

UNDER SECRETARY OF DEFENSE

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

JUN - 7 2018

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 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. The report documents certain challenges encountered and lessons learned during the implementation of the ACD, as well as steps taken to improve the program. It is far too early to fully assess the ACD's clinical impact on TRICARE beneficiaries diagnosed with Autism Spectrum Disorder. The Department is actively exploring research opportunities to evaluate the clinical efficacy of Applied Behavior Analysis (ABA) services within the ACD. The Department also conducted the first pilot report for medical record audit in 2016 under the Total Quality Management Contract, which found that overall compliance with TRICARE Operations Manual requirements for treatment plan documentation was at 95 percent. This audit will continue to provide clinical information for inclusion in subsequent reports.

The demand for ABA services by all TRICARE beneficiaries continues to increase—from 9,178 beneficiaries in FY 2015 to 13,930 beneficiaries in FY 2017. The program cost increased from \$132.1M in FY 2015 to \$261.9M in FY 2017.

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.

Sincerely,

Robert L. Wilkie

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Enclosure: As stated

cc:

The Honorable Jack Reed Ranking Member



UNDER SECRETARY OF DEFENSE

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

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Robert L. Wilkie

R. In + L. Wilkie

Enclosure: As stated

cc:

The Honorable Adam Smith Ranking Member

Report to the Committees on Armed Services of the Senate and House of Representatives



The Department of Defense Comprehensive Autism Care Demonstration June 2018

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

Requested by: Senate Report 114-49, page 157, accompanying S. 1376, the National Defense Authorization Act for Fiscal Year 2016

The estimated cost of this report or study for the Department of Defense is approximately \$5,710 for the 2017 Fiscal Year. This includes \$50 in expenses and \$5,660 in DoD labor.

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REPORT TO CONGRESS

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 requests a report to the Committees on Armed Services of the Senate and House of Representatives 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 based on FY 2017 claims data, and is the third 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 and/or psychologically 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 (ST) to treat deficits in speech and language development and promote communication skills; psychiatry to address psychopharmacological needs; psychotherapy and psychological testing. Additionally, the full range of medical specialties to address the medical conditions common to this population are covered.

Behavior analysis is the scientific study of the principles of learning and behavior, specifically about how behavior affects, and is affected by, past and current environmental events in conjunction with biological variables. ABA is the application of those principles to bring about meaningful changes in socially important behaviors in everyday settings. ABA, by a licensed and/or certified behavior analyst, focuses on treating behavior difficulties by changing an individual's environment (i.e., shaping behavior patterns through reinforcement and consequences). ABA is delivered optimally when family members/caregivers actively participate by consistently reinforcing the ABA interventions in the home and other settings in accordance with the prescribed Treatment Plan (TP) developed by the behavior analyst. ¹

The Department completed an extensive ABA coverage review and benefits determination in 2010 and 2013, and continually monitors the status of ongoing ABA research.

¹ Applied Behavior Analysis Treatment of Autism Spectrum Disorder: Practice Guidelines for Healthcare Funders and Managers, Behavior Analyst Certification Board, Second Edition, 2014 @ https://www.bacb.com/wp-content/uploads/2017/09/ABA_Guidelines_for_ASD.pdf

Although ABA services show promise, this technique 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 Programs (FEHBP). 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.

A comparative analysis of ABA services provided by 40 health care plans with ABA benefits comparable to those under the ACD was completed November 8, 2017. Health plans that were too stringent with benefit limitations were excluded from the comparison. These 40 plans consisted of 11 State Employee Health Plans (SEHP), 6 National FEHBPs, 7 local FEHBP Plans, and 16 State Medicaid Programs. The analysis highlighted four categories that represent the most differentiating ABA benefit features and provide the most illustrative comparisons to the TRICARE benefit:

- 1. Beneficiary cost-sharing (Active Duty Family Member (ADFM) copayments, coinsurance, deductibles, out-of-pocket cost limits);
- 2. Beneficiary cost-sharing (Non-Active Duty Family Member (NADFM));
- 3. Benefit limitations (age cap, treatment cap, expenditure limit, provider types); and
- 4. Other benefit authorization and program requirements (beneficiary eligibility, prior authorization, treatment plan and progress review, exclusion criteria).

With the exception of Medicaid (which charges no cost-sharing), large SEHPs and one local FEHBP plan, TRICARE ADFM cost-sharing is more generous than the comparison plans. ADFMs in TRICARE Prime pay no out-of-pocket costs, which is comparable to all 16 Medicaid plans and three state employee plans—in other words, 21 plans have less generous cost-sharing requirements when comparing a Health Maintenance Organization type benefit. This is significant because 70 percent of all ACD beneficiaries are ADFMs enrolled in Prime. TRICARE has better NADFM cost-sharing than 8 of 14 FEHBP plans and 8 of 11 SEHP health plans.

Under the ACD, TRICARE beneficiaries do not have a beneficiary age cap, service hours, or expenditure limits, and coverage is allowed for all provider types, including certified behavior technicians, making this ABA benefit relatively unrestricted (generous) in comparison to the other plans. While eight of the plans assessed had relatively equivalent benefit limitations overall, none of the SEHP, FEHBP, or Medicaid plans reviewed had benefits that were more generous than TRICARE's ABA benefit when it came to benefit limitations.

With the exception of two Medicaid programs and one SEHP, TRICARE benefit authorization and program requirements are more generous than those in comparison plans.

Such requirements are relatively similar across plans. In general, nearly all plans reviewed require prior authorization, a treatment plan, and progress reviews.

Overall, TRICARE's ABA benefits compare very favorably to the most generous non-TRICARE plans evaluated. Across the 40 comparable health plans with generous benefits, 50 percent of ADFMs and 63 percent of NADFMs had more generous beneficiary cost-sharing, 8 percent had more generous benefit authorization and program requirements, and none had a more favorable assessment on benefit limitations, when compared to TRICARE's ABA benefit program.

Table 1						
Overall Assessment of TRICARE Benefits and 40 Comparable Health Care Plans						
(Percentage of Comparable Plans with More Favorable Assessment than TRICARE)						
Specific Health Plan/Player	Number of	Cost Sharing	Cost Sharing	Benefit	Other Benefit Authorization	
	Plans	ADFMs	NADFMs	Limitations	and Program Requirements	
SEHP Benefits	11	27%	27%	0%	9%	
National FEHBP Plans	6	0%	67%	0%	0%	
Local FEHB Plans	<u>7</u>	<u>14%</u>	<u>29%</u>	<u>0%</u>	<u>0%</u>	
Subtotal	24	17%	38%	0%	4%	
State Medicaid Brogram Benefits	16	100%	100%	0%	13%	
State meanand program benefits	<u> 10</u>	100/0	100/0	<u>570</u>	1070	
Total	40	50%	63%	0%	8%	

While there is evidence to suggest that early behavioral and developmental interventions based on the principles of ABA services delivered in intensive (>15 hrs/week) and comprehensive programs can significantly affect the development of some children diagnosed with ASD, not all children diagnosed with ASD receiving ABA services show improvements. The research literature available regarding ABA services predominantly consists of single-case design studies, which does not meet criteria for "reliable evidence" under TRICARE standards. While the quality of research is improving, there are still methodological concerns that limit the strength of the research such as identified characteristics of children, providers, and types of treatment for positive outcomes; intensity, duration, and treatment fidelity; few to poor quality studies utilizing a control group; few longitudinal studies demonstrating long-term effectiveness; and no replication of similar results.

Currently, there are no defined Standards of Care (SoC) for the treatment of ASD. Practice parameters have been developed by various interest groups to guide the assessment, diagnosis, and treatment of ASD. However, due to the heterogeneous nature of ASD, research has not been able to demonstrate effective and consistent results to identify a clear SoC. Research has demonstrated that ABA services have produced the best results for targeted maladaptive behaviors. No one intervention has been found beneficial across all core symptoms of ASD. Consensus among recognized national organizations endorses the use of a comprehensive program that includes target deficits in the areas of: social communication, language, play skills, maladaptive function/behaviors, and ongoing parent education. No one comprehensive treatment model has emerged as superior.

² See 32 Code of Federal Regulations 199.2 Definitions: Reliable Evidence

Additionally, 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 utilize the same series of Category III CPT billing codes in covering payment for ABA services as an emerging technology or service. Category I CPT codes for ABA services have been developed with anticipated implementation set for January 1, 2019. These new codes may influence how ABA encounters are classified and reimbursed in the future.

The TRICARE ABA benefit has been authorized under the demonstration authority through the ACD since 2014 and runs until December 31, 2023. The ACD provides TRICARE reimbursement for ABA services to TRICARE eligible beneficiaries diagnosed with ASD. Based on the agency's experience in administering ABA services under the ACD, including engagement with beneficiaries, providers, advocates, associations, and other payers, much more analysis and experience is required in order to determine the appropriate characterization of ABA services as a medical treatment, or other classifications, under the TRICARE program coverage requirements – to include further research and evaluation of the results, whether Board Certified Behavior Analysts (BCBAs) may appropriately be recognized and treated as independent TRICARE authorized providers of a proven medical benefit, and what authorities are required to add ABA services as a permanent benefit under the TRICARE program – whether as a proven medical benefit or otherwise. The ACD is currently administered by the existing TRICARE regional Managed Care Support Contractors (MCSCs).

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 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 or a Qualified Autism Service Provider), and/or a paraprofessional Certified Behavior Technician(s) (BT) (a Registered Behavior Technician, a Board Certified Autism Therapist, or an Autism Behavior Analysis Therapist) 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 certain roles and

responsibilities as determined appropriate, that are 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.

The ACD authorizes TRICARE reimbursement of the following ABA services to TRICARE-eligible beneficiaries diagnosed with ASD by an authorized 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 TP with goals and objectives of behavior modification and specific evidenced-based interventions; one-on-one ABA interventions 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

The following information was generated using TRICARE purchased-care claims incurred during the last three FYs (FY 2015 – FY 2017) for which full year data is available for the ACD. All claims data examined in this report were extracted from the Medical Data Repository (MDR) on February 1, 2018 and our results are based upon data entered into the MDR by that date.

TRICARE ACD Program Participants

At the end of FY 2017, there were 13,930 beneficiaries with a diagnosis of ASD participating in the ACD: 10,528 ADFMs and 3,402 NADFMs (as shown in Table 2).

The annual number of ADFM beneficiaries diagnosed with ASD participating in the ACD has increased from 9,178 in FY 2015 to 10,528 in FY 2017. While the annual growth rate in ACD participants has remained positive, the rate has declined over time. Although ACD participants increased by 12 percent in FY 2016, this rate of increase declined to 2 percent in FY 2017. The annual number of NADFM beneficiaries diagnosed with ASD participating in the ACD has increased from 2,283 in FY 2015 to 3,402 in FY 2017. As is the case with ADFMs, the annual growth rate has been positive but has declined since the start of the ACD. Although ACD participants increased by 34 percent in FY 2016, this rate of increase declined to 11 percent in FY 2017.

The number of NADFM ACD participants is only about 32 percent of the ADFM level during FY 2017 (3,402 versus 10,528 ACD participants). This is due to four main factors:

- 1. The NADFM population diagnosed with ASD is about half the size of the ADFM population diagnosed with ASD;
- 2. ABA services use declines with age and NADFMs diagnosed with ASD tend to be older than ADFMs;

- 3. NADFMs have higher cost sharing requirements than ADFMs; and
- 4. NADFMs are more likely than ADFMs to have other health insurance.

Table 2					
Historical Number of TRICARE ADFM and NADFM ACD Program Participants					
(Based Upon MDR Data as of February 1, 2018)					
FY	Number of	% Growth in Participants			
FY	Participants	from Prior FY			
	ADFM Participants				
FY2015	9178				
FY2016	10321	12%			
FY2017	10528	2%			
NADFM Participants					
FY2015	2283				
FY2016	3070	34%			
FY2017	3402	11%			
	Total Participants				
FY2015	11461				
FY2016	13391	17%			
FY2017	13930	4%			

ABA Program Costs

Total government costs for the ACD at the end of FY 2017 were \$261.9 million (M): \$205.1M for ADFMs and \$56.8M for NADFMs (shown in Table 3). Reflecting the growth in the number of ACD participants, total government costs for ADFMs increased 64 percent from the FY 2015 level to FY 2017 (\$132.1M in FY 2015 and \$205.1M in FY 2017). Also, effective October 1, 2015, all beneficiary cost-sharing and deductibles and enrollment fees were aligned with the TRICARE Basic Program, and the maximum Government payment or annual cap for ABA services of \$36,000 was lifted. The annual catastrophic cap protections were applied to all ABA services for beneficiaries in the ACD.

Table 3					
Historical Government Expenditures for TRICARE ADFM and NADFM ACD Program (Based Upon MDR Data as of February 1, 2018)					
FV	Dollars in	% Growth in Dollars			
FY	Millions	From Prior FY			
	I	ADFM			
FY2015	\$132.1				
FY2016	\$185.6	41%			
FY2017	\$205.1	10%			
NADFM					
FY2015	\$29.4				
FY2016	\$46.5	58%			
FY2017	\$56.8	22%			
	All ACD				
FY2015	\$161.5				
FY2016	\$232.1	44%			
FY2017	\$261.9	13%			

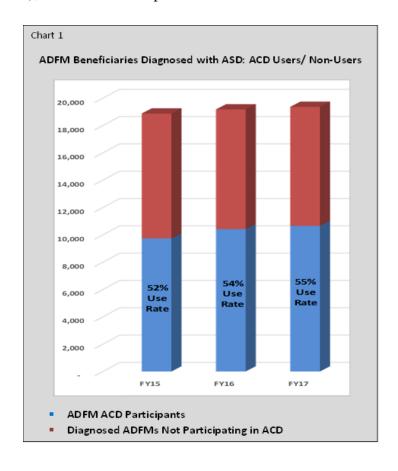
Average ADFM cost per ACD participant was \$14,393 in FY 2015, \$17,986 in FY 2016 (25 percent increase), and \$19,483 in FY 2017 (8 percent increase). Average NADFM expenditures per ACD participant increased from \$12,878 in FY 2015 to \$16,688 in FY 2017.

Table 4				
Historical Government Expenditures Per Participant for TRICARE ADFM and NADFM ACD Program (Based Upon MDR Data as of February 1, 2018)				
FV	Dollars in	% Growth in Dollars		
FY	Millions	From Prior FY		
ADFM Participant Expenditures				
FY2015	\$14,393			
FY2016	\$17,986	25%		
FY2017	\$19,483	8%		
NADFM Participant Expenditures				
FY2015	\$12,878			
FY2016	\$15,143	18%		
FY2017	\$16,688	10%		
All ACD Participant Expenditures				
FY2015	\$14,091			
FY2016	\$17,335	23%		
FY2017	\$18,801	8%		

Potential for Future Growth

With slowing annual ADFM ACD participant growth rates of two percent in FY 2017 (Table 2), it is important to understand the potential for program growth in the future. One approach is to examine the proportion of current ADFM beneficiaries diagnosed with ASD who are currently receiving 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 position). Based on this analysis, we estimate the number of ADFMs diagnosed with ASD in FY 2017 was 19,388.

In FY 2017, the number of ADFMs participating in the ACD was 10,528. Thus, 55 percent of those diagnosed with ASD (10,528/19,338) were using the ACD. Because 45 percent of ADFMs diagnosed with ASD are currently not using the ACD, there is room for continued growth in the future. This potential growth is demonstrated in Chart 1 (the red area on top of bars shows the potential for future growth). However, Chart 1 also appears to demonstrate that the share of ADFM beneficiaries diagnosed with ASD that are using ABA services may be plateauing (the blue areas), at about 55 to 60 percent.



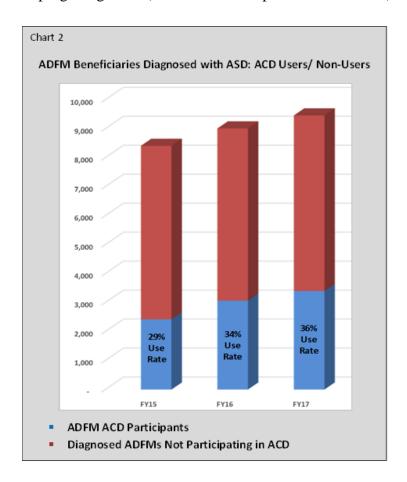
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³ DHA has previously used this operational definition of two or more claims to estimate the number of beneficiaries with ASD diagnoses. Beneficiaries with only one claim are excluded because they likely would have been diagnosed with a non- ASD diagnosis as a result of additional testing.

This plateau may be occurring because:

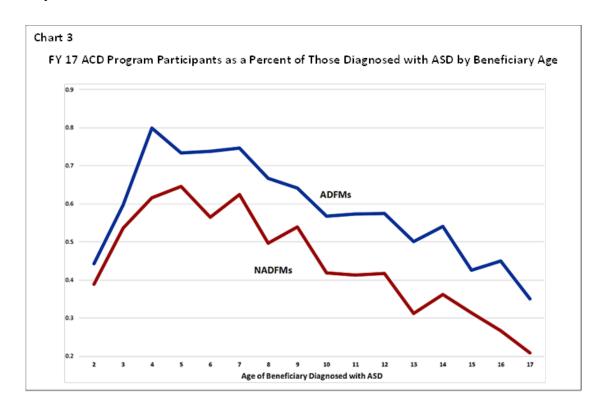
- There is a group of ADFM families who have chosen not to use ABA services to treat their children diagnosed with ASD or families may be receiving ABA services through other programs (i.e., school, Medicaid); and
- There are other ADFM families who may have treated their children with ABA services in the past but since have discontinued treatment.

The share of NADFMs diagnosed with ASD and using the ACD was 34 percent in FY 2016 and 36 percent in FY 2017. Because nearly two-thirds of the NADFM population diagnosed with ASD are not receiving TRICARE ABA services, this indicates that there is ample room for future program growth (the red area on top of bars in Chart 2).



After examining Charts 1 and 2, a natural question to arise is "Is the NADFM program use rate (36 percent in FY 2017) expected to reach or approach the ADFM program use rate (currently 55 percent)?" To address this question, ABA services use rates were compared to beneficiary age for ADFMs and NADFMs during FY 2017. Consistently, it was found that across nearly all ages (2 through 17), NADFM use rates were generally 10 to 20 percentage points lower than ADFM use rates (see Chart 3). This difference might reflect the fact that ADFMs have had access to TRICARE ABA services for more than a decade, while NADFMs

have only had access for a few years; thus, their demand continues to phase in. Another factor affecting the overall use rate is that NADFMs diagnosed with ASD tend to be older than ADFMs (median age of 10 for NADFMs and 7 for ADFMs, and according to Chart 3, use rates decline substantially with age. While there could be additional factors, the conclusion is that there are permanent factors in place that suggest that both age-specific and aggregate NADFM use rates are likely to remain lower than ADFM use rates.



Expenditures for Physical/Speech/Occupational Therapy and Prescription Drugs

In addition to the \$261.9M in FY 2017 expenditures in the ACD, participating beneficiaries also utilize other TRICARE medical services for PT, OT, and ST in both the purchased and direct care systems. Further, beneficiaries diagnosed with ASD also use the retail pharmacy, TRICARE Mail Order Pharmacy, and direct care pharmacy for prescription medications to treat ASD, Attention Deficit Hyperactivity Disorder (ADHD), and related mental health conditions. In examining the 13,390 TRICARE beneficiaries who participated in the ACD in FY 2017, we have determined that they have also utilized \$38.2M in PT, OT, and ST services (purchased care paid amounts and direct care full cost amounts) and \$15.1M in prescription medications. Combined expenditures increased by 0.5 percent in FY 2017, increasing from \$53.1M in FY 2016 to \$53.3M in FY 2017 (see Table 5).

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⁴ See Appendix B for a full list of medications included.

Table 5					
Hist	Historic Government Expenditures for PT/OT/ST Services and				
P	Prescription Medications for ACD Program Participants				
FY	PT/OT/ST Prescription		Total		
	Services	Medications ^{1/}	Total		
	Expenditures for ADFM ACD Program Participants				
FY2015	\$28,028,408	\$13,852,350	\$41,880,758		
FY2016	\$31,516,590	\$12,222,371	\$43,738,961		
FY2017	\$32,534,769	\$11,335,301	\$43,870,070		
Expenditures for NADFM ACD Program Participants					
FY2015	\$3,775,274	\$4,674,041	\$8,449,315		
FY2016	\$5,018,476	\$4,297,492	\$9,315,968		
FY2017	\$5,658,216	\$3,809,064	\$9,467,280		
Total ADFM and NADFM Expenditures					
FY2015	\$31,803,682	\$18,526,391	\$50,330,073		
FY2016	\$36,535,066	\$16,519,863	\$53,054,929		
FY2017	\$38,192,985	\$15,144,365	\$53,337,350		

Note: Include paid Government amounts for purchased care and full costs for the direct care.

Provider Availability

Under the ACD, an authorized ABA supervisor plans, delivers, and supervises an ABA program, and the ABA provider availability is vital to the success of the ACD. Based on contractor-submitted reports as of December 31, 2017, the number of TRICARE-authorized ABA supervisors was 10,685 across all TRICARE regions. In addition, according to contractor-submitted reports, there were 876 assistants, and 14,033 BTs supporting authorized ABA supervisors as of December 31, 2017. This totals 25,594 certified⁵ providers delivering ABA services to TRICARE beneficiaries.

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¹/Includes medication for ASD, ADHD, and other types of mental health diagnoses.

⁵ TRICARE accepts certification through the Behavior Analysis Certification Board; Behavior Intervention Certification Council; and the Qualified Applied Behavior Analysis Certification Board.

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

TRICARE has determined, through the benefit determination review process, that existing research data continues to be insufficient to effectively determine whether ABA services result in clinical improvement of children diagnosed with ASD. The Department is actively exploring research opportunities to study the clinical efficacy of ABA services and continues to support evaluations on the nature and effectiveness of ABA services. Determining health-related outcomes is a new requirement added to the ACD in Senate Report 114–255, page 205, accompanying S.2943, the NDAA for FY 2017. The publication of TRICARE Operations Manual (TOM) Change 199, dated November 29, 2016, for the ACD included the evaluation of health related outcome measures through the requirement three of standardized, normreferenced, valid, and reliable outcome measures that began collecting data on January 1, 2017. Outcome measures data for beneficiaries is required at baseline entry into the ACD program and every six months thereafter, with more comprehensive outcome measures at every 2-year increment of ABA services. This data is used as a factor in individual treatment plan review to ensure patients are making progress. However, in response to significant feedback from internal and external stakeholders, the outcome measures requirements were revised in May 2017. This change deleted two outcome measures at 2-year increments. Additionally, the every 6-month measure was not required to be reported by the MCSCs as this measure was not listed as an outcome measure. The December 29, 2017 publication of the TOM incorporated one new outcome measure and revised the language of the every six month measure to be reported as an outcome measure. Currently, the outcome measures are the Pervasive Developmental Disabilities Behavior Intervention (every 6 months) and the Vineland Adaptive Behavior Scale – Third Edition, (Vineland -3) and Social Responsibility Scale -2 (every 2 years). At the present time, available outcome measures present one data point (the Vineland-3) for each beneficiary that obtained a 2-year program review since implementation of the outcome measures. No comparison of outcome measures pre- and post-ABA services is available at this time since there is only one data point. It is anticipated that next year's annual Report to Congress will be able to report on the every 6-month measure for most beneficiaries. Additionally, some beneficiaries will have completed a 2-year cycle and their 2-year outcome measures will be available for analysis at that time. Thus, next year's annual report will likely include preliminary data on the effectiveness of ABA. The single point data currently available demonstrates a very diverse presentation of beneficiaries diagnosed with ASD with respect to adaptive functioning.

The Defense Health Agency (DHA) Annual TRICARE Quality Monitoring Contract ACD Audit

DHA conducted the first TRICARE Quality Monitoring Contract (TQMC) audit in 2016. The purpose of this study was to conduct an audit of the TRICARE ACD that serves as a pilot study for the full implementation of the required annual audits that began in 2016. Annual audits will be conducted hereafter. This audit provided valuable information regarding the ACD, the beneficiaries who utilize ABA services under the ACD, and the administration and compliance of the ACD as outlined in the TOM.

This study used 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 that included the following categories:

• 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.

These combined statistics provide a broad view of the ACD, but the results cannot conclude by definition that compliance or completeness was found. Only a subjective inference is possible at this time. What this comprehensive examination does provide, however, is an informative foundation that can be useful in the current understanding of the ACD, in the development of measures and benchmarks, and ultimately in the fulfillment of the ACD's overarching goals.

This study provided descriptive analyses of the outlined TOM components, and these results were utilized to comprehensively examine the status of the ACD. Study results showed an overall average of 95 percent completeness for treatment plan documentation of recommended hours of services for one-on-one services, parental guidance, and supervision. All records included measurable goals and objectives and were associated at minimum with social interaction, communication, and behavioral domains. The vast majority of records showed that some measures were used throughout the course of the treatment. Progress/improvement/positive change was reported in 80 percent of records.

Additional notable findings from this audit include:

- 8.6 percent of audit beneficiaries have received seven or more years of ABA services;
- Almost 40 percent of treatment plans had zero to minimal (less than 30 minutes per week) parental participation;
- 70 percent of treatment plans documented Functional Behavioral Assessments for maladaptive behaviors;
- Only 58 percent of treatment plans used standardized, norm-referenced, valid, and reliable outcome measures.

Congressionally Directed Medical Research Program Study

Additional research results are essential to evaluating the nature and efficacy of ABA services, the appropriate characterization of ABA providers, and the optimum, means to administer coverage of ABA services under TRICARE. The agency is working with the Congressionally Directed Medical Research Program (CDMRP) to award a contract to a research group to analyze the TRICARE ACD participants' outcome measures, particularly assessing their responses to ABA service delivery as a total population. The CDMRP research study has the potential to be the largest sample population of ABA services for the diagnosis of ASD in the entire body of research literature, therefore contributing significantly to the understanding of the efficacy of ABA service delivery. Under this study, the government will not only gain information about what TRICARE beneficiaries are receiving under the ACD and respective outcomes, the government will also gain greater insight and understanding of ASD in the TRICARE population, ABA services being delivered to TRICARE beneficiaries, and outcomes data generally.

The CDMRP Request for Proposal (RFP) announcement was published Fall of 2017 and closed in January 2018. Currently, submitted RFPs are under review. Anticipated announcement of the award for this study is late Fall 2018. Annual reports of the study's progress will be due annually.

LESSONS LEARNED

Since implementation of the ACD in July 2014, the Department has conducted 10 ACD round table and provider information session events. The most recent provider information session event was held on September 18, 2017. These events 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 event and directly from interested stakeholders. The Department greatly appreciates the participation of all interested parties and through this process, gains additional insights about how to further refine and implement an optimum care delivery and reimbursement system for TRICARE beneficiaries diagnosed with ASD. Recent issues raised as a result of this feedback that required adjustments under the ACD⁶ include:

- 1. Modification of outcome measures requirements: due to significant feedback from stakeholders, to include feasibility of completion of objective outcome measures completed by specialty care providers, the outcome measures were revised to include questionnaires completed predominantly by parents at set intervals;
- 2. Expansion of the types of eligible TRICARE authorized providers who may complete the testing: with the revising of the outcome measures to be predominantly parent report, this change allowed for the expansion of eligible providers to review and submit the measures;

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⁶ Changes were published in the TRICARE Operations manual on December 29, 2017 and were effective January 27, 2018.

- 3. Creation of an additional assessment code for the BCBA/BCBA-Ds to use since the ABA providers are not recognized as a TRICARE authorized individual professional provider category under the Basic program as defined by 32 CFR 199.6: with the expansion of eligible providers completing and submitting the measures, DHA created a new temporary reimbursement code specifically for BCBAs/BCBA-Ds to as other specialty care providers already possess a reimbursement code for assessments; and
- 4. Implementation of additional quality controls revisions to address the Department of Defense (DoD) Office of the Inspector General's (OIG) recommendations: due to the recent findings of the DoD OIG audits, DHA implemented better quality controls to address the issues of improper payments.

In order to improve the ACD, DHA has worked closely with industry experts, advocacy groups, providers, and beneficiaries to identify the important components of an effective contract to provide ABA services for TRICARE beneficiaries diagnosed with ASD. A Request for Information was developed and sent to interested parties in July 2017. As a follow-up, DHA hosted an Industry Day in Aurora, CO from October 24-26, 2017. Numerous overarching themes and elements of interest emerged for improving the ABA benefit. The DHA is currently evaluating these elements and will implement any improvements with an upcoming policy update not later than early 2019. These include, but are not limited to:

- 1. Specialized case management and/or care coordination teams assigned to each family are essential to the comprehensive management of this unique population. Teams should manage the full range of care for both medical and behavioral health services. Case managers and/or care coordination teams focused on the beneficiary, to include reviewing prior interventions, cultural factors, family resources as well as community resources, can help determine appropriate treatment options. Issues that require timely attention such as treatment response, family involvement, and other issues can be addressed quickly through such an approach. Teams will ideally be comprised of dedicated staff with specific ABA experience and expertise to assist families. The ability to collaborate with multiple behavioral health and medical providers, including outside agencies, is an essential element of care coordination. Also, care coordination teams will allow a centralized focus around the special needs of military families including continuity of care as families transition from region to region due to permanent change of station or retirement from Active Duty. Families should have a single point-of-contact who guides them through the system related to their child's care.
- 2. Network management is crucial to maintain access to ABA services for the beneficiary population. For example, the credentialing process, to include timelines, needs to be addressed and improved as part of the requirements development process. Information technology solutions, a strong provider relations program, and provider incentives, among other initiatives, can help facilitate and improve network management.

- 3. Most health plans do not have clearly defined or well established criteria for the treatment and management of ASD. Utilization management is a critical element for a successful ABA Benefit Program. Several solutions to utilization management have introduced decision support for ASD, and it is recommended that DHA explore such solutions as part of a way forward. DHA will implement evidence based utilization management solutions that consistently review impairments, level of functioning, and treatment goals and protocols (treatment plan) to ensure the needs of the beneficiary and family are being met.
- 4. Discharge planning is another critical component of a comprehensive ABA Benefit Program and discharge criteria must be implemented through modifications to the current MCSC and TRICARE Overseas Program contracts. Such criteria should be included in the initial assessment and treatment plan/goals in measurable terms to ensure the beneficiary is progressing.
- 5. Nearly all Industry Day participants stated that parental involvement and support is imperative to a beneficiary's success. Per available research, outcomes are better when parents are actively involved. Requiring their participation in the process, and commitment to their child's ABA TP with reinforcements or consequences, also enables the managed benefit to move from an external dependency to a family competence for long term care. If families cannot support intensive ABA services, then family issues should be addressed first.
- 6. Parents of children diagnosed with ASD have a great deal of stress and need support. Thus, respite care is an important component of a supportive ABA Program. DHA currently offers 16 hours of respite care per month for active duty families under Extended Care Health Option (ECHO). Expansion of respite care to all families with a child who has a diagnosis of ASD was recommended, as it can provide needed relief and enhance parental involvement by means of resilience in the family members.
- 7. The use of "Value Based Initiatives" was not recommended at this time. None of the Industry Day participants were aware of value based ABA initiatives, although such initiatives could be developed in the future once the field has developed clinical standards of care and service delivery models to include elements such as dose response. Some presenters felt that parental engagement could be used in this manner, though they were not aware of any models that currently do so.

DoD OIG Reports

The DoD OIG recently completed an audit of ABA services in the former TRICARE North Region. The audit was requested by the Director, TRICARE Health Plan (THP). The audit results were released to the public on March 16, 2018. The Director, THP requested this audit based on findings in a more limited audit of five large ABA providers in the former TRICARE South Region. Based on the DoD OIG reports, beneficiary progress notes (medical records) either lacked documentation or had insufficient documentation to support the payment to the ABA companies. The DoD OIG recommended that the Director, DHA, "[r]evise policy to

require annual comprehensive medical reviews on a statistically representative sample of ABA providers' claims for the TRICARE North, South, and West Regions (TRICARE East and West Regions as of January 1, 2018) to ensure that an adequate number of claims are reviewed. Reviews should compare the beneficiaries' session notes to the providers' claims to determine whether all required documentation exists and adequately supports payments received. The reviews should cover claims from 2015 and all future years."

The DHA concurred with the DoD OIG findings and recommendation. As a result, the DHA implemented policy changes to the TOM, Chapter 18, Section 4, ACD, on January 29, 2018. This change enhances the process of quality monitoring and oversight of claims submitted for ABA services for eligible TRICARE beneficiaries. These changes reflect the DoD OIG's recommendations of conducting annual comprehensive medical reviews of ABA providers' claims for the TRICARE East and West Regions. DHA will also review and pursue appropriate action, such as recouping any overpayments, on the claims in review by the DoD OIG sample for which there was insufficient or no documentation from the ABA companies.

NEW LEGISLATIVE AUTHORITIES REQUIRED TO IMPROVE THE PROVISION OF ABA SERVICES

There continues to be advocacy from beneficiaries, advocacy groups, legislators, and others, for the DoD to expand coverage of ABA services. 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.

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 are widely perceived as "helpful." The Department completed the ABA ACD parent satisfaction survey from FY 2016, and will conduct another such survey in 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 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 2014, under the broad demonstration authority of Federal statutes, 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 NADFMs). 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 Federal regulations, 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 ABA CPT codes are not approved by that time, the 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 2023 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

The Department is committed to ensuring all TRICARE-eligible beneficiaries diagnosed with ASD reach their maximum potential, and that all treatment provided supports this goal. At the end of FY 2017, there were 13,930 beneficiaries with a diagnosis of ASD participating the ACD: 10,528 ADFMs and 3,402 NADFMs at a cost of \$261.9M. Therefore, the Department is pursuing a more effective method of delivering and validating the effectiveness of these ABA services. The Department will implement the ACD improvement recommendations through contract modification to the current managed care support contracts.

It is far too early to fully assess the ACD's clinical impact on TRICARE beneficiaries diagnosed with ASD as comparable data has not been obtained due to the outcome measures cycle and revisions to the TOM. The Department is actively exploring research opportunities to evaluate the clinical efficacy of ABA services within the ACD. The DoD OIG completed two audits, in the former North and South Regions, which found a significant number of improper payments, predominantly due to lacking or insufficient medical records (progress notes) documentation. Additionally, the Department conducted the first pilot report for medical records (treatment plans) audit in 2016 under the TOMC. This pilot report provided a descriptive

analyses of the outlined TOM components. Study results showed an overall average of 95 percent completeness for treatment plan documentation requirements. Additionally, this pilot found that 80 percent of records noted improvements, but only 58 percent of treatment plans used standardized, norm-referenced, valid, and reliable outcome measures; 8.6 percent of audit beneficiaries have received seven or more years of ABA services; and almost 40 percent of treatment plans had zero to minimal (less than 30 minutes per week) parental participation. This TQMC audit, as well as other DoD initiatives, will continue to provide clinical information for program improvement.

The Department has conducted a series of ACD round tables and provider information session events since implementation of the ACD. These events were well attended by various stakeholders and provided the Department with invaluable feedback on how to improve the delivery of ABA services. In summary, TRICARE continues to be the most robust ABA benefit nationwide 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.