

OFFICE OF THE UNDER SECRETARY OF DEFENSE

4000 DEFENSE PENTAGON WASHINGTON, D.C. 20301-4000

AUG 1 6 2017

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 requests the Secretary of Defense provide an annual report on the Autism Care Demonstration (ACD).

The report provides information on the current state of the ACD, including enrollment and costs. 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 diagnosed with Autism Spectrum Disorder, 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—from 2,292 beneficiaries in FY 2009 to 12,155 beneficiaries in FY 2015. As a result, there has been a 640 percent cost increase from \$31M in FY 2009 to \$198.8M in FY 2015.

The Department fully supports continued research on the effectiveness of ABA services, as this field evolves from an educational discipline toward a health care discipline. Thank you for your interest in the health and well-being of our Service members, veterans, and their families.

A. M. Kurta

14 Kurta

Performing the Duties of the Under Secretary of Defense for Personnel and Readiness

Enclosure: As stated

cc:

The Honorable Jack Reed Ranking Member

Report to the Committee on Armed Services of the Senate



The Department of Defense Comprehensive Autism Care Demonstration August 2017

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

Requested by: Senate Report 114-49, accompanying S. 1376, the National Defense Authorization Act for Fiscal Year 2016

The estimated cost of report for the Department of Defense (DoD) is approximately \$14,000.00 for the Fiscal Year (FY) 2017. This includes \$0.00 in expenses and \$14,000.00 in DoD labor.

Generated on March 9, 2017

RefID: 1-50CBCEC

INTRODUCTION

This report is in response to the Senate Report 114-49, page 157, accompanying S. 1376, the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2016, which requests a report to the Committee on Armed Services of the Senate on the results of the Comprehensive Autism Care Demonstration (ACD) no later than April 1, 2016, and annually thereafter for the duration of the program. This report is for FY 2017 and is the second of these annual reports. 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 offers a comprehensive health benefit offering a full array of medically necessary services to address the needs of all TRICARE beneficiaries diagnosed with ASD.

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 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 in Federal regulations, 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 incorporates any techniques that apply 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 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 Federal regulations, to be scientifically proven medical/psychological care for the diagnosis of 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 acknowledges there are evolving changes in commercial and private healthcare plans which influence the national landscape of the acceptability of ABA services as a medical benefit.

Although much has been published asserting that ABA services are 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, well controlled studies of clinically meaningful endpoints, published in refereed medical literature. In order for ABA services to be scientifically proven for TRICARE coverage purposes, efficacy must be established through randomized controlled trials (RCTs). TRICARE commissioned several health technology assessments through an external review of literature. The resulting report recommends more research and continues to assess the literature to be of low to fair quality. 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.

Additionally, the current state of the research does not identify the specific variables for an effective treatment program of ABA services. 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 services help some, but not all children diagnosed with ASD, but the characteristics of which children are likely to benefit from ABA services 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.

Furthermore, 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, in July 2014 the AMA 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 of Federal regulations and TRICARE policy. Medicaid and other commercial and private healthcare plans utitlize the same series of Category III CPT billing codes in covering payment for ABA services as an emerging technology or service.

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, which had been previously provided under a patchwork of the TRICARE Basic Program (i.e., the medical benefits authorized under Federal regulations),

the ECHO Enhanced Access to Autism Services Demonstration (hereafter the "ECHO Autism Demonstration;" i.e., the supplemental ABA benefits authorized for certain ADFMs), and the ABA Pilot (i.e., the 1-year supplemental ABA benefit authorized for certain non-Active Duty Family Members (NADFMs)—including retiree dependents and others—under section 705 of the NDAA for FY 2013).

TRICARE coverage of ABA services under the ACD is provided under the demonstration authority in Federal statutes and 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. 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 services 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 a paraprofessional Certified Behavior Technician(s) (BT) (a Registered Behavior Technician (RBT), a Board Certified Autism Therapist (BCAT), or an Autism Behavior Analysis Therapist (ABAT)) who work one-on-one with the beneficiary diagnosed with ASD in the home 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. This requirement is consistent with the certification board requirements. 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 tiereddelivery 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

Data reflects all ABA services to include the ECHO program (exclusively for ADFMs), TRICARE's ABA Pilot (an expired program previously exclusively for NADFMs), the TRICARE Basic ABA program, and the ACD. This information was generated using TRICARE purchased-care claims incurred during FY 2014 (October 1, 2013, through September 30, 2014), FY 2015 (October 1, 2014, through September 30, 2015), and the first half of FY 2016 (October 1, 2015, through March 31, 2016). All claims data examined in this report were extracted on August 1, 2016, and the results are based upon data as of that date.

TRICARE ABA Users

In FY 2015 there was a total of 12,155 beneficiaries with an ASD diagnosis using TRICARE ABA services: 9,739 ADFMs and 2,416 NADFMs (as shown in Table 1).

The annual number of ADFM beneficiaries with an ASD diagnosis using TRICARE ABA programs more than quadrupled between FY 2009 and FY 2015 (from 2,292 users to 9,739) increasing at an average annual rate of 27 percent. While the annual growth rate in users has remained positive, it has declined over time. 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, by 13 percent between FY 2013 and FY 2014, and by 9 percent between FY 2014 and FY 2015. Comparing the rate of growth between the first 6 months of FY 2015 and the first 6 months of FY 2016, the rate of growth of ABA program users further declined to 6 percent (from 7,998 to 8,473).

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. NADFM ABA users increased by 55 percent during FY 2015 when compared to FY 2014 (from 1,555 to 2,416 users). NADFM growth rates, while remaining strong, declined between the first six months of FY 2015 and the first six months of FY 2016 at 30 percent (from 1,776 users to 2,312 users). Even though there were 50 percent more NADFM eligibles than ADFMs, the number of NADFM ABA program participants was only one-quarter of the ADFM level during this time period (2,312 users versus 9,739 users) due to three main factors: 1) TRICARE NADFM ABA programs were still in their infancy; 2) NADFMs had less children in the age group, which used ABA services (ages 2 to 12); and 3) NADFMs had higher cost sharing requirements for ABA services than ADFMs.

Table 1

| His | torical Number | of Combine (Based Upor | | | | Program Us | sers | | | |
|----------------------|-----------------------------------|---------------------------|-------------------------------|--------------------------|---|-------------------------|----------------------------|-------------------------|--|--|
| | | Number of | Users | | Percent Growth in Users from Prior Year | | | | | |
| | ECHO & Tutor Pilot Programs | TRICARE Basic ABA | New Autism Care Demo | Total Unique Users | ECHO & Tutor Pilot Programs | TRICARE Basic ABA | New Autism Care Demo | Tota Unique Users | | |
| | By 6 Month Increments | | | | | | | | | |
| FY12 First 6 Months | 5,317 | 50 | - | 5,342 | | | | | | |
| FY12 Second 6 Months | 6,064 | 192 | ** | 6,140 | | | | | | |
| FY13 First 8 Months | 6,184 | 1,834 | - | 6,958 | 16% | 3568% | | 30% | | |
| FY13 Second 6 Months | 5,943 | 3,020 | * | 7,838 | -2% | 1473% | | 28% | | |
| FY14 First 6 Months | 6,010 | 3,699 | | 8,219 | -3% | 102% | | 1896 | | |
| FY14 Second 6 Months | 6,583 | 4,774 | 14 | 9,410 | 11% | 58% | | 20% | | |
| FY15 First 6 Months | 5,350 | 3,287 | 8,938 | 9,774 | -1196 | -1196 | | 1996 | | |
| FY15 Second 6 Months | 179 | | 10,732 | 10,771 | -97% | -100% | | 14% | | |
| FY16 First 6 Months | 335 | * | 10,728 | 10,785 | -94% | -100% | | 10% | | |
| | By Fiscal Years | | | | | | | | | |
| FY11 | 5,140 | 9 | * | 5,149 | | | | | | |
| FY12 | 6,465 | 221 | | 6,685 | 26% | 2356% | | 30% | | |
| FY13 | 7,215 | 3,526 | | 8,743 | 12% | 1495% | | 31% | | |
| FY14 | 7,581 | 5,848 | 14 | 10,462 | 5% | 88% | | 20% | | |
| FY15 | 5,420 | 3,287 | 11,445 | 12,155 | -28% | -44% | | 16% | | |

ABA Program Costs

Combined ADFM and NADFM ABA program costs for direct ABA services reached \$198.8M in FY 2015. The TRICARE beneficiaries who used TRICARE ASD services during FY 2015, also utilized \$31.6M in Physical Therapy, Occupational Therapy, and Speech Therapy services, and \$18.5M in medications. The total cost is \$248.9M for the full range of ABA services provided for beneficiaries enrolled under the TRICARE ACD Program.

Reflecting the growth in the number of program users, total government costs for ADFM ECHO and Basic ABA program participants with a diagnosis of ASD have increased by more than five times between FY 2009 and FY 2015 (from \$31.0M to \$163.8M) increasing at an average annual rate of 32 percent over the period. Costs also increased at a decreasing rate: by 84 percent between FY 2009 and FY 2010, by 49 percent between FY 2010 and FY 2011, by 29 percent between FY 2011 and FY 2012, by 15 percent between FY 2012 and FY 2013, by 11 percent between FY 2013 and FY 2014, and by 18 percent between FY 2014 and FY 2015. These trends primarily reflect trends in ACD program users. ADFM program cost increases were 20 percent between the first 6 months of FY 2015 and the first 6 months of FY 2016. While virtually no costs were observed for ADFMs in the ACD prior to FY 2015, this program represented 99.5 percent of total ADFM ABA services costs (\$90.1/\$90.6M) during the first 6 months of FY 2016.

NADFM costs also reflect trends in users. Given that program participation growth was initially very slow, NADFM costs were only \$0.1M in FY 2012. However, these costs increased by 153 percent from \$8M in FY 2013 to \$20.2M in FY 2014, with the start of the ABA Tutor Pilot. Costs increased by 74 percent from \$20.2M in FY 2014 to \$35M in FY 2015. When comparing the first six months of FY 2015 to the first 6 months of FY 2016, NADFM costs increased by 48 percent (from \$14.6M to \$21.6M) reflecting the start of the ACD program.

NADFM program costs were equivalent to 24 percent of ADFM costs during the first half of FY 2016 (\$21.6M versus \$90.6M) due to the three main factors stated above.

Table 2

| | | Dollars in M | illions | | Percent Growth in Dollars From Prior Year | | | | | |
|----------------------|-----------------------------------|-------------------------|-------------------------------|------------------|---|-------------------------|----------------------------|-------|--|--|
| | ECHO & Tutor Pilot Programs | TRICARE Basic ABA | New Autism Care Demo | Total Dollars | ECHO & Tutor Pilot Programs | TRICARE Basic ABA | New Autism Care Demo | Total | | |
| | By 6 Month Increments | | | | | | | | | |
| FY12 First 6 Months | \$50.9 | \$0.1 | \$0.0 | \$51.0 | | | | | | |
| FY12 Second 6 Months | \$58.0 | \$0.2 | \$0.0 | \$58.2 | | | | | | |
| FY13 First 6 Months | \$55.3 | \$6.7 | \$0.0 | \$62.0 | 9% | 9836% | | 22% | | |
| FY13 Second 6 Months | \$52.9 | \$18.1 | \$0.0 | \$71.0 | -9% | 8647% | | 22% | | |
| FY14 First 6 Months | \$49.3 | \$24.0 | \$0.0 | \$73.3 | -11% | 257% | | 18% | | |
| FY14 Second 6 Months | \$52.7 | \$32.6 | \$0.0 | \$85.4 | 0% | 81% | | 20% | | |
| FY15 First 6 Months | \$23.1 | \$13.9 | \$53.1 | \$90.1 | -53% | -42% | | 23% | | |
| FY15 Second 6 Months | \$0.3 | \$0.0 | \$108.4 | \$108.7 | -99% | -100% | | 27% | | |
| FY16 First 6 Months | \$0.4 | \$0.0 | \$111.7 | \$112.1 | -98% | -100% | | 24% | | |
| | By Fiscal Years | | | | | | | | | |
| FY11 | \$84.7 | \$0.0 | \$0.0 | \$84.7 | | | | | | |
| FY12 | \$108.9 | \$0.3 | \$0.0 | \$109.2 | 29% | | | 29% | | |
| FY13 | \$108.2 | \$24.8 | \$0.0 | \$133.0 | -196 | 8940% | | 22% | | |
| FY14 | \$102.0 | \$56.6 | \$0.0 | \$158.6 | -6% | 128% | | 1996 | | |
| FY15 | \$23.4 | 513.9 | \$161.5 | \$198.8 | -77% | -75% | 529044% | 25% | | |

Potential for Future ABA Program Growth

With robust ADFM ABA user growth rates of 41 percent in FY 2011, 29 percent in FY 2012, 19 percent in FY 2013, 13 percent in FY 2014, and 9 percent in FY15, it is important to understand how much room there is for potential program growth in the future. One approach is to examine the proportion of current ADFM beneficiaries diagnosed with ASD who are currently getting 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 2015, the number of ADFMs using TRICARE ABA services had increased by 325 percent to 9,739. However, because the number of ADFMs diagnosed with ASD had also increased—by 81 percent to 18,980—we estimate that 51 percent of those diagnosed (9,739/18,980) were using TRICARE ABA services. We also note that the ADFM program use rate increased from 51 percent during FY 2015 to 53 percent during the first half of FY 2016, even though 47 percent of ADFMs diagnosed with ASD do not make use of TRICARE ABA services.