ranging from \$75,000 to \$200,000 over a lifetime. Persons with knee or hip conditions that affect walking abilities could face additional costs of \$80,000 to \$150,000 over a lifetime. Those who use crutches may face carpal tunnel wrist surgery, which may carry a cost of \$7,500; elbow surgery, which is estimated to cost \$16,000; or shoulder surgery, which costs approximately \$25,000.<sup>23</sup>

The ACA reports that savings to private and public sector has been shown in studies conducted in Texas, Massachusetts, Colorado, California and New Jersey.<sup>24</sup> Studies conclude:

The public sector would save public dollars via decreased Medicaid costs and decreased vocational rehabilitation spending. Medical complications

such as flexion contractures, skin breakdown, osteoporosis, muscle loss and depression, along with costs associated with nursing home and/or home care would be eliminated because the prosthetic care would be direct, and would be viewed as restorative.

A statement on the ACA website indicates that curtailing or eliminating reimbursement for O&P services can cost money in the long run. For states enacting prosthetic coverage laws, more individuals can be reemployed, and those states can save money because health insurers' profits in those states would increase at a rate greater than the Cost Performance Index (CPI).<sup>25</sup>

According to the DMAS website, qualifying recipients of any prosthetic device are not responsible for a deductible or co-insurance payment. Federal requirements prohibit DMAS (Medicaid) from paying prosthetic device providers more than the Medicare payment for the same service. DMAS reported spending \$4,251,928 on 5,681 active claims related to orthotic and prosthetic procedures in fiscal years 2005 and 2006.<sup>26</sup>

According to the ACA, for every dollar spent on rehabilitation, including prosthetic care, \$11 is saved in disability benefits.<sup>27</sup> The ACA also reports that studies conducted by 5 of the 7 states with prosthetic parity laws, reflect that the increase in the monthly insurance premium was about \$.12 to \$.25 per member.<sup>28</sup> A study produced by the Colorado Department of Health Care Policy and Financing found that the cost of providing prosthetic coverage would be 12 cents per member per month. Analysis conducted by the California Health Benefits Review Program (CHBRP) estimated the cost to be about 16 cents per member per month.<sup>29</sup>

In a 2006 national survey conducted in partnership with Hanger Orthotic Group, Inc. and the ACA, 38 different companies/facilities in 10 states indicated various insurance coverage restrictions as the chart indicates below.<sup>30</sup>

<b>Financial Restrictions</b>	<b>Exclusions</b>	<b>Co-payments</b>	<b>Notes</b>
\$5,000 cap per year	Coverage for repairs	50% co-payment	Coverage changed from \$10,000 to \$2,000
\$1,000 cap per year	Coverage for replacements	Patient pays 50% of the costs for prosthetics	No coverage. Prosthesis considered "cosmetic."
One prosthesis per lifetime	A max out on benefits if the patient had received a prosthesis from another insurance company	\$1,500 annual out-of-pocket	

<b>Financial Restrictions</b>	<b>Exclusions</b>	<b>Co-payments</b>	<b>Notes</b>
\$2,500 cap per calendar year	20% reimbursement	\$2,000 out of pocket to receive any coverage	
\$2,500 - \$7,500 max lifetime cap	No coverage for above elbow myoelectric prosthesis		
2,500 - \$7,000 max lifetime cap	No coverage for biomechanical devices		
\$3,500 cap over 3 years	Limitations on myoelectric upper extremity prosthetics		
\$2,500 cap every 3 years	Battery replacements are not covered		
\$3,500 annual benefit limit			
\$15,000 annual benefit limit			
\$40,000 lifetime benefit limit			
\$50,000 lifetime benefit limit			
\$5,000 annual benefit limit			
\$10,000 maximum per occurrence			
1 prosthesis every 3 years and \$5,000 limit			
\$10,000 lifetime cap			
\$65,000 lifetime cap			

Amputee Coalition of America in collaboration with the Hanger Orthopedic Group, Inc., February, 2007. Retrieved June 15, 2007, from <http://www.amputee-coalition.org/advocacy/federal/national-coverage-restrictions.pdf>.

The ACA reports that 29 percent of its members had experienced reductions in healthcare coverage for prosthetics, and 8 percent had benefits eliminated altogether. Also, the ACA conducted a comparison of insurance reimbursements comparing prosthesis to bariatric bypass surgery or hip replacement. The outcome was that the reimbursement for prostheses was lower.<sup>31</sup>

## **MEDICAL EFFICACY**

Virginia Prosthetics indicated in written testimony that amputees who have access to prosthetic care and devices show a reduction in the secondary conditions caused by a sedentary lifestyle, have decreased dependence on caretakers, and a reduced chance of diabetic-related complications leading to additional limb amputation.



Prosthetic care is restorative and prevents other more costly, secondary conditions. As such, it should be viewed as a critical health service and should be covered by all health insurance.<sup>32</sup>

A sedentary lifestyle can lead to increased complications resulting from diabetes, heart attack due to peripheral vascular disease and the subsequent surgical treatment and hospitalization. Other secondary health-related concerns arise from distress placed on knees, hips or wrists, elbow, and shoulder.<sup>33</sup>

The CHBRP determined that O&P devices can improve the physical and psychological functioning of persons with amputations, injuries and congenital physical disabilities by enabling them to exercise and perform activities of daily life, thereby reducing their dependence on caretakers.<sup>34</sup> For individuals who have had lower extremities amputated, exercise is especially important because a sedentary lifestyle can increase the risk of cardiovascular disease, hypertension, and adult-onset diabetes. The ability to exercise is improved by a well-fitting orthotic or prosthetic device that is appropriate for a person's individual exercise activity.<sup>35</sup> The sedentary lifestyle and decreased activity can lead to the potential dangers of weakened muscles and decreased vascular flow in the residual limb. If the limb begins to waste away, a number of other medical conditions may contribute to further deterioration.<sup>36</sup>

An article entitled, "Lower-Limb Pediatric Prosthetics: General Considerations and Philosophy," which appeared in the Journal of Prosthetics and Orthotics promotes special health care consideration for children and young adult candidates requiring prosthetic devices. The article states that to accommodate a child's growth and development, prosthetic designs and components should be staged based on a child's readiness; the child's age at fitting, as well as, the etiology and future health care needs; and the child's activity level.<sup>37</sup>

The article explains that a child's walking ability and gait pattern may change many times during the first five years of life, describing how children grow both longitudinally and circumferentially which changes bony alignment. As a result, a child's growth and maturity will impact each new prosthetic in design, alignment and componentry. The authors recommend evaluating children for prosthetic devices every three to four months. Frequent necessary modifications include a relief for bony prominences and lengthening of the prosthesis. The authors suggest a new prosthesis would probably be necessary for a growing child every 18 months on average. Actual useful lifespan of the prosthesis depends primarily on the child's rate of skeletal growth.<sup>38</sup>

The website, Health AtoZ discusses co-morbidities and related information associated with amputation. The five-year survival rate for all lower extremity amputees is less than 50%. For diabetic amputees, the rate is less than 40%. Up to 50% of people who have one leg amputated because of diabetes will lose the other within five years. Amputees who walk using prostheses have a less stable gait. Three to five percent of these people fall and break bones because of this instability. Although

fractures can be treated, about half the amputees who suffer them then remain wheelchair bound. Alternatives to amputation depend on the medical cause underlying the decision to amputate and the degree of medical urgency. In some cases, drug therapy may be considered as an alternative, particularly with serious complication of diabetes. The development of foot ulcers can often lead to amputation.<sup>39</sup>

Research data from the Healthcare Cost and Utilization Project from 1988 through 1996 were used to calculate rates of congenital deficiency, trauma-related, cancer-related, and dysvascular amputations in the United States. Dysvascular amputations accounted for 82% of limb loss discharges, and increased over the period studied. Over all years, the estimated increase in the rate of dysvascular amputations was 27%. Rates of trauma-related and cancer-related amputations both declined by approximately half. The incidence of congenital deficiencies remained stable. Data in the same study indicate a total of 1,199,111 extremity amputations in the United States based on ICD-9 hospital discharge codes. The data also reflect 133,235 annual limb loss-related discharges.<sup>40</sup>

Advanced Arm Dynamics, Inc. indicates that not all amputee candidates choose to be fitted for prostheses for a number of reasons. They report six general options categorically available to amputees and the considerations involved in the amputee's decision. The typical factors involved in an amputee's decision to choose prosthesis are level of amputation, condition of residual limb, individual goals and work requirements. Usually, personal preferences will relate to functionality, cosmetics, or psychological considerations.

The six prosthetic options are<sup>41</sup>:

**No Prosthesis:** One half of all upper-extremity amputees receive prosthetic services. Of those, as many as half choose not to use or wear their prosthesis one year from initially receiving it. In some cases, functionality may not be enhanced by use of prostheses. Some amputees experience pain, discomfort or poor functionality due to the prosthesis. Or in other cases, an amputee may not afford the prosthesis.

**Cosmetic Restoration/Passive Prosthesis:** The prosthetic hand is non-functional and rarely provides the ability to grasp items. This design replaces what was lost from amputation or congenital deficiency with a prosthesis that is similar in appearance to the non-affected arm or hand; provides simple aid in balancing and carrying.

**Body-Powered/Conventional Prosthesis:** This type of device is powered and controlled by gross body movements. These movements, usually of the shoulder, upper arm or chest are captured by a harness system, which is attached to a cable that is connected to a terminal device (hook or hand). For some levels of amputation or deficiency, an elbow system can be added to provide the patient additional function. This type of prosthesis is highly durable and can be used for tasks that involve water and dust and in other potentially damaging environments. An advantage is increased control due to a phenomenon called proprioception, which gives the wearer feedback as

to the position of the terminal device. There is also a reduced maintenance cost for a body-powered prosthesis. Disadvantages include the uncomfortable and restrictive control harness; range of motion restrictions; and several additional patient requirements/considerations to manage the prosthesis.

**Electrically-Powered Prosthesis:** This category of prosthesis uses small electrical motors to provide function located in the terminal device (hand or hook), wrist and elbow. This type of prosthesis utilizes a rechargeable battery system to power the motors. Because electric motors are used to operate hand function, grip force of the hand is significantly increased, often in excess of 20-32 pounds. Operating this type of prosthesis includes Myoelectric Control, Servo Control, Linear Potentiometer, Force Sensitive Resistors (FSR), Push Button Control and Harness Switch Control. Several other control schemes may be used on the same prosthesis to provide enhanced function. This type of prosthesis uses a battery that requires charging, discharging, eventual disposal and replacement. Because of the battery system and the electrical motors, the electrically-powered prosthesis tends to be heavier than other prosthetic options, although advanced suspension techniques can minimize this sensation. Repairs can be more expensive than other options due to their sophistication. Additionally, an electrically-powered prosthesis is susceptible to damage when introduced to moisture.

**Hybrid Prosthesis:** A hybrid prosthesis combines body power and electrical power in a single prosthesis. Most commonly, hybrid prostheses are used for individuals with transhumeral (above the elbow) amputations or deficiencies. The hybrid prosthesis utilizes a body-powered elbow and a myoelectrically-controlled terminal device (hook or hand). Another type of hybrid prosthesis combines an electrically-powered elbow with a body-powered hook or hand. An advantage of a hybrid prosthesis is the ability to simultaneously control elbow flexion and extension while opening or closing the electric hand/hook or while rotating the wrist. The other prosthetic options generally require the wearer to control one function at a time (flex the elbow, lock the elbow, open or close the terminal device). The hybrid prosthesis weighs less and is less expensive than a similar prosthesis with an electrically-powered elbow and hand.

**Activity-Specific Prosthesis:** An activity-specific prosthesis is designed specifically for an activity in which the use of a passive, body-powered, electrically-powered or hybrid prosthesis would place unacceptable limitations on function or durability (fishing, swimming, golfing, hunting, bicycle riding and weight lifting; work-related tasks).

The U.S. Department of Veterans Affairs Technology Assessment Program (VATAP) completed a systematic review on computerized limb prostheses in March 2000 to evaluate the effectiveness of microprocessor controlled lower-limb prostheses. The C-LEG® is one of the first microprocessor-controlled lower extremity prostheses available to the public market. Although the review of the C-LEG® was inconclusive, the proposed benefits of microprocessor-controlled use include an increased confidence by patient in the prosthesis, decreased effort to walk, improved gait symmetry, and a

more natural gait which would allow for more freedom of use on stairs, uneven terrain, or in low light conditions.<sup>42</sup>

The California Health Benefits Review Program (CHBRP) reports the following as a result of a proposed mandate (Assembly Bill 2012, 2006) which would require group health insurance plans to offer health insurance coverage for O&P benefits under the same cost-sharing arrangements as other benefits. The analysis reported that<sup>43</sup>:

Most studies of the effectiveness of new O&P technologies are small observational studies that do not have control groups and do not adjust for other factors that may affect the results, such as age, co-morbidities, and level of physical activity. Thus, the evidence of the effectiveness of these technologies is not based on studies with rigorous research designs.

Most studies have assessed young and middle-aged adults who are physically active and in good health aside from their amputations. The results of these studies, therefore, may not be generalized to incorporate children and older adults who have a sedentary lifestyle and/or major co-morbidities, such as diabetes.

There is weak evidence that newer technologies for lower limb prostheses benefit young and middle-aged adults who are healthy and active. There is also insufficient evidence regarding the effects of new technologies used in upper limb prostheses and spinal orthoses.

Microprocessors are the most recent technological advance in prostheses. To date, no research studies that compare upper limb prostheses with microprocessors to upper limb prostheses that use older technologies have been published.

Three studies presented in the CHBRP compared energy-storing prosthetic feet to solid ankle cushion heel (SACH) prosthetic feet suggest that energy-storing feet reduce exertion and improve stability, speed, and ability to walk on inclines and declines. However, the evidence is ambiguous with regard to effects on oxygen consumption, gait, and satisfaction.

CIGNA HealthCare Mid-Atlantic, Inc. summarized its coverage of Lower Limb Prosthetic Devices, Myoelectric Prosthesis, and Lower Limb Orthoses on its website as follows:

While many amputees use conventional prostheses successfully, myoelectric prosthetic devices may be indicated either as alternatives to conventional prosthetic devices or as hybrid devices. The patient must

possess a minimal microvolt threshold and be able to isolate muscle contraction in order to use the device.

Evidence in the published, peer-reviewed, scientific literature is inconsistent in regard to demonstrating the superiority of myoelectric prostheses compared to standard devices, although most authors report improved function and range of motion. Most of the studies reviewed are limited to case series that evaluated subjective measures, such as patient preference. Most sample sizes are small, and the studies lack data measuring objective outcomes, improved performance and specific patient selection criteria. Additional well-designed, controlled clinical trials are required to determine the overall benefit of these devices compared to standard devices. However, myoelectric prosthetic devices may be indicated for those patients who cannot use body-powered devices or when a standard prosthetic device is insufficient to meet the functional needs of the patient. (Coverage position No. 0233)

Lower limb prostheses are used to replace the function of a lower extremity. Recently, microprocessor controlled/ computer-controlled devices have been recommended by some authors as an alternative to standard basic prostheses. Some studies support reduced oxygen consumption and improvement in ambulation with use of microprocessor-controlled devices. The published, scientific literature supports the use of microprocessor-controlled/computer-controlled devices for selected patient populations. (Coverage position No. 0194)

The orthotic devices identified in the Lower Limb Orthoses Coverage Position may be considered medically necessary for specific conditions. Some clinical studies provide strong support of efficacy, and others do not. Reported patient outcomes vary and include patient satisfaction, relief of pain, correction of deformity and correct positioning and motion. The majority of published, peer-reviewed, scientific literature does support the use of some types of orthoses for alleviating some symptoms, preventing certain deformities and potentially enhancing performance. (Coverage Position 0150).

## **SIMILAR LEGISLATION IN OTHER STATES**

The Amputee Coalition of America (ACA) reports that Colorado (2001), Maine (2003), Rhode island (2006), Massachusetts (2006), New Hampshire (2004), Oregon and California (2006, a mandated offer) have mandated coverage for prosthetic devices.

Six states have enacted “parity” laws. Generally, these states mandate that private insurers in the state offer coverage or provide coverage for prosthetic devices that, at a minimum, equal federal laws and regulation for the aged and disabled. “Parity”

laws are intended to eliminate differential cost-sharing arrangements, such as coinsurance rates or annual benefit maximums, between benefits for prosthetic devices and benefits for other type of services.<sup>44</sup>

## **CURRENT INSURANCE COVERAGE**

The State Corporation Commission Bureau of Insurance (BOI) recently surveyed 50 of the top writers of accident and sickness insurance in Virginia regarding each of the bills to be reviewed by the Advisory Commission this year. Forty companies responded by July 23, 2007. Nine companies indicated they have little or no applicable health insurance business in force in Virginia, and therefore could not provide the information requested.

Of the 31 respondents completing the BOI survey, 27 companies reported providing coverage for prosthetic devices and components as a standard benefit in Virginia. Of the 27 companies providing coverage as a standard benefit, four insurers specifically indicated the coverage was not the same as or equal to Medicare coverage as required in Senate Bill 931. Four insurers did not provide coverage for prosthetics devices and components as a standard benefit in Virginia.

Eight companies provided premium estimates ranging from \$.12 to \$1.00 per month to provide the coverage in individual standard contracts required by Senate Bill 931. Two companies indicated the individual standard contract cost as \$10 per year (\$.83 per month). One company provided the monthly premium for a standard contract and did not provide premium attributable to the individual bill. Twenty insurers did not respond to the question about premium costs. Three companies estimated the cost of providing the coverage on an optional basis for individual contracts. The responses ranged from \$.12 to \$5.00 per month.

Thirteen companies provided estimates for the cost of standard group coverage that ranged from \$.11 per month to \$1.70 per month. One company identified its cost at 2% of the premium amount. Three companies provided estimates of monthly costs for coverage on an optional basis for group contracts. Two companies estimated the cost at \$.11 per month to provide the coverage on an optional basis for group contracts. One company indicated the cost at 4% of premium for coverage on an optional basis for group contracts. One company provided the monthly premium for a standard contract and did not provide premium attributable to the individual bills. Twenty-seven insurers did not respond to the question about premium costs.

The survey asked insurers if coverage for ocular prosthetics was included in their standard coverage. Twenty-five companies indicated that it was included in its standard plan; one company responded it was included in its standard coverage, but with limited restrictions. Two companies referred to its website for further clarification. Three companies indicated that it did not include coverage for ocular prosthetics in its standard coverage.

The survey asked if the O&P benefit was covered under a specific category, and if so, asked insurers to name the specific category. Eight companies reported not covering the O&P benefit under a specific category. Six companies covered the benefit under a Prosthetic and Orthotic benefit; seven companies covered the benefit under DME; two companies covered it under a non-implanted prosthetic device category; two companies covered it under Medical equipment/supplies or medical devices category; another company covered it under both, DME and medical equipment; one company covered it under Artificial Limbs; and one company covered the benefit but did not list a specific benefit category. One company did not respond to the question and one company indicated that its provision of O&P coverage is not equivalent to requirements of Senate Bill 931.

The insurers provided information on various coverage limitations and annual dollar/lifetime limits under their policies. The coverage limitations ranged from (1) those specific to the benefit plan chosen or specific to the coverage provided by the rider; (2) coverage limited by medical necessity and/or appropriateness; (3) the initial prosthesis only and (4) detailed listings of exclusions, experimental devices, or exact co-payment amounts or percentages. The annual dollar/lifetime limits varied, and ranged from the plan's general lifetime limit for all covered expenses to (1) no limit if services are provided within the network; and (2) \$5,000 maximum benefit while insured for out-of-network services. Another company indicated an annual limit of \$3,000 to \$5,000 depending on the plan chosen. One company's lifetime maximum was \$50,000; another company indicated its coverage for artificial limbs is limited to \$10,000 per limb per lifetime per occurrence for up to two occurrences per limb to allow for growth. Five companies indicated no coverage limitations; two companies referenced information on their websites and one company did not respond. As to annual dollar/lifetime limits, six companies responded there was no annual dollar/lifetime limits, and four companies did not respond or indicated this category was not applicable.

Six of the 31 respondents do not cover repairs. Of the six not covering repairs, two companies indicated they would cover repairs when due to pathological changes or physical growth. Also, 25 respondents indicated that repairs fall under the same category as prosthetic devices. One company noted that repairs would not be covered in the event repairs were a result of negligence or abuse.

In response to a question concerning separate annual dollar limits for repairs, 23 companies indicated there was no separate annual dollar limit for repairs. One company responded it did impose a separate annual dollar limit for repairs. Another company stated that repairs/replacements are covered up to an annual maximum combined with repair and replacement for DME of \$500 per member per year, and repairs for artificial limbs are included in \$10,000 annual benefit/lifetime maximums. Two companies referred to information on their websites, and three companies did not respond to the question.

The survey asked if there was a time requirement imposed prior to submitting claims for a replacement. Nine companies indicated there was no time requirement;

one company indicated it would review each case independently; one company replied medical necessity determined the time; two companies indicated a two-year minimum wait; and one company indicated a three-year minimum wait. Three companies indicated a five-year minimum wait. One company emphasized it would pay initial costs only and would replace a device only for a child when replacement was due to growth. One company indicated that language referring to a time requirement variable was not included in the certificate. Eleven companies did not respond to the question.

## **REVIEW CRITERIA**

### **SOCIAL IMPACT**

- a. *The extent to which the treatment or service is generally utilized by a significant portion of the population.*

The prevalence rate for amputation in Virginia is 4.9 per 1,000. Approximately 37,450 amputees reside in of Virginia. The ACA reports that about 24,717 amputees have private health insurance in Virginia.<sup>45</sup>

Experts in the field indicate that not all amputee candidates choose to be fitted for prostheses for a number of reasons. Therefore, it is difficult to determine specific numbers of individuals utilizing the treatment options included in Senate Bill 931. However, the Virginia Department of Rehabilitative Services (DRS) reported that between FY 2002 and FY 2007, it assisted approximately 1,300 clients with limb amputations.<sup>46</sup> The JLARC assessment reported that the Virginia Department of Human Resources (DHRM) which administers the State Employee Health Plan estimates that it has covered treatment for 1,230 prosthetic and ocular devices since 2001.<sup>47</sup>

VAHP indicated that Senate Bill 931 may impact approximately 25% of the Commonwealth's population because self-insured plans, including those offered by many large employers, and government programs would be exempted from the mandate.

- b. *The extent to which insurance coverage for the treatment or service is already available.*

According to proponents, the intent of Senate Bill 931 is to overcome restrictions and exemptions related to prosthetic care being imposed by companies. Proponents believe that amputees have poor access to private health insurance coverage due to exemptions and limitations for prosthetic care in policies. The observation of the ACA is that persons with prosthetic and orthotic needs may be excluded from coverage as a result of underwriting practices by private insurance companies.

According to the American Academy of Orthotists and Prosthetists, the current practice of health maintenance organizations and insurance carriers is to provide orthotic and prosthetic (O&P) benefits as a part of a standard benefit package or by



rider. Also, there is no requirement that insurers must provide coverage for prosthetics devices, except in connection with the mandate for coverage for reconstructive breast surgery. Some policies provide coverage for prosthetic devices under the Durable Medical Equipment (DME) benefit and impose an annual dollar limitation.<sup>48</sup>

Other policies may provide coverage for the initial prosthesis but not for ongoing repairs beyond the warranty period, or they may place an annual dollar limit for repairs. Coverage for prosthetic devices may be limited to one prosthetic device per lifetime or require that an extended period of time pass before benefits are available for a new prosthesis, regardless of the degree of changes in the residual limb or person's functional ability.<sup>49</sup>

The State Corporation Commission Bureau of Insurance (BOI) recently surveyed 50 of the top writers of accident and sickness insurance in Virginia regarding each of the bills to be reviewed by the Advisory Commission this year. Forty companies responded by July 23, 2007. Nine companies indicated they have little or no applicable health insurance business in force in Virginia, and, therefore, could not provide the information requested.

Of the 31 respondents completing the BOI survey, 27 companies reported providing coverage for prosthetic devices and components as a standard benefit in Virginia. Of the 27 companies providing coverage as a standard benefit, four insurers specifically indicated the coverage was not the same as or equal to Medicare coverage as required in Senate Bill 931. Four insurers did not provide coverage for prosthetics devices and components as a standard benefit in Virginia. One company indicated that its provision of O&P coverage is not equivalent to requirements of Senate Bill 931.

The BOI survey reflected wide variation in insurance coverage for prosthetic devices. Coverage variations included carriers categorizing the benefit differently; benefit caps on annual expenditures and caps on lifetime expenditures; different co-payment amounts; and some devices specifically excluded from coverage. JLARC staff acknowledged the varied plan designs and individual insurer restrictions, exclusions and limitations. Each respondent to the BOI survey could manage prosthetic repairs independently from the prosthetic device requirement. Each insurer could establish different time requirements for each condition or course of action. These restrictions, exclusions, limits and time requirements could lead to a gap in the consumers' expectation of what devices the insurer will cover and the actual level of coverage.

The VAHP testified that its member health plans provide coverage for medically necessary prosthetic devices.<sup>50</sup>

*c. If coverage is not generally available, the extent to which the lack of coverage results in persons being unable to obtain necessary health care treatments.*

Generally, providers, including treating physicians who prescribe orthotics and prosthetic devices and prosthetists who craft and design the devices are accessible throughout the Commonwealth. Of the 31 respondents completing the BOI survey, 87%

(27 companies) reported providing some coverage for prosthetic devices and components as a standard benefit in Virginia. Proponents of the bill cited several instances when individuals could not afford the expense of a prescribed device because of disproportionate co-payments, reimbursements or other limitations.

The ACA reported that insurers often reduce or eliminate their coverage for prosthetics. In a recent membership survey, the ACA found that 24 percent of its members had experienced reductions in healthcare coverage for prosthetics, and four percent had benefits eliminated altogether. Many consumers are unaware of inadequate coverage until a need for a prosthetic arises.

The VAHP agreed that prosthetic coverage is available. In written comments, the VAHP stated that the extent of O&P coverage should be based on the individual's or the individual's employer's ability to purchase more expansive benefits. In particular, VAHP noted that not mandating Senate Bill 931 would give small employers or those employers challenged with the decision of what level of coverage to provide their employees the opportunity to buy a more basic, affordable product.<sup>51</sup>

*d. If the coverage is not generally available, the extent to which the lack of coverage results in unreasonable financial hardship on those persons needing treatment.*

A number of variables could impact cost or influence an individual's ability to obtain prosthetic devices or care. Some insurance plans provide coverage for one limb per lifetime, or a \$2,500 maximum lifetime benefit or a \$500 limit on treatment per year.<sup>52</sup> The expense of artificial limbs does include additional maintenance costs because artificial limbs are usually replaced every 3 to 4 years as a result of normal wear and tear, weight loss or gain, or significant changes in the residual limb or patient's functional ability.<sup>53</sup>

A 2006 survey conducted in partnership with Hanger Orthotic Group, Inc. and the ACA in 10 states indicated a range of co-payments from 50% of total prosthetic cost to a \$500 deductible plus a \$2,000 out-of-pocket cost before coverage commences.<sup>54</sup> The 2007 JLARC assessment concluded that a prosthetic device could represent a significant financial hardship on many households.<sup>55</sup>

Proponents support mandating O&P insurance coverage consistent with Medicare coverage because they believe insurance policies that impose both annual and lifetime limits on reimbursements inflict a financial hardship on those patients due to typically lowered reimbursements. The California Health Benefits Review Program (CHBRP), which conducted an analysis of a proposal to mandate orthotic and prosthetic devices in California in 2006, provided evidence indicating that limiting O&P services has the potential to cause substantial and lasting disabilities. Evidence indicates that patients will struggle to achieve proper use and maintenance of worn out and defective O&P devices, which would increase the likelihood of chronic disability and injury.<sup>56</sup>

Proponents contend there is disparity in prosthetic reimbursement throughout the insurance industry. ACA points out that once it is established that prosthetic care is not a covered benefit, individuals may lose employment which could negatively impact the individual and family environment. In this circumstance, individuals may become compelled to use other resources to obtain prostheses. Some financial alternatives used to obtain prostheses include retirement benefits, children's college savings, bank loans, home mortgages, or credit cards. Some individuals may seek public insurance to receive prosthetic care. The shift to public programs, such as the state Medicaid program or the state vocational rehabilitation program, would mean additional expense to the Commonwealth. In addition to this specific cost, the Commonwealth may incur other expenses related to individual loss of employment and associated expenses.<sup>57</sup>

Opponents contend coverage is generally available. The market may provide the coverage; however, the employer or individual must make the determination to purchase the coverage, which usually takes the form of a rider or bears an additional cost.

e. The level of public demand for the treatment or service.

The prevalence rate for amputation in Virginia is 4.9 per 1,000. Approximately 37,450 amputees reside in of Virginia. The Virginia Department of Medical Assistance Services (DMAS) reported that in fiscal years 2005 and 2006, it processed 5,681 claims for prosthetic devices.

Amputation, limb loss and the need for prosthetics vary according to individual circumstances and choices. (Congenital deficiency, trauma-related, cancer-related, or dysvascular amputations require different treatment and management. The patient's age, individual goals, and work requirements are personal preferences and individualized. Also, the prescribed prosthetic device is individualized to accommodate the level of amputation and condition of residual limb.) An amputee may chose to not be fitted for a prosthetic device. As a result of these diverse variables, it is difficult to determine the specific level of public demand for prosthetic devices.

Generally, individuals affected by Senate Bill 931 would include those consumers enrolled in plans not currently offering coverage for prosthetic devices and those consumers enrolled in plans with low caps or high co-payment amounts or other restrictive underwriting practices.

f. *The level of public demand and the level of demand from providers for individual and group insurance coverage of the treatment or service.*

In Virginia, support for Senate Bill 931 comes from a cross section of professional groups and interested parties. According to the ACA, the American Academy of Family Physicians, the American Diabetes Association and the American Congress of Rehabilitation Medicine support this bill. Also, the three organizations representing prosthetists, as well as the organization responsible for accrediting

prosthetists, support this bill: The American Academy of Orthotists and Prosthetists (AAOP); The American Orthotic and Prosthetic Association (AOPA); The Orthotic and Prosthetic Alliance; and The American Board for Certification in Orthotics, Prosthetics, and Pedorthics (ABC).

Representatives from Powell Orthotics and Prosthetics (Richmond) and Lawrence Rehabilitation submitted written comments in support of the bill. Virginia Prosthetics (Roanoke) also provided written comments and testified before the Advisory Commission.

At the public hearing on September 20, 2007 in Richmond, 30 amputees and family members addressed the Advisory Commission in support of Senate Bill 931. Over 100 concerned citizens attended the public hearing in support of Senate Bill 931. Written comments in support of Senate Bill 931 were received from seven concerned citizens and ACA, which also presented 251 signatures on behalf of Virginia residents.

DMAS reported that in fiscal years 2005 and 2006, it processed 5,681 claims for prosthetic devices. DRS reported that between FY 2002 and FY 2007, it assisted approximately 1,300 clients with limb amputations.<sup>58</sup> The VHA reported 60,324 discharges with amputation from VHA facilities between 1989 and 1998.<sup>59</sup>

In the United States, there are approximately 1.9 million people living with limb loss. It is estimated that one out of every 200 people in the U.S. has had an amputation. Approximately 185,000 amputations take place each year in the United States. Limb deficiency occurs 1 in 3,846 live births in the United States (or at a rate of 2.6 per 10,000 live births).

According to the Orthotic and Prosthetic Alliance, Medicare data also suggests greater demand for O&P care in the younger age groups than in older beneficiaries, suggesting that quality O&P care will be pivotal in enabling people with disabilities to return to work, live independently, and improve the quality of their lives.<sup>60</sup>

Representatives from VAHP and the VCC spoke against Senate Bill 931. VAHP noted in written comments dated October 11, 2007 that some proponents of Senate Bill 931 were satisfied with the prosthetic coverage provided by their employer-sponsored plans; however, they attended the public hearing to support other proponents whose employer sponsored coverage was not as expansive.<sup>61</sup>

*g. The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts.*

The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts is unknown.

*h. Any relevant findings of the state health planning agency or the appropriate health system agency relating to the social impact of the mandated benefit.*

The Advisory Commission is not aware of any findings of the state health planning agency or health system agency relating to the social impact of prosthetic devices.

## FINANCIAL IMPACT

- a. *The extent to which the proposed insurance coverage would increase or decrease the cost of treatment or service over the next five years.*

A prosthetic device can range in cost from \$5,000 to \$40,000. The ACA believes that enactment of Senate Bill 931 would not increase the cost of a prosthetic device. The ACA provided data indicating that an increase in insurance premiums to include prosthetic coverage would be minimal. In the long term, mandating coverage for prosthetic devices has the potential to decrease overall health care costs due to Senate Bill 931, but has the potential to impact accessibility to insurance coverage.

JLARC determined that mandating coverage for prosthetic devices is not expected to impact the cost. Moreover, mandating coverage for prosthetic devices has the potential to decrease overall health care costs due to a reduction in secondary complications.

- b. *The extent to which the proposed insurance coverage might increase the appropriate or inappropriate use of the treatment or service.*

Proponents anticipate that the proposed mandate would not increase appropriate utilization of medically prescribed devices. However, mandating coverage equal to Medicare would allow more individuals to have access to prosthetic devices. Inappropriate use is not expected to increase.

Opponents expressed concern that Senate Bill 931 has the potential to increase the inappropriate use of expensive, technologically advanced prostheses.

- c. *The extent to which the mandated treatment or service might serve as an alternative for more expensive or less expensive treatment or service.*

Virginia Prosthetics indicated in written testimony that amputees who have access to prosthetic care and devices show a reduction in the secondary conditions caused by a sedentary lifestyle; have decreased dependence on caretakers; and a reduced chance of diabetic-related complications leading to additional limb amputation. Prosthetic care is restorative and prevents other more costly, secondary conditions. As such, it should be viewed as a critical health service and should be covered by all health insurance in an effort to lower or lessen alternative or more expensive treatments.<sup>62</sup> Alternatives to amputation depend on the medical cause underlying the decision to amputate and the degree of medical urgency. In some cases, drug therapy may be considered as an alternative, particularly with serious complication of diabetes.

The ACA points out that prosthetic devices and components are medically prescribed, and the determination and assessment of the specific need includes surgeons, physicians and physical therapists. Further evaluation includes designing, fabricating and fitting the unique device by the prosthetist for the individual.<sup>63</sup>

*d. The extent to which the insurance coverage may affect the number and types of providers of the mandated treatment or service over the next five years.*

JLARC determined that there are more than 200 providers in all areas of Virginia, and concluded in its assessment that Senate Bill 931 is not expected to significantly increase the number of providers. Also, the bill would not mandate a new class of providers, nor does it seek to mandate a new class of practitioners.<sup>64</sup>

*e. The extent to which insurance coverage might be expected to increase or decrease the administrative expenses of insurance companies and the premium and administrative expenses of policyholders.*

ACA indicated that Senate Bill 931 would decrease the amount of time and cost insurers invest in the number of appeals initiated by consumers who challenge eligibility for devices, determination decisions, low reimbursement fees, or other individual insurer practices. A limited increase in the administration expenses of insurance companies and policyholders may occur as a result of monitoring Medicare coverage policies or revisions to policy design form filing, claims processing systems, and marketing.

JLARC indicated that insurers would be required to monitor Medicare schedule for changes. However, insurers would expect a decrease in costs associated with negotiating device rates, since the mandate would set the reimbursement rates at the Medicare rate.<sup>65</sup>

The VCC expressed in written comments that mandates will add to the cost of providing coverage and will cause employers to reassess how, or if health insurance can remain a benefit to employees.

VAHP expressed in written comments that mandating businesses to provide prosthetic coverage equal to Medicare may endanger the ability of already struggling employers to offer health insurance benefits. VAHP expressed its opposition by arguing that Senate Bill 931 would remove the ability of health plans to produce affordable products by eliminating the plans' capacity to negotiate rates and craft varying benefit design packages.<sup>66</sup>

Eight companies provided premium estimates ranging from \$.12 to \$1.00 per month to provide the coverage in individual standard contracts required by Senate Bill 931. Two companies indicated the individual standard contract cost as \$10 per year (\$.83 per month). One company provided the monthly premium for a standard contract and did not provide premium attributable to the individual bill. Twenty insurers did not

respond to the question about premium costs. Three companies estimated the cost of providing the coverage on an optional basis for individual contracts. The responses ranged from \$.12 to \$5.00 per month. Three companies estimated the cost of providing coverage on an optional basis for individual contracts. The responses ranged from \$.12 to \$5.00 per month.

Thirteen companies provided estimates for the cost of standard group coverage that ranged from \$.11 per month to \$1.70 per month. One company identified its cost at 2% of the premium amount. Three companies provided estimates of monthly costs for coverage on an optional basis for group contracts. Two companies estimated the cost at \$.11 per month to provide the coverage on an optional basis for group contracts. One company indicated the cost at 4% of premium for coverage on an optional basis for group contracts. One company provided the monthly premium for a standard contract and did not provide premium attributable to the individual bills. Twenty-seven insurers did not respond to the question about premium costs.

Proponents of Senate Bill 931 cite several studies conducted in Texas, Colorado, Massachusetts, California and New Jersey, which do not anticipate an increase in costs as a result of prosthetic parity or a mandate to cover prosthetics and orthotics at the same level as Medicare. The studies estimate an increase in premium to range from \$.12 to \$.25 per member per month.

*f. The impact of coverage on the total cost of health care.*

Advocates of Senate Bill 931 believe that mandating prosthetic care and devices would reduce costs related to secondary conditions caused by a sedentary lifestyle, dependence on caretakers, and increased chances of diabetic-related complications leading to additional limb amputation. Other secondary health-related concerns arise from distress placed on knees, hips or wrists, elbows, and shoulders. The CHBRP determined that O&P devices can improve the physical and psychological functioning of persons with amputations, injuries and congenital physical disabilities by enabling them to exercise and perform activities of daily life.

For uninsured and underinsured O&P patients, necessary medications for increased diabetes-related care could cost up to \$100 per month (\$240,000 for 20 years). An individual suffering a heart attack due to peripheral vascular disease might incur costs ranging from \$75,000 to \$200,000 over a lifetime. Persons with knee or hip conditions that affect walking abilities could face additional costs of \$80,000 to \$150,000 over a lifetime. Those who use crutches may face carpal tunnel wrist surgery, which may carry a cost of \$7,500, elbow surgery which is estimated to cost \$16,000; or shoulder surgery, which costs approximately \$25,000.

A concerned citizen testified as to her experience and a physical therapist testified of his knowledge of insurers paying for physical therapy, additional surgery, and related expenses as a result of injury due to an amputee falling. Their testimony indicated subsequent costs to the health care system could include the burden of caring

for a segment of the population through unemployment insurance, rehabilitation and counseling programs, and other social welfare systems, rather than allowing amputees to become contributing members of society by providing prosthetic care. Written comments from ACA estimates that for every dollar spent on rehabilitation, more than \$11 is saved.

### MEDICAL EFFICACY

- a. *The contribution of the benefit to the quality of patient care and the health status of the population, including the results of any research demonstrating the medical efficacy of the treatment or service compared to alternatives or not providing the treatment or service.*

According to ACA, studies provide evidence that the working population and middle class who do have insurance are typically underinsured with coverage that is geared more toward acute care and will not meet their specific chronic and long-term care needs. These needs can include assistive or rehabilitation technology devices and related services such as training, therapy, or maintenance required for persons to be able to use the devices that provide the greatest benefit. Some benefits derived from prostheses affect one's quality of life, and are less measurable.<sup>67</sup>

The ACA cites studies conducted in Texas, Massachusetts, Colorado, California and New Jersey which reflect cost savings to private and public sector due to prosthetic care. Studies conclude:

The public sector would save public dollars via decreased Medicaid costs and decreased vocational rehabilitation spending. Medical complications such as flexion contractures, skin breakdown, osteoporosis, muscle loss and depression, along with costs associated with nursing home and/or home care would be eliminated because the prosthetic care would be direct, and would be viewed as restorative.

A statement on the ACA website indicates that curtailing or eliminating reimbursement for O&P services can cost money in the long run. For states enacting prosthetic coverage laws, more individuals can be reemployed, and those states can save money because health insurers' profits would increase at a rate greater than the Cost Performance Index (CPI).<sup>68</sup>

Some individuals may seek public insurance to receive prosthetic care. The shift to public programs, such as the state Medicaid program or the state vocational rehabilitation program, would mean additional expense to the Commonwealth. In addition to this specific cost, the Commonwealth may incur other expenses related to individual loss of employment and associated expenses.<sup>69</sup>



- b. *If the legislation seeks to mandate coverage of an additional class of practitioners:*

*The results of any professionally acceptable research demonstrating the medical results achieved by the additional class of practitioners relative to those already covered.*

Not applicable.

*The methods of the appropriate professional organization that assure clinical proficiency.*

Not applicable.

### EFFECTS OF BALANCING THE SOCIAL, FINANCIAL AND MEDICAL EFFICACY CONSIDERATIONS

- a. *The extent to which the benefit addresses a medical or a broader social need and whether it is consistent with the role of health insurance.*

Proponents believe that Senate Bill 931 addresses both medical and social needs of individuals requiring prosthetic devices. Insurance restrictions, exclusions and limitations can lead to delayed recovery, financial difficulties and can influence long-term quality of life results.

The JLARC assessment reports that the benefit is consistent with the role of health insurance because prosthetic devices are restorative and can allow an individual to regain a level of social functioning equal to his pre-amputation condition. Further, prosthetic devices may prevent additional medical complications, although the device may not have the capacity to treat the initial cause for the amputation. The proposed mandate would establish a basic level of coverage for prosthetic devices and help to bridge the gap between a consumer's expectation of insurance coverage and the actual insurance coverage.

- b. *The extent to which the need for coverage outweighs the costs of mandating the benefit for all policyholders.*

Proponents believe that the need for coverage outweighs the cost of mandating the benefit for all policyholders because it is more cost effective to provide prosthetic coverage and care than it is to treat secondary conditions resulting from lack of coverage or care. JLARC concurs in its assessment by affirming that amputation may not immediately endanger the life of an individual, but may force an individual into a more sedentary lifestyle without access to a medically prescribed prosthetic device. The sedentary lifestyle may lead to an inability to maintain employment, an increased

reliance on caretakers, an increased likelihood of experiencing depression, and increased morbidity.<sup>70</sup>

VAHP and VCC cite employer costs to offer expansive health insurance benefits as a reason to oppose the bill.

JLARC cites in its assessment several considerations why this proposed mandate outweighs its cost. The premium impact for policyholders is low, the mandate establishes a basic level of coverage for prosthetic devices, and a change in the bill language could allow insurers to pay 80% of the patient charges, but not require insurers to follow the Medicare fee schedule for devices which would not constrain the insurers' ability to negotiate specific device costs.<sup>71</sup>

c. *The extent to which the need for coverage may be solved by mandating the availability of the coverage as an option for policyholders.*

In the case of individual coverage, the market may provide the coverage; however, the individual must make the determination to purchase the coverage, which usually comes in the form of a rider and bears additional cost. In the case of group coverage, the decision whether to select the optional coverage or not would lie with the master contract holder and not the individual insureds.

## **RECOMMENDATION**

The Advisory Commission voted on November 29, 2007 to recommend enacting Senate Bill 931 (Yes- 6, No-4).

## **CONCLUSION**

The Advisory Commission discussed the changing needs of health care, the increase of health care costs, maintaining affordable health insurance and health care for all Virginians, and the cross-section of the population impacted by Senate Bill 931. The Advisory Commission believes the benefits of the proposed mandate are considerable and would significantly impact an individual's life. When compared to the cost of providing ensuing care as a result of not providing the coverage for prosthetic devices, the bill should be enacted.

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