

January 20, 2011

Annual Mandated Health Insurance Services Evaluation

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



John Welch
Karen Bender, FCA, ASA, MAAA
David Kerr, ASA, MAAA
Randall Fitzpatrick, ASA, MAAA

Contents

Introduction Evaluation of Proposed Mandated Health Insurance Services	i
1. Prescription Drug Cost-Sharing Obligations	1
▪ Medical Impact	2
▪ Social Impact	3
▪ Financial Impact	9
▪ References	12
2. Cancer Chemotherapy Cost-Sharing Equity	13
▪ Medical Impact	16
▪ Social Impact	20
▪ Financial Impact	26
▪ References	29
3. Expansion of Habilitative Services – Financial Impact Analysis	33
▪ Background	33
▪ Introduction	34
▪ Recap of 2007 Cost Estimates – Expansion of Coverage to Ages 19 to 64	34
▪ Financial Impact	36
▪ 2010 Carrier Survey	37
▪ Independent Mercer 2010 Cost Estimates	39
▪ Phase-In of Proposed Mandate	42
▪ References	45
4. Coverage for Treatment of Spinal Muscular Atrophy	47
▪ Medical Impact	49
▪ Social Impact	51
▪ Financial Impact	56
▪ References	59
5. Coverage of Preventive Physical Therapy Services for Patients Diagnosed with Multiple Sclerosis	61
▪ Medical Impact	62
▪ Social Impact	68
▪ Financial Impact	71
▪ References	74

**Introduction**

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 evaluations of proposed changes to existing mandates or proposed newly mandated benefits: Extension of habilitative services to older ages; parity cost sharing for oral chemotherapy drugs; limitations on cost sharing for specialty drugs; preventive physical therapy for insureds with muscular sclerosis; and private duty nursing for insureds with spinal muscular atrophy.

Patient Protection and Affordable Care Act

On March 23, 2010, President Obama signed the Patient Protection and Affordable Care Act (PPACA), which incorporates significant reforms in the commercial (i.e., non-Medicare and non-Medicaid) market. PPACA requires several benefit reforms to be effective on the first anniversary/renewal occurring on or after September 23, 2010 including:

- Extending coverage for adult children to age 26
- Elimination of lifetime maximums for essential benefits
- Phase in of elimination of annual maximums for essential benefits
- Guarantee issue to children <19 years of age
- Prohibition of policy rescissions in most cases
- Elimination of cost sharing for certain preventive services
- Requiring same cost sharing for emergency services in a non-network facility

- Participant’s flexibility to choose providers in plans assigning or designation primary care physicians

Beginning with calendar year 2011, PPACA requires minimum loss ratios of 80% for each insurer’s nongroup block of business; 80% for each insurer’s small group block of business and 85% for each insurer’s large group block of business.

These reforms may impact some of the proposed mandates more than others and some markets more than others. The combination of requiring guarantee issue (GI) to children <19, extending coverage for adult children to age 26 and prohibition of policy rescissions has a greater impact on the nongroup market than on the group market^{1,2}. Another PPACA benefit impacting the nongroup market more than the group market is the elimination of cost sharing for certain preventive services. A 2007 study showed that only about 60% of nongroup high deductible health policies (HDHP) included any first dollar coverage for some preventive benefits where as 96% of small group and 99% of large group HDHP policies provided first dollar coverage for some preventive benefits.³

PPACA will magnify the impact of some of the proposed mandated benefits for the nongroup market, especially those proposed benefits for whom the major recipients will be children under age 26 (habilitative services, private duty nursing for members with spinal muscular atrophy). At least two carriers in Maryland are offering child-only policies in the nongroup market on a GI basis, which creates the possibility of significant anti-selection. All carriers operating in the nongroup market will be required to accept all children for family contracts and continue coverage until age 26. There are fewer members in the nongroup market for which to spread risks in general. Inclusion of mandated benefits targeted at these age groups may magnify the potential for even more anti-selection.

The major insurance reforms under PPACA are effective in 2014, including guarantee issue for all entrants; elimination of medical underwriting; elimination of most rating factors; creation of exchanges for nongroup and small group policies; expansion of Medicaid eligibility; availability of premium subsidies for individuals purchasing nongroup insurance through the exchange, among others. The benefit plans to be offered through the exchanges will be based upon “essential benefits” as defined by HHS.⁴

PPACA requires the state to pay, for every policy purchased through the health benefits exchange, the additional premium associated with any state-mandated benefits that

¹ Previously passed federal legislation (HIPAA) required GI for all small employers and portability of coverage for individuals between carriers in the group market. However, GI was not required for any (except individuals transferring from group to nongroup coverage within a prescribed period of time) in the nongroup market at the federal level.

² Rescissions of group contracts are almost unheard of, whereas, while representing only about 3.7 per 1,000 policies issued, rescissions do occur in the nongroup market, mainly for failure to disclose pre-existing conditions. National Association of Insurance Commissioners (NAIC), Rescission Data Call of the NAIC Regulatory Framework (B) Taskforce, Draft, December 2009.

³ AHIP, A Survey of Preventive Health Benefits in Health Savings Account (HSA) Plans, July 2007. AHIP Center for Policy and Research, November 2007. http://www.ahipresearch.org/pdfs/HSA_Preventive_Survey_Final.pdf

⁴ HHS has not yet defined “essential benefits.”

exceed the “essential benefits” determined by HHS. The essential benefits package is supposed to be similar to the benefits package offered in a typical self-insured employer’s plan, presumably nationwide. Interestingly, Mercer’s quadrennial mandate analysis performed for the Commission assesses the extent to which existing Maryland mandates exceed the benefits in a typical Maryland self-insured employer’s plan. Three years ago Mercer estimated this “marginal cost” of Maryland mandates at 2.2% of the premium. Legislators may wish to consider the possibility that, beginning in 2014, the State will bear the cost of any enacted mandates that have not been included in the essential benefits package.

This report includes information from several sources to provide more than one perspective on each proposed mandate. Mercer's intent is to be unbiased. At times, as a result, the report contains conflicting information. Although we included only sources that we consider credible, we do not state that one source is more credible than another. The reader is advised to weigh the evidence.

1

Prescription Drug Cost-Sharing Obligations

Senate Bill 663 of the 2010 legislative session would prohibit carriers from imposing a cost-sharing obligation for a prescription drug that exceeds the dollar amount of the cost-sharing obligation for a prescription drug in a specified category.

Carriers that offer prescription drug coverage often incorporate cost-sharing tiers as a way to incent members to use lower-cost drugs. The cost-sharing charged for prescription drugs has traditionally been a fixed-dollar copay, which is lower for lower-tiered drugs. However, in recent years, some carriers have begun offering drug plans with coinsurance, where the member pays a constant percentage of the drug cost in an effort to share in the rapidly increasing drug costs. A tiered drug benefit program that only varies cost-sharing between generic and brand is called a “two-tier” program. A tiered drug program that further differentiates the cost-sharing between “preferred brand” and “non-preferred brand” is called a “three-tier” program. Nationwide, some carriers and health plans have begun to expand the differentiation even further, with a “four-tier” program, to reflect the very high cost of certain “specialty” drugs.

Specialty drugs are generally classified as drugs used to treat chronic and complex conditions, such as cancer, rheumatoid arthritis (RA), multiple sclerosis (MS), and hemophilia. Specialty drugs often have complex treatment regimens, and require special delivery and administration. Generally, these drugs are also considerably more expensive than non-specialty medications, often without lower-cost substitute drugs with similar effectiveness. The purpose of the proposed mandate is to protect individuals who may need these drugs from incurring large out-of-pocket costs.

Each plan that offers prescription drug coverage must provide members a list of drugs covered under the drug plan. This listing of drugs is known as the plan’s formulary. Each health insurance carrier structures its formulary differently, so formularies are not usually consistent among carriers. Some carriers structure drug benefit tiers by cost, with the most expensive drugs in Tier 4. Other carriers structure drug benefits based on medical necessity, with drugs in Tier 4 having an alternative available on another tier. Without each carrier’s formulary, it is impossible to determine whether the drugs provided in Tier 4 are high-cost specialty drugs, or drugs with alternatives available in

other tiers. Based on information gathered from meetings with the medical directors of the largest plans in Maryland, we learned that carriers that offer four-tier plans predominantly use the fourth tier for specialty drugs.

For the purposes of this paper, non-preferred drugs are considered those drugs offered in Tier 3. Carriers that offer a four- or five -tier plan would be subject to cover drugs in Tier 4 and Tier 5 with cost-sharing provisions no higher than those in Tier 3 – which, in essence, would require plans to have a maximum of three tiers based on typical prescription drug coverage plan designs. Some specialty medications need to be administered by a physician. These medications may be covered under the medical plan rather than under the drug plan. This paper will focus on the implications of requiring carriers to pay for specialty drugs offered under a prescription drug plan at Tier 3 cost-sharing levels.

What follows is a discussion of the medical, financial, and social impacts of this proposed mandate.

Medical Impact

- **To what extent are specialty drugs recognized by the medical community as being effective in treating patients?**
- **To what extent is the efficacy of specialty drugs generally recognized by the medical community, as demonstrated by a review of scientific and peer review literature?**
- **To what extent are specialty drugs generally available and utilized by treating physicians or pharmacies?**

As mentioned above, specialty drugs are generally classified as drugs used to treat chronic and complex conditions, such as cancer, rheumatoid arthritis (RA), multiple sclerosis (MS), and hemophilia. Specialty drugs often have complex treatment regimens and require special delivery and administration. Generally, these drugs are also considerably more expensive than non-specialty medications, often without lower cost drug alternatives with similar effectiveness.

Before any drug (specialty as well as non-specialty) can be offered to the public, the Food and Drug Administration (FDA) must approve it to ensure it is safe and effective. For most drugs, the FDA requires a formal approval process, which takes an average of 12 years and costs over \$350 million.⁵ On average, 999 in 1,000 compounds never make it to clinical human testing.⁶ Those drugs that do make it to clinical testing must undergo five stages of drug development and review:⁷

⁵ Drugs.com. New Drug Approval Process.

⁶ FierceBiotech. "FDA Approval Process."

⁷ U.S. Food and Drug Administration. "The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective."

In the first phase, Investigational New Drug Application (IND), the FDA reviews the manufacturer's preclinical testing results and determines whether the compound is safe enough for human testing. This phase can take over three years to complete.⁸ The next three phases are human clinical trials. The first phase of this process tests the drug on a small number of healthy patients (typically 100). This phase focuses on safety, i.e., how well the drug is processed, whether the dosing is correct, and how well the drug is tolerated. In the second phase of human clinical trials, the manufacturer tests the drug's overall effectiveness. In this phase, 100 to 300 people with the targeted disease are tested. The third phase expands on Phases 1 and 2 of clinical human trials, where 1,000 to 3,000 people with the targeted disease are tested. In this phase, the goal is to show the drug's safety and effectiveness. Once a drug has gone through the three human clinical trial phases (each trial usually takes several years), the manufacturer can submit a New Drug Application (NDA) to the FDA. The FDA then thoroughly reviews the NDA before granting approval.

Drugs that complete the formal FDA approval process described above have proven "clinical endpoints." Certain drugs can also be approved using the FDA's authority to streamline the approval process of drugs that provide innovative clinical outcomes for serious and life-threatening illnesses that lack satisfactory treatments. In the process's simplest form, drugs are approved based on laboratory findings that are likely to predict a clinical benefit, e.g., findings showing that a drug reduces the level of cancerous cells in a laboratory setting. Drugs that are approved using the accelerate approval process are required to complete post-marketing studies. Manufacturers are then required to report the status of these studies in annual status reports (ASR).

In short, the medical efficacy of individual prescription drugs varies considerably. The purpose of this section is not to determine the effectiveness of a specific drug, but to determine the overall effectiveness of specialty drugs. As outlined above, before a prescription drug is given FDA approval, years of clinical trials and research are invested to ensure the drug's safety and effectiveness. In addition, carriers cover only certain specialty drugs and limit utilization of these generally high -cost specialty drugs to certain circumstances where they are expected to be effective. For this reason, Tier 4 and Tier 5 specialty drugs are generally viewed as effective.

Social Impact

- **To what extent are specialty drugs 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?**

⁸ FierceBiotech.

- **To what extent does a lack of coverage result in individuals' avoiding necessary health care treatments?**
- **To what extent is the proposed mandate covered by self-funded employers in the state who employ at least 500 employees?**

The mandate in question is a requirement for carriers to cover drugs in Tiers 4 and 5, with cost-sharing limited to Tier 3 levels.⁹ In turn, the mandate does not require a plan to cover drugs that are not currently available to plan members. We note that not all specialty drugs are covered by all carriers. Each carrier that offers prescription drug coverage has a predefined formulary stating which drugs are covered and specifying the cost-sharing applicable to each drug. Formularies vary from carrier to carrier. Some carriers structure the benefit plan by cost, with the most expensive drugs in Tier 4. Others structure the benefit based on medical necessity, with drugs in Tier 4 having an alternative drug available in another tier.

Each year, Mercer surveys employer-sponsored health plans regarding different aspects of the health care coverage they provide. In 2009, over 2,900 employers were surveyed, and over 1,700 of them had more than 500 employees. The proposed mandate would impact only those health plans that offer Tier 4 and Tier 5 benefit plans. Of the employers surveyed, 9% stated they offer drug coverage with four or five tiers.¹⁰ The survey results are also available by state. In Maryland, 29 employers with more than 500 employees were surveyed; none of them reported offering drug coverage with four or five tiers.¹¹ It is important to note that, while over 90% of the employers surveyed offer drug benefits with three tiers or fewer, that does not mean these employers cover any specialty medications. As mentioned earlier, formularies can vary significantly from plan to plan. Based on the Mercer survey, 9% of the large group employer plans would be affected if drugs in Tiers 4 and 5 were required to be offered at Tier 3 cost-sharing. Also, the mandated coverage could already be largely available, as none of the sampled Maryland plans had more than three tiers.

Specialty drugs are utilized by a small percentage of the population, but account for a significant portion of drug costs. According to CuraScript's 2009 Specialty Drug Trend Report, less than 1% of members nationwide utilized specialty drugs, yet specialty

⁹ Carriers can offer Tier 4 and Tier 5 drugs at lower cost-sharing levels than Tier 3, but the mandate states that the maximum cost-sharing for these drugs is the Tier 3 cost-sharing.

¹⁰ Mercer. "2009 Mercer National Survey of Employer-Sponsored Health Plans."

¹¹ Mercer.

medications accounted for more than 12% of total costs. (The average cost per script in 2009 was \$1,867.)¹²

The chart on the following page shows the prevalence of selected health conditions, the specialty drugs available to treat them, and the drugs' costs.¹³

¹² CuraScript. "2009 Specialty Drug Trend Report: A Market and Behavioral Analysis." April 2010.

¹³ Walgreens. "Outlook – State of the Industry Report." August 2009.

Condition/Therapy	Approximate U.S. Population Affected	Average Annual Specialty Drug Cost per Patient	Notable Specialty Products
Biologic response modifiers	Crohn's disease: 500,000 Psoriasis: Between 5.8 and 7.5 million Psoriatic arthritis: 10% to 30% with psoriasis Rheumatoid arthritis: 1.3 million Ulcerative colitis: 500,000	\$12,000 to \$78,000	Amevive®, Cimzia®, Enbrel®, Humira®, Kineret®, Orencia®, Remicade®, Rituxan® Simponi™
Bleeding disorders	Hemophilia A: 1 in 5,000 male births Hemophilia B: 1 in 25,000 male births von Willebrand disease: 1% to 2% of population	\$150,000+	Advate®, Alphanate®, BeneFIX®, Humate-P®, NovoSeven®, RT, XYntha™
Hepatitis C	3.2 million chronically infected	\$23,000 (for interferon alone) \$33,000 (combination therapy with interferon and ribavirin)	Infergen®, Pegasys®, PegINTRON™, ribavirin
HIV/AIDS	1.1 million	\$26,000	Atripla®, Insetress®, Kaletra®, Norvir®, Prezista®, Reyataz®, Selzentry™, Sustiva®, Truvada®
Infertility	2.1 million females	\$15,000 (based on 3 cycles)	Bravelle®, Cetrotide®, Follistim®, AQ, Ganirelix, Gonal-F®, Gonal-F® RFF, human chorionic gonadotropin, Luveris®, Menopur®, Ovidrel®, Repronex®
Multiple sclerosis	400,000	\$36,000	Avonex®, Betaseron®, Copaxone®, Rebif®, Tysabri®
Oral chemotherapy	1.4 million new cancer cases per year	\$42,000 to \$130,000 Varies by type of cancer	Gleevec®, Nexavar®, Revlimid®, Sprycel®, Sutent®, Tarceva®, Tassigna®, Temodar®, Thalomid®, Tykerb®, Xelodia®
Respiratory syncytial virus	75,000 to 125,000 infants hospitalized per year	\$6,000 to \$12,000 based on variations in weight-based dosing	Synagis®
Transplant	> 163,000 persons living with a functioning organ transplant	\$16,000	CellCept®, Neoral®, Prograf®, Rapamune®

As shown in the table above, the cost of this sample of specialty drugs can range from \$6,000 to over \$150,000 annually. In 2009, roughly 25% of Americans lived in households with incomes that were under 133% of the Federal Poverty Level (FPL) and 32% of Americans lived in households with incomes over 400% FPL.¹⁴ Based on the Health and Human Services 2009 poverty guidelines, an annual income of \$10,830 is 100% FPL for a single person.¹⁵ For a family of four at 400% FPL (or \$88,200 in household income), prescription drug costs of \$6,000 would be almost 7% of their income. Requiring members to pay a significant portion of the cost of specialty drugs could result in unreasonable financial hardship, though it is unclear what portion of the cost a member would actually pay for specialty drugs approved on a given formulary due to cost-sharing and out-of-pocket limits.

Health Affairs completed a study that analyzed the change in members' utilization given a change in their cost-sharing for specialty drugs taken for cancer, kidney disease, rheumatoid arthritis (RA), and multiple sclerosis (MS). In effect, the study analyzed the elasticity of demand. The study included pharmacy and medical claims from 55 health plans offered by 15 large employers in 2003 and 2004. The data covered approximately 1.5 million beneficiaries. On average, the population utilizing specialty drugs ranged from 1% to 5% of a typical plan membership. The study showed that the demand for these specialty drugs did not change considerably with an increase in cost. Doubling the copay resulted in a 1% reduction in use for cancer, a 21% reduction in use for RA, an 11% reduction for kidney disease, and a 7% reduction for MS.¹⁶

Given the seriousness of the underlying conditions, the inelasticity of demand for specialty drugs under the copay changes noted in the study is not surprising. However, in order to utilize these medications, one needs to be able to pay for them, and some studies have shown that financial issues preclude some people from utilizing the drugs they need.

“In 2007, one in seven Americans under age 65 reported not filling a prescription in the previous year because they couldn't afford the medication...The increase in affordability problems likely stemmed from higher prescribing rates, drug prices that are rising faster than workers' earnings, higher patient cost sharing in private insurance and the introduction of expensive new medications.”¹⁷

¹⁴ The Henry J. Kaiser Family Foundation. “Distribution of Total Population by Federal Poverty Level, states (2008-2009), U.S. (2009).”

¹⁵ U.S. Department of Health and Human Services. “2009 HHS Poverty Guidelines.”

¹⁶ Dana P. Goldman, et al. “Benefit Design and Specialty Drug Use.” *Health Affairs* Vol. 25, No. 5: 1319.

¹⁷ Laurie E. Felland and James D. Reschovsky. “More Nonelderly Americans Face Problems Affording Prescription Drugs.” The Center for Studying Health System Change. Tracking Report No. 22, January 2009.

A significant number of working-age adults with chronic conditions reported they have unmet prescription drug needs (21.3% of high-income earners and 41.3% of low-income earners). In addition, it is more likely that prescription drug needs are met for people in employer-sponsored plans than in individual or Medicaid plans, with uninsured individuals having the highest unmet prescription drug needs.¹⁸

It is likely that many of the individuals not receiving necessary drug therapies did not have drug coverage – or any health coverage at all. It is unclear from this study the extent to which increased cost-sharing for certain drugs led to Maryland residents not receiving necessary drug therapies.

Mercer surveyed six major carriers in Maryland to obtain information on the prevalence of drug plans with more than three tiers in the individual, small group, insured, and self-funded large group markets. We received responses from four carriers. The table below shows the average percentage of members that currently have a drug plan with more than three tiers.

Table 1

Health Plan	Average Percentage of Members with Drug Plans with more than Three Tiers
Carrier # 1	0%
Carrier # 2	60%
Carrier # 3	1%
Carrier # 4	10%

As previously mentioned, the proposed mandate does not require that coverage be expanded to additional medications, but it does require that drug plans with four or five tiers cover those drugs in Tier 4 and Tier 5 with cost-sharing provisions no higher than those in Tier 3. In essence, this would require plans to have a maximum of three tiers based on typical prescription drug coverage plan designs. The estimates provided above merely show the percentage of members that would be impacted by this mandate.

For those carriers that responded, drugs offered in Tier 4 are typically self-administered injectibles. Based on the responses, *carriers in Maryland are currently providing Tier 4 drugs that are either subject to the same cost-sharing as Tier 3 drugs or include a separate out-of-pocket limit and/or per-drug cap in order to limit major financial hardship.* This indicates that currently carriers are affording Maryland insureds protection from extremely high cost sharing for these types of drugs, for which the annual cost for can vary from \$6,000 to over \$150,000. In the absence of separate out-of-pocket limits, Maryland residents would have a significant issue purchasing specialty medications.

¹⁸ Laurie E. Felland and James D. Reschovsky.

The collective bargaining agents surveyed do not know of any contracts that include this mandate, but they generally support the concept of capping the cost-sharing for Tier 4 and 5 drugs at Tier 3 levels. However, they recognize this would lead to increased costs, and they would rather see increases in coverage in other areas.

Financial Impact

In this section we estimate the cost of enacting the proposed mandate and compare the results of our analysis to other sources, including the estimates submitted by health carriers in Maryland.

In addition to asking carriers about the prevalence of prescription drug plans with more than three tiers, Mercer asked these carriers to provide cost and utilization statistics for Tier 4 drugs and the estimated premium impact if they are required to offer Tier 4 drugs at Tier 3 cost-sharing.

Of the responding carriers, only two identified more than 5% of the membership as having a drug plan with more than three tiers. Of these two, one carrier indicated that the drug premium impact of this mandate would range from 1.0% to 1.5%.¹⁹ The other carrier stated that the mandate's cost would be 0%, as the cost-sharing for Tier 4 drugs is already the same as Tier 3. The other two carriers indicated that the proposed mandate would have no premium impact.

The financial impact would vary depending on the plan formulary and the difference in cost-sharing requirements between Tier 3 and Tier 4. Mercer completed an independent calculation of the cost impact under multiple cost-sharing assumptions. As discussed throughout this paper, drugs on Tier 4 are assumed to be specialty drugs.

According to CuraScript's 2009 Specialty Drug Trend Report, the 2009 average cost per script for specialty drugs was \$1,867, roughly 1% of members utilized specialty drugs, and the average 2009 per-member per-year cost was \$111.²⁰ Using this information, Mercer calculated the plan cost given specific cost-sharing amounts. Based on the responses from carriers and the Mercer large employer survey, the average Tier 3 copay in Maryland is roughly \$45. For those Maryland carriers that offer four-tier drug plans, Mercer did not receive adequate information for the average Tier 4 cost-sharing. The single response we received stated that Tier 4 coinsurance is 25% with a \$75 copay cap. Based on the 2010 CVS Caremark Benefit Planning Survey, representing 7.3 million lives, the specialty member cost-share goal for these employers is 20%.²¹ We estimated the increase in plan costs when changing the specialty cost-sharing from a \$90 copay to a

¹⁹ The drug premium represents a relatively small percentage of the total premium for a typical health plan that offers medical and prescription drug coverage.

²⁰ CuraScript.

²¹ CVS Caremark. "2010 Client Benefit Planning Survey."

\$45 copay and from 20% coinsurance to a \$45 copay. The following table summarizes the results.

Table 2

Fixed Copay		Coinsurance	
Member Copay	Plan PMPM	Member Coinsurance	Plan PMPM
0	\$9.25	0%	\$9.25
40	9.05	20%	7.40
45	9.03	25%	6.94
50	9.00	30%	6.48
55	8.98	35%	6.01
60	8.95	40%	5.55
65	8.93	45%	5.09
70	8.90	50%	4.63
75	8.88		
80	8.85		
85	8.83		
90	8.80		
Cost-Sharing Change	\$90 copay to \$45 copay		20% coins to \$45 copay
Estimated PMPM Impact	\$0.22		\$1.63

As shown in the table above, reducing the member cost-sharing from \$90 to \$45 results in an increase in plan claim costs of \$0.22 PMPM, or a 0.07% increase in the average cost of a group policy. Reducing the member cost-sharing from 20% coinsurance to a \$45 copay results in an increase in plan claim costs of \$1.63, or a 0.50% increase in the average cost of a group policy.

Continuing with the example above, the mandate’s financial impact is moderate. The table below summarizes the mandate’s cost impact on Maryland residents and carriers.

Table 3

	Cost
Estimated cost of mandated benefits as a percentage of average cost per group policy	0.07% to 0.5%
Estimated cost as a percentage of average wage	0.01% to 0.07%
Estimated annual per employee cost of mandated benefits for group policies	\$5 to \$36

These results are consistent with the responses we received from carriers reporting that the financial impact of this mandate is insignificant.

The estimates provided above assume the member pays the same cost-sharing for each drug dispensed. Based on survey responses provided by carriers, applying out of pocket and maximum copay limits to Tier 4 drugs is common. Including these types of cost-sharing in the plan design would dampen the premium increases.

One of the surveyed carriers emphasized that some employer groups have been requesting information on drug plans with four and five tiers. The additional tiers are one option to reduce the cost to provide coverage. The proposed mandate would not allow carriers the flexibility to reduce premiums by adding cost-sharing tiers to the drug plan. ***One option that carriers may elect as a means to contain premiums would be to increase the cost-sharing for all prescription drugs. Another unintended consequence of the proposed mandate could be carriers' moving away from fixed-dollar (copay) plans to coinsurance drug plans without any annual maximum out of pocket limitation, which could ultimately lead to a significant increase in member cost-sharing and member dissatisfaction.*** The coinsurance approach without annual out-of-pocket limit would significantly increase the insured's liability from the current levels based upon the responses from the carriers regarding their existing benefits and practices.

References

Campbell, Jim. "Drugs Approved Under the FDA's 'Accelerated Approval' Program." *Healthier Talk*. November 28, 2009.

<http://www.healthiertalk.com/drugs-approved-under-fdas-accelerated-approval-program-1056>

CuraScript. "2009 Specialty Drug Trend Report: A Market and Behavioral Analysis." April 2010. http://www.curascript.com/bin_web/documents/09DrugTrendReportCuraScript.pdf

CVS Caremark. "Client Benefit Planning Survey."

<http://info.cvscaremark.com/newsroom/press-releases/cvs-caremark-annual-employer-survey-finds-majority-employers-rate-managing-c>

Drugs.com. "New Drug Approval Process."

<http://www.drugs.com/fda-approval-process.html>

Felland, Laurie E., and James D. Reschovsky. "More Nonelderly Americans Face Problems Affording Prescription Drugs." Center for Studying Health System Change. Tracking Study No. 22, January 2009. <http://www.hschange.com/CONTENT/1039/#ib2>

FierceBiotech. "FDA Approval Process."

http://www.fiercebiotech.com/topics/fda_approval_process.asp

Goldman, Dana P., Geoffrey F. Joyce, Grant Lawless, William H. Crown, and Vincent Willey. "Benefit Design and Specialty Drug Use." *Health Affairs*. Vol. 25, No. 5 (2006): 1319.

<http://content.healthaffairs.org/cgi/reprint/25/5/1319>

The Henry J. Kaiser Family Foundation. "Distribution of Total Population by Federal Poverty Level, states (2008-2009), U.S. (2009)."

<http://www.statehealthfacts.org/comparebar.jsp?ind=9&cat=1>.

Mercer. "2009 Mercer National Survey of Employer-Sponsored Health Plans." P. 11

U.S. Department of Health and Human Services. "2009 HHS Poverty Guidelines."

<http://aspe.hhs.gov/poverty/09poverty.shtml>

U.S. Food and Drug Administration. "The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective."

<http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm>

United States Government Accountability Office. "FDA Needs to Enhance Its Oversight of Drugs Approved on the Basis of Surrogate Endpoints." September 2009.

<http://www.gao.gov/new.items/d09866.pdf>

Walgreens. "Outlook – State of the Industry Report." August 2009.

<http://www.walgreenshealth.com/pdf/newsletterreport/SOIRreport2009.pdf>



2

Cancer Chemotherapy Cost-Sharing Equity

House Bill 626 would prohibit carriers that cover cancer chemotherapy from imposing different cost sharing levels for orally administered cancer chemotherapy that are less favorable than those that apply to cancer chemotherapy administered intravenously or by injection.

Anticancer medications can be administered in several ways, including the following:

- **Orally** – taken by mouth (usually as pills)
- **Intravenously** – infused through a vein
- **By injection** – injected into a muscle or under the skin.

Older, less common means also exist. Some medications can be applied topically, infused directly into another part of the body, or injected directly into a tumor.²² Older injectable cytotoxic chemotherapeutic drugs, such as doxorubicin or cyclophosphamide, are used for many types of cancers. Due to their potential for severe side effects, these drugs need to be administered in a physician’s office, clinic, or hospital by intravenous infusion in short cycles.

Oral anticancer medications have been available for several decades and are becoming an increasingly popular treatment option for cancer patients. Oral treatments offer certain advantages over other delivery methods, including increased convenience; fewer

²² California Health Benefits Review Program (CHBRP). “Analysis of Senate Bill 161, Health Care Coverage: Chemotherapy Treatment.” Report to California State Legislature April 17, 2009, revised June 26, 2009.

complications associated with administration; greater flexibility in timing, duration, and location of administration; and, often, fewer side effects.²³ In addition, oral medications may be less costly to administer since they do not require an office visit or nursing staff.²⁴ On the other hand, some cancer patients cannot assume the considerable responsibility of potentially complex treatment regimens, and health care professionals must invest significant time educating the patient and providing technical support. Although oral medications may offer many advantages, health benefit plans often require enrollees to pay higher out-of-pocket costs for them.²⁵

By early 2009, the FDA had approved 40 oral anticancer medications for treatment of 54 different cancers. Of these medications, 28% had intravenous/injected substitutes and 23% had generic equivalents.²⁶ Since then, 11 more anticancer medications have been approved.²⁷

With the exception of some limited benefit plans and small employer plans, chemotherapy is generally a covered expense, regardless of how it is administered. However, because of the historic evolution of these plans, oral anticancer medications are covered differently from intravenous or injected medications, often by entities that are separate. The key determinant is the site of administration. Cancer medications administered in a doctor's office or hospital are covered under the plan's medical provisions. Oral medications are generally covered under separate prescription drug plans.²⁸ As a result, benefits vary a great deal.

A plan's "medical" benefit usually covers a higher percentage of eligible expenses than a plan's pharmacy benefit since the medical benefit usually requires only a copayment for the chemotherapy visit (although some plans may have a coinsurance design for office visits, which may result in high cost sharing requirements). Pharmacy plans, in contrast, commonly have a tiered benefit design with expensive oral drugs often in the highest tier. Usually this tier is a high copayment tier for non-preferred brand name drugs, but in some

²³ Texas Department of Insurance. "Patient Cost Disparity Between Orally and Intravenously Administered Chemotherapies." Report on Senate Bill 1143, Section 3. 81st Legislature, Regular Session, 2009, August 2010.

²⁴ Texas Department of Insurance.

²⁵ Texas Department of Insurance.

²⁶ CHBRP.

²⁷ Centerwatch. "FDA Approved Drugs."

²⁸ CHBRP.

plan designs, the highest tier is designated a “specialty drug tier” and carries a significant cost-sharing in the form of coinsurance.²⁹

Traditional pharmacy benefit designs, with fixed copays, such as \$10 per prescription for generic drugs, \$25 for formulary brand drugs, and \$40 for other brand drugs, do not impose large cost sharing for expensive drugs and, in fact, may cover a higher percentage of the costs of expensive oral medications than the typical medical benefit.³⁰ However, some plan designs (one estimate is 18% of all pharmacy benefit plans nationwide³¹) have unlimited coinsurance provisions, typically 20% for generic drugs, 25% for formulary brand drugs, and 35% for other brand drugs.³² These can impose a significant cost sharing burden when the prescription costs thousands of dollars, as is often the case. (UnitedHealthcare reported that the average prescription costs of the more than two dozen oral anticancer medications covered in 2008 were \$3,400.³³) At this time it appears that insurance carriers in Maryland have not adopted unlimited coinsurance provisions for drugs as readily as other parts of the country, but this could change rapidly.³⁴

Nine states and the District of Columbia have passed “chemotherapy equity” legislation, and others have similar legislation pending.³⁵ Many have “no less favorable” language similar to Maryland’s bill. While the expectation is that carriers subject to these provisions will comply by reducing current cost-sharing requirements for oral anticancer medications to match the cost-sharing provisions applicable to intravenous drugs,³⁶ the legislation does not require that action. In today’s climate, some carriers might choose to comply by raising the cost-sharing features of intravenous, et al, drugs to meet the arguably higher provisions of the oral medications.

²⁹ K. Fitch, K. Iwasaki, and B. Pyenson. “Parity for Oral and Intravenous/Injected Cancer Drugs.” Prepared by Milliman, Inc., NY, for GlaxoSmithKline. January 25, 2010.

³⁰ Fitch, et al

³¹ Takeda Pharmaceuticals. “2009-2010 Prescription Drug Benefit Cost and Plan Design Report.” Table 15: Trends in Common Plan Configurations 2007-2009.

³² Watson Wyatt COMPARISON Database: 2008 Statistical Summary. Watson Wyatt, 2009.

³³ UnitedHealth Group. “Facts and Perspective on Legislation Mandating Certain Benefits for Oral Chemotherapy Agents.” January 2010.

³⁴ 2009 Mercer Survey of Employer Sponsored Health Plans, Maryland Large Employers. This proprietary report shows that in 2009 only 8% of large employers (500 or more employees) in Maryland use coinsurance for one or more drug categories.

³⁵ Texas Department of Insurance.

³⁶ Texas Department of Insurance.

Medical Impact

In this section, we answer questions regarding chemotherapy coverage equity.

- **Does the medical community recognize oral anticancer medications as being essential and/or effective in slowing the growth of or eliminating certain forms of cancer?**
- **Are oral anticancer medications recognized as appropriate and necessary by the medical community, as evidenced by scientific and peer review of literature?**
- **Do treating physicians utilize oral anticancer medications?**

As previously mentioned, oral anticancer medications have been available for decades. However, the last few years have seen a proliferation of new oral anticancer medicines.³⁷ This trend is expected to continue. National Comprehensive Cancer Network (NCCN) experts estimate that the number of FDA-approved oral medications (currently 40) could easily triple in the next few years.³⁸

There are three primary approaches to cancer treatment: anticancer drug therapy, surgical treatment, and radiation therapy. These approaches can be used individually or in combination, depending on the type of cancer, the stage of the disease, and the patient.³⁹

Over 100 anticancer medications are currently in use, and they are administered in a variety of ways. They vary widely in their chemical makeup, the types of cancer they target, and their side effects.⁴⁰ There are three basic categories of anticancer drug therapy: cytotoxic agents, biologic/targeted agents, and hormonal agents.⁴¹

Cytotoxic agents are intended to kill cancer cells by impairing cell division in rapidly dividing cells. These agents generally do not discriminate, killing both cancer and healthy cells. Because of their side effects, they are usually administered intravenously in

³⁷ Saul Weingart, Elizabeth Brown, Peter Bach, et al. "NCCN Task Force Report: Oral Chemotherapy." *Journal of the National Comprehensive Cancer Network*.6, Supplement 3. March 2008.

³⁸ Weingart, et al.

³⁹ Fitch, et al.

⁴⁰ University of Iowa Hospitals and Clinics. "Types of Chemotherapy." University of Iowa Health Care website. February 2004. Revised November 2006.

⁴¹ CHBRP.

the maximum dose that the patient can tolerate.⁴² However, in some instances, oral administration is an option.⁴³

Biologic/targeted agents are targeted specifically at cell surface proteins or at pathways that are relatively specific to cancer biologic pathways.⁴⁴ These medications attack cells that contain mutated genes or cells that contain duplicates of a particular gene. These agents often have less systemic but unique side effects because they are targeted at cancer cells.⁴⁵ They may be taken orally and are most effective when administered on a regular and recurring basis.⁴⁶

Hormonal agents are not chemotherapy in the strictest sense, as they do not directly kill or slow the growth of cancer cells. Instead, they interfere with the activity of hormones that can promote the development or growth of cancer cells.⁴⁷ These medications, typically less expensive than cytotoxic or targeted anticancer medications, may be administered orally, as an infusion, or as an injection.⁴⁸ Almost half of patients receiving chemotherapy use oral products only, and most of that usage is lower costing hormonal agents.⁴⁹

Spending on oral chemotherapy drugs more than doubled between 2002 and 2006.⁵⁰ More attention is being given to the administration of oral chemotherapy as the availability of these agents has increased and many patients prefer oral options when they are available.⁵¹

NCCN publishes evidence-based treatment guidelines that are designed to improve the quality, effectiveness, and efficiency of oncology practice. The NCCN Clinical Practice

⁴² Fitch, et al.

⁴³ Weingart, et al.

⁴⁴ Weingart, et al.

⁴⁵ American Cancer Society. "Chemotherapy Principles: An In-Depth Discussion of the Techniques and Its Role in Cancer Treatment." 2009.

⁴⁶ Fitch, et al.

⁴⁷ CHBRP.

⁴⁸ Texas Department of Insurance.

⁴⁹ Fitch, et al.

⁵⁰ Weingart, et al.

⁵¹ Kathryn Ruddy, MD, et al. "Patient Adherence and Persistence with Oral Anticancer Treatments." *CA: A Cancer Journal for Clinicians*. 2010.

Guidelines in Oncology are the recognized standard for clinical policy in oncology.⁵² These guidelines provide recommended cancer treatment protocols based on the type of cancer and the stage of the disease.

Some NCCN guidelines recommend the administration of a single intravenous anticancer medication or a single oral anticancer medication. Other protocols call for various combinations. When a drug is available in both forms, the guidelines indicate that these drugs can be substituted for each other.⁵³ The choice largely depends on the preferences of the patient and the attending physician – and on the patient’s ability to adhere to the treatment regimen.⁵⁴

As indicated earlier, research has produced new, orally administered cancer drugs that are more targeted and better tolerated than the older injectables. These new drugs are causing a paradigm shift toward long-term maintenance use in an ambulatory setting, rather than the use of short-term cyclic treatments. These oral treatments are expensive – they frequently cost in the range of \$5,000 to \$10,000 for only a month of therapy. Many new cancer drugs are used on a long-term basis in addition to or sequentially with other treatments, so they can be significant drivers of utilization growth⁵⁵ and the related aggregate treatment costs.

The degree of compliance with the oral regimen is a concern. (The International Society for Pharmacoeconomics and Outcome Research (ISPOR) recently defined *adherence* as synonymous with *compliance* – that is, “the degree or extent of conformity to the recommendations about day-to-day treatment by the provider with respect to the timing, dosage, and frequency.”⁵⁶ The ISPOR group distinguished *adherence* from *persistence*, which was defined as the “duration of time from the initiation to the discontinuation of therapy.”⁵⁷) Optimal adherence and persistence occur when a patient follows his or her prescribed treatment regimen exactly. A patient is optimally adherent if no doses are missed, no extra doses are taken, and no doses are taken in the wrong quantity or at the wrong time. A patient shows optimal persistence if he or she takes a medication as long as it is prescribed.

⁵² National Comprehensive Cancer Network. “About the NCCN Clinical Practice Guidelines in Oncology.”

⁵³ NCCN.

⁵⁴ Weingart, et al.

⁵⁵ Medco. “2010 Drug Trend Report.”

⁵⁶ Ruddy, et al.

⁵⁷ Ruddy, et al.

Non-adherence to oral therapies can result in adverse consequences. The oncologist may incorrectly assume that the agent is not effective if the cancer is still growing, when the true cause may be that the patient simply is not taking the full medication at the proper intervals. Rates of adherence to and persistence with oral cancer therapies have been documented to range between 16% and 100% in adult populations.⁵⁸ The 2010 study by Kathryn Ruddy et al. on patient adherence recommends that providers monitor adherence rates and ascertain the cause(s) for noncompliance (for example, is the regimen causing side effects or distress?). For patients who have difficulties adhering to the regimen, physicians will need to re-emphasize the importance of adherence. Providing pill boxes or medication diaries may help – and, where possible, discussions with pharmacists should be encouraged.⁵⁹

To quantify the prevalence of oral chemotherapy, Milliman Inc. performed a detailed analysis of data from the Thomson Reuters Medstat database. This study found that 1.5% of the population with commercial insurance has a claim for cancer each year and 25% of these receive chemotherapy. Of this group, 48% receive oral treatment only, 35% receive intravenous treatment only, and 17% receive both.⁶⁰

In a 2009 analysis of a similar mandate for California based on 2006 data, the California Health Benefits Review Program (CHBRP) estimated that 0.5% of the individuals covered by its mandate use anticancer medications each year. Almost 70% used oral medications only, 20% percent used intravenous or injected medications only, and 10% used a combination.⁶¹

In their survey response, one carrier questioned the medical appropriateness of singling out oral chemotherapy drugs for special coverage:

“Medically speaking, it would seem discriminatory in a broad sense to provide coverage for this condition, and not other, similar conditions. There are and will be many more diseases that have expensive treatments that include both the infusion route and pills. The concern is, what will this mandate cost in the future when other disease entities are included?”

⁵⁸ Ruddy, et al.

⁵⁹ Ruddy, et al.

⁶⁰ Fitch, et al.

⁶¹ CHBRP.

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 available?**

- **To what extent does the 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 these services?**

- **How interested are collective bargaining agents in negotiating privately for including this coverage in group contracts?**

- **To what extent is the proposed health insurance service covered by self-funded employers in the state with at least 500 employees?**

The Department of Health and Mental Hygiene reports the following incidence rates of all types of cancer and compares them to the national incidence rates. Please note that these incidence rates cover all ages, including those over age 65.

Table 1:
All Cancer Sites Incidence Data*
By Gender and Race, Maryland and the United States, 2004-2006⁶²

	Total	Males	Females	Whites	Blacks	Other
2004						
MD New Cases (count)	25,419	12,460	12,942	18,780	5,677	795
MD Incidence Rate	462.6	524.4	421.5	469.8	444.4	344.9
US SEER Rate ^{††}	464.6	545.4	408.9	471.7	501.6	314.7
2005						
MD New Cases (count)	25,513	12,765	12,719	18,756	5,719	877
MD Incidence Rate	457.4	528.3	409.0	466.4	434.9	362.9
US SEER Rate	456.4	527.5	407.9	465.3	480.9	306.2
2006						
MD New Cases (count)	24,203	12,246	11,895	17,629	5,391	903
MD Incidence Rate [†]	426.3	495.6	376.9	434.3	395.7	353.1
US SEER Rate	450.5	521.9	401.0	458.1	467.3	299.7

* Rates are per 100,000 and are age-adjusted to 2000 US standard population

† 2006 Maryland case counts and incidence rates are lower than actual due to case underreporting for Montgomery and Prince George counties (See Appendix C, Section A.1)

†† Surveillance Epidemiology and End Results

Total includes cases reported as transexual, hermaphrodite, unknown gender, and unknown race

Sources:

Maryland Cancer Registry (MD incidence data), National Cancer Institute SEER statistics (US SEER 17 rates)

Please note that, as defined by the table above, “incidence” measures a person only once – in the year that the cancer was initially diagnosed. If a person received treatment over a period of years, he or she would not be counted in any of the subsequent years. Thus, this definition of “incidence rate” significantly understates the number of individuals receiving care for cancer in any single year.

The current estimate of individuals in the US diagnosed with cancer is 5,700,000, or about 15 in 1,000⁶³ based on a population estimate of 380,000,000.⁶⁴ This rate is about three times the incidence rate in the previous table. We would expect the number of individuals with cancer in any given year to be significantly higher than the number of individuals newly diagnosed. Approximately 25% of these cancer patients (or 4 per

⁶² Maryland Department of Health and Mental Hygiene. “Cancer Report 2009.”

⁶³ Fitch, et al.

⁶⁴ Robert Schlesinger. “US Population, 2010: 308 Million and Growing.” *US News and World Report*. Politics & Policy Blog. December 30, 2009.

1,000) receive chemotherapy;⁶⁵ approximately 65% of these individuals utilize oral medications.⁶⁶

In 2008, The Hilltop Institute reported in its “Overview of the Existing Insurance Market in Maryland” that there were 3,590,609 individuals with private insurance in Maryland.⁶⁷ Based on this estimate of the covered population and the incidence rates reported above, there are approximately 13,500 insured Marylanders receiving chemotherapy annually; 65% of these (or 8,500 to 9,000 individuals) utilize oral anticancer medications to some extent. In California, 98% of covered individuals had coverage for oral anticancer medications.⁶⁸ In Texas, the estimate was closer to 82%.⁶⁹ No comparable number for Maryland is currently available. However, based on feedback from the carriers, we would expect the percentage to be similar to California’s. In the Maryland small group market, all carriers must offer some type of drug coverage. The 2010 Kaiser/HRET Employer Health Benefits Survey shows that 99% of covered workers in employer-sponsored plans have prescription drug coverage.⁷⁰

Almost all Maryland medical plans cover chemotherapy, regardless of how it is administered. Few, however, cover oral and injectable/infused medications in the same way. Table 2 summarizes information provided by the health plans responding to the survey:

Table 2: Coverage of Anticancer Medicines

Health Plan	Coverage of Infused/Injectable Anticancer Medicines	Coverage of Oral Anticancer Medicines
A	Medical plan	Pharmacy benefit
B	Major medical benefit	Prescription benefit
C	Medical plan	Pharmacy benefit
D	Medical plan	Medical plan
E	Medical benefit	Pharmacy benefit
F	Medical benefit	Pharmacy benefit

⁶⁵ Fitch, et al.

⁶⁶ Texas Department of Insurance.

⁶⁷ Charles Milligan. “Overview of the Existing Insurance Market in Maryland.” The Hilltop Institute. University of Maryland, Baltimore County. August 2010.

⁶⁸ CHBRP.

⁶⁹ Texas Department of Insurance.

⁷⁰ Kaiser Family Foundation/Health Research & Educational Trust (HRET). “Employer Health Benefits 2010 Annual Survey.” September 2010.

One carrier indicated that 95% of its insured plans in Maryland have the same cost-sharing provisions and out-of-pocket dollar limits for cancer chemotherapy regardless of how it is administered. Others indicated that medical and pharmacy benefits differ.

Maryland carriers treat cancer chemotherapy differently depending on where and how the chemotherapy is administered. This reflects the nationwide trend. Express Scripts reports that 81% of drug chemotherapy occurs in the medical benefit while 19% occurs in the drug benefit.⁷¹

However, this pattern is changing. Medco reports that currently, more than 800 new cancer drugs and new indications for existing cancer drugs in clinical development.⁷² New, more specialized and better tolerated orally administered cancer drugs are prompting a trend toward long-term maintenance use of these drugs in an ambulatory setting, rather than the use of short-term cyclic intravenous or infused treatments.

Out-of-pocket costs for all treatment regimes are becoming a concern to oncologists. In a recent survey, 84% of oncologists indicated that their decisions regarding the type of treatment to prescribe are influenced by patients' out-of-pocket expenses. While 67% of oncologists in the survey believe that every US citizen should have access to effective cancer treatments regardless of costs, 56% indicated that the cost of new cancer drugs influenced their treatment recommendations. In addition, 58% indicated that patients should have access to effective cancer treatments only if the treatments provide "good value for the money" or are cost effective.⁷³ The challenging questions, of course, are: who determines whether a treatment provides good value for the money and what comparative effectiveness or pharmacoeconomic evidence is available to guide that determination?

The out-of-pocket costs for oral chemotherapy and intravenous/injectable chemotherapy for individuals vary depending on their medical plan design and their prescription drug plan design.

⁷¹ Express Scripts. "2009 Drug Trend Report." April 2010.

⁷² Medco. "2010 Drug Trend Report."

⁷³ Peter J. Neumann, Jennifer A. Palmer, Eric Nadler, ChiHui Fang, and Peter Ubel. "Cancer Therapy Costs Influence Treatment: A National Survey of Oncologists." *Health Affairs* 29, Issue 1. Jan. 2010.

One carrier analyzed its own claims for similar legislation in other states and found that requiring parity for chemotherapy treatments would actually increase out-of-pocket costs for some individuals.⁷⁴ Details are as follows:

- 75% of affected members would be favorably impacted by approximately \$150 annually
- 18% would be unfavorably impacted by approximately \$165 annually
- 7% would be unfavorably impacted by approximately \$1,600 annually

Of the 7% that would be unfavorably impacted by approximately \$1,600, 40% would incur an additional out-of-pocket cost of \$2,700 due to the proposed mandate. [We are assuming that, for these individuals, the oral chemotherapy drug benefit (which currently has copays) would be changed to reflect the medical benefit (which, for these individuals, has higher front-end deductibles, a coinsurance cost sharing requirement, and higher out-of-pocket limits).] This carrier indicated that currently, it only has drug benefits with a maximum of three tiers of copayments, and that it does not subject any of the drugs under the non-integrated drug plans to coinsurance cost sharing without out-of-pocket maximums.

For individual employees enrolled in plans that use coinsurance for a high-cost or specialty tier of medicines without any out-of-pocket limit, the costs for oral chemotherapy can be substantial.⁷⁵ For example, a 25% coinsurance provision for a \$100 drug is a manageable \$25 for an employee, but the same provision for a \$10,000 prescription would be \$2,500, a substantial burden.

None of the surveyed health plans in Maryland indicated that they classify oral chemotherapy medications separately for their insured plans. A recent survey reported that, nationwide, 14% of large employers have drug plans with coinsurance,⁷⁶ but others are considering implementing coinsurance in light of prescription drug cost trends. The 2009 Mercer survey shows that only 8% of large groups in Maryland use coinsurance for one or more drug categories.⁷⁷

⁷⁴ UnitedHealth Group.

⁷⁵ Fitch, et al.

⁷⁶ The Pharmacy Benefit Management Institute. "Prescription Drug Benefit Cost and Plan Design Online Report." 2008-2009 Edition.

⁷⁷ Mercer. "2009 Mercer Survey of Employer Sponsored Health Plans, A Special Report: Maryland Large Employers." 2009.

We surveyed health plans in Maryland to ascertain the current level of copays for oral chemotherapy drugs. Table 3 illustrates the results.

**Table 3:
Maryland Health Plan Copays for Oral Chemotherapy Drugs**

Carrier	Copays for Oral Chemotherapy Drugs (Per 30-day Supply)
A*	\$200
B	\$20 to \$25
C	\$0 to \$60
D	\$20 to \$75
E	\$0 to \$50
F	\$25 to \$30

* Carrier A was the only carrier reporting a unique copay for oral chemotherapy drugs. All the other carriers reported that these drugs are considered the same as any other drug, meaning that some of these drugs qualify as generic (and are subject to the generic copay), some qualify as preferred brand-name drugs (and are subject to the preferred brand-name drug copay) and some may be classified as non-preferred brand-name drugs (and would be subject to the non-preferred brand-name drug copay). With the exception of Carrier A, the carriers indicated that they did not base their classifications of chemotherapy drugs on costs, and that many were available under both generic and preferred brand-name drug tiers.

Maryland carriers reported that almost all of the large self-insured plans that they administer treat chemotherapy expenses the same way the insured plans treat chemotherapy expenses, and that when a self-insured plan elected a coinsurance design for a specialty tier, the cost sharing per prescription would usually be capped at an amount commonly between \$75 and \$200.

The Milliman study indicates that plan provisions affect anticancer drug use. In particular, the study demonstrates that higher cost sharing for oral chemotherapy medicines is associated with lower utilization of these drugs.⁷⁸ Data shows an inverse relationship between the percentage of cost sharing and the number of claims per patient. “These data suggest that oral/intravenous/ injected chemotherapy parity will increase drug utilization, which will increase cost.”⁷⁹

⁷⁸ Fitch, et al.

⁷⁹ Fitch, et al.

It is difficult to estimate the financial burden for individuals. Only three carriers provided any information on the average cost sharing for oral chemotherapy drugs paid through the pharmacy benefit versus cost sharing for chemotherapy paid through the medical benefit. Even this information was inconsistent with one carrier reporting higher cost sharing for chemotherapy claims under the medical benefit: one carrier reporting higher cost sharing for chemotherapy paid under the drug benefit; and one carrier indicating the cost sharing are the same. Therefore, cost-sharing comparisons based on Maryland-specific data are not possible with the information we received.

We would like to have obtained more information from more carriers, but the other carriers indicated this information was not available.

Maryland's unions are generally in favor of this proposed mandate, but some cited concerns about how it would be administered. Union spokespeople indicated that the provision was not currently a part of most contracts.

Financial Impact

In this section, we estimate how much it would cost to enact the proposed mandate. We compare our estimates with those of other sources, including Maryland health carriers.

Mercer asked six major carriers in Maryland to estimate how adopting this mandate would affect claims costs. Five carriers provided estimates.

The following table summarizes the carriers' responses.

Table 4
Carriers' Estimates of Proposed Mandate's Cost Impact

Carrier	\$ per Member per Year	% of Claims
1	\$13.14 to \$17.08	0.4% to 0.6%
2	\$0.00	0.00%
3	\$0.00 to \$6.20	0.0% to 0.2%
4	\$0.00	0.0%
5	\$0.03	0.0%

The Maryland Department of Legislative Services prepared a Fiscal and Policy Note estimating the cost of this proposed benefit at \$10.77 per member per year.⁸⁰ This is

⁸⁰ Department of Legislative Services, Maryland General Assembly. 2010 Session. "Fiscal and Policy Note for House Bill 626." February 2010.

within the range that we observe from the survey of carriers, although it is toward the high end.

Mercer completed an independent estimate. Because of the carriers' incomplete survey responses regarding incidence rates and the utilization of oral chemotherapies for the currently insured population, we had to rely on public data. We were able to use Maryland carrier data for information on copays for drug programs. We used the following assumptions:

- The incidence rate of members seeking cancer care for the commercial population varied from a low of 0.5 per thousand members⁸¹ to a high of 1.5 per thousand members.⁸²
- The percentage of individuals with cancer-seeking chemotherapy ranged from 25%⁸³ to 33%.⁸⁴
- The percentage of chemotherapy patients that use oral chemotherapy ranges from 65%⁸⁵ to 80%.⁸⁶
- The average number of prescriptions for oral chemotherapy per patient per year is 26.⁸⁷
- The average copayment per prescription in Maryland as a whole ranges from \$15 to \$50. This range is based on the carriers' responses, which are then weighted based on their percentage (based on premium) of the Maryland group market. We are also assuming that those who are undergoing chemotherapy will have satisfied any out-of-pocket cost sharing under the medical plan via other benefits. This is a conservative assumption.⁸⁸
- Compliance with this mandate will be achieved by eliminating the cost-sharing provisions under the drug program. We have not provided for any decrease in benefit resulting from this proposed mandate.

⁸¹ CHBRP.

⁸² Fitch, et al.

⁸³ Fitch, et al.

⁸⁴ CHBRP.

⁸⁵ Fitch, et al.

⁸⁶ CHBRP.

⁸⁷ CHBRP.

⁸⁸ As Table 5 shows, the estimated range of the full cost of this mandate is immaterial, so the conservativeness attributable to this assumption is immaterial.

Table 5
Estimates of Full Costs

	Low	High
Rate of members seeking cancer treatment in any year	5/1,000	15/1,000
% of members seeking cancer treatment that use chemotherapy	25%	33%
% of members using chemotherapy that use oral chemotherapy	65%	80%
# scripts per year	26	26
Copay per script	\$15	\$50
\$PMPY	\$0.32	\$5.20
Members/EE	1.827	1.827
\$PEPY	\$0.58	\$9.50
% of claims	0.0%	0.2%

The carriers estimating no impact on premium represent 70% of the group medical premium in Maryland. Based on this statistic, we assume a marginal cost of 30%.

Table 6
Estimates of Full and Marginal Costs

	Full Cost	Marginal Cost
Estimated cost as a percentage of average cost per group policy	0.0% – 0.2%	0.0% – 0.1%
Estimated cost as a percentage of average wage	0.00% – 0.02%	0.01% – 0.01%
Estimated annual per- employee cost	\$0.58 – \$9.50	\$0.17 – \$2.85

Please note that these estimates do *not* include any provision for additional administrative costs. Several carriers expressed concerns regarding the costs of administering this benefit. These concerns were also expressed during a discussion with the medical directors of several of the carriers.

Since the medical benefits and the drug benefits are often administered under entirely different systems – and sometimes by different entities – the cost of integrating these systems for one subset of benefits would be very high. Several carriers questioned whether these additional costs were justified, given the limited number of insureds who would benefit from this change (and also given the fact that some might actually experience an increase in cost sharing). None of the carriers provided any dollar estimates for implementation costs.

References

American Cancer Society. "Chemotherapy Principles: An In-Depth Discussion of the Techniques and Its Role in Cancer Treatment." 2009.

<http://www.cancer.org/acs/groups/cid/documents/webcontent/002995-pdf.pdf>

California Health Benefits Review Program (CHBRP). "Analysis of Senate Bill 161, Health Care Coverage: Chemotherapy Treatment." Report to California State Legislature April 17, 2009, revised June 26, 2009.

http://www.chbrp.org/docs/index.php?action=read&bill_id=39&doc_type=2

Centerwatch. "FDA Approved Drugs." www.centerwatch.com/drug-informations/fda-approvals/

Department of Legislative Services, Maryland General Assembly. 2010 Session. "Fiscal and Policy Note for House Bill 626." February, 2010.

http://mlis.state.md.us/2010rs/fnotes/bil_0006/hb0626.pdf

Dr. Diane Dwyer, Medical Director of Maryland Cancer Registry. September 27, 2010.

Express Scripts. "2009 Drug Trend Report." April 2010.

<http://www.express-scripts.com/research/studies/drugtrendreport/2009/dtrFinal.pdf>

Fitch, Kathryn, Kosuke Iwasaki, and Bruce Pyenson. "Parity for Oral and Intravenous/Injected Cancer Drugs." Prepared by Milliman Inc., NY, for GlaxoSmithKline. January 25, 2010 <http://publications.milliman.com/research/health-rr/pdfs/parity-oral-intravenous-injected.pdf>

Kaiser Family Foundation/Health Research & Educational Trust (HRET). "Employer Health Benefits 2010 Annual Survey." September 2010. <http://ehbs.kff.org/>

Maryland Department of Health and Mental Hygiene. "Cancer Report 2009."

http://fha.maryland.gov/pdf/cancer/2009_crf_cancer_report.pdf

Medco. "2010 Drug Trend Report."

http://www.drugtrend.com/art/drug_trend/pdf/DT_Report_2010.pdf

Mercer. "2009 Mercer Survey of Employer-Sponsored Health Plans, A Special Report: Maryland Employers." 2009.

Milligan, Charles. "Overview of the Existing Insurance Market in Maryland" The Hilltop Institute. University of Maryland, Baltimore County. August, 2010. P. 4. National Cancer Institute. "Cancer Trends Progress Report – 2009/2010 Update." <http://progressreport.cancer.gov/>

National Comprehensive Cancer Network. "About the NCCN Clinical Practice Guidelines in Oncology." www.nccn.com/home/40/238-about-nccn-professional-guidelines.html.

Neumann, Peter J., Jennifer A. Palmer, Eric Nadler, ChiHui Fang, and Peter Ubel. "Cancer Therapy Costs Influence Treatment: A National Survey of Oncologists." *Health Affairs* 29 Issue 1. Jan. 2010.

The Pharmacy Benefit Management Institute. "Prescription Drug Benefit Cost and Plan Design Online Report." 2008-2009 Edition. www.pbmi.com/2008_report/index.html

Ruddy, Kathy, MD, et al. "Patient Adherence and Persistence with Oral Anticancer Treatments. CA: A Cancer Journal for Clinicians." 2010. <http://caonline.amcancersoc.org/cgi/reprint/59/1/56>.

Schlesinger, Robert. "US Population, 2010: 308 Million and Growing." *US News and World Report* Politics & Policy Blog. December 30, 2009. <http://politics.usnews.com/opinion/blogs/robert-schlesinger/2009/12/30/us-population-2010-308-million-and-growing>

Takeda Pharmaceuticals. "2009-2010 Prescription Drug Benefit Cost and Plan Design Report."

Texas Department of Insurance. "Patient Cost Disparity Between Orally and Intravenously Administered Chemotherapies: Report on Senate Bill 1143, Section 3, 81st Legislature, Regular Session, 2009." August 2010. <http://insurance.tx.gov/reports/life/documents/chemostudy.pdf>

UnitedHealth Group: "Facts and Perspective on Legislation Mandating Certain Benefits for Oral Chemotherapy Agent." January 2010. Received from United November 23, 2010.

University of Iowa Hospitals & Clinics. “Types of Chemotherapy.” University of Iowa Health Care website. February 2004. Revised November 2006.

<http://www.uihealthcare.com/topics/medicaldepartments/cancercenter/chemowhattoexpect/types.html>

Watson Wyatt COMPARISON Database: 2008 Statistical Summary. Watson Wyatt. 2009.

Weingart, Saul, Elizabeth Brown, Peter Bach, et al. “NCCN Task Force Report: Oral Chemotherapy.” *Journal of the National Comprehensive Cancer Network*. 6, Supplement 3, March 2008.

http://www.nccn.org/JNCCN/PDF/JNSU3_combined_Oral_Chemo_2008.pdf

**3**

Expansion of Habilitative Services – Financial Impact Analysis

Background

In 2007, a proposed mandate requiring coverage of habilitative services, regardless of age was introduced but did not pass. Mercer, the Commission’s consulting actuary, prepared an evaluation of the proposed mandate, as presented in a report dated December 20, 2007.

As presented, HB 1192/SB 944 (2007) would have required a health insurer, nonprofit health service plan, Medicaid managed care organization, or HMO (further referred to as a “carrier”) to provide coverage for habilitative services for persons of all ages who suffered “congenital or genetic birth defects,” including but not limited to autism spectrum disorder (ASD) or cerebral palsy (CP). Guidance from the Maryland Department of Legislative Services (DLS) indicated that the intent of this proposed mandate was *to limit services to individuals who suffered developmental disabilities resulting from these conditions*. As defined in the proposed legislation, habilitative services are occupational, physical, and speech therapy (OT, PT, and ST) treatments that enhance the functioning ability of a person with the prescribed conditions. Mercer used this interpretation and definition for its analysis.

The state of Maryland currently mandates coverage of these services for children who are developmentally disabled by birth defects, ASD, or CP through age 18. This proposed mandate would have extended coverage to affected persons from 19 through 64 years of age.

Introduction

In a letter dated March 11, 2010, the Senate Finance Committee (Committee) of the State of Maryland requested that the Commission examine the impact of a new proposed mandate very similar to the earlier proposal in 2007. This new proposed mandate, introduced as SB 445 of 2010, and before that as SB 564 of 2009, would require health insurers in the State to cover habilitative services up to age 25. The Committee has requested this additional analysis due to the potential cost impact of these bills on health insurance plans in the State.

The Committee has also requested that the Commission examine the potential cost impact to health insurance plans of a gradual phase-in of the requirement (i.e., up to and including age 19 in the first year after enactment of such a mandate, up to and including age 20 in the second year, and so on, until age 25, at which time coverage for the services would end).

In the conduct of the cost analysis, Mercer assumed (at the Commission's direction) that the only difference between this proposed mandate and the 2007 proposed mandate is the ages to which the covered services would be provided.

If either the parameters for the services to be provided or the population to whom these services would be extended differed significantly from those assumed, these estimates would not be appropriate.

A discussion of the financial impact of this proposed mandate follows. Mercer was not asked to address the medical or social impact of the proposal, as those aspects of the proposed mandate were covered in the 2007 report.

Recap of 2007 Cost Estimates – Expansion of Coverage to Ages 19 to 64

Below is a summary of the 2007 cost estimates for ages 19 to 64. Mercer included this summary in this report for reference, as these results and the underlying pricing approach have been used, in part, in determining cost estimates for the 19 to 24 age group under the new proposal (discussed later in this report).

As background, it was noted in the 2007 report that statistics on the incidence and costs associated with habilitative services were not readily available for ages 19 through 64. Below are examples of statements to that effect from the 2007 report.

“Although there are many studies and articles about the positive outcomes of the various therapies, the studies and articles do not access the cost of these therapies nor the cost benefit that results.”

“Data that track the use of these services by treating physicians for the target population were not available.”

“Efforts to use data from the Maryland Medicaid program as a proxy proved problematic because claims data focus on the primary diagnosis being treated, not any underlying conditions that may have been present at birth. Therefore, a search of the claims data by diagnosis would yield a very modest return, especially for services rendered to adults. There is no clear identifier or reasonable proxy for sorting the Medicaid claims data.”

“Statistics for incidence and costs of habilitative services for adults disabled by birth defects, ASD and CP are not readily available.”

However, in the 2007 report, Mercer did note the various sources of information available to determine the extent to which habilitative services were generally utilized by a portion of the population. Mercer had considered all of those sources and estimated that the prevalence of developmentally disabling birth defects, ASD, and CP among people age 19 to 64 was between 1% and 2%. Mercer stated: *“due to the low prevalence rates, it can be presumed that only a small portion of the population generally uses these services.”*

Mercer had also surveyed four major carriers in Maryland in 2007, asking them to provide financial estimates as to how rates would be affected. Responses include the following:

- **Carrier A** – *“It is very difficult to anticipate premium increases, but, in addition to costs of care, we anticipate programming and operational changes costing in the 10’s of millions of dollars.”*
- **Carrier B** – *“This company’s actuaries indicated that there was no way to estimate the increase in premium based on the language in the proposed mandate. With no defined scope of services, and with the wide variety of possible conditions and treatments, they felt they could not begin to quantify that information.”*
- **Carrier C** – *“Removing age limits would require a rate increase of between \$4.00 and \$8.00 PMPM. Our calculations indicate that this equates to 2% to 3% of premium.”*
- **Carrier D** – *“This carrier estimated that premiums would increase by 0.7%.”*

Because of the very limited data available regarding the use and cost of habilitative services for adults who suffer from developmental disabilities associated with congenital or genetic birth defects, Mercer had provided a range of cost estimates using two different methods, as illustrated below in Table 1. These cost estimates reflected three primary sources, including 1) various sources of information cited in the 2007 report; 2) responses from the carrier surveys, and; 3) Medicaid data in other states.

Table 1
Claim Cost Estimates for Habilitative Services – Ages 19 to 64
December 20, 2007 Report
(Excluding Potential Increases in Administrative Costs)

	Approach A		Approach B	
	Low	High	Low	High
Estimated cost as a percentage of average cost per Maryland policy	0.8%	5.1%	0.9%	1.9%
Estimated cost as a percentage of average wage	0.1%	0.4%	0.1%	0.2%
Estimated annual per-employee cost for Maryland's policies	\$39	\$261	\$50	\$100

Financial Impact – Expansion of Coverage to Ages 19 to 24 (Current Proposal)

Health Plan Medical Directors' Input

To help assess potential financial and administrative concerns about the current proposed mandate, MHCC invited the medical directors of several of Maryland's larger health plans to provide insight. Several issues were raised during these discussions.

One carrier expressed difficulty in defining habilitative versus rehabilitative services. This carrier also expressed concern about being responsible for administering any treatment plans that may be associated with habilitative services.

A second carrier expressed concern over whether there would be enough provider capacity for the necessary habilitative services (occupational, physical, and speech therapy).

A third carrier stated that the mandate could be very costly and cited several concerns, as follows: 1) The mandate does not address the need for any required plan of care or continued need for care. 2) What would stop the age cap from being extended beyond age 25? 3) Had any analysis ever proved that these services improved patient outcomes? 4) Any "creep" in scope and diagnosis of services would potentially add to the cost.

The general conclusion from these interviews was that, while carriers were concerned with the costs and issues that could arise during the proposed mandate's implementation and ongoing administration, at the time of these discussions no carrier had quantified the potential cost impact.

2010 Carrier Survey

To supplement the interviews with the carriers' medical directors, Mercer conducted a written survey of several of the major carriers in Maryland, as was done in 2007. The purpose was to determine 1) the extent to which carriers already cover habilitative services up to age 25; 2) the cost of those services; 3) the services' estimated impact on premium; and 4) other administrative issues that the carriers might foresee with the proposed mandate. Five carriers answered the Mercer survey, and their responses suggested a wide range of possible outcomes. Key results are as follows:

- **Current Coverage:** Based on our interpretation of the carriers' survey responses, carriers are providing habilitative services up to age 19 only, and no carrier is currently providing the benefits of the proposed mandate up to age 25.
- **Claim Costs:** Claim cost estimates for habilitative services for the existing mandate vary widely by carrier, as noted in the following:
 - **Carrier # 1: \$22.36 PMPY**
 - **Carrier # 2: \$50.09 PMPY**
 - **Carrier # 3: \$79.90 PMPY**
 - **Carrier # 4: \$174.15 PMPY**
 - **Carrier # 5: The average cost ranged from \$9,100 to \$18,200 per year for people who utilize habilitative services. No PMPY cost was provided.**
 - **Average: \$81.63 PMPY, excluding Carrier # 5.**
- **Premiums:** Carriers were asked to estimate the impact on premium for this proposed mandate. Responses varied across a wide range of possible outcomes, as follows:
 - **Carrier #1: 0.02% of premium**
 - **Carrier #2: 0% (This carrier said there would be no impact on premium)**
 - **Carrier #3: 0.4% to 1.1% of premium, depending on plan design**
 - **Carrier #4: \$.03 PMPM premium, or \$0.36 PMPY**
 - **Carrier #5: Did not quantify, but qualified their estimate as a "moderate" to "significant" impact on premium**

These results show that the carriers have widely varying estimates for the reasons given above related to the broad and non-specific nature of the proposed mandate.

Results of the annual small group health plan premium survey conducted by MHCC show that the average annual premium per policy (for all lives covered under the policy) was approximately \$7,100 in 2009. Mercer estimates this to be a reasonable proxy for the average combined premium of group (small and large) and individual plans. Using the estimates from the carriers above, this would result in an average premium for habilitative services for the age group 19 to 24 ranging from \$0 to \$78. The high end of the range of \$78 represents 1.1% (from Carrier #3 above) of \$7,100. This range of premium estimates could be even greater, as Carrier #5 did not provide a specific estimate, but indicated that the premium impact could be significant.

- **Administrative issues:** Only one carrier (Carrier #1) expressed concern in the survey over potential administrative issues or additional related administrative costs associated with the proposed mandated benefit. This differed from the 2007 survey results, in which several carriers raised concern over certain potential administrative issues and their potential costs. This also differed from the opinions that the carriers' medical directors conveyed during the telephone interviews this year (as noted above). The survey response from Carrier #1 was as follows:

“Habilitative care is repetitive in nature and often delivered by non-licensed persons. We are concerned with the educational and license status of several of the behavioral and other types of therapists who deliver habilitative services. Our estimated cost assumes no expansion in the current scope of covered habilitative services (only the increase in age); any “creep” in scope could considerably increase costs.”

Although the new carrier surveys revealed more details on potential cost estimates than were available in the 2007 surveys, the results that are discussed above reveal that potential costs and premiums could vary across a relatively wide range of estimates.

A summary of this carrier information is outlined in Table 2 below. As illustrated, no direct correlation appears to exist between the costs for habilitative services at ages 0 to 18 and the range of premium estimates for ages 19 to 24.

Table 2
Estimated Cost and Premium for Habilitative Services
Summary of 2010 Carrier Surveys

Carrier	Estimated PMPY Cost Current Mandate (Ages 0 – 18)	Estimated PMPY Premium Proposed Mandate (Ages 19 – 24)
# 1	\$22.36	\$1.42 *
# 2	\$50.09	\$0
# 3	\$79.90	\$28.40 – \$78.10 *
# 4	\$174.15	\$0.36
# 5	<i>Not available</i>	“Moderate” to “Significant”
Average All Carriers	\$81.63	\$7.55 – \$19.97
Range	\$22.36 – \$174.15	\$0 – \$78.10

* Based on an assumed average annual premium of \$7,100

Independent Mercer 2010 Cost Estimates – Expansion of Coverage to Ages 19 to 24 - (Methods A and B)

While the carrier surveys serve as one resource for determining the proposed mandate’s potential cost, Mercer has developed two other methods for estimating the potential costs of extending habilitative services up to age 25.

Method # 1: Indirect Method – Ages 19 to 24 Relative to Ages 19 to 64

The first method provides a proxy for the cost of the 19 to 24 age group relative to the cost for the 19 to 64 age group. This method uses two primary sources of information: 1) an update to the results from the 2007 study for ages 19 to 64, using the same approaches (Approach A and Approach B) from that study, and 2) new information Mercer obtained from the Maryland Medicaid program for both age groups 19 to 24 and 19 to 64.

Mercer updated the cost estimates for ages 19 to 64 using the most recent 2010 cost information and trends available from several of the same sources used in the 2007 study. These estimates, shown below in Table 3, are updates of the estimated costs presented above in Table 1 from the 2007 study.

Table 3
2010 Claim Cost Estimates for Habilitative Services – Ages 19 to 64
Update to 2007 Study
(Excluding Potential Increases in Administrative Costs)

	Approach A		Approach B	
	Low	High	Low	High
Estimated cost of mandated benefits as a percentage of average cost per Maryland policy	0.66%	4.46%	1.20%	2.39%
Estimated cost as a percentage of average wage	0.08%	0.53%	0.14%	0.28%
Estimated annual per-employee cost of mandated benefits for Maryland's policies	\$39	\$266	\$71	\$143

Using the cost estimates in Table 3 for ages 19 to 64 and the new Maryland Medicaid data, Mercer estimated the costs for habilitative services for the 19 to 24 age group.

Mercer obtained the new Maryland Medicaid data from the Department of Health and Mental Hygiene (DHMH)⁸⁹ and The Hilltop Institute of the University of Maryland, Baltimore County (UMBC)⁹⁰. This data was instrumental to Mercer's analysis as it contained complete medical service records as well as cost and utilization information for calendar years 2006 through 2009 for enrollees using habilitative services. This level of detail and completeness in the data was not available at the time of the 2007 study. Mercer wishes to thank the DHMH and UMBC for their help in preparing this data. Under this method, Mercer used summary information for the Maryland Medicaid data for age groups 19 to 24 and 19 to 64. While not without limitation, the data enabled Mercer to estimate the cost of habilitative services for the 19 to 24 age group relative to the cost for these same services for the 19 to 64 age group. These cost relativities are presented in Table 4.

⁸⁹ Maryland Department of Health and Mental Hygiene.

⁹⁰ The Hilltop Institute at the University of Maryland, Baltimore County.

Table 4
Average Annual Maryland Medicaid Amounts 2006 to 2009
for Enrollees Receiving Habilitative Services

	Ages 19 – 24	Ages 19 – 64	Ratio
Number of Enrollees	350	785	45%
Medicaid Allowed Charges	\$7,096,526	\$33,097,088	21%
Number of Services	44,803	192,915	23%
Services per Enrollee	128	246	52%
Services/Enrollee/Week	2.5	4.7	52%
Charge per Service	\$158.39	\$171.56	92%
Charge per Enrollee	\$20,305	\$42,189	48%

Table 4 illustrates that the average annual number of enrollees, number of services per enrollee, and allowed charges per enrollee over the four-year period of 2006 through 2009 for the 19 to 24 age group are approximately half of those for the 19 to 64 age group. However, the ratio for the overall number of services and allowed charges is only slightly more than 20%, suggesting that providing these services for the 19 to 24 age group costs approximately one-fifth as much as it does for the 19 to 64 age group.

Applying the 21% cost ratio in line 2 of Table 4 to the estimated cost values in Table 3 for ages 19 to 64 yields a cost estimate for habilitative services for the 19 to 24 age group. Results are presented in Table 5.

Table 5
2010 Cost Estimates for Habilitative Services – Ages 19 to 24:
21% of the Estimated Cost for Ages 19 to 64 in Table 3
(Excluding Potential Increases in Administrative Costs)

	Approach A		Approach B	
	Low	High	Low	High
Estimated cost of mandated benefits as a percentage of average cost per Maryland policy	0.14%	0.94%	0.25%	0.50%
Estimated cost as a percentage of average wage	0.02%	0.11%	0.03%	0.06%
Estimated annual per-employee cost of mandated benefits for Maryland's policies	\$8	\$56	\$15	\$30

Method # 2: Direct Method – Cost Estimate for Expansion of Coverage to Ages 19 to 24 (Approach C)

Under this second method, Mercer utilized detailed service records for each individual enrollee aged 19 to 24 from the Maryland Medicaid data cited above for calendar years 2006 through 2009, along with publicly available Maryland Medicaid enrollee data, to directly estimate the cost of habilitative services for the 19 to 24 age group. The Medicaid service records exclude all personal information that could be used to identify the person receiving the services. Mercer adjusted this cost analysis for trend and anticipated reimbursement levels in the commercial market. Table 6 presents the results of Mercer’s analysis (labeled as Approach C) compared with the results from Method #1 above (Approach A and Approach B) from Table 5.

Table 6
2010 Direct Cost Estimates for Habilitative Services – Ages 19 to 24
(Approach C)
(Excluding Potential Increases in Administrative Costs)

	From Table 5				Approach C	
	Approach A		Approach B		Low	High
	Low	High	Low	High		
Estimated cost of mandated benefits as a percentage of average cost per Maryland policy	0.14%	0.94%	0.25%	0.50%	0.49%	0.82%
Estimated cost as a percentage of average wage	0.02%	0.11%	0.03%	0.06%	0.06%	0.10%
Estimated annual per-employee cost of mandated benefits for Maryland’s policies	\$8	\$56	\$15	\$30	\$29	\$49

Given that the Maryland Medicaid data appears to be the most complete and credible source available, Approach C represents Mercer’s best estimate of the costs under the proposed mandate. The range of cost estimates under Approach C is somewhat higher than the range under Approach B, but within the range of Approach A. Also, the estimated annual per-employee costs under all three approaches fall within the estimated PMPY premium range of \$0 to \$78 from the carrier surveys in Table 2 above.

Phase-In of Proposed Mandate

As requested, Mercer also estimated the cost impact of phasing in the proposed mandate over a six-year period. Under this approach, habilitative services would be covered for only age 19 during the first year of implementation, ages 19 and 20 during the second year, and so on, until mandated habilitative services for ages 19 through 24 were covered during the sixth and later years after the mandate’s implementation.

Table 7 below presents cumulative cost estimates at the end of each year of the proposed phase-in period based on 2010 dollar levels. The year six values are the same as illustrated above for Approach C in Table 6. Note that this distribution assumes that costs, premiums, and wages will all trend at the same rate each year. To the extent that any one or all three of these items trend at different rates or inflate beyond the 2010 dollar level, the distribution of anticipated costs in this table could differ from what is shown.

Table 7
Estimated Distribution of Habilitative Costs Over a Six-Year Phase-In Period:
Cost Estimates Under Method # 2, Approach C

2010 Dollar Levels		Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
		Age 19	Ages 19–20	Ages 19–21	Ages 19–22	Ages 19–23	Ages 19–24
% Total Cost		20%	38%	63%	78%	88%	100%
Cost as % Pure Premium/Cert	Min	0.10%	0.18%	0.31%	0.38%	0.43%	0.49%
	Max	0.16%	0.31%	0.51%	0.64%	0.72%	0.82%
Cost as % Wage	Min	0.01%	0.02%	0.03%	0.04%	0.05%	0.06%
	Max	0.02%	0.04%	0.06%	0.08%	0.09%	0.10%
Average Cost/Cert per Year	Min	\$6	\$11	\$18	\$23	\$26	\$29
	Max	\$10	\$18	\$31	\$38	\$43	\$49

The cost pattern shown above would be replicated for estimates using the other two cost approaches. By this, we mean that 20% of the ultimate costs would be expected in the first year, 38% of the ultimate costs would be expected in the second year, and so on as shown in the table above, until 100% of the costs would be expected by the sixth year.

The relative complexities associated with healthcare reform (PPACA), particularly with respect to the timing and interaction of the various anticipated changes over the next several years, make it difficult to project the potential cost impact of this proposed mandate beyond 2010. Therefore, these cost estimates are based upon the market prior to any potential effects of PPACA. For example, PPACA requires extension of benefits to children up to age 26 as well as guarantee issue for children under age 19, among other benefit modifications.⁹¹ These two changes in particular could result in an increase in membership of children who need habilitative services, and therefore these cost estimates may be aggressive (i.e., understated). While it is expected that the small group and large group market segments will see increases in the number of children due to the extension of dependent coverage up to 26, the individual market segment is probably most susceptible to anti-selection, especially for those carriers offering child only policies. The small group and large group markets have more members over which to spread these

⁹¹ Maryland already required coverage to dependents to age 25 prior to PPACA, but had more restrictive eligibility standards than PPACA.

additional costs than the individual market and minimize selection by employer contributions to the cost of insurance. This is not the case in the individual market, where parents/custodians must fund the entire premium and may elect to defer coverage for healthy children until they need insurance, but will have financial incentives to purchase insurance immediately for higher cost children, such as those that would use this benefit.

References

California Health Benefits Review Program (CHBRP). CHBRP Comparisons, 2009 v. 2008 By Delivery System With Riders. December 31, 2009. As provided by the Maryland Health Care Commission.

The Hilltop Institute at the University of Maryland, Baltimore County.
<http://www.hilltopinstitute.org/>

Maryland Department of Health and Mental Hygiene. <http://www.dhmf.state.md.us/>

Maryland Health Care Commission (MHCC). Annual Mandated Health Insurance Services Evaluation. December 20, 2007.
http://mhcc.maryland.gov/health_insurance/habilitative15_1501.pdf

Medicaid Home and Community-Based Services (HCBS). Statistics.
http://www.pascenter.org/state_based_stats/pick_a_state.php?url=http%3A%2F%2Fwww.pascenter.org%2Fstate_based_stats%2Fmedicaid_hcbs.php&title=Medicaid+HCBS+Data

**4**

Coverage for Treatment of Spinal Muscular Atrophy

House Bill 1557, entitled “Health Insurance – Coverage for Treatment of Spinal Muscular Atrophy”, introduced during the 2010 legislative session, outlines proposed coverage of certain nursing services for the treatment of spinal muscular atrophy (SMA). The bill would have required carriers to provide coverage for private duty nursing services as recommended by the treating physician for the treatment of SMA but the carrier would not be required to provide coverage exceeding 12 hours per day.

According to the Spinal Muscular Atrophy Foundation, SMA is a rare, inherited disease characterized by muscle atrophy and loss of motor function, caused by the absence of or defect in the Survival Motor Neuron 1 (SMN1) gene. This gene is responsible for a protein that is crucial to the health and survival of the nerve cells in the spinal cord that control muscle contraction. As these neurons become unhealthy due to the reduced SMN1 levels, muscles weaken and become atrophic.⁹²

Clinically, the disease is classified into four types, by degree of severity (as shown in Table 1).

⁹² Spinal Muscular Atrophy (SMA) Foundation. “Frequently Asked Questions.” Accessed July 2010.

Table 1

Clinical Classification of Spinal Muscular Atrophy (SMA)			
SMA Type	Age of Onset	Highest Function	Natural Age of Death
Type 1 (severe)	0 - 6 months	Never sits	< 2 years
Type 2 (intermediate)	7 - 18 months	Never stands	> 2 years
Type 3 (mild)	> 18 months	Stands and walks	Adult
Type 4 (adult)	Second or third decade	Walks during adult years	Adult

There are many differences among the types but, for classification purposes, clinicians have focused on the age at onset, the highest function, and the typical age at death.⁹³

Type 1, also called Werdnig-Hoffmann disease, is the most severe and the most prevalent. About 60% of SMA patients have this form.⁹⁴ Type 1 patients display signs of SMA during their first six months of life, or in some instances, in utero. These patients are never able to sit and rarely survive beyond the age of two. They do maintain normal intellectual and emotional development, as do patients in the other three classifications.⁹⁵

Type 2 patients (approximately 27% of SMA patients) have an intermediate form of the disease. Onset generally occurs within seven to 18 months after birth, and patients may survive into adulthood. During this time, patients may be able to sit unassisted, but they are never able to stand or walk.

Type 3, also called Kugelberg-Welander or Juvenile Spinal Muscular Atrophy, is considered a mild form of SMA. Symptoms appear after 18 months, and these patients often survive well into adulthood. They can stand and walk with limited assistance during much of their lives.

Little information exists on Type 4, an adult form of the disease. This less common form involves a slower progression of symptoms that typically affect walking. Symptoms begin to show during the second or third decade of life.

⁹³ C.H. Wang, R.S. Finkel, E.S. Bertini, M. Schroth, A. Simonds, B. Wong, A. Aloysius, L. Morrison, M. Main, T.O. Crawford, A. Trela, and Participants of the International Conference of SMA Standard of Care. "Consensus Statement for Standard of Care in Spinal Muscular Atrophy." *Journal of Child Neurology* 22, No. 8 (August 2007).

⁹⁴ SMA Foundation. "Frequently Asked Questions."

⁹⁵ SMA Foundation. "Frequently Asked Questions."

Medical Impact

This section, we address questions regarding coverage of private-duty nursing services for SMA patients.

- **Does the medical community consider private-duty nursing essential and/or effective in treating SMA patients?**
- **Does the medical community consider private-duty nursing to be appropriate and necessary, as evidenced by scientific and peer review of literature?**
- **Is private-duty nursing available to and utilized by treating physicians?**

According to the International Standard of Care Committee for Spinal Muscular Atrophy (the Committee), care for SMA patients should be determined by current functional status rather than original classification of disease type.⁹⁶ The current classifications include (1) non-sitters, or patients who cannot sit independently, (2) sitters, including those who can sit independently but cannot walk, and (3) walkers. In seeking to develop a consensus statement, the Committee focused on five care areas:

- diagnostic/new interventions
- pulmonary
- gastrointestinal/nutrition
- orthopedics/rehabilitation
- palliative care.

Consensus was achieved in many areas, and these have become the basis for standards of care for SMA. The Spinal Muscular Atrophy Foundation summarizes the Committee's recommendations as follows:

- **Confirm the diagnosis** – Verify the diagnosis with a simple genetic blood test, to help medical professionals plan for and provide patient-specific care.
- **Manage breathing** – Respiratory problems are cited as the top cause of illness and the most common cause of death among children with SMA types 1 and 2. The goal is to educate patients and families on how to (1) manage breathing and employ techniques to maintain clear airways, (2) take measures to prevent respiratory problems, and (3) learn how to minimize the impact of respiratory infection.
- **Manage eating and nutrition** – Patients with SMA are susceptible to both over- and under-nutrition problems. Families and health care professionals work together to monitor growth and closely follow personal nutrition plans.

⁹⁶ C.H. Wang, et al.

- **Muscle movement and daily activities** – Maintaining function of trunk, arm, leg, and neck muscles helps patients achieve their highest level of function and independence. Health care professionals design individual physical therapy plans and recommend assistive devices, tools and exercises to help slow or prevent complications of SMA.
- **Prepare for illness** – Families are encouraged to develop plans for the inevitable medical emergencies and to share the plans with all health care professionals involved in the patient’s care.⁹⁷

The “standard of care” literature for SMA makes no explicit reference to private-duty nursing services. Nevertheless, treatment for SMA types 1 and 2 is care intensive and draws on the skills of numerous health professionals who participate in the assessment, contribute to the chronic care plan, monitor the patient’s status, adjust the plan as necessary, and respond as circumstances warrant. Chronic management requires discussion of the family’s goals, including balancing caring for the child at home for as long as possible, long-term survival, quality of life and comfort, the availability of resources, and the illness’s potential burden on the family.⁹⁸

Experts note that there is a wide range of care for SMA patients. A reasonably comprehensive plan may draw on the skills of medical doctors, physical therapists, occupational therapists, nutritionists, respiratory therapists, and/or hospice professionals. Disparity in family resources, medical practitioners’ knowledge, and regional and cultural standards contribute to variations in care plans even when severity is similar.⁹⁹ One example is pulmonary care for Type 1 children and the use of mechanical ventilation. Some patients and their families are not offered any form of respiratory support, while others are routinely treated with a full array of respiratory assistance and supportive care.¹⁰⁰ Certain treatments, such as invasive mechanical ventilation, may lead to extensive nursing care.^{101 102}

Much of the ongoing care that is provided under the direction of these professionals is highly technical but can be provided by family caregivers. Indeed, as will be reported in the next section, some carriers specifically allow the skilled nursing benefit when the

⁹⁷ SMA Foundation. “Frequently Asked Questions.”

⁹⁸ C.H. Wang, et al.

⁹⁹ C.H. Wang, et al.

¹⁰⁰ M.K.M. Hardart, R.D. Truog. “Spinal Muscular Atrophy – Type 1 – The Challenge of Defining a Child’s Best Interests.” *Archives of Disease in Childhood* 88 (2003).

¹⁰¹ M.K.M. Hardart, et al.

¹⁰² There is a wide range of care for SMA patients. Literature indicates that ventilation in the US is less common than it is in other parts of the world, e.g., Japan, and that invasive ventilation is even rarer, in part because of its significant expense in relation to non-invasive measures.

services involve teaching family members how to deliver the needed care. However, the emotional and financial¹⁰³ burden on caregivers can be substantial. As a result, private-duty nurses may play important roles in providing hands-on care to SMA Type 1 and 2 patients in relief of family caregivers.

In addition to a review of the literature, Mercer participated in a conference call with the medical directors of the major carriers to discuss the medical aspects of several proposed mandates including SMA.

During the call, concern was expressed regarding this benefit. Several medical directors questioned why this particular condition should be given special treatment when there are other conditions as severe that would not enjoy the benefit. Concern was also expressed regarding “diagnosis creep” – specifically that the mere availability of private duty nursing services increases the demand for and cost of private duty nursing services and hinders development of a “circle of need” for care and may prevent or discourage caregivers from learning how to care for members with this condition.

It should be noted that carriers often provide private duty nursing services as a respite for family members when a physician indicates that the respite care is necessary.

It is particularly important to note the impact of the proposed mandate on the carriers. According to the Maryland Insurance Administration, those carriers that exclude private duty nursing coverage would need to modify their plans to cover these services. In addition, those carriers that do not exclude the coverage but instead apply their own medical necessity criteria to determine coverage would be required to defer to the treating physicians’ recommendations. In effect, the proposed mandate removes any opportunity for anyone other than the attending physician to review the clinical necessity and appropriateness of these services.¹⁰⁴

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 available?**
- **To what extent does the lack of coverage result in individuals’ avoiding necessary health care treatments?**

¹⁰³ David Greenberg. “A Cost-Benefit Analysis of Maryland’s Medical Child Care Centers.” Maryland Institute for Policy Analysis and Research. University of Maryland, Baltimore County. December 2008.

¹⁰⁴ Assistant Attorney General. Maryland Insurance Administration. January 2011.

- **To what extent does lack of coverage result in unreasonable financial hardship?**
- **What is the level of public demand for these services?**
- **To what extent is the mandated health insurance service covered by self-funded employers in the state with at least 500 employees?**

It is estimated that one in 6,000 to one in 10,000 live births are affected with SMA, making it one of the most common lethal genetic diseases.¹⁰⁵ Over 60 percent of these babies have the most severe form¹⁰⁶ and generally do not survive beyond their second birthday.¹⁰⁷ Others with Types II and III SMA generally live into adulthood and could have normal life expectancy.¹⁰⁸

Maryland health plans that were surveyed as part of this study indicated limited incidence among their covered populations, ranging from a low of 0.01 cases per 1,000 member years to a high of .1 per 1,000 members years. The majority of companies reported incidences of .01 per 1,000 member years to .05 per 1,000 member years.

The estimates of the surveyed health plans are generally supported by national figures. The SMA Foundation in its “Introduction for SMA Families” estimates that there are 25,000 SMA patients in the US.¹⁰⁹ Based on an estimated national population of 380,000,000 in 2010¹¹⁰, there are six to seven SMA patients per 100,000 Americans nationally. If this rate were mirrored among Maryland’s covered population of 3,590,609¹¹¹, there would be 215 to 251 patients in the state distributed among insured, self-funded, and public programs.¹¹²

Although many covered individuals already have coverage for SMA nursing services, others do not. Table 2 summarizes the responses of the health plans responding to the survey.

¹⁰⁵ B.C. Hendrickson, C. Donohoe, V.R. Akmaev, E.A. Sugarman, P. Labrousse, L. Boguslavskiy, K. Flynn, E.M. Rohlf, A. Walker, B. Allitto, C. Sears, and T. Scholl. “Differences in SMN1 allele frequencies among ethnic groups within North America.” *Journal of Medical Genetics* published online June 21, 2009.

¹⁰⁶ B.C. Hendrickson, et al.

¹⁰⁷ M.K.M. Hardart, et al.

¹⁰⁸ SMA Foundation. “Frequently Asked Questions.”

¹⁰⁹ “Spinal Muscular Atrophy: Introduction for SMA Families.” SMA Foundation, New York, New York. February 2010.

¹¹⁰ Robert Schlesinger. “U.S. Population, 2010: 308 Million and Growing.” *U.S. News and World Report Politics & Policy Blog*. December 30, 2009.

¹¹¹ Charles Milligan. “Overview of the Existing Insurance Market in Maryland.” The Hilltop Institute. University of Maryland, Baltimore County. August 2010.

¹¹² The differences between the rate of live births with SMA and the population incidence rates reported by the carriers is in large part attributable to the high mortality among Type I patients during the first two years following birth.

Table 2

Health Plan	Coverage of SMA Private Duty Nursing Services
Carrier 1	Most fully insured plans exclude; some self-insured plans have limited coverage
Carrier 2	No insured plans cover but there is an approved endorsement available, although to date no one has purchased the endorsement
Carrier 3	All plans cover, subject to certain guidelines and limitations
Carrier 4	All plans cover
Carrier 5	Limited coverage for certain home health services; none for unskilled, or custodial, supportive nursing care

When services are covered, there often must be specific conditions. For example, Kaiser's covered home health care services are limited to evaluating, implementing, and teaching skilled nursing services to family care providers following a change in status. CIGNA covers services if they (1) are provided in lieu of institutionalization or (2) are established by a physician as part of an approved treatment plan.

Likewise, benefits may be limited. Aetna reports that, when home health care visits are covered, they are routinely limited to 120 days per year. CIGNA's contract options include duration limits of 40 to "unlimited" days. Of course, the cost will depend on the option selected.

All of the surveyed health plans limit or exclude coverage for services that are custodial in nature, and it appears that certain services contemplated by the proposed legislation fit the definition of custodial care. Table 3 illustrates.

Table 3

Health Plan	Custodial Care Definition
Aetna	<p>Services and supplies that are primarily intended to help [the patient] meet personal needs... It may involve artificial methods such as feeding tubes, ventilators, or catheters. Examples ... include:</p> <ul style="list-style-type: none"> ▪ Routine patient care, such as changing dressings, periodic turning and positioning in bed, administering medications; ▪ Care of a stable tracheostomy (including intermittent suctioning); ▪ Care of a stable colostomy; ▪ Care of a stable gastrostomy/jejunostomy/nasogastric tube (intermittent or continuous) feedings; ▪ Care of a stable indwelling bladder catheter (including emptying/changing containers and clamping tubing); ▪ Watching or protecting [the patient]; ▪ Respite care, adult (or child) day care or convalescent care; ▪ Institutional care, including room and board for rest cures, adult day care and convalescent care; ▪ Help with daily living activities, such as walking, grooming, bathing, dressing, getting in or out of bed, toileting, eating, or preparing foods; ▪ Any services that a person without medical or paramedical training could be trained to perform; and ▪ Any service that can be performed by a person without any medical or paramedical training.
CareFirst	<p>Any care that would not require a licensed health care professional. Private-Duty Nursing means skilled nursing care services, ordered by a physician that can only be provided by a licensed health care professional, based on a plan of treatment that specifically defines the skilled services to be provided as well as the time and duration of the proposed services. If the proposed services can be provided by a caregiver, or if the caregiver can be taught and demonstrates competency in the administration of same, then Skilled Nursing Care is not medically necessary. Skilled Nursing Care excludes services for performing the Activities of Daily Living including but not limited to bathing, feeding, or toileting.</p>

Table 3 (continued)

Health Plan	Custodial Care Definition
CIGNA	<p>Any services which are not intended primarily to treat a specific injury or sickness (including mental health and substance abuse). Custodial services include but are not limited to:</p> <ul style="list-style-type: none"> ▪ Services related to watching or protecting a person; ▪ Services related to performing – or assisting a person in performing – any activities of daily living, such as (a) walking, (b) grooming, (c) bathing, (d) dressing, (e) getting in or out of bed, (f) toileting, (g) eating, (h) preparing foods, or (i) taking medications that can be self-administered; and <p>Services not required to be performed by trained or skilled medical or paramedical personnel.</p>
Coventry	<p>Care that is primarily for meeting personal needs. For example, custodial care includes help in walking; getting in and out of bed; bathing; dressing; shopping; preparing and eating meals; performing general household services; taking medicine; or providing other home services mainly to help people in meeting personal, family, or domestic needs, to include extraordinary personal needs created by the illness of a family dependent. If no skilled need is identified, then the service would be classified as “custodial.”</p>
Kaiser	<p>Any care and/or service which is not medically necessary and required for treatment of a condition or illness.</p>

The timing of services can also be important. Certain private-duty nursing services that are rendered immediately after a change in status (such as after acute illness requiring hospitalization) may be covered, but only for a limited time. Examples of these services include evaluating, implementing, and teaching skilled nursing services to family care providers. At other times, these same services would not be covered.

Survey responses indicate that large self-insured plans are very similar to smaller insured plans with respect to these services. Insurers such as CIGNA and Coventry, which indicated that these services are covered if certain conditions are met, reported that the self-insured plans they administer generally cover them on the same basis. Health plans such as Aetna and Kaiser, which do not generally cover these services for their insured customers, were not providing them to any of the self-insured plans that they administer. Finally, CareFirst reported that no self-insured plans had adopted its optional coverage endorsement.

Surveys of organized labor also indicated that this benefit is included in few, if any, contracts. The unions are mixed on supporting this particular mandate. Some thought it was a valid issue, while others were concerned that it would be subject to abuse and be difficult to administer properly. Unions are very concerned about the cost of health benefits in general and recognize that they must be selective of the mandates they are

willing to support, as money spent on health benefits is not available for salaries or pension funding.

It is important to note that in the literature we reviewed, there is no evidence that patients are foregoing necessary care because their plan fails to cover certain private-duty nursing services. There is occasional reference to quality-of-life decisions with regard to SMA care.¹¹³ Likewise, family life considerations are raised. Finally, there is also the infrequent report of major financial hardship.¹¹⁴ Since most of the uncovered services that are addressed in the proposed legislation can be readily provided by family caregivers (albeit often at great inconvenience), little is written about foregone care.

That is not to say that the financial burden on those who choose to retain private-duty nurses to provide much of the custodial care is not substantial. A study of the cost-effectiveness of medical child care centers in Maryland estimated the private-duty nursing costs in 2008 to be \$19.20 – \$46.20 per hour.¹¹⁵ Based on 12 hours a day for 365 days, this amounts to \$84,096 – \$202,356 in 2008 dollars. We would expect that private duty nursing services in the home setting would be more expensive than in a medical child care setting. Of course, there is a good chance that the patient may be hospitalized at some point(s) during the year so it is unreasonable to assume that these services would be provided for 365 days.¹¹⁶ It is also important to reiterate that many of these services can be – and currently often are – provided by family caregivers.

Financial Impact

In this section, we estimate the cost of enacting the proposed mandate and compare the results of our analysis to those of other sources, including the estimates submitted by health carriers in Maryland.

Mercer surveyed six major carriers in Maryland to obtain information on current practices regarding providing private-duty nursing services for members with spinal muscular atrophy. Mercer also asked these carriers to provide incidence rates and estimates as to how premium would be affected if coverage were mandated for private-duty nursing services up to 12 hours per day with no other annual limit.

We received responses from five of the six carriers. Of the responding carriers, two indicated that they did not cover this benefit for fully insured plans (although one did

¹¹³ M.K.M Hardart, et al. and C.H. Wang, et al.

¹¹⁴ William S. Ehart. “NY Insurance Company Ends Program Rather Than Pay Out Big.” *The Washington Times*. October 14, 2009.

¹¹⁵ David Greenberg.

¹¹⁶ David Greenberg, et al. study showed that 73.2% of the children of survey respondents (who attend one of the two centers) were hospitalized during any given year. Note that this data includes children with many different serious medical conditions, not just SMA.

offer a rider), two indicated that they covered private-duty nursing services under certain circumstances subject to annual limits, and one indicated that it would cover these services if a formal plan of care is submitted and it is deemed medically necessary. The following table summarizes the results of the proposed benefit's financial impact.

Table 4

Carrier	\$ per Member per Year	% of Claims
1	\$12.48	0.4%
2	\$10.80	0.3%
3	\$2.17	0.07%
4	\$31.50	1.0%
5	\$6.20 – \$12.40	0.2% – 0.4%

The Department of Legislative Services completed a Fiscal and Policy Note of this proposed benefit. Its estimate was a cost of \$0.57 \$PMPM, or \$6.84 per member per year. This is within the range that we observe from the survey of carriers.

Mercer completed an independent estimate. We employed the following assumptions:

- Incidence rates reported by the responding carriers ranged from one per 100,000 to five per 100,000. (We discounted the one respondent reporting 10 per 100,000 because the rate was so much higher than those provided by the other respondents and in the literature).
- We had two carrier sources for costs per day for private duty nursing services, ranging from \$600 per 12-hour day (\$50 per hour) to \$1,000 per 12-hour day (\$83 per hour).
- We estimated that 87% of individuals diagnosed with spinal muscular atrophy would need this type of care, based on the medical literature.
- We assumed there would be no cost sharing, as members with this type of condition would have met any out-of-pocket maximum on other services.

Table 5

	<u>Low</u>	<u>High</u>
Incidence	1/100,000	5/100,000
Cost per Day	\$ 600	\$1,000
Days/Year	365	365
Cost per Year	\$ 219,000	\$ 365,000
% Needing PDN	0.87	0.87
\$ per Year	\$ 190,530	\$ 317,550
\$PMPY	1.91	15.88
Members/Employee	1.827	1.827
\$PEPY	\$ 3.48	\$ 29.01
% of Claims	0.1%	0.5%

While most carriers indicated that private duty nursing services would be covered under very specific circumstances, most indicated that the majority of the services anticipated under this proposed mandate would not currently be provided. We estimate that about 10 percent of the services covered under this mandate are currently being provided. This would cover the types of circumstances described earlier in this paper. This is a very rough estimate, as these statistics are not readily available. Table 6 shows estimated costs.

Table 6

	Full Cost	Marginal Cost
Estimated Cost as a Percentage of Average Cost Per Group Policy	0.1% – 0.5%	0.1% – 0.4%
Estimated Cost as a Percentage of Average Wage	0.01% – 0.06%	0.01% – 0.06%
Estimated Annual Per Employee Cost	\$3.48 – \$29.01	\$3.13 – \$26.10

Since few of the services required by this mandate proposal are currently covered by large, self-insured plans - the reference point for the essential benefits package - there is some likelihood that the state would have to fund these mandated services for policies delivered through the Maryland health benefits exchange after January 1, 2014.

References

- Ehart, William S. "NY Insurance Company Ends Program Rather Than Pay Out Big." *The Washington Times*. October 14, 2009. http://insurancenewsnet.com/article.aspx?a=top_lh&lnid=1055762211
- Greenberg, David. "A Cost-Benefit Analysis of Maryland's Medical Child Care Centers." Maryland Institute for Policy Analysis and Research, University of Maryland, Baltimore County. December 2008. <http://www.umbc.edu/blogs/mipar/Medical%20Child%20Care%20Centers%20Final%20Report.pdf>
- Hardart, M.K.M., R.D. Truog. "Spinal Muscular Atrophy – Type 1 – The Challenge of Defining a Child's Best Interests." *Archives of Disease in Childhood* 88 (2003). <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1719334/pdf/v088p00848.pdf>
- Hendrickson, B.C., C. Donohoe, V.R. Akmaev, E.A. Sugarman, P. Labrousse, L. Boguslavskiy, K. Flynn, E.M. Rohlfs, A. Walker, B. Allitto, C. Sears, and T. Scholl. "Differences in SMN1 allele frequencies among ethnic groups within North America." *Journal of Medical Genetics*, published online June 21, 2009. <http://www.ncbi.nlm.nih.gov/pubmed/19625283>
- Milligan, Charles. "Overview of the Existing Insurance Market in Maryland." The Hilltop Institute, University of Maryland, Baltimore County. August 2010. <http://www.healthreform.maryland.gov/workgroups/documents/100810insurancemarketpp.pdf>
- Spinal Muscular Atrophy (SMA) Foundation. "Frequently Asked Questions." July 2010. <http://www.smafoundation.org/faq>
- Spinal Muscular Atrophy (SMA) Foundation. "Spinal Muscular Atrophy: Introduction for SMA Families." February 2010. <http://www.smafoundation.org/reg>
- Schlesinger, Robert. "U.S. Population, 2010: 308 Million and Growing." *U.S. News and World Report* Politics & Policy Blog. December 30, 2009. <http://politics.usnews.com/opinion/blogs/robert-schlesinger/2009/12/30/us-population-2010-308-million-and-growing>
- Wang, C.H., R.S. Finkel, E.S. Bertini, M. Schroth, A. Simonds, B. Wong, A. Aloysius, L. Morrison, M. Main, T.O. Crawford, A. Trela, and Participants of the International Conference of SMA Standard of Care. "Consensus Statement for Standard of Care in Spinal Muscular Atrophy." *Journal of Child Neurology* 22, No. 8 (August 2007). https://smaregistry.iu.edu/Links/Downloads/ICC_SMA_SoC_Consensus_Statement_EN.pdf

**5**

Coverage of Preventive Physical Therapy Services for Patients Diagnosed with Multiple Sclerosis

Baltimore County Delegate Shirley Nathan-Pulliam is considering introducing legislation that would require carriers to include coverage of preventative physical therapy services for patients diagnosed with multiple sclerosis (MS). She envisions that the bill will closely follow a similar mandate adopted by the State of Illinois. Key provisions of that legislation are as follows:

- “A group or individual policy of accident and health insurance or managed care plan ... must provide coverage for medically necessary preventative physical therapy for insureds diagnosed with multiple sclerosis.”
- For this purpose “preventative physical therapy” means “physical therapy that is prescribed by a physician licensed to practice medicine in all of its branches for the purpose of treating parts of the body affected by multiple sclerosis, but only where the physical therapy includes reasonably defined goals, including but not limited to, sustaining the level of function the person has achieved, with periodic evaluation of the efficacy of the physical therapy against those goals.”
- Such coverage will be subject to “the same deductible, coinsurance, waiting period, cost sharing limitation, treatment limitation, calendar year maximum, or other limitations as provided for other physical or rehabilitative therapy benefits covered by the policy.”¹¹⁷

¹¹⁷ Illinois Public Act 094-1076, Sec. 10, adding Sec. 365z.8 to the Illinois Insurance Code.

According to the National Multiple Sclerosis Society, MS is a chronic, unpredictable disease of the central nervous system (the brain, optic nerves, and spinal cord). It is thought to be an autoimmune disorder; the immune system incorrectly attacks the person's healthy tissue. It can cause blurred vision, loss of balance, poor coordination, slurred speech, tremors, numbness, extreme fatigue, problems with memory and concentration, paralysis, blindness, and other complications. These problems may be permanent or may come and go.¹¹⁸ Approximately 400,000 Americans have MS.¹¹⁹

Most people with MS are diagnosed between the ages of 20 and 50, although individuals as young as two and as old as 75 have developed it. It is not considered fatal, and the vast majority of afflicted people live a normal life span. Quality of life is a different issue, though. Most people with MS have difficulty living as productively as they would like, often facing increasing limitations.¹²⁰

At least two to three times more women than men are diagnosed with MS. Studies suggest that genetic factors make some individuals more susceptible than others, but there is no indication that MS is directly inherited. The disease occurs in most ethnic groups but is more common in Caucasians of northern European ancestry.¹²¹

Medical Impact

In this section, we answer questions regarding coverage of preventive physical therapy (PT) for MS patients.

- **Does the medical community recognize physical therapy as being essential and/or effective in preventing the progression of the effects of MS?**

- **Does the medical community recognize preventive physical therapy as being appropriate and necessary, as evidenced by scientific and peer review of literature?**

- **Is preventive physical therapy utilized by treating physicians?**

We will begin by, summarizing the course of illness and outlining the National Multiple Sclerosis Society's recommended care for persons diagnosed with MS. We then examine

¹¹⁸ National Multiple Sclerosis Society. "Multiple Sclerosis: Just the Facts." Nov. 2009.

¹¹⁹ "Multiple Sclerosis: Just the Facts."

¹²⁰ "Multiple Sclerosis: Just the Facts."

¹²¹ "Multiple Sclerosis: Just the Facts."

physical therapy services as they relate to treating MS. Specifically, we examine the types of physical therapy services and distinguish between those generally covered by the carriers, which focus on restoring function, and those that are not, which focus on maintaining function and preventing a deterioration of function. Finally, we will point out the challenges of determining what is preventive and what is not and touch on evidence supporting the efficacy of preventive PT.

Course and treatment of the disease

There are four courses of MS, each of which may be mild, moderate, or severe. They are:

- **Relapsing-Remitting MS** – Clearly defined attacks of worsening neurological function. Attacks – sometimes called “relapses,” “flare-ups,” or “exacerbations” – are followed by partial or complete recovery periods, during which no disease progression is apparent. Approximately 85% of those afflicted by MS are initially diagnosed with relapsing-remitting MS.
- **Primary-Progressive MS** – Characterized by slowly worsening neurological function from the beginning, with no distinct relapses or remissions. The rate of progression may vary over time, with occasional plateaus and temporary minor improvements. Approximately 10% of people with MS are diagnosed with primary-progressive MS.
- **Secondary-Progressive MS** – After an initial period of relapsing-remitting MS, the disease worsens more steadily with or without occasional flare-ups, minor recoveries, or plateaus. Before disease-modifying medications became available, approximately 50% of people with relapsing-remitting MS developed this form within 10 years.
- **Progressive-Relapsing MS** – Steadily worsening from the onset, with clear attacks of worsening neurological function along the way. People may experience some recovery, but the disease continues without remission. Approximately 5% are diagnosed with progressive-relapsing MS.¹²²

Most patients with MS initially have a “relapse-remitting” experience, meaning that they experience a period of time when the symptoms manifest themselves (very often with increasing magnitudes) followed by periods of partial or total remission. About 30% to 50% have periods of progressive symptoms within the first 10 years of diagnosis.¹²³ Relapse rates vary widely (0.1 to 1 attack per year), and patients with higher relapse rates

¹²² National Multiple Sclerosis Society. “What Is Multiple Sclerosis? The Four Courses of MS.”

¹²³ Judith A. O'Brien et al. “Cost of Managing an Episode of Relapse in Multiple Sclerosis in the United States.” BMC Health Services Research. 2003.

in the first two years have been observed to be at greater risk of more rapid progression to a severe level of disability.

There are wide variations in the severity and duration of relapses, which can include sensory loss, optical neuritis, and weakness of the limbs – leading to fatigue, disturbance of gait, and loss of dexterity. Some relapses can last up to several months.¹²⁴

According to the National Multiple Sclerosis Society, recommended care for individuals diagnosed with MS includes:

1. Treatment with one of the FDA-approved “disease modifying” drugs as soon as possible after diagnosis. Drug therapy is recommended after an episode that places the individual at high risk for subsequently developing clinically definite MS.
2. For patients with secondary-progressive, progressive-relapsing, or worsening relapsing-remitting MS, an FDA-approved chemotherapeutic agent might reduce disability and/or the frequency of attacks. (This drug has a lifetime dosage limit to prevent heart damage.)¹²⁵

There are additional therapies for many MS symptoms including spasticity, pain, bladder problems, fatigue, sexual dysfunction, weakness, and cognitive problems.¹²⁶

PT as rehabilitation

Rehabilitation is an important part of health care delivery for people with MS. In a clinical bulletin devoted to PT in MS rehabilitation, the National Multiple Sclerosis Society summarizes, “With the advent of disease modifying agents to prolong time between attacks and slow disease progression, OT [occupational therapy] and PT interventions are more important... than ever before. Interventions have the potential to last longer and have greater impact on improving quality of life.”¹²⁷ Many people are at the peak of their career or their childrearing years when they are diagnosed with MS.¹²⁸

The role of physical therapy varies across the disease’s course. Given of the variable nature of the illness, rehabilitation practices often vary. In Europe, there appears to be

¹²⁴ O’Brien, J., et al.

¹²⁵ “Multiple Sclerosis: Just the Facts.”

¹²⁶ “Multiple Sclerosis: Just the Facts.”

¹²⁷ R. Kalb, ed. “Multiple Sclerosis: Focus on Rehabilitation.” New York: National Multiple Sclerosis Society. 2001.

¹²⁸ P.G. Provance. “Physical Therapy in Multiple Sclerosis Rehabilitation.” National Multiple Sclerosis Society. Clinical Bulletin: Information for Health Professionals. 2008.

general consensus that physical therapy services have an important place.¹²⁹ There is little if any documentation of similar consensus in the United States. As noted, interventions focus on helping the patient achieve and maintain “optimal functional independence, safety and quality of life.”¹³⁰ In the entire rehabilitation process, PT is but one part. As members of multi-disciplinary teams dedicated to the patient’s care, physical therapists are concerned with:

- “Promoting the health and wellbeing of individuals and society through physical activity and exercise”,
- “Preventing impairments, activity limitations, participatory restrictions and disabilities” in at-risk individuals,
- Providing treatments to “restore the integrity of body systems essential to movement, maximize function and recuperation, minimize incapacity, and enhance the quality of life...” among impaired individuals, and
- “Modifying environmental, home and work access and barriers to ensure full participation in one’s normal and expected societal roles.”¹³¹

The goal of MS rehabilitation is to reduce the consequences of the disease on function, personal activity, and social participation to allow patients as much independence as possible with the highest possible quality of life. However, its effectiveness is difficult to evaluate for a number of reasons:

- The disease course varies greatly between and among individuals and is difficult to predict in the different forms of the disease,
- Triggers of relapses and progression are not well-defined and the pathological processes may not be heterogeneous and can be discriminated accurately with standard neuro-radiological techniques, and
- It is hard to find a homogeneous patient group which satisfies scientific requirements for evaluating the efficacy of therapeutic interventions.¹³²

As a result, there are few studies that effectively measure the effects of rehabilitative measures in MS. Earlier studies were uncontrolled, and most were retrospective

¹²⁹ K. Rasova, P. Feys, T. Henze, H. van Tongeren, D. Cattaneo, J. Jonsdottir, A. Herbenova. “Emerging Evidence-based Physical Rehabilitation for Multiple Sclerosis – Towards an Inventory of Current Content across Europe.” Health and Quality of Life Outcomes. October, 2010.

¹³⁰ Provance.

¹³¹ “Description of Physical Therapy.” World Confederation for Physical Therapy. 2007.

¹³² J. Kesseling, S. Beer. “Rehabilitation in Multiple Sclerosis.” ACNR. Vol 2 Number 5. November/December 2002.

observations on small, heterogeneous patient groups. Still, there have been a few controlled trials published.^{133 134 135}

These demonstrate the efficacy of rehabilitation but indicate both that physiotherapy alone or other specific therapies may lead to some improvement in mobility and reduction of disability and that the effects are often relatively short-lived. There are long-term benefits but these are apparently attributable to improved compensation, adaptation and reconditioning and better use of personal and social resources. Rehabilitation measures seem to have no direct influence on the ongoing disease process and the progression of the disease and the benefits of physical therapies are temporary.¹³⁶

Preventative PT

Because restorative physical therapy is typically covered by the carriers and preventative PT is often not, it is important to differentiate between the two. The goal of the former is the restoration of function and usually involves strengthening and retraining muscles as well as adapting to decreased function with new techniques. Restorative rehabilitation is especially useful following an exacerbation or acute attack of MS symptoms. Preventative PT, in contrast, seeks to prevent or slow functional decline and unnecessary complications before they occur.¹³⁷ Provance suggests that there are many potential preventative physical therapy interventions that may be appropriate during the course of the disease. For example:

- **At the time of diagnosis**, patients may benefit from education, support, and a baseline evaluation by an experienced PT professional.
- **As the disease progresses**, the focus is on support, resourcing, avoiding deconditioning, maintaining safety, and maximizing health and independent function. This includes assessing the need for mobility aids now and in the future. Patients

¹³³ J. A. Freeman, DW Langdon, JC Hobart, et al. "The Impact of Inpatient Rehabilitation on Progressive Multiple Sclerosis. *Ann Neurol*. 1999.

¹³⁴ A. Solari, G Filippini, P Gaasco, et al. "Physical rehabilitation has a positive effect on disability in multiple sclerosis patients." *Neurology*. 1999.

¹³⁵ CM Wiles, RG Newcombe, KJ Fuller, et al. "Controlled randomized crossover trial of the effects of physiotherapy on mobility in chronic multiple sclerosis." *Journal of Neurology, Neurosurgery & Psychiatry*. 2001.

¹³⁶ Ibid.

¹³⁷ L. Bain with R. Schapiro. "Managing MS Through Rehabilitation." National Multiple Sclerosis Society. April 2009.

transitioning from relapsing-remitting MS are unable to return to baseline due to the disease's progression, and they demonstrate a slow decline in function.

- **During advanced MS**, patients have significant disease burden, are non-ambulatory, and are at risk for secondary health conditions. The focus of PT at this stage is on seated trunk positioning and control, transfers, upper extremity strength, respiratory function, and equipment needs.¹³⁸

It should be noted that some of the PT services described above, such as PT services provided for a short period of time following onset of a remission, may be considered rehabilitative and as such would be currently covered.

Carriers have various requirements for determining when a PT service is “rehabilitative.” Generally there is a requirement that there be “significant improvement” of the person's condition within a short period of time (such as 60 days) or that the services will return a person to their usual state of functioning. Some carriers provide coverage for PT services as long as they are for a medical condition and they are restorative in nature and not for maintenance care; some plans require a pre-authorization plan even for rehabilitative PT.

But in general, PT that is intended to maintain function or prevent complications would not be covered, in part because it is impossible in a given situation to determine whether PT is having any beneficial effect on the course of a disease that is inherently variable. Similarly, because of this variability, it is very difficult to demonstrate in well-controlled trials a benefit for preventative PT, so the evidence base supporting the proposed mandate is weak.

In meetings with the medical directors of the largest plans, concern was expressed regarding this benefit. Several plans had conducted research and could find no evidence-based studies that support the use of preventive physical therapy for the treatment of MS. Several questioned why this particular condition should be given special treatment when there are other conditions as severe that would not receive a similar benefit.

¹³⁸ Provance.

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 available?**
- **To what extent does the 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 these services?**
- **How interested are collective bargaining agents in negotiating privately for including this coverage in group contracts?**
- **To what extent is the proposed mandated health insurance service covered by self-funded employers in the state with at least 500 employees?**

The current estimate of individuals in the US with MS is 400,000,¹³⁹ or about 1 in 1,000 based on a population estimate of 380,000,000.¹⁴⁰ Maryland carriers surveyed as part of this study indicated similar incidence among their covered populations, approximately 1.4 to 1.5 per 1,000 members.

In 2008, The Hilltop Institute reported in its "Overview of the Existing Insurance Market in Maryland" that there were 3,590,609 individuals with private insurance in Maryland.¹⁴¹ Based on this estimate of the covered population and the incidence rates reported above, Maryland insurance plans cover about 5,000 to 5,400 individuals diagnosed with MS.

¹³⁹ "Multiple Sclerosis: Just the Facts."

¹⁴⁰ Robert Schlesinger. "US Population, 2010: 308 Million and Growing." *US News and World Report*. Politics & Policy Blog (December 30, 2009).

¹⁴¹ Charles Milligan. "Overview of the Existing Insurance Market in Maryland." The Hilltop Institute. University of Maryland, Baltimore County. August 2010.

Table 1 summarizes the carrier's survey responses for preventive physical therapy for coverage of MS.

Table 1

Health Plan	Coverage of MS Preventive Physical Therapy Services
1	Not currently covered. Policies require that there be an expectation of "significant improvement" of the person's condition within 60 days from the date therapy begins. PT aimed at slowing or preventing further deterioration of a body function is not generally covered. Only services rendered for the treatment of delays in speech development – unless resulting from disease, injury, or congenital defect – are covered.
2	No insured plans cover.
3	All plans cover for any medical condition as long as it is restorative in nature and not for maintenance care, subject to certain guidelines and limitations. Plan does not distinguish between preventive and other physical therapy. Prior authorization is required.
4	All plans cover. Plan does not distinguish between preventive physical therapy and other physical therapy. Prior authorization is required.
5	Not currently covered. All PT services must meet the criteria for rehabilitation, which is defined as returning a person to the usual state of functioning. PT is limited to restoring an existing or recently existing physical function.

When PT services are covered, there are usually limits as to the annual number of visits, ranging from 20 to 60 (for all therapy services – PT, occupational, and speech – combined). One carrier indicated that employers can purchase unlimited visits but reported that very few do. Two carriers require prior authorization for PT services. One carrier provided the following description of its administration of PT services:

“All PT services require pre-authorization and must include physician prescribed goals to improve environmental safety, restore activities of daily living (ADLs) and independent activities of daily living (IADLs) or rehabilitate for function, usually ambulation. A plan of care is usually written during the first therapy evaluation visit, based on input and demonstration from the patient and caregiver, and plans out exercises and functional adaptations in measured steps towards the primary goal(s). Often home and functional safety evaluations require only one session. Here, the therapist provides recommendations, adaptations, and exercises, but if no rehabilitative or restorative goals are identified, the services terminate after the initial evaluative session.”

Only three carriers responded to the question regarding the dollar amount of claims denied in 2009 attributable to physical therapy for MS patients. One reported \$0 claims denied; a second reported \$465, and the third carrier indicated that there were “approximately three physical therapy denials per week.”

Survey responses indicate that large self-insured plans are very similar to smaller insured plans with respect to these services.

The literature we reviewed showed no evidence that patients are forgoing necessary care because some plans do not cover these services. Among the carriers, there was a wide range in the percentage of members with MS that utilize the covered physical therapy benefit, from a low of 7% to a high of 69%. For the carriers responding to this question, an average of about 30% of all MS patients used PT in a given year. This is consistent with a broader study focusing on middle-aged and older adults with MS, which reported that:

1. 36% of those surveyed reported never using physical therapy services,
2. 33% reported using PT services within the past year, and
3. 31% reported using PT services more than a year prior.¹⁴²

It is difficult to estimate the financial burden of not covering preventive PT for MS patients. According to the Maryland affiliate of the National Multiple Sclerosis Society, many survey respondents who have MS indicate that physical therapy services have not been covered.¹⁴³ That information is inconsistent with the responses of the carriers surveyed, several of which cite few limitations. The apparent disconnect lies in 1) the definition of “preventative” in the language of the proposed mandate and 2) the nature of the illness, where physical therapy does not restore one’s condition but instead allows the patient to maintain a given level of activity rather than deteriorate further. This therapy, probably intended to be covered in the proposed mandate, can easily be considered as “maintenance” and excluded.

¹⁴² M. Finlayson, et al. “Use of Physical Therapy Services Among Middle-Aged and Older Adults with Multiple Sclerosis.” *Physical Therapy Journal*. August 26, 2010.

¹⁴³ Telephone conversation with M. Viel, Director of Public Policy, Maryland Affiliate, National Multiple Sclerosis Society. November 1, 2010.

It is often said that no two MS cases are alike¹⁴⁴ – and the need for preventive PT services varies as a result. A patient might require PT services several times a week for an entire year, or a patient might require little or no physical therapy. In the former case, assuming a visit rate of \$95, the financial burden could be as high as \$14,820 annually (52 weeks x three visits a week x \$95), most of which might be excluded as maintenance. As noted, however, the vast majority of MS patients do not utilize PT services.

Maryland’s unions are mixed in support of this potential mandate. It is not specifically mentioned in most bargaining agreements. Some unions expressed concern that it could be subject to abuse and challenging to administer.

Financial Impact

In this section, we estimate the cost of enacting the proposed mandate and compare the results of our analysis with those of other sources, including the estimates submitted by carriers in Maryland. We also include a discussion of any administrative concerns the carriers have expressed.

Mercer surveyed six major carriers in Maryland to obtain information on current practices regarding providing preventive PT for MS patients.

We received responses from five of the six carriers. Of the responding carriers, only one currently covers this benefit.

The following table summarizes the results of the proposed benefit’s financial impact.

Table 2

Carrier	\$ per Member per Year	% of Claims
1	\$3.28 to \$4.93	0.1% to 0.2%
2	\$4.08	0.2%
3	\$0.00 to \$6.20	0.0% to 0.2%
4	0.00	0.0%
5	\$6.20	0.2%

Mercer developed an independent estimate using the following assumptions:

¹⁴⁴ “Multiple Sclerosis: Just the Facts.”

- Incidence rates reported by the responding carriers ranged from 1.12 per 1,000 to 4.2 per 1,000. The majority of the incidence rates were within the 1.12 per 1,000 to 1.5 per 1,000 range. We used this as the range.
- We had three carrier sources for costs per PT session, ranging from \$95 to \$108.
- The number of sessions in a year varied between 30 and 45, the general range of the annual limits of therapy sessions indicated by the carriers.
- We assumed a range in cost sharing from zero (assuming that individuals with MS would meet their out-of-pocket limits with other services) to \$15, the median copayment for office visits for large employers in Maryland.¹⁴⁵

Table 3

	<u>Low</u>	<u>High</u>
Incidence	1.12/1000	1.5/1,000
Cost per PT Session	\$ 95	\$108
Cost Sharing	0	15
Sessions/Year	\$ 30	\$ 60
Cost per Year	\$ 2,850	\$ 5,580
Annual Cost per Member	\$ 3.19	\$ 8.37
Members/Employer	1.827	1.827
\$PEPY	5.83	15.29
% of Claims	0.1%	0.3%
% of Wages	0.01%	0.03%

Only one carrier indicated that it currently covers preventive PT for MS patients. This carrier represented about 5% of the entire group medical premium in Maryland, based on 2009 statutory reports. Thus, we assumed that the marginal cost would reflect about 95% of the full cost.

Table 4

	Full Cost	Marginal Cost
Estimated Cost as a Percentage of Average Cost Per Group Policy	0.1% – 0.3%	0.1% – 0.3%
Estimated Cost as a Percentage of Average Wage	0.01% – 0.03%	0.01% – 0.03%
Estimated Annual Per-Employee Cost	\$5.83 – \$15.29	\$5.54 – \$14.53

¹⁴⁵ Mercer. “2009 National Survey of Employer-Sponsored Health Plans.” 2010.

Only one carrier identified *administrative* concerns (as opposed to the medical concerns discussed in the previous section) associated with the proposed mandate:

The body of administrative services to support physical therapy would require reengineering and oversight. All services would require redefinition, and training would be required for all therapists to provide:

- Therapies to maintain functions that have not actually declined;
- Therapies to maintain optimal functioning, which is not measurable because the progressive path of MS is so variable;
- Care plans without measurable goals (since the targeted functions already exist);
- New preventive muscle- and nerve-preserving therapies, which are differentiated from both rehabilitative therapies and those exercises that a person with MS can perform independently on a daily basis;
- A large increase in the number of visits for each member with MS because preventive therapies for MS patients would be, by definition, daily exercises.

References

Bain, L., with R. Schapiro. "Managing MS Through Rehabilitation." National Multiple Sclerosis Society. April, 2009.

Barret, C.L. "A Randomized Trial to Investigate the Effects of Functional Electrical Stimulation and Therapeutic Exercise on Walking Performance for People with Multiple Sclerosis." *Multiple Sclerosis* 15. April 1, 2009.

Bjarnadottir, O.H., A.D. Konradsdottir, K. Reynisdottir, and E. Olafsson. "Multiple Sclerosis and Brief Moderate Exercise. A Randomised Study." *Multiple Sclerosis* 13 No. 6. First published March 15, 2007.

Freeman, J. A., DW Langdon, JC Hobart, et al. "The Impact of Inpatient Rehabilitation on Progressive Multiple Sclerosis. *Ann Neurol* 1999.

Finlayson, M., M. Plow, and C. Cho. "Use of Physical Therapy Services Among Middle-Aged and Older Adults with Multiple Sclerosis." *Physical Therapy Journal*. August 26, 2010.

Illinois Public Act 094 – 1076, Section 10, adding Sec. 365z.8 to the Illinois Insurance Code.

Kalb, R., ed. "Multiple Sclerosis: Focus on Rehabilitation." New York: National Multiple Sclerosis Society 2001.

J Kesselring, S. Beer. "Rehabilitation in Multiple Sclerosis." *ACNR*. Vol 2, Number 5, November/December 2002.

Mercer. "2009 Mercer National Survey of Employer-Sponsored Health Plans." 2010.

Milligan, Charles. "Overview of the Existing Insurance Market in Maryland." The Hilltop Institute. University of Maryland, Baltimore County. August 2010.

National Multiple Sclerosis Society. "What Is Multiple Sclerosis? The Four Courses of MS." <http://www.nationalmssociety.org/about-multiple-sclerosis/what-we-know-about-ms/what-is-ms/index.aspx>.

O'Brien, Judith, Ara J. Ward, A.R. Patrick. "Cost of Managing an Episode of Relapse in Multiple Sclerosis in the United States." *BMC Health Services Research*. 2003. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC201004/>.

Provance, P.G. "Physical Therapy in Multiple Sclerosis Rehabilitation." *Clinical Bulletin: Information for Health Professionals*. National Multiple Sclerosis Society. 2008.

K. Rasova, P. Feys, T. Henze, H. van Tongeren, D. Cattaneo, J. Jonsdottir, A. Herbenova. "Emerging Evidence-based Physical Rehabilitation for Multiple Sclerosis – Towards and Inventory of Current Content across Europe." *Health and Quality of Life Outcomes*. October, 2010. <http://www.medscape.com/viewarticle/729235>

Romberg, A. "Effects of a 6-month Exercise Program on Patients with Multiple Sclerosis; A Randomized Study." *Neurology*. 2004. <http://www.neurology.org/content/63/11/2034.abstract>.

Schlesinger, Robert. "US Population, 2010: 308 Million and Growing." *US News and World Report*. Politics & Policy Blog. December 30, 2009.

Solari, G Filippini, P Gaasco, et al. "Physical rehabilitation has a positive effect on disability in multiple sclerosis patients". *Neurology*. 1999.

Svensson, Britta, Gjorn Gerdle, and Jessica Elert. "Endurance Training with Patients with Multiple Sclerosis: Five Case Studies." *Journal of the American Physical Therapy Association*. 1994. <http://ptjournal.apta.org/content/74/11/1017.abstract>.

Telephone conversation with M. Viel, Director of Public Policy, Maryland Affiliate, National Multiple Sclerosis Society. November 1, 2010.

CM Wiles, RG Newcombe, KJ Fuller, et al. "Controlled randomized crossover trial of the effects of physiotherapy on mobility in chronic multiple sclerosis." *Journal of Neurology, Neurosurgery & Psychiatry*. 2001

World Confederation for Physical Therapy. "Description of Physical Therapy." 2007.

OLIVER WYMAN

411 East Wisconsin Avenue, Suite 1600
Milwaukee, WI 53202-4419
1 414 223 7989