UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND
READINESS

MAY 11 2016

The Honorable John McCain
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The enclosed report is in response to the Senate Report 114-49, page 157, accompanying S. 1376, the National Defense Authorization Act for Fiscal Year (FY) 2016, which requested the Department to provide an annual report on the Autism Care Demonstration (ACD). The Department provides a comprehensive health benefit with a full array of medically and psychologically necessary services to address the needs of all beneficiaries, including those diagnosed with Autism Spectrum Disorder (ASD).

The report provides information on the current state of the ACD, including enrollment and costs. Also included are some of the lessons learned and challenges encountered during the implementation of the ACD, as well as steps taken to improve the program. However, for this report, we were unable to determine if children with ASD who received Applied Behavior Analysis (ABA) therapy under the ACD improved clinically. We will provide this information in subsequent reports.

Although the annual growth rate in the number of TRICARE beneficiaries using ABA services has declined over time, the demand for ABA services by all TRICARE beneficiaries continues to increase. As a result, we have seen a 525 percent cost increase (from $31.0 to $163.4 million) since FY 2009.

The ACD offers comprehensive ABA services for all TRICARE-eligible beneficiaries diagnosed with ASD. Furthermore, ABA services are not limited by the beneficiary's age, dollar amount spent, or number of services provided. We continue to see growth in the program from both beneficiaries and ABA service providers. The Department fully supports continued research on the nature and effectiveness of ABA services and the evolution of the field from an educational discipline toward a health care discipline. A similar letter is being sent to the Chairman of the House Armed Services Committee.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families.

Sincerely,

Peter Levine
Acting

Enclosure:
As stated

cc:
The Honorable Jack Reed
Ranking Member

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND
READINESS

MAY 11 2016

The Honorable William M. "Mac" Thornberry
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The enclosed report is in response to the Senate Report 114-49, page 157, accompanying S. 1376, the National Defense Authorization Act for Fiscal Year (FY) 2016, which requested the Department to provide an annual report on the Autism Care Demonstration (ACD). The Department provides a comprehensive health benefit with a full array of medically and psychologically necessary services to address the needs of all beneficiaries, including those diagnosed with Autism Spectrum Disorder (ASD).

The report provides information on the current state of the ACD, including enrollment and costs. Also included are some of the lessons learned and challenges encountered during the implementation of the ACD, as well as steps taken to improve the program. However, for this report, we were unable to determine if children with ASD who received Applied Behavior Analysis (ABA) therapy under the ACD improved clinically. We will provide this information in subsequent reports.

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The ACD offers comprehensive ABA services for all TRICARE-eligible beneficiaries diagnosed with ASD. Furthermore, ABA services are not limited by the beneficiary's age, dollar amount spent, or number of services provided. We continue to see growth in the program from both beneficiaries and ABA service providers. The Department fully supports continued research on the nature and effectiveness of ABA services and the evolution of the field from an educational discipline toward a health care discipline. A similar letter is being sent to the Chairman of the Senate Armed Services Committee.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families.

Sincerely,

Peter Levine
Acting

Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member

Report to the Senate Armed Services Committee

The Department of Defense

Comprehensive Autism Care Demonstration

REPORT ON EFFORTS BEING CONDUCTED BY THE DEPARTMENT OF DEFENSE ON APPLIED BEHAVIOR ANALYSIS SERVICES

Requested by: Senate Armed Services Committee Report 114-49 for Fiscal Year 2016

The estimated cost of report for the Department of Defense (DoD) is approximately $5,710.00 for the 2016 Fiscal Year. This includes $50.00 in expenses and $5,660.00 in DoD labor.

INTRODUCTION

This report is in response to Senate Report 114-49, page 157, accompanying S. 1376, the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2016, which requested a report to the Armed Services Committee on the results of the Comprehensive Autism Care Demonstration (ACD) not later than April 1, 2016, and annually thereafter for the duration of the program. Specifically, the annual report should include a discussion of the evidence regarding clinical improvement of children with Autism Spectrum Disorder (ASD) receiving Applied Behavior Analysis (ABA) therapy and a description of lessons learned to improve administration of the demonstration program. In the report, the Department should also identify any new legislative authorities required to improve the provision of autism services to beneficiaries with ASD.

BACKGROUND

ASD affects essential human behaviors such as social interaction, the ability to communicate ideas and feelings, imagination, and the establishment of relationships with others. The TRICARE Basic Program, set forth in Title 32, Code of Federal Regulations (C.F.R.), Section 199.4, offers a comprehensive health benefit offering a full array of medically necessary services to address the needs of all TRICARE beneficiaries diagnosed with ASD. TRICARE's Basic Program provides occupational therapy (OT) to treat deficits and promote the development of self-care skills, physical therapy (PT) to treat motor skill deficiencies and promote coordination, speech and language pathology therapy to treat deficits in speech and language development and promote communication skills, psychiatry to address psychopharmacological needs, psychotherapy provided by TRICARE authorized therapists, and psychological testing conducted by doctoral-level licensed clinical psychologists. Additionally, the full range of medical specialties to address the medical conditions common to this population is covered.

Apart from the medical benefits covered under the TRICARE Basic Program for all TRICARE-eligible beneficiaries, there is separate authority to provide supplemental services not otherwise covered under the TRICARE Basic Program to dependents of Active Duty Service members with a qualifying condition. The Extended Care Health Option (ECHO), set forth at Title 32, C.F.R., Section 199.4, provides an integrated set of services and supplies to Active Duty Family Members (ADFMs) with special needs who have enrolled in the Exceptional Family Member Program through the sponsor's branch of Service and registered for ECHO with case managers in each TRICARE region. ECHO services supplement TRICARE Basic Program benefits and, by law, may not duplicate such benefits.

ABA is based on the principles of behavior modification, which consists of processes such as operant and respondent conditioning, to socially significant behavior in the real-world setting. ABA is based on the principle that an individual's behavior is determined by past and current environmental events in conjunction with organic variables such as the individual's genetic endowment and ongoing physiological variables. ABA, provided by a licensed and/or certified behavior analyst, focuses on treating behavioral difficulties by changing an individual's environment (i.e., shaping behavior patterns through reinforcement and consequences). ABA is

delivered optimally when family members and caregivers participate by consistently reinforcing the ABA interventions in the home setting in accordance with the prescribed treatment plan developed by the behavior analyst.

The Department completed an extensive ABA coverage review and benefits determination in 2010 and in 2013, and continually monitors the status of ongoing ABA research. Although ABA shows promise, it has not been shown to meet the TRICARE Basic Program coverage requirements of Title 32, C.F.R., Section 199.4(g)(15), to be scientifically proven medical/psychological care for ASD. The legal definition regarding proven medical care that governs what TRICARE may cover is more precise than what may be generally covered in the larger health care industry, Medicaid programs, and Federal Employees Health Benefit plans. Under commercial plans in particular, many unproven benefits are covered with premiums adjusted accordingly and without requiring scientific proof of efficacy.

TRICARE, in contrast, is not health insurance, which fundamentally involves a contract guaranteeing the indemnification of an insured party against a specified loss in return for a premium paid. Instead, TRICARE is a statutorily-defined health benefit program enacted by Congress for specific categories of beneficiaries, to include Active Duty and retired Service members, certain members of the National Guard and Reserves, eligible dependents of Active Duty, retired, and eligible Guard/Reserve Service members, and certain survivors. TRICARE benefits, including coverage for specific services, are established by Congress through statute and implemented by Department of Defense (DoD) regulations. Those statutes and regulations set forth requirements and standards for what may be covered under TRICARE as a medical benefit, under the separate dental benefit authorities, or otherwise provided as an extended non-medical benefit. Under TRICARE, the term "medical" includes psychological treatments.

The longstanding TRICARE coverage standard was clarified nearly two decades ago (Federal Register, Volume 62, Issue 3 (Monday, January 6, 1997), pages 625-631). In that final rule, TRICARE is referred to by its earlier name of CHAMPUS (Civilian Health and Medical Program of the Uniformed Services). The reasons for imposing a high standard of scientific proof for TRICARE coverage were set forth as follows:

> "Under statutes governing CHAMPUS, including 10 U.S.C. 1079, CHAMPUS payments are prohibited for health care services that are "not medically or psychologically necessary." The purpose of this provision, common in health care payment programs, is to prevent CHAMPUS beneficiaries from being exposed to less than fully developed and tested medical procedures and to avoid the associated risk of unnecessary or unproven treatment. CHAMPUS regulations and program policies restrict benefits to those procedures for which the safety and efficacy have been proven to be comparable or superior to conventional therapies. In general, the CHAMPUS regulations and program policies exclude cost-sharing of procedures which are unproven, including those that remain in a developmental status. The evolution of any medical technology or procedure from unproven status to one of national acceptance is often controversial, with those members of the medical community who are using and promoting the procedure arguing that the procedure has national acceptance."

The 1997 Federal Register publication further explained that "[t]his final rule does not present new agency policy. Rather, it reaffirms and clarifies existing CHAMPUS policy in the body of the CHAMPUS regulation."

Although much has been published asserting that ABA is the most effective therapy for ASD, there are currently no studies that meet the definition of proven medical care that governs the TRICARE program – specifically: "[w]ell controlled studies of clinically meaningful endpoints, published in refereed medical literature." Specifically excluded from consideration under TRICARE coverage requirements 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 set forth at Title 32, C.F.R., Section 199.2(b), 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.

In order for ABA to be scientifically proven for TRICARE coverage purposes, efficacy must be established through randomized controlled trials (RCTs). To provide a thorough and objective assessment of ABA for ASD, TRICARE commissioned a separate external review of the literature, conducted by Hayes, Inc. These external health technology assessments were completed on November 27, 2012, December 9, 2014, and again on November 17, 2015. The report recommends more research and continues to assess the literature to be of low to fair quality. As discussed at length in the ABA benefit determination, the few published RCTs studying intensive ABA models had methodological flaws and/or conflicting findings that prevent them from rising to the level of reliable evidence. The reason most ABA studies fail to meet the reliable evidence standard as a "well-controlled study" is the lack of subject assignment randomization.

Additionally, the current state of the research does not identify the specific variables for an effective treatment program. Generally, there is support by the community that early intervention services are recommended for approximately 25 hours per week. However, there is no consensus in the literature regarding what specific ABA techniques are effective for what behaviors or symptoms at what intensity and for what duration. There is general consensus that ABA helps some but not all children diagnosed with ASD, but the characteristics of which children are likely to benefit from ABA have not been identified. The literature also does not address the tiered delivery model or what provider type is best suited for the delivery of ABA services.

Further, the clinical efficacy documented in the literature does not meet the American Medical Association (AMA) Evidence-Based Medicine levels standards for Category I codes (see the AMA Web site: http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/about-cpt/category-iii-codes.page). Therefore, the AMA recently (July 2014) established Category III ABA Current Procedural Terminology (CPT) billing codes, defined as "a temporary set of codes for emerging technologies, services, and procedures." TRICARE is prohibited by regulation from covering Category III CPT codes under the TRICARE Basic program (the medical benefit) because Category III codes are for promising new treatments not yet considered proven medical care

under the TRICARE reliable evidence standards (see Title 32, C.F.R., Section 199.2(b), and TRICARE Policy Manual: Chapter 1, Section 12.1).

The Department created the ACD, effective July 25, 2014, which provides all TRICARE-covered ABA services under one comprehensive demonstration. This consolidated demonstration covers ABA services that had been previously provided under a patchwork of the TRICARE Basic Program (i.e., the medical benefits authorized under Title 32, C.F.R., Section 199.4), the ECHO Enhanced Access to Autism Services Demonstration (hereafter the "ECHO Autism Demonstration;" i.e., the supplemental ABA benefits authorized for certain ADFMs under Title 32, C.F.R., Section 199.5), and the ABA Pilot (i.e., the 1-year supplemental ABA benefit authorized for certain non-ADFMs—including retiree dependents and others—under section 705 of the NDAA for FY 2013).

Coverage of ABA services under the ACD applies comprehensively to all TRICARE-eligible beneficiaries with a diagnosis of ASD. Eligible beneficiaries include dependents of Active Duty, retired, TRICARE-eligible Reserve Component, eligible National Guard, and certain other non-Active Duty members. Because there was insufficient time to accomplish the congressional intent behind the 1-year ABA Pilot authorized by section 705 of the NDAA for FY 2013, reconcile the various temporary authorities, and address the resulting complexity of the interim TRICARE policies concerning coverage of ABA services for ASD, the Department relied on the demonstration authority in section 1092 of title 10, United States Code (U.S.C.), to consolidate TRICARE coverage of ABA services in a manner that avoided any disruption of services to beneficiaries and was more practical for the TRICARE regional contractors to implement. The overarching goal of the ACD is to analyze, evaluate, and compare the quality, efficiency, convenience, and cost effectiveness of those ABA services that do not constitute the proven medical care provided under the medical benefit coverage requirements that govern the TRICARE Basic Program. This demonstration authority remains in effect until December 31, 2018, unless further extended or replaced by other sufficient coverage authority.

DESCRIPTION OF THE ACD

The ACD offers comprehensive ABA services for all TRICARE-eligible beneficiaries diagnosed with ASD by an approved provider. Under the ACD, a Board Certified Behavior Analyst (BCBA) or BCBA-Doctorate, or other TRICARE authorized provider who practices within the scope of his or her state licensure or state certification, referred to as an "authorized ABA supervisor," plans, delivers, and supervises an ABA program. The authorized ABA supervisor can either deliver ABA under the tiered delivery model or the sole provider model. In the sole provider model, ABA services are rendered by only the authorized ABA supervisor. In the tiered delivery model, the authorized ABA supervisor may be supported by the assistant behavior analyst(s) (a Board Certified Assistant Behavior Analyst (BCaBA) or a Qualified Autism Service Provider) and/or a paraprofessional Behavioral Technician(s) (BT) (a Registered Behavior Technician (RBT), a Board Certified Autism Therapist (BCAT), or a Autism Behavior Analysis Therapist (ABAT)) who work one-on-one with the beneficiary diagnosed with ASD in the home and/or community setting to implement the ABA intervention protocol designed, monitored, and supervised by the authorized ABA supervisor. An assistant behavior analyst working within the scope of his or her training, practice, and competence may assist the

authorized ABA supervisor in various roles and responsibilities as determined appropriate, and delegated to the assistant behavior analyst (to include supervision of BTs), and consistent with the certifying body guidelines and requirements. As such, the ACD specifically requires that an assistant behavior analyst work under the supervision of an authorized ABA supervisor. BTs also work under the supervision of an authorized ABA supervisor who is responsible for all of the ABA services delivered to a beneficiary. One of the goals of the ACD is to provide a comparative assessment of ABA services delivered by the sole provider model or by the tiered-delivery model in terms of access, quality, and cost.

The ACD authorizes TRICARE reimbursement of the following ABA services to TRICARE-eligible beneficiaries diagnosed with ASD by an appropriate provider: an initial ABA assessment, to include administration of appropriate assessment measures and a functional behavioral assessment and analysis as required; development of an ABA Treatment Plan (TP) with goals and objectives of behavior modification and specific-evidenced based interventions; one-on-one ABA interventions and assessments in accordance with the TP goals and objectives; periodic ABA TP updates that reflect re-assessment of the beneficiary's progress toward meeting treatment goals and objectives specified in the ABA TP; supervision of assistant behavior analysts and BTs; and, family guidance of the ABA TP.

FINDINGS

Transition of beneficiaries from the legacy ABA programs to the ACD occurred during the period of July 25, 2014, through December 31, 2014. Billing under the legacy programs ceased as of January 1, 2015, when all ABA services began billing under the ACD. As a result, not all ABA services in FY 2015 occurred under the ACD (October 2015 through December 2015). Therefore, in order to provide a more comprehensive account on utilization of ABA services in TRICARE during the first half of FY 2015, data reflect all ABA services to include the ECHO program (exclusively for ADFMs), TRICARE's ABA Pilot (exclusively for non-ADFMs), the TRICARE Basic ABA program, and the new ACD. This information was generated using TRICARE purchased-care claims incurred during FY 2013 (October 1, 2012, through September 30, 2013), FY 2014 (October 1, 2013, through September 30, 2014), and the first half of FY 2015 (October 1, 2014, through March 31, 2015). All claims data examined in this report were extracted on August 1, 2015, and the results are based upon data as of that date.

TRICARE ABA Users

The annual number of ADFM beneficiaries diagnosed with ASD using TRICARE ABA programs nearly quadrupled between FY 2009 and FY 2014 (from 2,292 users to 8,987), increasing at an average annual rate of 31 percent. Since then, the number of users continues to increase annually, but the rate of growth has slowed. Users increased by 59 percent between FY 2009 and FY 2010, by 41 percent between FY 2010 and FY 2011, by 29 percent between FY 2011 and FY 2012, by 19 percent between FY 2012 and FY 2013, and by 14 percent between FY 2013 and FY 2014. Between the first 6 months of FY 2014 and the first 6 months of FY 2015, the rate of growth of ABA users declined to 8 percent (from 7,299 to 7,877). During the first 6 months of FY 2015, with the advent of the ACD, ECHO program participation declined and

more than 90 percent of ADFM users transitioned to the ACD (7,094 out of 7,877 total users used the ACD).

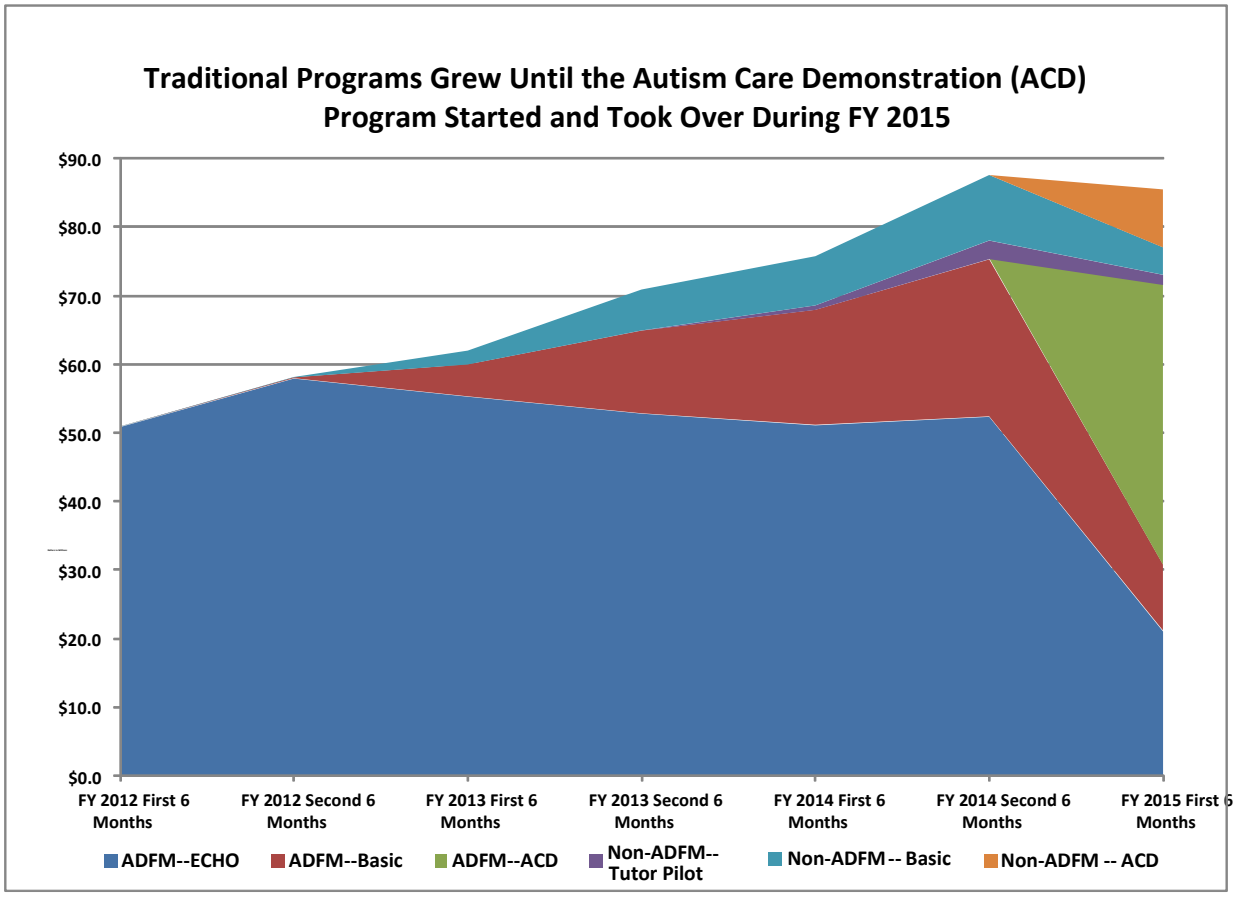
Non-ADFMs gained access to TRICARE ABA services starting in FY 2012 as a result of the court-ordered coverage of ABA under the TRICARE Basic program. Only ABA provided by a masters-level (or above) BCBA was covered under the TRICARE Basic Program ordered interim benefit, with tiered model ABA services (i.e., supervised tutors, now called BTs) available only to ADFMs under the legacy ECHO Autism Demonstration. Although the court order was reversed in June 2013, the Department continued such coverage to avoid any disruption of ongoing care to beneficiaries while it determined the appropriate way-ahead in light of the various ABA coverage authorities and limitations. Most beneficiaries at that time (FY 2012) were ADFMs receiving tiered model ABA services under the legacy ECHO Autism Demonstration. The growth rate of ABA services provided directly by a masters-level (or above) BCBA under the terms of the TRICARE Basic Program as an interim benefit was initially very slow. The growth rate increased over time with the start of the ABA Pilot in FY 2013 (832 users), and there were dramatic increases when the ACD started in FY 2015. Non-ADFM ABA users increased by 87 percent during FY 2014 when compared to FY 2013 (from 832 users to 1,554 users) and 73 percent between the first 6 months of FY 2014 and the first 6 months of FY 2015 (from 994 users to 1,720 users). Even though there are 50 percent more non-ADFM eligibles than ADFMs, the number of non-ADFM ABA program participants is only one-fifth of the ADFM level during this time period (1,720 users versus 7,877 users) due to three main factors: 1) TRICARE non-ADFM ABA programs are in their infancy; 2) non-ADFMs have fewer children in the age group that most commonly uses ABA services (ages 2 to 12); and, 3) non-ADFMs had higher cost sharing requirements than ADFMs.

ABA Program Costs

Reflecting the growth in the number of program users, total government costs for ABA services provided to ADFM ECHO Autism Demonstration and TRICARE Basic Program participants diagnosed with ASD have more than quadrupled between FY 2009 and FY 2014 (from $31.0 to $163.4 million), increasing at an average annual rate of 36 percent over the period. However, the rate of cost increases has slowed: by 84 percent between FY 2009 and FY 2010, 49 percent between FY 2010 and FY 2011; 30 percent between FY 2011 and FY 2012; 15 percent between FY 2012 and FY 2013; and, 15 percent between FY 2013 and FY 2014. These trends primarily reflect trends in users. ADFM program cost increases also declined to 5 percent between the first 6 months of FY 2014 and the first 6 months of FY 2015. While virtually no costs were observed for ADFMs in the ACD prior to FY 2015 as ADFMs were receiving ABA under the legacy ECHO Autism Demonstration, this program represented 57 percent of total ADFM costs ($40.9/$71.6 million) during the first 6 months of FY 2015 due to ADFMs transitioning to the ACD.

Non-ADFM costs also reflect trends in users. Given that program participation growth was very slow, non-ADFM costs were only $0.1 million in FY 2012. However, these costs increased by 150 percent from $8.0 million in FY 2013 to $20.1 million in FY 2014, with the start of the ABA Pilot. When comparing the first 6 months of FY 2014 to the first 6 months of FY 2015, non-ADFM costs increased by 78 percent (from $7.8 million to $13.9 million)

reflecting the start of the ACD program. Non-ADFM program costs were equivalent to 19 percent of ADFM costs during the first half of FY 2015 ($13.9 million versus $71.6 million) due to the three main factors as stated above.



Potential for Future ABA Program Growth

With growth rates for ABA users of 41 percent in FY 2011, 29 percent in FY 2012, 19 percent in FY 2013, and 14 percent in FY 2014, it is important to understand the potential for continued program growth. One approach is to examine the proportion of ADFM beneficiaries diagnosed with ASD who were receiving ECHO Autism Demonstration and TRICARE Basic Program ABA services. To estimate the total number of ADFM beneficiaries diagnosed with ASD in a given year, we queried both direct and purchased care claims files and determined the number of ADFM beneficiaries ages 2 to 17 that had two or more separate claims with a diagnosis of ASD in any position (i.e., primary or secondary diagnosis).

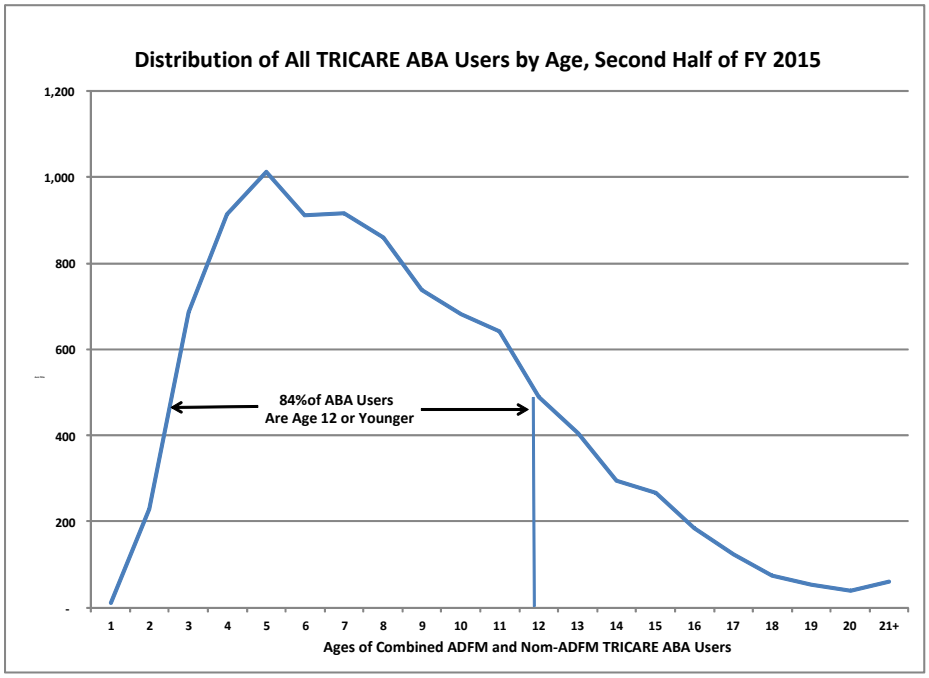
In FY 2009, there were an estimated 10,475 ADFMs diagnosed with ASD, and 2,292 (or 22 percent) were using TRICARE ABA services. By FY 2014, the number of ADFMs using TRICARE ABA services had increased by 292 percent to 8,978. However, because the number of ADFMs diagnosed with ASD had also increased by 88 percent to 19,651, we estimate as of FY 2014 that 46 percent of those diagnosed (8,978/19,651) were using TRICARE ABA services.

Because 54 percent of ADFMs diagnosed with ASD were not using TRICARE ABA services as of FY 2014, we fully expect the program use to grow in the future.

The share of non-ADFMs diagnosed with ASD and using TRICARE ABA services increased from 1 percent in FY 2012 to 23 percent in FY 2014 and to 28 percent in the first half of FY 2015. Because roughly three-quarters of the non-ADFM population diagnosed with ASD are not receiving TRICARE ABA services, this also indicates that there is ample room for future program growth.

Age Distribution of ABA Users

The chart below presents the age distribution of beneficiaries using TRICARE ABA services during the first half of FY 2015. Across both genders and both beneficiary types, 99.4 percent of TRICARE ABA users are younger than age 21, and 84.3 percent are younger than age 13. The median participant age is 8, the average age is 8.1, and the most common age of participating beneficiaries is 5. Roughly 4 out of 5 beneficiaries diagnosed with ASD and receiving TRICARE ABA services are boys. ADFM beneficiaries tend to be younger than non-ADFMs, with a median age of 7 versus 10 for non-ADFMs.



Expenditures for Physical/Speech/Occupational Therapy & Prescription Drugs

Children with a diagnosis of ASD tend to utilize other TRICARE medical services for PT, OT, and speech therapy in both the purchased and direct care systems. Further, beneficiaries diagnosed with ASD also used the retail pharmacy, TRICARE Mail Order Pharmacy, and direct care pharmacy for prescription medications to treat ASD, Attention Deficit Hyperactivity Disorder, and other related mental health conditions. The 10,541 TRICARE beneficiaries who used TRICARE ABA services in FY 2014, also used an additional $36.9 million in PT, OT, and

speech therapy services (purchased care paid amounts and direct care full cost amounts), and $5.5 million in prescription medications, suggesting that there are many other medical needs by this beneficiary population.

Provider Availability

Since 2005, there has been tremendous growth in the number of BCBAs. Across the U.S., the number of Behavior Analyst Certification Board (BACB)-certified BCBA providers grew to a total of 17,754 from 2005 to 2015. More than 15,100 providers have been added to the ranks of the 2,566 that existed in 2005 (Source: BACB).

Under the ACD, an authorized ABA supervisor plans, delivers, and supervises an ABA program and the authorized ABA supervisor's availability is vital to the success of the ACD. Based on contractor submitted reports as of September 30, 2015, the number of authorized ABA supervisors was 6,887 across all TRICARE regions. While TRICARE-eligible children diagnosed with ASD (age 2 to 17) represent only about 2 percent of the children in the U.S., they used a disproportionate number, 38 percent, of the 17,754 BACB-certified providers in the U.S. in FY 2015. In addition, according to contractor submitted reports, there were 523 BCaBAs and 19,421 BTs supporting authorized ABA supervisors as of September 30, 2015. The Department will continue to closely monitor provider participation in the program as this is a key metric in determining appropriate reimbursement rates.

DISCUSSION OF THE EVIDENCE REGARDING CLINICAL IMPROVEMENT OF CHILDREN DIAGNOSED WITH ASD

Data are insufficient at present to effectively determine whether ABA results in clinical improvement of children diagnosed with ASD. The Department is actively exploring research opportunities to study the clinical efficacy of ABA services under the ACD. In addition, the Department plans to study, through audit of claims data and medical records, the quality of ABA services provided to TRICARE beneficiaries diagnosed with ASD by authorized ABA supervisors, assistant behavior analysts, and BTs. This study will use clinical data obtained through audit claims data and medical records reviews on a statistically valid sample of new and continuously enrolled ACD beneficiaries during each FY, beginning with FY 2015 data as outlined below:

- Descriptive analysis of the beneficiary population receiving ABA services under the ACD;

- Descriptive analysis of ABA initial assessments and re-assessments and ABA TPs/TP updates conducted over the course of ABA service delivery to include the length of time that each beneficiary has been receiving ABA services;

- Descriptive analysis of ABA assessment tools used (to include the use of standardized measures, skills tracking graphs, and/or data sheets, etc.);

- Analysis of the symptom domains (e.g., social, behavioral, communication, other) and the specific symptom targets (e.g., receptive and expressive language, imitation skills, disruptive behavior) of the ABA services;

- An assessment of the methods used to assess progress (to include the identification of standardized progress measures, skills tracking graphs, and/or data sheets, etc.) and aggregate findings regarding clinical improvement; and,

- An assessment of the frequency of supervision episodes per month and number of hours of supervision provided by the authorized ABA supervisor to the BT under the ABA tiered model, expressed as a percentage or ratio of BT hours supervised to total hours of ABA delivered.

LESSONS LEARNED

After implementation of the ACD in July 2014, the Department conducted five ACD round table events and one information session for parents, advocacy groups, and other stakeholders (October 15, 2014; December 3, 2014; May 5, 2015; July 28, 2015; September 18, 2015; and, December 3, 2015). The round tables were well attended and senior Department officials listened to concerns, answered questions, and took matters for further analysis and action. The Department received constructive feedback from each round table and directly from interested stakeholders. The Department greatly appreciated the participation of all interested parties, and through this process, gained additional insights about how to design and implement an optimum care delivery and reimbursement system for beneficiaries diagnosed with ASD. Among a number of issues raised by stakeholders, two fundamental concerns emerged from the October and December 2014 round table meetings that required immediate adjustments under the ACD.

The first was that the beneficiary cost-sharing provisions under the ACD may have an adverse financial impact on non-ADFM beneficiaries as the one-on-one ABA services did not accrue to the catastrophic cap and thus may have put ABA "out of reach" for some families financially. The second concern was that TRICARE reduced the reimbursement for one of the five covered ABA services provided by authorized ABA supervisors. The one-on-one intervention service rate of $125.00/hour was reduced to $68.00/hour and this reportedly would cause providers to disengage TRICARE beneficiaries leading to decreased access. The Department amended the ACD as outlined below in order to address these critical concerns.

<u>Cost-Sharing</u>

Under the TRICARE program, cost-sharing by beneficiaries is required by law. Cost sharing serves a number of purposes, including the means for obtaining a beneficiary's individual investment and commitment to the care sought, discouraging unnecessary use and overutilization of limited health care resources, and controlling overall TRICARE program costs to ensure sustainability of the benefit. Initially, TRICARE kept the various cost-shares related to ABA services under the ACD the same as cost-shares and co-payments previously established under the ECHO Autism Demonstration for ADFMs, the ABA Pilot for non-ADFMs, and ABA

under the Basic Program. All ABA services provided by an authorized ABA supervisor (i.e., initial ABA assessment and TP, ABA reassessments and TP updates, direct one-on-one ABA, and parent/caregiver guidance in ABA) counted toward the medical benefit catastrophic cap under the TRICARE Basic benefit. TRICARE covers 100 percent of charges for authorized ABA supervisor services after a family's out-of-pocket costs reach an annual cap of $1,000.00 for Active Duty and TRICARE Reserve Select families, and $3,000.00 for retirees and their families.

However, tiered model ABA services provided by supervised assistant behavior analysts and BTs were based on tiered model ABA services previously provided under ECHO and the ABA Pilot. Many families receive a bulk of their care under the tiered service delivery model. These ABA services include supervision and intensive one-on-one ABA which may take place for many hours over an extended period of time, and did not originally apply towards the benefit catastrophic cap. For tiered model ABA services, ADFMs paid the same monthly fee amount under ECHO based on the sponsor's pay grade. Non-ADFMs paid the same out-of-pocket costs under the ACD (as they did under the ABA Pilot) — 10 percent of the allowed charge for these services. Because these tiered model ABA services did not accrue to the annual catastrophic cap and out-of-pocket costs were not limited, there were concerns expressed by beneficiaries and advocates that this policy may have an adverse financial impact on some families and put tiered model ABA services "out of reach" for those families.

To address this concern, the Department amended the ACD policy, effective October 1, 2015, to apply all beneficiary cost-shares for ABA services under the ACD, including tiered model services (ABA provided by supervised assistant behavior analysts and BTs), toward the catastrophic cap in the same manner as TRICARE Basic program benefits generally. The Department implemented this amendment to the beneficiary cost-share requirements by aligning cost-shares for all ABA services under the ACD with existing TRICARE program cost-sharing requirements as defined in Title 32, C.F.R., Section 199.4 (TRICARE Standard program deductible and cost-share amounts), Title 32, C.F.R., Section 199.17 (TRICARE Extra program deductible and cost-share amounts), and Title 32, C.F.R., Section 199.18 (TRICARE Prime program enrollment fees and co-payments). This amendment received much positive feedback from interested stakeholders.

Provider Reimbursement Rates

The ACD as a demonstration has some flexibility in establishing reimbursement methodologies, rather than being completely bound to otherwise existing TRICARE program provider reimbursement requirements under the Basic Program. The Defense Health Agency has discretion to evaluate alternative methods of payment and the appropriate reimbursement rates for ABA services under the TRICARE demonstration authority. Although care available under the TRICARE program must generally be reimbursed using the reimbursement requirements of title 10, U.S.C., section 1079(h), and Title 32, C.F.R., Section 199.14(j), "to the extent practicable," or (in the absence of a practicable Medicare rate) to use the prevailing rate, the ACD can develop alternative reimbursement methodologies where and when appropriate while adhering to overall TRICARE reimbursement methodology principles as much as possible. As a

result, the ABA reimbursement rates under the ACD may be established through different mechanisms.

With the implementation of the ACD, the Department came under intense criticism from providers that the rate reduction for one-on-one ABA delivered by authorized ABA supervisors from $125.00 to $68.00 was too drastic. Some providers indicated they would disengage TRICARE beneficiaries as a result of the proposed rate reduction. The Department responded by placing the rate reduction in abeyance pending further evaluation and a determination of appropriate rates by the Department.

The Department subsequently obtained two analyses to determine the National rates for all ABA services that are both fair and in line with the standard practices used to create reimbursement rates for virtually all covered medical services. As a result of these data, the Department calculated new ABA reimbursement rates for the ACD to be effective in Spring 2016. In general, TRICARE professional rates are based on the Medicare reimbursement rates, but since Medicare does not cover ABA services, the studies were requested to determine the commercial and Medicaid reimbursements for the specific ABA services covered by the ACD. National rates for TRICARE were calculated using the statewide Medicaid rates (from the 35 States with established statewide rates) and increasing those rates to adjust for differences in reimbursement rates between Medicaid and Medicare.

We calculated that, on average, Medicare payment rates are about 28 percent higher than Medicaid rates for a sample of the three highest-volume TRICARE individual mental health service codes. The National rates (to be calculated annually) were then adjusted using the Medicare Geographic Practice Cost Index to create rates for each of the 89 localities recognized by Medicare, exactly as applied to all other TRICARE covered services. If Medicare establishes rates for the eight current ABA CPT codes that TRICARE recognizes, those rates will immediately be adopted as required by law. Although the general 15 percent limitation on reduction of TRICARE reimbursement rates set forth in title 10, U.S.C., section 1079(h)(2), does not apply to rate determinations for demonstrations established under the authority of title 10, U.S.C., section 1092, the Department will nonetheless gradually adjust rates (if needed based on the results of the independent analysis) by no more than 15 percent per year until alignment with the prevailing geographic rate, based on provider type, is reached.

This process also ensures the ABA reimbursement rates are not frozen, as they have been for the past 7 years, since they will now be reviewed and appropriately adjusted each year, as are all other TRICARE rates. The locality rates and the 15 percent adjusted locality rates for each geographic region were both published on December 1, 2015. Furthermore, an update to the December 2015 rate analysis was conducted to ensure that the rates set for spring 2016 reflected the most currently available rate information. The Department is confident that the careful analysis of rates resulted in fair and competitive reimbursement rates and will closely monitor provider participation as a key metric for success.

<u>Other Issues: Certification Requirements</u>

When a certification body exists, TRICARE is required to use certification requirement standards. Under the ACD, TRICARE accepts certification requirements for the RBT from the BACB, the ABAT from the Qualified ABA Certification Board, and the new Behavioral Intervention Certification Council's BCAT. These certifications maintain guidelines, which include the core tasks that are likely to be performed by BTs. The previous education requirements under the ECHO Autism Demonstration were maintained by design to further ensure BT competency. As implemented under the ACD, BTs hired from January 1, 2015, onward, had until December 31, 2015 (now extended to December 31, 2016, due to lack of compliance), to become BT certified. Legacy BTs have until December 31, 2016, to meet the new BT training requirements, which include Health Insurance Portability and Accountability Act (HIPAA), and 40 hours of ABA training. Training in HIPAA is part of the BACB's Guidelines for Responsible Conduct of RBTs.

Feedback from several authorized ABA supervisors asserted the credentialing process for each BT takes a minimum of 4 weeks once the provider submits the necessary paperwork, meaning that the BT cannot provide ABA services to TRICARE members during that time since they are not "fully credentialed." These providers claimed this timeline impedes TRICARE's ability to provide access to meet its members' needs. These providers also claimed that the credentialing of BTs creates administrative tasks for providers that are unique to TRICARE. As such, these providers requested that the BT requirements be revised to lessen the administrative burden on their practice by either delaying the BT requirement or reimburse for their training. The BT certification had already been delayed once from December 31, 2014, to December 31, 2015, and now has been delayed a second time until December 31, 2016, due to lack of compliance. As of January 1, 2016, all newly hired BTs are required to possess a BT certification prior to rendering ABA services. Reimbursement for provider training is not authorized under TRICARE for any provider category.

The Department is committed to ensuring patient safety, providing quality care, and preventing fraud. The education, training, and supervision requirements established for BT services under the ACD are designed to ensure safe, quality care is being delivered to all TRICARE beneficiaries. These requirements are informed by the evolution of professional requirements found in BACB guidance and that of other certification bodies, and TRICARE must ensure that TRICARE beneficiaries are safe when in the care of BTs.

Another revision to the certification requirement for all ABA providers is the addition of Basic Life Support (BLS) or the equivalent Cardiopulmonary Resuscitation (CPR) training. The ASD population has high rates of other comorbid medical conditions such as seizure disorder and gastrointestinal disorders. Also, with the use of food as reinforcements, there is a higher likelihood of choking by these beneficiaries. Per the recommendation of several BCBAs, the ACD now requires all ABA providers receive either BLS or the equivalent CPR certification. All ABA providers were required to be BLS or CPR certified by December 31, 2015.

NEW LEGISLATIVE AUTHORITIES REQUIRED TO IMPROVE THE PROVISION OF ABA SERVICES

There has been much advocacy for the DoD to expand coverage of ABA services, from beneficiaries, advocacy groups, legislators, and others. Such TRICARE coverage expansions, however, are not discretionary. TRICARE Basic Program benefit coverage determinations must be based solely on the following references, listed in order of relative weight, and commonly referred to as the TRICARE Basic Program's "hierarchy of reliable evidence:"

1. Well-controlled studies of clinically meaningful endpoints, published in referred medical literature;
2. Published formal technology assessments;
3. Published reports of national professional medical associations;
4. Published national medical policy organization positions; and,
5. Published reports of national expert opinion organizations.

Despite the many assertions to the contrary, the Department may not rely on reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence, or personal professional opinions. Further, the Department may not rely on the fact that a provider or number of providers have elected to adopt a drug, device, or medical treatment or procedures as their personal treatment or procedure of choice or standard of practice.

Absent published peer-reviewed results of well-controlled clinical studies that demonstrate the efficacy of ABA services for treating the underlying neurological condition(s) causing ASD, ABA services will remain outside the definition of "medical" for TRICARE Basic Program coverage purposes. Nevertheless, as documented by a subjective parental satisfaction survey conducted in conjunction with the ECHO Autism Demonstration in 2009, the legal characterization of ABA services as non-medical does not change the underlying reality that ABA services were widely perceived as "helpful." The Department plans to conduct an ABA ACD parent satisfaction survey in FY 2016 and FY 2018 to elicit current parent/caregiver views of the ACD program. Assuming the feedback continues to be positive, parents and caregivers will want ABA services continued, now and likely in the future, for all beneficiaries diagnosed with ASD. Furthermore, if ABA services become characterized as medical but still unproven, then, by law, ABA services will be excluded from ECHO entirely, in addition to being excluded from the TRICARE Basic Program.

Through implementation of the ACD in July 2015, under the broad demonstration authority of title 10, U.S.C., section 1092, TRICARE removed ABA services from the need to classify it as medical (i.e., to provide TRICARE coverage of ABA services outside of the TRICARE Basic Program, the ECHO Autism Demonstration, and other prior authorities such as the 1-year ABA Pilot for non-ADFMs). However, the scope and duration of the ACD is limited, and the Department does not have authority to cover ABA services as a permanent TRICARE Basic Program benefit. If evaluation of the coverage of ABA services under the ACD is determined successful, but the ABA research does not yet meet TRICARE criteria for coverage under the Basic Program as "proven medical care" under Title 32, C.F.R., Section 199.2(b), then the DoD would need permanent legislative authority to continue ABA services outside of TRICARE Basic and ECHO as a permanent TRICARE benefit for all beneficiaries diagnosed with ASD. Furthermore, until there are AMA Category I CPT codes for ABA services as "proven medical care," any interim coverage of ABA services under demonstration authority or

otherwise, requires continued use of the Category III ABA CPT codes to ensure proper claims processing by the managed care support contractors. The Category III ABA CPT codes are scheduled to sunset in in 2020. If the Category I CPT ABA codes are not approved by that time, then use of non-standard codes to ensure proper claims processing would be required.

The Department does not currently require additional authority from Congress to support providing ABA services because the current demonstration fully supports the TRICARE benefit in place. Additional authority may be needed at the end of the ACD in 2018 after review and analysis of the ACD's goals: analyzing, evaluating, and comparing the quality, efficiency, convenience, and cost effectiveness of those ABA services that do not constitute the proven medical care provided under the medical benefit coverage requirements that govern the TRICARE Basic Program.

CONCLUSION

Although the annual growth rate in users of ABA services has declined over time, the demand for ABA services by TRICARE beneficiaries continues to increase. This resulted in a 525 percent increase in Government costs since FY 2009 to provide these services to beneficiaries diagnosed with ASD (from $31.0 to $163.4 million). Given that only half of the ADFM population and one quarter of the non-ADFM population diagnosed with ASD are currently receiving ABA services while using a disproportionate number, 38 percent, of the 17,754 BACB-certified providers in the U.S. in FY 2015, the Department remains concerned about the availability of qualified providers to meet the demands, despite the growth of BCBAs nationwide. The Department will continue to closely monitor provider participation, and will continue to ensure that the TRICARE ABA benefit remains comprehensive and highly competitive, particularly in light of the revised reimbursement methodology and rates that will be implemented in spring 2016.

It is far too early to fully assess the ACD's clinical impact on beneficiaries diagnosed with ASD. The Department is actively exploring research opportunities to study the clinical efficacy of ABA services within the ACD. The Department plans to conduct claims and medical record audits in 2016 under the TRICARE Quality Management Contract and anticipates this effort will provide more definitive clinical information for inclusion in subsequent reports. Additionally, the Department asked the ABA providers during the December 2015 round table for their help identifying and implementing standardized outcome measures on the efficacy of ABA services under the ACD. It is our hope that despite the highly individualized nature of progress and outcome measurement within the field of ABA, ABA providers will recommend standardized outcome measures that we can include in the ACD to help us evaluate whether ABA services provided under the ACD are helping our beneficiaries diagnosed with ASD.

The Department has conducted a series of ACD round tables since implementation of the ACD. These round tables were well attended by various stake holders and provided the Department with invaluable feedback on how to improve the delivery of ABA services. As a result, the Department amended the ACD policy to decrease the financial burden on families and this effort has received much positive feedback. In addition, the Department has aligned the reimbursement rates and methodology to be consistent with other medical services, giving providers much needed visibility, uniformity, and stability in how they are reimbursed. The

Department intends to continue the ACD round tables periodically in order to gain further insights on how to properly structure the ABA benefit.

In summary, TRICARE continues to increase access to ABA services and is leading the Nation in fielding an effective ABA program model. The Department fully supports the continued research on the nature and effectiveness of ABA services and the evolution of the field from an educational discipline toward a health care discipline.