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Annual Mandated Health Insurance Services Evaluation

Prepared for the Maryland Health Care Commission
Pursuant to Insurance Article 15-1501
Annotated Code of Maryland



MERCER

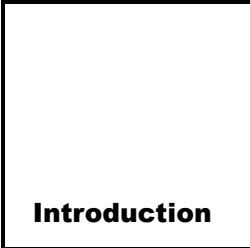


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Evaluation of Proposed Mandated Health Insurance Services

Insurance Article, § 15-1501, Annotated Code of Maryland, requires that the Maryland Health Care Commission (the Commission) annually assess the medical, social and financial impacts of proposed mandated health insurance services that fail passage during the preceding legislative session or that are submitted to the MHCC by a Legislator by July 1st of each year. The assessment reports are due to the General Assembly annually by December 31st.

Mercer and its sibling company, Oliver Wyman Actuarial Consulting, Inc., have been contracted as the Commission's consulting actuary, and have prepared the following evaluation of the proposed changes to existing mandates or proposed newly mandated benefits: expanded coverage of autism spectrum disorder, modification to the existing in vitro fertilization mandate, modification to the existing mandate involving mastectomies, coverage of prosthetic devices and coverage for shingles vaccine.

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Coverage of Autism Spectrum Disorder

The draft Act entitled “Health Insurance - Coverage of Autism Spectrum Disorder” (the Act) dated October 1, 2008, outlines proposed coverage of autism spectrum disorders. Key provisions of the Act are as follows:

- Insurers, health plans, and health maintenance organizations “... Shall provide coverage for the diagnosis of autism spectrum disorders and the evidence-based, medically necessary treatment for autism spectrum disorders in individuals under the age of 21 years.” Coverage is subject to an annual maximum of \$50,000 for 2010. The annual maximum increases each year by the Medical Care Component of the Consumer Price Index for all urban consumers (CPI-U).
- “Treatment of autism spectrum disorders” encompasses “habilitative or rehabilitative care” as well as pharmacy psychiatric, or psychological care prescribed by a physician or psychologist.
- “Habilitative or rehabilitative care” includes “applied behavior analysis” and other services, including the development and maintenance of an individual’s functioning – the main goal being to restore it to the maximum extent possible.

The following is a description of autism provided by the Centers for Disease Control (CDC).¹

Autism is one of a group of disorders known as autism spectrum disorders (ASDs). ASDs are developmental disabilities that cause substantial impairments in social interaction and communication and the presence of unusual behaviors and interests. Many people with ASDs also have unusual ways of learning, paying attention, and reacting to different sensations. The thinking and learning abilities of people with

¹ Centers for Disease Control and Prevention. <http://www.cdc.gov/ncbddd/autism/overview.htm>

ASDs can vary – from gifted to severely challenged. An ASD begins before the age of 3 and lasts throughout a person's life.

ASDs include autistic disorder, pervasive developmental disorder – not otherwise specified (PDD – NOS, including atypical autism), and Asperger syndrome. These conditions all have some of the same symptoms, but they differ in terms of when the symptoms start, how severe they are, and the exact nature of the symptoms. The three conditions, along with Rett syndrome and childhood disintegrative disorder, make up the broad diagnosis category of pervasive developmental disorders.

ASDs occur in all racial, ethnic, and socioeconomic groups and are four times more likely to occur in boys than in girls. CDC's Autism and Developmental Disabilities Monitoring (ADDM) Network released data in 2007 that found about 1 in 150 eight-year-old children in multiple areas of the United States had an ASD.

All health plans appear to have exclusions or limit coverage for autism treatments outside of those for habilitative services for children with ASDs mandated by Section 15-835, Insurance Article, Annotated Code of Maryland. The intent of the Act is to remove the coverage limitations for certain autism services.

One of the most significant aspects of the Act is that it specifically mandates coverage for services for applied behavior analysis (ABA), defined as “the design, implementation, and evaluation of environmental modifications using behavioral stimuli and consequences, to produce socially significant improvement in human behavior, or to prevent the loss of attained skill or function.”

A discussion of the medical, financial, and social impacts of this proposed mandate follows.

Medical Impact

In this section, we answer questions regarding coverage of additional services for autism spectrum disorders.

- **Does the medical community recognize services and treatments, including ABA, as being effective in treating patients with ASDs?**
- **Are the additional services that are provided to patients with ASDs under this mandate generally recognized by the medical community, as demonstrated by a scientific and peer review of literature?**
- **Are the additional services that are provided to patients with ASDs under this mandate available and utilized by treating physicians?**

According to the Autism Society of America, there currently are many different approaches in the treatment of autism, including auditory training, discrete trial training, vitamin therapy, anti-yeast therapy, facilitated communication, music therapy,

occupational therapy, physical therapy, and sensory integration. These approaches can generally be broken down into three categories:

- Behavioral and communication approaches
- Biomedical and dietary approaches
- Complementary approaches

Children with autism may receive eight to 11 hours a week of OT, PT, and ST as part of an intensive treatment plan based on an illustrative plan.²

Some of these treatment approaches have research studies that support their efficacy; others do not. The Autism Society of America asserts that long-term, scientific studies regarding the different treatment methods are difficult to complete since there is such a wide range of symptoms and skill sets associated with autism.³

However, the most accepted approach appears to be applied behavioral analysis (ABA).

Applied Behavioral Analysis (ABA)

ABA includes intensive one-on-one sessions with ABA therapists. It is not unusual for these sessions to be as frequent as six days a week for as many as 30 to 40 hours a week.⁴ ABA is almost universally excluded from health coverage, generally because insurers do not consider it a medical treatment, or do not believe it meets the standard of “medically necessary” or “medical necessity” as defined by insurers.

We would expect that most of the additional costs associated with this mandate would be due to the addition of coverage for ABA, as well as increased utilization of occupational, physical, and speech therapies.

The American Academy of Pediatrics (AAP) states the following in its report *Management of Children with Autism Spectrum Disorders*:

The effectiveness of ABA-based intervention in ASDs has been well documented through 5 decades of research by using single-subject methodology and in controlled studies of comprehensive early intensive behavioral intervention programs in university and community settings. Children who receive early intensive behavioral treatment have been shown to make substantial, sustained gains in IQ, language, academic performance, and adaptive behavior as well as

² Virginia General Assembly, Joint Legislative Audit and Review Commission. “Evaluation of Proposed Mandated Health Insurance Benefits. Evaluation of House Bill 83: Mandated Coverage of Autism Spectrum Disorders.” September 2008. <http://jlarc.state.va.us/Reports/Rpt371.pdf>

³ Autism Society of America. General Standards of Care. http://www.autism-society.org/site/PageServer?pagename=life_treat_standards

⁴ See note 2.

some measures of social behavior, and their outcomes have been significantly better than those of children in control groups.⁵

⁵ Myers, Scott M., MD and Chris Plauché Johnson, MD, Med. The Council on Children with Disabilities, "Management of Children with Autism Spectrum Disorders." *Pediatrics*. November 2007.
<http://pediatrics.aappublications.org/cgi/reprint/120/5/1162>

In the report *Mental Health: A Report of the Surgeon General*, the Surgeon General states, “Thirty years of research demonstrated the efficacy of applied behavioral methods in reducing inappropriate behavior and in increasing communication, learning, and appropriate social behavior. A well-designed study of a psychosocial intervention was carried out by Lovaas and colleagues (Lovaas, 1987; McEachin et al., 1993).”⁶

In the article, “Applied Behavior Analysis, Treatment of Autism: The State of the Art,” Richard M. Foxx asserts that ABA is a “scientifically validated and highly effective treatment” for autism.⁷ He cites many peer reviewed articles regarding the success of ABA as well as the fact that ABA is the only educational or treatment approach currently approved by the New York State Health Department for ASD.

Foxx emphasizes that ABA incorporates “all the factors identified by the US National Research Council as characteristic of effective interventions in educational programs for children who have autism.” The classification of ABA as treatment for a medical condition or as an educational tool is probably the issue prompting the greatest differences of opinion among policymakers.

The American Academy of Pediatrics (AAP) recognizes that ASDs are not “curable” but require chronic management. They assert, “Although outcomes are variable and specific behavioral characteristics change over time, most children with ASDs remain within the spectrum as adults and regardless of their intellectual functioning, continue to experience problems with independent living, employment, social relationships and mental health. The primary goals of treatment are to minimize core features and associated deficits, maximize functional independence and quality of life, and alleviate family distress. Facilitating development and learning, promoting socialization, reducing maladaptive behaviors and educating and supporting families can help accomplish these goals.”⁸

The paper goes on to discuss what it considers many “educational” intervention programs/methodologies – one of which is ABA. Most of the educational interventions have focused on very young children because it appears early intervention programs have the best outcomes. The AAP describes several additional types of educational intervention programs including:

- behavioral models,
- structured teaching models --the most recognized being the Treatment and Education of Autistic and Related Communication-Handicapped Children, or TEACCH, and
- developmental models--including the Denver model, development individual-difference relationship-based (DIR) models and responsive teaching (RT) curriculum.

⁶ US Surgeon General, *Mental Health: A Report of the Surgeon General*. Chapter 3: Autism. Accessed November 15, 2008. <http://www.surgeongeneral.gov/library/mentalhealth/chapter3/sec6.html#autism>

⁷ Foxx, Richard M., PhD. *Applied Behavior Analysis Treatment of Autism: The State of the Art*. Child and Adolescent Psychiatric Clinics of North America. October 2008.

⁸ See note 5 above.

The AAP recognizes that, while there are several studies documenting improvement in children using the other educational interventions described, controlled studies for these alternative interventions are generally not available.⁹

Carriers generally have differing opinions, as the following shows.

Magellan Health Services (Magellan) – a managed health care company that specializes in providing services for behavioral health conditions, and a subcontractor for at least one of the major carriers in Maryland – considers ABA to be an “investigational treatment.” It has based this determination on the “evaluation of the research findings where the evidence did not support ABA’s effect on health outcomes, its safety and efficacy against existing alternative treatments, and its ability to demonstrate that benefits outweigh the risks.”¹⁰

The team at Magellan that arrived at this conclusion included eight MDs, one DO, a registered nurse with a master’s degree in public health, and one PhD. Its clinical practice guidelines (CPGs) include two additional guidelines developed by the American Academy of Pediatrics: Practice Guideline for the Management of Children with Autism Spectrum Disorders (the paper previously cited) and Clinical Report – Identification and Evaluation of Children with Autism Spectrum Disorders.

The development of Magellan’s CPGs was based on a review of the prevailing literature through 2006, with an additional review of the clinical literature on assessment and treatment of autism spectrum disorders through May 2008.

One of the basic reasons for Magellan’s determination is the lack of randomized controlled studies of ABA. Magellan believes that many of the results of studies published to date “have several methodological problems, including lack of a clear definition of the ABA treatment and its protocols, lack of control groups using established treatment alternatives, poorly chosen or poorly specified samples, outcomes measured only in limited areas (e.g., IQ), and outcomes measures giving little information regarding the totality of the treatment impact.”¹¹ Magellan notes that most of the research for ABA programs has focused on the very youngest (preschoolers). There is very little research regarding outcomes for older children or adults with autism.

⁹ See note 5 above.

¹⁰ Magellan Health Services. “Introduction to Magellan’s Adopted Clinical Practice Guidelines for the Treatment of Children with Autism Spectrum Disorders.” 2008. This document can be found by: entering: <http://www.magellanhealth.com/>, then selecting “Provider,” “Clinical Guidelines,” “Clinical Practice Guidelines,” “Autism,” “Magellan Introduction.”

¹¹ Ibid

Magellan cites the following other limitations (in addition to the limited research on medical efficacy) to the use of ABA treatments for children with autism.¹²

- ABA is very intense and intrusive in its format and delivery, which can result in stressful reactions by the child.
- Positive results may appear to occur in one environment when an autistic individual is responding to specific stimuli, but fail to occur in a broader or different environment. The goal of any therapy should be to promote skills that will be used in real world settings.
- The use of any single treatment may not be advisable given the broad range of symptoms associated with autism, age of the child, emotional resources of the families, etc.

CareFirst, the Maryland-based carrier with the largest premium, has deemed that medical and mental health services for the treatment of PDDs, including autism, are considered not medically necessary because “no medical or mental health treatments have been proven effective” for these diagnoses. ABA is considered experimental/investigational. CareFirst defines “experimental/investigational” as follows:

Experimental/Investigational¹³

The term "experimental/investigational" describes services or supplies that are in the developmental stage and are in the process of human or animal testing. Services or supplies that do not meet all 5 of the criteria listed below adopted by the BlueCross BlueShield Association Technology Evaluation Center (TEC) are deemed to be experimental/investigational:

1. The technology* must have final approval from the appropriate government regulatory bodies; and
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes; and
3. The technology must improve the net health outcome; and
4. The technology must be as beneficial as any established alternatives; and
5. The improvement must be attainable outside the investigational settings.

* *Technology includes drugs, devices, processes, systems, or techniques.*

¹² Ibid

¹³ CareFirst BlueCross BlueShield. *CareFirst Medical Policy Reference Manual*. Accessed November 2008 .<http://notesnet.carefirst.com/ecommerce/medicalpolicy.nsf/vwwebtablex?OpenView&Start=1&Count=200&Expand=1#1>

CareFirst indicates that ABA does not meet criteria numbers two through five of its definition. In arriving at this conclusion, CareFirst provides the following:¹⁴

Rationale:

The National Institute of Neurological Disorders and Stroke (NINDS) conducts research in its laboratories at the National Institutes of Health (NIH) and also supports additional research through grants to major medical institutions across the country for pervasive developmental disorders including autism. As part of the Children's Health Act of 2000, the NINDS and three sister institutes have formed the NIH Autism Coordinating Committee to expand, intensify, and coordinate NIH's autism research. Eight dedicated research centers across the country have been established as "Centers of Excellence in Autism Research" to bring together researchers and the resources they need. The Centers are conducting basic and clinical research, including investigations into causes, diagnosis, early detection, prevention, and treatment of autism.*

Currently there is a lack of clinically based evidence on the cause or treatment of Pervasive Developmental Disorders including autism.

** Information from NINDS Autism Information Page and NINDS Pervasive Developmental Disorders Information Page (2005)*

Update 2007:

A search of the peer-reviewed literature was performed for the period of May 2005 through June 2007. Findings in the recent literature do not change the conclusions regarding the cause or treatment of pervasive developmental disorders, including autism.

Aetna has the following language on their clinical policy bulletin (CPB) for pervasive developmental disorders (PDD), under which autism would fall:

“There is insufficient evidence for the superiority of any particular intensive educational intervention strategy (such as applied behavioral analysis, structured teaching, or developmental models) over other intensive educational intervention strategies.”¹⁵

¹⁴ CareFirst BlueCross BlueShield. Medical Policy 3.01.006 Pervasive Developmental Disorders (e.g., Autism). Accessed November 2008.
http://notesnet.carefirst.com/ecommerce/medicalpolicy.nsf/vwwwebtablex?searchview&query=autism*&Start=1&Count=100&SearchOrder=4

¹⁵ Aetna. Clinical Policy Bulletin. “Pervasive Developmental Disorders.” Accessed November 2008.
http://www.aetna.com/cpb/medical/data/600_699/0648.html

In this general document, Aetna provides the research that they reviewed to arrive at this conclusion, which includes 110 studies and articles. Among the specific studies cited was the finding by the National Academy of Sciences (NAS) in 2001 that there is no known cure for autism, and that “[e]ducation, both directly of children, and of parents and teachers, is currently the primary form of treatment for autistic spectrum disorders.” The National Academy of Sciences recommends that educational services begin as soon as a child is suspected of having autistic spectrum disorder, and that those services include a minimum of 25 hours a week, 12 months a year, in which the child is engaged in systematically planned and developmentally appropriate educational activity toward identified objectives. Aetna references another study by Brasic (2003), which stated that “while parents may choose to utilize a variety of experimental treatments including medication, they should concurrently utilize intensive individual special education by an educator familiar with instructing children with autistic disorder and related conditions.”¹⁶

Autism Speaks, an autism advocacy organization, comments, “Private health insurance coverage of autism services will allow children with autism to access Applied Behavior Analysis (ABA), a proven treatment for their condition. Several studies have shown that as many as 47 percent of the children that undergo early intensive behavioral therapies achieve higher education placement and increased IQ levels. A significant portion of children who receive ABA are placed into mainstream educational settings. Children who begin their treatment with minimal IQ levels end treatment with substantially higher levels of intellectual functioning. These results have been shown to last well beyond the end of treatment. As such, the effectiveness of ABA therapy has allowed many children to forego costly intensive special education in the future.”¹⁷

Another area of significant differences in opinion regarding ABA appears to be whether this is a medical treatment or whether this is an educational intervention. As shown, some medical experts assert that ABA is a recognized medical treatment. Others believe it is investigative/experimental because of the lack of randomized, controlled studies. Due to the small number of individuals who have ASD, it may be difficult to develop sufficient randomized, controlled studies that meet scientific/medical standards. Current literature however, demonstrates that ABA is the treatment most cited as helpful for individuals with ASD.

Occupational, Physical, and Speech and Language Therapies

Autistic patients often need occupational, physical, and speech and language therapies. In a report on ASDs, the AAP states that “Traditional occupational therapy often is provided to promote development of self-care skills (e.g., dressing, manipulating fasteners, using utensils, personal hygiene) and academic skills (e.g., cutting with scissors, writing). Occupational therapists also may assist in promoting development of play skills, modifying classroom materials and routines to improve attention and organization, and

¹⁶ Ibid

¹⁷ Autism Speaks. “Arguments in Support of Private Insurance Coverage of Autism-Related Services.” October 2007. http://www.autismspeaks.org/docs/arguments_for_private_insurance_coverage.pdf

providing prevocational training. However, research regarding the efficacy of occupational therapy in ASDs is lacking. Sensory integration (SI) therapy often is used alone or as part of a broader program of occupational therapy for children with ASDs.”¹⁸

The report further states, “A variety of approaches have been reported to be effective in producing gains in communication skills in children with ASDs. People with ASDs have deficits in social communication, and treatment by a speech-language pathologist usually is appropriate.”¹⁹

Occupational, speech and language, and physical therapy services are generally widely available and utilized to treat autistic children. However, there is likely a need to better understand the best way to use these types of therapies in treating autistic children. Some of these therapies are eligible for payment under the existing habilitative services mandate, Section 15–835 of the Maryland Insurance Article. Occupational, speech and language, and physical therapy services are also routinely provided to autistic children to treat comorbid conditions.

Social Impact

In this section, we address the following questions:

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

A 2005 study estimated the prevalence of specific ASDs. This study, based on preschool children living in England, found that of those children that had some type of ASD, about one-third had autistic disorder, one-sixth had Asperger’s syndrome, and one-half had Pervasive Developmental Disorder - Not Otherwise Specified (PDD – NOS).²⁰ This

¹⁸ See note 5 above.

¹⁹ See note 5 above.

²⁰ See note 2 above.

would translate into prevalence rates of approximately two per 1,000 for autistic disorder, one per 1,000 for Asperger's syndrome, and three per 1,000 for Pervasive Developmental Disorder - Not Otherwise Specified (PDD – NOS). From this, we can estimate an ASD prevalence of one in 150, or six to seven per 1,000. This is confirmed, as noted by the CDC, which reports that approximately one in 150 children has an ASD.

The CDC estimated that, nationwide, the prevalence of ASDs among eight-year-old children ranged from 3.3 to 11.9 per 1,000 children. For Maryland, the CDC estimated the prevalence of ASDs among eight-year old children to be 6.7 per 1,000 children, which was within the nationwide range.²¹ This indicates that it is reasonable to use the CDC nationwide estimates for prevalence of ASD for Maryland.

This mandate covers services only for individuals under age 21 – which, based on Census statistics, would account for about 32% of Maryland's non-Medicare (under age 65) population.²² So, a reasonable estimate would be that approximately one in 460 people covered by insurance in Maryland, or about 0.2% of the insured population, could potentially receive additional benefits under this mandate. However, the actual number would likely be lower, as the very young and many higher-functioning autistic children would not actually be diagnosed or receive treatment at each age under 21. Conversely, there is a potential that the estimated number could increase if the prevalence rate for autism continues to increase.²³

Because services in general for the treatment of ASD and specifically ABA are not typically covered by insurance, Mercer believes that additional services provided under this mandate would vary from insurer to insurer, but generally could be put into one of three categories:

- *Services not currently covered due to broad autism exclusions.* Certain plans have blanket-stated coverage exclusions for autism services other than the habilitative services already mandated.
- *Certain services not currently covered because they are specifically excluded by a plan.* For example, ABA is typically considered an educational program by insurers and is specifically stated as excluded in coverage position statements.
- *Services not currently covered because they do not meet defined “medically necessary” criteria.* Below is a sample definition of “medically necessary” (This is CIGNA's protocol; note that other insurer definitions are very similar.)²⁴

²¹ CDC Morbidity and Mortality Weekly Report. Prevalence of Autism Spectrum Disorders – Autism and Developmental Disabilities Monitoring Network, 14 Sites, United States 2002, February 8, 2007, <http://www.cdc.gov/mmwr/pdf/ss/ss5601.pdf>

²² U.S. Census Bureau. http://www.census.gov/hhes/www/hlthins/data_access.html

²³ By “prevalence rate” we mean the rate at which individuals are diagnosed with autism. Government statistics show autism is increasing at a rate of 10% to 17% annually. The rate of increase could be due to higher actual incidence, better diagnosis, or both. (Autism Speaks—FAQs <http://www.autismspeaks.org/whatisit/faq.php>)

²⁴ CIGNA website. Accessed November 15, 2008. http://www.cigna.com/health/provider/medical/procedural/medical_necessity.html#hc_prov_def.

Except where state law or regulation requires a different definition, “Medically Necessary” or “Medical Necessity” shall mean health care services that a Healthcare Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- a) in accordance with the generally accepted standards of medical practice;
- b) clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease; and
- c) not primarily for the convenience of the patient or Healthcare Provider, a Physician or any other Healthcare Provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "generally accepted standards of medical practice" means:

- standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community,
- Physician and Healthcare Provider Specialty Society recommendations,
- the views of Physicians and Healthcare Providers practicing in relevant clinical areas and
- any other relevant factors.

Autism treatments are frequently denied under the educational exclusion, with insurers citing that the American Academy of Pediatrics considers applied behavior analysis an educational intervention.²⁵ However, the Virginia Joint Legislative Audit and Review Commission has noted, “Medical experts indicate that even though there is often an attempt to classify ASD treatments as either educational or medical, many treatments can be considered both educational and medical, so such a distinction is not warranted.”²⁶

Additional examples of reasons for denying ASD or ABA services can be found in the following comments from insurers and their medical directors:

- In general, coverage is subject to medical necessity and the carrier does not cover treatments that will not result in improvement. Carriers may make short-term exceptions to cover acute exacerbations if there is a significant change in behavior.
- At this point, ABA is not covered because it is not considered evidence-based. No self-insured companies in Maryland using CareFirst or United as Third Party Administrators (TPAs) cover ABA.

²⁵ See note 5 above.

²⁶ See note 2 above.

- “Currently, services such as Applied Behavioral Analysis could be excluded under the Educational Services exclusion of our Maryland plans.”
- “If [ABA is] request is recognized as being related to ASD, no coverage would be authorized (excluded as educational). ASD is also considered a chronic condition and therefore excluded from coverage.”
- “Applied Behavioral Analysis treatments are generally denied for being experimental and investigational or not medically necessary... If therapy is covered due to an alternate diagnosis, then the 60-day limit will apply.”
- “...does not cover the following procedures/services for the assessment and/or treatment of ASD because they are considered experimental, investigational or unproven for this indication (these lists may not be all-inclusive)... intensive intervention programs for autism (e.g., Lovaas therapy, applied behavior analysis)”
- “This service is not covered ... under Excluded Services – ‘49. *Treatment for disorders relating to learning, motor skills, communication, and pervasive developmental conditions such as autism.*’”
- “... plans provide inpatient, outpatient (including PT, OT and speech therapy), emergency care, medical-surgical care, specialty care and pharmacy for members with autism and autism spectrum disorders (ASD) ... Some reasons for denial of services could include: services rendered by non-covered provider; services not preauthorized by health plan; education services not covered by health plan; services rendered are not effective.”

Only two carriers provided statistics on the dollar amount of claims they had denied during the most recent 12-month period for which data was available. One carrier reported about \$900 in denied claims and the other carrier reported \$1.2 million in denied claims. Only one carrier provided statistics on denied claims that were appealed and that carrier indicated there were 11 ASD denials appealed during the most recent 12-month period for which statistics were available. Most carriers indicated that they were unable to analyze their denied claims to determine those that would now be payable because they would need to define the services that would be covered by the proposed mandate by CPT codes or diagnostic codes. This would require significant time and resources.

Certain services are provided through state and locally administered education programs, as required by the Individuals with Disabilities Education Act (IDEA). IDEA parts B and C also require early intervention program services for toddlers and pre-school-aged children. Some of the services provided by these programs are similar to those covered by the mandate; however, the level and intensity of the services may be more limited than those recommended by treating physicians and covered by the mandate and vary in amount, duration and scope between localities.

In FY 2007, the Maryland Medicaid Waiver for Children with Autism Spectrum Disorder (AW) offered eight types of waiver services related to the treatment of autism spectrum disorders. Services covered under the waiver are as follows:²⁷

- Intensive individual support services
- Therapeutic integration services
- Supported employment
- Respite care
- Family training
- Environmental accessibility adaptations
- Regular residential habilitation
- Intensive residential habilitation

While there may be some overlap with the services contemplated in the mandate, the waiver program is targeted to severely affected individuals who likely could be institutionalized without supports. Enrollment under the AW is capped at 800, and in August 2008, a total of 2,535 children were on the Waiver Services Registry (which is essentially a waiting list). Therefore there is a total of 3,335 individuals either enrolled or on a waiting list for AW services. This represents about 60% of the total number of individuals that Mercer estimates could be covered under any mandate.²⁸ The average cost per child for only the waiver services in Maryland was slightly more than \$25,000 for fiscal year 2007. The average cost per child for waiver services and Medicaid State Plan services was slightly more than \$38,000.²⁹

The fees to non-institutional providers under the Medicaid program are significantly less than the corresponding fees observed in the commercial market. We could safely assume that, if these services were provided in the commercial market, the costs could be at least double. Maryland Medicaid indicated that they have not recovered any funds from carriers because it is their experience that commercial health plans do not cover the types of services that are provided under the waiver programs.

Based on the costs of ABA and other therapies, it is safe to assume that many families cannot afford the costs associated with the total compendium of non-covered therapies and, therefore, certain children would not receive them unless provided through a government program such as IDEA. In its analysis of Virginia's House Bill 83 – which would mandate autism coverage, including ABA therapy – the Joint Legislative Audit and Review Commission notes, “The costs of intensive behavior therapies could be ... from 38 percent to well over median household income.”³⁰

²⁷ Medicaid response to MHCC data request, October 2008.

²⁸ Maryland Medicaid indicates that the statistics regarding the waiting list the following limitations: Individuals on the waiting list have not been “pre-screened” to determine if they are eligible for coverage and it is unknown how many families are unaware of AW or the waiting list.

²⁹ See note 27 above.

³⁰ See note 2 above.

Some families who pay out of pocket for autism treatment face major financial hardships. Such hardships have been well documented in states that have had hearings on similar mandates, as well as in major media stories. The advocacy group Autism Speaks summarized the financial hardships some families face in accessing care for autistic children:

Families that refuse to allow their children to suffer through the inadequate Medicaid system and are denied coverage by their private health insurance carriers often end up paying for therapies out of their own pockets. For these families, the financial burden is immense. Without the negotiating powers of an insurance company behind them, out-of-pocket prices are extremely high. Parents can often spend upwards of \$50,000 per year on autism-related therapies, often being forced to wager their own futures and the futures of their non-autistic children to pay for necessary autism-related therapies. Children whose parents cannot afford to pay for behavioral and other therapies and who cannot access adequate therapies through the Medicaid system simply go without these interventions.³¹

In 2007, Michael Ganz Ph.D., Associate Director of Outcomes Research at Abt Bio-Pharma Solutions, Inc. completed a study that outlined the various costs associated with autism services. The costs were broken down between direct costs (based on the value of goods and services used) and indirect costs (based on the value of lost productivity). This often-cited study noted the following types of costs:

- Direct medical costs included physician and other professional services and supplies.
- Direct non-medical costs included special education, child care, respite care, out-of-home placements, and other costs associated with caring for someone with autism.
- Indirect costs involved lost productivity associated with those affected by autism during their lifetime as well as family members and other caregivers who may be forced to limit their work and productivity due to the need to commit time to care for someone with an ASD.

This study also provides an estimate of the societal costs of autism. Ganz comments, “The total annual societal per capita cost of caring for and treating a person with autism in the United States was estimated to be \$3.2 million and about \$35 billion for an entire birth cohort of people with autism.”³²

Studies have also estimated the benefits associated with early intervention. The report to the Pennsylvania Health Care Cost Containment Council by Abt Associates Inc. (Abt report) noted, “Jacobson, Mulick and Green further reported a study using Pennsylvania data to study early intensive behavioral intervention (EIBI) in which they found EIBI-related cost savings of approximately \$187 thousand to \$203 thousand for children served between the ages of 3 and 22; and, savings of \$656 thousand to \$1,082 million between the ages of 3 and 55. Initial cost differences for three (3) years of EIBI were estimated at

³¹ See note 17 above.

³² Ganz, Michael L., MS, PhD. “The Lifetime Distribution of the Incremental Societal Costs of Autism.” www.archpediatrics.com. Accessed on November 13, 2008. Prior to joining Abt Associates, Dr. Ganz was Assistant Professor at the Harvard School of Public Health.

\$33 thousand and \$50 thousand per child per year; the authors suggest that these figures represent a modest impact on cost/benefit ratios.³³

For families that would likely utilize autism services, there is obviously significant demand for the additional coverage outlined in the mandate. Autism also received significant press during the 2008 presidential campaign, with both major party candidates recognizing the hardships faced by families affected by autism, and the need to determine better ways to support them. On his website, President-elect Barack Obama says that he “will mandate insurance coverage of autism treatment and will also continue to work with parents, physicians, providers, researchers, and schools to create opportunities and effective solutions for people with ASD.”³⁴

Coverage mandates in other states have received widespread support, and have generally passed by wide margins. A recent (summer 2008) Wisconsin Checkpoint poll shows that about 55% of likely voters surveyed “strongly” support requiring insurance companies to cover treatment for children with autism, and that another 30% “somewhat” support an autism mandate. It does not appear that the question included any reference to impact on premium – which might have affected the response.³⁵

Currently, collective bargaining units have coverage for autism that is similar to that of large groups. If the collective bargaining agreement is a fully insured plan, some of the services are currently provided for children under the habilitative services mandate. If the agreement is self-funded, then services are generally limited to diagnosis of ASD and therapy services, such as speech, up to the contract maximums. None of the collective bargaining units surveyed for this analysis have benefits as extensive as those required under the proposed mandate. The interest for inclusion ranged from mild to moderate, depending on the cost. If the cost was between \$1 and \$2 PMPM, there was moderate interest. If the cost exceeded that range, the interest was mild.

ABA benefits – and many other benefits for services to treat autism – are typically limited or excluded for self-insured plans. CareFirst and United HealthCare noted that they did not administer any self-insured plans that cover ABA. While most large employers do not provide significant coverage for ABA, the US military's Tricare health insurance programs and some very large self-insured companies (including Microsoft and Home Depot) pay for autism behavior therapy.³⁶

³³ Abt Associates Inc. “Autism Spectrum Disorders Mandated Benefits Review Panel Report: Evidence Submitted Concerning Pennsylvania HB 1150.” June 18, 2008. Prepared for the Pennsylvania Health Care Cost Containment Council. <http://www.phc4.org/reports/mandates/HB1150/AutismPanelReport061808.pdf>

³⁴ <http://www.barackobama.com/pdf/AutismSpectrumDisorders.pdf>

³⁵ <http://www.autisminsurancenow.org/public-opinion-poll/>

³⁶ Spake, Amanda. “Families Change Microsoft’s View of Autism.” *Smart Money Magazine*. May 8, 2007. <http://www.smartmoney.com/personal-finance/health-care/families-changed-microsofts-view-of-autism-21226/>

The Federal Mental Health Parity and Addiction Equity Act of 2008 (Mental Health Parity) was recently passed by Congress as part of the emergency bill for the financial markets. Mental Health Parity precludes any health plan (fully insured or self-funded) that provides mental health benefits to employers with 51 or more employees from treating mental health benefits differently from any other medical benefits. If ASDs are defined as mental health conditions, then the proposed mandate would appear to conflict with federal legislation because of the \$50,000 annual benefit limit for ASD services. To retain the \$50,000 annual limit contained in the current language, Maryland would need to clearly state that ASDs are not considered mental health conditions. Based on the current knowledge and medical practice, the General Assembly could reasonably classify ASDs as neurological disorders rather than mental illnesses and impose an inside limit.

Financial Impact

Due to the general lack of coverage for ABA and the limitation or exclusion of other services that would now be covered under the mandate, cost data for these benefits based on insurance data does not exist. This lack of usable data hinders the direct development of cost estimates based on standard actuarial methodologies.

The following is a simplified explanation of how cost estimates are typically developed.

1. Develop utilization estimates for the additional services under consideration. In this case, utilization for the various treatments under the mandate would be based on treated prevalence of ASDs and the distribution of how frequently different types of services are utilized. These estimates would be developed by age, as they would be expected to vary significantly for the services under consideration.
2. Develop unit cost estimates by type of service.
3. Apply impact of cost-sharing provisions (copayments, coinsurance, deductibles, inside maximums (e.g., \$50,000 annual maximum as considered in this mandate).
4. Develop expected annual costs based on utilization, unit cost estimates, and cost-sharing provisions.
5. Add an amount for administrative costs.
6. Adjust for coordination with other benefits, and for anti-selection or anything else that would impact costs.

Some specific considerations and assumptions needed to develop costs and premium impacts under the mandate are as follows:

Treatment Prevalence

The prevalence of treatment for additional services covered by insurers under the mandate would be impacted by several factors, including (but not limited to):

- The actual prevalence of ASDs in Maryland's population.
- The existence of an ASD diagnosis. (While an ASD is typically diagnosed around age two or three, some individuals may be diagnosed when younger – or when older, in the case of those with high-functioning autism).

- The extent to which those diagnosed will seek treatment under their insurance policies. (Some individuals will not seek treatment from their insurers after being diagnosed).
- The perceived quality and sufficiency of any therapies provided through the educational system. (This would affect the use of services covered by insurance).

Hard data are not available on the impact of these factors. In addition, there is some controversy and uncertainty of the prevalence rate of ASDs and the expected treated prevalence of ASDs. Our research showed the following:

- Independence Blue Cross expected a treated prevalence of 1 in 400 when they provided comments to the Commission studying the impact of the Pennsylvania autism mandate.³⁷
- BlueCross of Northeastern Pennsylvania expected a treated prevalence of 1 in 150 for the Pennsylvania mandate.³⁸
- In assessing the cost impact of the Louisiana mandate for autism services, James Boudier noted, "... it is reasonable to forecast the likely beneficiaries of HB 958 based on a treated prevalence of 1 in 500."³⁹
- A summary of IDEA⁴⁰ and Census⁴¹ data indicated the following rates for children receiving educational services in Maryland:

Table 1

Rates of Children with Autism Accessing the Educational System				
Age	Accessing System	MD Population	Rate per 1,000	Rate - 1 in ...
3 to 5	606	222,929	2.7	368
6 to 11	2,719	420,648	6.5	155
12 to 17	2,086	511,273	4.1	245

Based on the rate of six- to 11-year-olds with an ASD accessing the system, it is reasonable to assume the 1 in 150 prevalence rate for individuals who would seek treatment for benefits covered by the mandate. It is also reasonable to assume that this number could be lower for children younger than six (because they have not been diagnosed), and lower for older children because some may no longer receive treatment or support outside of a school setting.

³⁷ See note 33 above.

³⁸ Ibid

³⁹ Ibid

⁴⁰ http://www.autism-society.org/site/DocServer/Autism_Maryland_v3.pdf?docID=10883

⁴¹ Census Data web link. http://www.census.gov/hhes/www/hlthins/data_access.html

Intensity of Services by Age

The intensity of services would be expected to vary significantly by age and would generally be expected to be highest during the preschool years (ages three to five). During this period, many children would be expected to be diagnosed, and many would be able to tolerate and participate in intensive services. Costs would be expected to decrease for older children as they spend more time in school. Their therapies would be covered through educational programs and, after some period, expensive intensive behavioral therapies would be less prevalent since they would either be successful (and therefore wouldn't be needed as much) or not successful (and likely be eliminated from a therapy program).

The often-cited Ganz study⁴² showed direct and indirect costs associated with autism for five-year age bands starting at age three – the assumed age at diagnosis. It showed that direct medical costs (in 2003 dollars) were expected to be highest from ages three to seven, averaging around \$35,000, and then decrease significantly as children aged – to about \$6,000 for ages eight to 12, \$5,000 for ages 13 to 17, and \$3,000 for ages 18 to 22. The report states, “The large direct medical costs early in life are driven primarily by behavioral therapies that cost around \$32,000 during the first five-year age group and decline from about \$4,000 in the 8- to 12-year age group to around \$1,250 for the 18- to 22-year age group.”

The Virginia JLARC report on House Bill 83 noted, “A 2003 study estimated the annual cost of intensive behavioral therapies to be \$41,295 for preschool-aged children and to range from \$4,140 to \$5,914 for older children. A 2007 study estimated the cost of early intensive behavioral interventions to be approximately \$22,500 annually.”⁴³ Note “early intervention” is for children two years and under.

As noted previously, there are no insured data with actual utilization and unit costs for the services considered under the mandate; therefore, costs by age cannot be directly calculated. The Ganz study and the Virginia JLARC report provide useful information on how costs would be expected to vary by age. This information should be considered when assessing the likely cost differences by age for services covered under the mandate.

Cost Estimates for Other State Mandates

Table 2 in the Virginia JLARC report summarizes autism mandates in other states. We have included this table for your reference.⁴⁴

⁴² See note 32 above.

⁴³ See note 2 above.

⁴⁴ Ibid

Table 2: States with Autism Spectrum Disorder Mandates Including Coverage for Applied Behavior Analysis-Based Treatment

State	Year Enacted	Eligibility	Provider Requirements	Coverage Limits
Arizona	2008	Birth to 16 years.	Behavioral therapy services shall be provided or supervised by a licensed or certified provider	Annual: \$50,000 up to age 9 \$25,000 if between ages 9 & 16. Lifetime: None
Florida	2008	Under 18 years, or 18 years & older if in high school & have a developmental disability diagnosis at age 8 or younger.	ABA services shall be provided by an individual certified or licensed pursuant to Florida statute.	Annual: \$36,000 Lifetime: \$200,000
Indiana	2001	Not specified.	No licensing requirement.	Not specified.
Louisiana	2008	Under 17 years.	ABA providers must be certified by the Behavior Analyst Certification Board or provide comparable credentials.	Annual: \$36,000 Lifetime: \$144,000
Pennsylvania	2008	Under 21 years.	Behavior specialists must be licensed or certified by the State Board of Medicine according to statutory guidelines or be enrolled in Pennsylvania's medical assistance program.	Annual: \$36,000 Lifetime: None
South Carolina	2007	Under 16 years & diagnosed with an ASD at age 8 or younger.	Not specified.	Annual: \$50,000 Lifetime: None
Texas	2007	Older than 2 years & younger than 6 years.	Practitioners must hold a state or national license, certification, or registration or be certified under the TRICARE military health system.	Not specified

Source: Information on Arizona, Florida, Indiana, South Carolina, and Texas provided by Autism Speaks, PA HB 1150.

Due to coverage limitations (most important, those involving ages covered and lifetime maximums), cost estimates in most of these states would not be directly comparable to those expected for Maryland. From the table above, South Carolina's and Pennsylvania's costs would likely be most comparable to Maryland's. Cost analyses done for recent mandates in Wisconsin and Virginia are also instructive.

In the previously mentioned report concerning Pennsylvania HB 1150, Abt Associates noted the following regarding cost estimates in Pennsylvania and other states:⁴⁵

With regard to premium increases:

- The preponderance of evidence submitted indicates that the premium cost impact of Pennsylvania's mandated ASD benefit will be in the range of one (1) to one and one-half (1 ½) percent.
- A study by the opponents of South Carolina's autism mandate, which has a higher cap than Pennsylvania of \$50K per child per year, finds the increase to be \$48 per member per year, or \$4 per member per month (pm/pm) and just under 1% of current premiums.
- In Wisconsin, which has no cap, analyses of the mandated benefit review premium increases of \$3.45 to \$4.10 PMPM
- A study by the New Jersey Mandated Benefits Advisory Commission, reported in 2006, evaluated the impact of the ASD mandated benefit contained in Assembly Bill A-999, finding that the cost impact on a family health insurance policy was approximately \$10.17 per month, or approximately 1% of premium.

These estimates would indicate that the cost of the Maryland mandate could be approximately 1% of premium if the estimates for similar benefits in other states are reasonable.

The Abt report stated the following with regard to increases in the cost of benefits from "opponents" of Pennsylvania HB 1150:

- Highmark estimates \$81.5M in increased premium costs on a customer base of 4.1M (*This equates to about \$20 per member per year*).
- IBC estimates \$57M in increased premium costs based on a treated prevalence assumption of 1 in 400.
- Blue Cross of Northeast Pennsylvania (BCNEPA) estimates \$12M (\$11.5M medical and \$500K administrative) in increased premium costs on a customer base of 600K, with a treated prevalence assumption of 1 in 150, each of whom will use the maximum of \$36K per annum (*This equates to about \$20 per member per year*).
- The Chamber of Business and Industry cites 4% as a "conservative estimate" of premium increases on 16,000 contracts serviced by its PCI subsidiary, where the average monthly premiums equal \$550, and the premium increase is estimated at \$264 per year or \$22 per month per contract employee.
- The Insurance Federation of Pennsylvania cites estimates of actuaries at between 2% and 6%.

The insurer and interest groups opposing HB 1150 provided widely varying estimates. The Highmark estimate would indicate a cost of approximately \$20 per member per year, which is approximately 0.50% of premium, while the Insurance Federation of Pennsylvania noted a cost as high as 6%.

⁴⁵See note 33 above.

In Virginia, a survey of insurers was conducted to provide cost estimates of the state's proposed mandate. Twenty companies provided estimates for group coverage. The median estimate among those 20 carriers when the coverage was going to be required for all employers (and not optional) was \$4.88 PMPM, with the range varying from a low of \$0.04 PMPM to \$6.16 PMPM. The median increase for carriers operating in the individual market was also \$4.88 PMPM, with the range being \$0.14 PMPM to \$6.67 PMPM.⁴⁶

The estimated costs of the Virginia mandate are higher than observed in some other states, however, the Virginia analysis indicated that many other states cover autism through their mental health parity mandates, which do not include the types of services provided in ASD-type mandates. There were concerns that the mandate could increase the use of investigational or untested treatments for ASDs; result in a lack of coordination of services for individuals with ASDs and that only reputable providers should be covered by the mandate⁴⁷.

The wide variability of cost estimates provided by Virginia and Pennsylvania insurers and insurer interest groups illustrates the difficulty in developing cost estimates for autism coverage where there are essentially no data for any plans that provide benefits similar to those mandated.

Cost Estimates from Maryland Insurers

Large Maryland insurers provided very little information when asked, "What would be the premium increase if you were obligated to provide benefits for the diagnosis and treatment of autism spectrum disorders?"

- Two carriers provided cost estimates. One carrier estimated the cost at approximately \$45 million, or \$5.00 PMPM, or \$60 per member per year for Maryland-based fully insured businesses only. The other carrier, which has expended more resources estimating the costs of autism mandates in other states, estimated the cost at \$1.43 to \$3.22 PMPM, or \$17.16 to \$38.64 per member per year. This last estimate is based on the assumption that ASDs are not considered a mental illness and that the annual \$50,000 maximum would not be affected by the federal Mental Health Parity Act.
- Four insurers provided no quantitative estimate; one said the cost would cause no significant increase; the other three indicated that an estimate was unknown or not available.

⁴⁶ See note 2 above.

⁴⁷ Ibid

One carrier did provide some perspective on the reasons for not being able to quantify a premium impact, commenting, “This is difficult to estimate without more specific information, such as:

- the evidence based information related to the appropriate number of hours of treatment per day/week/month;
- types and numbers of appropriate treatments per day/week/month; appropriate ages for specific types of treatments;
- is there a limit/level where ABA is no longer effective;
- professional license/certification of providers of ABA care so a cost per service can be estimated. (For example, we have read that an ABA certified educator would charge about \$100 – \$130/hour, while an ABA trained staff would charge \$20 – \$30/hour).
- While the proposed bill specifically identifies and defines ABA as part of the mandate, there are other approaches to the care for autism and ASD that perhaps could be included in some of the very broad definitions. However, we are not aware of any evidence-based information that explains how or if ABA can be combined with other approaches or how other approaches could coordinate, replace or supplement ABA.

We are not able to factor in those possibilities.”

Insurers also expressed some of the concerns and uncertainties associated with providing the mandated benefits, as well as some of the likely administrative difficulties:

- *Increased credentialing costs for determining qualifications of ABA providers* – There may not be enough qualified providers to supply services if this proposal passes. Carriers have no experience contracting with non-health care providers but would have to develop a network of such caregivers if the mandate was enacted. Carriers would have to develop a fee schedule/payment level for non-health care providers, develop and/or work with public agencies to develop criteria for determining who is qualified to provide these services, and develop utilization management and medical policy standards and guidelines for ABA.
- *The costs of obtaining treatment plans* – An updated treatment plan can be requested every six months, but carriers would have to bear the costs of obtaining this plan. Currently, carriers generally do not pay providers for treatment plans.
- *Limitations on carriers’ ability to contain costs* – Current language appears to limit the carriers’ ability to implement cost containment measures, including the ability to perform utilization management and determine medical necessity. The treatment plan should be developed on the basis of an evaluation or re-evaluation of individuals in accordance with the recommendations of the American Academy of Pediatrics and should be a comprehensive plan across disciplines, including medical, behavioral, and mental (if appropriate).

- *What is the educational system's role in helping to treat autism* – Case management services appear to be critical in coordinating the care between the potential number of providers and the educational system. Who is going to have “ownership” for the case management plan of treatment---the educational system or the medical providers? How and who will measure progress under a specific treatment plan? It appears that some services that are currently provided by the school system would be transferred to the medical system. The educational system should be encouraged to improve the services provided to these children. We understand that existing federal law requires state and local school systems to provide appropriate services for children with autism and ASD. Why should employers – especially small employers – be required to subsidize the educational system through health premiums when health premiums are already perceived as being too high, and why should scarce health care dollars pay for educational services?
- *Reliance on ABA as sole treatment method* – The proposed mandate appears to rely on ABA as the only method of treatment; it does not allow for other methods. What happens if a study definitively demonstrates that ABA is of no value?
- *Uncertainty regarding the kind of qualifications and credentials to require of providers* – The proposed mandate states that ABA can be provided only by someone who is an MD or a PhD, or someone who is under the supervision of either of these two. This does not specify that they have any training in ABA. The other provision states that a provider could treat using ABA as long as they are credentialed by the Behavior Analyst Certification Board. Proposals in other states have recommended that treatment be provided by a certified licensed provider.
- *Potential increase in “diagnostic substitution”* – There may be increased use of nonspecific pervasive developmental disorder codes to access treatment of what previously may have been considered developmental delay, attention deficit disorders, and mental retardation. These are also diagnoses for which many proposed treatments are considered not medically necessary.

One carrier thought the current habilitative care mandate would need to be reworded to prevent duplicative care requirements. This same carrier observed that the current habilitative mandate covers children to age 18 while the proposed autism mandate provides coverage to age 21.

Another carrier suggested that the legislation include language to ensure that the benefits would not be considered mental health benefits and that carriers would be allowed to apply exclusions and limitations similar to those for other medical services, such as prohibition of providers from treating relatives, exclusion of experimental medical care and unproven treatments for ASDs, and exclusion of other experimental treatments. Two such examples are art therapy and chelation therapy (a practice of removing all heavy metals from the child – this has resulted in serious side effects and even death).

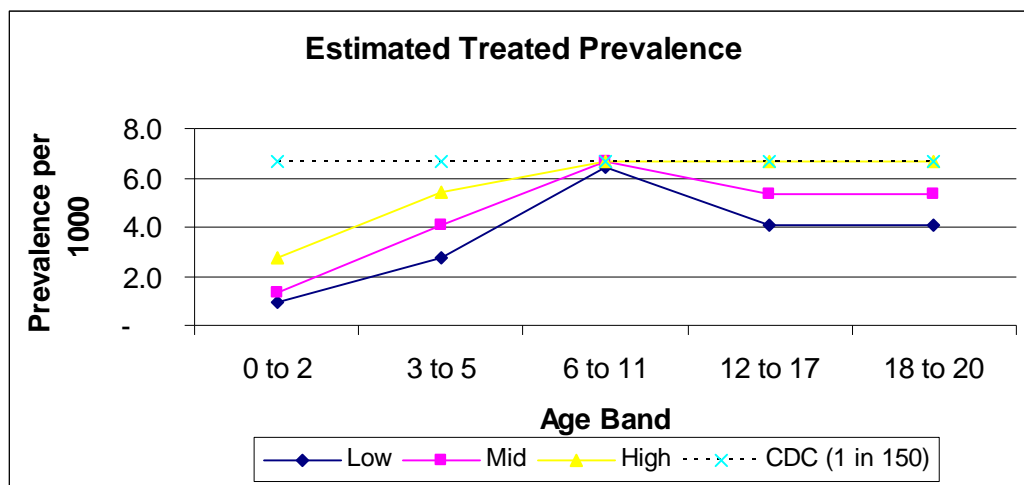
Independent Cost Estimates

The challenges of developing costs for the mandated services are highlighted by the variability in insurers’ cost estimates for mandated autism benefits as well as some of the insurers’ comments regarding projecting costs and overcoming anticipated administrative difficulties. Due to these challenges, it was essentially impossible to do any “bottom-up pricing” by estimating the expected utilization and unit costs associated with specific services by age to estimate costs.

To develop cost estimates, we had to use some judgment regarding treated prevalence, the typical costs of a treatment program, and the effect of age and the integration of educational supports on treatment costs. In light of the uncertainty associated with many of the assumptions needed to develop cost estimates for the services, we developed a range of estimates that provides some reasonable sensitivity to results.

Treated Prevalence – We used the IDEA datasets and population data to ascertain how many diagnosed autistic children were accessing the education system in Maryland. As shown previously, these numbers tend to spike in the six- to 11-year age band and are lower at younger and older ages. Also, the IDEA data does not include any specific data for children under three, so we assumed that the treated prevalence would be some portion of the three- to five-year-olds’ estimate. As some younger children might not access the educational system but could receive benefits under a mandate, we used IDEA educational access data as a lower limit for treated prevalence.

Table 3



Intensity of Services by Age – As noted previously, the Ganz study and the Virginia JLARC analysis both indicated that ABA-associated costs peaked at preschool ages and then decreased for older children. We would also anticipate relatively intensive usage from children two years or younger receiving treatment, but not as intensive as the usage for ages three to five, which we would expect to be highest. In fact, our model assumes that annual costs will be 60%, 80%, and 90% of the \$50,000 maximum for ages three to five. (These percentages represent the low, mid, and high estimates; for example, the low estimate would be 60% of the \$50,000 mandated maximum, or \$30,000; 80% represent

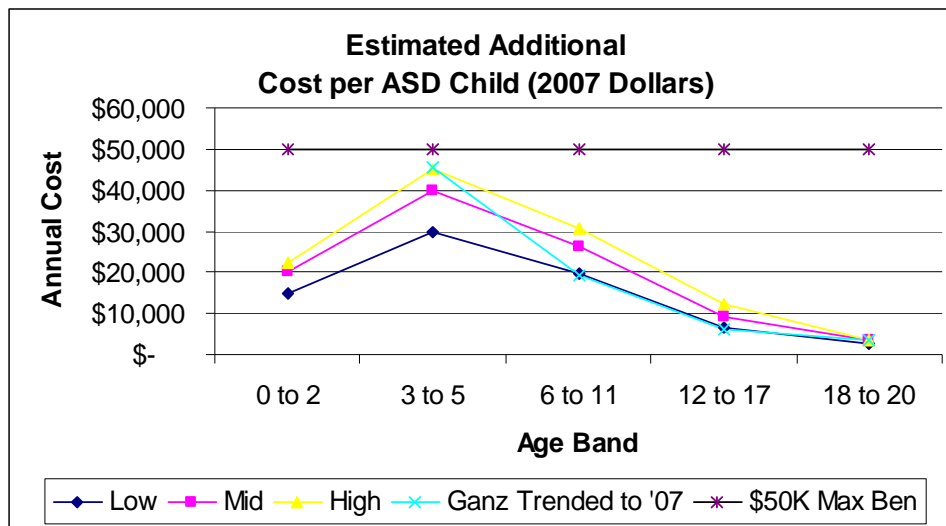
an average annual cost of \$40,000 and 90% represents an average annual cost of \$45,000).

In our review of data and information, simplified unit cost estimates could be \$100 per hour for OT, PT, or ST services, which would result in approximately \$5,000 annual cost per weekly hour of therapy. For ABA, costs could be approximately \$40 per hour (this includes a mix of higher and lower-cost therapists), or approximately \$2,000 annual cost per weekly hour of therapy. With intensive programs potentially requiring five to 10 hours weekly for OT, PT, and ST, and 15 to 40 hours weekly for ABA, costs for intensive therapies for preschool-aged children could easily exceed the \$50,000 annual maximum under the mandate, so the average costs would be a large percentage of the maximum. For older children, we would expect costs to decrease significantly, with a slope generally consistent with the costs by age shown by Ganz – though we estimate that the decrease in costs for older children would reflect a more gradual decreasing slope to account for the likelihood that, at least initially, there could be an expectation of higher ABA utilization for older children who have not received ABA previously. Costs would be expected to decrease for older children for three main reasons:

- Successful early interventions will result in a decreased need for therapies.
- Unsuccessful therapies will result in coverage for certain therapies being reduced or terminated.
- Older children spend a larger percentage of their time in school, where support services are paid by schools rather than by insurers. The time commitment associated with intensive programs is not practical if insured services are received at times other than during the school day.

Our estimates for the costs by age band are shown below. Note that the Ganz costs are trended to 2007, and the costs by the Ganz age bands are weighted to adjust for our use of different bands. We use 2007 as the base year because it is the year for which we have base premium data.

Table 4



Based on our estimates of the treated prevalence, medical costs for the noted age bands, and Maryland demographic data, we developed a range of estimates of the total annual costs that might be expected under our range of assumptions. We translated these benefit costs to a PMPM basis in 2007 dollars by dividing them by the under-65 Maryland population, and then adding administrative cost estimates based on typical insurer administrative costs. These amounts were also calculated as a percentage of per-member premium based on small group premium data. Our low, mid, and high estimates as a percentage of premium were 0.52%, 0.85%, and 1.22% of the CSHBP per-member premium. Summaries of these calculated amounts are shown in Table 5.

Table 5

<u>Low Estimate</u>				
Age Band	Age Band % of Population	ASD Treated Prevalence for Age Band	Cost per Treated Child	Mandate Cost per Insured MM
0 to 2	4.6%	0.09%	\$15,000	\$0.63
3 to 5	4.5%	0.27%	\$30,000	\$3.66
6 to 11	8.5%	0.65%	\$19,659	\$10.77
12 to 17	10.3%	0.41%	\$6,758	\$2.84
18 to 20	4.6%	0.41%	\$2,625	\$0.49
	<u>32.4%</u>			<u>\$18.39</u>
		Admin Estimate		\$1.49
		Admin % of Premium		7.50%
		Premium Increase Per Member		\$19.89
		MD 2007 Small Group Premium per Member		\$3,801
		Premium Increase % of Premium		0.52%
<u>Mid Estimate</u>				
Age Band	Age Band % of Population	ASD Treated Prevalence for Age Band	Cost per Treated Child	Mandate Cost per Insured MM
0 to 2	4.6%	0.14%	\$20,000	\$1.25
3 to 5	4.5%	0.41%	\$40,000	\$7.33
6 to 11	8.5%	0.67%	\$26,212	\$14.81
12 to 17	10.3%	0.53%	\$9,011	\$4.95
18 to 20	4.6%	0.53%	\$3,499	\$0.85
	<u>32.4%</u>			<u>\$29.20</u>
		Admin Estimate		\$3.24
		Admin % of Premium		10.00%
		Premium Increase Per Member		\$32.44
		MD 2007 Small Group Premium per Member		\$3,801
		Premium Increase % of Premium		0.85%
<u>High Estimate</u>				
Age Band	Age Band % of Population	ASD Treated Prevalence for Age Band	Cost per Treated Child	Mandate Cost per Insured MM
0 to 2	4.6%	0.27%	\$22,500	\$2.82
3 to 5	4.5%	0.54%	\$45,000	\$10.99
6 to 11	8.5%	0.67%	\$30,455	\$17.21
12 to 17	10.3%	0.67%	\$12,153	\$8.35
18 to 20	4.6%	0.67%	\$3,499	\$1.06
	<u>32.4%</u>			<u>\$40.44</u>
		Admin Estimate		\$5.78
		Admin % of Premium		12.50%
		Premium Increase Per Member		\$46.22
		MD 2007 Small Group Premium per Member		\$3,801
		Premium Increase % of Premium		1.22%

These independent estimates are within the range we have observed in other studies.

We have made no attempt to differentiate between full costs and marginal costs, as some autism services are covered under the habilitative services mandate. We did not have any hard data to estimate their costs, which we would expect to be relatively low compared with the costs of the additional services under this mandate, especially ABA services.

Table 6: Summary of Cost Estimates for Autism Benefits

	Cost
Estimated cost of mandated benefits as a percentage of average cost per group policy	0.52% to 1.22%
Estimated cost as a percentage of average wage	0.07% to 0.17%
Estimated annual per employee cost of mandated benefits for group policies	\$36 to \$83

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2**Coverage of In Vitro Fertilization**

Insurance Article 15-810, Annotated Code of Maryland, prohibits a health insurer, non-profit health service plan, or HMO (carrier) from refusing to issue a policy providing in vitro fertilization (IVF) benefits after: (1) an applicant is tested for infertility; or (2) a test performed on an applicant results in a diagnosis of unexplained infertility or a similar diagnosis. In addition, Section 15-810(b)(3) of the mandate states that benefits must be provided for outpatient expenses arising from IVF procedures if the patient and/or the patient's spouse have a history of infertility of at least two years, or the infertility is associated with endometriosis, exposure to diethylstilbestrol (DES), blockage or removal of fallopian tubes, or abnormal male factors.

The proposed change to the mandate addresses Section 15-810(b)(3)(i) and specifies that the duration of infertility will be counted without regard to any pregnancy terminating as a result of a miscarriage. Since Section 15-810 already requires insurers to cover IVF for beneficiaries who meet the current mandate's requirements, the additional cost of the proposed change would result from a subset of women who are not considered infertile based on the definition of infertility under the current mandate, or potentially women who could meet the definition earlier due to a miscarriage not counting towards the "duration of infertility."

We anticipate that the mandate would largely affect IVF coverage for three groups of women:

(1) Women (or couples) who have an underlying condition or conditions not specified in the mandate, that could be expected to conceive, but not carry a pregnancy to term. These women have some underlying condition that results in pregnancies being terminated by miscarriage for which IVF has been shown to be more effective than other fertility treatments.

(2) Women who have experienced at least one miscarriage and are seeking aggressive reproductive treatments and desire IVF due to its perceived higher likelihood of producing a pregnancy relative to other treatments but do not necessarily have an underlying condition that would make IVF more effective.

(3) Women who have experienced a miscarriage, or a limited number of miscarriages who could potentially meet the two-year infertility requirement under the current mandate, but who would meet it sooner under the proposed mandate. A discussion of the medical, financial, and social impacts of this proposed mandate follows.

Medical Impact

In this section, we answer questions regarding IVF coverage for women who have had at least one miscarriage and a history of fertility problems.

- **Does the medical community recognize IVF as being effective in treating patients with a history of miscarriages?**
- **Is IVF generally recognized by the medical community, as demonstrated by a scientific and peer review of literature?**
- **Is IVF available and utilized by treating physicians?**

With the implementation of Section 15-810 of the Insurance Article, Maryland recognized that IVF meets the medical efficacy requirements to become a mandated benefit. A discussion of IVF's merits has been rigorously reviewed by the Maryland Legislature and therefore not replicated in this report. However, the proposed change to the legislation does prompt the question of how effective IVF is in treating infertility in women who have had one or more miscarriages relative to other reproductive treatments.

A miscarriage is commonly defined as the loss of a fetus within the first 20 weeks of pregnancy and may result from a variety of causes. Chromosomal problems, uterine abnormalities, hormonal issues, immune system problems, and infections are among the main causes. These factors also top the list for causes attributed to repeat miscarriages.⁴⁸

Additionally, women with the following characteristics are at a greater risk of miscarriage.⁴⁹

- Previous miscarriage
- Over age 35
- Maternal illness
- Alcohol consumption – more than two drinks per day
- Cigarette smoking – over half a pack per day increases chances significantly
- Excessive consumption of caffeine

⁴⁸ Marchofdimes.com: Medical References, Miscarriage. http://www.marchofdimes.com/professionals/14332_1192.asp

⁴⁹ www.umn.edu: University of Maryland Medical Center, Miscarriage. <http://www.umn.edu/altmed/articles/miscarriage-000108.htm>

According to the American College of Obstetricians and Gynecologists (ACOG): *Miscarriage is the most common type of pregnancy loss. Studies reveal that anywhere from 10-25% of all clinically recognized pregnancies will end in miscarriage. Chemical pregnancies may account for 50-75% of all miscarriages. This occurs when a pregnancy is lost shortly after implantation, resulting in bleeding that occurs around the time of her expected period. The woman may not realize that she conceived when she experiences a chemical pregnancy.*⁵⁰ Due to the nature of chemical pregnancies, we would not anticipate that they would have a significant impact on IVF eligibility under the current or proposed criteria, since they most likely would not have been documented by medical professionals or carriers.

The proposed changes in the mandated IVF coverage should target women who have an underlying condition that allows them to conceive, however, does not allow them to carry a pregnancy to term, and IVF would increase the likelihood of a successful pregnancy versus another means of treatment.

According to Alan Zwerner, MD, Mercer's Ob-Gyn consultant with extensive infertility practice experience, elimination of counting miscarriages in determining the two-year waiting period prior to initiating infertility treatment is reasonable and fair. The primary goal of infertility treatment is a live birth and healthy baby. Miscarriages, by definition, do not result in this outcome; i.e., a live birth. Therefore, it is reasonable to not count the occurrence of a miscarriage when determining if a woman is infertile. However, that said, elimination of counting miscarriages should not imply that IVF is the appropriate intervention. The couple first needs to undergo a logical, comprehensive work-up to ascertain the underlying cause of the infertility, which will determine the recommended clinical approach. IVF may be one of several possible treatments. For instance, if the underlying cause of the miscarriage(s) is a genetic abnormality of sperm, donor sperm may be a more practical and less invasive approach than IVF. If the underlying cause of the miscarriage(s) is a structural uterine abnormality, then IVF in and of itself will not help the woman carry a fetus to a live birth.

One statistic that suggests that IVF should generally not be automatically covered is that even without treatment, women who have had multiple miscarriages have a 60 to 70 percent chance of a successful pregnancy.⁵¹ The decision to undergo IVF treatment or cover it should be taken very seriously based on the potential risks associated with multiple births which include greater risk of premature birth, low birth weight and birth defects, as well as increased risks to the women, including high blood pressure and postpartum depression.⁵²

⁵⁰ American Pregnancy Association, *Miscarriage*—quoting statistics from American College of Obstetricians and Gynecologists, last updated 2007. <http://www.americanpregnancy.org/pregnancycomplications/miscarriage.html>

⁵¹ Mayo Clinic Staff. "Pregnancy: Understanding Miscarriage." January 23, 2008. <http://www.mayoclinic.com/health/miscarriage/PR00097>

⁵² Medical News Today. "Wall Street Journal Examines Persistent Multiple Births After IVF As Doctors Ignore Guidelines." October 10, 2005. <http://www.medicalnewstoday.com/articles/31784.php>

Additionally, studies indicate that 30% to 40% of pregnancies with three or more births in the U.S. occur due to the implantation of more than the recommended number of embryos during IVF.⁵³ In the opinion of Mercer's medical staff, "Front loading" and use of multiple embryo implants raises medical and ethical issues. For example, if four embryos survive, would the patient and physician contemplate the possibility of selective harvesting? Although the likelihood of success increases with multiple implants, indeed there is a significant price to pay from the added costs and compromised outcomes that accompany multiple gestations.

In theory women who have had recurrent miscarriages would be most likely to seek IVF treatment under the proposed mandate, although there could also be another category or women whose age makes conceiving more difficult who may want to go directly to IVF after a single miscarriage. An underlying condition reducing the likelihood that a pregnancy would result in a live birth could manifest itself through recurrent miscarriages which are a serious problem for a small percentage of women. In many cases there is likely a persistent underlying cause for pregnancy loss in a portion of the women who have experienced recurring miscarriages.⁵⁴ Women who have had multiple miscarriages are encouraged to have testing done to determine the underlying cause. Discovering the underlying cause allows for treatment to prevent future miscarriages.

The overwhelming majority of procedures used to treat recurrent miscarriages do not include IVF. Due to the invasive nature and emotional stress of IVF, most doctors would recommend other treatments, and the mandate requires the use of other treatments if they are covered under the insurance contract. However, under certain circumstances, IVF appears effective in treating recurrent miscarriages. In 3% – 5% of all recurrent miscarriages, a form of IVF treatment known as pre-implantation genetic diagnosis can be used to treat couples with chromosomal abnormalities from either the male or the female – where the woman may be able to conceive, but the chromosomal abnormality causes the pregnancy to terminate.⁵⁵ IVF allows doctors to examine an embryo for chromosomal abnormalities before it is placed back into the woman.⁵⁶

According to the Centers for Disease Control's *2005 ART Report*, 70,068 advanced reproductive treatment (ART) cycles were performed in the US in 2005 on women who had not previously given birth. (Note that ART and IVF are generally synonymous). Of those cycles, 27% were reported by women who had one or more previous miscarriages. An analysis of the success rates showed that women with one or more previous miscarriages were as likely to have a live birth as women without a history of miscarriages. Thus, ART procedures are currently being performed on women with a history of one or more miscarriages, and the success of those procedures does not appear to be hindered by a history of miscarriage.⁵⁷

⁵³ Ibid

⁵⁴ Investigation of Treatment of Couples with Recurrent Miscarriage, Royal College of Obstetricians and Gynaecologists. Guideline No. 17. http://www.rcog.org.uk/resources/Public/pdf/Recurrent_Miscarriage_No17.pdf

⁵⁵ Ibid

⁵⁶ Brody, E. Jane. "Trying Again After Recurrent Miscarriages." *The New York Times*. March 25, 2008. <http://www.nytimes.com/2008/03/25/health/25brod.html>

⁵⁷ Centers for Disease Control. "2005 ART Report." 35. October 2007. <http://www.cdc.gov/art/art2005/download.htm>

According to the Centers for Disease Control and Prevention (CDC), a woman's age is the most important factor in the success of IVF. The older the woman, the less likely IVF will result in a live birth. This is especially true for women over age 40. A study by the CDC shows that 37% of ART cycles among women under age 35 resulted in live births, while only about 16% of cycles among women age 40 resulted in live births. This percentage decreases about 3% - 4% each year after age 40. Women who have had fertility problems and at least one miscarriage would be eligible to receive IVF treatment earlier than the current mandate provides. This could be expected to increase the probability of a successful IVF cycle for older women, particularly for women over age 40.⁵⁸

Mercer surveyed several major insurers that provide coverage in Maryland. The carriers expressed concern over the increased cost and lack of clinical rationale for the proposed change. Their concern was that women would receive IVF treatment despite a low chance of a successful pregnancy. Additionally, carriers viewed the clinical definition of infertility as the inability to get pregnant; a miscarriage would not meet that definition.

Several insurers noted these concerns in survey responses, as follows:

- “The statistics on spontaneous abortions (SAB) or recurrent pregnancy loss (RPL) is [are] varied since many pregnancies result in early loss that is not reported and in fact the woman may not even know that she is pregnant.... The benefit of IVF as a treatment for SAB/RPL is unclear and unproven.... The potential for identifying a large population as having a history of SAB coupled with varied and unproven treatment methodologies creates an environment conducive to over- and mis-utilization....”
- “...proponents of the legislation should be asked to provide the clinical research/study results documenting that women with a history of miscarriages can safely and successfully carry to term a baby conceived through IVF.”

Similar concerns were expressed during a conference call among some of the medical directors from major insurers in Maryland, the MHCC, and Mercer: During the conference call, it was noted that there are many causes for multiple miscarriages, and identifying the underlying cause(s) is more important to a successful delivery. By definition, if a woman has had multiple miscarriages, she has been able to conceive.

The medical directors on the conference call indicated that infertility is now generally defined clinically as greater than one year of regular unprotected intercourse without conception. Most IVF protocols allow eligibility for IVF after only one year of infertility, as opposed to the existing law's two-year requirement.

Ignoring pregnancy and miscarriage occurring during the two-year period required in Maryland law effectively accelerates the eligibility for IVF by months or years. Some natural pregnancies that might have normally occurred after 13, 14 or 15 months of "infertility" as it is customarily defined will be pre-empted.

⁵⁸ Ibid

Shortening the time interval during which women can begin IVF will increase the likelihood of a successful pregnancy in large part due to the patient being younger by roughly one year. Furthermore, the mandate limiting the treatment to three cycles does encourage fertility specialists to "front load" and use multiple embryo implants. This raises medical and ethical issues. For example, if four embryos survive, would the patient and physician contemplate the possibility of selective harvesting? Although the likelihood of success increases with multiple implants, indeed there is a significant price to pay from the added costs and compromised outcomes that accompany multiple gestations.

Social Impact

In this section, we address the following:

- **To what extent will the proposed change generally be utilized by a significant portion of the population?**
- **To what extent is the insurance coverage already generally available?**
- **To what extent does lack of coverage result in individuals' avoiding necessary health care treatments?**
- **To what extent does lack of coverage result in unreasonable financial hardship?**
- **What is the level of public demand for the services?**
- **How interested are collective bargaining agents in negotiating privately for inclusion of this coverage in group contracts?**
- **To what extent is the mandated health insurance service covered by self-funded employers in the state with at least 500 employees?**

The CDC is required to oversee all advanced reproductive treatments (ART). In 2008, it released the results for cycles that began in 2005. The report shows that, from a reported 422 clinics, there were 92,405 cycles.⁵⁹ Comparing this with the 6.1 million women with infertility problems, the number and percentage of infertile women who choose some form of ART is relatively small. Likewise, utilization for the entire population is even smaller.⁶⁰

In Maryland, of an estimated 740,000 women of child-bearing age⁶¹ with employer-based coverage, the number of CDC-reported cycles was 4,078 in 2005.⁶² This would indicate an incidence of approximately 6 per 1,000 women of child-bearing age, or 1 per 1,000 for all members. In either case, the benefit would be used by a small portion of the

⁵⁹ Ibid, 85

⁶⁰ National Center for Health Statistics. Infertility. <http://www.cdc.gov/nchs/FASTATS/fertile.htm>

⁶¹ US Census Bureau. Health Insurance Table Creator. http://www.census.gov/hhes/www/cpstc/cps_table_creator.html

⁶² Centers for Disease Control, 280-286

population. The relatively low incidence of IVF treatment does limit the number of settings in which it is performed, and availability is less widespread in geographic areas with limited populations. As the 2005 CDC data indicated, IVF was performed at only seven sites in Maryland that year.

Maryland currently mandates IVF coverage after a two-year infertility period and for infertility associated with certain factors. Carriers must provide three in vitro fertilization attempts per live birth, at a maximum benefit of \$100,000. The change in the mandate language would cover additional women, or cover women sooner who have experienced miscarriages.

In general, carriers do not recognize infertility treatment as medically necessary. Although there may be health effects associated with infertility, and the lack of access to infertility treatment may contribute to mental health issues involving stress or depression, most carriers would consider infertility treatment a choice, rather than a necessity, as there are no direct medical consequences for people who do not seek IVF treatment. Regardless of necessity, we would also question the appropriateness of mandating coverage of IVF for individuals when there is no medical evidence to suggest that IVF would result in a better outcome than other means who potentially have IVF treatments covered by the mandate. Some have asserted that the urgency for curing infertility is rather low compared with other medical priorities.⁶³

The financial impact for the individuals affected by the mandate is significant. In the *Financial Impact* section of this report, we note a per cycle cost of \$15,000 to \$20,000. The changes in the proposed mandate would allow some women to become eligible for IVF coverage who previously were not, and others to become eligible for covered benefits sooner. The financial hardship for women and their families who pay for IVF treatments out-of-pocket could be significant, however, as noted in many cases there are alternative, frequently utilized lower-cost alternatives to costly IVF treatments available. While the actual number affected would be small, there would likely be a great deal of demand in receiving this benefit by those affected.

All collective bargaining agents who responded to the survey indicated that this benefit was already covered. However, it is quite possible that the bargaining agents are not totally conversant with all of the details of their current benefits. This is a rather “subtle” change in the verbiage. Mercer also surveyed sponsors and administrators of self-funded plans and determined that coverage of IVF benefits as defined in the current Maryland mandate varied. Generally, coverage varied from carrier to carrier, and specific coverage was also plan specific and based on the plan sponsor’s preference. One carrier noted that the IVF coverage consistent with the current mandate was not part of any self-insured plan, while another indicated that all self-insured plans had benefits consistent with the current mandate.

Financial Impact

⁶³ Mandated Benefits Review by the Pennsylvania Health Care Cost Containment Council. March 2006. <http://www.phc4.org/reports/mandates/HR400/docs/mandateHR400report.pdf>

The commonly accepted definition of infertility is 12 months or more of unprotected intercourse without pregnancy,⁶⁴ and the current provision in Section 15-810(b)(3) of the Insurance Article states that the duration of infertility must be at least two years (or the infertility must be associated with certain factors) for benefits to be provided. Since Section 15-810 already requires insurers to cover IVF for beneficiaries who meet the conditions in the current mandate, the additional cost of the proposed change would be for those groups of women identified in the first page of this report.

Data from the 2005 CDC ART study for Maryland indicated that 4,078 IVF cycles were undertaken at Maryland facilities in 2005.⁶⁵ We could make the assumption that the vast majority of these IVF treatments would be provided to insured individuals though the treatments may not be covered. We are also assuming that the cost per cycle ranges from \$15,000 to \$20,000 – which is consistent with the Department of Legislative Services' *HB 701: Fiscal and Policy Note* – and that a woman undergoing IVF treatment would have 1.5 cycles per year, which is consistent with our prior MHCC in vitro analysis, conducted in 2002. We note that our analysis of cost impact is not nearly as sensitive to the per-cycle cost assumptions as it is to the uncertainty and necessary ranges around other assumptions related to the estimates of the number of treatments affected by the proposed mandate and the expected increase in IVF utilization.

Determining exactly how many additional cycles would be undertaken or undertaken sooner, and how many cycles that would have been undertaken, anyway, in the absence of the revised mandate and paid for out-of-pocket because they did not qualify for coverage under the existing mandate is challenging. Specific information and data on the nature of the reason for the IVF treatment, the incidence and timing of miscarriages for those who have received IVF, and the incremental additional women eligible for covered IVF treatments based on the revised eligibility criteria who would now utilize IVF do not appear to exist.

As noted previously, 27% of the national IVF cycles in 2005 for women who had never given birth were reported for women who had had one or more previous miscarriages. Based on this statistic, 27% is a reasonable starting point for an estimate of the total percentage of IVF cycles that could be impacted by the change in the mandate eligibility requirements. As this 27% is only a reasonable starting point for the percentage of IVF treatments under the current mandate that could have their coverage impacted by the proposed mandate, a range could be 20% - 35%. We would expect that coverage could be impacted for this group in the following manner:

- (1) No effect (e.g., women who have one of the specified conditions - endometriosis, exposure to diethylstilbestrol (DES), blockage or removal of fallopian tubes, or abnormal male factors and would already be covered)
- (2) Covered sooner (e.g., women who could meet the current two year requirement, but will meet it sooner by not considering miscarriage(s) in the two year period)

⁶⁴ Definition of Infertility. <http://www.medterms.com/script/main/art.asp?articlekey=3977>

⁶⁵ Centers for Disease Control, 280-286

(3) Covered when previously not covered (e.g., would not be expected to meet the two year period for infertility under the current mandate due to miscarriage(s))

As part of the financial impact analysis, we have estimated the additional costs associated with the IVF cycles that would be performed under the current mandate for women who have had miscarriage(s), but could be covered differently under the proposed mandate as noted in (1) – (3) above. In order to do this, we had to develop estimates as to the percentage of the IVF cycles undertaken by women who have had miscarriages that under the proposed mandate would be covered in the same manner, be covered sooner, and would now be covered but were not previously.

In estimating the cost of accelerated services for IVF, we have assumed that services would be provided one year earlier and that the cost is based on the time value of money, assuming a 5% interest rate.

In addition, we need to consider additional costs that may be incurred for IVF treatments undertaken by women who would seek IVF due to the fact that it would be covered under the proposed mandate. We have based the estimates of the additional IVF cycles undertaken by developing a range of estimates for the increased IVF utilization based on a New England Journal of Medicine study of the difference in utilization when IVF is covered by insurance mandates versus when it is not.⁶⁶

⁶⁶ Tarun Jain, M.D., Bernard L. Harlow, Ph.D., and Mark D. Hornstein, M.D. "Insurance Coverage and Outcomes of in Vitro Fertilization." *The New England Journal of Medicine*. October 29, 2002.

Our resulting estimate of the incremental cost of the covered benefits is approximately 0.03% – 0.22% of premium, as outlined in Table 7 below.

Table 7: Estimated Cost of Mandated In Vitro Benefits

	Scenario		
	Low	Mid	High
Total Number of Cycles in Maryland per CDC Data	4,078	4,078	4,078
Estimated Cost per In Vitro Cycle	\$ 15,000	\$ 17,500	\$ 20,000
Estimated Maryland In Vitro Cost with Current Mandate	\$ 61,170,000	\$ 71,365,000	\$ 81,560,000
% of IVF Cycles for Women who have had a Previous Miscarriage	20%	27%	35%
Total Cycles Currently Undertaken by Women having Prior Miscarriage	816	1,101	1,427
Impact of Mandate for Currently Performed IVF			
(1) % of Cycles Unaffected by Mandate	60%	40%	20%
(2) % of Accelerated Cycles	20%	30%	40%
(3) % of Cycles Covered by Proposed Mandate Previously Uncovered	20%	30%	40%
Cost per Cycle of Proposed Mandate for Currently Performed IVF			
(1) Cycles Unaffected by Mandate	\$0	\$0	\$0
(2) Accelerated Cycles	\$750	\$875	\$1,000
(3) Cycles Covered by Proposed Mandate Previously Uncovered	\$15,000	\$17,500	\$20,000
Cost of Proposed Mandate for Currently Performed IVF			
(1) Cycles Unaffected by Mandate	\$ -	\$ -	\$ -
(2) Accelerated Cycles	\$ 122,340	\$ 289,028	\$ 570,920
(3) Cycles Covered by Proposed Mandate Previously Uncovered	\$ 2,446,800	\$ 5,780,565	\$ 11,418,400
Cost of Proposed Mandate for Currently Performed IVF	\$ 2,569,140	\$ 6,069,593	\$ 11,989,320
Cost of Additional IVF Cycles			
Multiple of Cycles Covered by Proposed Mandate Previously Uncovered	100%	139%	177%
Cost of Additional IVF Cycles due to Proposed Mandate	\$ 2,446,800	\$ 8,006,083	\$ 20,210,568
Total Additional Cost	\$ 5,015,940	\$ 14,075,676	\$ 32,199,888
Approximate Employer Based Coverage Cost	\$14,376,246,170	\$14,376,246,170	\$14,376,246,170
Current Mandate Base Cost/Year (Per member)	15.50	17.27	18.40
Marginal Additional Cost/Year (Per member)	1.33	3.72	8.51
Proposed Mandate Full Cost/Year (Per member)	16.82	20.99	26.91
2007 CSHBP Premiums	\$1,587,121,749	\$1,587,121,749	\$1,587,121,749
2007 CSHBP Member Months	5,010,080	5,010,080	5,010,080
2007 CSHBP PMPM Premiums	\$317	\$317	\$317
Base Cost/Year as % of SG Per Member Premium	0.41%	0.45%	0.48%
Incremental Cost/Year as % of SG Per Member Premium	0.03%	0.10%	0.22%

We have not included any additional costs associated with the increase in complicated pregnancies, live births, and multiple births that can be expected from the increased accessibility to and utilization of IVF. This is difficult to quantify and the mandate will likely impact costs in multiple ways that are offsetting to some extent. If we assume additional IVF cycles are undertaken, then there would be an expected increase in costs for high risk pregnancies and multiple births. However, it is also likely that the corresponding costs for IVF cycles that were previously paid for out-of-pocket could be lower as these women potentially would implant a smaller number of embryos if the costs of the IVF cycles are covered. Also, the costs for pre-natal care, live births, including multiple births, resulting from self-pay IVF are reflected in the current premiums, since the insured health plans would be responsible for pre-natal care, etc. regardless of how the

woman conceived. Additionally, our range of cost estimates does not include the impact of cost-sharing provisions.

Table 8 summarizes the detailed cost estimates developed in Table 7. Note that most of the costs of the mandated in vitro benefit as contemplated in the proposed mandate are covered under the current in vitro benefit. We would expect that the incremental impact of newly covered in vitro benefits would be to increase costs by about 10% – 40%.

Table 8: Summary of Full and Marginal Cost Estimates for In Vitro Benefits

	Full Cost	Marginal Cost
Estimated cost of mandated benefits as a percentage of average cost per group policy	0.44% to 0.71%	0.03% to 0.22%
Estimated cost as a percentage of average wage	0.06% to 0.1%	0% to 0.03%
Estimated annual per employee cost of mandated benefits for group policies	\$30 to \$48	\$2 to \$15

In a survey of some of the larger insurers in Maryland, only three respondents provided any estimate as to the cost impact. These estimates ranged from a premium increase of 0.1% of premium to “maybe 1 - 2%” of premium. It is not clear how much rigor went into the cost analyses done to develop these estimates. However, the low-end estimate falls within our range of estimates, and any estimated increase of 1% or more would essentially require the assumption that the cost of IVF would roughly triple assuming that current IVF costs are about 0.5% of premium. It is also possible that the carrier estimates assume other significant costs (e.g., multiple births) that we did quantify in our estimates.

Two insurers also provided estimated costs per cycle of \$12,000 and \$21,000, and it was unclear what was included in those amounts (initial IVF treatment only, or initial treatment plus other services, costs associated with multiple births, etc.). This would indicate that our per-cycle cost estimates of \$15,000 to \$20,000 are reasonably consistent with carrier estimates.

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**3**

48-Hour Hospital Inpatient Stay Following Mastectomy

This proposed mandate would require insurers, non-profit health service plans, and HMOs (“carriers”) to provide coverage for a 48-hour hospital inpatient stay following a mastectomy. The state of Maryland currently does not mandate a minimum of 48 hours of inpatient coverage for this service. Instead, Section 15-832 of the Insurance Article, Annotated Code of Maryland, requires carriers to provide one home visit within 24 hours after discharge and an additional home visit if prescribed by the patient’s attending physician for a patient who receives less than 48 hours of inpatient hospitalization. The current law allows the carrier to decide whether to cover the inpatient stay or the home visits. The proposed mandate would allow the patient and the physician to make the decision as to whether to stay in the hospital or accept the home visit.

A discussion of the medical, social, and financial impact of this proposal follows.

Medical Impact

In this section, we answer the following questions related to mandatory coverage of 48-hour hospital inpatient stays following mastectomy:

- **Is it recognized by the medical community as being effective in treating patients?**
- **Is a 48-hour inpatient stay medically necessary for all mastectomy patients?**
- **How do complication rates, readmission rates, and patient satisfaction differ for outpatient and inpatient mastectomy surgeries?**
- **Is it recognized by the medical community, as demonstrated by scientific and peer review literature?**
- **Is it available and utilized by treating physicians?**

“A mastectomy is a common surgical treatment method for breast cancer. A mastectomy involves partial or entire surgical removal of the breast or both breasts. A mastectomy can also be done for preventive measures for those who are at extreme high risk for developing breast cancer.”⁶⁷ Surgeons often perform reconstructive surgery at the time of mastectomy, which would extend the length of stay depending on the degree of cancer.

Mastectomies are performed in both inpatient and outpatient settings. Several studies have been conducted to explore the outcomes of outpatient, or short-stay, and inpatient mastectomy procedures. Following are descriptions and outcomes of the studies.

Researchers at the National Cancer Institute and the Health Care Financing Administration conducted an analysis to explore the difference in medical outcomes for inpatient and outpatient mastectomy procedures in women ages 65 and older who were enrolled in Medicare Parts A and B.⁶⁸ The analysis was based on a retrospective look at inpatient and outpatient simple and modified mastectomy data from 1986 to 1995. Joan Warren, PhD, a member of the research team, summarized the findings:

“These results show that for the women in this study who underwent outpatient mastectomy, the risks of surgery-related complications were modest in terms of both the degree of relative risk and the types of health complications reported. However, the slightly higher rates of hospital readmission suggest that ongoing monitoring of the use and outcomes of outpatient mastectomy is needed, particularly if there is broader utilization of this procedure. . . . Furthermore, it is important to note that this study did not address an important aspect of assessing outpatient mastectomy, namely women's satisfaction with undergoing an outpatient procedure.”⁶⁹

In a 1997 study, L. R. Tan and J. M. Guenther explored complication and readmission rates in outpatient mastectomy patients.⁷⁰ The study was based on 100 consecutive patients from August 1994 to July 1996 who had procedures for lymph node dissection and partial, simple, and modified radical mastectomy. Fifty patients were discharged on the day of their surgery, 44 patients were hospitalized, and six patients remained hospitalized for two or more days after surgery. Tan and Guenther found no complications in the 50 outpatient procedures. There was one complication of a wound infection in the 50 inpatient procedures.

William Dooley, MD, a surgical oncologist at Johns Hopkins Breast Center, released the results of a study in 2002 that explored complication and readmission rates for 87 patients who had outpatient lumpectomy or mastectomy surgery from March 2001 to October

⁶⁷ About.com: Cancer. “Mastectomy Overview.” <http://cancer.about.com/od/mastectomy/a/mastectomy.htm>

⁶⁸ Warren, Joan L., et al. “Trends and Outcomes of Outpatient Mastectomy in Elderly Women.” *Journal of the National Cancer Institute*. Vol. 90, No. 11. June 3, 1998.

⁶⁹ National Institutes of Health. “Modest Risks Found in First Population-Based Study of Outpatient Mastectomies.” (1998), <http://www.nih.gov/news/pr/jun98/nci-02.htm>

⁷⁰ Tan, L. R. and J. M. Guenther. “Outpatient Definitive Breast Cancer Surgery.” *The American Surgeon*, Vol. 63, Issue 10: 865-867. October 1997.

2001.⁷¹ Of the 87 patients, 86 were discharged within 2.5 hours of the surgery. Dooley compared the outpatient results to the results of lumpectomy and mastectomy patients at the same hospital during 2000. The average length of stay for these patients was 1.6 days. The distribution of age and insurance coverage was the same between the two groups, but the patients in 2000 had a slightly lower rate of breast conservation (59%, versus 74% in the outpatient group). Dooley's study found that, of the 87 outpatient cases, four patients experienced nausea, two had seromas following drain removal, and one had a wound infection. In comparison, the 2000 study, which consisted of inpatient mastectomies, included a 6% complication rate for wound infections. Dooley's study indicated that complication rates were lower for outpatient procedures, but that may be partly due to less complicated outpatient procedures.

Dooley also completed a study that focused more on patient satisfaction.⁷² The study consisted of 204 mastectomy patients who were treated from 1995 to 1997. The patients chose whether to have the mastectomy procedure completed on an inpatient or outpatient basis. The physiological impacts and patient satisfaction results will be discussed later.

Richard G. Margolese, MD, and Jean-Claude M. Lasry, PhD, completed a study comparing the outcomes for total mastectomy, lumpectomy, and auxiliary breast surgeries between inpatient and outpatient groups.⁷³ The study included patients from April 1994 through September 1996. Before April 1995, all mastectomy procedures were performed on an inpatient basis. From April 1995 onward, all mastectomies were completed on an outpatient basis. The outpatient group was comprised of 55 consecutive patients from April 1995 to September 1996. The inpatient group consisted of 35 patients who had a mastectomy between April 1994 and March 1995. Age, demographics, and complexity of the procedure were similar between the inpatient and outpatient groups.

Readmission Rates

The analysis completed by the National Cancer Institute and the Health Care Financing Administration showed that the total rate of readmission within 30 days of surgery for *simple* mastectomy procedures was 43% higher for the outpatient group; the total rate of readmission within 30 days of surgery for *modified radical* mastectomy was 28% higher for the outpatient group. However, these outcomes were heavily influenced by factors not directly related to the surgery and, with these external factors removed, the readmission rates for complications that were definitively related to the surgery were about the same for the inpatient and outpatient groups, suggesting that readmission rates are not worse for outpatient mastectomies. The outpatient group had more readmissions for conditions such as dehydration, pneumonia, and urinary tract infections – conditions that were not definitively related to the mastectomy surgery.

⁷¹ Walling, Anne D., MD. "Early Hospital Discharge Following Mastectomy." *American Family Physician*. April 1, 2003.

⁷² Davis, Jeanie Lerche. "Outpatient Mastectomy a Viable Option for Many Women." *WebMD Health News*. (2000). <http://www.webmd.com/news/20000324/outpatient-mastectomy-option-women>

⁷³ Margolese, Richard, MD and Jean-Claude Lasry, PhD. "Ambulatory Surgery for Breast Cancer Patients." *Annals of Surgical Oncology*. (2000) 7(3): 181–187. <http://www.annalssurgicaloncology.org/cgi/reprint/7/3/181>

Dooley found that none of the outpatients in his 2001 study required readmission to the hospital after being discharged. This is compared with the 2000 inpatient results, in which 2% of the patients were readmitted after their initial discharge. Dooley's study indicated that readmission rates were lower for outpatient procedures, but that may be partly due to less complicated outpatient procedures.

Physiological Impacts and Patient Satisfaction

The results of the Margolese and Lasry study show that recovery times were shorter for the outpatient group by about 10 days and that the outpatient group adjusted better emotionally after the surgery. Pain levels were about the same between the two groups. In the outpatient group, 41% of patients reported that they would have rather had inpatient surgery because it might have provided a greater feeling of security.

Dooley's patient satisfaction study showed that 98% of the mastectomy patients who were allowed to choose whether to undergo the procedure as an inpatient or an outpatient had "very good" or "excellent" satisfaction scores. "The most commonly cited reason for high satisfaction was the empowerment felt by the patient and family to participate in the decision-making process and treatment process."⁷⁴

In addition to the studies described above, members of the medical community have commented on the effectiveness of outpatient mastectomies versus inpatient mastectomies. Michael Torosian, MD, clinical director of breast surgery research at Fox Chase Cancer Center in Philadelphia, has stated that, "...outpatient mastectomy is a viable option for 'selected patients'." He characterizes those 'selected patients' as, "...young patients with no other medical problems and who handle anesthesia well."⁷⁵

Concerns have been expressed about additional resources that should be considered if patients elect to have outpatient mastectomies. Dooley has said that "Outpatient mastectomy is both medically safe and can be a positive treatment experience if patients and families are well prepared."⁷⁶ He also expressed his concern that more education, support from local home care agencies, and provisions for hotels for overnight stays for out-of-town patients are needed.

Lawrence Gratkins, MD, an obstetrician-gynecologist at Christie Clinic in Champaign, Illinois, states his concern that insurance companies are trying to reduce their hospital costs and shift the costs to physicians' offices and patients. He also shares Dooley's concern that "... before we can make a national standard for outpatient mastectomy, we must provide adequate education to nurses and patients and families and community-based resources, like home health providers."⁷⁷

⁷⁴ Davis, Jeanie Lerche. "Outpatient Mastectomy a Viable Option for Many Women." *WebMD Health News*. (2000). <http://www.webmd.com/news/20000324/outpatient-mastectomy-option-women>

⁷⁵ Imaginis. "Many Breast Cancer Patients Candidates for Outpatient Mastectomy," (2000). <http://www.imaginis.com/breasthealth/news/news3.27.00.asp>

⁷⁶ See note 74 above.

⁷⁷ See note 74 above.

Therefore, the medical community recognizes that outpatient mastectomies may be appropriate for some – but not all – patients, and 48-hour inpatient hospital stays are not necessary for every patient. This is consistent with current Maryland policy. However, the medical community has also acknowledged that if mastectomies are to be performed on an outpatient basis, additional resources and benefit coverage may be required to obtain optimal results.

Approximately 45% of patients undergoing a mastectomy remain in the hospital for more than 1 day.⁷⁸ Based on this statistic, Mercer estimates that less than 45% of mastectomy patients are currently utilizing services at the proposed mandate level and remaining in the hospital for at least 48 hours following mastectomy. On the other hand, this demonstrates that 55% of mastectomy patients are utilizing services below the proposed mandate level (i.e., hospital stays less than 48-hours) and may elect to be discharged from the hospital less than 48 hours following mastectomy, even if the proposed mandate was in place.

Social Impact

In this section, we address the following questions related to 48-hour hospital inpatient stays following a mastectomy:

- **To what extent is the service generally utilized by a significant portion of the population?**
- **To what extent is insurance coverage already generally available?**
- **To what extent does lack of coverage result in individuals avoiding necessary health care treatments?**
- **To what extent does lack of coverage result in unreasonable financial hardship?**
- **What is the level of public demand for this coverage?**
- **Do self-funded employers in the State who employ at least 500 employees generally provide this level of coverage?**
- **What is the level of interest of collective bargaining agents in negotiating privately for inclusion of this coverage in group contracts?**
- **To what extent is 48-hour hospital stay coverage for mastectomies mandated in other states?**

⁷⁸ Chustecka, Zosia. "Mastectomy Rates Have Risen Recently, as Has Breast MRI." *Medscape Medical News*. (2008). <http://www.medscape.com/viewarticle/574832>

To estimate the percentage of the population that would be impacted by the proposed mandate, Mercer combined several statistics. The Henry J. Kaiser Family Foundation reports that about 51% of employer-covered insureds are female.⁷⁹ The incidence of breast cancer in females under age 65 is about 0.08%,⁸⁰ and about 43% of females having breast cancer surgery have mastectomies.⁸¹ Based on these three statistics, the estimated incidence of mastectomies for the under-age-65 population is 0.018%, or about 18 per hundred thousand members.

Nationwide, 65% of patients having a mastectomy are sent home within 24 hours of the procedure.⁸² This figure, combined with the incidence of mastectomies, indicates that about 0.01% of the population under age 65 has a mastectomy and is sent home within 24 hours of the procedure. This is the subset of the population that would be impacted by the proposed mandate.

Mercer surveyed six major carriers doing business in Maryland and found that two carriers already provide coverage for at least the first 48 hours following a mastectomy. The other four carriers provide coverage that they determine to be medically necessary. In addition, Mercer discussed the current coverage of the proposed mandate with medical directors of several large insurers operating in Maryland. The medical directors indicated that they routinely approve 48-hour inpatient stays for mastectomies when requested by either the physician or the patient.

Mercer was unable to find any evidence that individuals are avoiding mastectomy procedures because coverage for a 48-hour hospital stay following mastectomy is not mandated.

Since all of the surveyed insurers cover hospital stays as medically necessary, we do not expect financial hardship to occur without the proposed mandate. However, it is possible that a patient could decide to stay in the hospital for 48 hours or more and the insurer could deem the stay unnecessary; however, there is no evidence this is occurring. Presumably, the insurer would cover the costs for the first day but would not cover costs for the second day of the hospital stay. In this case, without the proposed mandate, the patient would be responsible for the cost of the second day of the hospital stay, which we estimate to be the average cost of all hospital days, which is around \$5,422,¹⁷ (the average hospital charge per day in Maryland in 2006). Such cost would be no different than for any patient choosing to stay in the hospital beyond the period of medical necessity.

Several self-funded employer groups in Maryland have been surveyed regarding the proposed mandate. One-third of the groups provide mandatory coverage for the first 48

⁷⁹ The Henry J. Kaiser Family Foundation. "Health Insurance Coverage of the Total Population, states (2006-2007), U.S. (2007)." <http://www.statehealthfacts.org/comparebar.jsp?ind=125&cat=3>

⁸⁰ Surveillance Epidemiology and End Results. "Cancer Statistics Fast Stats by Age at Diagnosis/Death." 2005 Female Breast Cancer Incidence. <http://seer.cancer.gov/faststats/selections.php?series=age>

⁸¹ See note 78 above.

⁸² See note 78 above.

⁸³ Agency for Healthcare Research and Quality, Healthcare Cost and Utilization Project (HCUP). Maryland Mastectomy Average Length of Stay and Charges for Under 65. (2006). <http://hcupnet.ahrq.gov/HCUPnet.jsp>

hours following a mastectomy. The remainder provide coverage for the first 48 hours following mastectomy, subject to medical necessity. Therefore, it appears that mandatory coverage for a 48-hour hospital stay following mastectomy is not a service in high demand at the self-funded employer group level.

Of the self-funded employer groups surveyed, only one responded with regard to the level of interest in having the proposed mandate included in their benefits. This group responded that they had a moderate level of interest (based on a scale of no interest, mild, moderate, and high interest).

Mercer surveyed collective bargaining agents in Maryland and obtained mixed reactions. Generally, the benefit plans do not cover a minimum 48-hour hospital stay, but do cover the length of stay determined by the carrier/third party administrator. About half of the respondents indicated they had a high level of interest in including the proposed mandate in their benefits.

In 2008, 20 states mandate coverage for mastectomies. The mandated coverage ranges from 48-hour minimum coverage to unlimited inpatient coverage as determined by the physician and/or patient.⁸⁴ Seven states mandate 48-hour coverage. Ten states mandate coverage for inpatient hospital stays where the length of time is determined by the physician and/or patient.

Financial Impact

In this section, we estimate the cost of enacting the proposed mandate and compare the results of our analysis to other publicly available sources.

As previously developed in the “Social Impact” section, the estimated incidence of mastectomies for the under-age 65 population is 0.018%. Mercer assumes that the extra cost of this proposed mandate would be the cost for any additional hospital days that were previously considered by the insurer to be medically unnecessary, up to a total hospital stay of 48 hours. In other words, the maximum cost for this proposed benefit would be the cost for patients who currently have one day of coverage and would have two days of coverage under the proposed mandate.

Currently, 65% of patients having a mastectomy are sent home within one day of the procedure.⁸⁵ In Maryland, the average length of stay for a mastectomy is about 2.0 days.⁸⁶ Therefore, patients who are in the hospital for more than one day have an average length of stay of 3.9 days. We assume that, under the proposed mandate, each one-day stay would now be two days. We recalculated the average length of stay to be 2.6 days (an increase of 0.6 days).

⁸⁴ Kaiser State Health Facts. “State Mandated Benefits: Inpatient Mastectomy Stay, 2008.” <http://www.statehealthfacts.org/comparemaptable.jsp?ind=489&cat=10>

⁸⁵ See note 78 above.

⁸⁶ See note 83 above.

The 2006 average hospital charge per day in Maryland for a mastectomy was \$5,422.⁸⁷ The cost of the additional 0.6 day would increase the total mastectomy cost by \$3,416. Since it is estimated that only 0.018% of the population under age 65 has a mastectomy in a given year, the additional cost of the proposed mandate spread over the entire insured under-65 population is estimated to be \$0.61 annually. This is the maximum estimated annual cost, as it assumes that every mastectomy patient will stay in the hospital for at least two days, and does not assume any member cost sharing will be applied to the additional stay. Based on an average annual premium of \$3,930,⁸⁸ the estimated additional cost of the proposed mandate is 0.02% of annual premium.

Mercer recognizes that the cost per hospital day utilized in the development of the premium estimate is based on the average of all hospital days for mastectomies in Maryland and not the average of hospital days subsequent to the initial surgery day. Mercer realizes that the costs for the first day of hospitalization are generally higher than the costs for subsequent days. If we assume that the initial day costs 25% more than subsequent days, the impact to premium would only be \$0.10 per member per year, which is, in Mercer's opinion, immaterial. Since there are no Maryland mastectomy-specific statistics for the variation in costs by day available, and the absolute change in the estimated cost per member per year is so low, we elected to use the actual Maryland average hospital charges. As a result, our estimate is slightly conservative.

The following table summarizes our cost estimates of the proposed mandated benefit. The *full* cost is the cost for the additional hospital days assumed under the proposed mandate. The *marginal* cost adjusts the full cost to reflect that some carriers already provide coverage at the proposed mandated benefit level. Based on our carrier survey, 33% (or two out of six carriers) already provide coverage at the proposed mandated benefit level. This is inconsistent with the previously referenced discussion between Mercer and medical directors of several of the largest carriers operating in Maryland. This inconsistency may be due to a technical point: existing benefits may not be specifically provided for a 48-hour inpatient stay, but they may be provided in practice. However, to be conservative, we assume that only 33% of carriers currently provide a 48-hour inpatient stay.

⁸⁷ See note 83 above.

⁸⁸ The Henry J. Kaiser Family Foundation. "Maryland: Average Single Premium per Enrolled Employee for Employer-Based Health Insurance, 2006." <http://www.statehealthfacts.org/profileind.jsp?ind=270&cat=5&rgn=22>

	Full Cost	Marginal Cost
Estimated cost of mandated benefits as a percentage of average cost per group policy	0.02%	0.01%
Estimated cost as a percentage of average annual wage ⁸⁹	0.001%	0.001%
Estimated annual per employee cost of mandated benefits for group policies ⁹⁰	\$1.09	\$0.73

A similar study was completed by a consulting actuarial firm in 2000 for the state of Texas, which estimated the cost of mandating a 48-hour minimum hospital stay following a mastectomy to be 0.0% of premium.⁹¹ This is consistent with the estimate that Mercer has developed for the proposed mandate in Maryland.

To verify Mercer's cost estimate, Mercer surveyed six carriers doing business in Maryland on the additional cost of the proposed mandate. Two of the six carriers already guarantee coverage for at least the first 48 hours following mastectomy. No additional premium charges would be needed for the proposed mandate for these two carriers. The other four carriers cover hospital inpatient stays following mastectomy according to medical necessity. Two of these four carriers indicated that the premiums would need to increase slightly, by 0.1% or 0.2%, to provide the additional coverage as specified by the proposed mandate.

⁸⁹ Assumed average annual wage of \$48,239.

⁹⁰ Assumed 1.79 average covered lives per employee.

⁹¹ Albee, Susan, Esther Blout, Mulloy Hansen, Tim Lee, Mark Litow, and Mike Sturm. "Cost Impact Study of Mandated Benefits in Texas." *Milliman & Robertson, Inc.*, (2000).
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4**Coverage of Prosthetic Devices**

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

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

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

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

Medical Impact

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

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

Amputation of a limb can be caused by congenital limb deficiency, vascular disease, cancer, or trauma. The ability to return to normal activities (or, in the case of individuals with congenital physical disabilities, the ability to learn normal activities) is critical to maximizing the physical and psychological functioning of this population. Properly fitted prosthetic devices facilitate this development by enabling individuals to continue to exercise, perform the activities of daily life that most of us take for granted, return to work, and contribute to society.⁹²

According to the Amputee Coalition of America, the prevalence rate for individuals with one or more missing limbs was roughly 2.8 per 1,000 for the non-elderly population.⁹³ Maryland's non-elderly population in 2007 was roughly 5 million people. Assuming a prevalence rate of 2.8 per 1,000, there are roughly 14,000 non-elderly people living with limb loss in Maryland. The location of the amputation varies significantly among the causes listed below.

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

From 1988 to 1996, on average, 82% of amputations were caused by vascular disease.⁹⁴

⁹² Bender, Karen, et al. "Review and Evaluation of LD 125: An Act to Promote Fairness and Opportunity for Working Amputees." Maine Bureau of Insurance. 2003. <http://www.maine.gov/pfr/legislative/documents/ld125final.pdf>

⁹³ Amputee Coalition of America. Frequently Asked Questions, 1996 statistic (the most recent available) http://www.amputee-coalition.org/nllic_faq.html

⁹⁴ Dillingham, Timothy R., MD, et al. "Limb Amputation and Limb Deficiency: Epidemiology and Recent Trends in the United States." *Southern Medical Journal*. 95 (2002): 875-83. http://www.amputee-coalition.org/fact_sheets/amp_stats_cause.html

It is extremely important for individuals with lower extremity (LE) amputations to exercise. Studies have shown that non-vascular LE amputees have higher rates of cardiovascular disease, hypertension and adult-onset diabetes when compared to the non-disabled population.⁹⁵ Ken Pitetti, PhD, a professor at Wichita State University, says that it is important for an LE amputee to have a comfortable prosthetic limb (or limbs) suited for exercise. Having prosthetics that fit should reduce medical costs for the treatment of cardiovascular disease, hypertension, and adult-onset diabetes for LE amputees.

It has been shown that 70% to 90% of amputees return to work sometime after their injury, and that those who have access to prosthetic devices show a reduction in secondary conditions caused by their disability.⁹⁶ In the report, “Analysis of Assembly Bill 2012 – Amended: Orthotic and Prosthetic Devices,” the California Health Benefits Review Program (CHBRP) states: “Conventional prosthetic devices have been established as the standard of care for improving physical and psychological functioning of persons with amputations and congenital limb deformities.”

Medicare Standards

Medicare is the largest financial resource for prosthetic care.⁹⁷ Coverage is provided under Medicare’s durable medical equipment, prosthetics and orthotics (DMEPOS) benefit. To qualify for any type of DMEPOS, an individual’s equipment must be necessary and reasonable to treat an illness or injury, or to improve the function of a malformed body member. In addition, to be covered under the Medicare Part B program, the equipment must be rented or purchased by a beneficiary for home use. A physician’s prescription is required for all DMEPOS and, for prosthetics, a physician must complete a Certificate of Medical Necessity.

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

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

⁹⁵ Pitetti, Ken, PhD. Professor, College of Health Professions, Wichita State University. “Epidemiology and Pathophysiology of Amputation.” http://www.ncpad.org/disability/fact_sheet.php?sheet=58&view=all

⁹⁶ Cost Savings Analysis of the Prosthetic Parity Bill from Five States, Division of Health Care Finance and Policy, Commonwealth of Massachusetts, “Review and Evaluation of Proposed Legislation to Mandate Coverage for Certain Prosthetic Devices: H. 837.” April 2005.

⁹⁷ Amputee Coalition of America. Fact Sheet: “Financial Assistance for Prosthetic Services, Durable Medical Equipment and Other Assistive Devices.” Revised 2008. http://www.amputee-coalition.org/fact_sheets/assist_orgs.html.

and what the terms “qualified physical therapist” and “qualified occupational therapist” mean.⁹⁸

Medicare has established Level II modifiers, or “K-Modifiers,” that classify the patient's rehabilitation potential as determined by the prosthetist and ordering physician. Criteria considered for assessing the functional level include the patient's history, current condition (including the status of the residual limb and the nature of other medical problems), and desire to ambulate. Classification levels are⁹⁹.

- K0 (Level 0) – Does not have the ability or potential to ambulate or transfer safely with or without assistance, and a prosthesis does not enhance the quality of life or mobility.
- K1 (Level 1) – Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence – typical of the limited and unlimited household walker.
- K2 (Level 2) – Has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces – typical of the limited community walker.
- K3 (Level 3) – Has the ability or potential for walking with variable cadence – typical of the community walker who is able to traverse most environmental barriers and may have vocational, therapeutic or exercise activity that demands prosthetic use beyond simple walking.
- K4 (Level 4) – Has the ability or potential for prosthetic use that exceeds basic walking skills, exhibiting high impact, stress or energy levels – typical of the prosthetic demands of the child, active adult, or athlete.

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

The following determination of coverage for selected prostheses and components with respect to potential functional levels represents the usual case. Exceptions are considered in individual cases if additional documentation is included that justifies the medical necessity. Prostheses are denied as not medically necessary if the patient's potential functional level is “0.”¹⁰⁰

⁹⁸ American Physical Therapy Association. “FAQs Regarding Billing for DME, Orthotics, and Prosthetics.” <http://www.apta.org/AM/Template.cfm?Section=Home&CONTENTID=30021&TEMPLATE=/CM/ContentDisplay.cfm>

⁹⁹ See note 97 above.

¹⁰⁰ See note 97 above.

Feet:

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

Knees:

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

Ankles:

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

The following are general policies regarding coverage of prosthetic sockets:

- Test (diagnostic) sockets for “immediate prostheses” are not medically necessary.
- No more than two test sockets for an individual prosthesis are medically necessary without additional documentation.
- No more than two of the same socket inserts are allowed per individual prosthesis at the same time.
- Socket replacements are considered medically necessary if there is adequate documentation of functional or physiological need. The Durable Medical Equipment Regional Carrier (DMERC) recognizes that there are situations where the explanation includes but is not limited to changes in the residual limb, functional need changes, or irreparable damage or wear/tear due to excessive patient weight or prosthetic demands of very active amputees.

Non-Medicare Standards

The focus of prosthetic devices is to restore function in the area of limb loss. Technology advancements in prosthetics are geared toward improving mobility and functional capability. Major advancements – to name a few – include microprocessors, lithium-polymer battery technology, improved silicone suction suspension, and body-powered designs.¹⁰¹

¹⁰¹ O&P Digital Technologies website. http://www.oandp.com/edge/issues/articles/2003-01_01.asp

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

Many amputees – especially those losing upper limbs – have very high expectations for what a prosthesis can accomplish. These expectations may be reinforced by movies and TV shows (such as “The Six Million Dollar Man” and “The Bionic Woman.”). While technology is improving, it may not be able to match all pre-amputation physical abilities and functionality. The rehabilitation team should encourage patients to become informed regarding the different prosthetic options and research, and should also encourage them to have realistic expectations.¹⁰²

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

Patients fitted within 30 days of the date of amputation return to work earlier and reported less pain from their amputation.¹⁰³ In their 2006 article, Chris Lake and Robert Dodson quoted a study by S. Fletchall, evaluating “the value of specialized rehabilitation of trauma and amputation” and found similar trends, indicating an approximate 96% success rate for patients who were seen immediately after their trauma versus a 56% success rate for those who were delayed from starting a specialized rehabilitation program. Additionally, 84% of those patients seen immediately by a specialized rehabilitation group remained in contact with their prosthetist/therapist, as compared with only 41% of those patients who were delayed from starting a specialized rehabilitation program.

There are five major categories of upper-limb prostheses: cosmetic, body-powered, battery-powered, hybrid, and microprocessor-controlled. Each of these devices has pros and cons. Cosmetic devices are the lightest-weight and require minimal harnessing to wear. However, cosmetic devices are the least functioning and may have a large price tag if custom made. Body-powered prostheses are moderately priced, lightweight, and durable, and have high sensory feedback. They also require the most harnessing and need the most body movement to operate. Battery-powered prostheses require the least amount of body movement to operate and provide more functional capabilities than body-powered devices; however, battery-powered devices are also the heaviest and the most expensive. They require the most maintenance, and users must undergo extended training to operate them. Hybrid prosthetics use a combination of body power and battery power, and as a result share the pros and cons of each type of prosthetic.¹⁰⁴ Microprocessor-

¹⁰² Lake, C., Dodson, R. “Progressive Upper Limb Prosthetics.” *Physical Medicine and Rehabilitation Clinics of North America*. 2006. http://www.armdynamics.com/PMR_Clinics_NA_Feb06.pdf

¹⁰³ O&P Digital Technologies website. http://www.oandp.com/edge/issues/articles/2003-01_01.asp

¹⁰⁴ E Medicine website. <http://www.emedicine.com/pmr/topic174.htm#ref1>

controlled prosthetic devices are still evolving and are much more common with lower-limb prosthetics. The technologically advanced device automatically adjusts the movement of the wrist and/or elbow joint based on data it collects.¹⁰⁵

A long-term study conducted by R.C. Crandall and W. Tomhave compared below-elbow pediatric amputees from the Shriners Hospital for Children/Twin Cities regarding the use of a variety of prosthetic options. All the patients were considered “consistent” prosthetic users by the clinic team. The average follow-up was 14 years, with some children being followed through to adulthood. The patients were sent questionnaires, and the authors conducted patient and chart reviews. Final analysis indicated that 15 patients (44%) selected a simple cosmetic “passive hand” as their prosthesis of choice. In long-term follow-up, 14 patients (41%) continued as multiple users. Fourteen patients (41%) selected the conventional prosthesis using a voluntary closing terminal device as the prosthesis of choice. Only five patients (15%) selected the myoelectric device as their primary prosthesis. The authors conclude that successful unilateral pediatric amputees may choose multiple prostheses on the basis of function and that, frequently, the most functional prosthesis selected in the long-term is the simplest in design. The authors believe strongly that unilateral pediatric amputees should be offered a variety of prosthetic options to help with normal activities of daily living.¹⁰⁶

Lower-limb amputations are more common than upper-limb amputations. This is largely due to dysvascular amputations associated with diabetes. There are two types of lower-limb prosthesis: below-knee (transtibular) and above-knee (transradial) prosthesis. As expected, transradial amputations require more complex prostheses in order to restore function in the amputated leg. Currently, over 100 prosthetic knee designs are available.¹⁰⁷ Each prosthetic knee can be categorized as either mechanical, hydraulic, pneumatic, or microprocessor.

“Microprocessor-controlled prosthetic knees may provide increased safety, stability, and function: for example, sensors are designed to recognize a stumble and stiffen the knee, thus avoiding a fall.”¹⁰⁸ Another example of a microprocessor-controlled prosthetic is the bionic foot. The bionic foot ranges in cost from \$15,000 to \$20,000 and has the following abilities:¹⁰⁹

- “Senses an incline or decline and adjusts angle of foot to handle the slope with minimum effort.”

¹⁰⁵ California Health Benefits Review Program (CHBRP), “Analysis of Assembly Bill 2012 - Amended: Orthotic and Prosthetic Devices” (June 15, 2006). California Health Benefits Review Program. CHBRP Report to California Legislature. Paper 30. <http://repositories.cdlib.org/chbrp/crcl/30>

¹⁰⁶ Crandall, R.C. and W. Tomhave. “Pediatric Unilateral Below-Elbow Amputees: Retrospective Analysis of 34 Patients Given Multiple Prosthetic Options.” *Journal of Pediatric Orthopedics*. 2002; 22(3): 380-383. abstract can be found at:<http://www.ncbi.nlm.nih.gov/pubmed/11961460>

¹⁰⁷ Virginia General Assembly, Joint Legislative Audit and Review Commission. <http://jlarc.state.va.us/Reports/Rpt358.pdf>

¹⁰⁸ Ibid

¹⁰⁹ America’s Health Insurance Plans website. http://www.ahipwire.org/News/Default.aspx?doc_id=186144

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

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

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

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

Given that qualifier, the VA found that:

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

wide range of patients, and has arranged with the manufacturer for a program to lend critical components, should these components of the prosthesis require factory repair.¹¹⁰

In October 2007, the VA released a statement that the Center for Restorative and Regenerative Medicine at the VA medical center and Brown University in Providence, R.I., are at the leading edge of a movement to create artificial limbs that function almost like natural ones. The VA is approving C-LEG and other similar types of prosthetics when medically warranted.¹¹¹

A comprehensive review of literature completed by the University of California, San Francisco and prepared for the California Health Benefits Review Program in 2006 found there was “weak evidence that newer technologies for lower limb prostheses benefit young and middle-aged adults who are healthy and active, but insufficient evidence to determine whether these technologies benefit children or older adults who have a sedentary lifestyle and/or major co-morbidities.” There was also “insufficient evidence regarding the effects of new technologies used in upper limb prostheses.”¹¹²

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

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

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

¹¹⁰ Veterans Administration, VA Technology Assessment Program, Short Report Computerized Lower Limb Prostheses, March 2000. www.va.gov/vatap/pubs/ta_short_3_00.pdf.

¹¹¹ Department of Veteran’s Affairs. Fact Sheet. “VA’s Prosthetics and Sensory Aids.” October 2007. <http://www.va.gov/OPA/fact/docs/pros-sensory.doc>

¹¹² California Health Benefits Review Program, A Report to the 2005-2006 California State Legislature, “Analysis of Assembly Bill 2012 – Amended: Orthotic and Prosthetic Devices.”

SB 98 Standards

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

However, SB 98 does not thoroughly explain the phrase “adequately meets the medical needs of the insured.” Is it adequate that the prosthetic will restore enough functional capability to go back to work, or will an insured be able to petition to receive the most technologically advanced prosthetic to gain marginal capabilities? Is a body-powered upper-limb prosthetic more or less adequate than a battery-powered one? The subjectivity of the language in the bill may require carriers to cover extremely expensive prostheses (currently up to \$100,000)¹¹³ which, according to carriers surveyed, would not be considered “medically necessary” under current standards.

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

While not every city in Maryland will have a physician specializing in prosthetic devices, we find that care is widely available. We were able to locate over 100 prosthetic device suppliers within 100 miles of Baltimore, and over 30 suppliers in Baltimore.¹¹⁴

¹¹³ Garibaldi, Matthew. Orthopaedic Surgery News, Myoelectric Prostheses Offer Advantage. Winter 2006. <http://www.ucsfhealth.org/common/pubs/ortho/winter2006/myoelectric/index.html>

¹¹⁴ California Health Benefits Review Program, A Report to the 2005-2006 California State Legislature. “Analysis of Assembly Bill 2012 – Amended: Orthotic and Prosthetic Devices.” <http://www.medicare.gov/Supplier/Include/DataSection/Questions/Results.asp>

Social Impact

In this section, we address the following:

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

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

SB 98 requires that carriers provide prosthetics coverage that is “at least equivalent to the coverage and payment provided under federal laws and regulations for the aged and disabled.” Medicare is the federal program that provides health benefits for the aged and disabled. Currently, the federal government provides coverage for prosthetics when medically necessary for those individuals enrolled in Medicare Part B . Benefits are payable at a rate of 80% of the Medicare allowable fees after satisfaction of an aggregate annual deductible that is applicable to all Medicare Part B services. The majority of Medicare Part B benefits are for physician-related services. The Part B deductible for 2009 is \$135. This deductible is subject to change every year. There are no annual maximum benefits for Medicare Part B, and no out-of-pocket limits.

It is unclear whether SB 98 intends for prosthetics to be provided at the Medicare coinsurance level, or through a combination of the Medicare-allowable fee schedule and coinsurance, or according to the rules for other medical benefits (which was the ultimate interpretation of similar legislation in New Jersey.)¹¹⁵ It appears that the legislation leans toward the use of the well defined Medicare guidelines.

¹¹⁵ Bulletin 8-10, P. L. 2007c-345. “Health Benefits Coverage for Orthotic and Prosthetic Appliances.” May 29, 2008. http://www.state.nj.us/dobi/bulletins/blt08_10.pdf

According to a recent bulletin published by the Indiana Department of Insurance,¹¹⁶ Indiana recently enacted coverage for prosthetic and orthotic devices (for arms and legs only) whereby carriers must provide the same dollar amount coverage provided for the same device, repair, or placement under the federal Medicare program. Such coverage, subject to utilization review, must be provided when the physician determines that a prosthetic and/or orthotic device is necessary to maintain or restore the ability to perform activities of daily living or essential job related activities, rather than solely for the comfort and convenience of the individual. Moreover, carriers must follow the federal Medicare reimbursement schedule unless a different reimbursement rate is negotiated. Coverage may not be subject to a cost-sharing provision that is less favorable than that which applies generally to other items and services. Prosthetics are considered durable medical equipment and therefore are subject to separate DME cost sharing provisions and limits. Finally, any lifetime maximum coverage limitation that applies to these devices must be equal to and separate from the lifetime maximum coverage limitation that applies to all other items and services. It would seem more appropriate in Maryland to mandate that inside limits on prosthetics be prohibited, rather than impose a lifetime maximum coverage limitation.

¹¹⁶ Bulletin 167. "Coverage for Prosthetic and Orthotic Devices." Indiana Department of Insurance. October 28, 2008.

In the following table, we show the mandates in place in other states.¹¹⁷

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

¹¹⁷ Novak, Donna. "Review and Evaluation of Required Coverage for Prosthetics." NovaRest Consulting. 2008.

Mercer surveyed six carriers representing the vast majority of insured medical lives in Maryland regarding their current coverage provisions for prosthetics. All six carriers indicated that coverage was available for prosthetics, although most offered groups the option of purchasing policies that had internal annual limits. Aetna was the only company that indicated it was “not aware of any insured plans that limit coverage.” The majority of the carriers indicated that they believed they were already providing benefits consistent with Medicare levels, with the exception that there are annual limitations for these types of services – some as low as \$2,500 or \$5,000 for all types of durable medical equipment (DME).

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

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

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

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

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

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

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

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

Device Cost Estimates¹¹⁸

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

We note that some of the more advanced prostheses can cost as much as \$100,000.¹¹⁹

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

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

¹¹⁸ Virginia General Assembly, Joint Legislative Audit and Review Commission. <http://jlarc.state.va.us/Meetings/Other/prosthet.pdf>

¹¹⁹ Long, Frank. “Work with What You’ve Got.” Rehab Management –December 2007. http://www.rehabpub.com/issues/articles/2007-12_02.asp

In spite of these additional payment sources, amputees and others do have significant difficulties paying for prosthetics. A proponent of the SB 98 and the Federal Prosthetics Parity Act of 2008, referenced below, the Amputee Coalition of America, cites numerous examples of people with amputations who need to take out a loan from retirement savings, college savings, or a bank in order to cover the cost of a prosthetic device.¹²⁰

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

Financial Impact

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

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

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

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

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

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

“Our Prosthetic benefit rider is similar to the Medicare benefit in terms of types of devices covered. However, employers are provided coverage options (annual maximums) when purchasing the prosthetic rider. As we understand the Medicare benefit, an annual ‘cap’ is not available. If mandated to purchase a prosthetic benefit equal to the existing Medicare benefit, employers’ costs will increase to the extent they currently provide no benefit or a benefit with an annual maximum. A benefit with no annual

¹²⁰ <https://www.amputee-coalition.org/advocacy/stories.html>

maximum for a technology that continues to change and becomes more expensive to purchase and maintain undoubtedly will increase costs for employers and employees subject to a state mandate.”

As indicated previously, there is a very broad range for the cost and repair of prosthetic devices. Thus, the actual cost for any single health plan may vary significantly from the average, depending on the concentration of high-cost/low-cost devices provided/maintained in any one year.

As examples, the CHBRP reported that the average cost for a prosthetic device in 2006 was \$965.40.¹²¹ The Division of Health Care Finance and Policy in Massachusetts has estimated the per-patient cost of a prosthesis to be \$1,669 in 2010.¹²² Assuming that 2.8 per 1,000 people in Maryland are living with limb loss and all amputees use prosthetic devices, the expected allowed PMPM cost would be between \$0.23 and \$0.39. The plan liability PMPM, or full cost of the mandate, would be roughly 80% of the allowed PMPM, or between \$0.18 and \$0.31. We define the marginal cost of implementing the mandated benefit as the additional cost the carriers will incur if required to provide the service (or device, in this case) at a minimal level.

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

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

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

¹²¹ California Health Benefits Review Program (CHBRP). “Analysis of Assembly Bill 2012 - Amended: Orthotic and Prosthetic Devices.” June 15, 2006. California Health Benefits Review Program. CHBRP Report to California Legislature. Paper 30. <http://repositories.cdlib.org/chbrp/crcl/30>

¹²² See note 96 above.

Several other states have completed analysis for similar benefits.

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

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

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5**Coverage of the Shingles (Herpes Zoster) Vaccine**

The proposal would require health insurers, nonprofit health service plans, Medicaid managed care organizations, and HMOs (collectively referenced as “carriers” in this report) to provide coverage for the shingles (herpes zoster) vaccine to individuals who are 60 or older.

The state of Maryland currently does not mandate coverage of this service.

A discussion of the medical, social, and financial impact of this proposal follows.

Medical Impact

- **To what extent is the vaccine generally recognized by the medical community as being effective in treating patients?**
- **To what extent is the vaccine’s efficacy generally recognized by the medical community as demonstrated by a review of scientific and peer review literature?**
- **To what extent is the vaccine generally available and utilized by treating physicians or vaccine administrators?**

The Advisory Committee on Immunization Practices (ACIP), an advisory group to the Centers for Disease Control and Prevention (CDC), recently added Zostavax, the vaccine for shingles, to the Adult Immunization Schedule for 2008. This full recommendation is an upgrade from the provisional recommendation made by the CDC in 2006.¹²³

¹²³ Centers for Disease Control. “CDC Recommends Shingles Vaccine.” CDC Press Release. May 15, 2008.

Approximately one million individuals are expected to contract shingles annually. The rash commonly associated with shingles can be preceded by other symptoms for days or weeks. These symptoms can include headache, excessive sensitivity to light, general discomfort, abnormal skin sensations, and pain. People who contract shingles have a 10% – 18% chance of contracting post-herpetic neuralgia (PHN), which is characterized by severe and debilitating pain.¹²⁴

In addition, 10% – 25% of patients may suffer from infections in the skin around the eye, which can lead to permanent pain, facial scarring, and vision loss.¹²⁵

Approximately 3% of patients who contract shingles are hospitalized; many suffer from weakened immune systems. Death from shingles is rare for people with healthy immune systems.¹²⁶

Although uncommon, another complication of shingles is Ramsay Hunt syndrome, which is caused by a herpes zoster infection of a facial nerve. Signs and symptoms of Ramsay Hunt syndrome can include pain, dizziness, hearing loss, sensitivity to sound, ringing in the ears, and loss of taste. Bell's palsy, caused by paralysis of the facial nerve, may be caused by viral reactivation as well.¹²⁷

Additional complications, while rare, can include automatic and regulatory peripheral nerve dysfunction, motor weaknesses, inflammation of blood vessels in the central nervous system, swelling of the spinal cord, inflammation of the brain and/or surrounding lining, and Guillain-Barré syndrome (an inflammation of the nervous system that can result in systemic paralysis if left untreated). Though the prognosis for these complications is generally good, inflammation of the brain and spinal cord can be life-threatening. The risk of developing these complications is higher in people with weakened immune systems.¹²⁸

People with weakened immune systems are also at risk for the shingles rash to spread. Rash spreading can be a sign that the virus is in the blood. This can lead to additional infection in the lungs, liver, digestive track, and brain – which may cause pneumonia, hepatitis, encephalitis, and a reduction in the blood's ability to clot. Death rates from the virus spreading to the organs are between 5% and 15%, and most of these deaths are caused by pneumonia.¹²⁹

¹²⁴ Harpaz, Rafael, MD, Ismael R. Ortega-Sanchez, PhD and Jane F. Seward, MBBS. "Prevention of Herpes Zoster, Recommendations of the Advisory Committee on Immunization Practices." May 15, 2008. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr57e0515a1.htm>

¹²⁵ Ibid

¹²⁶ Ibid

¹²⁷ Ibid.

¹²⁸ Ibid

¹²⁹ Ibid

Patients with HIV tend to have less severe symptoms and less organ infection from the virus than people with other immune system weakening conditions. However, patients with HIV who develop shingles tend to have more aggressive forms of retina inflammation (which may result in vision loss), as well as cell death of the bone around the teeth (possibly resulting in tooth loss) and unusual skin rashes.¹³⁰

The risk for shingles appears to be elevated in people with inflammatory diseases, such as lupus (15 – 91 cases per 1,000 persons/year); rheumatoid arthritis (10 cases per 1,000 persons/year); inflammation of the blood vessels (45 cases per 1,000 persons/year); Crohn’s disease (1.6 cases per 1,000 persons/year); and sore-forming colitis (1.2 cases per 1,000 persons/year).¹³¹

For non-inflammatory diseases, findings have not been consistent. Two studies have documented an association between shingles and diabetes, but this finding was absent from two other studies. An additional study indicated an increased risk for shingles in persons who were diagnosed with multiple sclerosis.¹³²

The cost of treating acute shingles and the cost-effectiveness of using the shingles vaccine were addressed by the CDC in its May 18, 2008 report, which states:

Costs associated with acute [shingles] have been evaluated. Among patients with acute episodes of [shingles], average expenditures ranged from \$112–\$287 per episode of outpatient care, \$73–\$180 per antiviral treatment, and \$3,221–\$7,206 per hospitalization (2006 dollars). Additional costs associated with managing non-PHN complications (e.g., [eye], neurologic, and [skin]) ranged from \$1,158–\$11,255 per complication, and from \$566–\$1,914 per episode of PHN. Among the subset of patients with PHN persisting from 30 days to 12 months, annualized health-care costs, including costs of the acute episode, range from \$2,159 to \$5,387.¹³³

In 2008, a panel of four leading experts in adult immunizations concluded that mortality and hospitalizations are not the primary risk associated with shingles. Instead, PHN caused by the onset of shingles was the main concern and could be prevented by the vaccine. They state:

Although most people recover from shingles after 3 or 4 weeks of misery, a significant proportion, particularly in older individuals, develop a continuing syndrome of pain that can persist for months or even years, something called post herpetic neuralgia (PHN), which is a debilitating complication and which really can wreck the lives of older individuals.

¹³⁰ Ibid

¹³¹ Ibid

¹³² Ibid

¹³³ Ibid

...the Shingles Prevention Study demonstrated that the burden of illness caused by shingles pain...and how long it lasted – was reduced by 61% in people who received the vaccine compared to placebo. Even more important, the complication of [PHN] and incidence of [PHN] was reduced by two thirds.¹³⁴

The pain associated with PHN and the reductions in quality of life have been clinically documented. The CDC states: “Approximately half of patients with [PHN] describe the pain as ‘horrible’ or ‘excruciating’, ranging in duration from a few minutes to constant on a daily or almost daily basis.”¹³⁵

The lifestyle changes made by a patient suffering from PHN have been described by medical professionals:

The widow of a very distinguished San Diego infection-disease physician who was very active – obviously well off because her husband had good retirement benefits – active politically, played tennis every morning, then developed shingles involving her forehead and around her eye. The pain that resulted from that had 2 giant consequences. First of all, every time she ran to the net to play tennis, the wind on her forehead resulted in unbearable pain, so she quit playing tennis. Then she was taking [acetaminophen/hydrocodone] and oxycodone for the pain, which inhibited her from driving, so she became isolated. She stopped participating in her social and political activities, and she ended up, otherwise perfectly fine, but in a nursing home in Los Angeles really because of the consequences of the persisting pain, the [PHN] from her shingles.¹³⁶

Treatments for PHN can include acetaminophen, nonsteroidal anti-inflammatory agents, tricyclic antidepressants, opiates, anticonvulsants, and other topical anesthetics. In cases where severe pain is reported, referral to a pain specialist, or hospitalization and the administration of localized, nonsystemic pain relief is considered. However, patients who have reduced physiologic reserve and who are already taking medications for other pre-existing chronic conditions may not be able to take other medications to manage the onset of PHN.¹³⁷

In a survey of medical directors from various carriers operating in Maryland, the medical directors indicated that the medical efficacy of this vaccine for adults age 60 and over is well proven.

¹³⁴ Schmader, Kenneth, MD, Kevin J. High, MD, Kristin L. Nichol, MD and Michael N. Oxman. “Adult Immunization Update.” Medscape search for Adult Immunization Update. June 2008.

¹³⁵ See note 124 above.

¹³⁶ See note 134 above.

¹³⁷ See note 124 above.

As of June 2008, the Zostavax vaccine (produced by Merck) is the only vaccine clinically proven and currently licensed by the FDA to prevent shingles.¹³⁸ The *New England Journal of Medicine* publicized the results of Merck's phase 3 trials – the clinical trials aimed at definitively assessing how effective the vaccine is at preventing shingles. The phase 3 trials consisted of a double-blind randomized, placebo-controlled trial involving 38,546 healthy adults aged 60 and over. People excluded from the study included people with allergies to the vaccine, a history of shingles, existing conditions that weakened their immune systems, or other conditions that could interfere with the study evaluations. Efficacy of the shingles prevention was highest among individuals aged 60 to 69 years. The results of the vaccine's phase 3 clinical trials indicate that the vaccine was effective at reducing the burden of illness due to shingles by 61.1%, reduced the incidence of PHN (pain) by 66.5%, and reduced the incidence of shingles by 51.3%.¹³⁹ The vaccine's efficacy measure declined the year after vaccination, but remained stable for the three years following.¹⁴⁰

Besides the shingles vaccine, Zostavax, there are no other scientifically proven methods for preventing the onset of shingles although there has been conflicting evidence that exposure to varicella, the virus that causes chicken pox, may protect against shingles.

Several studies performed in the United Kingdom indicate that social contact with children (as a proxy for varicella exposure) or occupational contact with sick children is protective against shingles. Adults living with children had both an increased exposure to varicella and a 25% decrease in the incidence of shingles. However, contrary evidence exists that indicates varicella exposure does not increase protection against shingles. Women are at a greater risk for developing shingles despite being in greater contact with young children who experience varicella. Additionally, a Japanese study indicated that the risk for shingles was not reduced after repeated varicella exposure.¹⁴¹

Adverse events as a result of vaccination were studied during the phase 3 clinical trials for determining the effectiveness of the shingles vaccine. A significantly larger number of subjects in the vaccine group experienced one or more adverse events than in the placebo group. The most frequent adverse events at the injection site were redness of the skin, pain or tenderness, swelling, and an itching sensation, and were found to be more common among the vaccine recipients (48.3%) than the placebo recipients (16.6%). These mild events were resolved within four days. Less serious systemic events, such as headaches, were more common in vaccine recipients (6.3%) than in placebo recipients (4.9%).¹⁴²

¹³⁸ See note 134 above.

¹³⁹ Oxman, M.N., et al. Shingles Prevention Study Group. "A Vaccine to Prevent Herpes Zoster and Postherpetic Neuralgia in Older Adults." *The New England Journal of Medicine*, Vol. 352, No. 22, 2271-2284.

¹⁴⁰ See note 124 above.

¹⁴¹ See note 124 above.

¹⁴² Ibid.

The license granted to Merck by the Food and Drug Administration for the shingles vaccine was limited to people over age 60 who have not received the varicella (chicken pox) vaccine.¹⁴³

People should consult a physician before receiving the vaccination if they have a history of shingles, have (or expect to have) a weakened immune system, take antiviral medications, or receive blood products.¹⁴⁴

Although the shingles vaccine's proven effectiveness has prompted physicians to prescribe the vaccine, its high cost (at \$154 per dose wholesale) and the necessity to keep the vaccine frozen until use are prohibiting doctors from keeping the vaccine in stock. Pharmacies recently began stocking it, and pharmacists holding immunology licenses can administer the vaccines, process insurance forms, and notify doctors of the inoculation. Even with pharmacists being able to administer the vaccine, there have been recent reports of vaccine shortages nationwide.¹⁴⁵

Social Impact

- **To what extent is the service generally utilized by a significant portion of the population?**
- **To what extent is the insurance coverage already generally available?**
- **To what extent does a lack of coverage result in unreasonable financial hardship?**
- **How interested are collective bargaining agents in negotiating privately for including this coverage in group contracts?**
- **To what extent does a lack of coverage result in individuals' avoiding necessary health care treatments?**
- **To what extent is the mandated health insurance service covered by self-funded employers in the state who employ at least 500 employees?**

Merck reports that since the Food and Drug Administration approved Zostavax, 2.5 million people nationwide have been vaccinated, but 43 million people age 60 and over remain at risk.¹⁴⁶ In other words, only 5.5% of eligible individuals have received the vaccine. The CDC reported a much lower level of utilization in its National Immunization

¹⁴³ Ibid.

¹⁴⁴ Ibid.

¹⁴⁵ Templeton, David. "Shingles Vaccine Costly, Hard to Find for Seniors." *Pittsburgh Post-Gazette*. June 29, 2008.

¹⁴⁶ Ibid.

Survey. It reported that in 2007, 1.9% of people age 60 and over received the vaccine for shingles.¹⁴⁷

Possible explanations for low utilization rates include low levels of education about the importance of vaccination. Currently, there is little coordination among public health agencies, private medical providers, and adult vaccine makers. As with most other vaccines, adults who do not take advantage of the shingles vaccine often lack education on the importance of vaccination. Although the federal program to promote vaccinations for children has been largely successful in its educational efforts, there is no program to educate adults.¹⁴⁸

Additionally, several incidences of insufficient supply and month-long waits for the vaccine indicate an additional barrier to receiving it; even if an individual is willing to get the vaccine, access may be limited.¹⁴⁹

Mercer surveyed the major carriers, collective bargaining agents, and large self-funded employers operating in the state of Maryland to obtain information on the level of insurance coverage for Zostavax. Among major carriers, over half of the respondents stated that they provide coverage for the vaccine in all of their benefit plans, subject to member cost sharing and medical necessity. The other respondents indicated that a large number – if not a large majority – of plans already include coverage for the shingles vaccine.

A single dose of the Zostavax vaccine has been reported to cost \$165 to \$300.¹⁵⁰ Though only a single dose is recommended by the CDC, the cost of the vaccine may present a financial burden to certain individuals without insurance coverage.

Due to the June 6, 2008 CDC publication, which included an official recommendation for the shingles vaccine, health insurers and Medicare/Medicaid officials have begun to adopt the vaccine as standard care for their patients.¹⁵¹

The survey results for collective bargaining agents, self-funded plan administrators, and large, self-funded employers indicated significant coverage for most groups. All collective bargaining agents who responded to the survey indicated that this benefit was already covered. Of the carriers who administer benefits for self-funded plans, all responded that all or at least most self-funded plans they administer for employers already cover the shingles vaccine. And all large, self-funded employers who responded to Mercer's survey reported that the shingles vaccine is considered a medically necessary

¹⁴⁷ Center for Disease Control and Prevention, "Adult National Immunization Survey for 2007." <http://www.cdc.gov/vaccines/stats-surv/nis/downloads/nis-adults-summer-2007.pdf>

¹⁴⁸ Landro, Laura. "The Informed Patient – Get Your Shots: Adults Need Vaccines, Too – Public-Health Experts Push for National Inoculation Plan; A Rise in Whooping Cough." *Wall Street Journal*. July 9, 2008.

¹⁴⁹ See note 145 above.

¹⁵⁰ Brody, Jane E. "A Vaccine as an Option to Keep Shingles at Bay." *New York Times*. October 2, 2007.

¹⁵¹ See note 145 above.

preventative service, and that it is covered for individuals age 60 and over if the plan provides for preventive services.

Due to the broad range of coverage for the shingles vaccine among health plans, self-funded employers, and collective bargaining groups, Mercer's survey results indicate relatively high rates of insurance coverage; however, utilization rates for the vaccine remain low. This may indicate that a lack of coverage is not a primary reason for the public's avoidance of the shingles vaccination.

Financial Impact

Expected Change in Premium Due to Mandated Shingles Vaccination Coverage

Mercer surveyed major carriers in Maryland to obtain information on current practices regarding the coverage of the shingles vaccine and to determine how rates would be affected by mandatory coverage of the shingles vaccination.

Over half of the respondents indicated that all plans currently cover the shingles vaccine and that they would not incur any additional cost if the proposed shingles vaccine was mandated. All additional respondents indicated that the cost of covering the shingles vaccine, per the CDC guidelines for persons age 60 or older, would increase premium for those members by 0.1% of premium or less.

Additionally, all self-funded groups and collective bargaining agents who responded to Mercer's survey reported that the shingles vaccine was already covered. Therefore, we infer that there would be no additional premium increase due to the addition of a shingles vaccine mandate.

No fiscal analysis was completed for this proposed mandate. Thus, there is no estimate of the impact on the State Employee and Retiree Health and Welfare Benefit Plan (i.e., the State plan).

We used the demographic information provided by Maryland insurers representing over 95% of the small group population in Maryland. Under the assumptions of no cost sharing, an average vaccine cost of \$230, and utilization by 20% of eligible members, we estimate that the average increase in premium per group policy would be less than 0.1%, which would constitute 0.01% of the average Maryland employee's wage, or \$5.98 per employee per year. Considering the current low utilization rates of the vaccine (due to a lack of adult vaccination education and lack of coordination among government agencies, health care providers, and adult vaccine manufacturers), we feel that the 20% assumption may be overly conservative, but it helps to demonstrate the expected cost associated with instituting the proposed mandate.

The following chart shows our best estimate for full cost and marginal cost of this proposed mandate expressed as a percentage of premium, wages and annual cost per employee per year. Based on feedback from the carriers and self-funded plans, we estimate the marginal cost for this benefit to be about 10% of the full cost.

	Full Cost	Marginal Cost
Estimated cost of mandated benefits as a percentage of average cost per group policy	0.091%	0.009%
Estimated cost as a percentage of average wage	0.012%	0.001%
Estimated annual per employee cost of mandated benefits for group policies	\$5.98	\$0.60

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