BEFORE THE OFFICE OF ADMINISTRATIVE HEARINGS STATE OF CALIFORNIA

In the Matter of:

CLAIMANT

and

INLAND REGIONAL CENTER, Service Agency

DDS No. CS0017474

OAH No. 2024060075

DECISION

Abraham M. Levy, Administrative Law Judge, Office of Administrative Hearings (OAH), State of California, heard this matter on August 12, 2024, in San Bernardino, California.

Claimant's mother represented claimant, who was not present.

Keri Neal, Fair Hearings Representative, Inland Regional Center (IRC), represented the service agency.

Oral and documentary evidence was received. The record was closed, and the matter submitted for decision on August 12, 2024. This matter was consolidated for

hearing with DDS No. CS0017475, OAH No. 2024060077, which is an appeal request for claimant's sibling. Separate decisions are issued for this consolidated hearing.

ISSUE

Is IRC required to fund treatment through the Brain Balance Program?

FACTUAL FINDINGS

Background and Jurisdiction

1. Claimant is 11 years old and is eligible for IRC services under the Autism Spectrum Disorder (ASD) category. At his school, he receives speech therapy, behavioral therapy, and has a 1:1 aide for patience and socialization. He is receiving 283 hours per month of In-Home Supportive Services. He receives behavioral therapy through Easter Seals. IRC funds 68 hours of preferred provider respite for claimant. IRC recently authorized pharmacology and nutrition consults for him.¹

2. Claimant is asking IRC to fund services through the Brain Balance in Redlands (Brain Balance) to help ameliorate claimant's problem behaviors. In claimant's most recent Individual Program Plan, his mother reported that he engages in disruptive social behaviors and outbursts daily that require intervention.

¹ On June 4, 2024, OAH issued an order consolidating the hearing for claimant's appeal with the appeal of his brother, OAH Case Number 2024060077. Both appeals involve the same factual and legal matters.

3. Brain Balance offers multi-modality treatments for children and young people with ASD, Attention Deficit Hyperactivity Disorder (ADHD), Tourette's syndrome, dyslexia, and related disorders. Brain Balance is not vendorized through IRC and has not applied to become an IRC vendor. The owner of the franchise, Donna Horn, who testified in this hearing, said she plans to start the vendorization process. Claimant submitted an invoice from Brain Balance for its services in the amount of \$32,604 for 156 sessions.

4. On May 28, 2024, IRC received claimant's request to appeal IRC's denial to fund Brain Balance treatments. IRC, on April 23, 2024, denied claimant's request on the basis that Brain Balance treatments are not evidence-based therapy, and regional centers are prohibited from purchasing experimental treatments, therapeutic services, or devices that have not been clinically determined or scientifically proven pursuant to Welfare and Institutions Code section 4648, subdivision (a)(17). In addition, IRC denied the request to fund Brain Balance because Brain Balance does not have a rate agreement or contract with IRC.

Evidence Regarding Brain Balance Treatments

BRAIN BALANCE'S PROGRAM

5. Brain Balance Achievement Centers, L.L.C. franchises Brain Balance Centers around the country and in Southern California. Brain Balance Centers, as its Franchise Disclosure Statement states, "offer an effective and replicable non-medical, non-pharmaceutical program designed to help children become more focused, improve their academic performance, and exhibit positive behavior, resulting in enhanced communication and social interaction skills." Brain Balance advertises its

program as designed to help individuals with ADHD, dyslexia, Autism, Asperger's, Tourette's, and related disorders.

Brain Balance's Franchise Disclosure Document states the following:

[The] goal of the Brain Balance Program® is to correct a fundamental imbalance between the two hemispheres of the brain – a 'communication breakdown' that results in a range of negative symptoms and behaviors. The Brain Balance Program® integrates physical activities (sensory based stimulation and motor exercises) with effective educational and behavioral methods, as well as supportive nutritional initiatives, in order to promote optimum brain and body function.

The Franchise Statement includes this disclaimer regarding the information in its Franchise Disclosure statement: **"Note, however, no governmental agency has verified the information contained in this document."** (Emphasis in original.)

TESTIMONY OF HOLLY MILLER-SABOUHI, PSY.D.

6. Holly Miller-Sabouhi, Psy.D., IRC staff psychologist, testified that there is not a high-quality study that substantiates the efficacy of Brain Balance's treatment for ASD. In her analysis, Dr. Miller-Sabouhi said for a study to be credited it must be valid in terms of both the accuracy of the instruments used in the study and the study's reliability in terms of the consistency of the instruments used in the study over time. Validity and accuracy are foundational concepts in scientific research. Dr. Miller-Sabouhi stated no studies have shown that Brain Balance's treatment for ASD have met this test. 7. IRC introduced two studies as part of the record regarding Brain Balance's treatment.² One study was published in the Mental Health Journal on January 17, 2020. Dr. Miller-Sabouhi stated the value of the study is limited because its authors concluded only that more research is needed to determine "the potential value of nonpharmacological training programs in improving emotional functioning" in children with "developmental and learning challenges."

8. Notwithstanding its limited conclusion that more study is needed, Dr. Miller-Sabouhi questioned the study's value on its merits for a number of reasons. First, the primary researcher of the study works for Brain Balance Achievement Centers. As a result, the primary author has an inherent conflict of interest. Thus, the study's transparency is questionable.

9. In addition, the study looked at children who participated in the Brain Balance program, but the study looked only at outcomes in general and relied on parent surveys. Second, it was not clear whether the study included children who dropped out of the program or only those who chose to continue. Third, the standardization of the study as a matter of measuring how the treatments were administered was not clear. Fourth, the study found 100 percent of children surveyed experienced progress, and a 100 percent efficacy rate in any study is unusual. It suggested to Dr. Miller-Sabouhi other factors were present. (The study states that 75 percent showed up to 25 percent improvement after 5 to 6 months of participation, and 25 percent demonstrated 60-85.7 percent improvement in specific areas, including panic attacks/anxiety, obsessive thoughts or behaviors, social withdrawal, pessimism,

² It is not clear from the record why these two studies were selected and made part of the record.

and emotional regulation.) Dr. Miller-Sabouhi said the conclusion of 100 percent efficacy limited the value of the study empirically in terms of measuring the study's validity and reliability.

10. Dr. Miller-Sabouhi also discussed a second study from January 2023 that was admitted as evidence. She said this study is more of a summary and lacks details. The study concludes only that more research was needed to determine the efficacy of Brain Balance's program. Dr. Miller-Sabouhi questioned the study's ability to measure Brain Balance's efficacy for treatment of ASD because the study concerned the efficacy of Brain Balance for the treatment of ADHD and anxiety. She did not see a strong statistical analysis in this study to reach conclusions regarding the efficacy of Brain Balance for children with autism or children in general.

11. In addition to her testimony regarding these studies, Dr. Miller-Sabouhi addressed Brain Balance's assessment of claimant as documented in a report titled "Cognitive Assessment Report." She questioned the value of the assessment because it contains a disclaimer in a footnote that the assessment is not "diagnostic" for purposes of treating claimant's ASD. This footnote reads: "CBS [Cambridge Brain Study, the study used in the assessment] is not a diagnostic tool."

12. With regard to the merits of the assessment, Dr. Miller-Sabouhi gave the assessment no weight. She said the focus of the assessment seemed to be on the standing of an individual in a group based on a normative sample Brain Balance references in the assessment. This normative sample is not identified in the assessment. The only measure used in the assessment is based on the parent as a source, but with this noted, she said the sourcing of this information was not entirely clear. Dr. Miller-Sabouhi added no statistical information is contained in the assessments.

TESTIMONY OF EDITH VELASCO

13. Edith Velasco is a Board Certified Behavior Analyst (BCBA). She has worked on staff at IRC since 2022. Ms. Velasco testified regarding evidence-based treatments for ASD.

Ms. Velasco testified that a BCBA is ethically obligated to follow evidence-based practices in treating persons with ASD. In her opinion Brain Balance is not an evidence-based treatment for persons with ASD. Evidence based practices for individuals with ASD are treatments or therapies that have gone through rigorous research and review and have been found effective in the treatment of persons with ASD. To help determine which interventions have "passed this test," and are considered evidence based, two independent groups of researchers have studied and evaluated the treatment options available: The National Clearinghouse on Autism Evidence and Practice Review Team at the University of North Carolina (National Clearinghouse), and the California Autism Professional Training and Information Network (CAPTAIN). National Clearinghouse developed a report to describe a set of practices that have clear evidence of positive effects with autistic children and youth. CAPTAIN is a multi-agency network created to develop and support the understanding and use of evidence-based practices for persons with ASD.

14. Ms. Velasco reviewed reports from both organizations which identify evidence-based treatments for ASD. She testified that both organizations do not identify Brain Balance as providing evidence-based treatment for persons with ASD.

15. As further support for the conclusion that Brain Balance's treatment is not evidence based, Ms. Velasco cited a recent decision of San Diego Regional Center (SDRC) concerning Brain Balance's appeal of SDRC's denial of its request for

vendorization with that regional center. Ms. Velasco testified that she agrees with SDRC's decision, which was admitted.

16. SDRC determined that Brain Balance does not offer clinically determined or scientifically proven treatments for ASD, and SDRC was barred from funding Brain Balance pursuant to Welfare and Institutions Code section 4648, subdivision (17). SDRC cited National Clearinghouse's report that Brain Balance is not an evidencebased program.

17. In its decision, SDRC cited a June 29, 2018, study from the Wisconsin Department of Health Services (Wisconsin DHS). This decision is part of the record. The Wisconsin DHS determined that Brain Balance's treatment components lack empirical evidence, authoritative sources have not recognized Brain Balance as having an emerging evidence base, and there is not one high quality study that demonstrates experimental control and favorable outcomes of the treatment package. Wisconsin DHS added that the author of one study, R. Melillo, developed Brain Balance treatments, and was involved in all of the research.

Evidence Regarding Brain Balance's Vendorization

18. Amanda McGuire, IRC Resource and Transportation Unit Program Manager, testified regarding Brain Balance's ability to become vendorized with IRC. Vendorization is the process wherein regional centers require providers to establish a rate of reimbursement for a specific service. (Cal. Code Reg., title 17, 57300.) Service codes are assigned by types of services. (Cal. Code Reg., title 17, 54342.) At IRC, Ms. McGuire is responsible for reviewing vendorization requests.

19. Ms. McGuire reviewed Brain Balance's publication of its services entitled "The Brain Balance Program: Making Breakthroughs Possible" for the types of services

Brain Balance provides and their applicability to different service codes. Based on this publication, she identified possible service codes that might apply to Brain Balance's therapies: Specialized Recreational Therapy (Service Code 106), Educational Services (107), Adaptive Skills Trainer (605), Associate Behavioral Analyst (613), Dietician or Nutritionist (720), Physical Therapist (772), and Recreational Therapist (694). All these service codes require that persons have certifications in these areas. Brain Balance does not employ persons with these required certifications, as Ms. Horn acknowledged in her testimony as summarized below. Ms. McGuire concluded that Brain Balance does not meet any regional center category or service requirement for vendorization.

20. Ms. McGuire also reviewed SDRC's decision to deny Brain Balance's vendorization appeal, as previously discussed. SDRC determined that Brain Balance's services do not fall under a service code SDRC is allowed to vendor, Brain Balance was not offering Special Recreational services, and Brain Balance did not meet the credentialing requirements for the Adaptive Skills Trainer service code. Further, as discussed above, SDRC found the requested services to be experimental. Ms. McGuire agreed with SDRC's decision.

Claimant's Evidence

DOCUMENTARY EVIDENCE

21. Claimant's mother submitted the following documents as evidence: Brain Balance's assessment of claimant, as discussed above; an unsigned Cognitive Assessment Report for claimant; a document from Brain Balance entitled "Building and Optimizing Brain Health and Connectivity-Brain Balance: An Integrative Approach to Improving Attention, Behavior, and Cognition-Research and Results"; the invoices mentioned above; a letter from Anshu Batra, M.D., a developmental pediatrician

regarding the value of Brain Balance; a letter from Emma Boda, PA.C.; and a statement from claimant's mother.

22. The "Research and Results" document asserts that a "mounting body of evidence supports the efficacy of the Brain Balance program." The document includes summaries of studies under five domains: Sensory, Motor, Behavioral, Social-Emotional, and Cognitive. The document also contains summaries from "Collateral Research" that supports Brain Balance and four studies regarding Brain Balance outcomes.

23. These summaries do not lead to the conclusion that Brain Balance's Program has gone through rigorous research and review and is effective in the treatment of persons with ASD. The summaries are just that, summaries, brief descriptions of studies. They don't identify their research methodology, whether they have been subject to review, or how their conclusions might apply to the efficacy of Brain Balance's treatments for children with ASD.

24. Dr. Batra's July 31, 2024, letter is addressed to the San Diego Regional Center's "Administrative Hearing Committee." Dr. Batra endorses Brain Balance in general for persons with developmental disabilities and asks SDRC to fund the program "to contribute to the overall goal of helping individuals with developmental delays." He does not address the issue of whether the Brain Balance Program offers evidence-based treatments, and for this reason, his view that Brain Balance may help persons with developmental delays is given no weight.

25. Ms. Boda works with claimant's pediatrician. She states in a note dated August 8, 2024, she believes claimant could benefit from the Brain Balance Program.

TESTIMONY OF DONNA HORN

26. In her testimony, Ms. Horn denied Brain Balance is experimental. She described Brain Balance as an after school supplemental education program. She said Brain Balance is evidence-based because 70,000 children have participated in the Program with 85 percent of families completing surveys, and 85 percent of these families say they are happy with the Brain Balance Program. She also cited five-star reviews Brain Balance has received from families. She acknowledged that Brain Balance's staff are not licensed or credentialed. As mentioned above, she stated she plans to apply for vendorization with IRC.

TESTIMONY OF CLAIMANT'S MOTHER

27. Claimant's mother stated she just wants something that works for her son, and she believes he can benefit from the Brain Balance Program. She is struggling to find something that works for him and wants the opportunity that Brain Balance offers for him after trying everything else without improvement. She wants her son to live a normal and healthy lifestyle without depending on specialists and medications. She wants to try Brain Balance to accomplish this goal. She understands that Brain Balance may take some time to work.

LEGAL CONCLUSIONS

Purpose of the Lanterman Act

1. The purpose of the Lanterman Developmental Disabilities Act (Lanterman Act) is to provide a "pattern of facilities and services . . . sufficiently complete to meet the needs of each person with developmental disabilities, regardless of age or degree

of handicap, and at each stage of life." (Welf. & Inst. Code § 4501; *Association of Retarded Citizens v. Department of Developmental Services* (1985) 38 Cal.3d 384, 388.)

Burden and Standard of Proof

2. Each party asserting a claim or defense has the burden of proof for establishing the facts essential to that specific claim or defense. (Evid. Code, §§ 110, 115, 500; *McCoy v. Bd. of Retirement* (1986) 183 Cal.App.3d 1044, 1051, footnote 5.) In this case, claimant bears the burden to prove IRC should fund the service he seeks. The standard by which each party must prove those matters is the "preponderance of the evidence" standard. (Evid. Code, § 115.) A preponderance of the evidence means that the evidence on one side outweighs or is more than the evidence on the other side, not necessarily in number of witnesses or quantity, but in its persuasive effect on those to whom it is addressed. It is "evidence that has more convincing force than that opposed to it." (*People ex rel. Brown v. Tri-Union Seafoods, LLC* (2009) 171 Cal.App.4th 1549, 1567.)

Evaluation and Disposition

3. Claimant failed to establish that the Brain Balance Program offers nonexperimental services that have been clinically determined or scientifically proven to be effective for the treatment or remediation of ASD. Claimant's argument contradicted the testimony of Dr. Miller-Sabouhi, Ms. Velasco, and the documentary evidence that Brain Balance's services are essentially untested and unproven. Pursuant to Welfare and Institutions Code section 4648, subdivision (a)(17), IRC is thus prohibited from purchasing Brain Balance's services. Accordingly, IRC may not fund the Brain Balance Program for claimant.

4. Claimant further failed to establish that the Brain Balance Program offers services that "reflect evidence-based practices, promote positive social behaviors, and ameliorate behaviors that interfere with learning and social interactions" pursuant to Welfare and Institutions Code section 4686.2, subdivision (B)(1)(A), based on the findings immediately above.

5. Regarding the issue of Brain Balance not being vendored with IRC as a basis to deny claimant's appeal, IRC may only purchase services or supports "pursuant to vendorization or a contract" as set forth in Welfare and Institutions Code section 4648, subdivision (a)(3). Thus, it cannot fund a non-vendored service such as Brain Balance. Alternatively, to the extent claimant and Ms. Horn were objecting to Brain Balance not being an IRC vendor, that issue is not ripe for review. Brain Balance has not applied to become a vendor with IRC, and IRC thus has not decided whether to contract with Brain Balance as a vendor. (Cal. Code Reg., title 17, § 54320, subdivision (a).) OAH, further, does not have jurisdiction to hear an appeal of a regional center's decision regarding vendoring of Brain Balance. (Cal. Code Reg., title 17, § 54385, subdivision (a).)

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ORDER

Claimant's appeal from Inland Regional Center's determination to deny claimant's request to fund Brain Balance services is denied. Inland Regional Center may not fund Brain Balance for claimant.

DATE: August 22, 2024

ABRAHAM M. LEVY Administrative Law Judge Office of Administrative Hearings

NOTICE

This is the final administrative decision. Each party is bound by this decision. Either party may request a reconsideration under Welfare and Institutions Code section 4713, subdivision (b), within 15 days of receiving the decision, or appeal the decision to a court of competent jurisdiction within 180 days of receiving the final decision.