



PERSONNEL AND
READINESS

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

AUG 09 2023

The Honorable Mike D. Rogers
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The Department's response to House Report 117-397, page 182, accompanying H.R. 7900, the National Defense Authorization Act for Fiscal Year 2023, "Autism Care Demonstration Program Extension," is enclosed.

The Autism Care Demonstration (ACD) began July 25, 2014, and was set to expire on December 31, 2023; however, the Department extended the program to December 31, 2028, via a Federal Register Notice published August 4, 2022. The Notice stated that additional analysis and experience is required to determine the appropriate characterization of Applied Behavior Analysis services as a medical treatment, or other modality, under the TRICARE program coverage requirements. The Department will obtain additional information about which services TRICARE beneficiaries are receiving under the ACD and how to target services providing the most benefit.

The extension also allows the Department to review the findings of the Congressionally Directed Medical Research Program study and the congressionally directed National Academies of Sciences, Engineering, and Medicine's analysis.

Thank you for your continued strong support for the health and well-being of our Service members and their families. I am sending a similar letter to the Senate Armed Services Committee.

Sincerely,

//Signed

Gilbert R. Cisneros, Jr.

Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member



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WASHINGTON, D.C. 20301-4000

AUG 09 2023

The Honorable Jack Reed
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

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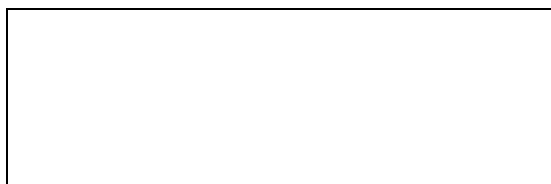
cc:
The Honorable Roger F. Wicker
Ranking Member

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



Autism Care Demonstration Program Extension

August 2023



DEPARTMENT OF DEFENSE COMPREHENSIVE AUTISM CARE DEMONSTRATION PROGRAM EXTENSION

1) EXECUTIVE SUMMARY

This report is in response to House Report 117–397, page 182, accompanying H.R. 7900, the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2023, which requests that the Department of Defense (Department) provide a report to the Committees on Armed Services of the Senate and the House of Representatives not later than February 1, 2023, on its consideration of the Autism Care Demonstration (ACD) Program extension that includes: (1) the timeline considered to extend the ACD; (2) the cost of extending the ACD; and (3) any other policy considerations the Secretary deems appropriate.

2) BACKGROUND

The ACD offers Applied Behavior Analysis (ABA) services for all TRICARE beneficiaries diagnosed with Autism Spectrum Disorder (ASD) who meet the ACD eligibility criteria. ABA services are not limited by the beneficiary’s age, dollar amount spent, number of years of services, or number of sessions provided. Presently, ABA services for the diagnosis of ASD is not cost-shared under the TRICARE Basic (i.e., medical) benefit because the available medical literature still does not meet the hierarchy of reliable evidence standards for proven medical care as defined in the statutes and regulations governing TRICARE. Thus, TRICARE may only cover ABA services that are clinically necessary and appropriate, and target only the core symptoms of ASD under the demonstration authority of the ACD. All ABA services rendered by ABA providers are offered through the Private Sector Care component of the Military Health System.

The ACD began July 25, 2014, and was set to expire on December 31, 2023; however, the Defense Health Agency (DHA) extended the program to December 31, 2028, via a Federal Register Notice published August 4, 2022.¹ The Notice stated that additional analysis and experience is required in order to determine the appropriate characterization of ABA services as a medical treatment, or other modality, under the TRICARE program coverage requirements. The Department will obtain additional information about which services TRICARE beneficiaries are receiving under the ACD and how to target services providing the most benefit. The extension also allows the Department to review the findings of the Congressionally Directed Medical Research Program (CDMRP) study and the congressionally directed National Academies of Sciences, Engineering, and Medicine (“National Academies”) analysis.

¹ Notice. “Extension of the Comprehensive Autism Care Demonstration for TRICARE Eligible Beneficiaries Diagnosed With Autism Spectrum Disorder.” *Federal Register* 87, no. 149 (August 4, 2022) 47731-47733.

3) DISCUSSION

a) The Timeline Considered to Extend the ACD

Since implementation of the ACD, Congress directed DHA to add outcome measures as a requirement to the program. Outcome measures were implemented on January 1, 2017, and are aimed at assessing individual progress for each beneficiary, as well as evaluating program effectiveness with the beneficiary population participating in the demonstration. In addition to the ACD's outcome measures, a grant was awarded under the CDMRP to the University of Rochester in September 2018 that is evaluating traditional intensive ABA services compared to a modified ABA service delivery model (<https://clinicaltrials.gov/ct2/show/study/NCT04078061>).

ABA research to date does not yet meet TRICARE's hierarchy of reliable evidence standards for proven medical care as defined in the Code of Federal Regulations. The existing evidence base has significant gaps, notably a shortage of randomized controlled trials (RCTs), studies with small sample sizes limiting generalizability, limited data on whether Early Intensive Behavioral Intervention (EIBI) reduces ASD symptoms, and few studies on outcomes of EIBI in community settings such as private agencies where most children with ASD receive services. The investigators in the CDMRP study are evaluating if combining targeted interventions via an individualized, adaptive, and modular ABA approach (10 hours per week) could be at least as effective as EIBI (20 hours per week or more) over the course of a 24-week RCT at follow-ups conducted 24 weeks after intervention and 90 weeks after intervention.

It is anticipated that the results of the CDMRP study will not only further the Department's understanding of the impact of ABA services delivered to the ACD participants, but also that findings from this study may benefit the larger community of individuals diagnosed with ASD and their families. The findings will leverage clinical outcomes while informing program development, structure, and long term impacts. Additionally, the findings may offer more clinical program choices to families, potentially identifying variables beneficial to clinical success. Findings may also lead to lowering costs to families and payers while also increasing access to effective and targeted ABA services. This study is scheduled to conclude at the end of 2023.

Further impacting the ACD, Congress directed that, via enactment of the NDAA for FY 2022, and subsequently revised in the NDAA for FY 2023, the Department enter into an agreement with the National Academies to conduct an independent analysis on the effectiveness of the ACD and develop recommendations for the Department based on such analysis. The analysis would include, among other goals, a review of the expected health outcomes for an individual who has received ABA services over time, and other analyses to measure the effectiveness of the demonstration. At the conclusion of the analysis, the National Academies will develop and provide the Department a list of findings and recommendations related to the measurement, effectiveness, and increased understanding of the ACD and its effect on beneficiaries under the TRICARE program. The National Academies' analysis will take significant time to complete, and the Department will then require additional time to evaluate the National Academies' recommendations and make any appropriate and authorized changes.

Experience from administering the ACD to date informed the Department's ability to publish a significant policy update (March 23, 2021) to address the clinical needs of the beneficiary population as well as revise program oversight requirements. This policy update focused on providing enhanced beneficiary and family support, improving clinical outcomes, encouraging parental involvement, and improving utilization management controls. These revisions are anticipated to improve the quality of, and access to, clinically necessary and appropriate care and services, and will also improve management and accountability of both the Managed Care Support Contractors and ABA providers.

Based on the above factors, it was necessary for the Department to extend the ACD for an additional 5 years to December 31, 2028. While much information has been learned about ABA while administering these services under the demonstration authority, the Department needs time to further evaluate the goals of the demonstration, collect and evaluate outcome measures, incorporate results of the CDMRP study award, and address recommendations from the National Academies. In addition, by extending the ACD, the Department will not only be able to fully implement the program improvements, but also will continue to gain greater insight and understanding of the effectiveness of ABA services being delivered to TRICARE beneficiaries based on outcomes data.

b) The Cost to Extend the ACD

A health care cost analysis estimated that an extension of the ACD for 5 years would cost approximately \$3.8 billion. However, cost is not a consideration for coverage determinations and did not impact the overall decision to extend the demonstration. Instead, the demonstration was extended based on the need to collect and analyze data from multiple sources including the CDMRP study, the National Academies' analysis, and findings from the March 2021 policy update.

c) Additional Policy Considerations the Secretary Deems Appropriate

The Department has covered ABA services under various authorities since 2001. Characterization and coverage authorities have evolved over time based on congressional direction and industry evolution. To date, ABA services do not meet the hierarchy of reliable evidence standards for proven medical care. The Department continues to review the latest evidence in published literature regarding the effectiveness of ABA services for the diagnosis and treatment of ASD. At this time, no significant additions to the evidence-based literature have been published since the last annual report regarding the "dose-response" (including intensity, frequency, or duration), treatment effectiveness, most effective use of ABA with other services, use of a tiered model compared to Board Certified Behavior Analysts only, benchmarks for outcomes, or anticipated/expected changes in ASD symptom presentation.

Since implementation of the ACD in July 2014, the Department has conducted 25+ ACD round table and provider information session events where senior Department officials listened to concerns, answered questions, and noted key issues for further analysis and action. DHA continues to receive constructive feedback from interested stakeholders. DHA appreciates the participation of all interested parties and, through this process, gained additional insights about

how to further refine and implement an optimum care delivery and reimbursement system for TRICARE beneficiaries diagnosed with ASD. DHA will continue to evaluate and revise the program as appropriate to incorporate lessons learned and program improvement and oversight efforts.

4) CONCLUSION

An ongoing CDMRP study and a pending congressionally-directed independent analysis by the National Academies may provide additional information regarding DHA's review and potential determination regarding whether or not ABA services might meet the hierarchy of reliable evidence standards for proven medical care. Thus, DHA extended the ACD for an additional 5 years to continue evaluation of ABA services while new policy updates to the ACD are fully implemented and evaluated and the results of these studies and analyses on the effectiveness of ABA services under the ACD are pending. These findings, along with previous findings, may inform DHA's final benefit coverage determination. Additionally, this extension will ensure continuity of care for beneficiaries currently receiving ABA services and for those beneficiaries who will be diagnosed with ASD in the near future, as well as ensure these beneficiaries are receiving clinically necessary and appropriate ABA services.