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Annual Mandated Health Insurance Services Evaluation

Prepared for the Maryland Health Care Commission
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Annotated Code of Maryland

MARYLAND

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2008 Report (Redacted Version)

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 evaluation of the proposed changes to existing mandates or proposed newly mandated benefits: expanded coverage of autism spectrum disorder and modification to the existing in vitro fertilization mandate.

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Coverage of Autism Spectrum Disorder

In 2008, a proposed autism mandate was analyzed. Key provisions of that proposal were as follows:

- Insurers, health plans and health maintenance organizations "... Shall provide coverage for the diagnosis of autism spectrum disorders and the evidence-based, medically necessary treatment for autism spectrum disorders in individuals under the age of 21 years." Coverage is subject to an annual maximum of $50,000 for 2010. The annual maximum increases each year by the Medical Care Component of the Consumer Price Index for all urban consumers (CPI-U).

- "Treatment of autism spectrum disorders" encompasses "habilitative or rehabilitative care" as well as pharmacy psychiatric, or psychological care prescribed by a physician or psychologist.

- "Habilitative or rehabilitative care" includes "applied behavior analysis" and other services, including the development and maintenance of an individual's functioning – the main goal being to restore it to the maximum extent possible.

Mercer provided an in-depth analysis of the medical, social and financial impact of this proposed mandate. The mandate was not implemented.

In 2009, another autism mandate has been proposed. It is essentially the same as the 2008 mandate, with the following key revisions:

- All age limitations have been eliminated.
- All annual benefit caps have been eliminated.

Because of the extensive analysis completed in 2008, MHCC asked Mercer to focus this year's analysis on the medical efficacy and financial impact portions of the proposal.

Medical Efficacy

MHCC proposed three options for consideration:

Option 1: Mandate without limits on annual amount or age, but with the usual "medical necessity" determination regarding appropriate and established treatments.

Option 2: Mandate without limits on annual amount or age, with applied behavioral analysis specified as a covered service as well as other services determined to be medically necessary. Treatment frequency and intensity would be subject to review for appropriateness.

Option 3: Mandate with the following limits on annual amount and age:

a. $50,000 annually up to age 21
b. $50,000 annually for ages 1 to 5; $20,000 annually for ages 6 to 12

For each option, Mercer was asked to address the following questions:

- Can a straightforward mandate without contractual/statutory limits on age or annual amount be administrated using just medical necessity criteria?

- Are there any treatments that would be regarded as meeting the medical necessity criterion for most cases of autism?

- Does imposing an annual limit have any real effect on the benefit provided – either reducing payments because of the contractual limit on the amount of the benefit or possibly increasing payments because providers may be more likely to bill to the annual limit?

These options and questions were submitted to the major insurance carriers in Maryland as well to solicit their input.

Mercer Analysis

Mercer posed these options and questions to its experts in behavioral medicine, who have provided the opinions below based on their expertise. We have also attached the report that was completed in 2008. The 2008 report contains a more in-depth analysis of the social impact and medical efficacy of services provided to autistic children.

Option 1: Mandate without limits on annual amount or age, but with the usual "medical necessity" determination regarding appropriate and established treatments.

This option mandates coverage for autism treatment, but appears to permit employers' health plans to determine which autism spectrum disorder (ASD) treatments will be covered. Without a definition for “medical necessity,” health plans would be free to determine which services are experimental (i.e., the treatment’s effectiveness has not been scientifically established) or “educational” rather than “treatment-oriented” – and, as a result, not covered. We would anticipate that this option would commonly result in coverage that included psychological evaluation (for treatment planning rather than educational purposes) and some genetic testing; occupational, physical and speech therapies; and pharmacological intervention for symptoms that interfere with daily functioning, such as aggressive, self-injurious or repetitive behaviors.

We would also expect that applied behavior analysis (ABA) and parent training programs would be covered infrequently, as health plans would deem the interventions investigational or educational in nature. If this were the case, schools would remain central in providing the structure needed for children with ASDs to receive these services. This might preclude younger children from having access to ABA services at the age at which they have been shown to make the most impact.

In our opinion, intensive behavioral interventions represent a promising practice, as reflected by the growing numbers of studies demonstrating their effectiveness in improving social skills and overall functioning for some children with ASDs. Although ABA is one of these interventions, the literature has not shown one particular intensive behavioral intervention to be better than the others.

We do not believe that intensive behavioral interventions, including ABA, constitute an evidence-based practice for *all* children with an ASD regardless of condition severity, symptoms or age of the child. Additional clarification is needed from actual studies about when ABA is indicated, as well as the optimal frequency, intensity and duration of treatment by age group. Once this information is available, it may be more appropriate to describe intensive behavioral interventions (including but not limited to ABA) as evidence-based treatments for specific ASD conditions and symptoms. For example, ABA may be found to be identified as an evidence-based practice for children under 4 with a diagnosis of autism, with social interaction deficits, who are unable to attend preschool.

We disagree however with the assertion that ABA is purely educational in nature. ABA can be treatment-oriented or educationally oriented, depending on the problems it targets. ABA that focuses on helping a child learn new skills may be an educational intervention, but ABA that addresses social deficits or self-injurious behavior could be treatment-oriented.

Using medical necessity as a determinant could mitigate the potential cost impact of “unlimited” services or the absence of age limitations in Option 1. Proposed treatments would be evaluated in the context of the specific patient’s needs and the likely effectiveness of the treatment, which takes the patient’s age into account. The anticipated covered services described above (except the intensive behavioral therapies) are not overly expensive or typically required to be provided on an intensive basis, so the cost impact should be small. The absence of limits could result in health plans’ requiring precertification for some or all of these services – which, in the case of the occupational, physical and speech therapies, could require providers to submit treatment plans to obtain ongoing authorization for coverage.

Option 2: Mandate without limits on annual amount or age, with applied behavioral analysis specified as a covered service as well as other services determined to be medically necessary. Treatment frequency and intensity would be subject to review for appropriateness.

Like Option 1, Option 2 appears to permit employers' health plans to determine which ASD treatments to cover, with the exception of ABA. As stated above, many health plans deem ABA to be experimental or educational in nature and would argue that ABA is never medically necessary. As a result, they may find it challenging to review the frequency and intensity of ABA for appropriateness.

Alternatively, under this option, plans reviewing treatment for appropriate frequency and intensity could review care against treatment guidelines and ensure that care is delivered based on a comprehensive assessment by experienced, credentialed providers. ABA could be limited to the age groups for which it has been found to be the most effective in the literature. Health plans might require providers to submit ABA treatment plans, and might also review the following for continued service authorizations:

- treatment-oriented goals
- a frequency of service that is consistent with the other services provided by schools and other agencies (for example, children in school Monday through Friday, 8:00 to 3:00, would likely not benefit from eight hours of ABA on weekdays)
- ongoing demonstrated need
- ongoing measurable progress toward goals.

Appeals for ABA service denials may be difficult to uphold, however, as the literature does not clearly indicate for which symptoms, at what frequency, and for how long ABA should be provided to be effective..

If ABA coverage is mandated, it is quite probable that some of the costs currently borne by the schools in providing ABA services to children with ASDs would shift to employers. If ASDs are declared medical or neurodevelopmental in nature, psychotherapy may no longer be a covered treatment option, and management of the benefit could be limited to medical plans and not managed behavioral health organizations (MBHOs), which are currently most experienced with many of the ASD treatments, such as ABA.

Without annual cost limits, health plans will have increased pressure to develop cost-effective management strategies. Disease management programs may be developed to focus on the management and coordination of ASD treatments, with school services and family needs. (To date, disease management programs for other conditions have had limited effectiveness, partly due to problems with participation and program completion.) Health plans would need to develop and credential networks of providers qualified to perform ABA services. ABA providers may be willing to negotiate fees for a higher volume of referrals and less frequent concurrent review. Overall "outcomes" might improve due to increased requirements for progress and delivery of effective treatments to obtain coverage.

Option 3: Mandate with limits on annual amount and age

a. $50,000 annually up to age 21
b. $50,000 annually for ages 1 to 5, $20,000 annually ages 6 to 12

As stated above, adding dollar and age limits to Option 1 would be unlikely to have significant impact, as most plans would probably exclude coverage for the more expensive treatments, such as ABA, citing them as experimental or educational in nature.

Adding limits to Option 2, which includes ABA, could have more impact. For example, administrative limits are easier to enforce than medical necessity determinations. If dollar limits are in place, health plans are more likely to rely on them and less likely to develop some of the care management strategies described in Option 2. In addition, members may view dollar limits as "entitlements" rather than upper limits and seek care up to that limit. Providers may adjust their fees to obtain the annual dollar amount. On the positive side, annual dollar limits limit the employers' financial risk and assist with budget planning.

Because there may be providers who would use this legislation solely to build revenue, health plans might benefit from the inclusion of tools to ensure treatment quality and avoid unnecessary costs. For example, the mandate could

- require a formal diagnostic assessment before ABA is initiated
- ensure treatment plans are developed and monitored by licensed and qualified mental health professionals
- recommend certification and certain credentialing standards for technicians providing services
- permit plans to cover the services on an in-network basis only
- allow precertification of services
- direct plans to review treatment for ongoing improvement, appropriate treatment goals and reasonable frequency or service.

The Mental Health Parity and Addiction Equity Act (MHP Act) regulations may preempt the proposed limits described in this option or the requirements described in the paragraph above, even if this legislation declares ASDs to be medical or neurodevelopmental. The MHP Act permits employers to determine which mental health conditions they will cover, but if a condition is covered, then the Act could be read to apply to all associated treatments. The Act also does not address whether a health plan can exclude certain services or can set limits on services delivered by medical or ancillary providers with respect to mental health conditions. ASDs are listed in the Diagnostic and Statistical Manual of Mental Disorders, as are dementia and other neurological disorders, even though the most common treatments for these disorders are not delivered by mental health professionals. If the regulations rely on the classification of the diagnosis to determine whether a condition is subject to the Act, then the dollar limits in Option 3 may not be allowed. In addition, plans that offer out-of-network coverage for medical conditions could be required to offer out-of-network coverage for ASD treatments such as ABA.

Carrier Survey

The major health insurance carriers in Maryland were asked to respond to three questions regarding the proposed mandate. Five carriers responded to the survey. Their responses are summarized below.

Question 1: Is a straightforward mandate without contractual/statutory limits on age or annual amount administrable using just medical necessity criteria?

The responses to this question can be summarized into two categories. One group of insurers viewed a mandate administered using medical necessity as no change from the current environment, as insurers already cover the services that they believe are medically necessary (for example, speech therapy). They would continue to view ABA as educational or experimental and not medically necessary. Therefore, under this scenario, ABA would continue not to be covered.

Other insurers interpreted this scenario to require coverage of ABA, thus requiring insurers to develop medical necessity criteria providing for ABA services. The carriers with this viewpoint indicated that it would be difficult to administer the benefit in this way. One insurer thought it could lead to disagreements with the educational systems because “there is no proven medically necessary treatment.” Another insurer thought that once ABA was started it would be “difficult to determine the therapy no longer meets medical necessity since the child may continue to have the deficit.”

Question 2: Today, is there any treatment that you would regard as meeting the medical necessity criterion for most cases of autism?

The carriers indicated there are no treatments they regard as appropriate for all or most cases of autism. Some noted that they already cover services that they consider medically necessary for certain children, such as speech therapy, occupational therapy and physical therapy. None of the carriers that responded to the survey consider ABA to be medically necessary.

Question 3: Does imposing an annual limit have any real effect on the benefits you would provide – either reducing payments because of the contractual limit on the amount of the benefit, or possibly increasing payments because providers may be more likely to bill to the annual limit?

The carriers generally thought that imposing limits would result in lower costs than an unlimited benefit. One carrier expected that costs would reach the caps that were outlined in the scenarios, but saw it not as "billing to the limit" but rather that "the programs are just that costly." Another insurer thought that without a benefit limit it would be difficult to stop ABA therapy once started, and therefore a benefit limit is needed to control costs.

The carriers were also asked to comment on the three options that are under consideration:

Option 1: Mandate without limits on annual amount or age, but with the usual "medical necessity" determination regarding appropriate and established treatments.

Under this option, ABA can be considered not medically necessary. Therefore, it is no different than current policy and the carriers considered it to have no impact.

Option 2: Mandate without limits on annual amount or age, with applied behavioral analysis specified as a covered service as well as other services determined to be medically necessary. Treatment frequency and intensity would be subject to review for appropriateness.

Carriers generally thought it would be difficult to apply frequency/intensity utilization review, given that they do not see the treatments as medically necessary or evidence based. One carrier thought it would be important to coordinate the benefits with the habilitative services benefits, and to require providers to be licensed providers and board-certified behavioral analysts. Another carrier provided a cost estimate of $3.86 PMPM for this option.

Option 3: Mandate with limits on annual amount and age

a. $50,000 annually up to age 21
b. $50,000 annually for ages 1 to 5, $20,000 annually ages 6 to 12

Carriers' comments on this option were similar to those on Option 2. One carrier believes limits are administratively difficult if applied to multiple services (for example, ABA services and medical services such as speech therapy), and that limits that vary by age would be particularly difficult to administer. That carrier also indicated that an inflationary adjuster should not be included; however, no reason was provided. While the carriers generally supported placing limits on coverage, one carrier noted that limits could conflict with the federal Mental Health Parity Act. Only one carrier provided cost estimates: $3.21 PMPM for Option 3a and $1.07 PMPM for Option 3b. Another carrier provided a cost estimate for a proposed mandate in Pennsylvania that would provide up to

$36,000 of annual coverage. The estimate was $25.20 per member per year, and was based on an autism prevalence rate of 1 in 180. Adjusting the maximum benefit to $50,000 and applying the CDC's most recent prevalence rate of 1 in 100, we estimate this carrier would have produced an estimate of about $60 per member per year or $5 PMPM for Option 3a.

Financial Analysis

The independent analysis that was conducted in 2008 included a detailed financial analysis of the proposed mandate. In analyzing the three options, we started with the financial modeling (and the assumptions underlying the modeling) from the 2008 report. However, two important modifications have been made.

First, the Centers for Disease Control and Prevention (CDC) recently updated its estimate of the prevalence rate of autism.[1] The CDC now estimates a prevalence rate of 1%, or 1 in 100 children. This represents an increase from the prior estimate of 1 in 150. Where we previously relied on the CDC's prevalence rate of 1 in 150, we have reflected this new rate of 1 in 100 in the assumptions used to model the three options.

Second, the 2008 report estimated costs as of 2007, which is the most recent year for which premium data was available at the time the report was completed. Currently, the most recent premium data available is from 2008. We have therefore trended the cost estimates forward one additional year to 2008.

Below, we discuss the financial analysis of the three options. We focus our discussion on areas that differ from the 2008 analysis. The 2008 report is attached as a reference for those aspects of the analysis that are unchanged. As in the 2008 report, we have not differentiated between full costs and marginal costs in options 2 and 3, as some autism services are covered under the habilitative services mandate. We do not have data to quantify these costs, and we expect the cost of these additional services to be relatively low compared with the costs of ABA services.

Option 1: Mandate without limits on annual amount or age, but with the usual "medical necessity" determination regarding appropriate and established treatments.

This option represents no change from the current environment. Carriers would make their own medical necessity determinations, and we would expect carriers to continue considering ABA as educational or experimental in nature in the absence of new reliable studies to the contrary. Therefore, the marginal cost would be zero. The full cost would equal the relatively low costs that are already being covered for services that carriers believe are medically necessary, such as speech and other forms of therapy, or for services that are required under the habilitative services mandate.

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[1] Centers for Disease Control and Prevention, http://www.cdc.gov/ncbddd/autism/data.html (accessed October 29, 2009).

Option 2: Mandate without limits on annual amount or age, with applied behavioral analysis specified as a covered service as well as other services determined to be medically necessary. Treatment frequency and intensity would be subject to review for appropriateness.

Option 2 is similar to the proposed mandate that was analyzed in 2008, except that it removes the $50,000 annual limit on costs and the age limit of 21. Our methodology for modeling the annual cost is similar to the 2008 methodology, which relied on trending costs from the GANZ study.[2] However, at age three to five, the costs in last year's study were being reduced due to the $50,000 annual limit in the prior proposed mandate.

In modeling Option 2, we used 95% of the trended costs as our cost estimate at age three to five for the mid estimate. We used less than 100% of the cost because it is believed that one reason for the increased prevalence estimate is greater recognition of less severe cases of autism. We would expect that these less severe cases would have lower-than-average costs at ages three to five, which are when the most intensive treatments are provided; therefore, we have reduced the cost estimate slightly at those ages. For the low and high estimates, we varied the expected costs by 10% from the mid estimate at these ages. In addition, we added in the costs for those aged 21 and older using the same methodology as other age groups. The results of our analysis are in the tables below.

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[2] Michael L. Ganz, MS, PhD, "The Lifetime Distribution of the Incremental Societal Costs of Autism," www.archpediatrics.com (accessed November 13, 2008). Before joining Abt Associates, Dr. Ganz was Assistant Professor at the Harvard School of Public Health.

Table 1: Development of Option 2 Premium Increase

Low Estimate

Age Band	Age Band % of Population	ASD Treated Prevalence for Age Band	Cost per Treated Person	Mandate Cost per Insured MM
0 to 2	4.6%	0.09%	$16,875	$0.71
3 to 5	4.5%	0.27%	$40,500	$4.95
6 to 11	8.5%	0.65%	$21,972	$12.04
12 to 17	10.3%	0.41%	$7,301	$3.07
18 to 20	4.6%	0.41%	$2,756	$0.51
21 to 64	67.6%	0.41%	$1,820	$5.02
	100.0%			$26.29
			Admin Estimate	$2.13
			Admin % of Premium	7.50%
			Premium Increase Per Member	$28.42
			MD 2008 Small Group Premium per Member	$3,723
			Premium Increase % of Premium	**0.76%**

Mid Estimate

Age Band	Age Band % of Population	ASD Treated Prevalence for Age Band	Cost per Treated Person	Mandate Cost per Insured MM
0 to 2	4.6%	0.14%	$22,500	$1.41
3 to 5	4.5%	0.41%	$45,000	$8.24
6 to 11	8.5%	1.00%	$29,296	$24.84
12 to 17	10.3%	0.80%	$9,734	$8.02
18 to 20	4.6%	0.80%	$3,674	$1.34
21 to 64	67.6%	0.80%	$1,820	$9.83
	100.0%			$53.69
			Admin Estimate	$5.97
			Admin % of Premium	10.00%
			Premium Increase Per Member	$59.65
			MD 2008 Small Group Premium per Member	$3,723
			Premium Increase % of Premium	**1.60%**

High Estimate

Age Band	Age Band % of Population	ASD Treated Prevalence for Age Band	Cost per Treated Person	Mandate Cost per Insured MM
0 to 2	4.6%	0.27%	$24,750	$3.10
3 to 5	4.5%	0.54%	$49,500	$12.09
6 to 11	8.5%	1.00%	$33,307	$28.24
12 to 17	10.3%	1.00%	$12,965	$13.36
18 to 20	4.6%	1.00%	$3,674	$1.68
21 to 64	67.6%	1.00%	$1,832	$12.38
	100.0%			$70.84
			Admin Estimate	$10.12
			Admin % of Premium	12.50%
			Premium Increase Per Member	$80.96
			MD 2008 Small Group Premium per Member	$3,723
			Premium Increase % of Premium	**2.17%**

Table 2: Summary of Cost Estimates for Option 2

	Cost
Estimated cost of mandated benefits as a percentage of average cost per group policy	0.76% to 2.17%
Estimated cost as a percentage of average wage	0.1% to 0.29%
Estimated annual per employee cost of mandated benefits for group policies	$51 to $145

Only one carrier provided a cost estimate for Option 2 of about $46 per member per year, versus our per member per year range of costs of $26 to $71. We are assuming that the carrier's cost estimate does not include administrative expenses.

Option 3: Mandate with limits on annual amount and age

a. $50,000 annually up to age 21
b. $50,000 annually for ages 1 to 5, $20,000 annually ages 6 to 12

Option 3a

Option 3a is identical to the coverage that was modeled in the 2008 report. Therefore, the modeling is also identical, with the exception of the updated prevalence rate and the trending to 2008 that was discussed previously. The results of the updated modeling are shown in the following tables.

Table 3: Development of Option 3a Premium Increase

Low Estimate

Age Band	Age Band % of Population	ASD Treated Prevalence for Age Band	Cost per Treated Child	Mandate Cost per Insured MM
0 to 2	4.6%	0.09%	$15,750	$0.66
3 to 5	4.5%	0.27%	$31,500	$3.85
6 to 11	8.5%	0.65%	$20,642	$11.31
12 to 17	10.3%	0.41%	$7,096	$2.98
18 to 20	4.6%	0.41%	$2,756	$0.51
	32.4%			$19.31
			Admin Estimate	$1.57
			Admin % of Premium	7.50%
			Premium Increase Per Member	$20.88
			MD 2008 Small Group Premium per Member	$3,723
			Premium Increase % of Premium	**0.56%**

Mid Estimate

Age Band	Age Band % of Population	ASD Treated Prevalence for Age Band	Cost per Treated Child	Mandate Cost per Insured MM
0 to 2	4.6%	0.14%	$21,000	$1.32
3 to 5	4.5%	0.41%	$42,000	$7.69
6 to 11	8.5%	1.00%	$27,523	$23.33
12 to 17	10.3%	0.80%	$9,462	$7.80
18 to 20	4.6%	0.80%	$3,674	$1.34
	32.4%			$41.48
			Admin Estimate	$4.61
			Admin % of Premium	10.00%
			Premium Increase Per Member	$46.09
			MD 2008 Small Group Premium per Member	$3,723
			Premium Increase % of Premium	**1.24%**

High Estimate

Age Band	Age Band % of Population	ASD Treated Prevalence for Age Band	Cost per Treated Child	Mandate Cost per Insured MM
0 to 2	4.6%	0.27%	$23,625	$2.96
3 to 5	4.5%	0.54%	$47,250	$11.54
6 to 11	8.5%	1.00%	$31,978	$27.11
12 to 17	10.3%	1.00%	$12,761	$13.15
18 to 20	4.6%	1.00%	$3,674	$1.68
	32.4%			$56.44
			Admin Estimate	$8.06
			Admin % of Premium	12.50%
			Premium Increase Per Member	$64.50
			MD 2008 Small Group Premium per Member	$3,723
			Premium Increase % of Premium	**1.73%**

Table 4: Summary of Cost Estimates for Option 3a

	Cost
Estimated cost of mandated benefits as a percentage of average cost per group policy	0.56% to 1.73%
Estimated cost as a percentage of average wage	0.08% to 0.23%
Estimated annual per employee cost of mandated benefits for group policies	$37 to $116

One carrier provided a cost estimate for Option 3a of about $39 per member per year. A second carrier provided an estimate of $60 when adjusted to reflect Maryland benefits. We are assuming that neither of these estimates included administrative expenses. This compares to our estimates of about $19 to $56.

Option 3b

Option 3b reduces coverage for those aged 6 to 12 to $20,000 and eliminates additional mandated coverage for those aged 13 and older, relative to option 3a.

At ages 0 through 5, the estimated costs are identical to option 3a. While option 3b does not require any coverage for those aged 0, we are assuming that there are negligible costs at that age since a diagnosis is not likely to be made in the first year of life. At ages 6 to 12, the modeling of the costs is similar to option 3a except that the annual costs are limited to $20,000 at ages at which the option 3a costs were estimated to exceed $20,000. At ages 13 to 20, we have assumed that the annual costs will be similar to those for adults ages 23 to 27. We're not estimating the costs to be zero because the carriers' medical necessity criteria and the habilitative services mandate are expected to lead to positive claim costs at these ages. We used ages 23 to 27 to estimate the non-ABA cost level that may be expected to be incurred. The tables below summarize the results of our analysis of option 3b.

Table 5: Development of Option 3b Premium Increase

Low Estimate

Age Band	Age Band % of Population	ASD Treated Prevalence for Age Band	Cost per Treated Child	Mandate Cost per Insured MM
0 to 2	4.6%	0.09%	$15,750	$0.66
3 to 5	4.5%	0.27%	$31,500	$3.85
6 to 11	8.5%	0.65%	$14,935	$8.18
12 to 17	10.3%	0.41%	$3,288	$1.38
18 to 20	4.6%	0.41%	$2,756	$0.51
	32.4%			$14.58
			Admin Estimate	$1.18
			Admin % of Premium	7.50%
			Premium Increase Per Member	$15.77
			MD 2008 Small Group Premium per Member	$3,723
			Premium Increase % of Premium	**0.42%**

Mid Estimate

Age Band	Age Band % of Population	ASD Treated Prevalence for Age Band	Cost per Treated Child	Mandate Cost per Insured MM
0 to 2	4.6%	0.14%	$21,000	$1.32
3 to 5	4.5%	0.41%	$42,000	$7.69
6 to 11	8.5%	1.00%	$19,913	$16.88
12 to 17	10.3%	0.80%	$4,385	$3.61
18 to 20	4.6%	0.80%	$3,674	$1.34
	32.4%			$30.85
			Admin Estimate	$3.43
			Admin % of Premium	10.00%
			Premium Increase Per Member	$34.28
			MD 2008 Small Group Premium per Member	$3,723
			Premium Increase % of Premium	**0.92%**

High Estimate

Age Band	Age Band % of Population	ASD Treated Prevalence for Age Band	Cost per Treated Child	Mandate Cost per Insured MM
0 to 2	4.6%	0.27%	$23,625	$2.96
3 to 5	4.5%	0.54%	$47,250	$11.54
6 to 11	8.5%	1.00%	$20,000	$16.96
12 to 17	10.3%	1.00%	$5,844	$6.02
18 to 20	4.6%	1.00%	$3,674	$1.68
	32.4%			$39.16
			Admin Estimate	$5.59
			Admin % of Premium	12.50%
			Premium Increase Per Member	$44.75
			MD 2008 Small Group Premium per Member	$3,723
			Premium Increase % of Premium	**1.20%**

Table 6: Summary of Cost Estimates for Option 3b

	Cost
Estimated cost of mandated benefits as a percentage of average cost per group policy	0.42% to 1.2%
Estimated cost as a percentage of average wage	0.06% to 0.16%
Estimated annual per employee cost of mandated benefits for group policies	$28 to $80

Only one carrier provided a cost estimate for Option 3b of about $13 per member per year versus our per member per year range of costs of $15 to $39. We are assuming that the carrier's cost estimate does not include administrative expenses.

Resources

Centers for Disease Control and Prevention, http://www.cdc.gov/ncbddd/autism/data.html (accessed October 29, 2009).

Ganz, Michael L., MS, PhD, "The Lifetime Distribution of the Incremental Societal Costs of Autism," www.archpediatrics.com (accessed November 13, 2008). Before joining Abt Associates, Dr. Ganz was Assistant Professor at the Harvard School of Public Health.

Weaver, Linda. Principal for Mercer's Total Health Management Specialty Practice with expertise in behavioral health; Juris Doctor, Cum Laude, Georgetown University Law Center, PhD in Clinical Psychology, with Honors, University of South Florida BA in Psychology, with distinction, Douglass College, Rutgers University.

Welch, John, Karen Bender, et al. "Annual Mandated Health Insurance Services Evaluation." December 31, 2008. Prepared for the Maryland Health Care Commission. http://mhcc.maryland.gov/health_insurance/index.html.

2

Coverage of In Vitro Fertilization

Insurance Article 15-810, Sections (b) and (c) of the mandate state that benefits must be provided for outpatient expenses arising from in vitro fertilization (IVF) procedures if the patient and/or the patient's spouse have a history of infertility of at least two years' duration, or if the infertility is associated with endometriosis, exposure to diethylstilbestrol (DES), blockage or removal of fallopian tubes, or abnormal male factors.

The proposed change to the mandate addresses Section 15-810(c)(3)(i) and specifies that the history of infertility will be reduced from at least two years' duration to at least one year's duration. Since Section 15-810 already requires insurers to cover IVF for beneficiaries who meet the current mandate's requirements, the additional cost of the proposed change would result from the cost of treatments for women who would now use IVF under a one-year requirement but would not have under a two-year requirement, and reimbursement to women who paid for IVF treatments out of pocket after at least one year of infertility, but did not meet the two-year requirement.

Since Mercer completed an in-depth analysis last year of a proposed change to the existing IVF mandate, MHCC determined that only an analysis of the financial impact of the currently proposed mandate would be necessary. Interested parties may refer to last year's report to review our analysis of the medical and social impacts of this type of legislation. The following is a discussion of the financial impact of this proposed change in the mandate.

Financial Impact

The additional cost of the proposed change would be for those groups of women identified earlier in this report who would use or be reimbursed for additional IVF treatments, including:

(1) Additional treatments undertaken due to higher utilization that could be expected with a shorter required minimum period of infertility, and

(2) Additional treatments that would be reimbursed for women whose coverage required a two-year duration of infertility but who elected to self-pay for the treatment.

It is challenging to determine exactly how many additional cycles would be undertaken, or would be reimbursed, when they previously would have been paid for out of pocket because the insured did not qualify for coverage under the existing mandate. Specific information does not appear to exist regarding the reasons for, and the duration of infertility for those who have received IVF, or for the incremental additional women eligible for covered IVF treatments based on the revised eligibility criteria who would now use IVF.

Data from the Centers for Disease Control Advanced Reproductive Therapies (CDC ART) studies[3] indicated that 4,078 and 4,062 IVF cycles were undertaken at Maryland facilities in 2005 and 2006, respectively. As the most recent CDC data available did not indicate significant utilization changes between 2005 and 2006, we believe the 2006 CDC ART data provides a reasonable estimate of the number of cycles that could have been undertaken in 2008 (the base year for this study), since it is the most recent year for which Maryland CSHBP premium and enrollment data is available. We make the assumption that the vast majority of these IVF treatments would be provided to insured individuals, even though the treatments may or may not be covered by insurance.

We are also assuming that the cost per cycle ranges from $15,000 to $20,000 – which is consistent with the Department of Legislative Services' *HB 701: Fiscal and Policy Note* that was provided when we reviewed IVF costs in 2008. We note that our cost impact analysis is not nearly as sensitive to the per-cycle cost assumptions as it is to the assumptions related to the number of treatments affected by the proposed mandate and the expected increase in IVF utilization.

To estimate how reducing the period of infertility from two years to one year would impact IVF utilization (recognizing that demand for IVF is driven largely by whether or not IVF is covered by insurance), we reviewed utilization experience in states that mandate IVF coverage after one year of infertility. During the course of this review, we determined that of the limited number of states that mandate IVF treatment coverage after one year of inability to conceive, Massachusetts would be the most reasonable state to study though we certainly recognize that there are differences in the demographics and economies of the two states that could influence IVF utilization.

In reviewing the Massachusetts CDC ART data[4] and demographic information,[5] it appears that IVF utilization is approximately 40% higher in Massachusetts than in Maryland. This 40% increase is probably a reasonable estimate for an upper limit of the

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[3] See ART Studies.

[4] http://www.cdc.gov/ART/ExcelFiles/Clinic_Tables_Data_2006.xls (accessed October 2009).

[5] http://www.census.gov/hhes/www/cpstc/cps_table_creator.html (accessed October 2009 to develop population counts by age)

potential increase in utilization, considering that utilization will be affected by (1) the required duration of infertility for coverage and (2) whether IVF is covered at all under a policy – and that the Massachusetts mandate applies to all insurance markets, whereas small group policyholders in Maryland may not have IVF insurance coverage. We note that this 40% upper bound is an estimate of the one-time increase, and that future cost increases will be driven by the unit costs of IVF treatments, and any changes in utilization patterns driven by factors other than mandated coverage. In using the available Massachusetts utilization data as a baseline, we are also making an implicit assumption that other factors that are known to affect utilization (such as income, geography and provider availability) would not contribute significantly to any utilization differences between Maryland and Massachusetts, as the two states are sufficiently similar with regard to these factors. Based on the rationale outlined above, in our modeling we assumed that utilization would increase 10%, 20% and 40% in our respective low, mid and high estimates.

We also developed estimates for the costs of services that would be reimbursed for women whose coverage required a two-year duration of infertility but who elected to pay for IVF treatment out of pocket after a period of infertility between one and two years. To determine the number of cycles that would fit this criteria, we first used our estimates of the additional cycles that we expected to be undertaken due to the change in the durational requirement, and applied a range of ratios for the estimated increased IVF utilization based on a *New England Journal of Medicine* study of the difference in utilization when IVF is covered by insurance mandates versus when it is not.[6] Based on this study, we assumed that the existence of a mandate would increase utilization by 100% to 177%. We estimated that approximately 10 to 20% of IVF cycles are for women who pay out of pocket after a duration of infertility of between one and two years. This percentage could be expected to be fairly low due to the high cost of IVF treatment.

Our resulting estimate of the incremental cost of the covered benefits is approximately 0.08% – 0.33% of premium, as outlined in Table 1 below.

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

Table 1: Estimated Cost of Mandated IVF Benefits

	Low	Mid	High
Total Number of Cycles in Maryland estimated for 2008	4,062	4,062	4,062
Estimated Cost per In Vitro Cycle	$ 15,000	$ 17,500	$ 20,000
Estimated Maryland In Vitro Cost with Current Mandate (includes self-pay)	$ 60,930,000	$ 71,085,000	$ 81,240,000
Expected Increase due to 2 year vs. 1 year Infertility Period	**10%**	**20%**	**40%**
Additional Cycles	406	812	1,625
Cost of Additional IVF Cycles due to Proposed Mandate	**$ 6,093,000**	**$ 14,217,000**	**$ 32,496,000**
Assumed increase due to existence of Mandate	100%	139%	177%
Additional Insurer Costs for Current Self-Pay	**$ 6,093,000**	**$ 10,264,982**	**$ 18,359,322**
Total Additional Insurer Costs	**$ 12,186,000**	**$ 24,481,982**	**$ 50,855,322**
Approximate Employer Based Coverage Cost	15,452,566,101	15,452,566,101	15,452,566,101
Current Mandate Base Cost/Year (Per member)	13.21	14.65	15.15
Marginal Additional Cost/Year (Per member)	2.94	5.90	12.25
Proposed Mandate Full Cost/Year (Per member)	16.15	20.55	27.40
2008 CSHBP Premiums	$1,550,485,486	$1,550,485,486	$1,550,485,486
2008 CSHBP Member Months	4,997,610	4,997,610	4,997,610
2008 CSHBP PMPM Premiums	$310	$310	$310
Base Cost/Year as % of SG Per Member Premium	**0.35%**	**0.39%**	**0.41%**
Incremental Cost/Year as % of SG Per Member Premium	**0.08%**	**0.16%**	**0.33%**

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

Additionally, our range of cost estimates does not include the impact of cost-sharing provisions. This reflects an implied assumption that cost-sharing provisions will have been satisfied through other services.

Table 2 summarizes the detailed cost estimates developed in Table 1. Note that most of the costs of the mandated IVF benefit as contemplated in the proposed mandate are covered under the current IVF benefit. We would expect the incremental impact of newly covered IVF benefits to be that IVF costs would increase by approximately 20% to 80%.

Table 2: Summary of Full and Marginal Cost Estimates for IVF Benefits

	Full Cost	Marginal Cost
Estimated cost of mandated benefits as a percentage of average cost per group policy	0.43% to 0.74%	0.08% to 0.33%
Estimated cost as a percentage of average wage	0.06% to 0.1%	0.01% to 0.05%
Estimated annual per employee cost of mandated benefits for group policies	\$29 to \$49	\$5 to \$22

In response to our carrier survey, we received estimates regarding the current costs of IVF treatments and the estimated impact of the change in the mandated benefits. Several insurers responded that they already provide coverage; however, based on market share it appears that the majority of insureds are covered by insurers who require a two-year duration of infertility. Similar to previous survey responses, these cost estimates varied widely, and it is unclear how much rigor went into the cost analyses done to develop these estimates. It is also possible that the carrier estimates assume other significant costs (e.g., multiple births) that we did not quantify in our estimates, or that PMPM (per member/per month) costs were developed only for the populations that could use these services.

Current cost estimates provided by the carriers ranged from \$0.01 to \$29.00 PMPM, with two insurers indicating current costs of \$2.50 to \$2.75 PMPM and \$2.95 PMPM respectively for IVF coverage; these two carrier estimates are reasonably close to our cost estimates. Based on proprietary carrier data that we have reviewed for other clients, IVF costs could be expected to be \$1 to \$3 PMPM. This is also consistent with a couple of recent studies completed in Massachusetts.[7] Only one carrier that currently requires a minimum two-year duration of infertility provided an estimate of the marginal impact of changing from the two-year duration to the one-year duration, and this estimate was <\$0.05 PMPM, though the carrier noted that it didn't have utilization statistics to support this estimate.

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[7] DHCFP Review and Evaluation of Proposed Legislation Entitled: An Act Relative to Increasing Coverage for Infertility Treatments, Senate Bill 485, August 2009, http://www.mass.gov/Eeohhs2/docs/dhcfp/r/pubs/09/Infertility_Report.pdf and

Compass Health Analytics, "State-Mandated Health Insurance Benefits and Health Insurance Costs in Massachusetts," prepared for Division of Health Care Finance and Policy, July 2008,

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

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Annual Mandated Health Insurance Services Evaluation

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

MARYLAND

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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 evaluation of the proposed changes to existing mandates or proposed newly mandated benefits: expanded coverage of autism spectrum disorder, modification to the existing in vitro fertilization mandate, modification to the existing mandate involving mastectomies, coverage of prosthetic devices and coverage for shingles vaccine.

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Coverage of Autism Spectrum Disorder

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

- Insurers, health plans, and health maintenance organizations "... Shall provide coverage for the diagnosis of autism spectrum disorders and the evidence-based, medically necessary treatment for autism spectrum disorders in individuals under the age of 21 years." Coverage is subject to an annual maximum of $50,000 for 2010. The annual maximum increases each year by the Medical Care Component of the Consumer Price Index for all urban consumers (CPI-U).

- "Treatment of autism spectrum disorders" encompasses "habilitative or rehabilitative care" as well as pharmacy psychiatric, or psychological care prescribed by a physician or psychologist.

- "Habilitative or rehabilitative care" includes "applied behavior analysis" and other services, including the development and maintenance of an individual's functioning – the main goal being to restore it to the maximum extent possible.

The following is a description of autism provided by the Centers for Disease Control (CDC).[8]

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

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[8] Centers for Disease Control and Prevention. http://www.cdc.gov/ncbddd/autism/overview.htm

> ASDs can vary – from gifted to severely challenged. An ASD begins before the age of 3 and lasts throughout a person's life.
>
> ASDs include autistic disorder, pervasive developmental disorder – not otherwise specified (PDD – NOS, including atypical autism), and Asperger syndrome. These conditions all have some of the same symptoms, but they differ in terms of when the symptoms start, how severe they are, and the exact nature of the symptoms. The three conditions, along with Rett syndrome and childhood disintegrative disorder, make up the broad diagnosis category of pervasive developmental disorders.
>
> ASDs occur in all racial, ethnic, and socioeconomic groups and are four times more likely to occur in boys than in girls. CDC's Autism and Developmental Disabilities Monitoring (ADDM) Network released data in 2007 that found about 1 in 150 eight-year-old children in multiple areas of the United States had an ASD.

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

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

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

Medical Impact

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

- **Does the medical community recognize services and treatments, including ABA, as being effective in treating patients with ASDs?**

- **Are the additional services that are provided to patients with ASDs under this mandate generally recognized by the medical community, as demonstrated by a scientific and peer review of literature?**

- **Are the additional services that are provided to patients with ASDs under this mandate available and utilized by treating physicians?**

According to the Autism Society of America, there currently are many different approaches in the treatment of autism, including auditory training, discrete trial training, vitamin therapy, anti-yeast therapy, facilitated communication, music therapy, occupational therapy, physical therapy, and sensory integration. These approaches can generally be broken down into three categories:

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

Children with autism may receive eight to 11 hours a week of OT, PT, and ST as part of an intensive treatment plan based on an illustrative plan.[9]

Some of these treatment approaches have research studies that support their efficacy; others do not. The Autism Society of America asserts that long-term, scientific studies regarding the different treatment methods are difficult to complete since there is such a wide range of symptoms and skill sets associated with autism.[10]

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

Applied Behavioral Analysis (ABA)

ABA includes intensive one-on-one sessions with ABA therapists. It is not unusual for these sessions to be as frequent as six days a week for as many as 30 to 40 hours a week.[11]

ABA is almost universally excluded from health coverage, generally because insurers do not consider it a medical treatment, or do not believe it meets the standard of "medically necessary" or "medical necessity" as defined by insurers.

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

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

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

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

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

[11] See note 2.

> some measures of social behavior, and their outcomes have been significantly better than those of children in control groups.[12]

In the report *Mental Health: A Report of the Surgeon General*, the Surgeon General states, "Thirty years of research demonstrated the efficacy of applied behavioral methods in reducing inappropriate behavior and in increasing communication, learning, and appropriate social behavior. A well-designed study of a psychosocial intervention was carried out by Lovaas and colleagues (Lovaas, 1987; McEachin et al., 1993)."[13]

In the article, "Applied Behavior Analysis, Treatment of Autism: The State of the Art," Richard M. Foxx asserts that ABA is a "scientifically validated and highly effective treatment" for autism.[14] He cites many peer reviewed articles regarding the success of ABA as well as the fact that ABA is the only educational or treatment approach currently approved by the New York State Health Department for ASD.

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

The American Academy of Pediatrics (AAP) recognizes that ASDs are not "curable" but require chronic management. They assert, "Although outcomes are variable and specific behavioral characteristics change over time, most children with ASDs remain within the spectrum as adults and regardless of their intellectual functioning, continue to experience problems with independent living, employment, social relationships and mental health. The primary goals of treatment are to minimize core features and associated deficits, maximize functional independence and quality of life, and alleviate family distress. Facilitating development and learning, promoting socialization, reducing maladaptive behaviors and educating and supporting families can help accomplish these goals."[15]

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

- behavioral models,

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

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

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

[15] See note 5 above.

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

> The AAP recognizes that, while there are several studies documenting improvement in children using the other educational interventions described, controlled studies for these alternative interventions are generally not available.[16]

Carriers generally have differing opinions, as the following shows.

Magellan Health Services (Magellan) – a managed health care company that specializes in providing services for behavioral health conditions, and a subcontractor for at least one of the major carriers in Maryland – considers ABA to be an "investigational treatment." It has based this determination on the "evaluation of the research findings where the evidence did not support ABA's effect on health outcomes, its safety and efficacy against existing alternative treatments, and its ability to demonstrate that benefits outweigh the risks."[17]

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

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

One of the basic reasons for Magellan's determination is the lack of randomized controlled studies of ABA. Magellan believes that many of the results of studies published to date "have several methodological problems, including lack of a clear definition of the ABA treatment and its protocols, lack of control groups using established treatment alternatives, poorly chosen or poorly specified samples, outcomes measured only in limited areas (e.g., IQ), and outcomes measures giving little information regarding the totality of the treatment impact."[18] Magellan notes that most of the research for ABA programs has focused on the very youngest (preschoolers). There is very little research regarding outcomes for older children or adults with autism.

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[16] See note 5 above.

[17] Magellan Health Services. "Introduction to Magellan's Adopted Clinical Practice Guidelines for the Treatment of Children with Autism Spectrum Disorders." 2008. This document can be found by: entering: http://www.magellanhealth.com/, then selecting "Provider," "Clinical Guidelines," "Clinical Practice Guidelines," "Autism," "Magellan Introduction."

[18] Ibid

Magellan cites the following other limitations (in addition to the limited research on medical efficacy) to the use of ABA treatments for children with autism.[19]

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

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

> **Experimental/Investigational**[20]
> The term "experimental/investigational" describes services or supplies that are in the developmental stage and are in the process of human or animal testing. Services or supplies that do not meet all 5 of the criteria listed below adopted by the BlueCross BlueShield Association Technology Evaluation Center (TEC) are deemed to be experimental/investigational:
>
> 1. The technology* must have final approval from the appropriate government regulatory bodies; and
> 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes; and
> 3. The technology must improve the net health outcome; and
> 4. The technology must be as beneficial as any established alternatives; and
> 5. The improvement must be attainable outside the investigational settings.
>
> * *Technology includes drugs, devices, processes, systems, or techniques.*

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[19] Ibid

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

CareFirst indicates that ABA does not meet criteria numbers two through five of its definition. In arriving at this conclusion, CareFirst provides the following:[21]

> Rationale:
> The National Institute of Neurological Disorders and Stroke (NINDS) conducts research in its laboratories at the National Institutes of Health (NIH) and also supports additional research through grants to major medical institutions across the country for pervasive developmental disorders including autism. As part of the Children's Health Act of 2000, the NINDS and three sister institutes have formed the NIH Autism Coordinating Committee to expand, intensify, and coordinate NIH's autism research. Eight dedicated research centers across the country have been established as "Centers of Excellence in Autism Research" to bring together researchers and the resources they need. The Centers are conducting basic and clinical research, including investigations into causes, diagnosis, early detection, prevention, and treatment of autism.*
>
> Currently there is a lack of clinically based evidence on the cause or treatment of Pervasive Developmental Disorders including autism.
>
> * *Information from NINDS Autism Information Page and NINDS Pervasive Developmental Disorders Information Page (2005)*
>
> Update 2007:
> A search of the peer-reviewed literature was performed for the period of May 2005 through June 2007. Findings in the recent literature do not change the conclusions regarding the cause or treatment of pervasive developmental disorders, including autism.

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

> "There is insufficient evidence for the superiority of any particular intensive educational intervention strategy (such as applied behavioral analysis, structured teaching, or developmental models) over other intensive educational intervention strategies."[22]

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

[22] Aetna. Clinical Policy Bulletin. "Pervasive Developmental Disorders." Accessed November 2008. http://www.aetna.com/cpb/medical/data/600_699/0648.html

In this general document, Aetna provides the research that they reviewed to arrive at this conclusion, which includes 110 studies and articles. Among the specific studies cited was the finding by the National Academy of Sciences (NAS) in 2001 that there is no known cure for autism, and that "[e]ducation, both directly of children, and of parents and teachers, is currently the primary form of treatment for autistic spectrum disorders." The National Academy of Sciences recommends that educational services begin as soon as a child is suspected of having autistic spectrum disorder, and that those services include a minimum of 25 hours a week, 12 months a year, in which the child is engaged in systematically planned and developmentally appropriate educational activity toward identified objectives. Aetna references another study by Brasic (2003), which stated that "while parents may choose to utilize a variety of experimental treatments including medication, they should concurrently utilize intensive individual special education by an educator familiar with instructing children with autistic disorder and related conditions."[23]

Autism Speaks, an autism advocacy organization, comments, "Private health insurance coverage of autism services will allow children with autism to access Applied Behavior Analysis (ABA), a proven treatment for their condition. Several studies have shown that as many as 47 percent of the children that undergo early intensive behavioral therapies achieve higher education placement and increased IQ levels. A significant portion of children who receive ABA are placed into mainstream educational settings. Children who begin their treatment with minimal IQ levels end treatment with substantially higher levels of intellectual functioning. These results have been shown to last well beyond the end of treatment. As such, the effectiveness of ABA therapy has allowed many children to forego costly intensive special education in the future."[24]

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

Occupational, Physical, and Speech and Language Therapies

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

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[23] Ibid

[24] Autism Speaks. "Arguments in Support of Private Insurance Coverage of Autism-Related Services." October 2007. http://www.autismspeaks.org/docs/arguments_for_private_insurance_coverage.pdf

providing prevocational training. However, research regarding the efficacy of occupational therapy in ASDs is lacking. Sensory integration (SI) therapy often is used alone or as part of a broader program of occupational therapy for children with ASDs."[25]

The report further states, "A variety of approaches have been reported to be effective in producing gains in communication skills in children with ASDs. People with ASDs have deficits in social communication, and treatment by a speech-language pathologist usually is appropriate."[26]

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

Social Impact

In this section, we address the following questions:

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

A 2005 study estimated the prevalence of specific ASDs. This study, based on preschool children living in England, found that of those children that had some type of ASD, about one-third had autistic disorder, one-sixth had Asperger's syndrome, and one-half had Pervasive Developmental Disorder - Not Otherwise Specified (PDD – NOS).[27] This

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[25] See note 5 above.

[26] See note 5 above.

[27] See note 2 above.

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

The CDC estimated that, nationwide, the prevalence of ASDs among eight-year-old children ranged from 3.3 to 11.9 per 1,000 children. For Maryland, the CDC estimated the prevalence of ASDs among eight-year old children to be 6.7 per 1,000 children, which was within the nationwide range.[28] This indicates that it is reasonable to use the CDC nationwide estimates for prevalence of ASD for Maryland.

This mandate covers services only for individuals under age 21 – which, based on Census statistics, would account for about 32% of Maryland's non-Medicare (under age 65) population .[29] So, a reasonable estimate would be that approximately one in 460 people covered by insurance in Maryland, or about 0.2% of the insured population, could potentially receive additional benefits under this mandate. However, the actual number would likely be lower, as the very young and many higher-functioning autistic children would not actually be diagnosed or receive treatment at each age under 21. Conversely, there is a potential that the estimated number could increase if the prevalence rate for autism continues to increase.[30]

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

- *Services not currently covered due to broad autism exclusions.* Certain plans have blanket-stated coverage exclusions for autism services other than the habilitative services already mandated.

- *Certain services not currently covered because they are specifically excluded by a plan*. For example, ABA is typically considered an educational program by insurers and is specifically stated as excluded in coverage position statements.

- *Services not currently covered because they do not meet defined "medically necessary" criteria.* Below is a sample definition of "medically necessary" (This is CIGNA's protocol; note that other insurer definitions are very similar.)[31]

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

[29] U.S. Census Bureau. http://www.census.gov/hhes/www/hlthins/data_access.html

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

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

> Except where state law or regulation requires a different definition, “Medically Necessary” or “Medical Necessity” shall mean health care services that a Healthcare Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:
>
> > a) in accordance with the generally accepted standards of medical practice;
> > b) clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease; and
> > c) not primarily for the convenience of the patient or Healthcare Provider, a Physician or any other Healthcare Provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.
>
> For these purposes, "generally accepted standards of medical practice" means:
>
> - standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community,
> - Physician and Healthcare Provider Specialty Society recommendations,
> - the views of Physicians and Healthcare Providers practicing in relevant clinical areas and
> - any other relevant factors.

Autism treatments are frequently denied under the educational exclusion, with insurers citing that the American Academy of Pediatrics considers applied behavior analysis an educational intervention.[32] However, the Virginia Joint Legislative Audit and Review Commission has noted, “Medical experts indicate that even though there is often an attempt to classify ASD treatments as either educational or medical, many treatments can be considered both educational and medical, so such a distinction is not warranted.”[33]

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

- In general, coverage is subject to medical necessity and the carrier does not cover treatments that will not result in improvement. Carriers may make short-term exceptions to cover acute exacerbations if there is a significant change in behavior.

- At this point, ABA is not covered because it is not considered evidence-based. No self-insured companies in Maryland using CareFirst or United as Third Party Administrators (TPAs) cover ABA.

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[32] See note 5 above.

[33] See note 2 above.

- "Currently, services such as Applied Behavioral Analysis could be excluded under the Educational Services exclusion of our Maryland plans."

- "If [ABA is] request is recognized as being related to ASD, no coverage would be authorized (excluded as educational). ASD is also considered a chronic condition and therefore excluded from coverage."

- "Applied Behavioral Analysis treatments are generally denied for being experimental and investigational or not medically necessary… If therapy is covered due to an alternate diagnosis, then the 60-day limit will apply."
- "…does not cover the following procedures/services for the assessment and/or treatment of ASD because they are considered experimental, investigational or unproven for this indication (these lists may not be all-inclusive)… intensive intervention programs for autism (e.g., Lovaas therapy, applied behavior analysis)"

- "This service is not covered … under Excluded Services – '*49. Treatment for disorders relating to learning, motor skills, communication, and pervasive developmental conditions such as autism.*'"

- "… plans provide inpatient, outpatient (including PT, OT and speech therapy), emergency care, medical-surgical care, specialty care and pharmacy for members with autism and autism spectrum disorders (ASD) … Some reasons for denial of services could include: services rendered by non-covered provider; services not preauthorized by health plan; education services not covered by health plan; services rendered are not effective."

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

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

In FY 2007, the Maryland Medicaid Waiver for Children with Autism Spectrum Disorder (AW) offered eight types of waiver services related to the treatment of autism spectrum disorders. Services covered under the waiver are as follows: [34]

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

While there may be some overlap with the services contemplated in the mandate, the waiver program is targeted to severely affected individuals who likely could be institutionalized without supports. Enrollment under the AW is capped at 800, and in August 2008, a total of 2,535 children were on the Waiver Services Registry (which is essentially a waiting list). Therefore there is a total of 3,335 individuals either enrolled or on a waiting list for AW services. This represents about 60% of the total number of individuals that Mercer estimates could be covered under any mandate.[35] The average cost per child for only the waiver services in Maryland was slightly more than $25,000 for fiscal year 2007. The average cost per child for waiver services and Medicaid State Plan services was slightly more than $38,000.[36]

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

Based on the costs of ABA and other therapies, it is safe to assume that many families cannot afford the costs associated with the total compendium of non-covered therapies and, therefore, certain children would not receive them unless provided through a government program such as IDEA. In its analysis of Virginia's House Bill 83 – which would mandate autism coverage, including ABA therapy – the Joint Legislative Audit and Review Commission notes, "The costs of intensive behavior therapies could be … from 38 percent to well over median household income."[37]

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[34] Medicaid response to MHCC data request, October 2008.

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

[36] See note 27 above.

[37] See note 2 above.

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

> Families that refuse to allow their children to suffer through the inadequate Medicaid system and are denied coverage by their private health insurance carriers often end up paying for therapies out of their own pockets. For these families, the financial burden is immense. Without the negotiating powers of an insurance company behind them, out-of-pocket prices are extremely high. Parents can often spend upwards of $50,000 per year on autism-related therapies, often being forced to wager their own futures and the futures of their non-autistic children to pay for necessary autism-related therapies. Children whose parents cannot afford to pay for behavioral and other therapies and who cannot access adequate therapies through the Medicaid system simply go without these interventions.[38]

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

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

This study also provides an estimate of the societal costs of autism. Ganz comments, "The total annual societal per capita cost of caring for and treating a person with autism in the United States was estimated to be $3.2 million and about $35 billion for an entire birth cohort of people with autism."[39]

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

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[38] See note 17 above.

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

$33 thousand and $50 thousand per child per year; the authors suggest that these figures represent a modest impact on cost/benefit ratios."[40]

For families that would likely utilize autism services, there is obviously significant demand for the additional coverage outlined in the mandate. Autism also received significant press during the 2008 presidential campaign, with both major party candidates recognizing the hardships faced by families affected by autism, and the need to determine better ways to support them. On his website, President-elect Barack Obama says that he "will mandate insurance coverage of autism treatment and will also continue to work with parents, physicians, providers, researchers, and schools to create opportunities and effective solutions for people with ASD."[41]

Coverage mandates in other states have received widespread support, and have generally passed by wide margins. A recent (summer 2008) Wisconsin Checkpoint poll shows that about 55% of likely voters surveyed "strongly" support requiring insurance companies to cover treatment for children with autism, and that another 30% "somewhat" support an autism mandate. It does not appear that the question included any reference to impact on premium – which might have affected the response.[42]

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

ABA benefits – and many other benefits for services to treat autism – are typically limited or excluded for self-insured plans. CareFirst and United HealthCare noted that they did not administer any self-insured plans that cover ABA. While most large employers do not provide significant coverage for ABA, the US military's Tricare health insurance programs and some very large self-insured companies (including Microsoft and Home Depot) pay for autism behavior therapy.[43]

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

[41] http://www.barackobama.com/pdf/AutismSpectrumDisorders.pdf

[42] http://www.autisminsurancenow.org/public-opinion-poll/

[43] Spake, Amanda. "Families Change Microsoft's View of Autism." *Smart Money Magazine.* May 8, 2007. http://www.smartmoney.com/personal-finance/health-care/families-changed-microsofts-view-of-autism-21226/

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

Financial Impact

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

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

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

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

Treatment Prevalence

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

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

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

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

- Independence Blue Cross expected a treated prevalence of 1 in 400 when they provided comments to the Commission studying the impact of the Pennsylvania autism mandate.[44]
- BlueCross of Northeastern Pennsylvania expected a treated prevalence of 1 in 150 for the Pennsylvania mandate.[45]
- In assessing the cost impact of the Louisiana mandate for autism services, James Bouder noted, "… it is reasonable to forecast the likely beneficiaries of HB 958 based on a treated prevalence of 1 in 500."[46]
- A summary of IDEA[47] and Census[48] data indicated the following rates for children receiving educational services in Maryland:

Table 1

Rates of Children with Autism Accessing the Educational System

Age	Accessing System	MD Population	Rate per 1,000	Rate - 1 in …
3 to 5	606	222,929	2.7	368
6 to 11	2,719	420,648	6.5	155
12 to 17	2,086	511,273	4.1	245

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

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[44] See note 33 above.

[45] Ibid

[46] Ibid

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

[48] Census Data web link. http://www.census.gov/hhes/www/hlthins/data_access.html

Intensity of Services by Age

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

The often-cited Ganz study[49] showed direct and indirect costs associated with autism for five-year age bands starting at age three – the assumed age at diagnosis. It showed that direct medical costs (in 2003 dollars) were expected to be highest from ages three to seven, averaging around $35,000, and then decrease significantly as children aged – to about $6,000 for ages eight to 12, $5,000 for ages 13 to 17, and $3,000 for ages 18 to 22. The report states, "The large direct medical costs early in life are driven primarily by behavioral therapies that cost around $32,000 during the first five-year age group and decline from about $4,000 in the 8- to 12-year age group to around $1,250 for the 18- to 22-year age group."

The Virginia JLARC report on House Bill 83 noted, "A 2003 study estimated the annual cost of intensive behavioral therapies to be $41,295 for preschool-aged children and to range from $4,140 to $5,914 for older children. A 2007 study estimated the cost of early intensive behavioral interventions to be approximately $22,500 annually."[50] Note "early intervention" is for children two years and under.

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

Cost Estimates for Other State Mandates

Table 2 in the Virginia JLARC report summarizes autism mandates in other states. We have included this table for your reference.[51]

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[49] See note 32 above.

[50] See note 2 above.

[51] Ibid

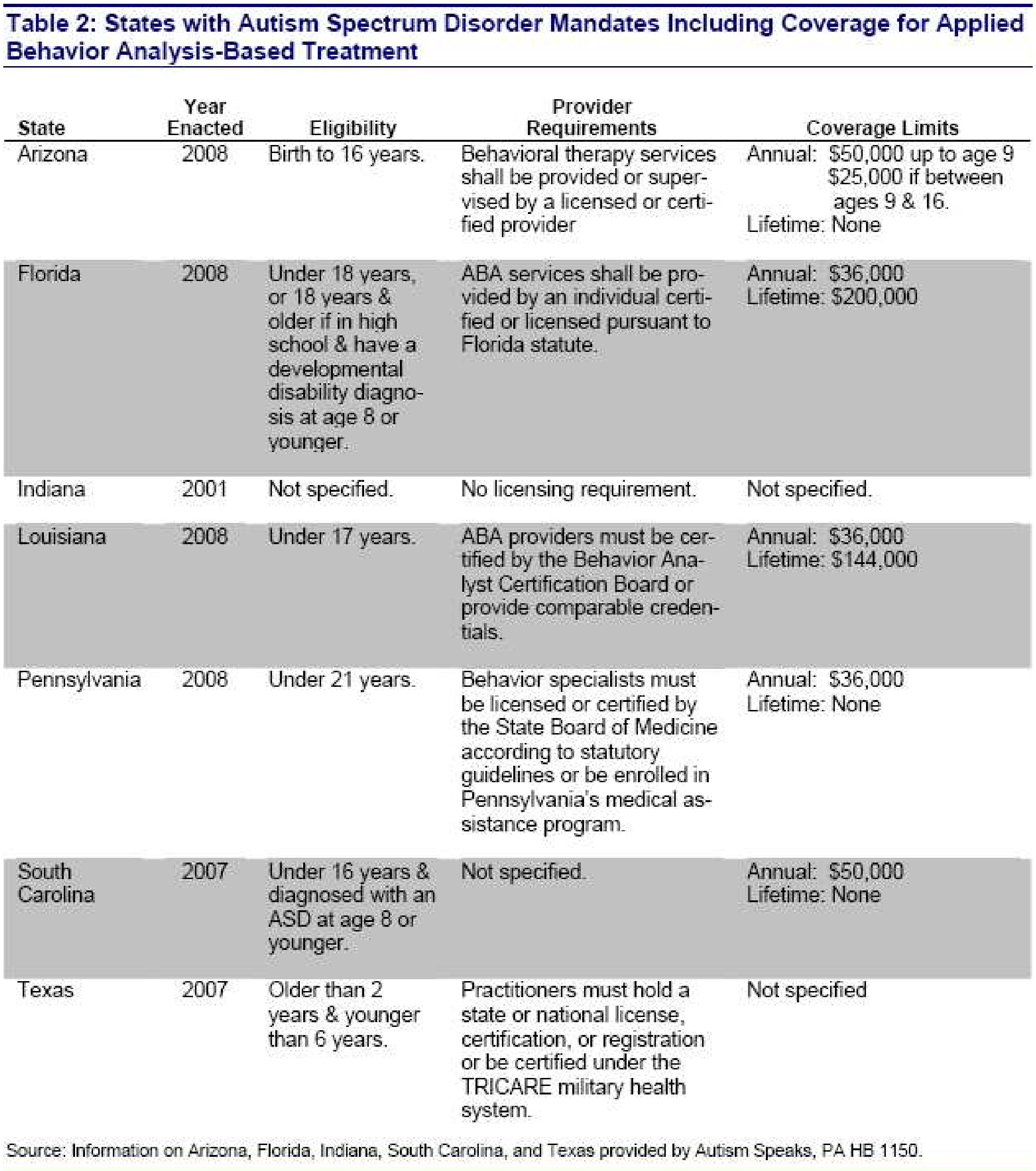

Table 2: States with Autism Spectrum Disorder Mandates Including Coverage for Applied Behavior Analysis-Based Treatment

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

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

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

In the previously mentioned report concerning Pennsylvania HB 1150, Abt Associates noted the following regarding cost estimates in Pennsylvania and other states:[52]

With regard to premium increases:

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

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

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

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

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

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[52] See note 33 above.

In Virginia, a survey of insurers was conducted to provide cost estimates of the state's proposed mandate. Twenty companies provided estimates for group coverage. The median estimate among those 20 carriers when the coverage was going to be required for all employers (and not optional) was $4.88 PMPM, with the range varying from a low of $0.04 PMPM to $6.16 PMPM. The median increase for carriers operating in the individual market was also $4.88 PMPM, with the range being $0.14 PMPM to $6.67 PMPM.[53]

The estimated costs of the Virginia mandate are higher than observed in some other states, however, the Virginia analysis indicated that many other states cover autism through their mental health parity mandates, which do not include the types of services provided in ASD-type mandates. There were concerns that the mandate could increase the use of investigational or untested treatments for ASDs; result in a lack of coordination of services for individuals with ASDs and that only reputable providers should be covered by the mandate[54].

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

Cost Estimates from Maryland Insurers

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

- Two carriers provided cost estimates. One carrier estimated the cost at approximately $45 million, or $5.00 PMPM, or $60 per member per year for Maryland-based fully insured businesses only. The other carrier, which has expended more resources estimating the costs of autism mandates in other states, estimated the cost at $1.43 to $3.22 PMPM, or $17.16 to $38.64 per member per year. This last estimate is based on the assumption that ASDs are not considered a mental illness and that the annual $50,000 maximum would not be affected by the federal Mental Health Parity Act.

- Four insurers provided no quantitative estimate; one said the cost would cause no significant increase; the other three indicated that an estimate was unknown or not available.

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[53] See note 2 above.

[54] Ibid

> One carrier did provide some perspective on the reasons for not being able to quantify a premium impact, commenting, “This is difficult to estimate without more specific information, such as:
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> - the evidence based information related to the appropriate number of hours of treatment per day/week/month;
> - types and numbers of appropriate treatments per day/week/month; appropriate ages for specific types of treatments;
> - is there a limit/level where ABA is no longer effective;
> - professional license/certification of providers of ABA care so a cost per service can be estimated. (For example, we have read that an ABA certified educator would charge about $100 – $130/hour, while an ABA trained staff would charge $20 – $30/hour).
> - While the proposed bill specifically identifies and defines ABA as part of the mandate, there are other approaches to the care for autism and ASD that perhaps could be included in some of the very broad definitions. However, we are not aware of any evidence-based information that explains how or if ABA can be combined with other approaches or how other approaches could coordinate, replace or supplement ABA.
>
> We are not able to factor in those possibilities.”

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

- *Increased credentialing costs for determining qualifications of ABA providers* – There may not be enough qualified providers to supply services if this proposal passes. Carriers have no experience contracting with non-health care providers but would have to develop a network of such caregivers if the mandate was enacted. Carriers would have to develop a fee schedule/payment level for non-health care providers, develop and/or work with public agencies to develop criteria for determining who is qualified to provide these services, and develop utilization management and medical policy standards and guidelines for ABA.

- *The costs of obtaining treatment plans* – An updated treatment plan can be requested every six months, but carriers would have to bear the costs of obtaining this plan. Currently, carriers generally do not pay providers for treatment plans.

- *Limitations on carriers’ ability to contain costs* – Current language appears to limit the carriers’ ability to implement cost containment measures, including the ability to perform utilization management and determine medical necessity. The treatment plan should be developed on the basis of an evaluation or re-evaluation of individuals in accordance with the recommendations of the American Academy of Pediatrics and should be a comprehensive plan across disciplines, including medical, behavioral, and mental (if appropriate).

- *What is the educational system's role in helping to treat autism* – Case management services appear to be critical in coordinating the care between the potential number of providers and the educational system. Who is going to have "ownership" for the case management plan of treatment---the educational system or the medical providers? How and who will measure progress under a specific treatment plan? It appears that some services that are currently provided by the school system would be transferred to the medical system. The educational system should be encouraged to improve the services provided to these children. We understand that existing federal law requires state and local school systems to provide appropriate services for children with autism and ASD. Why should employers – especially small employers – be required to subsidize the educational system through health premiums when health premiums are already perceived as being too high, and why should scarce health care dollars pay for educational services?

- *Reliance on ABA as sole treatment method* – The proposed mandate appears to rely on ABA as the only method of treatment; it does not allow for other methods. What happens if a study definitively demonstrates that ABA is of no value?

- *Uncertainty regarding the kind of qualifications and credentials to require of providers* – The proposed mandate states that ABA can be provided only by someone who is an MD or a PhD, or someone who is under the supervision of either of these two. This does not specify that they have any training in ABA. The other provision states that a provider could treat using ABA as long as they are credentialed by the Behavior Analyst Certification Board. Proposals in other states have recommended that treatment be provided by a certified licensed provider.

- *Potential increase in "diagnostic substitution"* – There may be increased use of nonspecific pervasive developmental disorder codes to access treatment of what previously may have been considered developmental delay, attention deficit disorders, and mental retardation. These are also diagnoses for which many proposed treatments are considered not medically necessary.

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

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

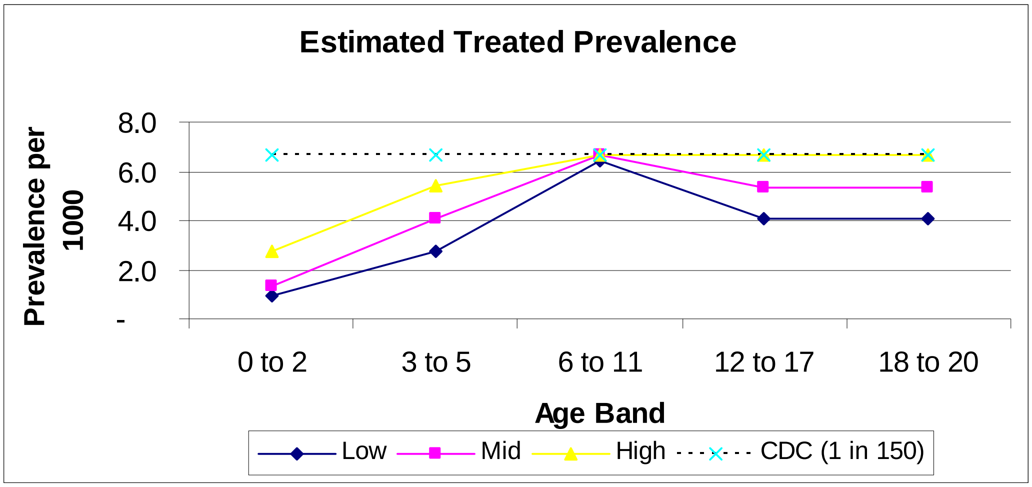
Independent Cost Estimates

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

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

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

Table 3



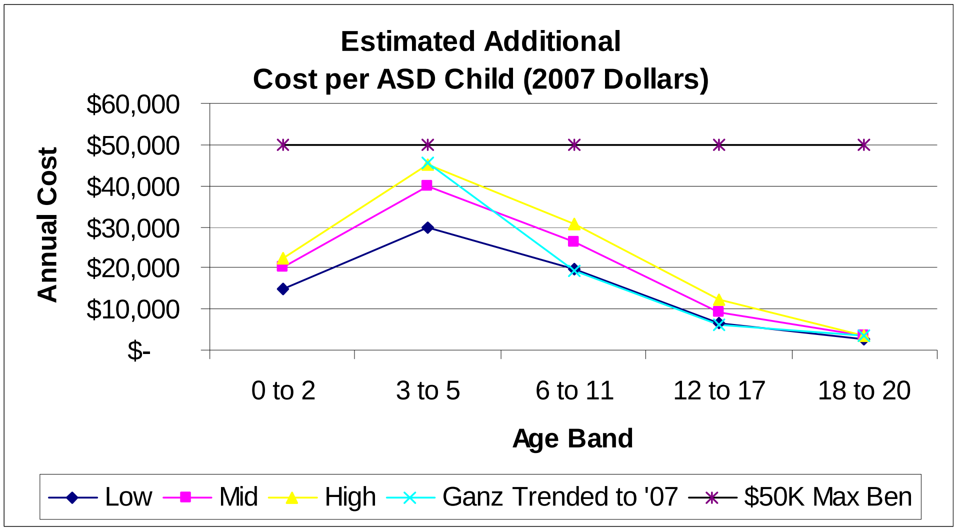
Intensity of Services by Age – As noted previously, the Ganz study and the Virginia JLARC analysis both indicated that ABA-associated costs peaked at preschool ages and then decreased for older children. We would also anticipate relatively intensive usage from children two years or younger receiving treatment, but not as intensive as the usage for ages three to five, which we would expect to be highest. In fact, our model assumes that annual costs will be 60%, 80%, and 90% of the $50,000 maximum for ages three to five. (These percentages represent the low, mid, and high estimates; for example, the low estimate would be 60% of the $50,000 mandated maximum, or $30,000; 80% represent an average annual cost of $40,000 and 90% represents an average annual cost of $45,000).

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

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

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

Table 4



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

Table 5

Low Estimate

Age Band	Age Band % of Population	ASD Treated Prevalence for Age Band	Cost per Treated Child	Mandate Cost per Insured MM
0 to 2	4.6%	0.09%	$15,000	$0.63
3 to 5	4.5%	0.27%	$30,000	$3.66
6 to 11	8.5%	0.65%	$19,659	$10.77
12 to 17	10.3%	0.41%	$6,758	$2.84
18 to 20	4.6%	0.41%	$2,625	$0.49
	32.4%			$18.39
			Admin Estimate	$1.49
			Admin % of Premium	7.50%
			Premium Increase Per Member	$19.89
			MD 2007 Small Group Premium per Member	$3,801
			Premium Increase % of Premium	**0.52%**

Mid Estimate

Age Band	Age Band % of Population	ASD Treated Prevalence for Age Band	Cost per Treated Child	Mandate Cost per Insured MM
0 to 2	4.6%	0.14%	$20,000	$1.25
3 to 5	4.5%	0.41%	$40,000	$7.33
6 to 11	8.5%	0.67%	$26,212	$14.81
12 to 17	10.3%	0.53%	$9,011	$4.95
18 to 20	4.6%	0.53%	$3,499	$0.85
	32.4%			$29.20
			Admin Estimate	$3.24
			Admin % of Premium	10.00%
			Premium Increase Per Member	$32.44
			MD 2007 Small Group Premium per Member	$3,801
			Premium Increase % of Premium	**0.85%**

High Estimate

Age Band	Age Band % of Population	ASD Treated Prevalence for Age Band	Cost per Treated Child	Mandate Cost per Insured MM
0 to 2	4.6%	0.27%	$22,500	$2.82
3 to 5	4.5%	0.54%	$45,000	$10.99
6 to 11	8.5%	0.67%	$30,455	$17.21
12 to 17	10.3%	0.67%	$12,153	$8.35
18 to 20	4.6%	0.67%	$3,499	$1.06
	32.4%			$40.44
			Admin Estimate	$5.78
			Admin % of Premium	12.50%
			Premium Increase Per Member	$46.22
			MD 2007 Small Group Premium per Member	$3,801
			Premium Increase % of Premium	**1.22%**

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

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

Table 6: Summary of Cost Estimates for Autism Benefits

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

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Coverage of In Vitro Fertilization

Insurance Article15-810, Annotated Code of Maryland, prohibits a health insurer, non-profit health service plan, or HMO (carrier) from refusing to issue a policy providing in vitro fertilization (IVF) benefits after: (1) an applicant is tested for infertility; or (2) a test performed on an applicant results in a diagnosis of unexplained infertility or a similar diagnosis. In addition, Section 15-810(b)(3) of the mandate states that benefits must be provided for outpatient expenses arising from IVF procedures if the patient and/or the patient's spouse have a history of infertility of at least two years, or the infertility is associated with endometriosis, exposure to diethylstilbestrol (DES), blockage or removal of fallopian tubes, or abnormal male factors.

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

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

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

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

(3) Women who have experienced a miscarriage, or a limited number of miscarriages who could potentially meet the two-year infertility requirement under the current mandate, but who would meet it sooner under the proposed mandate.

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

Medical Impact

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

- **Does the medical community recognize IVF as being effective in treating patients with a history of miscarriages?**

- **Is IVF generally recognized by the medical community, as demonstrated by a scientific and peer review of literature?**

- **Is IVF available and utilized by treating physicians?**

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

A miscarriage is commonly defined as the loss of a fetus within the first 20 weeks of pregnancy and may result from a variety of causes. Chromosomal problems, uterine abnormalities, hormonal issues, immune system problems, and infections are among the main causes. These factors also top the list for causes attributed to repeat miscarriages.[55]

Additionally, women with the following characteristics are at a greater risk of miscarriage.[56]

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

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

[56] www.umn.edu: University of Maryland Medical Center, Miscarriage. http://www.umm.edu/altmed/articles/miscarriage-000108.htm

According to the American College of Obstetricians and Gynecologists (ACOG): *Miscarriage is the most common type of pregnancy loss. Studies reveal that anywhere from 10-25% of all clinically recognized pregnancies will end in miscarriage. Chemical pregnancies may account for 50-75% of all miscarriages. This occurs when a pregnancy is lost shortly after implantation, resulting in bleeding that occurs around the time of her expected period. The woman may not realize that she conceived when she experiences a chemical pregnancy.*[57] Due to the nature of chemical pregnancies, we would not anticipate that they would have a significant impact on IVF eligibility under the current or proposed criteria, since they most likely would not have been documented by medical professionals or carriers.

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

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

One statistic that suggests that IVF should generally not be automatically covered is that even without treatment, women who have had multiple miscarriages have a 60 to 70 percent chance of a successful pregnancy.[58] The decision to undergo IVF treatment or cover it should be taken very seriously based on the potential risks associated with multiple births which include greater risk of premature birth, low birth weight and birth defects, as well as increased risks to the women, including high blood pressure and postpartum depression. [59]

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

[58] Mayo Clinic Staff. “Pregnancy: Understanding Miscarriage.” January 23, 2008. http://www.mayoclinic.com/health/miscarriage/PR00097

[59] Medical News Today. “Wall Street Journal Examines Persistent Multiple Births After IVF As Doctors Ignore Guidelines.” October 10, 2005. http://www.medicalnewstoday.com/articles/31784.php

Additionally, studies indicate that 30% to 40% of pregnancies with three or more births in the U.S. occur due to the implantation of more than the recommended number of embryos during IVF.[60] In the opinion of Mercer's medical staff, "Front loading" and use of multiple embryo implants raises medical and ethical issues. For example, if four embryos survive, would the patient and physician contemplate the possibility of selective harvesting? Although the likelihood of success increases with multiple implants, indeed there is a significant price to pay from the added costs and compromised outcomes that accompany multiple gestations.

In theory women who have had recurrent miscarriages would be most likely to seek IVF treatment under the proposed mandate, although there could also be another category or women whose age makes conceiving more difficult who may want to go directly to IVF after a single miscarriage. An underlying condition reducing the likelihood that a pregnancy would result in a live birth could manifest itself through recurrent miscarriages which are a serious problem for a small percentage of women. In many cases there is likely a persistent underlying cause for pregnancy loss in a portion of the women who have experienced recurring miscarriages.[61] Women who have had multiple miscarriages are encouraged to have testing done to determine the underlying cause. Discovering the underlying cause allows for treatment to prevent future miscarriages.

The overwhelming majority of procedures used to treat recurrent miscarriages do not include IVF. Due to the invasive nature and emotional stress of IVF, most doctors would recommend other treatments, and the mandate requires the use of other treatments if they are covered under the insurance contract. However, under certain circumstances, IVF appears effective in treating recurrent miscarriages. In 3% – 5% of all recurrent miscarriages, a form of IVF treatment known as pre-implantation genetic diagnosis can be used to treat couples with chromosomal abnormalities from either the male or the female – where the woman may be able to conceive, but the chromosomal abnormality causes the pregnancy to terminate.[62] IVF allows doctors to examine an embryo for chromosomal abnormalities before it is placed back into the woman.[63]

According to the Centers for Disease Control's *2005 ART Report*, 70,068 advanced reproductive treatment (ART) cycles were performed in the US in 2005 on women who had not previously given birth. (Note that ART and IVF are generally synonymous). Of those cycles, 27% were reported by women who had one or more previous miscarriages. An analysis of the success rates showed that women with one or more previous miscarriages were as likely to have a live birth as women without a history of miscarriages. Thus, ART procedures are currently being performed on women with a history of one or more miscarriages, and the success of those procedures does not appear to be hindered by a history of miscarriage.[64]

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[60] Ibid

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

[62] Ibid

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

[64] Centers for Disease Control. "2005 ART Report." 35. October 2007. http://www.cdc.gov/art/art2005/download.htm

According to the Centers for Disease Control and Prevention (CDC), a woman's age is the most important factor in the success of IVF. The older the woman, the less likely IVF will result in a live birth. This is especially true for women over age 40. A study by the CDC shows that 37% of ART cycles among women under age 35 resulted in live births, while only about 16% of cycles among women age 40 resulted in live births. This percentage decreases about 3% - 4% each year after age 40. Women who have had fertility problems and at least one miscarriage would be eligible to receive IVF treatment earlier than the current mandate provides. This could be expected to increase the probability of a successful IVF cycle for older women, particularly for women over age 40.[65]

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

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

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

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

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

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

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[65] Ibid

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

Social Impact

In this section, we address the following:

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

The CDC is required to oversee all advanced reproductive treatments (ART). In 2008, it released the results for cycles that began in 2005. The report shows that, from a reported 422 clinics, there were 92,405 cycles.[66] Comparing this with the 6.1 million women with infertility problems, the number and percentage of infertile women who choose some form of ART is relatively small. Likewise, utilization for the entire population is even smaller.[67]

In Maryland, of an estimated 740,000 women of child-bearing age[68] with employer-based coverage, the number of CDC-reported cycles was 4,078 in 2005.[69] This would indicate an incidence of approximately 6 per 1,000 women of child-bearing age, or 1 per 1,000 for all members. In either case, the benefit would be used by a small portion of the

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[66] Ibid, 85

[67] National Center for Health Statistics. Infertility. http://www.cdc.gov/nchs/FASTATS/fertile.htm

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

[69] Centers for Disease Control, 280-286

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

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

In general, carriers do not recognize infertility treatment as medically necessary. Although there may be health effects associated with infertility, and the lack of access to infertility treatment may contribute to mental health issues involving stress or depression, most carriers would consider infertility treatment a choice, rather than a necessity, as there are no direct medical consequences for people who do not seek IVF treatment. Regardless of necessity, we would also question the appropriateness of mandating coverage of IVF for individuals when there is no medical evidence to suggest that IVF would result in a better outcome than other means who potentially have IVF treatments covered by the mandate. Some have asserted that the urgency for curing infertility is rather low compared with other medical priorities.[70]

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

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

Financial Impact

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

The commonly accepted definition of infertility is 12 months or more of unprotected intercourse without pregnancy,[71] and the current provision in Section 15-810(b)(3) of the Insurance Article states that the duration of infertility must be at least two years (or the infertility must be associated with certain factors) for benefits to be provided. Since Section 15-810 already requires insurers to cover IVF for beneficiaries who meet the conditions in the current mandate, the additional cost of the proposed change would be for those groups of women identified in the first page of this report.

Data from the 2005 CDC ART study for Maryland indicated that 4,078 IVF cycles were undertaken at Maryland facilities in 2005.[72] We could make the assumption that the vast majority of these IVF treatments would be provided to insured individuals though the treatments may not be covered. We are also assuming that the cost per cycle ranges from $15,000 to $20,000 – which is consistent with the Department of Legislative Services' *HB 701:Fiscal and Policy Note* – and that a woman undergoing IVF treatment would have 1.5 cycles per year, which is consistent with our prior MHCC in vitro analysis, conducted in 2002. We note that our analysis of cost impact is not nearly as sensitive to the per-cycle cost assumptions as it is to the uncertainty and necessary ranges around other assumptions related to the estimates of the number of treatments affected by the proposed mandate and the expected increase in IVF utilization.

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

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

(1) No effect (e.g., women who have one of the specified conditions - endometriosis, exposure to diethylstilbestrol (DES), blockage or removal of fallopian tubes, or abnormal male factors and would already be covered)

(2) Covered sooner (e.g., women who could meet the current two year requirement, but will meet it sooner by not considering miscarriage(s) in the two year period)

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[71] Definition of Infertility. http://www.medterms.com/script/main/art.asp?articlekey=3977

[72] Centers for Disease Control, 280-286

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

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

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

In addition, we need to consider additional costs that may be incurred for IVF treatments undertaken by women who would seek IVF due to the fact that it would be covered under the proposed mandate. We have based the estimates of the additional IVF cycles undertaken by developing a range of estimates for the increased IVF utilization based on a New England Journal of Medicine study of the difference in utilization when IVF is covered by insurance mandates versus when it is not.[73]

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

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

Table 7: Estimated Cost of Mandated In Vitro Benefits

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

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

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

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

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

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

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

Resources

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