UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

KENNETH BERGE, ET. AL,	)	
	)	
Plaintiffs,	)	Civil Action No. 10-373
	)	(RBW)
	)	
vs.	)	
	)	
UNITED STATES OF AMERICA, ET. AL,	)	
	)	
Defendant.	)	
	)	

SUPPLEMENTAL DECLARATION OF MICHAEL O'BAR

I, Michael W. O'Bar, declare under penalty of perjury as follows:

I. Responsibilities

1. I serve as the Deputy Chief, TRICARE Policy and Operations Directorate. I have held that position since August 30, 2009, when I was appointed to the Senior Executive Service of the United States Government. Previously, I served in an acting capacity beginning in April, 2008. I joined TRICARE Management Activity (TMA) in 2001 after spending 31 years as an active duty U.S. Navy aviator.

2. My duties include providing executive leadership on organizational, programmatic, operational, and policy matters pertaining to the worldwide management of TRICARE managed care and associated contracting functions as well as purchased care programs within the Military Health System (MHS), which is under the overall direction of the Assistant Secretary of Defense for Health Affairs (the ASD(HA)). I am responsible for ensuring that ongoing TRICARE purchased care operations are working smoothly and efficiently, that future needs are properly planned for, including policy for the introduction of new best business practices, technologies and approaches to existing and future programs.

3. I supervise two subordinate directorates: Acquisition Management and Support (AM&S) and TRICARE Policy and Operations. I provide senior executive direction over the development and execution of TRICARE policies, healthcare benefits and reimbursement systems, TRICARE healthcare contract operations, TRICARE and other healthcare program requirements, and TRICARE acquisition management and support. I serve as the Program Manager for the acquisition of major healthcare programs and initiatives and, as such, provide executive leadership for the acquisitions.

4. In addition, I participate in the development, formulation, implementation, and advocacy of healthcare operational policies, MHS transformation, and program objectives of critical importance to the goals of the Secretary of Defense. I am responsible for coordinating resolution of programmatic and operational issues raised by the three TRICARE Regional Offices and coordinating resolution of programmatic and operational overseas issues raised by the three TRICARE Area Offices along with coordinating the management of the overseas healthcare delivery contract.

5. Furthermore, I provide senior executive direction to address and resolve issues and requirements resulting from new or modified legislation, regulations and/or court orders that may impact the delivery of health care within the MHS. These are complex in nature and may have long-range implications. They include policy, medical benefit, beneficiary eligibility, enrollment options, efficiencies, fees, and costs.

II. Immediate Compliance with Court Order to Cover ABA under the Basic Program

6. In compliance with the Court's Order of July 26, 2012, the Assistant Secretary of Defense for Health Affairs (ASD(HA)) immediately directed TMA to develop and issue contract modifications to the TRICARE regional Managed Care Support Contractors (MCSCs) to implement coverage of ABA as a medical benefit under the TRICARE Basic Program.

7. Specifically, DoD instructed its contractors on July 27, 2012, orally, and in written communication on July 30, 2012, that no claims for ABA coverage for ASD should be denied under the Basic Program but should rather be held in abeyance until DoD could provide further clarification.

8. DoD provided the initial clarification with interim guidance on August 10, 2012, that authorized coverage for ABA under the Basic Program so long as the provision of care for each particular beneficiary was consistent with DoD's regulatory standards for Basic Program coverage, with the understanding that additional implementing guidance would be forthcoming in the near future to ensure compliance with all applicable TRICARE guidelines that would now apply to the provision and clinical management of ABA as a medical benefit under the TRICARE Basic Program.

9. For purposes of the initial guidance, and in consideration of the restrictions of who qualifies as a TRICARE Basic Program provider under the applicable TRICARE guidelines as listed in 10 U.S.C. 1079(a)(13) and 32 C.F.R. § 199.6(c), DoD determined in its August 10, 2012, guidance that only masters-level Board Certified Behavior Analysts (BCBAs) or doctoral-level BCBA-Ds may provide ABA as a Basic Program benefit.

10. In addition to providing coverage under the Basic Program, DoD also noted in its interim guidance that it would continue to provide reimbursement for ABA reinforcement for active duty family members as a non-medical benefit under the Extended Care Health Option (ECHO) Autism Demonstration, authorizing non-medical providers to provide one-on-one ABA reinforcement as a supplement to the ABA provided by masters-level BCBAs or doctoral-level BCBA-Ds under the Basic Program.

11. In concert with issuing its initial interim guidance on August, 10, 2012, TMA's Policy and Operations Directorate, working with the Office of the Chief Medical Officer, commenced an extensive effort to refine the interim ABA Coverage Guidance in order to comply with other applicable TRICARE Basic Program guidelines.

III. Impact of Section 705 of NDAA FY2013 on TRICARE Coverage of ABA

12. On January 2, 2013, the President signed into law the National Defense Authorization Act (NDAA) for Fiscal Year 2013, which provides further authority for TMA to expand ABA coverage and review the delivery of such coverage.

13. Section 705 of NDAA FY2013 authorizes TMA to establish a one-year ABA Pilot to expand coverage of ABA reinforcement to include non-active duty family members (NADFMs) while continuing coverage of ABA provided by masters-level Board Certified Behavior Analysts (BCBAs) or doctoral-level BCBA-Ds under the Basic Program for all beneficiaries, and ABA reinforcement under ECHO Autism Demonstration for active duty family members (ADFMs), consistent with the Interim ABA Coverage Guidance of August 10, 2012.

14. Section 705 of NDAA FY2013 requires DoD to submit a report to Congress that includes: (1) an assessment of the feasibility and advisability of establishing a cost share option, (2) a comparison of providing such treatment under ECHO and other TRICARE programs, and (3) any recommendations and information the Secretary considers appropriate. In view of this language, the metrics outlined in the pilot program speak to the spirit and intent of the legislation and have the potential to provide valuable information to the overall discussion of the value of this behavioral intervention. The Department will submit a preliminary report to the House and Senate Armed Services Committees in December 2013, concerning the one-year ABA Pilot, with a final report to follow upon completion.

15. TMA has issued guidance in the form of a Common Letter dated July 18, 2013, to the TRICARE Managed Care Support Contractors to implement statutorily required ABA Pilot program effective July 25, 2013.

IV. TRICARE Compliance with Section 705 of NDAA FY2013

16. As of the January 2, 2013, signing of the NDAA FY2013 into law by the President, the efforts of TMA's Policy and Operations Directorate, working with the Office of the Chief Medical Officer, to refine the interim ABA Coverage Guidance in order to comply with other applicable TRICARE Basic Program guidelines were expanded to also address the requirements of Section 705 of NDAA FY2013. After coordinating the proposed Manual Changes with the MCSCs and numerous Directorates, TMA issued revised interim guidance to its MCSCs in June 25, 2013, to go into effect July 25, 2013. The six-month period required to design and implement this complex new benefit compares favorably with the amount of time needed to enact a number of other new TRICARE benefits specified in previous National Defense Authorization Acts. During the period, pertinent clinical, programmatic, fiscal, operational, contractual, and legal considerations were identified, reviewed, and integrated to develop the new benefit.

17. Subsequent to TMA issuing preliminary TRICARE Manual Changes on June 25, 2013, to assist the MCSCs in implementing the ABA Pilot and related TRICARE autism coverage changes for a July 25, 2013 start, the ASD(HA) clarified the nature and scope of the ABA Pilot on July 17, 2013. In order to sustain appropriate access to ABA while evaluating the options for ABA coverage long-term, and while addressing the congressional requirements of NDAA FY2013, TMA's revised interim ABA coverage guidance, transmitted to the MCSCs by TMA Common Letter of July 18, 2013 (attached as Attachment A), provides that:

    a. All active duty family members (ADFMs) will continue under the TPM Change 73 of Aug 10, 2012, "Interim ABA Coverage Guidance". They receive ABA under the Basic Program and ABA reinforcement under the ECHO Autism Demo based solely on an ASD diagnosis and seeing a BCBA, or more qualified provider, for Basic Program services; they can see a Board Certified assistant Behavior Analyst (BcaBA) or ABA Tutor under the ECHO Autism Demo for ABA reinforcement -- i.e., the status quo.

    b. Any non-active duty family members (NADFMs) will continue under the TPM Change 73 of Aug 10, 2012, "Interim ABA Coverage Guidance". They get ABA under the Basic Program based solely on an ASD diagnosis and seeing a BCBA or above for Basic Program services; however, they do not qualify for ABA **reinforcement under ECHO -- i.e., the status quo. NADFMs are TRICARE-eligible** dependents of Retirees and Reserve Component members, and those in the Continued Health Care Benefits Program (CHCBP) (*i.e.*, DoD's version of COBRA coverage).

    c. Any NADFMs who wish to participate in the pilot to reinforce and supplement the ABA they now receive under the Basic Program must meet the requirements outlined in TPM, Change 90 published June 25, 2013 as well TOM, Change 101 published on June 25, 2013. This will allow evaluation of the ABA Pilot, per Section 705 of NDAA FY2013, and consideration of the impact of psychometric testing and other assessment/follow-up requirements as an impediment/barrier to access for ABA and/or ABA reinforcement. NADFMs will pay a 10% cost share for ABA reinforcement under the ABA Pilot (regardless of sponsor status or their Basic Program option), with a $36,000 annual cap comparable to the ECHO annual cap.

V. Further Review of ABA Coverage Under the Basic Program

18. The ASD(HA), acting in his dual-hatted capacity as Director TMA, issued an interim ABA Coverage Determination on June 28, 2013 (attached as Attachment B), reaffirming TRICARE's October 19, 2010, conclusion that ABA is not by its nature medical care nor is it proven under the TRICARE regulations to be covered as medical care apart from the authority provided by the NDAA for FY 2013. The final determination will consider experience under the ABA Pilot, as relevant to the management of ABA as a TRICARE benefit, and any other pertinent new information to inform the status of ABA as medical, and if so as to whether it is proven.

19. At this date, TRICARE authorizes non-medical providers to provide one-on-one ABA reinforcement as a supplement to the ABA provided by masters-level BCBAs or doctoral-level BCBA-Ds under the Basic Program. ABA reinforcement may now be covered for active duty family members under the ECHO Autism Demonstration when supervised by BCBAs or BCaBAs and, when supervised by BCBAs, under the ABA Pilot (per Section 705 of NDAA FY2013) for non-active duty family members.

20. TMA's authority for the ABA Pilot expires after July 24, 2014.

21. TMA has authority to continue the ECHO Autism Demonstration past its current expiration date of March 14, 2014.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on: July 26, 2013.

Michael W. O'Bar

Michael W. O'Bar

Attachment A

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
HEALTH AFFAIRS
16401 EAST CENTRETECH PARKWAY
AURORA, COLORADO 80011-9066

TRICARE
MANAGEMENT ACTIVITY

13-CODAA-003785 July 18, 2013

Mr. Orie T. Mullen, Jr.
President, Humana Military
Humana Government Business, Inc.
500 W. Main Street
Louisville, KY 40202

Subject: Clarification of Implementation of National Defense Authorization Act (NDAA), Section 705, Pilot Program for the Treatment of Autism Spectrum Disorder, Including Applied Behavior Analysis (ABA)

Reference: Contract Number HT94002-11-C-0003
Contract Modification Numbers P00227; P00333; P00470

Dear Mr. Mullen:

This letter advises that TMA has received concerns from our active duty beneficiaries as well as your feedback on the implementation of the ABA Pilot. Beneficiaries have expressed significant apprehension that the new policy places added requirements on the provision of ABA that are overly burdensome and may be difficult to meet. Most concerning to our active duty beneficiaries is that the July 25, 2013 implementation date will create a gap in care for some beneficiaries whose current authorizations are expiring now or will expire shortly after the July 25th date. We understand these beneficiaries may not have had an opportunity to obtain the ABA assessment, testing, and treatment plans that are required under the change to obtain continued care authorizations.

In light of these concerns, the Assistant Secretary of Defense (Health Affairs) has directed that for all active duty family members, claims for ABA will continue to be paid in accordance with the guidance provided in TPM; Change 73, published on August 10, 2012. In addition, active duty family members may continue to receive ABA services under the provisions of the Extended Care Health Option Enhanced Access to Autism Services Demonstration in accordance with TOM; Change 68 published January 11, 2012.

A non-active duty family member currently receiving ABA under the TRICARE Basic Program needs a diagnosis and standardized testing in accordance with the requirements published on June 25, 2013, only if he/she wants ABA reinforcement services in the ABA Pilot. In the meantime, we will continue to pay for their TRICARE

Basic Program ABA services in accordance with the guidance provided in TPM, Change 73, published on August 10, 2012.

This direction will remain in force until the conclusion of the ABA Pilot or until further notice. I request you take the appropriate actions necessary to implement this direction and inform your provider network accordingly. Any required changes to the TRICARE manuals will be forthcoming. Please direct any questions about this letter, in writing, to your Contracting Officer's Representative (COR).

Sincerely,

William H. Coffenberry
Contracting Officer

cc:
William Thresher, Regional Director
Beatrice De Los Santos, South Region ACO
George Mitchell, Humana
Katherine Bennett, Humana
Kevin Link, Humana
Jane Carr, Humana
Cindy Roegner, TMA-PI
Maj Timothy Morris, TRO-South, Aurora Ops Div.
Ken Reid, TRO-South, Aurora Div.
John Meeker, Chief, COD-A
Rita Franks, COD-A Staff Assistant

Attachment B

MEDICAL BENEFIT DETERMINATION
FOR APPLIED BEHAVIOR ANALYSIS (ABA)
FOR TREATMENT OF AUTISM SPECTRUM DISORDERS (ASD)

Course of Action #1: That the Director, TMA, concur with one or both of the following Recommendations (#1 & #2):

Recommendation #1: That the Director, TMA, concur with the finding that the intervention of ABA as delivered by ABA practitioners does not meet the TRICARE definition of "medical" as defined in 32 C.F.R. § 199.2.

_____ Approve Date: 6/28/2013

_____ Disapprove Date: _____

Recommendation #2: That the Director, TMA, concur with the finding that ABA has not been shown by reliable evidence to meet the requirements of 32 C.F.R. § 199.4(g)(15) to be proven as medically or psychologically necessary or as appropriate medical care for ASD. The reliable evidence standard for cost-sharing required by 32 C.F.R. § 199.4(g)(15) has not been met, and claims for provision of ABA for treatment of ASD under the TRICARE Basic Program cannot be reimbursed except: (a) in compliance with the authority of a court order; or, (b) under the authority of a time-limited pilot mandated by Section 705 of NDAA FY 2013.

_____ Approve Date: 6/28/2013

_____ Disapprove Date: _____

Course of Action #2: That the Director, TMA, concur with the following Recommendation (#3):

Recommendation #3: That the Director, TMA, approves Recommendations #1 and #2 on an interim basis, but defers final decision pending reassessment based on experience under the Pilot and any other pertinent new information. During this interim period, TMA will continue ABA coverage under the Basic Program per existing policy.

_____ Approve Date: 6/28/2013

_____ Disapprove Date: _____

TRICARE MANAGEMENT ACTIVITY ASSESSMENT OF APPLIED BEHAVIOR ANALYSIS FOR AUTISM SPECTRUM DISORDERS

I. PURPOSE

This document summarizes the TRICARE Management Activity (TMA) review of the evidence regarding Applied Behavior Analysis (ABA) as a medically or psychologically necessary intervention for Autism Spectrum Disorders (ASDs), comprised of disorders under the category of Pervasive Developmental Disorders (PDDs) in the Diagnostic and Statistical Manual, Fourth Edition – Text Revision (DSM-IV-TR). This review focuses particularly on clinical peer-reviewed literature on ABA for ASD, including information provided to the Department from the Office of Senator Gillibrand and the findings of evidence reviews conducted external to the Department to determine the following:

> *Does the reliable evidence support a conclusion that ABA is proven as "medically or psychologically necessary" and that it is "appropriate medical care" for ASD as defined in 32 Code of Federal Regulations (C.F.R.), Section 199.2 and in accordance with the requirements of 32 Code of Federal Regulations (C.F.R.), Section 199.4(g)(15)?*

This review consisted of an internal review of the literature conducted by the Office of the Chief Medical Officer, TMA, and an external health technology assessment conducted by Hayes, Inc. Recent health technology assessments and published reports of national professional medical associations, national medical policy organizations, and national expert opinion organizations were also captured in these reviews.

Additionally, TMA addresses issues and concerns raised in the United States District Court of the District of Columbia opinion in *Berge vs. U.S.* of July 26, 2012, the central questions being:

(1) *Is ABA "medical" as defined in 32 Code of Federal Regulations (C.F.R.), Section 199.2?*

(2) *If considered "medical", is ABA "proven" for treatment of ASD under the reliable evidence standard [32 Code of Federal Regulations (C.F.R.), Section 199.4(g)(15)]?*

In addition to making a medical benefit determination within the scope of the agency's regulations, TMA seeks to address the specific concerns raised in the Court's opinion in this determination.

This document is organized around the following outline:

Appendix B. State Licensure of ABA Practitioners

II. RECOMMENDATIONS

Based on the findings noted in this report, it is recommended that in light of the medical literature, the Director, TMA, find that ABA for ASDs is not covered under the TRICARE Basic Program. As a primary Course of Action, the following two recommendations are submitted for consideration by the Director, TMA:

- **ABA as delivered by ABA practitioners does not meet the TRICARE definition of "medical" as defined in 32 C.F.R. § 199.2.**

(See page 64 under Section VI, "Summary and Recommendations," for an outline of the observations leading to this conclusion.)

- **ABA has not been shown by reliable evidence to meet the requirements of 32 C.F.R. § 199.4(g)(15) to be proven as medically or psychologically necessary or as appropriate medical care for ASD. The reliable evidence standard for cost-sharing required by 32 § C.F.R. 199.4(g)(15) has not been met, and claims for provision of ABA for treatment of ASD under the TRICARE Basic Program cannot be reimbursed except: (a) in compliance with the authority of a court order; or, (b) under the authority of a time-limited pilot mandated by Section 705 of NDAA FY 2013.**

(See page 65 under Section VI, "Summary and Recommendations," for an outline of the observations leading to this conclusion.)

However, given that Section 705 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2013 requires TRICARE to implement a pilot on the behavioral treatment of ASDs, to include ABA, the following secondary Course of Action is submitted for consideration by the Director, TMA:

- **That the Director, TMA, defer final decision on this medical benefit determination until the conclusion of the ABA Pilot and reassess this determination based on any relevant findings of the ABA Pilot; and, pending such determination, that TMA continue ABA coverage under the Basic Program per existing policy.**

III. BACKGROUND

Statement of the Issue

In October 2010, TMA conducted a review of the evidence for ABA as necessary treatment for ASD (*Assessment of Applied Behavior Analysis for Autism Spectrum Disorders*). The assessment found that ABA has not been shown by reliable evidence to meet the requirements of 32 C.F.R. 199.4(g)(15) to be proven as medically or psychologically necessary or as appropriate medical care for ASD. Thus, the assessment concluded there is no current authority for TMA to provide ABA coverage under the TRICARE Basic Program. These findings were consistent with external technology assessments that were conducted at that time (e.g., Hayes, Inc., 2010) and with the 2009 findings of the Defense Health Board, which had been asked by the Assistant Secretary of Defense for Health Affairs (ASD(HA)) to conduct an objective review of the evidence on ABA for ASD and advise the Department on this topic. The Defense Health Board's September 2009 memo to ASD(HA) recommended that TMA re-review the literature regarding ABA in two to three years' time. Dr. George Peach Taylor, Jr., Acting Director, TRICARE Management Activity, concurred with TMA's 2010 recommendation not to include ABA for the treatment of ASD as a medical benefit, but issued direction that TMA periodically revisit the published literature to determine if ABA meets the reliable evidence criteria as medically or psychologically necessary for treatment of ASD.

On June 21, 2012, Dr. Karen Guice, Principal Deputy Assistant Secretary of Defense for Health Affairs, (PDASD(HA)), testified before the Senate Armed Services Committee, Subcommittee on Military Personnel, at a hearing on Department of Defense (DoD) programs and policies to support military families with special needs. In the course of the PDASD(HA)'s testimony, Dr. Guice was asked to revisit TMA's 2010 assessment of ABA therapy, reviewing any new information that may have been published since 2010. Dr. Guice invited others to submit information if they had credible evidence or peer reviewed publications that would inform TMA about a different coverage decision. The Office of Senator Gillibrand subsequently provided the Department a collection of 30 documents compiled by Dr. Geraldine Dawson of the ASD advocacy organization, Autism Speaks, and Dr. Vera Tait of the American Academy of Pediatrics.

In the litigation over TRICARE coverage for ABA for ASD, on July 26, 2012, the U.S. District Court for the District of Columbia found in Berge vs. U.S. that TMA's *Assessment of Applied Behavior Analysis for Autism Spectrum Disorders,* dated 14 October 2010, was arbitrary and capricious. However, the U.S. District Court for the District of Columbia issued a new order and opinion on June 5, 2013, granting the Government's motion to vacate the injunction issued July 26, 2012, and it instead remanded the matter to the Department of Defense for further consideration under the law and regulations and in light of the Court's opinions regarding ABA coverage under TRICARE. Therefore TMA's current review focused on all published literature on ABA for ASD, including previously reviewed literature and literature that has been published

since TMA's October 2010 assessment, to determine if there is reliable evidence for TMA to cover provision of ABA for ASDs. To provide a thorough and objective assessment of ABA for ASD, TMA commissioned a separate external review of the literature, conducted by Hayes, Inc. This external health technology assessment was completed on November 27, 2012.

What are the Autism Spectrum Disorders?

ASD diagnoses are described under the Pervasive Developmental Disorder (PDD) category of the most current edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM) containing disorders that are usually first diagnosed in infancy, childhood, or adolescence, although sometimes those disorders are not diagnosed until adulthood. A diagnosis of ASD includes PDDs and their associated DSM, Fourth Edition, Text Revision, (DSM-IV-TR) diagnostic code: Autistic Disorder (299.00), Rett's Disorder (299.80), Childhood Disintegrative Disorder (CDD) (299.10), Asperger's Disorder (299.80), and Pervasive Development Disorder Not Otherwise Specified (PDDNOS) (including Atypical Autism) (299.80). The National Institute of Mental Health (NIMH, 2009) states that those five PDDs are more often referred to today as autism spectrum disorders (ASD).

These five DSM-IV-TR diagnostic codes are converted to corresponding codes in the currently used edition of the International Classification of Diseases, Clinical Modification manual (currently ICD-9 CM) as part of the claims process under TRICARE. The ICD-9 CM codes for the five ASDs are: Autistic Disorder 299.0, Rett's Syndrome 330.8 (found under "Other Specific Cerebral Degenerations"), Childhood Disintegrative Disorder 299.1, Asperger's Disorder 299.8 and Pervasive Developmental Disorder, Not Otherwise Specified (PDD NOS), to include Atypical Autism is 299.9.

[NOTE: The DSM-IV TR and the ICD-9 CM use the same numeric diagnosis codes for three of the five ASD Diagnoses (Autistic Disorder, Childhood Disintegrative Disorder, and Asperger's). The DSM IV-TR uses one code 299.80 to refer to Rett's Disorder, PDD and Asperger's Disorder whereas the ICD-9 CM designates a unique code for each diagnosis and therefore has a different code for Rett's and PDD.]

PDDs are characterized by severe and pervasive impairment in several areas of development: reciprocal social interaction skills, communication skills, or the presence of stereotyped behavior, interests, and activities. The qualitative impairments that define these conditions are distinctly deviant relative to the individual's developmental level or mental age. The Centers for Disease Control and Prevention (2010) stated that there is currently no cure for ASD.

Autistic Disorder

The essential features of Autistic Disorder are the presence of markedly abnormal or impaired development in social interaction and communication and a markedly restricted repertoire of activity and interests. The impairment in reciprocal social interaction is gross and sustained.

There may be marked impairment in the use of multiple nonverbal behaviors (e.g., eye-to-eye gaze, facial expression, body postures and gestures) to regulate social interaction and communications. There may be failure to develop peer relationships appropriate to developmental level that may take different forms at different ages. The impairment in communication is also marked and sustained and affects both verbal and nonverbal skills. There may be delay in, or total lack of, the development of spoken language. In individuals who do speak, there may be marked impairment in the ability to initiate or sustain a conversation with others or a stereotyped and repetitive use of language or idiosyncratic language. There may also be a lack of varied, spontaneous make-believe play or social imitative play appropriate to developmental level. Individuals with Autistic Disorder have restricted, repetitive, and stereotyped patterns of behavior, interests, and activities. There may be an encompassing preoccupation with one or more stereotyped and restricted patterns of interest that is abnormal either in intensity or focus; an apparently inflexible adherence to specific, nonfunctional routines or rituals; stereotyped and repetitive motor mannerisms; or a persistent preoccupation with parts of objects. Individuals with Autistic Disorder display a markedly restricted range of interests and are often preoccupied with one narrow interest (e.g., dates, phone numbers, radio station call letters). The disturbance must be manifest by delays or abnormal functioning in at least one (and often several) of the following areas: social interaction, language as used in social communication, or symbolic or imaginative play.

Rett's Disorder

The essential feature of Rett's Disorder is the development of multiple specific deficits following a period of normal functioning after birth. Individuals have an apparently normal prenatal and perinatal period with normal psychomotor development through the first 5 months of life. Between ages 5 and 48 months, head growth decelerates. There is a loss of previously acquired purposeful hand skills between ages 5 and 30 months, with the subsequent development of characteristic stereotyped hand movements resembling hand-wringing or hand washing. Interest in the social environment diminishes in the first few years after the onset of the disorder, although social interaction may often develop later in the course. Problems develop in the coordination of gait or trunk movement. There is also severe impairment in expressive and receptive language development, with severe psychomotor retardation. Data are limited to mostly case series, and it appears that Rett's Disorder is much less common than Autistic Disorder. This disorder has been reported only in females.

Childhood Disintegrative Disorder

The essential feature of Childhood Disintegrative Disorder is a marked regression in multiple areas of functioning following a period of at least 2 years of apparently normal development reflected age-appropriate verbal and nonverbal communication, social relationships, play, and adaptive behavior. After the first 2 years of life (but before age 10 years), the child has a clinically significant loss of previously acquired skills in at least two of the following areas:

expressive or receptive language, social skills or adaptive behavior, bowel or bladder control, play, or motor skills. Most typically, acquired skills are lost in almost all areas and individuals with this disorder exhibit the social and communicative deficits and behavioral features generally observed in Autistic Disorder. Although initial studies suggested an equal sex ratio, the most recent data suggest that the condition is more common among males.

Asperger's Disorder

The essential features of Asperger's Disorder are severe and sustained impairment in social interaction and the development of restricted, repetitive patterns of behavior, interests, and activities. The disturbance must cause clinically significant impairment in social, occupations, or other important areas of functioning. In addition, during the first 3 years of life, there are no clinically significant delays in cognitive development as manifested by expressing normal curiosity about the environment or in the acquisition of age-appropriate learning skills and adaptive behaviors (other than in social interaction). Finally, the criteria are not met for another specific Pervasive Developmental disorder or for Schizophrenia. This condition is also termed Asperger's syndrome. The impairment in reciprocal social interaction is gross and sustained. There may be marked impairment in the use of multiple nonverbal behaviors (e.g., eye-to-eye gaze, facial expression, body postures and gestures) to regulate social interaction and communication. There may be failure to develop peer relationships appropriate to developmental level that may take different forms at different ages.

Pervasive Developmental Disorder Not Otherwise Specified (Including Atypical Autism)

This category is used when there is a severe and pervasive impairment in the development of reciprocal social interaction associated with impairment in either verbal or nonverbal communication skills or with the presence of stereotyped behavior, interests, and activities, but the criteria are not met for other specific PDDs or other diagnoses. For example, this category includes "atypical autism" — presentations that do not meet the criteria for Autistic Disorder because of late age at onset, atypical symptomatology, or sub-threshold symptomatology, or all of these.

An important consideration for TMA's review of ABA for ASD is that the diagnostic criteria for ASD are anticipated to be radically revised with publication of the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V), expected in May of 2013.

What is Applied Behavior Analysis?

According to the "Model Act for Licensing/Regulating Behavior Analysts" (Sept, 2012):

> "'Practice of behavior analysis means the design, implementation, and evaluation of instructional and environmental modifications to produce socially significant improvements in human behavior. It includes the empirical identification of

> functional relations between behavior and environmental factors, known as functional assessment and analysis. Applied behavior analysis interventions are based on scientific research and the direct observation and measurement of behavior and the environment. Behavior analysts utilize contextual factors, motivating operations, antecedent stimuli, positive reinforcement, and other consequences to help people develop new behaviors, increase or decrease existing behaviors, and emit behaviors under specific environmental conditions. The practice of behavior analysis expressly excludes psychological testing, diagnosis of a mental or physical disorder, neuropsychology, psychotherapy, cognitive therapy, sex therapy, psychoanalysis, hypnotherapy, and long-term counseling as treatment modalities." (p. 3).

Frequently, references to applied behavior analysis or ABA are associated with the "Lovaas" model of applied behavior analysis because of the seminal works for advancing treatment of children with autism by Dr. O. Ivar Lovaas. Often cited is the Lovaas et al. (1987) publication wherein Dr. Lovaas re-states that medically and psychologically oriented therapies [for autism] have not proven effective in altering outcome (DeMyer, Hingtgen, & Jackson, 1981), and reports the results of his behavioral-intervention project that sought to maximize behavioral treatment gains by treating autistic children during most of their waking hours for many years. The project hypothesized that construction of a special, intense, and comprehensive learning environment for very young autistic children would allow some of them to catch up with their normal peers by first grade. The operative method of this therapy consisted of using reinforcement, which, as a last resort could take the form of an aversive technique (e.g., loud "no" or a slap on the thigh) to modify behavior by teaching imitation, expressive and early abstract language, interactive play with peers, and appropriate and varied expressions of emotions. Aversive consequences are no longer used, which limits the ability to generalize findings using Lovaas' techniques to current ABA methods.

The current model of intensive behavioral intervention (IBI), or early intensive behavioral intervention (EIBI), aims to teach social, motor, and verbal behaviors as well as reasoning skills using careful behavioral observation and positive reinforcement and prompting to teach each step of a behavior. Skills are broken down into small tasks, which are taught in a very structured manner, accompanied by praise and reinforcement. Undesirable behaviors are reduced by ignoring them or introducing more socially acceptable forms of behavior. (Berkovitz & Hofkosh, 2007)

The Early Start Denver Model (ESDM) is a comprehensive program based in part on ABA methodology along with developmental and relationship-based approaches.

TRICARE Coverage of ABA Under the Basic Program and the Extended Health Care Option (ECHO) for Medical and Non-Medical Services

TRICARE is not an insurance program. Rather, it is a statutorily-defined federal health benefits program for specific categories of beneficiaries. Care is delivered directly through Military Treatment Facilities (MTFs) and purchased under regional managed care support contracts. Title 10 United States Code Chapter 55 authorizes the TRICARE Program including:

- TRICARE Basic Program – the medical benefit for all eligible TRICARE beneficiaries
- The Extended Health Care Option (ECHO) – the supplemental services program only for Active Duty Family Members (ADFM)

The benefits are implemented through federal regulation (32 C.F.R. § 199) and the TRICARE Manuals, which are incorporated into the regional managed care support contracts.

The TRICARE Basic Program is a comprehensive health benefit plan offering a full array of medically necessary services to address the needs of all beneficiaries, including those with an ASD diagnosis. TRICARE's Basic Program provides: occupational therapy (OT) to promote the development of self-care skills; physical therapy (PT) to promote coordination/motor skills; speech and language pathology (SLP) to promote communication skills; child psychology to provide psychological testing and address emotional and mental health needs; child psychiatry to address psychopharmacological needs; comprehensive prescription drug benefit; and coverage of durable equipment (DE) and durable medical equipment (DME). The full range of medical specialties to address the additional medical conditions common to this population are covered.

Any TRICARE Basic Program (*i.e.*, medical) benefit must be **proven medically or psychologically necessary and appropriate care based on reliable evidence**, in accordance with 10 U.S.C. § 1079(a)(13) [imposing the "medically necessary" element], 32 C.F.R. § 199.4(g)(15) [implementing the "medically necessary" element and adding the "proven" element"] and 32 C.F.R. § 199.2 [adding the "appropriate" element by defining "appropriate medical care", and adding the "reliable evidence" standard for what is considered "proven"]. Additionally, providers of medical care under the Basic Program, including providers of behavioral medicine, must meet more stringent training, licensure and certification standards set forth in 32 C.F.R. § 199.6(c)(2)(i) and (ii) (authorized providers for "medical" care under the Basic Program) than are required for the additional services covered under ECHO per 32 C.F.R. § 199.6(e)(ii)(b) (authorized providers for coverage under ECHO).

By statute (10 U.S.C. 1079(e)) and regulation (32 C.F.R. § 199.5(a)), ECHO may only cover benefits that are not already covered benefits under the Basic Program. Coverage under ECHO requires a "qualifying condition," such as moderate or severe mental retardation, serious physical disability, or extraordinary physical or psychological condition including ASD. Coverage also requires enrollment in the Exceptional Family Member Program for the sponsor's Service. Congress thus gave DoD much more discretion in its coverage of ECHO benefits than it has

concerning medical benefits provided under the Basic Program. ECHO enables DoD to provide additional support services for Active Duty Family Members who are subject to frequent relocations to geographic locations that lack sufficient state resources for individuals with special needs. ECHO includes the authority to provide home health care supplies and services, respite care, training, special education, and other services. DoD has authority under ECHO to provide coverage of ABA as an "other service" to minimize the debilitating effects of ASD.

It is important to note that most services covered under ECHO are non-medical in nature. However, ECHO may cover medical treatments and therapeutic procedures that are not otherwise covered under the Basic Program – but only such medical treatments and therapeutic procedures for which the safety and efficacy have been established under the reliable evidence standard. Apart from the possibility of coverage of proven medical care otherwise not covered under the Basic Program in limited circumstances, ECHO for the most part covers any "other services and supplies as determined appropriate by the [Director, TMA], notwithstanding the limitations in [10 U.S.C. 1079(a)(13)]." These non-medical services are **not** subject to the Basic Program reliable evidence standard required by 32 C.F.R. § 199.4(g)(15) for medical care. Instead, such ECHO non-medical services as respite care and behavior modification need only be determined by the Director, TMA, to "assist in the reduction of the disabling effects of the ECHO-eligible dependent's qualifying condition."

Thus, coverage of a **medical service** under ECHO is limited to only such medical services that are (i) not otherwise covered under the Basic Program, and (ii) nonetheless are proven medically or psychologically necessary and appropriate care based on reliable evidence.

Coverage of **all other services** (*i.e.*, non-medical services) under ECHO need only be determined "appropriate" by the Director, TMA, to "assist in the reduction of the disabling effects of the ECHO-eligible dependent's qualifying condition." In practice, this means that any service determined by the Director, TMA, to be (i) not harmful to a beneficiary, and (ii) that provides some assistance with the reduction of the disabling effects of a qualifying condition. Such **non-medical services** are not subject to the far more stringent standards of proven efficacy required for covered **medical services**.

The TRICARE Basic Program specifically excludes certain services. In particular, "special education" is excluded from Basic Program coverage by 10 U.S.C. § 1079(a)(9). There is no specific statutory or regulatory exclusion of ABA per se. Thus, coverage of ABA must be authorized in accordance with either the Basic Program coverage requirements and limitations or the ECHO coverage requirements and limitations.

TRICARE Coverage of ABA under the Extended Health Care Option (ECHO)

In 2001, TRICARE began coverage of ABA for autism as "special education" under the Program for Persons with Disabilities (PFPWD). By law, "special education" was, and remains, excluded from Basic Program coverage, per 10 U.S.C. 1079(a)(9). In contrast, "special education" was

included as an authorized service under the PFPWD. As of September 2005, ABA continued to be covered as "special education" under the ECHO program, as the successor to the PFPWD.

In April of 2009 ECHO increased monetary government liability for benefits from $2500 monthly to $36,000 annually. The "Enhanced Access to Autism Services Demonstration" (ECHO Autism Demo) began on March 15, 2008, because accessing ABA services provided by the state had been problematic for ADFMs due to the frequent relocation of Military Service. The ECHO Autism Demo uses a tiered service delivery model in addition to the direct ABA services already provided by Board Certified Behavior Analysts (BCBA), who are master's level or above, and Board Certified Assistant Behavior Analysts (BCaBA), who have a bachelor's degree, as ECHO-only ABA providers (i.e., these providers did not meet the separate qualifications applicable to the Basic Program). Under the optional ECHO Autism Demo tiered service delivery model the assessment and planning functions were still provided by BCBAs or BCaBAs, but reinforcement services could be provided by ABA Tutors, who have no degree or certification, if supervised by a BCBA or BCaBA.

In October 2010, TMA conducted a review of the evidence for ABA as necessary treatment for ASD (Assessment of Applied Behavior Analysis for Autism Spectrum Disorders). The assessment found that ABA had still not been shown by reliable evidence to meet the requirements of 32 C.F.R. 199.4(g)(15) to be proven as medically or psychologically necessary or as appropriate medical care for ASD. The Director, TMA, did conclude, however, that the results of that assessment supported coverage of ABA under the authority of 10 U.S.C. § 1079(d)-(e) (the ECHO program) as an "other service", instead of the prior characterization as "special education". In particular, the October 2010 Assessment of Applied Behavior Analysis for Autism Spectrum Disorders noted (on page 21) that "there does not appear to be consensus on any one characterization", yet "a precise characterization of ABA is not required for coverage under ECHO as long as ABA: 1) does not meet the definition of a benefit under the medical program; and 2) can be reasonably characterized as a benefit under any one of the seven categories listed in 1079(e)(3)." Thus, from October 2010 until the subsequent Court Order of July 26, 2012 (discussed in detail below), TRICARE covered ABA provided generally under ECHO (*i.e.*, by BCBAs or above, and BCaBAs) or under the ECHO Autism Demo (*i.e.*, which authorized the services of supervised ABA tutors in addition to the services of BCBAs or above, and BCaBAs).

For FY 2012, 1802 beneficiaries received ABA provided by BCBAs or above, or BCaBAs under ECHO, and 4758 beneficiaries received ABA under the ECHO Autism Demo tiered service delivery model from tutors supervised by BCBAs or BCaBAs. Between FY09 and FY12, total ASD ECHO users nearly tripled from 2,292 to 6,560. Nearly 83 percent of this growth can be explained by growth in the ECHO Autism Demo.

Since 2008, DoD has continuously evaluated participation and satisfaction of the Autism Demo and provided semi-annual reports to Congress. Surveys indicated high parental satisfaction with

the services of the ECHO Autism Demo. Importantly, the clinical treatment effectiveness of ABA was not measured, because ABA was being provided as a non-medical service under ECHO and the ECHO Autism Demo and as such was not subject to the reliable evidence standard applicable to medical care under the Basic Program (or the limited categories of medical care excluded from/not otherwise covered by the Basic Program that may be covered under ECHO if they meet the reliable evidence standard per 32 C.F.R. § 199.5(d)(12), which in turn refers to 32 C.F.R. § 199.4).

Court-Order that TRICARE Cover ABA Under the Basic Program

In March 2010, a class action lawsuit (Berge vs. U.S.) was filed against the U.S. government, alleging TRICARE wrongfully refused to provide coverage for ABA to retiree family member beneficiaries. The plaintiffs claimed that TRICARE improperly excluded ABA from the TRICARE Basic Program medical benefits available to all TRICARE eligible beneficiaries. The lawsuit was brought before the Federal District Court for the District of Columbia and on July 26, 2012, the Court granted the plaintiffs' motion for summary judgment and denied the government's cross-motion. The Court enjoined TMA from denying coverage of ABA, on the basis that it is either non-medical or unproven medical care, for TRICARE Basic Program beneficiaries who otherwise qualify for reimbursement, and ordered that such reimbursement be provided in compliance with the applicable TRICARE guidelines for the expenses incurred to acquire ABA therapy.

Although the U.S. District Court for the District of Columbia issued a new order and opinion on June 5, 2013, granting the Government's motion to vacate the injunction issued July 26, 2012, and remanding the matter to the Department, TRICARE coverage of autism services will continue under revised interim guidance with the addition of services under the ABA Pilot authority enacted in the National Defense Authorization Act for Fiscal Year 2013, pending this ABA coverage determination. TRICARE Management Activity issued interim ABA coverage guidance under the TRICARE Policy Manual (TPM) Chapter 7, Section 3.18, which directed Managed Care Support Contractors (MCSC) to pay all beneficiary claims for ABA under the TRICARE Basic Program (with no annual cap) when the following criteria are met: presence of an ASD diagnosis made by an authorized ASD diagnosing provider; and, ABA provided by a BCBA or BCBA-D (i.e., a doctoral-level Board Certified Behavior Analyst) who is a TRICARE authorized provider. ABA services provided by BCBA or BCBA-D must be supervised by a TRICARE-authorized Primary Care Provider (PCP) or by a specialized ASD provider defined as: (a) physician board-certified or board-eligible in behavioral developmental pediatrics, neurodevelopmental pediatrics, pediatric neurology or child psychiatry; or, (b) Ph.D. clinical psychologist working primarily with children.

The ABA tiered service delivery model provided under the ECHO Autism Demo is not replicated under the TRICARE Basic Program, as the minimum educational preparation to qualify as a TRICARE authorized individual behavioral health provider under the Basic Program

is the master's degree. All of the behavioral health provider types authorized by TRICARE under the Basic Program (specifically: Clinical Psychologists, Clinical Social Workers, Certified Psychiatric Nurse Specialists, Marriage and Family Therapists, Pastoral Counselors, and both TRICARE-certified Mental Health Counselors and Supervised Mental Health Counselors) possess a minimum of a master's degree, in addition to a state license or state certification. Only BCBAs or BCBA-Ds possess a master's degree according to BACB Guidelines. Individuals with less than a master's degree, such as the bachelor's level BCaBAs or the ABA tutors, clearly do not meet the minimum education and training criteria to be TRICARE authorized behavioral health providers under the Basic Plan.

TRICARE coverage of autism services will continue under revised interim guidance with the addition of services under the ABA Pilot authority enacted in the National Defense Authorization Act for Fiscal Year 2013, pending final disposition of this ABA coverage determination. There is no immediate change to the Department's current course of action regarding autism services, which is: a) for all beneficiary categories, TRICARE is covering ABA services provided by Master's degree and above certified providers; b) for active duty families in the ECHO program, TRICARE is covering ABA services from supervised assistant providers at the bachelor's degree level and non-degree level tutors; and c) TRICARE will under the ABA Pilot authority begin in July 2013 to cover for non-active duty families services similar to those for active duty families in the ECHO program.

Office of Personnel Management Benefit Review Panel for ABA

The Office of Personnel Management (OPM) Benefit Review Panel evaluated the status of ABA for children with autism, summarized in an internal February 2012 report. Previously, ABA was considered to be an educational intervention and not covered under the Federal Employee Health Benefits (FEHB) Program. The Panel concluded that there is now sufficient evidence to categorize APA as a medical therapy. FEHB health care plans may now propose benefit packages which include ABA. OPM's decision stopped short of mandating that ABA coverage be provided by plans that participate in the FEHB Program. OPM stated that the evidence does not yet support mandating widespread, standardized dissemination, and OPM noted that that there is still insufficient knowledge about critical aspects of ABA including (but not limited to): specific treatment components with the greatest effect; treatment outcomes; optimal child characteristics; and scalable, exportable methods into "real world" settings. For the 2013 benefit year, only 67 of 230 (29%) FEHB plans offer coverage of ABA as a medical therapy.

Mandated State Insurance Coverage for ABA

Thirty-two states now mandate some coverage for ABA for ASDs. (See Appendix A for the table outlining detailed state requirements.) All but five states specify a monetary cap on benefits allowed for ABA. These caps range from $12,000 to $50,000 per year, and in some states the caps vary depending on the age of the child. For example, Arizona, Colorado,

Connecticut, Kansas, Kentucky, Michigan, Montana, New Hampshire, and Wisconsin have tiered annual limits such that younger children have a higher monetary cap than older children. The modal annual cap across states and age ranges is $36,000 per year, with eight states listing this uniform cap for all age ranges. Eight states require coverage up to $50,000 per year for some age groups. However, while in some states the annual monetary cap applies specifically to ABA, in most states the annual cap applies to all treatment for ASDs, including physical therapy, occupational therapy, speech therapy, pharmacotherapy, and other medical services in addition to ABA. Several states (Michigan, California, and Wisconsin) explicitly make provisions in the law that do not require any benefits to be provided that exceed the essential health benefits defined by the Institute of Medicine (IOM, Oct 2011) and required by the federal Patient Protection and Affordable Care Act.

Other variations in mandated coverage across states include which types of insurance programs must cover ABA. California, for example, explicitly specifies the coverage requirement applies to "every policy of disability insurance that covers hospital, medical, or surgical expenses in the state." Illinois similarly requires that "habilitative services" for Pervasive Developmental Disorders (which include ASDs) be provided by "all individual and group accident and health insurance or managed care plans." In other states, such as Iowa and Kansas, coverage for the diagnosis and treatment of autism spectrum disorders is required only for state employee health care plans.

All states that require provision of ABA demonstrate significant variations in coverage across age ranges. In Iowa, for example, coverage must be provided for individuals up to the age of 21, while in Kansas the coverage is required until age 19. Some states additionally set requirements for the age by which the diagnosis of an ASD must be made, such as South Carolina and West Virginia which state the child must be diagnosed by age eight.

State laws regarding coverage for ABA also vary greatly by which providers may order or prescribe ABA. As of November 2012, only seven states provide licensure for board certified behavior analysts. Eleven states explicitly specify that treatment for ASDs must be "medically necessary," and several states indicate that all therapy must be prescribed or ordered by a physician, or in some cases, a psychologist. In North Carolina, all ABA therapy must be supervised by a licensed clinical psychologist or licensed psychology associate, even if delivered by a licensed behavior analyst. Wisconsin and Maine both explicitly indicate that board certified behavior analysts may be compensated as providing or supervising ABA provided to beneficiaries, while most states do not ascribe such roles.

Although some sort of ABA coverage for ASD is mandated in more than half of the states, as outlined above, the details of the mandated coverage vary considerably from state to state. Additionally, unlike the TRICARE Basic Program benefit, which is largely an entitlement without capitation, most states impose annual monetary caps, but these vary from one amount to fourfold depending on the state and age range covered. Moreover, the services that count toward

the monetary cap vary from ABA exclusively to all medical, habilitative, and rehabilitative services for ASD. A third of the states that cover ABA specify that it must be "medically necessary," which may lead coverage decisions open to interpretation by individual insurance carriers. Even if the 32 states mandating coverage of ABA were more consistent or uniform in their requirements, TMA would still have to adhere to the reliable evidence criteria specified in 32 C.F.R. § 199.4(g)(15) instead of the coverage requirements of one or more states.

IV. TRICARE REGULATIONS AND POLICY

Statutory Authority

Title 10 United States Code Chapter 55, Section 10718 authorizes a uniform program—Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)—of medical benefits and dental care for members and certain former members of the Uniformed Services and their dependents. Administration of that chapter is the responsibility of the Secretary of Defense and certain other Secretaries (Section 1073). TRICARE is authorized at Sections 1079, 1086, and 1091 to contract with civilian providers for the health care program benefits authorized under Section 1077.

Regulations and Definitions

Title 32, Part 199 of the Code of Federal Regulations (32 C.F.R. §199) prescribes the guidelines and policies for the administration of the TRICARE Program.

32 C.F.R. § 199.1(d) specifies that the program authorized under Chapter 55, Title 10, United States Code, includes a program of medical benefits provided by the U.S. Government under public law to specified categories of individuals who are qualified for these benefits by virtue of their relationship to one of the seven Uniformed Services. Although similar in structure in many of its aspects, it is not an insurance program in that it does not involve a contract guaranteeing the indemnification of an insured party against a specified loss in return for a premium paid. Further, the program is not subject to those state regulatory bodies or agencies that control the insurance business generally.

Paragraph 32 C.F.R. § 199.1(e) specifies that the appropriated funds furnished annually by the Congress are used to adjudicate claims received under Part 199. That paragraph establishes that Part 199 is the regulatory guidance for administering the program, including setting out the benefits that are eligible for reimbursement.

The TRICARE regulation 32 C.F.R. § 199.2(b) (Definitions) defines the following terms:

"Medical"

The generally used term which pertains to the diagnosis and treatment of illness, injury, pregnancy, and mental disorders by trained and licensed or certified health professionals. For purposes of TRICARE, the term "medical" should be understood to include "medical, psychological, surgical, and obstetrical," unless it is specifically stated that a more restrictive meaning is intended.

"Medically or psychologically necessary"

The frequency, extent, and types of medical services or supplies which represent appropriate medical care and that are generally accepted by qualified professionals to be reasonable and adequate for the diagnosis and treatment of illness, injury, pregnancy, and mental disorders or that are reasonable and adequate for well-baby care.

"Appropriate medical care"

(i) Services performed in connection with the diagnosis or treatment of disease or injury, pregnancy, mental disorder, or well-baby care which are in keeping with the generally accepted norms for medical practice in the United States;

(ii) The authorized individual professional provider rendering the medical care is qualified to perform such medical services by reason of his or her training and education and is licensed or certified by the state where the service is rendered or appropriate national organization or otherwise meets CHAMPUS standards; and

(iii) The services are furnished economically. For purposes of this part, "economically" means that the services are furnished in the least expensive level of care or medical environment adequate to provide the required medical care regardless of whether or not that level of care is covered by CHAMPUS.

"Mental disorder"

For purposes of the payment of [TRICARE] benefits, a mental disorder is a nervous or mental condition that involves a clinically significant behavioral or psychological syndrome or pattern that is associated with a painful symptom, such as distress, and that impairs a patient's ability to function in one or more major life activities. Additionally, the mental disorder must be one of those conditions listed in the DSM-III.

"Major life activity"

Breathing, cognition, hearing, seeing, and age appropriate ability essential to bathing, dressing, eating, grooming, speaking, stair use, toilet use, transferring, and walking.

"Reliable evidence"

(1) As used in 32 C.F.R. § 199.4(g)(15), the term reliable evidence means only:

(i) Well controlled studies of clinically meaningful endpoints, published in refereed medical literature.

(ii) Published formal technology assessments.

(iii) The published reports of national professional medical associations.

(iv) Published national medical policy organization positions; and

(v) The published reports of national expert opinion organizations.

(2) The hierarchy of reliable evidence of proven medical effectiveness, established by (1) through (5) of this paragraph, is the order of the relative weight to be given to any particular source. With respect to clinical studies, only those reports and articles containing scientifically valid data and published in the refereed medical and scientific literature shall be considered as meeting the requirements of reliable evidence. Specifically not included in the meaning of reliable evidence are reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence or personal professional opinions. Also not included in the meaning of reliable evidence is the fact that a provider or a number of providers have elected to adopt a drug, device, or medical treatment or procedure as their personal treatment or procedure of choice or standard of practice.

Is ABA "Medical Care"?

The D.C. District Court's opinion of July 26, 2012 in *Berge vs. U.S.* and the 2012 OPM Benefit Review regarding ABA for ASD has placed the question of whether ABA is a "medical" (vs. an "educational" or "other") intervention front and center regarding provision of ABA. The Court found that the Department's rationale that ABA is not "medical" care under to its own regulatory definition to be arbitrary and capricious. The Court agreed with the plaintiffs in *Berge vs. U.S.* that the Department focused selectively on the "reliable evidence" regulation in determining whether ABA is "medical" care, and that the Department failed to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." (Motor Vehicle Mfrs. Ass'n of U.S.). Therefore, this review requires a deconstruction of the definition of "medical" as defined by 32 C.F.R. § 199.2(b) and analysis of its applicability to ABA for ASD. The following discussion seeks to address these concerns.

"Medical: The generally used term which pertains to . . ."

The Court in its opinion in Berge vs. U.S. (p. 22) discusses the meaning of the word, "medical," noting that "medical" can mean "relating to, or concerned with physicians or the practice of medicine or "requiring or devoted to medical treatment."

However, the TRICARE definition of "medical" is set forth at 32 C.F.R. § 199.2(b) as "The generally used term which *pertains to*. . . ." Referring to the same dictionary source as the court,

the Merriam-Webster Online Dictionary, (http://www.merriam-webster.com/dictionary), notes that "pertains" is defined as:

> 1: a (1): to belong as a part, member, accessory, or product (2): to belong as an attribute, feature, or function <the destruction pertaining to war> (3): to belong as a duty or right <rights that pertain to fatherhood> b: to be appropriate to something <which rule pertains?>
>
> 2: to have reference <books pertaining to birds>

The essential/primary meaning of "pertains" requires a nexus of belonging or appropriateness. The secondary meaning, "to have reference" is obviously too vague to have applicability in defining the term "medical." To illustrate that point, if one were to interpret "medical" as anything that pertains to the treatment of a condition as meaning anything that "has reference to" such treatment would arguably lead to the conclusion that laughter is medical under the adage of "laughter is the best medicine." It is commonly accepted that positive attitude, caring friends and family members, good nutrition, diet and exercise, are essential to sustain life and health, restorative, habilitative, and therapeutic. However, it strains reason to assert that "medical" encompasses such a broad range of components essential to the human condition, or that anything that one claims to be therapeutic must be considered "medical." Therefore, for TRICARE purposes one must apply the first meaning of "pertains" as "to belong to a part, member, accessory, or product."

". . . the diagnosis and treatment . . ."

Literature on ABA does not indicate that it is used for "diagnosis," which rules out this portion of the definition. The word, "treatment," does not have a global definition under TRICARE [i.e., under 32 U.S.C 199.2(b)]. "Treatment" is a generic term used in both medical and non-medical contexts. Consulting again the Merriam-Webster Online Dictionary, (http://www.merriam-webster.com/dictionary), "treatment" has the following meanings:

> 1a : the act or manner or an instance of treating someone or something : handling, usage <the star requires careful treatment> b : the techniques or actions customarily applied in a specified situation
>
> 2a : a substance or technique used in treating b : an experimental condition

Definition 1a refers to handling and usage, and is overly broad to place ABA as "treatment" in a medical context. Definition 1b refers to "techniques" or "actions" "customarily applied," and again is overly broad to place ABA as "treatment" in a medical context, as it could also mean, for example, application of techniques or actions in an educational setting or context. Definition 2 (both a and b) refer to use of the word "treatment" to characterize what is administered in the

process of "treating," i.e., the "technique" or the "experimental condition," so both definition 2a and 2b are not helpful in characterizing whether ABA is "treatment" in medical context.

The Merriam-Webster Online Dictionary goes on to provide eight examples of use of the word "treatment" that emphasize the distinction between "treatment" in a non-medical context (first five examples) and "treatment" in a "medical" or health care context (last three examples):

"Examples of TREATMENT

- We want to ensure equal treatment for everyone.
- The law requires humane treatment of prisoners.
- It's a complicated issue that requires careful treatment.
- The book's treatment of this important issue is unimpressive.
- Previous treatments of this topic have ignored some key issues.
- The patient required immediate medical treatment.
- She is receiving treatment for cancer.
- The drug has been approved as a treatment for AIDS."

Because the definition of "medical" in 32 C.F.R. § 199.2 links "diagnosis and treatment," it is clear that health care related context of "treatment" is what is implied in the definition of "medical." Because 32 C.F.R. § 199.2 does not define what is considered "treatment," TMA must assume from the linking of the word "treatment" with "diagnosis" that meaning pertains to the medical health care industry context in which TMA operates. Otherwise, TMA would be in the unsupportable position of acknowledging any activity (e.g., laying on of hands, health and wellness retreats), substance (e.g., organic food), or device (e.g., copper wrist bracelets) claimed to be "treatment" for a diagnosed illness or injury must be considered "medical."

The use of the word "treatment" with respect to provision of medical care presently has a functional meaning that is understood in the health care industry, and "diagnosis and treatment" are often linked in the practice of health care in medical coding, where an indicated diagnosis (designated by a diagnostic code from the ICD-9 CM or the DSM-IV-TR) is noted along with the coded procedure or treatment that was applied in the medical encounter to address the indicated diagnosis. This process of medical coding is how health care providers are paid and how provider workload and productivity is assessed and measured. It is also how TRICARE, as a payer of health care services, reimburses providers of health care via its contract with Managed Care Support Contractors (MCSC). Therefore, medical coding is integral to the process of "diagnosis and treatment" in health care practice, and it presents the appropriate context in which to understand the meaning of the word, "treatment" for TRICARE purposes. Specifically, "treatment" in medical practice is recognized and codified in the health care field through use of Current Procedural Terminology (CPT®) codes designated by the American Medical Association (AMA). According to the AMA website (http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/about-cpt.page?):

> "Current Procedural Terminology (CPT®), Fourth Edition, is a listing of descriptive terms and identifying codes for reporting medical services and procedures. The purpose of CPT is to provide a uniform language that accurately describes medical, surgical, and diagnostic services, and thereby serves as an effective means for reliable nationwide communication among physicians and other healthcare providers, patients, and third parties.
>
> "CPT descriptive terms and identifying codes currently serve a wide variety of important functions. This system of terminology is the most widely accepted medical nomenclature used to report medical procedures and services under public and private health insurance programs. CPT is also used for administrative management purposes such as claims processing and developing guidelines for medical care review.
>
> "The uniform language is also applicable to medical education and research by providing a useful basis for local, regional, and national utilization comparisons.
>
> "The fourth edition, published in 1977, represented significant updates in medical technology, and a system of periodic updating was introduced to keep pace with the rapidly changing medical environment. . . . Today, in addition to use in federal programs (Medicare and Medicaid), CPT is used extensively throughout the United States as the preferred system of coding and describing health care services."

CPT codes provide technical data for what is considered treatment within the medical health care industry context in which TRICARE operates. On a practical level, if there are no CPT codes established for a particular medical treatment, then TRICARE does not have a conventional means to pay for the treatment. To reimburse a service not recognized as a bona fide treatment with an established CPT code, TRICARE must literally invent or independently reclassify an existing CPT code (usually one not currently utilized) and then form a contractual agreement with TRICARE's MCSCs that use of this particular invented CPT code will used as the mutually recognized code for reimbursement for the particular service.

Reviewing the list of current CPT codes, TMA finds there are no CPT codes assigned for ABA or any procedure related to ABA. ABA is not a recognized "treatment" by the AMA's CPT Panel in the health care industry or in the medical context in which TRICARE operates, and TRICARE cannot reimburse any entity for ABA without inventing a CPT code on its own initiative for its own purpose. While TRICARE does not rely on CPTs as defining what is "medical," TMA's decision regarding interpretation of law and regulation as to what is "medical" in the case of ABA is not inconsistent with how the AMA treats ABA under the CPT.

Furthermore, TMA observes that the 32 states mandating coverage for ABA by insurance plans are also struggling with how to view ABA as "medical treatment" in absence of a CPT code for ABA. This is apparent in the great variation in non-standard usage of CPT codes adopted by various states and health plans for coding ABA. A CPT code of ABA would provide the medical

community with a credible source for recognition that ABA is viewed as medical treatment by the professional organization representing the practice of medicine (i.e., the AMA).

As noted in many cited references, ABA is not new, and has been used with children with ASD at least since publication of the Lovaas et al. study in 1987, which was 26 years ago. Therefore, the issue cannot be that ABA is so new that there has not been time to assign it an appropriate CPT code. Again consulting the CPT website (http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/cpt-process-faq.page?), the CPT Panel holds its deliberations three times a year at the CPT Editorial Panel meetings, and the parameters for establishing a new CPT code are as follows:

> "Medical specialty societies, individual physicians, hospitals, third-party payers and other interested parties may submit applications for changes to CPT for consideration by the Editorial Panel. The AMA's CPT staff reviews all requests to revise CPT including applications for new and revised codes.
>
> "Category I CPT codes consist of a five-digit CPT code and descriptor nomenclature which describes in detail the medical procedure or service. New or revised codes (including a previously assigned Category III code[s]) are assigned Category I status if the CPT Editorial Panel determines, based on the evidence submitted:
>
> •that the service/procedure has received approval from the Food and Drug Administration (FDA) for the specific use of devices or drugs;
>
> •that the suggested procedure/service is a distinct service performed by many physicians/practitioners across the United States;
>
> •that the clinical efficacy of the service/procedure is well established and documented in U.S. peer review literature;
>
> •that the suggested service/procedure is neither a fragmentation of an existing procedure/service nor currently reportable by one or more existing codes; and
>
> •that the suggested service/procedure is not requested as a means to report extraordinary circumstances related to the performance of a procedure/service already having a specific CPT code."
>
> [Source: http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/applying-cpt-codes.page?]

TMA pursued the question as to whether an application to assign a CPT code for ABA had ever been made to the CPT Panel. Referring to the May 2012 CPT Editorial Panel Meeting Summary of Panel Actions, Updated 6/22/2012 (http://www.ama-assn.org/resources/doc/cpt/summary-of-panel-actions-may-2012.pdf), there was an official request (Tab #25) for a CPT code(s) for "Applied Behavior Analysis" with the listed description of "Establishment of codes to describe applied behavioral analysis." However, the description of the CPT Editorial Panel action under Tab #25 was that the request was "Withdrawn." There is no other additional description as to the

reason why the request was withdrawn, but in practice, other CPT code applications may be withdrawn when it becomes apparent that the procedure in question will **not** meet one or more of the CPT Editorial Panel's criteria listed above. Whatever the reason for the withdrawal, the fact remains that there are no established CPT codes for ABA, therefore ABA is not a recognized medical, psychological, surgical, or obstetrical treatment by the AMA.

In considering that there are no established CPT codes for ABA, it is also relevant to note that applicants for assignment of CPT codes and other interested parties are barred from engaging in "lobbying" for or against code change requests. "Lobbying" means unsolicited communications of any kind made at any time (including during CPT Editorial Panel meetings) for the purpose of attempting to improperly influence either: the formal evaluation of or comments regarding a code change request; or, the voting by members of the Editorial Panel on a code change request.

Additionally, TRICARE is required by 32 C.F.R. § 199.14 to follow Medicare reimbursement rates for clinical health care services and to follow changes in law affecting Medicare regarding reimbursement for covered services, to the extent practicable. In addition to providing coverage for those 65 and older, Medicare applies to severely disabled children with autism who qualify for Medicare Part A based on disability. However, there is no Medicare national coverage determination for ABA as a medical treatment.

While Medicare has no specific ABA benefit for children with ASD, ABA services are typically provided to children through state Medicaid programs, mainly via Section § 1915 (c) of the Social Security Act ("Medicaid Home and Community-Based Waiver Program"), which is designed to help individuals with disabilities to continue living in the community and avoid institutionalization. A cursory review of states offering ABA services under Medicaid indicates that 34 states offer Autism services (including "applied behavior analysis" or "behavior interventions") under this Home and Community Based Services (HCBS) Waiver Program rather than under the Medicaid Health Plan. This allows the States to waive Medicaid rules regarding medical necessity. In this aspect, HCBS Waiver Programs are similar to the TRICARE ECHO program in that both programs provide services to mitigate the debilitating effects of a disability that are not otherwise covered under the health plan as "medical" care. This is further indication that TRICARE's interpretation of ABA being non-"medical" is consistent with how ABA is interpreted by many states.

In summary, because the word "treatment" in the 32 C.F.R. § 199.2 definition of "medical" is undefined, for TRICARE purposes the Agency looks to the healthcare industry context for meaning of "treatment" (taken from the linking of "diagnosis and treatment") in the "medical" definition. TRICARE does not recognize ABA as "treatment" in this context, and this is consistent with (a) the AMA's non-recognition of ABA as "treatment" as evidenced by the lack of a CPT code for ABA; (b) the lack of a Medicare national coverage determination for ABA under Medicare Part A for persons with disabilities; and, (c) the states' coverage of ABA under

the Medicaid Home and Community-Based Waiver Program instead of the Medicaid Health Plan.

". . . of illness, injury, pregnancy, and mental disorders . . ."

TRICARE regulations define "mental disorder" as "a nervous or mental condition that involves a clinically significant behavioral or psychological syndrome or pattern that is associated with a painful symptom, such as distress, and that impairs a patient's ability to function in one or more major life activities." Based on the description, ASD can be considered a "nervous or mental condition" and one "that involves a clinically significant behavioral or psychological syndrome or pattern". ASD also clearly "impairs a patient's ability to function in one or more major life activities". It is not necessarily clear that the behavioral or psychological syndrome or pattern "is associated with a painful symptom, such as distress". Many with ASD are non-verbal, making it difficult to ascertain the level of distress experienced by those with ASD. There is a growing "Autism rights movement" of individuals with autism who are not distressed by their condition and assert that Autism is not a disorder but simply a different "way of being" and interacting with the environment. Nevertheless, as many individuals with ASD are more or less non-verbal, TMA cannot confirm that they do not experience a painful symptom, such as distress, and it seems apparent that at least some individuals with ASD do often experience distress and likely would experience considerable distress if left to provide for themselves without assistance or protection. Therefore, ASD appears to meet the TRICARE definition of a mental disorder.

Autism Spectrum Disorders are considered "mental disorders" in the DSM-IV-TR under the heading of "Pervasive Developmental Disorders," but regarding the diagnostic criteria for ASD, it is relevant to note that this category of mental disorders will be significantly revised upon publication of the Diagnostic and Statistical Manual of Mental Disorder, Fifth Edition (DSM-V). Given the relatively few number of randomized clinical trials (RCTs) of ABA for treatment of ASD (discussed below), the fact that the diagnostic criteria are changing is relevant in evaluating treatment effectiveness to the extent that these studies focus on diagnostic impairment in the areas of communication, social and behavioral functioning as clinical outcomes. In other words, if the new DSM-V criteria result in a significant change in the population of individuals diagnosed with ASD (e.g, exclusion of those diagnosed with Asperger's Disorder, which is a less severe variant of ASD), then the potential generalizability of findings from studies based on DSM-IV ASD-diagnosed samples will likely be limited, particularly given the findings from several studies that factors related to less severely impaired children with ASD have more favorable outcomes from ABA interventions, such as IQ at intake, adaptive behavior composite score at intake, autism subtype, and autism severity (Eldevik et al., 2010; Makrygianni and Reed, 2010).

". . . by trained and licensed or certified health professionals."

Central to this portion of the 32 C.F.R. § 199.2(b) definition of "medical" is the question of whether providers of ABA are "trained and licensed or certified health professionals." According to the BACB Guidelines, ABA providers fall into three categories: Board Certified Behavior Analysts (BCBA), Board Certified Behavior Analysts with a doctorate (BCBA-D), Board Certified Assistant Behavior Analysts (BCaBA). ABA Technicians, although noted as essential in the "tiered delivery model" of ABA according to the BCBA Guidelines (2012), are not recognized credentialed practitioners by the BACB (cf. p. 7).

Individual authorized providers under TRICARE are tied to statute – 1079(a)(13) (in general), including physicians, dentists, and "allied health professionals" (e.g. clinical psychologists, clinical social workers, certified psychiatric nurse specialists) who are only authorized if they meet requirements established by regulation through the Secretary's authority to administer the program. These are individuals who are "authorized to assess or diagnose illness, injury, or bodily malfunction as a prerequisite for CHAMPUS cost-share of otherwise allowable related preventive or treatment services or supplies" per 32 C.F.R § 199.6(c)(1)(i).

Ancillary to physicians, dentists, and other authorized health professionals, TRICARE regulations establish a fourth category of "Extramedical individual providers" under 32 C.F.R § 199.6(c)(3)(iv), who are defined as "Individuals who do counseling or non-medical therapy and whose training and therapeutic concepts are outside the medical field, as specified in [32 C.F.R] Sec. 199.6 of this part" according to the TRICARE definition found in 32 C.F.R. § 199.2. It is important to note that extramedical individual providers of behavioral healthcare only provide behavioral counseling of a medically necessary nature (i.e., to treat a diagnosed mental health condition) as a medical benefit under the Basic Program. They are not reimbursed for otherwise "non-medical counseling" and "non-medical therapy" that is not medically necessary. Some of these extramedical individual providers (e.g., pastoral counselors, supervised mental health counselors) can only provide services to TRICARE beneficiaries under physician referral and supervision per 32 C.F.R. § 199.6(c)(2)(iv).

In its July 26, 2012, Order, the Court enjoined DoD from denying coverage for ABA "on the ground that ABA therapy is not a covered benefit under the TRICARE Basic Program" and instructed the agency to provide reimbursement for Basic Program beneficiaries "in compliance with the applicable TRICARE guidelines for the expenses incurred by qualified beneficiaries to acquire ABA therapy for their children" (p. 65). ABA was defined by the Court as "a specialized intervention administered by a professional with advanced formal training in behavioral analysis . . . nationally certified" by "the Behavior Analyst Certification Board" with "a master's degree and several hundred hours of graduate level instruction or mentored or supervised experience with another board certified behavioral analyst" p. 43. When the Court's Order went into effect, ABA had to be provided under the Basic Program and could no longer be provided in the ECHO program (due to the ECHO exclusion under 32 C.F.R. § 199.5(d)(1) that benefits allowed under the TRICARE Basic Program will not be provided through the ECHO). The Order went into effect immediately, and in complying with the Court's Order, TMA

authorized coverage under the Basic Program when rendered by those providers who, consistent with the Court's definition, (1) have current State license to provide ABA services; (2) are currently State-certified as an Applied Behavioral Analyst; or (3) where such State license or certification is not available, are certified by the Behavioral Analyst Certification Board (BACB) as a Board Certified Behavior Analyst (TRICARE Policy Manual, Chapter 7, Section 3.18).

Per 32 C.F.R § 199.6(c)(2)(iii), regarding provider education, training and experience requirements: "The Director, OCHAMPUS, or designee, may establish for each category or type of provider allowed by this paragraph (c) specific education, training, and experience requirements as necessary to promote the delivery of services by fully qualified individuals." TMA did not have the opportunity to define the specific education, training, and experience requirements for qualified ABA providers under the Basic Plan using TMA's usual Agency rulemaking process, as the Court order enjoined the DoD from denying coverage for ABA immediately upon issuance. Existing TRICARE authorized providers of behavioral health care (e.g., psychologists, social workers, mental health counselors) are generally not qualified to practice ABA according to the Court's description because very few of them have obtained BCBA certification. If TMA had only authorized those existing categories of behavioral health providers under 32 C.F.R. § 199.4(c) who also possess BCBA certification as providers of ABA, then virtually no TMA beneficiaries would have been able to receive ABA because of a lack of available providers. While TMA was able to successfully argue in opposition to the plaintiff's motion for reconsideration (10 Sep 2012) that ABA practitioners with lesser qualifications (i.e., BCaBAs and ABA tutors) clearly do not meet criteria to be TRICARE authorized providers, analysis of BACB certification requirements indicates that even BCBAs do not have the required qualifications to be "trained and licensed or certified healthcare professionals" under TRICARE.

First, with respect to licensing, Behavior Analysts are licensed only in 11 states currently (see Appendix B for a listing). TRICARE only recognizes licensed or certified health care professionals, and TRICARE relies on state oversight, via licensing of healthcare professions, to ensure quality and safety of health care services provided. TRICARE is national in scope, and ABA practitioners being only licensed in 11 states does not provide a sufficient preponderance of licensed practitioners for ABA to be considered "medical":

> (2) Conditions of authorization—(i) Professional license requirement. The individual must be currently licensed to render professional health care services in each state in which the individual renders services to CHAMPUS beneficiaries. Such license is required when a specific state provides, but does not require, license for a specific category of individual professional provider. The license must be at full clinical practice level to meet this requirement. A temporary license at the full clinical practice level is acceptable. [32 C.F.R. § 199.6(c)(2)(i)]

It is relevant to note that TRICARE looks to "certification" only as a secondary credential for jurisdictions that do not have a license:

> (ii) Professional certification requirement. When a state does not license a specific category of individual professional, certification by a Qualified Accreditation Organization, as defined in Sec. 199.2, is required. Certification must be at full clinical practice level. A temporary certification at the full clinical practice level is acceptable.

While TMA accepts certification in lieu of licensing, that allowance is to accommodate the practice of health care by qualified professionals in jurisdictions that do not offer licensing. As TRICARE is a healthcare delivery organization, however, this allowance presumes that the certification would be of bona fide health professionals and that the Qualified Accreditation Organization meets all of the requirements of 32 C.F.R. 199.2.

With respect to certification, the BACB Guidelines (2012) claim that "the formal training of professionals certified by the BACB is similar to that of other medical and behavioral health professionals" (p. 6). However, close investigation of the requirements to become certified as a BCBA indicates that ABA practitioners do **not** have training commensurate with TRICARE certified providers of medical or behavioral healthcare, and it is possible to become a BCBA without any clinical healthcare experience or exposure whatsoever.

ABA practitioners certified by the BACB are not among the currently recognized TRICARE authorized non-physician behavioral health providers. Behavioral heathcare professionals (other than psychiatrists) authorized by TRICARE must meet specific education and clinical supervision requirements, which are, by type of provider:

Allied Health Professionals

Clinical psychologist [32 C.F.R. § 199.6(c)(3)(iii)(A)]:

> (1) Possesses a doctoral degree in psychology from a regionally accredited university; and
>
> (2) Has 2 years of supervised clinical experience in psychological health services of which at least 1 year is post-doctoral and 1 year (may be the post-doctoral year) is in an organized psychological health service training program; or
>
> (3) As an alternative to paragraphs (c)(3)(iii)(A)(1) and (2) of this section is listed in the National Register of Health Service Providers in Psychology.

Certified clinical social worker [32 C.F.R. § 199.6(c)(3)(iii)(F)]:

> (1) Is licensed or certified as a clinical social worker by the jurisdiction where practicing; or, if the jurisdiction does not provide for licensure or certification of clinical social workers, is certified by a national professional organization offering certification of clinical social workers; and
>
> (2) Has at least a master's degree in social work from a graduate school of social work accredited by the Council on Social Work Education; and

(3) Has had a minimum of 2 years or 3,000 hours of post-master's degree supervised clinical social work practice under the supervision of a master's level social worker in an appropriate clinical setting, as determined by the Director, OCHAMPUS, or a designee.

NOTE: Patients' organic medical problems must receive appropriate concurrent management by a physician.

Certified psychiatric nurse specialist [32 C.F.R § 199.6(c)(3)(iii)(G)]:

(1) Is a licensed, registered nurse; and

(2) Has at least a master's degree in nursing from a regionally accredited institution with a specialization in psychiatric and mental health nursing; and

(3) Has had at least 2 years of post-master's degree practice in the field of psychiatric and mental health nursing, including an average of 8 hours of direct patient contact per week; or

(4) Is listed in a CHAMPUS-recognized, professionally sanctioned listing of clinical specialists in psychiatric and mental health nursing.

Certified mental health counselor [32 C.F.R. § 199.6(c)(3)(iii)(N)]:

(2) The requirements of this paragraph are that the CMHC, prior to January 1, 2015:

(i) Possess a master's or higher-level degree from a mental health counseling program of education and training accredited by the [Council for Accreditation of Counseling and Related Educational Programs] CACREP and must have passed the National Counselor Examination (NCE); or

(ii) Possess a master's or higher-level degree from a mental health counseling program of education and training from either a CACREP or regionally accredited institution and have passed the NCMHCE; and

(iii) Must have a minimum of two (2) years of post-master's degree supervised mental health counseling practice which includes a minimum of 3,000 hours of supervised clinical practice and 100 hours of face-to-face supervision. This supervision must be provided by a mental health counselor who is licensed for independent practice in mental health counseling in the jurisdiction where practicing and must be conducted in a manner that is consistent with the guidelines for supervision of the American Mental Health Counselors Association.

Extramedical Individual Providers

Certified marriage and family therapists [32 C.F.R. § 199.6(c)(3)(iv)(A)]:

(1) Recognized graduate professional education with the minimum of an earned master's degree from a regionally accredited educational institution in an appropriate behavioral science field, mental health discipline; and

(2) The following experience:

(i) Either 200 hours of approved supervision in the practice of marriage and family counseling, ordinarily to be completed in a 2- to 3-year period, of which at least 100 hours must be in individual supervision. This supervision will occur preferably with more than one supervisor and should include a continuous process of supervision with at least three cases; and

(ii) 1,000 hours of clinical experience in the practice of marriage and family counseling under approved supervision, involving at least 50 different cases; or

(iii) 150 hours of approved supervision in the practice of psychotherapy, ordinarily to be completed in a 2- to 3-year period, of which at least 50 hours must be individual supervision; plus at least 50 hours of approved individual supervision in the practice of marriage and family counseling, ordinarily to be completed within a period of not less than 1 nor more than 2 years; and

(iv) 750 hours of clinical experience in the practice of psychotherapy under approved supervision involving at least 30 cases; plus at least 250 hours of clinical practice in marriage and family counseling under approved supervision, involving at least 20 cases;

(3) Is licensed or certified to practice as a marriage and family therapist by the jurisdiction where practicing (see paragraph (c)(3)(iv)(D) of this section for more specific information regarding licensure); and

(4) Agrees that a patient's organic medical problems must receive appropriate concurrent management by a physician.

Pastoral Counselors [32 C.F.R. § 199.6(c)(3)(iv)(B)]:

(1) Recognized graduate professional education with the minimum of an earned master's degree from a regionally accredited educational institution in an appropriate behavioral science field, mental health discipline; and

(2) The following experience:

(i) Either 200 hours of approved supervision in the practice of pastoral counseling, ordinarily to be completed in a 2- to 3-year period, of which at least 100 hours must be in individual supervision. This supervision will occur preferably with more than one supervisor and should include a continuous process of supervision with at least three cases; and

(ii) 1,000 hours of clinical experience in the practice of pastoral counseling under approved supervision, involving at least 50 different cases; or

(iii) 150 hours of approved supervision in the practice of psychotherapy, ordinarily to be completed in a 2- to 3-year period, of which at least 50 hours must be individual supervision; plus at least 50 hours of approved individual supervision in the practice of pastoral counseling, ordinarily to be completed within a period of not less than 1 nor more than 2 years; and

(iv) 750 hours of clinical experience in the practice of psychotherapy under approved supervision involving at least 30 cases; plus at least 250 hours of clinical practice in pastoral counseling under approved supervision, involving at least 20 cases;

Supervised Mental Health Counselor [32 C.F.R. § 199.6(c)(3)(iv)(C)]:

(1) Minimum of a master's degree in mental health counseling or allied mental health field from a regionally accredited institution; and

(2) Two years of post-masters experience which includes 3,000 hours of clinical work and 100 hours of face-to-face supervision; and

By contrast, to become a behavior analyst, according to the BACB, one must only have a master's degree in "behavior analysis or other natural science, education, human services, engineering, medicine or a field related to behavior analysis and approved by the BACB" (p. 38). Unlike TRICARE-certified behavioral health providers, there is no requirement that the master's degree be in a mental health or health-related science. In addition to medicine, acceptable master's degrees for BCBA certification can be in: natural sciences, which could include astronomy, biology, chemistry, the Earth sciences, and physics (Barr, 2006); education; human services ("broadly defined, uniquely approaching the objective of meeting human needs through an interdisciplinary knowledge base, focusing on prevention as well as remediation of problems, and maintaining a commitment to improving the overall quality of life of service populations," according to the National Organization for Human Services (http://www.nationalhumanservices.org/what-is-human-services)); and engineering, which is an extremely broad field and could include degrees from any of the four main branches of engineering – chemical, civil, electrical, and mechanical. For behavioral healthcare providers recognized by TRICARE, a master's degree must either be in the professional healthcare field itself (i.e., psychology, social work, psychiatric nursing, or mental health counseling) or in a "behavioral science field, mental health discipline" (for certified marriage and family therapists or pastoral counselors) or in an allied mental health field (for supervised mental health counselors).

In addition to an eligible master's degree, to become a BCBA, one must complete 225 classroom hours of graduate level instruction the following content areas and for the number of hours specified:

1. Ethical considerations - 15 hours

2. Definition & characteristics and Principles, processes & concepts - 45 hours

3. Behavioral assessment and Selecting intervention outcomes & strategies - 35 hours

4. Experimental evaluation of interventions - 20 hours

5. Measurement of behavior and Displaying & interpreting behavioral data - 20 hours

6. Behavioral change procedures and Systems support - 45 hours

7. Discretionary behavior-analytic content - 45 hours

The supervised experience requirement for BACB certification, according to the BACB Guidelines (2012) is 750 to 1500 hours of "supervised field work" (p. 38). "Appropriate activities" qualifying as supervised fieldwork include:

■ Conducting assessments related to the need for behavioral intervention (e.g., stimulus preference assessment, functional assessment, staff performance assessment);

■ Designing, implementing, and systematically monitoring skill-acquisition and behavior-reduction programs;

■ Overseeing the implementation of behavior-analytic programs by others;

■ Training, designing behavioral systems, and performance management;

■ Other activities normally performed by a behavior analyst that are directly related to behavior analysis such as attending planning meetings regarding the behavior analytic program, researching the literature related to the program, and talking to individuals about the program.

Other sources referenced as guidelines for evaluating "appropriate activities" qualifying as ABA fieldwork are "behavior-analytic skills related to the BACB Third Edition Task List." Consulting the BACB "BCBA & BCaBA Behavior Analyst Task List - Third Edition," the document makes no mention of interacting with identified patients or providing direct health care services.

Thus, by these criteria for BCBA certification by the BACB, one could obtain a master's degree in a natural science, education, or engineering, take the required 225 hours of graduate coursework, and obtain the required 750-1500 hours of fieldwork, all without ever having worked in the healthcare system or have provided direct care to an identified patient under the supervision of a qualified, licensed healthcare professional. Considering that the eligibility requirements to become a BACB do not require clinical education, supervised clinical training or clinical practicum, internship, or residency – or even interaction with the healthcare system in any capacity – TMA must conclude that ABA practitioners are not "trained and licensed or certified healthcare professionals," as they have less healthcare training and experience than "Extramedical individual providers" of behavioral healthcare under 32 C.F.R § 199.6(c)(3)(iv)

who provide "counseling or non-medical therapy and whose training and therapeutic concepts are outside the medical field" and who under certain circumstances are authorized by the Director, TMA, to provide behavioral counseling of a medically necessary nature as a medical benefit under the Basic Program, but (for pastoral counselors and supervised mental health counselors) only under the referral and supervision of a physician.

Lack of orientation and training in healthcare can impact quality of care, and providers authorized by TRICARE as behavioral healthcare professionals are trained as part of their education to recognize the presence of co-morbid conditions requiring medical attention. (Note that the C.F.R. requirements for certified clinical social workers and certified marriage and family therapists include the stipulation that "Patients' organic medical problems must receive appropriate concurrent management by a physician.") The BACB's lack of required education and supervision experience with identified patient populations receiving healthcare services indicates that ABA practitioners' training is not commensurate with that required for other TRICARE authorized provider of behavioral healthcare. This leaves them potentially poorly equipped in certain circumstances to recognized clinical issues requiring referral to qualified health professionals, unable to interact professionally with clinical health care providers, and largely ignorant of health care delivery processes and procedures.

The BACB may realize this lack of health care preparation in its certificants, because TMA recently noted a new BCBA degree requirement published in the BACB's February 2013 newsletter that will become effective for all completed applications received after December 31, 2015:

> "Possession of a minimum of a master's degree from an accredited university that was (a) conferred in behavior analysis, education, or psychology, or (b) conferred in a degree program in which the candidate completed a BACB approved course sequence."

Two and a half years from now, the BACB will no longer accept applicants with master's degrees in engineering, human services, or natural sciences. Even with this change, however, most of the master's degree preparation for BCBA certificants will likely be from non-health related subject areas. For the May 2012 BCBA examination, less than a third of BCBA applicants (450 of 1559) had master's degrees in psychology (333) or health-related disciplines, such as social work (48), counseling (38), communication disorders (25), nursing (2), or medicine (1) (Carr, J.E., email communication, 27 Apr 13).

Furthermore, for the reasons stated above regarding the lack of clinical healthcare training required or assessed by the BACB, the Director of TMA cannot recognize the BACB as a "qualified accreditation organization" per 32 C.F.R. § 199.2 for certification of behavior analysts as healthcare providers as it does not "apply standards, criteria, and certification processes which reinforce CHAMPUS [TMA] provider authorization requirements and promote efficient delivery of CHAMPUS benefits."

In examining the question of classification of behavior analysts as "health professionals," it is also relevant to note that the AMA does not recognize Board Certified Behavior Analysts (i.e., BCBAs, BCBA-Ds, or BCaBAs) as "healthcare professionals." According to the American Medical Association (AMA) website (www.ama-assn.org, accessed 14 April 2013), ABA is not a recognized medical specialty of the AMA, and no professional associations of behavior analysts are recognized by the AMA, including the Association of Professional Behavior Analysts (APBA, www.apbahome.net); the Association for Behavior Analysis International (ABAI, www.abainternational.org); or the Behavior Analyst Certification Board (www.bacb.com). Furthermore, "Behavior Analyst" is not listed among AMA's list of recognized health professions, as it is not listed in the AMA's Health Care Careers Directory, which lists information about more than 80 careers in health care and 8,400 accredited educational programs in those health care fields (across the broad categories of: Allied health; Complementary and alternative medicine and therapies; Communication sciences; Counseling; Dietetics; Dentistry and related fields; Expressive/creative arts therapies; Health information and communication; Laboratory science; Medical imaging; Medicine; Nursing; Pharmacy; Physician assisting; Podiatry; Psychology; Therapy and rehabilitation; Veterinary medicine; and Vision-related professions). If ABA were to "pertain to" the practice of medicine, the practitioners in the field would be recognized as bona fide health professionals by the AMA. As far as the category of "Therapy and rehabilitation," that is limited to speech and language pathology therapy, physical therapy, and occupational therapy and does not include providers of ABA. While TRICARE does not adhere to AMA's definitions or recognition of health professions in determining who is a TRICARE authorized provider, TMA's assessment that BCBAs are not "healthcare professionals" is not inconsistent with the AMA's lack of recognition for "Behavior Analyst" as a health profession.

For purposes of TRICARE, the term "medical" should be understood to include "medical, psychological, surgical, and obstetrical . . ."

ABA is based on the principles of learning theory and operant conditioning from the area of psychology known as Behaviorism, a theory of learning based upon the idea that all behaviors are acquired through conditioning (Watson, 1913). However, Behaviorism should not be confused with the practice of clinical psychology as meant by the inclusion of "psychology" in the definition of "medical" in 32 C.F.R § 199.2:"For purposes of TRICARE, the term "medical" should be understood to include "medical, psychological, surgical, and obstetrical". Psychological treatments, as practiced by psychologists and other TRICARE certified providers of behavioral healthcare, have their origin in the disciplines of psychiatry and clinical psychology. Thus, psychotherapy, which is derived from the tradition of psychoanalysis developed by psychiatry, "pertains to" the "medical" treatment of a mental disorder. Investigation of the BACB website confirms that the practice of ABA, as defined by the BACB, is considered wholly separate from the practice of clinical psychology and related behavioral health specialties as the established providers these specialties are explicitly barred from

practicing ABA by the BACB without a BCBA, BCBA-D, or BCaBC certification. None of TRICARE's authorized providers would be allowed to practice ABA unless also certified by the BACB as the BACB rejects their clinical experience and training as satisfying any training requirement for ABA. According to the question and answer (Q&A) portion of the BCBA website (http://bacb.com/index.php?page=6#14):

> **Q:** I have courses in clinical psychology, statistics, psychometrics, psychological testing, cognitive therapy, cognitive-behavioral therapy, behavior therapy, theories of special education, characteristics of autism and developmental disabilities and other courses that deal with behavior. Are these courses behavior analysis? May I use them to meet BACB coursework requirements?
>
> **A:** No, all coursework must be behavior analytic in nature. Although these non-behavior analytic courses may be valuable in other circumstances, they cannot be used to meet BACB eligibility requirements. The BACB uses the criteria found in "Some Current Dimensions of Applied Behavior Analysis" by D. M. Baer, M. M. Wolf, and T. R. Risley (Journal of Applied Behavior Analysis, Volume 1, 1968) to judge if courses are behavior analytic. You may also wish to review the Third Edition Behavior Analysis Task List for examples.

Referring to the article cited (Baer, Wolf & Risley, 1968), which the BACB asserts as their standard for evaluating eligible training in behavior analysis, there is no mention of the words "psychology," "psychological," "medical," "medicine," "health," or "healthcare." Two of the three references cited in the article are books by B.F. Skinner, an animal researcher considered the pioneer in the study of operant conditioning, and the third reference is from the Journal of the Experimental Analysis of Behavior (not a medical or healthcare related publication).

Based on this analysis, TMA must conclude that ABA is a completely separate discipline from the rest of conventional medical or psychological healthcare. If it did pertain to medicine or psychology as practiced by trained and certified health professionals, then psychologists and other TRICARE certified behavioral health providers would be able to practice ABA with minimal additional training, but the BACB bars them from doing so and rejects their clinical training as counting no more toward BCBA certification than a degree in engineering, education, or natural sciences. Thus, current TRICARE certified providers of behavioral health would require extensive (1000-1725 hours) of retraining and re-specialization in order to be practitioners of ABA. As the training and certification of BCBAs does not "pertain to" the practice of medicine, psychology, surgery, obstetrics, ABA cannot be considered "medical."

Further indications that the practice of ABA does not pertain to the practice of medicine or psychology are found in the "Model Act for Licensing Behavior Analysts" (Sept, 2012) under the "Requirements for Licensure" (Part C), which indicate that for a license as a BCBA, the only requirements are that the applicant:

> 1. is of good moral character and conducts his or her professional activities in accordance with accepted professional and ethical standards, including:
> (a) compliance with the BACB Professional Disciplinary and Ethical Standards and the BACB Guidelines for Responsible Conduct for Behavior Analysts; and
> (b) completion of a state approved criminal background check and/or jurisprudence examination; and
>
> 2. (a) for a Licensed Behavior Analyst applicant:
> (i) has passed the Board Certified Behavior Analyst® ("BCBA®") examination; and
> (ii) maintains active status as a Board Certified Behavior Analyst®;

These requirements for BCBA licensure are notable for being devoid of any healthcare related specifications or special health services designation for BCBAs who interact with identified patients (vs. educational or other settings). This is in stark contrast to the relevant section of the American Psychological Association (APA) Model Act for State Licensure of Psychologist (Feb 2010), which clearly states the expectations for psychologists who function in the health care setting:

> a. "Health service provider" (HSP)
>
> Psychologists are certified as health service providers if they are duly trained and experienced in the delivery of preventive, assessment, diagnostic, therapeutic intervention and management services relative to the psychological and physical health of consumers based on: 1) having completed scientific and professional training resulting in a doctoral degree in psychology; 2) having completed an internship and supervised experience in health care settings; and 3) having been licensed as psychologists at the independent practice level.

The APA Model Act for State Licensure of Psychologist (Feb 2010) goes on to contain language that would include applied behavior analysis within the practice of psychology, "The practice of psychology includes, but is not limited to . . . behavior analysis and therapy;" (p. 2). However, the "Model Act for Licensing Behavior Analysts" (Sept, 2012) advanced by the BACB proposes a license entirely separate from psychology or other healthcare disciplines, and those promoting licensure for applied behavior analysts have strenuously rejected association of the practice of ABA with that of psychology, as in this article by Dorsey et al. (2009):

> "While it is now up to professional applied behavior analysts to establish their field as a true and unique profession, the recruitment of advocacy groups that represent the individuals served by the profession of ABA to assist in this debate will strengthen the position of ABAI and help deflect the apparent aspirations of the APA. Applied behavior analysts must take the further steps necessary to delineate the parameters of this debate and to protect the profession from those outside the field whose intent it is to claim ABA as their own" (p.57).

This characterization of ABA as a unique discipline entirely separate from psychology is further indication that ABA does not "pertain to" the practice of medicine (where the term "medical,"

per the 32 C.F.R. 199.2 definition, "[f] or purposes of TRICARE, "should be understood to include "medical, psychological, surgical, and obstetrical") according to the BCBA and the practitioners and advocates of ABA themselves. The argument for ABA to be "medical" cannot lead to two contradictory conclusions: that on the one hand ABA is "psychological" or analogous to "psychological" and therefore must be considered "medical" for TRICARE purposes, yet on the other hand ABA is a separate discipline from the current practice of psychology and mental health care such that it requires its own separate state licensing boards and does not recognize or include any of the conventional mental health training received by current mental health care professionals in the field. TRICARE would not, for example, recognize an entirely new "surgical" or "obstetrical" discipline or field that was self-described as falling outside of and not subject to the existing training, supervision, licensing, and credentialing practices of its currently authorized surgeons and obstetricians. Nor should TRICARE recognize a new "psychological" discipline or field self-described as falling outside of and not subject to the existing training, supervision, licensing, and credentialing practices of psychologists or other recognized and authorized mental health care providers.

Conclusion Regarding ABA as "Medical"

Deconstruction and analysis of the TRICARE regulation indicates that **ABA as delivered by ABA practitioners does not meet the TRICARE definition of "medical" as defined in 32 C.F.R. § 199.2.** This finding is based on the following observations: (a) Taking the narrow meaning of the word "pertain," ABA does not "pertain to" or have a nexus of belonging as "a part, member, accessory, or product" with other forms of medical or behavioral health care delivered by TRICARE; (b) This finding for TRICARE is consistent with the observation that ABA is not a recognized medical or behavioral health "treatment" by the AMA as evidenced by the absence of any assigned CPT code(s) for ABA (even though at least one application for an ABA CPT code has been submitted), by the absence of a national coverage determination for ABA by Medicare Part A for persons with disabilities, and by the states' coverage of ABA under the Medicaid Home and Community-Based Waiver Program instead of the Medicaid Health Plan; (c) ABA practitioners are not "trained and licensed or certified healthcare professionals" by TRICARE regulations due to their lack of clinical healthcare education, training and preparation compared to currently authorized behavioral healthcare professionals, and even if authorized as under the category of "Extramedical individual providers of care" at the discretion of the Director, TMA, then under TRICARE regulations, ABA is a "non-medical therapy" and ABA practitioners' "training and therapeutic concepts are outside the medical field" per the TRICARE definition found in 32 C.F.R. § 199.2; and (d) The practice of ABA falls outside the practice of clinical "psychology" as evidenced by the BACB's self-description as a discipline separate from the practice of clinical psychology and related behavioral health care disciplines, rejection of traditional psychological and behavioral health care training as part of its curriculum, and active lobbying for ABA practitioners not to be licensed or regulated by state Boards of Psychology, but that the Regulatory Authority for ABA will "be a separate and independent behavior analyst

regulatory board or agency." (Model Act for Licensing/Regulating Behavior Analysts, revised Sept 2012, p. 2).

V. REVIEW OF RELIABLE EVIDENCE

A. Is ABA "Unproven" "Medical Care," Even If It Qualifies as "Medical Care?"

If ABA is considered to be "medical care", by the Director, TMA, or consistent with the ruling of Berge vs. U.S., then the Department must determine if ABA meets reliable evidence criteria to be considered proven medical care and eligible for cost-sharing under TRICARE regulations. As cited in 32 C.F.R. Sec. 199.4(g)(15), the term "reliable evidence" means only:

> (i) Well controlled studies of clinically meaningful endpoints, published in refereed medical literature.
>
> (ii) Published formal technology assessments.
>
> (iii) The published reports of national professional medical associations.
>
> (iv) Published national medical policy organization positions; and
>
> (v) The published reports of national expert opinion organizations.

Furthermore, the hierarchy of reliable evidence of proven medical effectiveness, listed above, is the order of the relative weight to be given to any particular source. Thus, for purposes of determining if ABA is "proven" or "unproven" "medical care", even if it qualifies as "medical care", this benefit determination places the most weight on "well-controlled studies of clinically meaningful endpoints, published in refereed medical literature." The following outlines TMA's review of the literature and other documents regarding their status as "reliable evidence".

Methodology

TMA's review was compiled using the following primary sources of data and information:

- Thirty documents on ABA provided by Dr. Geraldine Dawson and Dr. Vera Tait via Senator Gillibrand's office to Principal Deputy Assistant Secretary of Defense for Health Affairs on July 10, 2012
- Hayes, Inc. technology assessment entitled, *Intensive Behavioral Intervention Therapy for Autism,* dated October 25, 2010
- Hayes, Inc. updated technology assessment entitled, *Applied Behavior Analysis Therapy for Autism Spectrum Disorders (Short HTA)* dated November 27, 2012
- Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Review No. 26: *Therapies for Children With Autism Spectrum Disorders,* dated April 2011

- Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) Technology Assessment, *Special report: early intensive behavioral intervention based on applied behavior analysis among children with autism spectrum disorders* (2009)
- National Autism Center's (NAC) *National Standards Report* of the National Standards Project (2009)
- American Academy of Pediatrics (AAP) clinical report, *Management of Children With Autism Spectrum Disorders* (2007)
- American Academy of Child & Adolescent Psychiatry (AACAP), *Practice Parameters For The Assessment And Treatment Of Children, Adolescents, And Adults With Autism And Other Pervasive Developmental Disorders* (1999)
- *Mental Health: A Report of the U.S. Surgeon General* (1999)
- Technical Expert Panel (TEP), Southern California Evidence-Based Practice Center (EPC), and University of California Los Angeles (UCLA), *Nonmedical interventions for children with ASD: Recommended guidelines and further research needs* (2012)
- Subject-specific third party payer policies (i.e., Aetna, Cigna, Humana, Regence Group, United Healthcare)
- TMA's *Assessment of Applied Behavior Analysis for Autism Spectrum Disorders*, dated October 14, 2010
- Transcript and all submitted written prepared statements related to Principal Deputy Assistant Secretary of Defense for Health Affairs testimony before the Senate Armed Services Committee Subcommittee on Military Personnel on June 1, 2012
- Office of Personnel Management (OPM) evidence review entitled, *Applied Behavioral Analysis (ABA)*, dated February 13, 2012
- Interagency Autism Coordinating Committee (IACC), *Strategic Plan for Autism Spectrum Disorder Research* (2012)
- Letter from Thomas R. Insel, M.D., Director, National Institute of Mental Health, and Chair, Interagency Autism Coordinating Committee (IACC), to The Honorable Kathleen Sebelius, Secretary of Health and Human Services
- Defense Health Board Memo dated 18 September 2009 entitled, *Defense Health Board Findings Pertaining to Autism Treatment*
- Three additional documents specifically mentioned in the District of Columbia United States District Court opinion in Berge v. U.S. that the court construed as reliable evidence:
    - an article with recommendations from the Association for Science in Autism Treatment ("ASAT");
    - a letter from autism experts to the United States Armed Services Committee dated September 19, 2008; and,
    - a letter from autism organizations to Secretary Gates dated May 19, 2008
- Literature Search (described below)

Thirty documents provided by Senator Gillibrand's office were reviewed. Of those 30 documents, 14 were previously comprehensively reviewed and evaluated during TMA's 2010 assessment and/or reviewed as part of the 2010 Hayes assessment.[1] Sixteen documents provided by Senator Gillibrand were not referenced in either TMA's 2010 assessment or the 2010 Hayes assessment.

Literature Search

In addition to a careful review of the documents provided by Senator Gillibrand's office, a literature search was conducted to ensure all relevant literature was captured and reviewed. Literature searches were conducted in four primary databases for English-language articles. Because this was to serve as an update to TMA's 2010 assessment on ABA, publication dates were restricted to the time period of 2010 to the present, but articles were not restricted by country of publication. A list of keywords and search terms was developed based on both previous literature searches and the specific therapies referenced in the material provided though Senator Gillibrand's office. Using singular search terms and Boolean search operators, keywords and headings were entered into the following databases: Medline, PsychInfo, EMBASE and Cochrane. The search and retrieval of articles took place during September – November 2012.

Keywords used in searching these sources are as follows: autistic disorder, autism, child development disorders pervasive, pervasive developmental disorders, autism spectrum disorders, Lovaas, intensive behavioral intervention, early intervention education, early intervention, behavior therapy, intensive behavioral therapy, and applied behavioral analysis.

Initial searches of the four databases using the array of search terms related to ABA returned 1,016 articles published between 2010 and November 2012. To identify the most relevant articles for the review, analysts reviewed article titles and abstracts and excluded articles that were not relevant (i.e., those that did not address effectiveness of ABA directly). Exclusion criteria included: single case study or single case design; articles that were not in peer-reviewed journals (gray literature); and, studies that studied 10 or fewer participants.

These articles were added to relevant studies of ABA captured in previous literature reviews and technical assessments (i.e., prior to 2010) which were re-reviewed for this medical benefits determination.

[1] Eldevik, S., et al., 2010; Virues-Ortega, 2009; Eldevik, et al., 2009; Howlin, P., Magiati, I., & Charman, T., 2009; National Autism Center, 2009; Rechow, B., & Wolery, M., 2009; Spreckley, M., & Boyd, R., 2009; Blue Cross Blue Shield Association, 2009; Opsina, M.B., et al., 2009; Magiati, I., Charmoan, T. & Howlin., P, 2007; Sallows, G.O., & Graupner, T.D., 2005; Harris, S.L., & Handleman, J.S., 2000; Smith, T., Groen, A.D., & Wynn, J.W., 2000; McEachin, J.J., Smith, T., Lovaas, O.I., 1993.

External Review

To ensure unbiased comprehensive review of the evidence, Hayes, Inc., was commissioned by TMA to conduct an external health technology assessment concurrently with TMA's internal literature search and evidence review.

Clinical Literature: *Well controlled studies of clinically meaningful endpoints, published in refereed medical literature.*

Only four studies were randomized clinical trials (RCTs), two studying IBI (Smith et al., 2000; Sallows & Graupner, 2005) and two studying the Early Start Denver Model (ESDM; Dawson et al, 2010; Rogers et al., 2012), and one quasi-randomized trial (Sherman, 1988). As summarized below, these few RCTs studying intensive ABA models had methodological flaws and/or conflicting findings that prevent them from rising to the level of reliable evidence in accordance with 32 C.F.R. 199.2(b). The reason for other studies reviewed not meeting the reliable evidence standard as a "well-controlled study" was the lack of randomization in subject assignment.

Early Intensive Behavioral Intervention (EIBI) / Intensive Behavioral Intervention (IBI)

- Lovaas et al.'s (1987) original study findings of Intensive Behavioral Intervention (IBI) have not been replicated, where almost half of autistic children receiving IBI (47%, 9 of 19 children) passed normal first grade and achieved at least an average IQ score.
    - Methodological flaws of this study include: non-randomized assignment of subjects, non-uniform assessment and follow-up protocols, and unduly restrictive exclusion criteria (i.e., high IQ cut-off scores) rendering a non-representative sample of autistic children.
    - Most important, ABA employed in the Lovaas (1987) study included contingent aversive techniques (e.g., slapping, shouting) that have since been discontinued in ABA practice but have been posited as a possible factor in the dramatic outcomes observed.
- A subsequent quasi-randomized trial (Sherman et al., 1988) found that home-based IBI was somewhat more effective than residential or outpatient IBI, but the sample size (n=15) was very low resulting in lack of statistical power to detect significant group differences.
- An RCT with 28 children (Smith et al., 2000) compared IBI vs. a parent-training plus special education group and found significantly higher IQ, visual-spatial and language skills in the IBI group but no significant differences in adaptive functioning or behavior problems.
    - The sample included children with both Autism and Pervasive Developmental Disorder NOS but lacked sufficient power to detect group differences by diagnostic category.

- Aversive ABA techniques, similar to the Lovaas et al. (1987) study, were employed (reportedly "briefly" then stopped) with 4 children in the study sample.

- A subsequent RCT (Sallows & Graupner, 2005) found no post-treatment differences between a clinic-directed IBI group vs. a parent-managed treatment group. Pooling data from both groups indicated that half (48%) of all children were "rapid learners" whose significant gains on post-treatment measures were largely attributable to individual difference characteristics measured at pre-treatment (with IQ, receptive language and imitation scores, and autism diagnostic social and communication scores accounting for 70% of the observed variance in outcomes).

Several meta-analyses of IBI have been conducted, but as these studies aggregate data and findings from both randomized and non-randomized clinical trials, their findings are subject to the same biases and confounding factors as the non-randomized trials that comprise them. Four of five recent meta-analyses (Eldevik 2009; Reichow 2009; Makrygianni 2010; Virues-Ortega 2010) of Early Intensive Behavioral Intervention (EIBI) found that it was effective, while the fifth (Spreckely, 2009) did not.

Reichow, Barton, Boyd, and Hume (2012) conducted the most recent and extensive review of "Early Intensive Behavioral Intervention (EIBI) for young children with autism spectrum disorders (ASD)" included in the Cochrane Database of Systematic Reviews, 2012. The authors conducted a random-effects meta-analysis "to systematically review the evidence for the effectiveness of EIBI in increasing the functional behaviors and skills of young children with ASD." The plain language summary of the Cochrane review was as follows:

> "The purpose of our review was to examine the research on EIBI. We found a total of five studies that compared EIBI to generic special education services for children with ASD in schools. Only one study randomly assigned children to a treatment or comparison group, which is considered the "gold standard" for research. The other four studies used parent preference to assign children to groups. We examined and compared the results of all five studies. A total of 203 children (all were younger than six years old when they started treatment) were included in the five studies. We found that children receiving the EIBI treatment performed better than children in the comparison groups after about two years of treatment on tests of adaptive behavior (behaviors that increase independence and the ability to adapt to one's environment), intelligence, social skills, communication and language, autism symptoms, and quality of life. The evidence supports the use of EIBI for some children with ASD. However, the quality of this evidence is low as only a small number of children were involved in the studies and only one study randomly assigned children to groups" (p.2).

The authors' meta-analysis was based on only four case-controlled trials (CCTs) and they excluded the one RCT of EIBI they identified because the RCT results could not be combined with the CCT results. While the authors found significant main effects favoring EIBI for improvement in adaptive behavior, IQ, language, socialization and daily living skills, the authors

qualified their findings, noting that the inclusion of non-randomized studies introduced a high risk of bias in the findings. The overall quality of evidence was rated as "low" using a quality of evidence grading system, meaning that "future research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate" (p. 18). Also, of the four CCTs used in the meta-analysis, three of them showed group imbalance on baseline measures, meaning the treatment and comparison groups were different to start with. These concerns about the quality of the studies conducted led the authors to conclude:

"The primary issue is that the quality of the evidence to support the use of EIBI is quite limited, that is, we only have evidence from a handful of studies that are not of the optimum design. Only one study used a RCT design and across studies there were small sample sizes. We strongly recommend that decisions about the use of EIBI for children with ASD be made on a case by case basis. . . . Finally, comparative effectiveness studies are needed to determine if EIBI is more effective than other active treatments recommended for children with ASD" (p. 29). Early Start Denver Model (ESDM)

- One of two RCTs of the Early Start Denver Model (ESDM) intervention for very young children (Dawson et al., 2010) found that, compared with community treatment alone, therapist-delivered ESDM combined with parent training and community treatment resulted in significant and substantial gains on measures of cognitive ability, language skills, and an improved diagnostic status, over a 2-year period. However, there was no significant difference between the intervention and control groups in visual-spatial/non-verbal ability or autism severity.

    - As this is a mixed provider-parent intervention, its applicability for TMA benefit determination is limited since it is not possible to discriminate the effect of ESDM strategies provided by therapists (mean = 15.2 hours/week) versus EDSM strategies provided by parents (mean = 16.3 hours/week) as the mean number of hours per week were approximately equal.

    - As this study included receipt of community services in both the intervention and control groups, it is also not possible, given the study design and description, to isolate the effect of other potentially effective treatments (e.g. speech therapy, developmental preschool) that children may have received from community services during the study period in both the EDSM plus parent training plus community services group (mean = 5.2 hours/week) and the assess-and-monitor community services only control group (mean = 9.3 hours/week).

- Rogers et al.'s (2012) subsequent ESDM study of a short-term (12-week) intervention, consisting of parent training in ESDM strategies combined with community treatment, did not result in any differences from community treatment alone on measures of intelligence, language skills, spatial/nonverbal skills, or adaptive behavior.

• A follow-on study to Dawson et al. (2012) describing the subsequent neuroimaging of a subset of Dawson et al's (2010) subjects was also reviewed. Only 60% of the study participants had reliable EEG measurements, resulting in a very small sample size studied (15 of the original 24 in the ESDM group and 14 of 24 in the ASD-diagnosed control group). No pre- or post-intervention EEG data were collected, limiting the ability to attribute the brain activity measurements observed to the actual intervention. Finally, while brain activity measurements were reported to be correlated with social behavior, they were not correlated with other behavioral outcomes, i.e., diagnostic scores, IQ, language, or adaptive behavior. Thus, the claim that EIBI therapy "normalizes" brain function (as asserted by this study's title) is wildly unfounded based on the data presented.

Further discussion of the clinical literature, as summarized by Hayes, Inc. (2012) and others, is included in the following section on Formal Technology Assessments. A comparison of findings between related studies is also included in Tables 1, 2, and 3 at the end of this document.

Formal Technology Assessments

Hayes, Inc. (2012, 2010). The October 2010 assessment evaluated evidence from peer-reviewed literature published between 1966 and October 2010. The assessment concluded that while there is some evidence to suggest that treatment of young autistic children with ABA (including IBI, Lovaas) may promote gains in cognitive function, language skills and adaptive behavior, most studies had major limitations in design and methodology, including lack of randomization procedures, small sample sizes and a lack of blinded assessments to determine the treatment effects (Hayes, 2010). Ultimately, Hayes (2010) graded the evidence a "C" using the Hayes rating system. A grade of "C" in the Hayes rating system means, "Potential but unproven benefit," and that while some published evidence suggests that safety and impact on health outcomes are at least comparable to standard treatment/testing, substantial uncertainty remains about safety and/or impact on health outcomes because of poor-quality studies, sparse data, conflicting study results, and/or other concerns. The report suggested that there is an "urgent need for well-controlled studies on the efficacy of IBI for autistic children" and cautioned that IBI should not be presented to parents as a treatment that will result in normal function (Hayes, 2010, p. 5).

At the request of the Office of the Chief Medical Officer, TRICARE Management Activity (TMA), Hayes updated its 2010 health technology assessment on ABA for ASD. Also at the request of TMA, Hayes included studies evaluating the Early Start Denver Model (ESDM) as a developmentally focused ABA intervention for ASD.

With respect to specific study findings evaluating the effect of ABA-based treatment (i.e., IBI), Hayes, Inc. (2012) reported the following summary of results of non-randomized CCTs comparing IBI vs. eclectic interventions for autism (these findings are also presented in Table 1):

IBI Therapy Versus Other Autism-Specific Treatment: A total of 10 studies of poor to fair quality evaluated IBI therapy relative to eclectic treatment interventions developed for children with autism (Eikeseth et al., 2002; Howard et al., 2005; Eikeseth et al., 2007; Magiati et al., 2007; Reed et al., 2007b; Zachor et al., 2007; Zachor and Ben Itzchak, 2010; Fava et al., 2011; Magiati et al., 2011; Eikeseth et al., 2012; Eldevik et al., 2012; Strauss et al., 2012). . . There is some evidence that, compared with eclectic treatment for autism, IBI may improve visuospatial skills. The results were conflicting regarding the effects of IBI therapy on intelligence and cognitive abilities, language skills, adaptive behavior, and the proportion of children moved into mainstream classrooms. (p. 15-18)

Autism Severity: In general, results were consistent across all studies that IBI therapy did not result in significantly greater reduction of autism severity than eclectic interventions. Three studies reported that IBI and eclectic treatment groups did not differ on measures of autism severity at follow-up (Magiati et al., 2007; Reed et al., 2007b; Fava et al., 2011). Fava et al. (2011) did note that the group, which received early IBI therapy exhibited significant improvement from baseline measures of autism severity, while the eclectic group did not. However, in this study, there were nonsignificant differences in ADOS scores at baseline, and final scores at follow-up were similar in both groups. Thus, the improvement in the IBI group noted by the authors may reflect regression toward the mean as opposed to true reduction in the severity of autism symptoms. Zachor and Ben Itzchak (2010) did not report autism severity scores at follow-up, but evaluated change in diagnostic classification. They found that both IBI and eclectic groups showed similar stability and change of autism scores, such that 91% of children remained diagnosed with a classification of autism at follow-up. (p. 15)

Intelligence/Cognitive Abilities: Three studies, reported in four publications, found significantly higher IQ scores or cognitive function following IBI therapy compared with eclectic therapy (Eikeseth et al., 2002; Howard et al., 2005; Eikeseth et al., 2007; Eldevik et al., 2012). . . . Three other studies reported significant improvement in IQ or cognitive scores following both IBI and eclectic therapy, with no significant differences between groups receiving IBI or eclectic treatments (Magiati et al., 2007; Reed et al., 2007b; Zachor and Ben-Itzchak, 2010). These findings suggested that IBI and eclectic therapies for autism may produce similar improvement in cognitive abilities. (p. 15-16)

Visual-Spatial/Nonverbal Skills: Howard et al. (2005) found that children treated with IBI had significantly better visual-spatial skills than those treated with intensive eclectic therapy in a special education program or by nonintensive generic educational programming. Eikeseth et al. (2002) also reported that additional improvement was noted in visual-spatial skills following IBI therapy than after eclectic treatment, but the group difference was not statistically significant. (p. 16)

Language Skills: Six studies assessed language skills using various instruments (Eikeseth et al., 2002; Howard et al., 2005; Magiati et al., 2007; Fava et al., 2011; Strauss et al., 2012; Zachor et al., 2007). In three of six studies, the authors found that IBI therapy was superior to eclectic therapy for improving language skills (Eikeseth et

> al., 2002; Howard et al., 2005; Zachor et al., 2007). In the other three studies, the group differences with respect to improvement in language skills were not significant (Magiati et al., 2007; Fava et al., 2011; Strauss et al., 2012). (p. 17)
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> Adaptive Behavior: Four studies reported that IBI therapy is superior to eclectic therapy for improving adaptive behavior (Eikeseth et al., 2002; Howard et al., 2005; Eikeseth et al., 2007; Eikeseth et al., 2012; Eldevik et al., 2012) . . . five studies found improvement in adaptive behavior following both IBI and eclectic therapies, with no significant differences between the groups (Magiati et al., 2007; Reed et al., 2007b; Zachor and Ben Itzchak, 2010; Fava et al., 2011; Strauss et al., 2012). (p. 17-18)
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> School Placement: Only two studies reported on school placement measures following treatment for autism and the findings were equivocal (Eikeseth et al., 2007; Magiati et al., 2007). Eikeseth et al. (2007) indicated that 38% of children in the IBI treatment group compared with 8% in the eclectic treatment group were in mainstreamed classes and did not receive one-on-one treatment any longer. . . . In contrast, Magiati et al. (2007) reported that no children were in mainstream classrooms without one-on-one support. (p. 18)

Hayes, Inc. (2012) also reported the following summary of results of studies comparing IBI vs. other interventions not specifically focused on Autism (these findings are also presented in Table 2):

> *IBI Therapy Versus Other Treatment:* Four studies of poor to fair quality evaluated the efficacy of IBI therapy relative to other types of treatment. In general, these therapies did not appear to be targeted specifically at the treatment of autism. However, this was often difficult to ascertain due to the lack of detailed reporting regarding the interventions. Therapies compared to IBI treatment in the reviewed studies included special education programming combined with parent training (Smith et al., 2000), varying services selected by the family (Cohen et al., 2006), standard treatment provided by the local educational authority (Remington et al., 2007; Kovshoff et al., 2011), and portage treatment (Reed et al., 2007b). . . In general, the findings show that IBI therapy significantly raises IQ scores and increases the proportion of children in regular classroom settings relative to other therapies not specifically designed for autism. However, results were conflicting regarding the efficacy of IBI therapy to improve visual-spatial skills, language skills, and adaptive behavior. (p. 18-20)
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> Autism Severity: One study compared the efficacy of IBI therapy to another treatment (i.e., portage) for improving severity of autism (Reed et al., 2007b). Children receiving IBI therapy did not differ from those undergoing the portage intervention in severity of autism at baseline or follow-up (p. 19). Strauss et al. (2012) also found the "IBI group showed significant improvement from baseline on all ADOS autism severity scales" [while the eclectic treatment group did not, but in this study,] "results of statistical analysis for group differences were not reported" (p. 72).
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> Intelligence/Cognitive Abilities: In all studies [(Smith et al., 2000; Cohen et al., 2006; Reed et al., 2007b; Remington et al., 2007; Kovshoff et al., 2011)], children receiving IBI therapy had significantly higher IQ scores or measures of intellectual function than

those undergoing other, non-Autism specific types of therapy at the final follow-up interval. . . . It is important to note that in two studies, final IQ scores in the IBI groups still fell within the developmentally disabled range (IQ less than 75 points) (Smith et al., 2000; Remington et al., 2007). (p. 19)

Visual-Spatial/Nonverbal Skills: Smith et al. (2000) found that the IBI group had significantly better visual-spatial skills at follow-up than children receiving special education with parent training after the intervention. . . However, Cohen et al. (2006) reported that children receiving IBI therapy or other treatment did not differ in visual-spatial skills after treatment. (p. 19)

Language Skills: In the Smith et al. (2000) study, IBI therapy resulted in significantly better total language scores than special education with training, but the two groups did not differ significantly on the RDLS component scores of language comprehension and expressive language. Cohen et al. (2006) reported somewhat similar findings for RDLS component scores. Children receiving IBI therapy exhibited higher (i.e., better) language comprehension and expressive language scores than those receiving other therapy, but these differences not achieve statistical significance. . . . In the study by Remington et al. (2007) . . . [s]ignificantly more children in the IBI group than the comparison group achieved a standard score on the RDLS component scales (comprehension and expressive). . . . At the 2-year follow-up [Kovshoff et al. (2011)], significantly more children in the IBI group were still able to achieve a standard score than in the comparison group on the RDLS receptive (or comprehension) scale. However, these differences did not reach statistical significance for the RDLS expressive language scale. (p. 19-20)

Adaptive Behavior: Cohen et al. (2006) found that IBI therapy significantly improved the VABS composite score, communication score, [socialization score,] and daily living score compared with the comparison treatment . . . Remington et al. (2007) reported significant differences favoring IBI treatment on VABS daily living skills and motor skills scores, but there were no group differences in the VABS composite, socialization, and communication scores. However, these group differences did not persist at 2 year follow-up after the 24-month treatment program (Kovshoff et al., 2011). The remaining two studies did not find significant group differences for any VABS scales (Smith et al., 2000; Reed et al., 2007b). (p. 20)

School Placement: A greater proportion of children were in regular classroom settings without an aide following IBI therapy (27% to 29%) compared with other interventions (0% to 5%) (Smith et al., 2000; Cohen et al., 2006). Remington et al. (2007) reported that 74% of children in the IBI group attended mainstream school after therapy compared with 48% of children in the usual treatment group, but the number of children requiring additional assistance within the classroom was not reported. In the 2-year follow-up of the Remington et al. (2007) study, Kovshoff et al. (2011) found that significantly more children undergoing IBI therapy remained in mainstream school settings than children undergoing usual treatment (61% versus 22%, P=0.013). (p. 20)

The Hayes, Inc. (2012) technical assessment reviewed the two studies on ESDM, one comparing ESDM plus parent training in ESDM plus community services vs. community services alone over a two year period (Dawson et al., 2010) and the other comparing parent training in ESDM (P-ESDM) plus community services vs. community services alone over a twelve week period (Rogers et al., 2012). The following results were noted (a comparison of these findings is also presented in Table 3):

> Autism Severity: There were no significant group differences for autism severity at end of treatment in either study based on Autism Diagnostic Observation Schedule (ADOS) scores. However, Dawson et al. (2010) found that significantly more patients in the ESDM plus parent training plus community services had improved diagnostic status. (p. 22)
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> Intelligence/Cognitive Abilities: With regard to group differences, Dawson et al. (2010) reported that the ESDM plus parent training plus community services group exhibited significantly greater increase in Mullen Scales of Early Learning (MSEL) composite scores than the community services along group at the end of the 2-year study periods. The other study found that there were no significant group differences in a developmental quotient score (DQ) calculated from scores of the four subscales of the MSEL at the end of 12 weeks of parent training and delivery of ESDM (Rogers et al., 2012). (p. 22)
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> Visual-Spatial/Nonverbal Skills: For both studies (Dawson et al., 2010; Rogers et al., 2012), no significant group differences were found on measures of visual-spatial/nonverbal skills. (p. 22)
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> Language Skills: One study reported significantly greater gains in scores on . . . receptive and expressive language . . . for the ESDM … than the community group (Dawson et al., 2010). However, the other study found no significant differences . . . between groups undergoing P-ESDM with community treatment compared with community treatment alone (Rogers et al., 2012). (p.23)
>
> Adaptive Behavior: Both studies assessed adaptive behavior using the VABS composite and subscale scores (Dawson et al., 2010; Rogers et al., 2012). Findings were conflicting across the studies. One study reported that at the 2-year assessment, the ESDM with community treatment group showed significantly greater improvement on all measures of adaptive behavior . . . than the community treatment group alone (Dawson et al., 2010). In contrast, the other study reported that there were no significant differences in any VABS outcomes between groups that received P-ESDM with community treatment or that received community treatment alone (Rogers et al., 2012). (p.23)
>
> School Placement: Neither study of the ESDM therapy evaluated school placement measures. (p.23)

The overall evidence-based conclusions of the Hayes, Inc. (2012) revised health technology assessmentwere as follows:

> "The results of the available studies of IBI and ESDM therapy for young children with autism provide some evidence that these interventions may promote gains in cognitive function, language skills, and adaptive behavior in a subpopulation of children, with no adverse effects reported. However, the overall body of evidence from these studies was of low quality and did not show consistent benefit of treatment due to factors that included weakness in study design and methodology, conflicting study results, and in the case of ESDM, sparse data. No studies were available that directly compared IBI and ESDM interventions to each other. While some children appear to derive considerable benefit from these therapies, patient and treatment characteristics that predict this favorable response to the intervention are currently unknown. In addition, although the initial work by Lovaas suggested that some high-functioning autistic children who undergo IBI therapy can achieve normal school performance and behavior, other investigators have not replicated these studies" (p. 9).

Agency for Healthcare Research and Quality (AHRQ, 2011). The Vanderbilt Evidence-based Practice Center's systematic review of evidence on therapies for children ASDs included 78 behavioral health studies with 30 or more participants published from January 2000 to May 2010 and found:

> "Early intensive behavioral and developmental intervention may improve core areas of deficit for individuals with ASDs; however, few randomized controlled trials (RCTs) of sufficient quality have been conducted, no studies directly compare effects of different treatment approaches, and little evidence of practical effectiveness or feasibility exists.
>
> "Within this category, studies of UCLA/Lovaas-based interventions report greater improvements in cognitive performance, language skills, and adaptive behavior skills than broadly defined eclectic treatments available in the community. However, strength of evidence is currently low. Further, not all children receiving intensive intervention demonstrate rapid gains, and many children continue to display substantial impairment. Although positive results are reported for the effects of intensive interventions that use a developmental framework, such as the Early Start Denver Model (ESDM), evidence for this type of intervention is currently insufficient because few studies have been published to date" (p. ES-7).

Blue Cross and Blue Shield Association Technology Evaluation Center (TEC, 2009). The BCBS TEC reviewed a total of 19 studies (22 articles) including: 2 RCTs; 12 nonrandomized comparative studies; and 5 single-arm studies. Four meta-analyses were also included. This report concluded that the quality and consistency of this body of evidence were weak; therefore, no conclusions could be drawn regarding how well IBI works for treatment of children with ASD.

National Autism Center (NAC, 2009). The NAC's National Standards Project produced a National Standards Report which employed a classification system for treatment to include "established," "emerging," "unestablished," and "ineffective/harmful" treatments. Comprehensive behavioral treatment for young children (also referred to as ABA

programs, behavioral inclusive program, and EIBI) were rated as an "established" treatment on the basis of results from 22 studies. However, the Scientific Merit Rating Scale (SMRS) used to classify these studies included single-subject design studies. The CCT studies included in this category are predominantly the same as those noted in TMA's literature search and other reviews, and they are subject to the same biases and limitations as non-RCT studies.

Published Reports of National Professional Medical Associations:

American Academy of Pediatrics (AAP, 2007). AAP stated that, "children who receive early intensive behavioral treatment have been shown to make substantial, sustained gains in IQ (intelligence quotient), language, academic performance, and adaptive behavior as well as some measures of social behavior, and their outcomes have been significantly better than those of children in control groups" (Myers et al., 2007, p. 1164). However, the process used to develop these recommendations is not described and do not appear to be based on a systematic review of the literature. The AAP notes that all clinical reports automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before this time. This clinical report is past due for expiration given that it was published in 2007.

American Academy of Child & Adolescent Psychiatry (AACAP, 1999). The AACAP has published practice parameters on the assessment and treatment of children, adolescents, and adults with autism and other pervasive developmental disorders (PDD) (Volkmar et al., 1999). An update of these parameters reportedly is under final review currently but not yet available.

The AACAP website has a Frequently Asked Questions (FAQ) page on its "Autism Resource Center" webpage. In response to the FAQ, "Are there treatments available for autism?" the following response is noted:

> "There are no specific treatments to "cure" autism. Each child with an autism spectrum disorder has a unique constellation of developmental delays, speech deficits, social and cognitive impairments. Therefore, comprehensive treatment plans need to be developed to target each child's unique profile of strengths and functional impairments."
> (http://www.aacap.org/cs/autism_resource_center/faqs_on_autism#autismq5, accessed 28 Apr 2013).

Mental Health: A Report of the U.S. Surgeon General (1999). The U.S. Surgeon General mentions ABA on page 164:

> "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). Nineteen children with autism were treated intensively with behavior therapy for 2 years and compared with two control groups. Followup of the experimental group in first grade,

> in late childhood, and in adolescence found that nearly half the experimental group but almost none of the children in the matched control group were able to participate in regular schooling. Up to this point, a number of other research groups have, provided at least a partial replication of the Lovaas model (see Rogers, 1998)."

The U.S. Surgeon General Report primarily discusses the original Lovaas study and its follow-up study by McEachin et al. (1993). However, as noted above, the Lovaas study and its follow-up are marred by its use of contingent aversive techniques and significant, well-documented methodological flaws. This one paragraph discussing ABA in the Report of the Surgeon General cannot be accepted as reliable evidence given that: (a) it is fourteen years old, and (b) the most telling thing about it is that no researchers to date have achieved the dramatic replication of results reported in Lovass et al. (1987).

Published National Medical Policy Organization Positions and National Expert Opinion Organizations:

Technical Expert Panel (TEP), Southern California Evidence-Based Practice Center (EPC), and University of California Los Angeles (UCLA) (2012). The Maternal and Child Health Bureau of the U.S. Health Resources and Services Administration (HRSA) funds a research center aimed at investigating treatment of the behavioral aspects of ASD which is based at UCLA. UCLA contracted with the Southern California EPC to conduct a systematic review of the scientific evidence of the efficacy of non-medical interventions and to develop evidence-based guidelines based on the systematic review with guidance from a Technical Expert Panel (TEP) consisting of practitioners, researchers and parents. This review resulted in published recommended guidelines for "non-medical" interventions for children with ASD (Maglione et al., 2012). After reviewing the evidence, the TEP concluded that the evidence indicating that intensive interventions are effective at improving core deficits of ASD is of "moderate strength," (defining "moderate strength" as "moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of the effect and may change the estimate," Maglione et al, 2012, p.S171). The authors noted that only two randomized controlled trials had been completed, the majority of studies were either nonrandomized trials or observational, and there were few large samples. The authors concluded that:

- evidence is currently not sufficient to suggest the superiority of one type of behavioral curriculum over others;
- none of the evidence reaches the high level of strength;
- not all children who attend comprehensive programs will make significant gains in their core deficits; and
- the evidence is not clear as to which characteristics of participants are correlated with the success of various approaches.

It is relevant that Maglione et al. (2012) noted in their report that the multidisciplinary TEP (which included some parents of children with autism) arrived at their final consensus statements

by a voting process based not only on the evidence from the systematic review, but also on their own individual backgrounds. Results of votes for consensus statements as being "strong" or "weak" were translated into a rating system of A (with 90%–100% voting "strong"), B (with 80%–89% voting "strong"), or C (with <80% voting "strong"). Thus, "the rating for each guideline statement does not necessarily reflect the strength of evidence for a particular intervention, because the members of the TEP used their expertise and personal experience to inform their votes" (Maglione et al, 2012, p.S172). The panel was split in voting on the specific guideline that "children with ASD should be actively engaged in comprehensive intervention for a minimum of 25 hours per week throughout the year," which received only received a "C" rating, as only 56% of the panel rated this as a strong recommendation. Thus, the specific question of the benefit of intensive behavioral intervention for ASD was not answered by the TEP with a solid consensus. In fact, the TEP report noted that:

> "The goal of this [TEP] process was to reach a unanimous agreement on guideline statements and achieve a high level of enthusiastic agreement from all TEP members. Because the body of evidence on many of the interventions is not robust, because many of the findings are mixed, and because the various experts in the room subscribed to different philosophical schools and use differing methodological approaches (e.g., single study design versus controlled trials), some discussion was contentious." (S171-S172).

Third-party Payers: *Subject-specific third party payer policies (i.e., Aetna, Cigna, Humana, Regence Group, United Healthcare)*

Aetna: Aetna considers certain procedures and services as medically necessary for the treatment of autism and other PDDs when the following criteria are met:

- Any loss of language or social skills at any age.
- No two-word spontaneous phrases by 24 months of age (not only echolalic vocalizations).
- No babbling by 12 months of age.
- No gesturing by 12 months of age.
- No single words by 16 months of age.

Intensive behavioral interventions in which the child is engaged in systematically planned and developmentally appropriate educational activities directed toward identified objectives ***may*** be included as treatment for the member's condition. However, many plans exclude coverage of educational services. The policy also notes that there is insufficient evidence of the superiority of any one type of intensive intervention strategy over other intensive educational intervention strategies (Aetna, 2012).

CIGNA: CIGNA's coverage policy states that intensive behavioral interventions for autism (e.g., IBI, EIBI, Lovaas therapy, and ABA) are **not covered** as treatment for ASDs because they are considered experimental, investigational, or unproven for this indication (CIGNA, 2011).

Humana: Humana's coverage policy on PDD indicates that ABA (or Lovaas therapy, IBI, and EIBI) is **not an eligible treatment benefit** (Humana, 2012).

Regence Group: Regence Group's coverage policy on ABA for treatment of ASD indicates that ABA-based therapy is **considered investigational for all indications**, including but not limited to treatment of ASD (Regence Group, 2012).

United Healthcare (UHC): The medical policy identified on the UHC website states that IBI/ABA (including Early Start Denver Model [ESDM] programs) is **unproven for the treatment of ASDs** (UHC, 2012).

Other Documents:

Office of Personnel Management Benefit Review Panel for ABA (OPM, 2012). As noted in the "Background" section, the OPM Federal Employee Health Benefit (FEHB) Program Carrier Letter of April 19, 2012, noted the following regarding ABA:

> "The OPM Benefit Review Panel recently evaluated the status of Applied Behavior Analysis (ABA) for children with autism. Previously, ABA was considered to be an educational intervention and not covered under the FEHB Program. The Panel concluded that there is now sufficient evidence to categorize ABA as medical therapy. Accordingly, plans may propose benefit packages which include ABA." (p. 11)

The OPM Benefit Review Panel's review leading to the conclusion that ABA is "medical" is not published. Also this determination by the OPM Benefit Review Panel regarding ABA is not binding on insurance companies to provide ABA in their health care plans.

Interagency Autism Coordinating Committee Strategic Plan for Autism Spectrum Disorder Research (2012). The 2012 IACC Strategic Plan Update "covers advances and new opportunities in the field that have emerged between January 2011 and December 2012." In discussing treatments for ASD, the IACC document notes,

> "Evidence for the benefits of early behavioral intervention continues to mount, with researchers now focusing on testing interventions for infants and toddlers, identifying the most effective aspects of treatments, and disseminating these interventions in community settings. While gains have been made in this area of research, the effects of these interventions as measured to date are modest." (p. 28)

The IACC is a Federal Advisory Committee established under FACA. As a FACA, the committee comments and makes recommendations, but their opinions are not determinative or binding. It does not rise to the level of any of the medical or policy organizations listed in the regulation definition of "reliable evidence."

Letter from Thomas R. Insel, M.D., Director, National Institute of Mental Health, and Chair, Interagency Autism Coordinating Committee (IACC), to The Honorable Kathleen Sebelius, Secretary of Health and Human Services (HHS). The letter noted:

> "Given recent updates regarding the evidence base for the effectiveness of early intervention in improving functioning in many different domains, the Interagency Autism Coordinating Committee recommends support for coverage of and broad access to these treatments for children diagnosed with ASD."

As noted above, the IACC is a FACA, and the IACC's letter is also not a "published report" as required by the TRICARE regulation. Although this letter is not reliable evidence, it is interesting evidence in that this organization or group was attempting to persuade the Secretary of HHS to use the influence of her political office to make ABA mandated minimal coverage under the Affordable Care Act (ACA). As stated in the letter, this would have been over the protest of the insurance industry which did not believe ABA should be covered as a medical benefit.

Defense Health Board Findings Pertaining to Autism Treatment (DHB, 2009). This document was a memorandum from the Defense Health Board for Ellen P. Embrey, Deputy Assistant Secretary of Defense (FHP&R), Performing the Duties of the Assistant Secretary of Defense for Health Affairs. Among multiple recommendations regarding Autism treatment, the DHB stated, "Regarding long-term effects of treatment associated with ABA: insufficient evidence exists to draw conclusions regarding the long-term efficacy of any current intervention strategies." (p. 3). However, the DHB memorandum is not a published report and therefore not to be interpreted as reliable evidence.

Article with Recommendations from the Association for Science in Autism Treatment (ASAT, 2010). This document notes, "Because ABA currently has substantially more scientific support than any other behavioral or educational intervention for children with ASD, ASAT recommends that families and professionals strongly consider implementing ABA and be cautious about other approaches."

ASAT (http://www.asatonline.org/) is not a recognized National Medical Policy Organization or National Expert Opinion Organization. According to its website, "ASAT is a not-for-profit organization of parents and professionals committed to improving the education, treatment, and care of people with autism." It is supported by individual donors and over 40 professional partners. Therefore, the article posted on its website and its recommendations are not considered reliable evidence. As noted in the reliable evidence standard (32 C.F.R. Sec. 199.4(g)(15), "Specifically not included in the meaning of reliable evidence are reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence or personal professional opinions." As this document contains only abstracts of other reports, it does not meet TRICARE's reliable evidence criteria.

Letter from Autism Experts to the United States Armed Services Committee, dated September 19, 2008. This letter states, "The effectiveness of ABA-based intervention in Autism Spectrum Disorders has been well documented through 5 decades of research by using single-subject methodology and controlled studies of comprehensive early intensive behavioral intervention programs." It is signed by 58 individuals who describe themselves as "experts in the fields of autism research, education, treatment, and diagnosis." In examining their signature blocks, all of them either are or are affiliated with individual or institutional providers of services for ASD. Together they do not comprise a named organization that would be considered a National Medical Policy Organization or National Expert Opinion Organization, and none of them individually is a National Medical Policy Organization or National Expert Opinion Organization. As noted in the reliable evidence standard (32 C.F.R. Sec. 199.4(g)(15), "Specifically not included in the meaning of reliable evidence are reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence or personal professional opinions."

Letter from Autism Organizations to Secretary Gates, dated May 19, 2008. This letter states that, "Habilitative and rehabilitative care should include professional counseling and guidance services and treatment programs, including Applied Behavior Analysis and related structured behavior programs that are necessary to develop, improve, maintain, and restore to the maximum extent practicable, the functioning of the individual with autism spectrum disorders." The letter is signed by 13 autism organizations collectively called "The Autism Collaboration." They do not comprise a named organization that would be considered a National Medical Policy Organization or National Expert Opinion Organization. As noted in the reliable evidence standard (32 C.F.R. Sec. 199.4(g)(15), "Specifically not included in the meaning of reliable evidence are reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence or personal professional opinions."

Discussion of Reliable Evidence

Among other features, a "well-controlled study" should be designed as a randomized clinical trial (RCT), meaning that participants are randomly assigned either to the group receiving the intervention of interest or a suitable control group. This is the standard in evaluating a new drug or therapeutic procedure. According to the 2005 Presidential Task Force on Evidence-Based Practice commissioned by the American Psychological Association, "randomized clinical trials and their logical equivalents (efficacy research) are the standard for drawing causal inferences about the effects of interventions (context of scientific verification)" (p. 8). TMA's search of the literature and that of the external reviewer, Hayes, Inc. (2012), revealed only two RCTs of IBI and two RCTs of ESDM. One of the RCTs (Smith et al., 2000) comparing IBI versus a parent-training plus special education group and found mixed results, with significantly higher IQ, visual-spatial and language skills in the IBI group but no significant differences in adaptive functioning or behavior problems. As noted above, this study lacked sufficient power (due to the low number of subjects) to compare or control for group difference by diagnostic study, as

children with diagnoses of Autism and children with Pervasive Developmental Disorder were included in the sample, which could have been a source of bias in the findings. Also, ABA techniques involving aversive conditioning, which would be strictly prohibited for ABA provided under TRICARE, were used with four of the 28 children (14%). This limits the generalizability these findings based on Lovaas IBI using aversive techniques with ABA as currently practiced, which reportedly no longer uses aversive techniques. The subsequent study of RCT of IBI (Sallows & Graupner, 2005) was remarkable for not finding any post-treatment differences between a clinic-directed IBI group and a parent-managed treatment group. Furthermore, this RCT demonstrated that while ABA delivered by trained clinic staff was no more effective than what parents did with children at home, it was the individual characteristics of the children themselves (i.e., pre-treatment IQ, pre-treatment receptive language and imitation scores, and pre-treatment autism diagnostic social and communication scores) not the intervention, that determined whether or not they achieved significant gains at post-treatment. These pre-treatment, individual difference factors accounted for 70% of the variance in the outcomes observed.

Similarly, the two RCTs on ESDM had conflicting findings, with the original study (Dawson et al., 2010) showing significant effects for ESDM (plus parent training plus community services) on most outcomes, but the subsequent study (Rogers et al., 2012, comparing parent training in ESDM strategies combined with community treatment vs. community treatment alone over a 12-week period) did not replicate any of the Dawson et al. (2010) findings. Thus, the Dawson et al. (2010) findings have yet to be replicated to establish reliable evidence of its effectiveness. Consulting the Merriam-Webster Online Dictionary, (http://www.merriam-webster.com/dictionary), "reliable" has the following meanings:

1: suitable or fit to be relied on: dependable
2: giving the same result on successive trials

Definition 2 is exactly the relevant meaning of "reliable" as applied to the 32 C.F.R. § 199.4(g)(15) requirement for reliable evidence. In the scientific process, experimental results require replication to be considered reliable. This means that: (a) there should be several studies detecting the same outcome for a particular treatment, and that (b) the results of subsequent studies of a particular treatment should not be conflicting, where some studies show a significant effect of the intervention for a particular clinical outcome and other studies do not. Given the requirement for replication of findings in the published literature for evidence to be considered "reliable," the Dawson (2010) study does not meet criteria for reliable evidence under TRICARE. This frequently cited RCT of ESDM would require replication in better controlled RCTs to qualify as reliable evidence, particularly in light of the fact that replication of Lovaas' (1987) early dramatic findings in support of ABA for ASD have not been achieved.

A relevant example of the type of evidence TMA looks for to determine in an intervention is reliable would be the agency's 2010 determination of Eye Movement Desensitization and

Reprocessing (EMDR) as proven treatment for PTSD. Prior to this review, the agency's assessment of EMDR was consistent with the exclusion of EMDR as a proven intervention for PTSD as noted in TRICARE Policy Manual Chapter 7 Section 13.3 III. E, which stated, "Eye Movement Desensitization and Reprocessing (EMDR) is not psychotherapy," and since the treatment was not recognized as psychotherapy, it was not covered under the TRICARE program. What led to TMA's reversal of this view and recognition of EMDR as a proven treatment for PTSD was the strength of the clinical literature demonstrating it to as effective as psychotherapy for treatment of PTSD. By contrast, only four RCTs evaluating ABA for ASD, resulting in conflicting findings, there have been twelve RCTs evaluating EMDR for PTSD that compared EMDR not only to no-treatment control groups, but also to other established psychotherapeutic interventions such as stress inoculation and trauma-focused cognitive behavioral therapy/exposure therapy (Bisson & Andrew, 2007).

It has been argued elsewhere (Potter vs. Blue Cross Blue Shield of Michigan) that ABA is not conducive to the RCT study design because of ethical considerations (i.e., early intervention is the recommendation for children diagnosed with Autism) or parent protest (i.e., parents self-select the intervention for their ASD child and may perceive ABA as the most desirable intervention) (p. 17). Regarding these objections, it could be construed as a circular argument that an intervention being studied for its effectiveness cannot be subjected to a rigorous test of its effectiveness because it is already perceived as the most effective intervention. The issue of parent protest introduces an obvious and immediate source of selection bias in the studies that do not employ randomization. The findings of this review are that there are a variety of non-ABA early interventions that could ethically be provided to children with Autism as a control group condition, several of them being established medical interventions currently cost-shared by TRICARE, such as speech and language pathology therapy (SLP) or occupational therapy (OT). Furthermore, research studies could be designed such that different interventions (ABA, SLP, OT) are applied in sequence coupled with more frequent or granular assessment between conditions with a larger study sample such that studies are sufficiently powered to detect group differences across a shorter time frame. This type of design seems more appropriate from an ethical and scientific perspective than the non-random assignment of small numbers of children to intervention conditions for extended periods of time (i.e., one to two years).

A "well-controlled" study also means one that is relatively free of bias. Reichow et al.'s (2012) meta-analysis found that the CCTs studying IBI were subject to risk of performance bias and detection bias. Performance bias refers to systematic differences between groups in the care that is provided, or in exposure to factors other than the interventions of interest (i.e., ABA). Detection bias refers to systematic differences between groups in how outcomes are determined, in other words, the risk that knowledge of which intervention was received, rather than the intervention itself, affects outcome measurement. It may be very difficult to eliminate performance bias in all studies with children with ASD due to parents insisting that their child receive a particular intervention. Detection bias, however, was also a major threat to the validity

of the CCTs that were included in Reichow et al's (2012) meta-analysis because for all studies, the primary outcome (adaptive behavior) was assessed using parent self-report, yet parent selection of which intervention their child received (IBI vs. control) was the principal reason for the non-random assignment of participants. Additionally, in one of the four studies (Magiati, 2007), the outcome assessors of all measures were not blind to the treatment status of the participants they were assessing, which introduced another source of potential bias in the findings. Finally, because of the few number of controlled studies conducted (both RCTs and CCTs), the risk of publication bias, or the tendency to publish or report positive results over negative results, cannot be ruled out (Reichow et al., 2012). The presence of publication bias in the literature regarding IBI or ABA treatment would have the effect of generating a misleading bias in the overall published literature that the intervention is effective due to negative findings never receiving the visibility of publication.

Furthermore, in the Controlled Clinical Trials (CCTs) conducted, where there was non-random assignment of subjects to groups, the most recent Cochrane Review of EIBI for ASD (Reichow et al., 2012) also found that three of the four CCTs included in their meta-analysis had group imbalances on baseline measures. This difference between the treatment and comparison groups at baseline means that even the non-randomized CCTs of ABA were not "well-controlled studies" because the study did not control for (i.e., "balance out") these inherent differences between comparison groups.

"Well-controlled" also means that the intervention studied (in this case, ABA) was reasonably isolated as a treatment condition to determine the effect or impact of the intervention of interest. This means that the effects of confounding variables (e.g., ancillary interventions, variation in treatment delivery) have been minimized or controlled for to the maximum extent possible. The recent RCT of ESDM (Dawson et al., 2010) published in *Pediatrics* did not originally meet inclusion criteria for the Hayes (2010) technical report as it involved a mix of intervention by specialists and by parents, but it was specifically included in this TMA review and in Hayes' most recent 2012 technical assessment, in part because of Dr. Dawson's citation of her own study during her June 2012 testimony to the Senate Armed Service Committee, Subcommittee on Military Personnel. ESDM, as assessed in this study, was an eclectic therapeutic approach that included not only ABA, but also other potentially effective treatments (e.g. speech therapy, etc.) that children may have received during the study period in both the EDSM group (mean = 5.2 hours/week) and the assess-and-monitor control group (mean = 9.3 hours/week). The intervention evaluated was a mix of parent and provider intervention, and both the ESDM group and the assess-and-monitor control group received substantial community services making it difficult to standardize the specific intervention, and the types of treatment the control group received were not well-assessed or characterized.

For both IBI and ESDM interventions, the results of the RCTs and CCTs reviewed were conflicting with respect to clinically meaningful endpoints. As summarized in the Hayes (2012) review, above, and in Tables 1 and 2, the findings of studies of IBI ranged from across the board

improvement in all ASD outcomes assessed (e.g., Howard et al., 2005) to no apparent effect for ABA compared to the control group condition in any ASD outcome assessed (e.g., Magiati et al., 2007). Most studies showed mixed findings with significant between-group differences on some ASD outcomes but not others, but these outcomes were not consistent across studies:

- For intellectual and cognitive ability, six studies found significant differences between IBI and control groups (Eikeseth et al., 2002, 2007; Howard et al., 2005; Eldevik et al., 2012; Smith, 2000; Cohen et al., 2006; and Remington et al., 2007), two studies did not (Magiati, 2007; Zachor & Ben Itzchak, 2010), and Reed et al. (2007b) found the IBI group performed better while than the group receiving portage therapy but not the group in special nursery education.

- For visual-spatial and non-verbal skills, two studies found significant group differences in favor of IBI (Howard et al., 2005; Smith, 2000) and two studies did not (Eikeseth et al., 2002, 2007; Cohen et al., 2006).

- For language ability, four studies found significant group differences in favor of IBI (Eikeseth et al., 2002, 2007; Howard et al., 2005; Zachor et al., 2007; Zachor & Ben Itzchak, 2010), two studies did not (Cohen et al., 2006; Fava et al., 2011), and two studies had conflicting findings among the language ability measures used in the initial study (Strauss et al., 2012) or in the follow-up assessment (Remington et al., 2007, followed up by Kovshoff et al., 2011).

- For adaptive behavior, four studies found significant between-group difference favoring IBI (Eikeseth et al., 2002, 2007; Howard et al., 2005; Eikeseth et al., 2012; Cohen et al., 2006), six studies found no significant differences between groups (Magiati et al., 2007; Reed et al, 2007b; Zachor & Ben Itzchak, 2010; Fava et al., 2011; Strauss et al., 2012; Smith, 2000), and two studies found mixed results between groups among the various VABS subscales used (Eldevik et al., 2012; Remington et al., 2007,) and for one of these studies (Remington et al., 2007), the significant between-group differences noted on certain VABS subscales in the initial study were not detected in the follow-up assessment (Kovshoff et al., 2011).

- Four studies of IBI reported significantly more children receiving IBI being placed in mainstream schooling without one-on-one support (Eikeseth et al., 2007; Smith, 2000; Cohen et al., 2006; Remington et al., 2007; Kovshoff et al., 2011), and one study found no between-group difference in need for one-on-one support (Magiati et al., 2007).

- With respect to the most clinically meaningful outcome measure, autism severity, four of five studies of IBI (Magiati et al., 2007; Reed et al., 2007b; Fava et al., 2011; Zachor and Ben Itzchak, 2010) found no significant between-group differences on this outcome upon

final follow-up. In the one study that did note a between-group difference (Strauss et al., 2012), the results of statistical analysis for group differences were not reported.

It is relevant to note again that all of these studies of IBI, with the exception of Smith (2000), were CCTs and not RCTs. Thus even for CCTs, the results for IBI were mixed across studies. For the RCTs of ESDM, Dawson et al. (2012) found significant between-group differences on all outcome measures except autism severity, as measured by the ADOS, and visual-spatial/non-verbal ability, but none of these findings were replicated in the subsequent study by Rogers et al. (2012), again demonstrating mixed results ESDM. Therefore the findings of these studies of ABA indicate that ABA does not reliably produce clinically meaningful endpoints, which as reflected in the Merriam-Webster Online Dictionary definition of "reliable", means that ABA is not an intervention "giving the same results on multiple trials" and it is another indication of not meeting TRICARE's reliable evidence standard. It is not scientifically valid to cherry-pick from the contradictory findings of multiple studies to make the case that ABA improves all of the various outcomes of interest, i.e., autism severity, cognitive ability, visuospatial skills, language ability, adaptive behavior, mainstream classroom placement, etc.

Another relevant point to note is that cognitive ability, as measured by intelligence quotient ("IQ" score) or another measure is not, in and of itself, a clinically meaningful endpoint. "Intelligence" is a construct derived from theory, and scales such as IQ are artificial measures of that theoretical construct. In other words, IQ or other scales of cognitive ability should not be reified as a biological test of brain functioning, which they are not. Intellectual functioning is also not one of the defined core deficits in the diagnosis of ASD, as it is with the diagnosis of Mental Retardation, which is explicitly defined by IQ scores according to the DSM-IV-TR. As noted by Kasari & Lawton (2010), IQ as a primary outcome measure is problematic due to the confounding of true improvement in cognitive skills with an improved test-taking capability due to practice effects. Therefore, the theory that ABA elevates brain functioning or helps children with ASD approach or return to a normal "glideslope" of brain development cannot be substantiated by IQ or cognitive ability scores alone. The clinically meaningful endpoints for ASD involve demonstration of any skills acquired via ABA generalize to other tasks and behaviors or across settings. This is the reason for assessing functioning across multiple domains (i.e., language, adaptive behavior, school placement, etc.). Again, with respect to the most clinically meaningful endpoint, autism severity, studies of ABA produced mixed findings, with most studies not showing significant between-groups differences favoring ABA over standard educational interventions.

While there are some published reports of national organizations that advocate for ABA interventions with children with ASD, these must be given less weight than "well-controlled studies of clinically meaningful endpoints, published in refereed medical literature." As summarized above, these primarily non-randomized studies, of poor quality, yielding conflicting results, cannot be categorized as "well-controlled." Since the published reports of national organizations are drawing from these studies to make their recommendations, their conclusions

must be called into question. Multiple published reviews and meta-analyses have further discussed the limitations of existing research regarding ABA therapy for ASD. Specific limitations regarding the evidence-base for ABA as an effective intervention for ASD are listed below:

- Hayes (2012) short health technology assessment noted additional research of higher quality is needed to determine the benefit of IBI and ESDM in both controlled and real-worlds settings. These studies should focus on identifying which treatment variables and patient characteristics are associated with favorable treatment outcomes. Research in the area of ABA would be made more rigorous through use of randomization, standardized protocols, blinded evaluators, and treatment adherence. More longitudinal designs are needed to evaluate long-term outcomes of ABA with ASD in real-world environments.

- Maglione, Gans, Das, Timbie, & Kasara (2012) in their review of "Non-medical Interventions for Children with ASD" found significant heterogeneity in outcomes measures used in trials and interventions for ASD, use of assessment measures lacking previous validation studies, and outcome measures that were reported in nonstandardized ways. Furthermore, the small sample sizes limited the authors' ability to draw meaningful conclusions from reviews.

- Warren et al. (2011) conducted a systematic review of EIBI and noted the limitations of: single subject design; research with fewer than 20 participants; heterogeneity of the children in the studies; and, a variety of outcomes measures and interventions applied across the ASD population.

- Kasari & Lawton (2010) noted, as stated above, that IQ as a primary outcome measure is problematic due to the confounding of true improvement in cognitive skills with and improved test-taking capability due to practice effects. The authors also noted that in the studies they reviewed: few studies used a treatment manual; it was difficult to compare treatments that vary so drastically in terms of agent (parent vs. therapist) and mode of delivery (one-on-one, group, home, clinic); and, studies needed to more closely monitor moderators of treatment outcomes and better understand differences related to the dose and content of the treatment delivered.

- Makrygianni, & Reed, (2010) conducted a meta-analysis of the effectiveness of early behavioral intervention for ASD and identified the following methodological limitations: small sample size; lack of comparison groups and matched groups or randomized assignments, the use of a variety of measures in the same study; and, and the potential for floor effects, meaning that differences between intervention and control groups may be difficult to measure due to the data from both groups falling in the extreme bottom end of the distribution (e.g., IQ score).

- Virues-Ortega's (2010) meta-analysis identified several limitations in the studies, which included: lack of randomization to group assignment, even stating the use of quasi-random assignment strategies raised "various ethical and internal validity concerns" (p. 397); use of prospective designs; quality standards specific to the field were not followed; and, "publication bias was evident in all outcomes but daily living skills, motor functioning and composite adaptation" (p 398).

Several of the studies also highlighted research gaps and priorities that need to be addressed to establish reliable evidence of the effectiveness of ABA for treatment of ASD:

- Maglione et al. (2012) identified 5 top research priorities to address the current gaps in knowledge about the effectiveness of ABA: assessment and monitoring of outcomes; understanding and addressing the needs of pre- or non-verbal individuals with ASD; understanding and addressing the needs of adolescents and adults with ASD; identifying the most effective strategies to impact the specific core deficits of ASD; and, identification of the most effective amount and duration of interventions.

- Reichow (2011) identified the following research gaps: data providing information on the child characteristics that are most likely to be associated with the best outcomes are needed; additional knowledge on the characteristics of EIBI outside of the treatment studies is needed; "guidelines focusing on the intensity, duration, level of treatment fidelity, and therapist experience and/or training necessary to achieve optimal outcomes should be more closely measured and reported in future research" (p. 518). Reichow (2011) further identified a need for belter knowledge about treatment outcomes.

- Dawson & Burner (2011) identified the need for studies that focus on defining key active ingredients, comparing treatment options, and identifying predictors of response to treatment as well as longer term follow-up.

- Virues-Ortega (2010) recommended the following for future research: observation of clinical trials quality standards including intention to treat analysis and randomization; use of no-treatment, or matching treatment intensity and duration across groups; increasing treatment fidelity; and, direct comparison of different interventions.

Conclusions from findings in the clinical literature cannot be made separate from a consideration of the quality of that literature. Assessing the quality of the research conducted is standard practice in all health technology assessments. While some studies found ABA improved some clinical outcomes for some individuals, without consideration of the quality of the research or the weaknesses in the body of literature on ABA, other studies found that some clinical outcomes improved for some individuals who did not receive the specific intervention of interest. This

point, for example, was demonstrated by one of the few RCTs of IBI discussed above (Sallows & Graupner, 2005) which found no post-treatment differences between a clinic-directed IBI group vs. a parent-managed treatment group, but that after pooling data from both groups, the significant gains on post-treatment measures for half (48%) of the combined group of children were largely attributable to characteristics of these "rapid learners" (e.g., pre-treatment IQ, language/communication ability, etc.) and that these individual difference factors, not the interventions themselves, accounted for most (70% of the variance) of the improvement observed.

B. Is ABA "Safe?"

The Hayes (2012) review of ABA concluded, "No adverse outcomes or side effects have been reported with the use of IBI therapy, and there is no evidence that it causes harm or increases the severity of the disorder" (p. 8). However, TRICARE does not endorse nor cover aversive techniques, and the Hayes (2012) finding in this regard is understood to be based on the exclusion of aversive techniques.

While there may be no documented cases of harm or worsening of symptoms in the various studies of ABA, TMA's primary concern about the safety of ABA is the practice of healthcare by unlicensed practitioners who in many cases may have little to no training in the provision of healthcare or experience in the healthcare system. As noted in Section IV on "TRICARE Regulations and Policy," the lack of healthcare training and orientation requirements for many ABA practitioners (according to BACB certification requirements) presents a risk to quality of care in that they may not be trained, for example, to recognize co-morbid conditions, which frequently co-occur in patients with ASD, that require intervention by physicians or other healthcare professionals. Viewing the ASD patient from the purely behavioral or "stimulus-response" lens can increase the risk that physical, emotional, biological, or family systems factors are discounted or overlooked in comprehensive care of the ASD patient. ABA practitioners also may not, for example, be trained in common healthcare provision practices such as: basic clinical observation and interviewing skills; confidentiality and Health Insurance Portability and Accountability Act (HIPAA) requirements; body substance isolation practices; and recognizing situations requiring mandatory reporting of abuse or a duty to intervene and warn if the patient presents a danger to self or others.

C. How Can ABA be Covered Under ECHO If It Is Not "Proven?

ASD, or "Pervasive Developmental Disorders," meet the definition of a qualifying condition for purposes of the ECHO benefit under 32 C.F.R. § 199.5(b)(2)(iii) as an "Extraordinary physical or psychological condition . . . as defined in Sec. 199.2." Under ECHO, TRICARE may provide certain services to Active Duty Family Members (ADFMs) not covered under the Basic Plan. Among these services are:

> "Training that teaches the use of assistive technology devices or to acquire skills that are necessary for the management of the qualifying condition. Such training is also authorized for the beneficiary's immediate family." [32 C.F.R. § 199.5(c)(i)(3)]

TMA recognizes that children with ASD are difficult to care for and manage. Therefore, consistent with the purpose of the ECHO program, TRICARE has a long history of providing ABA to ADFMs with dependent children with ASD under the ECHO program. As noted in the "Model Act for Licensing/Regulating Behavior Analysts" (Sept, 2012), "'Practice of behavior analysis' means the design, implementation, and evaluation of instructional and environmental modifications to produce socially significant improvements in human behavior." (p. 3). Thus, TMA acknowledges this BACB definition of behavior analysis at face value and views ABA as imparting potentially helpful training or skills for ADFMs in the promotion of socially positive behavior of children with ASD rather than "medical" "treatment" of a disease or underlying illness.

There is a common layman's misunderstanding that ABA is the most effective "treatment" for ASD, and that ABA is the generally accepted norm and in fact the principal modality for treating ASD. That assertion is misleading because it is an incomplete statement and typically asserted out of the context of whether ABA is being discussed as an accepted medical modality delivered by a bona fide healthcare professional, or within the context of ABA being provided as behavior modification or "training . . . to acquire skills that are necessary for the management of the qualifying condition" as noted in the ECHO regulation.

In its semi-annual reports to Congress concerning evaluation of the ECHO Autism Demo, DoD has noted that ABA is "the most effective treatment for Autism". That statement was repeatedly made in the context of ABA being viewed as a non-medical service provided by non-medical providers to children with ASD. DoD's conclusions were based on an analysis of surveyed parental opinion and not on any inquiry into the medical nature and/or efficacy of ABA as a behavioral medicine modality or as to whether behavior analysts meet the requirements to be a TRICARE Basic Program medical providers and not merely ECHO-only program providers. IAll that the Department has recognized in the TRICARE ECHO Autism Demo is that ABA is perceived as helpful by parents in managing their dependent children with a diagnosis of ASD based on the subjective report of parents. While this is sufficient to sustain the Autism Demo as an ECHO program under the broad authority of 10 U.S.C. 1079(d-f), it is not sufficient to address the clinical research requirements necessary to satisfy proof of medical necessity under the reliable evidence standard so as to authorize TRICARE to cover ABA as a medical benefit.

D. Is Denial of ABA to TRICARE Basic Plan Beneficiaries Inconsistent With the Purpose of the Military Health Benefits Statute?

The Court in Berge vs. U.S. found the Department did not give due consideration to the stated purpose for the military health benefits statute's adoption, referring to 10 U.S.C. § 1071 ("The purpose of this chapter is to create and maintain high morale in the uniformed services by

providing an improved and uniform program of medical . . . care . . . ."). The implication is that not providing ABA services to military families with children with ASD will degrade the morale of those service members. The Department has acknowledged that Active Duty parents – who are typically relocated away from their extended families, often to remote locations, with varying degrees of community services, and often deployed leaving a single parent behind to care for their children – may need assistance and training with managing their beneficiary children with ASD or other qualifying conditions for special services, and this is precisely why ABA services were offered under the ECHO program. Retiree and non-Active Duty Service members, who are not eligible for ECHO, have more flexibility in where they choose to live and can relocate to access community services already provided for children with ASD. However, provision of supplemental services to Active Duty Service members who elect to avail themselves of those services is very different from prescribing a course of treatment on the presumption that it is effective in treating the underlying disorder of ASD and setting up the expectation that this treatment will "normalize" the brain functioning of the beneficiary with ASD.

TRICARE maintains high morale not only by providing a broad suite of medical care services but by providing high quality (i.e., "improved") services. Ensuring that the health care services provided are medically and psychologically necessary, with unbiased evidence of demonstrated effectiveness, delivered by appropriately trained and licensed health care professionals, is also necessary to maintain high morale. TRICARE must also be sensitive to the potentially harmful effect on families of authorizing an intervention that is not supported by sufficient reliable evidence of effectiveness. A recent study on families found that approximately 30% of parents reported being disappointed or upset by the limited progress shown by their child following ABA therapy (Grindle et al., 2009). This may have been because of high parental expectations based on the reported outcomes the early Lovaas (1987) study where 47% of children were able to participate in mainstream education after 2 years of therapy. After 25 years, these results have not been replicated, and recent claims that ABA "normalizes" brain function in children with ASD (Dawson et al., 2012) may again be setting up an unrealistic expectation for the parents children with ASD regarding the effectiveness of ABA. Thus, TRICARE views the promotion of an unproven intervention such as ABA as high quality, "improved" healthcare, when practiced by predominantly unlicensed practitioners, who have no certification requirement for clinical practicum or internship experience within the healthcare system and who have not been supervised by bona fide licensed healthcare professionals, as potentially harmful considering the vulnerable nature of the beneficiaries with ASD in question, who are typically non-verbal and cannot advocate for themselves if other significant symptoms are misdiagnosed or overlooked, or they themselves are mistreated, neglected, or abused.

E. Is TRICARE Ignoring Its Own Regulations in Declaring ABA "Unproven?"

With respect to ABA, TRICARE is being consistent with its own regulations and in applying those regulations, as TRICARE is holding provision of ABA up to the same standards it holds for behavioral health treatments. That is, behavioral health providers are expected to be

appropriately trained and licensed, or if not licensed, that the "qualified accreditation organization" has developed "knowledge standards and skill standards for health care professional certification testing" and that "apply standards, criteria, and certification processes which reinforce CHAMPUS provider authorization requirements." BACB standards for practitioners of ABA are not comparable to TRICARE's regulatory standards for its providers of behavioral health care. Additionally, by insisting on well-controlled studies of clinically meaningful endpoints in the form of RCTs demonstrating ABA effectiveness, TRICARE is being consistent with application of the reliable evidence standard for other interventions, such as EMDR for treatment of PTSD which has been demonstrated in at least twelve RCTs.

The TRICARE Basic Program is a comprehensive health benefit plan offering a full array of medically necessary services to address the needs of all beneficiaries with ASD, including: Occupational Therapy (OT); Physical Therapy (PT); Speech and Language Therapy (SLP); child psychiatry and child psychology to address psychopharmacological needs and psychological testing; the full range of medical specialties to address the additional medical conditions common to ASD; prescription drugs and Durable Medical Equipment (DME). These would be considered TRICARE's "standard means of treatment" of ASD. The Court in Berge vs. U.S. opined that TMA is ignoring its own regulations in declaring ABA "unproven" based on the following argument:

> "Because 32 C.F.R. § 199.4 specifically provides that a medical treatment's efficacy is properly determined in the context of how it compares to "standard means of treatment or diagnosis," it is significant that the Agency has not identified any treatment more effective for treating autism than ABA therapy. . . . In fact, the assessments cited by the Agency suggest that behavioral modification therapy is the closest intervention medical professionals have identified as the standard means for treating autism. (ABA is "the dominant and preferred treatment modality" for autism). Therefore, this Court is left to wonder what forms of autism treatment would satisfy the Agency's regulatory requirement of being proven when the very sources the Agency relies upon to declare ABA therapy unproven cannot identify one form of treatment that is more effective than ABA therapy." (p. 63-64.)

In TMA's review of the literature, it is precisely the lack of studies comparing ABA to standard means of treatment (SLP, OT, pharmacotherapy, etc.) that renders TRICARE unable to authorize ABA as a new "standard means of treatment." The studies of ABA that have been conducted have compared it to standard educational interventions provided in the schools or the community, not to established medical treatment currently cost-shared by TRICARE. TMA would welcome, for example, knowledge from head-to-head comparison of ABA to SLP to target the core ASD symptom of speech impairment or to OT to target the core ASD symptom of behavioral impairment. These studies were not captured in the literature of technical reports reviewed, and neither were any head-to-head comparisons of IBI to ESDM, which also would be informative. What was found was a confounding of

TRICARE's authorized means of treatment within the "comprehensive" interventions that include many other components besides ABA, particularly for ESDM.

Even assuming that standard means of treatment are not effective at treating symptoms of ASD, TRICARE would not be consistent in applying its reliable evidence standard to assert that because there are a lack of effective treatments for ASD that this justifies acceptance of a therapy that has not proved its effectiveness in well controlled studies of clinically meaningful endpoints. TRICARE must follow the reliable evidence standard, not a standard that requires TRICARE to provide an ineffective treatment because ASD is, as noted by the CDC, incurable and no treatments have been reliably shown to return children with ASD to "normal" functioning.

The reliable evidence standard set forth in the TRICARE regulations is there to ensure that the care TRICARE covers is generally accepted and shown to be safe and effective – but "generally accepted" refers to authoritative medical professional sources which carry significant weight throughout the medical profession, not just general public opinion. This distinction is becoming increasingly blurred with the expansion of various advocacy groups and pseudo-professional organizations that align their assertions on the basis of their agenda rather than on the strength of the science. The fact that the AMA and the AACAP have **not** come out with published reports endorsing ABA interventions for children with ASD is telling in this regard. The reliable evidence standard is there to keep special interest organizations from shaping the TRICARE program for monetary or other reasons, and it is TRICARE's obligation to apply the reliable evidence standard strenuously to protect its beneficiaries and to ensure the provision of an "improved," high-quality program of health care.

VI. SUMMARY AND RECOMMENDATIONS

ABA as delivered by ABA practitioners does not meet the TRICARE definition of "medical" as defined in 32 C.F.R. § 199.2. This finding is based on the following observations:

1. ABA does not "pertain to" or have a nexus of belonging with other forms of medical or behavioral health care delivered by TRICARE.
2. This finding for TRICARE is consistent with the observation that ABA is not a recognized medical or behavioral health "treatment" by the AMA as evidenced by the absence of any assigned CPT code(s) for ABA (even though at least one application for an ABA CPT code has been submitted) and by the absence of a national coverage determination for ABA by Medicare, which TRICARE is mandated to follow for reimbursement purposes.
3. ABA is not practiced by "licensed or certified healthcare professionals" as evidenced by the few number of states licensing ABA providers, and the noted absence of health care

delivery knowledge and skill standards required for BCBA national certification by the BACB (disqualifying the BACB as a "Qualified accreditation organization" of healthcare providers, per 32 C.F.R § 199.2), and rendering practitioners of ABA as having less healthcare training and experience than "Extramedical individual providers" under 32 C.F.R § 199.6(c)(3)(iv) who provide "counseling or non-medical therapy and whose training and therapeutic concepts are outside the medical field."

4. ABA does not pertain to the practice of "psychological" care as evidenced by the BACB's: (a) self-description as a discipline separate from the practice of clinical psychology and related behavioral health care disciplines; (b) rejection of traditional behavioral health care training as part of its curriculum; and, (c) active lobbying for ABA practitioners not to be licensed or regulated by state Boards of Psychology, but that the Regulatory Authority for ABA will "be a separate and independent behavior analyst regulatory board or agency." (Model Act for Licensing/Regulating Behavior Analysts, revised Sept 2012, p. 2).

The practice of Behavior Analysis, as stated by the BACB, "is the design, implementation, and evaluation of instructional and environmental modifications to produce socially significant improvements in human behavior." (Model Act for Licensing/Regulating Behavior Analysts, revised Sept 2012, p. 3). As such, ABA is an appropriate service to provide via ECHO to ADFMs who voluntarily seek assistance with the management of their dependent children with ASD as a form of parental assistance. If found ABA is not "medical" care, it may continue to be provided to beneficiaries with a qualifying condition under ECHO as it meets the regulatory criteria of 32 C.F.R. § 199.5(c)(i)(3) as:

> "Training that teaches the use of assistive technology devices or to acquire skills that are necessary for the management of the qualifying condition. Such training is also authorized for the beneficiary's immediate family."

This review of the evidence also supports the following recommendation to the Director, TMA:

ABA has not been shown by reliable evidence to meet the requirements of 32 C.F.R. § 199.4(g)(15) to be proven as medically or psychologically necessary or as appropriate medical care for ASD. The reliable evidence standard for cost-sharing required by 32 § C.F.R. 199.4(g)(15) has not been met, and claims for provision of ABA for treatment of ASD under the TRICARE Basic Program cannot be reimbursed except: (a) in compliance with the authority of a court order; or, (b) under the authority of a time-limited pilot mandated by Section 705 of NDAA FY 2013.

This determination is based on the following observations:

1. The findings of the studies reviewed: (a) do not consistently present or characterize the ABA interventions provided, which vary widely in terms of provider, setting, and targeted age range of the recipient; (b) are generally not well-controlled, with

comparatively few randomized clinical trials; (c) generally study very small sample sizes which limits generalization of findings to the clinical population of interest; and, (d) present conflicting findings across studies or fail to demonstrate clinically meaningful outcomes. The evidence overall is not reliable, and there have been no comparative effectiveness studies of ABA to TRICARE cost-shared treatments such as speech and language pathology or occupational therapy.

2. The RCT of IBI showing mixed positive results (Smith, 2000) was published thirteen years ago and utilized ABA techniques involving aversive conditioning with 14% of the study sample, which makes this study unsuitable as reliable evidence regarding modern ABA as practiced today, as these techniques would be strictly prohibited for ABA provided under TRICARE. A subsequent RCT of IBI (Sallows & Graupner, 2005) found no post-treatment differences between a clinic-directed IBI group vs. a parent-managed treatment group and attributed 70% of the observed variance in outcomes to individual difference characteristics measured at pre-treatment, not to the ABA intervention.

3. An RCT of ESDM (Dawson et al., 2010), which is a significantly different ABA approach from IBI, found significant between-group differences between an ESDM plus parent training plus community services group compared to community services alone. However, the highly eclectic nature of ESDM in this study prevents isolating the evidence in support of the ABA as delivered by clinicians since it is a mix of clinician and parent intervention, and this study presents other confounds in that it is not possible to isolate the effect of other potentially effective treatments (e.g. speech therapy, developmental preschool) that children may have received during the study period in both the EDSM group (mean = 5.2 hours/week) and the assess-and-monitor control group (mean = 9.3 hours/week). This means it cannot be considered "well-controlled" for TRICARE purposes. Also, the findings of this study have not been replicated, therefore they are not considered "reliable" evidence. The subsequent RCT of ESDM delivered by parents plus community services compared to community services alone (Rogers et al., 2012) did not produce a significant between-groups effect for ESDM on any outcome measure.

4. To date, the biases inherent in the CCT studies conducted do not provide a means to determine if ABA is effective as the outcomes observed may be attributable to or confounded by rater bias, practice effects, or other uncontrolled variables due to lack of random assignment to groups. The relative lack of RCTs (compared to other behavioral health interventions) published on ABA over the last 25 years since the original Lovaas et al. (1987) study is concerning given the ubiquity and intensity of ABA, and this calls into question the potential presence of publication bias where only certain positive findings have been reported. These well-documented research gaps need to be addressed before definitive conclusions can be made about the effectiveness of ABA for ASD, which must be based on <u>reliable</u> findings of improvement in clinically meaningful endpoints. It is

necessary and appropriate for TMA to expect this to be consistent with the level of evidence required for other recent medical benefit determinations for behavioral health care, such as that authorizing EMDR for cost-sharing as treatment of PTSD after its demonstrated effectiveness in multiple RCTs compared with established PTSD treatments cost-shared by TRICARE.

5. Although ABA is touted repeatedly by advocacy groups as the only proven effective therapy for ASD, TRICARE must follow the reliable evidence criteria of 32 C.F.R. 199.4(g)(15), which explicitly exclude "reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence or personal professional opinions" and also specifies "the fact that a provider or a number of providers have elected to adopt a drug, device, or medical treatment or procedure as their personal treatment or procedure of choice or standard of practice" does not constitute reliable evidence.

Alternatively, given that Section 705 of the NDAA for FY 2013 requires TRICARE to implement a pilot on the behavioral treatment of ASDs, to include ABA, the following secondary Course of Action is submitted for consideration by the Director, TMA:

That the Director, TMA, defer final decision on this medical benefit determination until the conclusion of the ABA Pilot and reassess this determination based on any relevant findings of the ABA Pilot; and, pending such determination, that TMA continue ABA coverage under the Basic Program per existing policy.

TMA will continue to monitor the published literature to identify potential well-controlled studies of clinically meaningful endpoints as possible evidence of ABA's effectiveness among children with ASD.

MEDICAL BENEFIT DETERMINATION
FOR APPLIED BEHAVIOR ANALYSIS (ABA)
FOR TREATMENT OF AUTISM SPECTRUM DISORDERS (ASD)

Course of Action #1: That the Director, TMA, concur with one or both of the following Recommendations (#1 & #2):

Recommendation #1: That the Director, TMA, concur with the finding that the intervention of ABA as delivered by ABA practitioners does not meet the TRICARE definition of "medical" as defined in 32 C.F.R. § 199.2.

_____Approve Date: _____

_____Disapprove Date: _____

Recommendation #2: That the Director, TMA, concur with the finding that ABA has not been shown by reliable evidence to meet the requirements of 32 C.F.R. § 199.4(g)(15) to be proven as medically or psychologically necessary or as appropriate medical care for ASD. The reliable evidence standard for cost-sharing required by 32 C.F.R. § 199.4(g)(15) has not been met, and claims for provision of ABA for treatment of ASD under the TRICARE Basic Program cannot be reimbursed except: (a) in compliance with the authority of a court order; or, (b) under the authority of a time-limited pilot mandated by Section 705 of NDAA FY 2013.

_____Approve Date: _____

_____Disapprove Date: _____

Course of Action #2: That the Director, TMA, concur with the following Recommendation (#3):

Recommendation #3: That the Director, TMA, defer final decision on this medical benefit determination until the conclusion of the ABA Pilot and reassess this determination based on any relevant findings of the ABA Pilot; and, pending such determination, that TMA continue ABA coverage under the Basic Program per existing policy.

_____Approve Date: _____

_____Disapprove Date: _____

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Table 1. Results of Non-Randomized Controlled Clinical Trials (CCTs) Comparing Intensive Behavior Intervention (IBI) vs. Eclectic Interventions for Autism

	Autism Severity	Intelligence / Cognitive Ability	Visual-Spatial / Non-Verbal	Language Skills	Adaptive Behavior					School Placement / Achievement
					VABS	VABS-C	VABS-DL	VABS-S	VABS-MS	
Eikeseth et al. 2002, 2007[1]		+	—	+	+	+	—	—		
		+			+	+	+	+		+
Howard et al. 2005		+	+	+	+	+	+	+	+	
Magiati et al. 2007	—	—		—	—	—	—	—		—
Reed et al. 2007b	—	—			—					
Zachor et al. 2007	—			+						
Zachor & Ben Itzchak, 2010	—	—		+	—	—	—	—		
Fava et al. 2011	—a			—a	—a	—a	—a	—a,b	—a	
Eldevik et al. 2012		+			+	+	—	+		

Strauss et al. 2012	+[c]			__ c,d	+ [c,e]	__ c	__ c	__ c	__c	__ c	
Eikeseth et al. 2012						+	+	+	+	+	

NOTES:

"+" = IBI group performed significantly better than eclectic group

"__" = no statistically significant difference between IBI group and eclectic group

[1] follow-up report of original study, with results listed in second row

[a] table reports the between-group differences noted at the 6 month follow-up period in the Fava et al. (2011) study

[b] the only significant between-group difference at 6 month follow-up in Fava et al. (2011) was that the eclectic group improved significantly more than the IBI group on the Vineland Adaptive Behavior Survey – Socialization Skills

[c] between-group statistical analyses not reported in Strauss et al. (2012)

[d] language comprehension, as measured by the MacArthur Communication Developmental Inventories (MCDI)

[e] language production, as measured by the MCDI

VABS = Vineland Adaptive Behavior Scale, composite; VABS-C = communication; VABS-DL = daily living; VABS-S = socialization; VABS-MS = motor skills

Table 2. Results of Studies Comparing Intensive Behavior Intervention (IBI) vs. Other Interventions Not Specifically Focused on Autism

	Autism Severity	Intelligence/ Cognitive Ability	Visual-Spatial, Non-Verbal	Language Skills			Adaptive Behavior					School Placement
				RDLS	RDLS-C	RDLS-E	VABS	VABS-C	VABS-DL	VABS-S	VABS-MS	
Smith, 2000[1]		+	+	+	—	—	—	—	—	—	—	+
Cohen et al. 2006[2]		+	—		—	—	+	+	+	+		+
Remington et al. 2007[3]; Kovshoff et al. 2011[4]		+			+	+	—	—	+	—	+	+
					+	—	—	—	—	—	—	+
Reed et al. 2007b	—	+					—	—	—	—	—	

NOTES:

"**+**" = IBI group performed significantly better than eclectic group

"**—**" = no statistically significant difference between IBI group and eclectic group

[1] Smith (2000) was the only Randomized Clinical Trial (RCT) among studies presented in Tables 1 and 2; comparison group was parent training; the study utilized ABA techniques involving aversive conditioning with 14% (4 of 28) of the study sample, which would be prohibited for ABA provided under TRICARE

[2] comparison group in Cohen et al. (2006) was varying services selected by the family

[3] comparison group in Remington et al. (2007) and Kovshoff et al. (2011) was standard treatment provided by the local educational authority

[4] follow-up report of original study, with results listed in second row

[5] comparison group in Reed (2007) was portage treatment, a home-based treatment program that entails a portage supervisor teaching parents to deliver training sessions to their child in a 1:1 situation where several skills are targeted per week

RDLS = Reynell Developmental Language Scales, total score; RDLS-C = comprehension; RDLS-E = expression

VABS = Vineland Adaptive Behavior Scale, composite; VABS-C = communication; VABS-DL = daily living; VABS-S = socialization; VABS-MS = motor skills

Table 3. Results of Studies Comparing Early Start Denver Model (ESDM) Plus Community Services vs. Community Services Alone

	Autism Severity		Intelligence/ Cognitive Ability	Visual-Spatial, Non-Verbal	Language Skills	Adaptive Behavior					School Placement
						VABS	VABS-C	VABS-DL	VABS-S	VABS-MS	
Dawson et al. 2010[1]	+[a]	__ b	+	__	+	+	+	+		+	
Rogers et al. 2012[2]	__ a		__	__	__	__	__	__	__		

NOTES:

"**+**" = ESDM plus community services group performed significantly better than community services alone group

"**__**" = no statistically significant difference between ESDM plus community services group and community services alone group

[1] RCT comparing ESDM plus community services plus parent training in ESDM vs. community services alone over a 2-year period

[2] RCT comparing parent training in ESDM plus community services vs. community services alone over a 12-week period

[a] no significant group differences in Autism Severity based on Autism Diagnostic Observation Schedule (ADOS) scores

[b] significantly more children in ESDM plus community services plus parent training group had improved diagnostic status at 2 year follow-up

VABS = Vineland Adaptive Behavior Scale, composite; VABS-C = communication; VABS-DL = daily living; VABS-S = socialization; VABS-MS = motor skills

Appendix A: State Legislation: Applied Behavior Analysis (ABA) Coverage in Commercial and Public Health Plans (current as of November 16, 2012)

State	Effective Date	Mandated Coverage	Includes ABA
Alabama	2012	Requires a health benefit plan to offer coverage for the screening, diagnosis, and treatment of ASD for child age 9 and younger.	Yes. $36,000/year up to age 9.
Alaska	2012	Requires health care insurers to provide coverage for the costs of diagnosis and treatment of ASD.	Yes. Up to age 21. Number of visits to an autism service provider for treatment may not be limited.
Arizona	7/1/2009	Requires many private insurers to cover diagnostic assessments & services for children with autism under age 16.	Yes. Up to $50,000/year up to age 9; $25,000 up to age 16 for behavioral therapy. Coverage for medically necessary behavioral therapy services may not be excluded or denied.
Arkansas	10/1/2011	Requires insurance companies to provide coverage of evidence-based, medically necessary autism therapies, including ABA.	Yes. $50,000/year up to age 18. Requires supervision by Board Certified Behavior Analyst. Only coverage limited by age/dollar cap.
California	7/1/2012-7/1/2014	Requires health care plans with hospital, medical or surgical coverage to include behavioral health treatment for PDD or autism. Must be prescribed by licensed physician/developed by licensed psychologist who is qualified autism service provider. Treatment must be provided by qualified autism service provider, professional or paraprofessional supervised & employed by qualified autism service provider.	Yes. Behavioral health treatment subject to same terms & conditions as all benefits under plan contract (i.e., maximum lifetime benefits, co-payments & individual/family deductibles).
Colorado	**7/1/2010**	Requires most state-regulated group insurance policies to provide coverage to assess, diagnose & treat ASD, including treatments that are medically necessary, appropriate, effective or efficient and shall include evaluation and assessment services; behavior training and management and applied behavior analysis; habilitative or rehabilitative care.	Yes. $34,000/year birth-age 9 & $12,000 ages 9-19. Only ABA subject to dollar limits / deductibles / coinsurance less favorable than those for physical illness.

State	Effective Date	Mandated Coverage	Includes ABA
Connecticut	1/1/2010	Requires many private insurers to cover diagnostic assessments & services for children with autism under age 15.	Yes. $50,000/year under age 9; $35,000/year 9-12; and $25,000/year 13-14. Services must be medically necessary; requested by licensed physician, psychologist or clinical social worker & based on a treatment plan. The policy may not impose limits on the number of visits to an autism services provider.
Florida	4/1/2009	Requires insurance plan to provide coverage to eligible individuals for diagnosis & treatment of ASD.	Yes. Limited to treatment that is prescribed by the insured's treating physician in accordance with a treatment plan and $36,000/year with $200,000 lifetime limit.
Illinois	10/2009	Requires all individual and group accident and health insurance or managed care plans to cover diagnostic assessments & treatments for individuals with autism up to age 21. Requires coverage for habilitative services for children less than 19 years of age with a congenital, genetic or early acquired disorder, including autism spectrum disorders.	Yes. $36,000/year up to age 21.
Indiana	5/1/2001	Requires coverage when prescribed by treating physician for individuals with pervasive developmental disorder. Coverage is limited to treatment that is prescribed by the insured's treating physician in accordance with a treatment plan.	Yes. ABA cannot be limited by number/days per year & must be provided year-round.
Iowa	1/1/2011	Requires state employees' health plan to cover diagnosis & treatment of ASD for state employees & their children under age 21.	Yes. $36,000/year. Services must be medically necessary & prescribed by a licensed physician/ psychologist/ social worker/or registered nurse practitioner. The coverage plan cannot limit the number of visits to an autism service provider for treatment**.**
Kansas	1/1/2011	Requires ASD diagnosis & treatment under age 19 if covered in Kansas State Employee Health Plan.	Yes. $36,000/year through age 6 & $27,000/year 7-19. Must be prescribed by licensed physician, psychologist or clinical social worker & provided by licensed professional.
Kentucky	4/14/2010	Requires insurance companies to cover evidence-based, medically necessary autism therapies.	Yes. Large group & state employee market age 1-7 is $50,000/year; age 7-21 is $1,000/month. Small group & individual market $1,000/month regardless of age.

State	Effective Date	Mandated Coverage	Includes ABA
Louisiana	1/1/2012	Requires many health insurance plans to cover diagnosis & treatment of ASD in children 21 & younger.	Yes. $36,000/year up to age 21. Treatment of autism spectrum disorders is defined to include habilitative or rehabilitative care (including applied behavior analysis), pharmacy, psychiatric, psychological and therapeutic care.
Maine	1/1/2011	Requires individual, group health insurance policies, and all individual and group health maintenance organization contracts to provide for autism services through age 5.	Yes. $36,000/year. Only treatment with service limitations. Requires provided/supervised by national certified behavior analyst.
Massachusetts	1/1/2011	Requires coverage by private insurers, state plan, hospital service plans & HMOs to diagnose & treat ASD.	Yes. Requires supervision of board certified behavior analyst.
Michigan	10/15/2012	Requires treatment up to age 18 for children with medical diagnosis on autism spectrum for behavioral health treatment (including ABA) & therapeutic care (OT, PT, speech therapy & social worker)	Yes. Allows cap on combined annual costs ABA, OT, speech therapy & other behavioral treatment: - $50,000: 6 years old and younger - $40,000: 7-12 years old - $30,000: 13-18 years old Behavioral treatment must be supervised by board-certified behavior analyst or licensed psychologist.
Missouri	1/1/2011	Requires all group health plans to cover ASD diagnosis & treatment. Individual plans not required to provide coverage, but make available at additional cost.	Yes. $40,000/year until 19th birthday. May exceed limit if insurer determines it's medically necessary & gives prior approval. Other services do not have monetary/age limits. Law creates “Behavior Analyst Advisory Board” under State Committee of Psychologists to license behavior analysts, review complaints & make recommendations to Committee about behavior analysts.
Montana	1/1/2010	Requires many private insurers to cover costs of diagnostic assessments & treatments for individuals with autism.	Yes. $50,000/year through age 8 & $20,000/year ages 9-19.
Nevada	1/1/2011	Requires insurance companies cover evidence-based, medically necessary autism therapies.	Yes. $36,000/year until age 18 or 22 as long as student in high school.
New Hampshire	1/1/2011	Amends mental health parity law to require coverage for diagnosis & treatment ASD.	Yes. $36,000/year for birth-12 & $27,000/year for 13-21. Requires supervision of nationally certified behavior analyst.

State	Effective Date	Mandated Coverage	Includes ABA
New Jersey	2/9/2010	Requires coverage for: screening & diagnosing autism/other developmental disability: medically necessary expenses prescribed in treatment plan& expenses incurred for medically necessary behavioral interventions based on principles of ABA & related structured behavioral programs as prescribed through a treatment plan.	Yes, if under age 21. Requires provided by/under supervision of professional credentialed by national Behavior Analyst Certification Board.
New Mexico	6/19/2009	Requires private health insurers & nonprofit health plans to provide coverage to diagnose & treat ASD & prohibits insurer from denying or restricting health coverage for medically necessary services for individuals with ASD.	Yes. $36,000/year & $200,000 lifetime cap for those age 19/younger or age 22/younger and enrolled in high school.
New York	11/1/2012	Requires state-regulated health plans to provide medically necessary coverage for screening, diagnosis & treatment of ASD for services provided outside educational setting prescribed by physician or psychologist.	Yes. Up to $45,000/year provided/supervised by Board Certified Behavior Analysts. Limit will increase annually based on increases in medical consumer price index. No limits on age or number of visits.
Pennsylvania	7/1/2009	Requires many private health insurance companies to cover diagnostic assessment & treatment ASD & services for children.	Yes. $36,000/year up to age 21. No lifetime maximum. .
Rhode Island	1/1/2012	Requires state-regulated group health insurance plans to cover certain treatments for Autism/PDD-NOS/ Asperger Syndrome: speech, occupational & physical therapy and ABA up to age 15.	Yes. $32,000/year up to age 15. Must be licensed & certified provider.
South Carolina	7/1/2008	Requires most state-regulated group insurance policies to provide coverage for the treatment of autism spectrum disorder as prescribed by the insured's treating medical doctor in accordance with a treatment plan.	Includes "behavioral care" $50,000/year up to age 16.
Texas	6/15/07 & 1/1/2010	Covers all generally recognized ASD services for enrollees under age 10 prescribed in treatment plan by primary care physician. After age 10, health plan's option to continue. 2010 law expanded from ages 3-5 to under age 10.	Yes.

State	Effective Date	Mandated Coverage	Includes ABA
Vermont	7/1/2012	Expands age cap requiring state regulated private health insurance plans to cover diagnosis & treatment of ASD between ages 6- 22. Expands definition of autism treatments to include behavioral health treatment with ABA. 2010 law only covered ages 18 months-6 years.	Yes. Birth up to age 21.
Virginia	1/1/2012-but implementation delayed until state implements an ABA licensure procedure	Require health plans cover evidence-based, medically necessary treatments prescribed by licensed physician or psychologist for children age 2 to 6 diagnosed with ASD. Does not preclude extending coverage ages 7 and up.	Yes. $35,000/year. May be only service subject to cap.
West Virginia	1/1/2012	Requires health insurance plans to provide coverage to diagnose & treat ASD for ages 3-18. To be eligible for coverage, the individual must be diagnosed with ASD at age 8 or younger	Yes. $30,000/year for first 3 consecutive years from date treatment begins. Then $2,000/month until age 18.
Wisconsin	11/1/ 2009	Requires private health insurance companies to provide coverage for diagnosis & treatment of ASD.	Yes as part of intensive services. Minimum $50,000/year for intensive therapy for ages 2-9 for minimum 4 years. Treatment only subject to minimum 30-35 hours/week. Then minimum $25,000/year required for non-intensive services.

Appendix B: State Licensure of ABA Practitioners (current as of April 26, 2013)

STATES THAT REQUIRE LICENSURE OF APPLIED BEHAVIOR ANALYSTS							
#	**State**	**Year Enacted**	**State Oversight**	**State Agency**	**Licenses Issued**	**BACB Certification Required**	**Model of Delivery**
1	Arizona	2007	Yes	Board of Psychology	Master's and above BCBAs **May supervise graduate students	Yes- or certification by other nationally recognized ABA certifying body	Licensed Provider Model
2	Missouri	2010	Yes	Committee of Psychologist: Behavior Analysis Advisory Board	-Master's and above + Licensed Behavior Analyst (LBA) -Bachelor's level- Licensed Assistant Behavior Analyst	Yes	Licensed Provider Model
3	Nevada	2009	Yes	Nevada Board of Psychological Examiners	-Licensed Behavior Analyst (BCBA + pass state exam) -Licensed Assistant Behavior Analyst (BCaBA +exam) -Certified Autism Behavior Interventionists - 40 hours trng	Yes BCBA +state exam BCaBA +state exam	Tiered Delivery Model allowed

#	State	Year Enacted	State Oversight	State Agency	Licenses Issued	BACB Certification Required	Model of Delivery
4	North Dakota	2012 as amended	Yes	ND State Board of Psychologist Examiners	-Licensed Applied Behavior Analyst-masters and -Registered Applied Behavior Analyst-Bachelor's level	BCBA+ oral exam BCaBA+ oral exam	Licensed + Registered Provider Model
5	Pennsylvania	2008	Yes	PA Board of Medicine	Licensed Behavior Specialist-master's and above ONLY	No	Licensed Provider Model
6	Virginia	2012	Yes	VA Board of Medicine	Master's Prepared BCBA Bachelor's level BCaBA *Can supervise non-licensed	Yes	Tiered Model allowed
7	Oklahoma	2010	Yes	Department of Human Services, Developmental Disabilities Division	-Master's level BCBAs, -Bachelor Level-BCaBAs *Allows for supervision of unlicensed under extended authority of Behavior Analyst	Yes	Tiered Model allowed

#	State	Year Enacted	State Oversight	State Agency	Licenses Issued	BACB Certification Required	Model of Delivery
8	Wisconsin	2009	Yes	Department of Regulation and Licensing: Department of Safety and Professional Services	Licensure of Master's level BCBA Licensure of Bachelor's level BCaBAs *Allows for supervision of unlicensed under extended authority of Behavior Analyst	Yes	Tiered Delivery Model allowed
9	Kentucky	2010	Yes	Applied Behavior Analysis Licensing Board	Licensure of Master's level BCBA Licensure of Bachelor's level BCaBAs *Allows for supervision of unlicensed	Yes	Tiered Delivery Model allowed
10	Rhode Island	2012	Yes	Department of Health	Licensed Applied Behavioral Analyst Licensed Applied Behavioral Assistant Analysis	No	Licensed Provider Model

#	State	Year Enacted	State Oversight	State Agency	Licenses Issued	BACB Certification Required	Model of Delivery
11	Massachu-setts	2013	Yes	Board of Registration of Applied Behavior Analysts	Licensed Applied behavioral Analyst Licensed Applied Behavioral Assistant Analysis	No	Licensed Provider Model