JOINT LEGISLATIVE AUDIT AND REVIEW COMMISSION
OF THE VIRGINIA GENERAL ASSEMBLY

EVALUATION OF PROPOSED MANDATED HEALTH INSURANCE BENEFITS

Evaluation of Senate Bill 931: Mandated Coverage of Prosthetic Devices

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Evaluation of Senate Bill 931: Mandated Coverage of Prosthetic Devices

JLARC SUMMARY

Limb or eye loss, as a result of disease or injury, may require the use of a prosthetic device in order for an individual to regain functionality. It is estimated that more than 1.2 million Americans are currently living with the absence of a limb, but only limited information is available on the number of individuals currently using prosthetic devices. Prosthetic devices are not appropriate for all amputees, and a physician must certify the medical necessity of any prosthetic device and component prescribed as a course of treatment. Senate Bill 931 would require health insurers, health care subscription plans, and health maintenance organizations to provide coverage for the cost of prosthetic devices and components including arms and legs, their associated components, and eyes, at a minimum of the coverage levels and reimbursement rates provided through the federal Medicare program.

MEDICAL EFFICACY AND EFFECTIVENESS

Safety and effectiveness studies are required by the U.S. Food and Drug Administration prior to issuing approval for prosthetic devices. Researchers have documented the positive effects prostheses can have on patients, including improved physical and psychological functioning of persons with amputations or congenital physical disabilities, by enabling them to perform activities of daily life. In addition, most individuals with prostheses return to some form of work and show a reduction in secondary conditions that can result from their disability.

In This Evaluation

Appendixes

SOCIAL IMPACT

While the specific number of individuals living in Virginia for whom a prosthetic device covered under SB 931 would be medically necessary is unknown, it is estimated that there are between 37,000 and 51,000 Virginians living with the loss of an eye or a limb. Current coverage varies widely; however, 13 percent of insurers' responding to a Bureau of Insurance survey indicated they do not provide any coverage for prosthetic devices. While some plans provide unlimited coverage of prosthetic devices, the majority do not provide coverage at the level comparable to Medicare. With the costs of prosthetic devices ranging from $2,000 to $30,000 or more, the financial hardship on patients may be significant if the plan has a cap on annual costs or if devices are not covered.

FINANCIAL IMPACT

Mandating coverage under SB 931 is not expected to impact the cost of prosthetic devices or increase the number of providers. However, mandating coverage will likely increase the number of individuals able to obtain devices that have been prescribed as a course of treatment and may reduce the overall costs of healthcare due to a reduction in secondary complications. Mandating coverage at a level directly linked to the federal Medicare program will require insurance companies to monitor federal program requirements; however, costs associated with negotiating rates with individual device suppliers would be reduced. Additionally, the impact on premiums charged to customers would be minimal and less than the estimated premium impact of other healthcare mandates.

BALANCING MEDICAL, SOCIAL, AND FINANCIAL CONSIDERATIONS

Given the potentially significant financial impact to an individual or family for obtaining a medically prescribed prosthetic device, the proposed mandate is consistent with the role of insurance and monthly premium increases are estimated to be consistent with other mandates. While the majority of Virginia's fully-insured plans offer some level of coverage for prosthetic devices, some plans do not offer any coverage of these devices, and coverage levels for other plans may be inadequate for an individual to obtain the device prescribed. Mandating coverage defined in SB 931 will establish a minimum level of coverage for individuals requiring prostheses and increase individual access to certain device types. While it is not possible to definitively conclude that the Medicare coverage level is most appropriate for meeting individual needs in all cases, it does establish a basic level of care, and several states have mandated the coverage level proposed in SB 931.

Evaluation of Senate Bill 931: Mandated Coverage of Prosthetic Devices

Senate Bill 931 of the 2007 General Assembly Session would mandate health insurance coverage for prosthetic devices including arms and legs, their associated components, and eyes, at a minimum of the coverage levels and reimbursement rates provided through the federal Medicare program.

BACKGROUND

Limb or eye loss, as a result of disease or injury, may require the use of a prosthetic device in order for an individual to regain functionality. It is estimated that more than 1.2 million Americans are currently living with the absence of a limb, but limited information is available on the number of individuals currently using prosthetic devices. Prosthetic devices are not appropriate for all individuals that have lost a limb or eye, and a physician must certify the medical necessity of any prosthetic device and component prescribed as a course of treatment. Senate Bill 931 would require health insurers, health care subscription plans, and health maintenance organizations to provide coverage for the cost of prosthetic devices and components including arms and legs, their associated components, and eyes, at a minimum of the coverage levels and reimbursement rates provided through the federal Medicare program. Coverage under SB 931 extends to both the initial cost of the device as well as its fitting, repair, and replacement.

a. Description of Medical Condition and Proposed Treatment

There are many reasons individuals suffer the loss of a limb or eye resulting in the potential need for a prosthetic device. Individuals requiring amputation are assessed by an orthopedic surgeon or referred to a physiatrist–a doctor specializing in physical medicine and rehabilitation of persons with physical disabilities–to determine if a prosthetic device is medically appropriate. In most instances, individuals prescribed a prosthetic device have the ability to seek device design, fabrication, and fitting from independent prosthetics providers. The following section provides background information on limb loss, prosthetic devices, and the current levels of Medicare coverage for these devices.

Limb and Eye Loss. Loss of a limb or eye affects more than 1.2 million people in the United States regardless of age, race, economic level, or location. Approximately 185,000 limb amputations occur each year nationally, the majority of which are due to complications of the vascular system (dysvascular complications), especially related to arterial disease and diabetes. Nationally, 82 percent of amputations are due to vascular disease. Other reasons for amputation include cancer and trauma. Congenital limb deficiencies also occur in 26 of 100,000 live births, but account for a small percentage of individuals requiring prostheses. While traumatic and cancer-related amputations are decreasing, dysvascular amputation rates are increasing largely because medical technology has allowed individuals with diabetes to live longer. Although limb loss is experienced among all ages, the highest rate is among people ages 65 and older.

Information on the reasons for and prevalence of eye loss is limited. Generally, eye loss is caused by trauma, tumor, or ocular disease including glaucoma and diabetes. The National Institutes of Health estimate that one in 12 people with diabetes over age 40 has lost vision to diabetic complications. However, estimates of individuals requiring an ocular prosthesis are not available. Additional information on the incidence of limb and eye loss is discussed later in this report.

Regardless of the reason for the loss of the limb or eye, not all individuals are candidates for a prosthesis. A determination of the medical necessity for certain components is based on the individual's functional abilities, the rehabilitative expectations of the patient, and other factors, including

- physical condition of the residual limb,
- compounding health issues such as vascular or arthritic problems in the non-amputated appendages which may affect prosthetic wear,
- demographic and lifestyle factors including employment and activity levels,
- independent living status; and
- timeframes for recovery and access to rehabilitative care.

A physician's clinical assessment of an individual's potential for rehabilitation, or functional level, is also used in determining medical necessity and appropriateness of a prosthetic device. These assessments are also used by insurance providers, through the medical review process, in determining an individual's access to particular devices.

The most appropriate design of a prosthetic device depends on the patient's underlying functional level (Table 1). Because of their greater rehabilitation potential, amputees in higher functional levels are generally prescribed more complex devices from a broader choice of prosthetic components, while prostheses are not medically necessary if the patient's potential functional level is zero. For example, the requirements of a prosthetic knee in an elderly, largely homebound individual will be quite different than a younger, active person.

Table 1: Amputee Functional Levels

Functional Level	Description
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 ambulator.
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 use beyond simple locomotion.
Level 4	Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills. Typical of the prosthetic demands of the child, active adult, or athlete.

Source: Colorado Department of Health Care Policy and Financing.

Lower Extremity Prostheses. The most commonly prescribed prosthetic devices are those of the leg. Due in large part to high rates of dysvascular amputations associated with diabetes, below-knee (transtibular) prostheses are more commonly prescribed than above-knee. Above-knee (transradial) amputations result in the need for more complex prosthetics utilizing a knee device; these are less common than below-knee amputations, but often result from similar causes. Over 100 different prosthetic knee designs are currently available. For example, fluid and hydraulic-controlled devices allow amputees to vary their walking speed by using hydraulic controls to match the movement of the shin portion of the prosthesis to the movement of the upper leg. However, hydraulic prostheses are heavier than other options and require gait training to function appropriately. Other examples include devices that

contain polycentric mechanical knees, swing-phase control, stance control, and other mechanical or hydraulic systems.

Microprocessor-controlled prosthetic knees, which automatically adjust the swing of the leg permitting a more natural walking pattern of varying speeds, were first licensed for use by the U.S. Food and Drug Administration (FDA) in 1999. By improving stance control, these devices may provide increased safety, stability, and function; for example, sensors are designed to recognize a stumble and stiffen the knee, thus avoiding a fall. Microprocessor-controlled knee prostheses also provide users with an improved ability to navigate stairs, slopes, and uneven terrain, and a reduction in energy expenditure and concentration required for ambulation. In general, higher costs for above-knee prostheses result from the knee joint device. As will be discussed later, coverage of microprocessor-controlled knee prostheses is contentious, and several insurance companies do not provide coverage for these devices.

Upper-Extremity Prostheses. Loss of an arm below the level of the elbow is common to traumatic injury, congenital disease, and, to a lesser extent, vascular disease. Limited information is available on the differences in the level of the amputation for upper-extremity amputation. However, amputations above the elbow (transhumeral) are less common and devices used for treatment are more complex, which can significantly increase the cost of the medically appropriate device. Upper-extremity prostheses can provide a range of functionality from a nonfunctional cosmetic hand to fully-functional devices controlled by an individual's nerve impulses.

Ocular Prostheses. Ocular prosthetics are custom-designed to fit in the individual's eye socket. The typical ocular prosthetic consists of two devices: an orbital implant and an artificial eye. After the eye has been removed, the orbital implant, which is made of a porous material, is surgically inserted in the eye socket to maintain the socket's shape. The artificial eye, which is usually made of acrylic plastic, is then placed in the socket. Generally, the prosthetic requires yearly polishing and examination by a professional. Research suggests that children suffering from rare ocular disorders may require up to four new prostheses before the age of 10.

Although the ocular prosthetic is designed to replace the diseased or surgically removed eye, it does not provide sight to the individual. However, ocular prosthetics are evolving and researchers are currently developing devices that may partially restore limited vision. These devices are currently being evaluated in clinical trials.

Prosthetic Device Lifecycles. Because prosthetic devices are unique to the individual, few medical guidelines exist for device

replacement. Moreover, factors such as device usage and compounding conditions impact timelines for repair and replacement. Federal Medicare laws (42 C.F.R. § 414.210) state that the useful lifetime shall not be less than five years.

Medicare Prosthetics Requirements

Medicare restricts payment for prosthetics to those supplied and fabricated by a qualified physician or prosthetist who is accredited by the American Board of Certification in Orthotics and Prosthetics, Inc, the Board for Orthotist / Prosthetist Certification, or other program.

Current Medicare Coverage Levels. Senate Bill 931 would require insurers to provide coverage and reimbursement rates at levels that are comparable to Medicare. Medicare is the federal program that helps pay for a variety of health care services and items on behalf of approximately 41 million elderly and disabled beneficiaries. Most Medicare beneficiaries elect to enroll in Part B insurance, which helps pay for certain physician, outpatient hospital, laboratory, and durable medical equipment (DME) expenses, including prosthetics, if they are medically necessary and prescribed by a physician. Under Part B, Medicare pays for prosthetics based on a series of state-specific fee schedules, which list the fees paid for specific items in each state. Medicare reimburses suppliers according to the supplier's actual charge or the Medicare fee schedule amount, whichever is lower.

With regard to patient costs, Medicare covers 80 percent of the allowable charge of the device, and the patient is responsible for the remaining 20 percent as their coinsurance. The beneficiary must also pay an annual deductible of $100 before Medicare Part B coverage begins for any covered service, not just prostheses. As noted above, Medicare also covers replacements (not less than every five years), repairs, and adjustments.

In an effort to control costs, Medicare now utilizes competitive bidding to set its payment rates for select DME, orthotics, and supply items. Lower and upper limb prosthetics have been excluded from competitive bidding because they are custom-fitted to beneficiaries, even though Medicare spent $463 million on these devices in 2002. However, the Centers for Medicare and Medicaid Services may include prosthetic devices in large-scale bidding in the future, in an effort to reduce payment levels by approximately 20 percent.

Technical Amendment Necessary. Senate Bill 931 as currently drafted contains an incorrect reference to federal Medicare regulations governing prosthetic device payment schedules and replacement timelines. Specifically, the proposed mandate contains an incorrect reference to 42 C.F.R. § 414.410 which should be amended to 42 C.F.R. § 414.210 in order to provide the coverage envisioned by the patron. This technical amendment also is required to provide the coverage levels and reimbursement amounts described in this review.

b. History of Proposed Mandate

A similar bill was previously considered by the Special Advisory Commission on Mandated Health Insurance Benefits in 2003. House Bill 2552 was introduced during the 2003 General Assembly Session; however, the proposed mandate was not tied to the federal Medicare program and only applied to coverage of prosthetic devices prescribed as the result of an above-knee amputation. The Special Advisory Commission voted 11-0 against recommending enactment, concluding that coverage would impact a very small population, and a mandate was not warranted at that time.

Senate Bill 931 is part of a national lobbying campaign by the Amputee Coalition of America to establish "prosthetic parity," and the language of the bill is derived from the advocate's model bill. Eight states currently provide prosthetic device coverage similar to that proposed in SB 931, but not all at Medicare levels: Colorado, Maine, New Hampshire, Massachusetts, Rhode Island, California, Oregon, and Maryland. Additionally, the national advocacy organization indicates that 27 states (including Virginia) are considering legislation based on the model bill, and draft language for a Congressional bill is being developed.

c. Proponents and Opponents of Proposed Mandate

Proponents and opponents of SB 931 will have the opportunity to officially express their views at the public hearing on September 20, 2007, conducted by the Special Advisory Commission on Mandated Health Insurance Benefits. Proponents of the bill appear to be advocates for patients with amputations requiring prosthetic devices, including representatives of the Amputee Coalition of America, the American Academy of Orthotists and Prosthetists, the National Academy of Physical Therapists, the American Academy of Family Physicians, the American Diabetes Association and the American Congress of Rehabilitation Medicine. In addition, proponents have collected more than 250 signatures on a petition in support of Senate Bill 931.

Proponents indicate that patients should have access to coverage of prosthetic devices at levels available through public payer programs to improve the quality of life and reduce long-term health care costs of amputees. Proponents of this legislation advocate that the intention of requiring coverage at the Medicare level is to create a minimum standard of care, a minimum payment rate, and a maximum co-payment amount that each private insurance plan must uphold.

The main opposition to the proposed mandate appears to be from the health insurance industry. Industry representatives oppose the

bill because they indicate that individuals have the ability to select coverage options most suited to their specific situation. Additionally, the industry has concerns over the difficulty in controlling payment amounts based on Medicare payment rates, and a reduction in the medical review role of the insurer. Moreover, industry representatives oppose the direct link to specific sections of federal law regarding Medicare coverage, asserting that the staff time for monitoring changes in federal coverage and modifying coverage positions to comply with Virginia requirements would be burdensome.

MEDICAL EFFICACY AND EFFECTIVENESS

Although safety and effectiveness studies are required by the FDA prior to issuing approval for devices, few empirical studies have been conducted on the efficacy of prosthetic devices. However, researchers have documented the positive effects prostheses can have on patients. The availability of prosthetic devices can improve the physical and psychological functioning of persons with amputations, injuries, and congenital physical disabilities by enabling them to exercise and perform other activities of daily life. In addition, most amputees with prostheses return to some form of work and show a reduction in secondary conditions that can result from their disability.

a. Medical Efficacy of Benefit

Medical Efficacy

Assessments of medical efficacy are typically based on clinical research, particularly randomized clinical trials, demonstrating the success of a particular treatment compared to alternative treatments or no treatment at all.

Given the restorative nature of prosthetics care, researchers have not conducted placebo-controlled studies evaluating the efficacy of each device. Indeed, medical experts in Virginia believe that these studies would be unethical. In the absence of medical efficacy literature, both private and public insurance providers have elected to provide coverage of prosthetic devices to some degree.

In the absence of controlled and randomized clinical studies, researchers have documented the effect prostheses can have on patients' lives since the 1500s. The loss of a limb usually results in functional disability for the person as well as significant psychological implications. For most people, prostheses help restore functional ability and independence. Between 70 and 90 percent of amputees return to some form of work sometime after their injury. Amputees who have access to prosthetic devices show a reduction in the secondary conditions caused by increased sedentary lifestyle, have decreased dependence on caretakers, and a reduced chance of additional medical complications leading to further amputations.

b. Medical Effectiveness of Benefit

The provision of prostheses results in a variety of benefits. Some are fiscal in nature, while others are related to quality of life issues. While research is available on the effectiveness of prosthetic device types, little information is available on the long-term benefits of the prosthetic device to the user. Areas in need of additional research include

- clear and uniform definitions for prosthetic rehabilitation,
- objective measures of patient evaluation to determine appropriateness of care,
- objective measures of improved results in mental health,
- objective measures of prosthetic quality and function; and
- evidence-based practices for the reliable and reproducible use of prosthetic components and designs.

Medical Effectiveness

Medical effectiveness refers to the success of a particular treatment in a normal clinical setting as opposed to ideal or laboratory conditions.

To more completely assess prosthetic use and the potential impact of the proposed mandate, the following empirical data, which is currently unavailable, would be helpful:

- primary reasons for prosthetic need by device type,
- number of individuals by device type,
- lifecycle and replacement costs by device type,
- average insurance reimbursement rates by device type,
- analysis of demographic data (age, location) by device type; and
- total and average individual costs per event (including associated surgical and rehabilitation costs).

SOCIAL IMPACT

Individuals most impacted by the proposed mandate would be Virginian's living with the loss of an eye of limb for whom a prosthetic device is medically necessary. While the specific number of individuals living in Virginia for whom a prosthetic device would be medically necessary is not available, it is estimated that there are between 37,000 and 51,000 Virginians living with the loss of an eye or a limb. Current coverage varies widely; however, 13 percent of insurers' responding to a State Corporation Commission Bureau of Insurance survey indicated that they do not provide coverage for prosthetic devices. While some plans provide unlimited coverage of prosthetic devices included under SB 931, the majority do not provide coverage at the level comparable to Medicare. With the costs of prosthetic devices ranging from $2,000 to $30,000 or more, the

financial hardship on patients may be significant if the plan has a cap on annual device costs or if prescribed devices are not covered.

a. Utilization of Treatment

The number of individuals using prosthetic devices in Virginia is unknown; however, the prevalence rate for amputations can be estimated using national data. Between 4.9 and 6.6 per 1,000 Americans live with limb loss. Based on an estimated Virginia population of 7.6 million, there may be between 37,450 and 50,952 amputees living in Virginia. However, as indicated previously, not all amputees are prescribed a prosthetic device as a course of treatment. While it is not possible to determine the number of individuals currently utilizing treatment options included in SB 931, more than 1,200 devices have been provided under the State employee health plan since 2001 (Table 2). Analysis of current members covered under the State's employee health plan indicates utilization rates similar to national trends. Approximately 60 percent of the individuals currently receiving the proposed benefits have received them for ocular prostheses. Within the group of limb amputees, half of the individuals currently utilizing prosthetic devices have below-knee amputations.

Table 2: Prosthetic Device Usage and Average Payment Amounts for State Employees Since 2001

Device Type	Total Number of Devices	Average Payment Through State Employee Health Plan
Transtibular (Below-Knee)	263	$7,300
Transfemoral (Above-Knee)	180	$11,700[1]
Transradial (Below-Elbow)	*	*
Transhumeral (Above-Elbow)	87	$31,600
Ocular	703	$2,200
Total	**1,233**	

* Data on differences in upper-extremity prostheses usage is not available.

[1] Average cost for above-knee prosthesis includes costs of required below knee device and approximately $4,400 for knee prostheses.

Source: Virginia Department of Human Resources Management and Anthem, Inc.

b. Availability of Coverage

Current coverage of prosthetic devices in Virginia varies widely. The Virginia State Corporation Commission Bureau of Insurance (BOI) surveys Virginia's top 50 insurers regarding proposed mandates. Forty insurers responded to the 2007 survey, with nine of those responses (23 percent) indicating that the company did not provide services in Virginia that would be subject to health insur-

ance mandates. Of the remaining 31 companies, 87 percent indicated that they provided some coverage for prosthetics, but that their coverage may not be equivalent to what SB 931 would require. Moreover, 13 percent of the responding insurers indicated that they do not offer any coverage of prosthetic devices.

While the majority of Virginia's insurers offer some coverage for prosthetics, coverage is often limited by restrictions. The BOI survey identified those restrictions. The most common restrictions were annual dollar limits ranging from $2,000 to $20,000; lifetime dollar limits ranging from $10,000 to $50,000; 50 percent copayments; and repair and replacement coverage only for cases of growth or physical change. Given the high cost of some prosthetic devices, these restrictions may prohibit individuals from obtaining medically prescribed devices. Additionally, some companies may define an amputation as a pre-existing condition and deny coverage for a prosthetic.

Wide variation exists among plan options offered by insurance providers, allowing individuals to select plans with coverage levels that best meet their needs. In addition, coverage of ocular prostheses may be separately included as part of an insurers' vision care plan. Moreover, coverage levels proposed in SB 931 are generally available to individuals who have amputations in response to traumatic injury and are covered outside of their health care insurance through worker's compensation or auto liability insurance.

Data are not available through the BOI survey on changes in coverage levels in Virginia in recent years. However, an online survey conducted by the Amputee Coalition of America in June and July 2007 found that over the past three years, insurance coverage was reduced for 29 percent and eliminated for eight percent of respondents nationally. Additionally, it is not possible to assess the availability of coverage provided by the 20 percent of insurance companies that did not respond to the BOI survey.

Microprocessor-Controlled Devices May be Excluded. Coverage of microprocessor-controlled devices may be excluded for a variety of reasons. Many insurance providers currently classify microprocessor-controlled prostheses as experimental devices and exclude coverage for them on this basis. Other insurers provide coverage for computerized devices such as microprocessors, but the financial caps on plans make these devices cost prohibitive. Some companies explicitly deny coverage for microprocessors or other computerized devices.

Coverage levels established under SB 931 would require coverage of microprocessor-controlled devices. Medicare provides computerized devices, including microprocessor devices, because it does not

consider these devices experimental or investigational. The Centers for Medicare and Medicaid Services (CMS) introduced a reimbursement code for microprocessors in 2002 and established a reimbursement rate of $2,547.

Benefit Categories Can Impact Coverage Limitations. How an insurance company classifies prosthetics may also impact coverage levels and restrictions. Generally, insurance companies group benefits into categories, referred to as "benefit categories," and may place certain limits on coverage of various categories. Proponents indicate that the majority of insurers classify prosthetic devices under the durable medical equipment (DME) benefit category. However, BOI survey responses indicated that 32 percent of insurers did not include prosthetics in a specific benefit category, 35 percent categorized prosthetics as DME, and 32 percent included prosthetics in a separate prosthetic category. The proposed mandate specifically states parameters for coverage of prosthetic care regardless of where it is found in the plan or how it is categorized.

c. Availability of Treatment/ Benefit

Prosthetics Providers in Virginia

The American Board for Certification in Orthotics, Prosthetics and Pedorthics (ABC) is the national certifying and accrediting body for prosthetists. There are 37 ABC-accredited facilities and 222 credentialed providers in Virginia.

Prosthetic devices are widely available in Virginia, although the wide range of devices and associated costs may prohibit individuals from receiving medically appropriate devices. Prosthetic devices are not available unless prescribed by a treating physician. Because Virginia has not elected to require State licensure of prosthetics providers, the total number and location of providers is not available. Therefore, it is not currently possible to identify areas of the State which may be underserved. However, medical professionals, insurance providers, and advocacy organizations contacted during this review indicated that while access to prosthetic device providers may be limited in some rural areas of the State, the overall availability of providers is not a concern.

Most insurance companies provide some level of coverage for prosthetics; however, the level of coverage may not meet the expectations of most people who require prosthetic devices, who expect their insurance to cover any device prescribed by a physician. Advocates and Virginia medical professionals interviewed cited multiple case studies of individuals unable to afford prescribed devices because of high co-payments and low annual expenditure maximums.

d. Availability of Treatment Without Coverage

As previously discussed, the costs of prosthetic devices can be substantial, and insurance coverage of these devices varies widely. Those individuals currently enrolled in the 13 percent of respond-

ing healthcare plans which indicated that they do not provide coverage of prosthetic devices are required to pay out-of-pocket for prosthetic devices prescribed as a course of treatment. Moreover, plans may cover a prosthetic device, but it may not be as advanced a device as prescribed. Additionally, individuals enrolled in plans with device caps or those with high co-payments are also required to cover the difference in the device charges and insurance payment. As will be discussed, these costs may be prohibitive to some individuals obtaining the prescribed device.

e. Financial Hardship

Several factors can impact an individual's ability to access prosthetic devices, foremost of which is cost. Developing an estimate of average cost for prosthetic devices by general type of amputation is difficult as prosthetic care is individualized. Costs can vary widely by device type and individual level of functionality, and individuals may have more than one amputation requiring multiple prostheses. However, if prosthetic care is not covered or individual co-payment amounts are high, individuals may be forced to use their retirement or college savings accounts, refinance a home mortgage, or obtain bank loans or credit lines in order to pay for a prescribed device. As illustrated in Table 3, costs vary by device type and can be substantial:

Limited Cost Data Available

Information on the average cost for prosthetic devices is largely proprietary, and rates are often contractually negotiated between product suppliers and individual prosthetists. Similarly, reimbursement rates paid by Medicare are negotiated and could under-represent current costs charged to private insurance providers. However, information available anecdotally and from patient advocacy groups can be used as general cost guidelines for benchmarking these costs.

- below-knee prostheses that allow the user to stand and walk on level ground costs approximately $5,000 to $7,000;
- prostheses that allow the user to go up and down stairs and traverse uneven terrain cost approximately $10,000;
- prostheses that facilitate running and functioning at a level nearly indistinguishable from someone with two legs cost approximately $12,000 to $15,000;
- microprocessor-controlled devices cost in excess of $30,000;
- nonfunctional cosmetic hands cost between $3,000 and $5,000;
- functional "split hook" device for below-the-elbow amputees cost approximately $10,000,
- fully-functional, cosmetically realistic myoelectric hands that open, close, and can sense pressure and temperature cost $20,000 to $30,000 or more; and
- ocular prostheses cost approximately $2,200.

Using information available anecdotally and from patient advocacy groups, as well as current Medicare reimbursement amounts, general cost guidelines can be developed. As shown in Table 3, individ-

Table 3: Types Prosthetic Devices and Estimated Costs

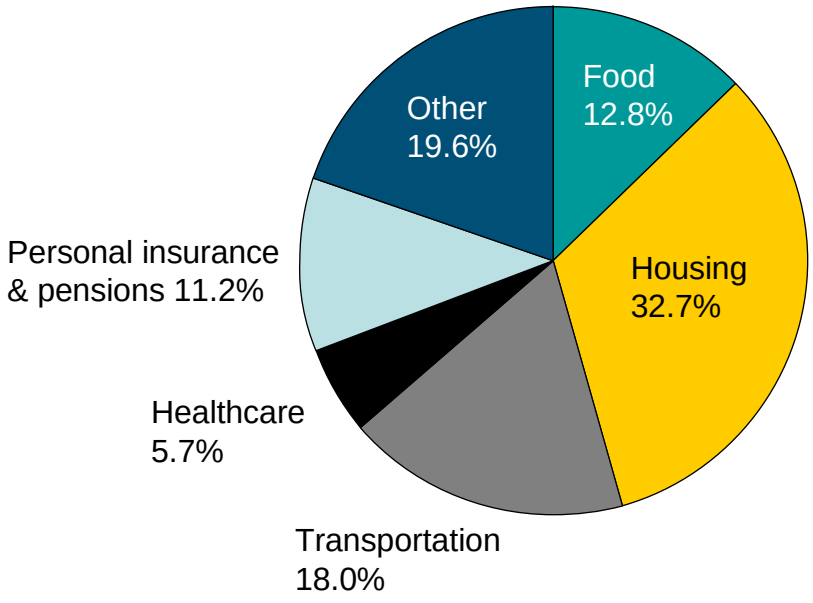
Type	Estimated Cost
Transtibular (Below-Knee)	$5,000 to $15,000
Transfemoral (Above-Knee)	$15,000 to $30,000 [1]
Transradial (Below-Elbow)	$3,000 to $10,000
Transhumeral (Above-Elbow)	$10,000 to $30,000
Ocular	$2,000 to $3,000

[1] Average payment for transfemoral prostheses through the State employee health plan included an estimated $7,300 in below-knee devices and $4,400 for the knee device.

Sources: National Limb Loss Information Center, California Amputee Services Technical Assistance Program, Virginia Department of Human Resources Management, and Anthem, Inc.

ual out-of-pocket cost for obtaining a prosthetic device ranges between $2,000 and $30,000. Based on a median household income of $56,859 in Virginia in 2007, this is between 3.5 and 53 percent of total household income (Figure 1). When considered in terms of estimated annual expenditures on health care of 5.7 percent of total income ($3,241), prosthetic device costs could account for between 62 and 926 percent of estimated expenses. While the cost of a prescribed prosthesis is unique to each individual, a prosthetic device could represent a significant financial hardship on many households.

Figure 1: Distribution of Total Annual U.S. Household Expenditures by Major Category, 2005



Source: Bureau of Labor Statistics, Consumer Expenditure Survey, 2005.

f. Prevalence/ Incidence of Condition

Routine reporting of data on the incidence of amputations in the United States is limited, and specific information for amputations in Virginia does not exist. Information on national incidence of amputation is available from the National Limb Loss Information Center funded through a cooperative agreement between the Centers for Disease Control and Prevention (CDC) and the Amputee Coalition of America, which is the primary proponent of SB 931. This information is the best available and is used in both academic and federal research.

Amputee Estimates for Virginia

According to the Johns Hopkins University Bloomberg School of Public Health, in 2007, one in 150 Americans live with limb loss. Older studies estimated the prevalence rate for amputation at 4.9 per 1,000 persons. Based on an estimated Virginia population of 7.6 million, there may be between 37,450 and 50,952 amputees living in Virginia.

Hospitals discharge approximately 185,000 amputation cases each year in the United States. The main cause of acquired limb loss is poor circulation in a limb due to arterial disease, with the vast majority of amputations occurring among people with diabetes mellitus (Table 4). The number of new cases of limb loss is greatest among persons with diabetes, with one out of every 185 persons diagnosed undergoing amputation of a limb. Amputation of a limb may also occur after a traumatic event or for the treatment of bone cancer. In addition, congenital limb deficiency, the complete or partial absence of a limb at birth, occurs at a rate of 2.6 per 10,000 live births. Of those, upper limb deficiency occurs 1.6 times more often than lower limb deficiency. While traumatic and cancer-related amputations are decreasing, dysvascular amputation rates are increasing largely because medical technology has allowed individuals impacted by diabetes to live longer. The risk of limb loss increases with age, with persons aged 65 years or older having the greatest risk of amputation. As with diabetes, compounding factors such as heart disease, smoking, lack of exercise, and improper nutrition may also increase the risk of limb loss.

Table 4: National Incidence of Limb Loss, 1996

Cause	Amputations per 10,000 persons
Diabetes Mellitus	54.0
Other Dysvascular Disease	4.60
Trauma	0.6
Bone and Joint Cancer	0.04
	Incidence per 10,000 live births
Congenital	2.6

Source: Health Care Utilization Project 1996, National Limb Loss Information Center.

g. Demand for Coverage

Mandating this benefit is not expected to have an impact on an individual demand for prosthetic devices. As previously mentioned, prosthetic devices are prescribed by a physician as a course of treatment for an individual. While an estimate of the total number

of individuals who will be impacted by the proposed mandate is not available, demand for the coverage levels proposed under SB 931 would largely be limited to those individuals enrolled in plans not currently offering coverage for prosthetic devices and those individuals enrolled in plans with low annual expenditure caps or high annual co-payment amounts. It may also affect those individuals with lifetime caps on reimbursement amounts or number of covered devices in younger amputees and children with congenital limb deficiencies.

h. Labor Union Coverage

Labor unions do not appear to have advocated specifically for the inclusion of this benefit in their health benefit packages, although prosthetic coverage has been the focus of worker's compensation concerns. Typically, labor unions advocate for broader benefits, rather than a benefit as specific as the proposed mandate. It is important to note that Virginians' requiring a prosthetic device as a result of a work-related injury should currently have coverage under workers' compensation insurance.

i. State Agency Findings

While government agencies in Virginia have not reviewed the incidence of amputation or utilization of prosthetic devices included in SB 931, multiple federal reviews have highlighted numerous instances of fraud within Medicare's durable medical equipment (DME) and prosthetics programs. In January 2007, the Government Accountability Office reported that between April 1, 2005, and March 31, 2006, Medicare made $700 million (approximately 7.5 percent of total billing) in improper payments for DME, prosthetics, orthotics, and supplies as a result of mistakes, misunderstanding of program rules, fraudulent activities, and abuse. For example, a Medicare beneficiary who has a prosthetic foot due to an amputation should not need a brace for the limb that no longer exists. However, Medicare paid over $2 million from October 2002 through March 2005 for beneficiaries' braces after the program had paid for prosthetics for the same beneficiaries' legs, feet, or ankles.

j. Public Payer Coverage

Several options exist to assist Virginians without health insurance in obtaining medically prescribed prosthetic devices. Virginians who are elderly or have a disability can obtain coverage through the federal Medicare program. Additionally, low-income, uninsured Virginians can receive coverage through the State's Medicaid program. Moreover, Virginia's medical colleges and several

private foundations have established indigent care programs designed to offset the costs for individuals who do not have insurance but are not eligible for public payer coverage options. Medical experts indicate that due to the wide variation in private insurance coverage policies, mandating private insurance coverage at Medicare levels may help establish a base level of care that should not impact the physician's ability to determine the most medically appropriate devices for each individual. Indeed, public health professionals have indicated that Medicare coverage is strictly for medically necessary devices and establishes a restrictive, rather than permissive, level of coverage.

As mentioned previously, the proposed mandate would require insurers to provide coverage of prosthetic devices at the level of Medicare coverage. Virginia's Medicaid program also covers prosthetic devices at levels comparable to Medicare. Medicaid covers prosthetics, including ocular prosthetics, in all cases where their use is medically necessary and appropriate; however, it will only pay for the "minimum applicable component necessary for the activities of daily living." The Department of Medical Assistance Services (DMAS) requires that the prosthetist obtain preauthorization prior to Medicaid covering the device. Medicaid pays the prosthetist the Medicaid fee schedule, the actual charge, or the Medicare payment amount, whichever is the lowest amount.

While it is not possible to estimate the direct impact on public payer programs, qualitative analysis suggests that mandating coverage at the Medicare level could have positive effects on public payer programs. Anecdotally, it has been reported that individuals with insufficient coverage for prosthetic devices have not been able to retain employment, thereby not being able to afford the prescribed device and having to obtain coverage through the federal and State programs. Mandating coverage under SB 931 is not expected to increase the number of individuals seeking care through Virginia's Medicaid program, and has the potential to reduce the number of individuals that may seek Medicaid coverage.

k. Public Health Impact

Public health impacts of mandating coverage of this benefit are expected to be minimal as these devices are restorative in nature and would apply only to those prosthetic device users whose amputations resulted from medical conditions or congenital disease. However, given that the population affected by this mandate would be under 65, the potential social impact of the proposed mandate would be the ability of individuals to more fully contribute to society. Qualitative data suggests that use of prosthetic devices increases the quality of life for the user. This has the potential to reduce the cost of additional complications or amputations,

as well as the incidence of compounding disease related to increased sedentary lifestyle.

FINANCIAL IMPACT

Mandating coverage under SB 931 is not expected to impact the cost of prosthetic devices or increase the number of providers. However, mandating coverage will likely increase the number of individuals able to obtain devices that have been prescribed as a course of treatment. Mandating coverage may reduce the overall costs of health care due to a reduction in secondary complications. Mandating coverage at a level directly linked to the federal Medicare program will require insurance companies to monitor federal program requirements; however, costs associated with negotiating rates with individual device suppliers would be reduced. Additionally, the impact on premiums charged to customers would be minimal and less than the estimated premium impact of other healthcare mandates.

a. Effect on Cost of Treatment

Mandating coverage at the Medicare level is not expected to increase the cost of ocular or prosthetic devices prescribed for individuals living with limb loss. Moreover, national efforts to contain Medicare costs may reduce reimbursement rates for the devices covered under SB 931, thereby reducing the amounts paid by private insurance providers if they are required to use Medicare reimbursement amounts.

b. Change in Utilization

Mandating coverage of prosthetic devices will not increase the incidence of amputations or the number of individuals for which a prosthetic device would be determined to be medically necessary and appropriate. However, mandating this level of coverage is anticipated to increase the number of individuals that have access to prosthetic devices and the types of devices to which they have access, thereby increasing utilization of prosthetic devices when prescribed as a course of treatment.

However, mandating that coverage must, at a minimum, be provided at the level of the federal Medicare program also has the potential to reduce benefits for individuals whose current benefit level and co-payment exceeds the Medicare standard. While insurance providers may continue to provide optional coverage, establishing Medicare as the standard level of care may reduce benefits or increase co-payment amounts for a subset of currently insured individuals.

The current demand for prosthetic devices is already relatively low, and the proposed mandate is not likely to affect physicians' determinations of medical necessity. In general, health insurance mandates only affect Virginians who receive insurance from a fully-insured employer or who purchase their health insurance through the individual market. Approximately 26.5 percent of Virginians fall into one of these categories. Of the group affected by mandates, according to the BOI survey of insurers, approximately 92 percent have some coverage for prosthetics. However, the level of coverage varies, and it may not be equivalent to the coverage required by SB 931.

c. Serves as an Alternative

Mandating coverage of prosthetic devices at the Medicare level would establish a minimum level of care for restoring functionality to individuals enrolled in plans that do not offer coverage of prosthetic devices. In many cases, a prosthesis may serve as an alternative to the individual being wheelchair bound, which may lead to additional medical complications, such as skin breakdown, osteoporosis, muscle loss, and depression. Additionally, ocular prostheses have the ability to help improve an individual's self-image and maintain employment. In cases where the existing level of coverage is less than the Medicare level, coverage at the Medicare level would provide improved (and potentially more expensive) alternatives for the devices available. As prosthetic devices are restorative in nature, the proposed coverage does not serve as an alternative to the causes of limb or eye loss.

d. Effect on Providers

Prosthetic care is provided by certified prosthetists in consultation with other health care professionals including surgeons, physicians and physical therapists. Once an individual has been assessed, and the prescription has been written, it is the responsibility of the prosthetist to design, fabricate, and fit the device. There are more than 200 providers in all areas of Virginia. This bill is not expected to significantly increase the number of providers of these services in Virginia. This bill also does not mandate a new class of providers and does not seek to mandate a new class of practitioners.

e. Administrative and Premium Costs

Mandating prosthetics coverage is expected to have a minimal effect on both health insurance premium costs and insurance company administrative expenses. As Medicare has an established fee schedule, insurance companies will be required to monitor the schedule for changes. However, insurance companies should ex-

perience a decrease in costs associated with negotiating device rates, since the mandate will set their reimbursement rates at the Medicare rate. Other states that have reviewed similar mandates have estimated the premium impact on the consumer to be between $0.12 and $0.35 per premium per month. Estimates for Virginia were even lower; with per premium per month impacts between $0.02 and $0.08.

Administrative Expenses of Insurance Companies. Insurance companies do not provide estimates on the administrative expenses separately in their responses to the BOI survey. However, the administrative expenses for insurance companies related to SB 931 would likely be similar to other mandates. The proposed mandate may require insurance companies to invest additional staff time in monitoring Medicare coverage policies, and to change their policies when Medicare policy changes. Additionally, because Medicare reimbursement rates are established on a state-by-state basis, insurance companies would be required to tailor products offered in Virginia to current Medicare reimbursement rates for Virginia. This has the potential to reduce the ability of providers to negotiate rates independent of Medicare rates. However, establishing the Medicare payment rate as the basis for coverage could have the effect of reducing the insurers' costs associated with negotiating device rates with prosthetics suppliers, as well as subject rates paid for devices to the current cost control and competitive bidding requirements that govern current Medicare reimbursement.

The bill does not impact the insurers' ability to require preauthorization to determine medical necessity and the eligibility of benefits for prosthetic devices and components, in the same manner that prior authorization is currently required for any other covered benefit. An insurer, corporation, or health maintenance organization may require that prosthetic services be rendered by a provider that contracts with the carrier and that a prosthetic device or component be provided by a vendor designated by that insurer.

Premium and Administrative Expenses of Policyholders. BOI annually surveys the top 50 Virginia health insurers on the premium impact of proposed mandates. While an overall response rate of 80 percent (40 companies) was achieved, a relatively small number of insurance companies provided estimated monthly premium costs for SB 931, which may limit the usefulness of the estimates. The estimates provided varied widely.

Among the 27 insurance companies indicating that coverage was available as part of either standard or optional packages, very few provided an estimate of monthly premium costs. In terms of individual policyholders, ten companies provided a monthly premium estimate for the standard benefit, and none of the companies pro-

vided an estimate for the optional benefit (Table 4). In terms of group policyholders, 14 companies provided an estimate for the standard benefit, and three companies provided estimates for the optional benefit.

For individual plans, premium estimates ranged from $0.12 to $1.00 for the standard benefit, and estimates for optional coverage were unavailable. The median premium impact estimate for individual standard coverage is $0.18 per member per month. This median premium estimate amounts to less than one one-hundredth of a percent of the average monthly premium for a standard single individual contract ($214), as defined in BOI's 2005 report on the financial impact of mandated health insurance benefits. As a result, the proposed mandate would probably have a smaller impact on premiums for individual coverage than any existing mandates. However, due to the very small sample size, it is difficult to know whether the premiums reported on the survey are representative of expected premium impacts.

For group plans, premium estimates ranged from $0.11 to $1.73 for the standard benefit, with the median premium impact estimate at $0.24 per member per month. Three plans reported estimates for optional group coverage, which ranged between $0.11 and $22.29, with the median estimate at $0.11. Given the few responses regarding the premium impact for optional group coverage, the median estimate is largely unreliable, but does establish the range of premium impact as estimated by insurance carriers. The BOI report on the financial impact of mandated health insurance benefits does not include information on the average monthly premium for group plans, so it is difficult to determine what proportion of the overall premium the proposed mandate would constitute. However, it is likely that the impact on monthly premiums would be relatively small compared to most existing mandates.

Table 4: Estimated Monthly Premium Impact of SB 931

	# of Responses	Median Estimate	Highest Estimate	Lowest Estimate
Individual (standard)	10	$0.18	$1.00	$0.12
Individual (optional)	0	--	--	--
Group (standard)	14	$0.24	$1.73	$0.11
Group (optional)	3	$0.11	$22.29	$0.11

Source: Bureau of Insurance Survey of Insurance Providers, 2007.

Studies from several other states including Texas, Massachusetts, Colorado, California, and New Jersey found the increase in individual standard premiums could range from 12 to 25 cents per member per month. Several of these studies also found a potential cost savings in both private and public sector health insurance from reduced spending on associated complications, physical rehabilitation, and coverage provided under State Medicaid programs.

f. Total Cost of Health Care

The proposed mandate is not expected to have a significant impact on overall healthcare costs in Virginia, and may reduce total overall costs. Costs to insurance companies will most likely increase as a result of providing increased coverage for prosthetic devices. However, establishing a baseline level of coverage has the potential to reduce costs associated with individual coverage appeals related to current restrictions on prosthetic care. Mandating this coverage will not reduce the incidence of precursor events resulting in the need for a prosthetic. However, individuals enrolled in plans that do not offer prosthetics coverage or those with low annual caps or high co-payments, may be unable to afford to cover the entire expense of a prosthetic device. Without prosthetic care, many individuals will lead a more sedentary lifestyle which may lead to secondary complications depending on procedures used and the patient's lifespan, including

- costs of medications for diabetes-related complications;
- instances of heart attack due to peripheral vascular disease, for which surgical treatment and hospitalization can cost from $75,000 to $200,000;
- development of knee or hip problems from being unable to walk correctly, for which surgery can cost from $80,000 to $150,000 or more; and
- crutch overuse leading to wrist, elbow and shoulder problems, which can cost between $7,500 and $25,000.

Medical experts in Virginia reported that increasing access to medically appropriate prosthetic devices for those that do not have adequate coverage reduces additional medical procedures associated with an increased sedentary lifestyle following an amputation.

BALANCING MEDICAL, SOCIAL, AND FIANCIAL CONSIDERATIONS

Given the potentially significant financial impact to an individual or family for obtaining a medically prescribed prosthetic device,

the proposed mandate is consistent with the role of insurance. While the majority of Virginia's fully-insured plans offer some level of coverage for prosthetic devices, some plans do not offer any coverage of these devices, and coverage levels for other plans may be inadequate for an individual to obtain the device prescribed. Mandating coverage defined in SB 931 would establish a minimum level of coverage for individuals requiring prostheses and increase individual access to certain device types. Moreover, the impact on monthly premium costs is estimated to be consistent with other mandates. While it is not possible to definitively conclude that the Medicare coverage level is most appropriate for meeting individual needs in all cases, several other states have mandated the coverage level proposed in SB 931.

a. Social Need/ Consistent With Role of Insurance

Based on the premise that the role of health insurance is to promote public health, encourage the use of preventive care, and to provide protection from catastrophic financial expenses for unexpected illness or injury, the proposed mandate appears consistent with the role of health insurance. Prosthetic devices are restorative in nature, and often allow a user to regain a level of social functionality comparable to their pre-amputation condition. While these devices do not treat the initial reason for the amputation, they may prevent additional medical complications.

However, the costs of these devices may prevent individuals from obtaining a prescribed course of medical treatment, and insurance companies have recognized this. While most Virginians covered through fully-insured plans have access to prosthetic device coverage at levels lower than the proposed mandate (an estimated 87 percent of plans offer some level of coverage), some plans are available that provide unlimited coverage of these devices, some plans do not offer any coverage of prosthetic devices, and some plans provide coverage levels which may be inadequate for an individual to obtain a medically prescribed device. Moreover, most individuals do not know what level of prosthetic device coverage they have until they need to use the benefit. This lack of information leads to a gap between an individual's expectation that their insurance will cover any device that a physician prescribes, and the coverage level actually provided. The proposed mandate would establish a basic level of coverage for these devices and help eliminate the gap between individual's expectations and actual insurance coverage.

b. Need Versus Cost

The amputee population in Virginia is relatively small, but a lack of adequate coverage of prosthetic devices can dramatically impact an individual's life. 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. This more sedentary lifestyle may lead to an inability to maintain employment, an increased reliance on caretakers, an increased likelihood of experiencing depression, and increased morbidity.

Given the potentially high costs of medically prescribed prosthetic devices for some consumers and the lack, or limitations, of coverage, obtaining a device prescribed as a course of medical treatment may be a considerable financial burden on an individual whose income may already be constrained as a result of the loss of limb or eye. Both Virginia medical professionals and advocates of the proposed mandate cite multiple examples of individuals unable to afford prescribed devices because of high co-payments and low annual expenditure caps for prosthetic devices. Mandating coverage under SB 931 would establish a basic level of coverage for these devices. Additionally, the mandate would better ensure that individuals have access to medically appropriate devices prescribed as a course of treatment.

The premium impact of mandating the proposed coverage should be relatively low because relatively few fully-insured individuals require prostheses. If the proposed level of coverage is mandated, the costs of more technically complex prostheses (transfemoral and transhumeral) will be spread over the large pool of fully-insured individuals. Median estimates of the increases in premium costs for standard individual and group coverage are $0.20 and $0.28 per month, respectively. While the proposed mandate will likely increase coverage levels for most insured Virginians, it is possible that the proposed mandate may eventually result in the reduction of coverage levels for a small subset of insured people who currently have more extensive prosthetic device coverage than the Medicare level.

Because the medically appropriate prosthetic device is based on an individual's specific medical condition, and associated costs are based on the device prescribed, it is not possible to definitively determine what minimum level of coverage would be most appropriate to meet the need of each fully-insured Virginian. Given the available data, Senate Bill 931 would establish a basic level of coverage both in terms of devices covered and individual consumer costs by mandating the Medicare level of coverage. Other states

that have mandated prosthetics coverage have based their benefit requirements on the Medicare coverage levels proposed in SB 931.

Insurance companies have raised the concern that linking coverage levels to federal Medicare policy may limit their ability to negotiate rates with prosthetic device providers and increase administrative costs associated with monitoring federal coverage levels. One alternative for addressing this concern may be to amend the proposed mandate to follow the Medicare framework regarding the devices covered by Medicare and require the insurer to pay 80 percent of the patient charges, but not require insurers to follow the Medicare fee schedule for devices. This approach would not constrain insurers' ability to negotiate specific device costs with prosthetic device manufacturers. Regardless, the proposed mandate requires a technical amendment to reference appropriate Medicare regulations governing prosthetic device payment schedules and replacement timelines to establish this coverage level.

c. Mandated Offer

A mandated offer of prosthetic coverage at the Medicare level may also address advocate and patient concerns over variations in coverage by ensuring that a uniform coverage option is widely available. However, based on responses to the BOI survey, a mandated offer may significantly increase the premium costs for individuals and companies that select this option; only three companies reported cost estimates for the group option, ranging from $0.11 to more than $22 per month for a group option.

A mandated offer would still require administrative costs associated with monitoring federal Medicare levels and developing products that would meet Virginia's requirements. However, a mandated offer would draw the healthcare purchaser's attention to prosthetic device coverage during the plan selection period. Some employers and individual consumers will likely purchase the upgraded prosthetic coverage. Other purchasers will not buy this extra coverage, but they will at least be made aware of their current level of prosthetic device coverage.

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the Virginia Association of Health Plans, and the Department of Human Resources Management.

Appendix A

Statutory Authority for JLARC Evaluation of Proposed Mandated Health Insurance Benefits

§ 2.2-2503. Special Advisory Commission on Mandated Health Insurance Benefits; membership; terms; meetings; compensation and expenses; staff; chairman's executive summary.

A. The Special Advisory Commission on Mandated Health Insurance Benefits (the Commission) is established as an advisory commission within the meaning of § 2.2-2100, in the executive branch of state government. The purpose of the Commission shall be to advise the Governor and the General Assembly on the social and financial impact of current and proposed mandated benefits and providers, in the manner set forth in this article.

B. The Commission shall consist of 18 members that include six legislative members, 10 nonlegislative citizen members, and two ex officio members as follows: one member of the Senate Committee on Education and Health and one member of the Senate Committee on Commerce and Labor appointed by the Senate Committee on Rules; two members of the House Committee on Health, Welfare and Institutions and two members of the House Committee on Commerce and Labor appointed by the Speaker of the House of Delegates in accordance with the principles of proportional representation contained in the Rules of the House of Delegates; 10 nonlegislative citizen members appointed by the Governor that include one physician, one chief executive officer of a general acute care hospital, one allied health professional, one representative of small business, one representative of a major industry, one expert in the field of medical ethics, two representatives of the accident and health insurance industry, and two nonlegislative citizen members; and the State Commissioner of Health and the State Commissioner of Insurance, or their designees, who shall serve as ex officio nonvoting members.

C. All nonlegislative citizen members shall be appointed for terms of four years. Legislative and ex officio members shall serve terms coincident with their terms of office. All members may be reappointed. However, no House member shall serve more than four consecutive two-year terms, no Senate member shall serve more than two consecutive four-year terms, and no nonlegislative citizen member shall serve more than two consecutive four-year terms. Vacancies occurring other than by expiration of a term shall be filled for the unexpired term. Vacancies shall be filled in the manner as the original appointments. The remainder of any term to which a member is appointed to fill a vacancy shall not constitute a term in determining the member's eligibility for reappointment.

D. The Commission shall meet at the request of the chairman, the majority of the voting members or the Governor. The Commission shall elect a chairman and a vice-chairman, as determined by the membership. A majority of the members of the Commission shall constitute a quorum.

E. Legislative members of the Commission shall receive such compensation as provided in § 30-19.12, and nonlegislative citizen members shall receive such compensation for the performance of their duties as provided in § 2.2-2813. All members shall be reimbursed for all reasonable and

necessary expenses incurred in the performance of their duties as provided in §§ 2.2-2813 and 2.2-2825. Funding for the compensation and costs of expenses of the members shall be provided by the State Corporation Commission.

F. The Bureau of Insurance, the State Health Department, and the Joint Legislative Audit and Review Commission and such other state agencies as may be considered appropriate by the Commission shall provide staff assistance to the Commission. The Joint Legislative Audit and Review Commission shall conduct assessments, analyses, and evaluations of proposed mandated health insurance benefits and mandated providers as provided in subsection D of § 30-58.1, and report its findings with respect to the proposed mandates to the Commission.

G. The chairman of the Commission shall submit to the Governor and the General Assembly an annual executive summary of the interim activity and work of the Commission no later than the first day of each regular session of the General Assembly. The executive summary shall be submitted as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents and reports and shall be posted on the General Assembly's website.

§ 30-58.1. Powers and duties of Commission.

The Commission shall have the following powers and duties:

A. Make performance reviews of operations of state agencies to ascertain that sums appropriated have been, or are being expended for the purposes for which such appropriations were made and to evaluate the effectiveness of programs in accomplishing legislative intent;

B. Study on a continuing basis the operations, practices and duties of state agencies, as they relate to efficiency in the utilization of space, personnel, equipment and facilities;

C. Make such special studies and reports of the operations and functions of state agencies as it deems appropriate and as may be requested by the General Assembly;

D. Assess, analyze, and evaluate the social and economic costs and benefits of any proposed mandated health insurance benefit or mandated provider, including, but not limited to, the mandate's predicted effect on health care coverage premiums and related costs, net costs or savings to the health care system, and other relevant issues, and report its findings with respect to the proposed mandate to the Special Advisory Commission on Mandated Health Insurance Benefits; and

E. Make such reports on its findings and recommendations at such time and in such manner as the Commission deems proper submitting same to the agencies concerned, to the Governor and to the General Assembly. Such reports as are submitted shall relate to the following matters:

1. Ways in which the agencies may operate more economically and efficiently;

2. Ways in which agencies can provide better services to the Commonwealth and to the people; and

3. Areas in which functions of state agencies are duplicative, overlapping, or failing to accomplish legislative objectives or for any other reason should be redefined or redistributed.

Appendix B

Proposed Mandated Benefit Requiring Coverage of Prosthetic Devices

SENATE BILL NO. 931
Offered January 10, 2007
Prefiled January 9, 2007

A BILL to amend and reenact § 38.2-4319 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 38.2-3418.15, relating to health insurance coverage for prosthetic devices and components.

Patrons-- Ticer and Howell; Delegate: O'Bannon

Referred to Committee on Commerce and Labor

Be it enacted by the General Assembly of Virginia:

1. That § 38.2-4319 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding a section numbered 38.2-3418.15 as follows:

§ 38.2-3418.15. Coverage for prosthetic devices and components.

A. Notwithstanding the provisions of § 38.2-3419, each insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; each corporation providing individual or group accident and sickness subscription contracts; and each health maintenance organization providing a health care plan for health care services shall provide coverage for the cost of prosthetic devices and components, if the treating physician certifies the medical necessity of the prosthetic device and component as a proposed course of treatment, that, at a minimum, equals the coverage provided under the federal Medicare program pursuant to 42 U.S.C. §§ 1395k, 1395l, and 1395m and 42 C.F.R. parts 414.202, 414.410, 414.228, and 410.100, as applicable.

B. As used in this section:

"Component" means the materials and equipment needed to ensure the comfort and functioning of a prosthetic device.

"Limb" means an arm, a hand, a leg, a foot or any portion of an arm, a hand, a leg, or a foot.

"Prosthetic device" means 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).

C. An insurer, corporation, or health maintenance organization 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.

D. Coverage under this section shall also include the fitting, repair, or replacement of a prosthetic device and component, 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.

E. An insurer, corporation, or health maintenance organization may require that prosthetic services be rendered by a provider that contracts with the carrier and that a prosthetic device or component be provided by a vendor designated by that insurer.

F. Coverage shall not be required for a prosthetic device that is designed exclusively for athletic purposes.

G. No insurer, corporation, or health maintenance organization shall impose upon any person receiving benefits pursuant to this section any copayment, coinsurance, or deductible amounts, or any policy year, calendar year, lifetime, or other durational benefit limitation or maximum for benefits or services, that is not equally imposed upon all terms and services covered under the policy, contract, or plan.

H. The requirements of this section shall apply to all insurance policies, contracts, and plans delivered, issued for delivery, reissued, or extended in the Commonwealth on and after January 1, 2008, or at any time thereafter when any term of the policy, contract, or plan is changed or any premium adjustment is made.

I. This section shall not apply to short-term travel, accident-only, limited or specified disease, or individual conversion policies or contracts, nor to policies or contracts designed for issuance to persons eligible for coverage under Title XVIII of the Social Security Act, known as Medicare, or any other similar coverage under state or federal governmental plans.

§ 38.2-4319. Statutory construction and relationship to other laws.

A. No provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-100, 38.2-136, 38.2-200, 38.2-203, 38.2-209 through 38.2-213, 38.2-216, 38.2-218 through 38.2-225, 38.2-229, 38.2-232, 38.2-305, 38.2-316, 38.2-322, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620, Chapter 9 (§ 38.2-900 et seq.), §§ 38.2-1017 through 38.2-1023, 38.2-1057, Article 2 (§ 38.2-1306.2 et seq.), § 38.2-1315.1, Articles 3.1 (§ 38.2-1316.1 et seq.), 4 (§ 38.2-1317 et seq.) and 5 (§ 38.2-1322 et seq.) of Chapter 13, Articles 1 (§ 38.2-1400 et seq.) and 2 (§ 38.2-1412 et seq.) of Chapter 14, §§ 38.2-1800 through 38.2-1836, 38.2-3401, 38.2-3405, 38.2-3405.1, 38.2-3407.2 through 38.2-3407.6:1, 38.2-3407.9 through 38.2-3407.16, 38.2-3411.2, 38.2-3411.3, 38.2-3411.4, 38.2-3412.1:01, 38.2-3414.1, 38.2-3418.1 through ~~38.2-3418.14~~ *38.2-3418.15*, 38.2-3419.1, 38.2-3430.1 through 38.2-3437, 38.2-3500, subdivision 13 of § 38.2-3503, subdivision 8 of § 38.2-3504, §§ 38.2-3514.1, 38.2-3514.2, 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3540.1, 38.2-3542, 38.2-3543.2, Article 5 (§ 38.2-3551 et seq.) of Chapter 35, Chapter 52 (§ 38.2-5200 et seq.), Chapter 55 (§ 38.2-5500 et seq.), Chapter 58 (§ 38.2-5800 et seq.) and § 38.2-5903 of this title shall be appli-

cable to any health maintenance organization granted a license under this chapter. This chapter shall not apply to an insurer or health services plan licensed and regulated in conformance with the insurance laws or Chapter 42 (§ 38.2-4200 et seq.) of this title except with respect to the activities of its health maintenance organization.

B. For plans administered by the Department of Medical Assistance Services that provide benefits pursuant to Title XIX or Title XXI of the Social Security Act, as amended, no provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-100, 38.2-136, 38.2-200, 38.2-203, 38.2-209 through 38.2-213, 38.2-216, 38.2-218 through 38.2-225, 38.2-229, 38.2-232, 38.2-322, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620, Chapter 9 (§ 38.2-900 et seq.), §§ 38.2-1017 through 38.2-1023, 38.2-1057, Article 2 (§ 38.2-1306.2 et seq.), § 38.2-1315.1, Articles 3.1 (§ 38.2-1316.1 et seq.), 4 (§ 38.2-1317 et seq.) and 5 (§ 38.2-1322 et seq.) of Chapter 13, Articles 1 (§ 38.2-1400 et seq.) and 2 (§ 38.2-1412 et seq.) of Chapter 14, §§ 38.2-3401, 38.2-3405, 38.2-3407.2 through 38.2-3407.5, 38.2-3407.6 through 38.2-3407.6:1, 38.2-3407.9 through 38.2-3407.09:02, subdivisions 1, 2, and 3 of subsection F of § 38.2-3407.10, 38.2-3407.11, 38.2-3407.11:3, 38.2-3407.13 through 38.2-3407.14, 38.2-3411.2, 38.2-3418.1, 38.2-3418.2, 38.2-3419.1, 38.2-3430.1 through 38.2-3437, 38.2-3500, subdivision 13 of § 38.2-3503, subdivision 8 of § 38.2-3504, §§ 38.2-3514.1, 38.2-3514.2, 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3540.1, 38.2-3542, 38.2-3543.2, Chapter 52 (§ 38.2-5200 et seq.), Chapter 55 (§ 38.2-5500 et seq.), Chapter 58 (§ 38.2-5800 et seq.) and § 38.2-5903 shall be applicable to any health maintenance organization granted a license under this chapter. This chapter shall not apply to an insurer or health services plan licensed and regulated in conformance with the insurance laws or Chapter 42 (§ 38.2-4200 et seq.) of this title except with respect to the activities of its health maintenance organization.

C. Solicitation of enrollees by a licensed health maintenance organization or by its representatives shall not be construed to violate any provisions of law relating to solicitation or advertising by health professionals.

D. A licensed health maintenance organization shall not be deemed to be engaged in the unlawful practice of medicine. All health care providers associated with a health maintenance organization shall be subject to all provisions of law.

E. Notwithstanding the definition of an eligible employee as set forth in § 38.2-3431, a health maintenance organization providing health care plans pursuant to § 38.2-3431 shall not be required to offer coverage to or accept applications from an employee who does not reside within the health maintenance organization's service area.

F. For purposes of applying this section, "insurer" when used in a section cited in subsections A and B of this section shall be construed to mean and include "health maintenance organizations" unless the section cited clearly applies to health maintenance organizations without such construction.

Appendix C

Evaluation Topic Areas and Criteria for Assessing Proposed Mandated Health Insurance Benefits

Topic Area	Criteria
1. Medical Efficacy	
a. Medical Efficacy of Benefit	The contribution of the benefit to the quality of patient care and the health status of the population, including the results of any clinical research, especially randomized clinical trials, demonstrating the medical efficacy of the treatment or service compared to alternatives or not providing the treatment or service.
b. Medical Effectiveness of Benefit *JLARC Criteria**	The contribution of the benefit to patient health based on how well the intervention works under the usual conditions of clinical practice. Medical effectiveness is not based on testing in a rigid, optimal protocol, but rather a more flexible intervention that is often used in broader populations.
c. Medical Efficacy of Provider	If the legislation seeks to mandate coverage of an additional class of practitioners: 1) The results of any professionally acceptable research, especially randomized clinical trials, demonstrating the medical results achieved by the additional class of practitioners relative to those already covered. 2) The methods of the appropriate professional organization to assure clinical proficiency.
d. Medical Effectiveness of Provider *JLARC Criteria**	The contribution of the practitioner to patient health based on how well the practitioner's interventions work under the usual conditions of clinical practice. Medical effectiveness is not based on testing in a rigid, optimal protocol, but rather more flexible interventions that are often used in broader populations.
2. Social Impact	
a. Utilization of Treatment	The extent to which the treatment or service is generally utilized by a significant portion of the population.
b. Availability of Coverage	The extent to which insurance coverage for the treatment or service is already generally available.
c. Availability of Treatment *JLARC Criteria**	The extent to which the treatment or service is generally available to residents throughout the state.
d. Availability of Treatment Without Coverage	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.
e. Financial Hardship	If the coverage is not generally available, the extent to which the lack of coverage result in unreasonable financial hardship on those persons needing treatment.
f. Prevalence/Incidence of Condition	The level of public demand for the treatment or service.
g. Demand for Coverage	The level of public demand and the level of demand from providers for individual or group insurance coverage of the treatment or service.

h. Labor Union Coverage	The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts.
i. State Agency Findings	Any relevant findings of the state health planning agency or the appropriate health system agency relating to the social impact of the mandated benefit.
j. Public Payer Coverage *JLARC Criteria**	The extent to which the benefit is covered by public payers, in particular Medicaid and Medicare.
k. Public Health Impact *JLARC Criteria**	Potential public health impacts of mandating the benefit.
3. Financial Impact	
a. Effect on Cost of Treatment	The extent to which the proposed insurance coverage would increase or decrease the cost or treatment of service over the next five years.
b. Change in Utilization	The extent to which the proposed insurance coverage might increase the appropriate or inappropriate use of the treatment or service.
c. Serves as an Alternative	The extent to which the mandated treatment or service might serve as an alternative for more expensive or less expensive treatment or service.
d. Impact on Providers	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.
e. Administrative and Premium Costs	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.
f. Total Cost of Health Care	The impact of coverage on the total cost of health care.
4. Effects of Balancing Medical, Social, and Financial Considerations	
a. Social Need/Consistent with Role of Insurance	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.
b. Need Versus Cost	The extent to which the need for coverage outweighs the costs of mandating the benefit for all policyholders.
c. Mandated Option	The extent to which the need for coverage may be solved by mandating the availability of the coverage as an option for policy holders.

*Denotes additional criteria added by JLARC staff to criteria adopted by the Special Advisory Commission on Mandated Health Insurance Benefits.

Source: Special Advisory Commission on Mandated Health Insurance Benefits and JLARC staff analysis.

Appendix D

Bibliography

PEER-REVIEWED RESEARCH

Alan, RK, et al (2007). Function of children with myelodysplasia and lower extremity amputations. Journal of Pediatric Orthopedics, 27: 51-53.

Bayne, T, Levy, N (2005). Amputees by choice: body integrity identity disorder and the ethics of amputation. Journal of Applied Philosophy, 22.

Boulias, C, et al (2006). Return to driving after lower-extremity amputation. Archives of Physical Medicine and Rehabilitation, 87:1183-1188.

Busse, JW, et al (2007). Limb salvage or early amputation for severe lower-limb injury: a meta-analysis of observational studies. Journal of Orthopaedic Trauma, 21: 70-76.

Canfield, MA, et al (2006). National estimates and race/ethnic-specific variation of selected birth defects in the United States, 1999–2001. Birth Defects Research (Part A), 76: 747–756.

Carrozza, MC, et al (2006). Design of a cybernetic hand for perception and action. Biological Cybernetics, 95: 629–644.

Cavanagh, SR, et al (2006). Psychiatric and emotional sequelae of surgical amputation. Psychosomatics, 47: 459–464.

Chin, T, Sawamura, S, Shiba, R (2006). Effect of physical fitness on prosthetic ambulation in elderly amputees. American Journal of Physical Medicine and Rehabilitation, 85: 992–996.

Cumming, JC, Barr, S, Howe, TE (2006). Prosthetic rehabilitation for older dysvascular people following a unilateral transfemoral amputation. Cochrane Database of Systematic Reviews, Issue 4. Art. No.: CD005260. DOI: 10.1002/14651858.CD005260.pub2.

Desmond, DM (2007). Coping, affective distress, and psychosocial adjustment among people with traumatic upper limb amputations. Journal of Psychosomatic Research, 62: 15– 21.

Eslami, MH, Zayaruzny, M, Fitzgerald, GA (2007). The adverse effects of race, insurance status, and low income on the rate of amputation in patients presenting with lower extremity ischemia. Journal of Vascular Surgery, 45: 55-59.

Gallagher, P, et al (2007): Body image in people with lower-limb amputation: a Rasch analysis of the amputee body image scale. American Journal of Physical Medicine and Rehabilitation, 86: 205–215.

Hafner, BJ, et al (2007). Evaluation of function, performance, and preference as transfemoral amputees transition from mechanical to microprocessor control of the prosthetic knee. Archives of Physical Medicine and Rehabilitation, 88: 207-217.

Hijjawi, JB, et al (2006). Improved myoelectric prosthesis control accomplished using multiple nerve transfers. Plastic and Reconstructive Surgery, 118: 1573-1578.

James, MA, et al (2006). Impact of prostheses on function and quality of life for children with unilateral congenital below-the elbow deficiency. Journal of Bone and Joint Surgery, American Volume. 88: 2356-2365.

MacKenzie, EJ, et al (2006). Early predictors of long-term work disability after major limb trauma. Journal of Trauma., 61: 688–694.

McCall, BP, Horwitz, IB (2006). An assessment and quantification of the rates, costs, and risk factors of occupational amputations: analysis of Kentucky workers' compensation claims, 1994–2003. American Journal of Industrial Medicine, 49:1031–1038.

Renzi, R, et al (2006). An international comparison of lower extremity amputation rates. Annals of Vascular Surgery, 20: 346-350.

Rypens F, et al (2006). Obstetric US: watch the fetal hands. RadioGraphics, 26:811–832. Published online: 10.1148/rg.263055113.

Schaffer, HM (2006). Advancements in prosthetic technology provide more options to amputees. Lippincott's Case Management, 11: 282-283

Schofeild, CJ, et al (2006). Mortality and hospitalization in patients after amputation. Diabetes Care, 29: 2252-2256.

Sorene, ED, Heras-Palou, C, Burke, FD (2006). Self-amputation of a healthy hand: a case of body integrity identity disorder. Journal of Hand Surgery (British and European Volume), 6: 593–595.

Taylor, SM, et al (2005). Preoperative clinical factors predict postoperative functional outcomes after major lower limb amputation: an analysis of 553 consecutive patients. Presented at the Southern Association for Vascular Surgery Meeting, Marco Island, FL, Jan 19-22, 2005. Society for Vascular Surgery.

U.S. Department of Health and Human Services National Institutes of Health National Eye Institute. Progress in Eye and Vision Research 1999-2006.

University of Missouri Handbook of Disabilities.

Venkat-Narayan, KM, et al (2006). Impact of recent increase in incidence on future diabetes burden, U.S. 2005-2050. Diabetes Care, 29L 2114-2116.

Williams, RM, (2006). Does having a computerized prosthetic knee influence cognitive performance during amputee walking? Archives of Physical Medicine Rehabilitation, 87: 989-994.

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