BEFORE THE
DEPARTMENT OF DEVELOPMENTAL SERVICES
STATE OF CALIFORNIA

In the Matter of:

CLAIMANT

and

SAN DIEGO REGIONAL CENTER, Service Agency

DDS No. CS0023155

OAH No. 2024120928

PROPOSED DECISION

Michelle C. Hollimon, Administrative Law Judge, Office of Administrative Hearings (OAH), State of California, heard this matter on April 2, 2025, by videoconference.

Claimant's father appeared at the hearing and represented claimant.

Erik Peterson, Appeals and Resolution Manager, represented San Diego Regional Center (SDRC).

Oral and documentary evidence was received. The record was closed and the matter was submitted for decision on April 2, 2025.

ISSUE

Should SDRC provide funding for Brain Balance program services through claimant's spending plan as a part of claimant's Self-Determination Program (SDP)?

FACTUAL FINDINGS

Background

1. Claimant is an eight-year-old male who resides with his parents. According to claimant's Individual Program Plan (IPP), he is eligible for regional center services under the categories of autism spectrum disorder (autism) and intellectual disability.

2. Claimant began participation in SDP effective January 1, 2025. Under the SDP, a budget and spending plan for claimant is prepared and approved by SDRC on an annual basis. Claimant requested his spending plan include funding for sessions for Brain Balance, a multi-modality treatment program designed to engage and strengthen different regions of the brain.

3. On October 22, 2024, SDRC issued a Notice of Action (NOA) that it was denying claimant's request to fund the Brain Balance program in claimant's current IPP. The basis for denial was that SDRC is prohibited from funding 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).

4. On December 20, 2024, claimant's father filed an appeal to the NOA, requested a mediation and hearing, and argued claimant should receive Brain Balance services through his SDP spending plan. The reason for claimant's father's appeal were: other families have received funding for the program through SDRC, Brain Balance provides the type of individualized support claimant requires to developmentally progress, Brain Balance funding will provide long-term benefits and reduce claimant's future support needs, Brain Balance is not experimental, and Brain Balance directly supports claimant's IPP goals.

5. This hearing followed claimant's father's appeal.

Self-Determination Program

6. In 2013, the legislature enacted Welfare and Institutions Code section 4685.8, requiring the Department of Developmental Services (DDS) to implement a statewide SDP to provide individuals and their families with more freedom, control, and responsibility in choosing services and supports to help them meet objectives in their IPP. Starting July 1, 2021, the SDP was available to all eligible regional center consumers.

7. Under the SDP, participants have more flexibility regarding which services they receive and who delivers those services. The total amount of regional center funds available to the participant to fund needed goods, services and supports is determined annually (individual budget). Once the individual budget amount is determined, the participant must develop a spending plan identifying the cost of each good, service, and support that will be purchased with regional center funds. Each item in the spending plan must relate to goals in the participant's IPP and be identified by a specific service code from a list of codes DDS publishes. Regional centers are required

to certify individual SDP budgets and review spending plans to ensure compliance with applicable laws and federally approved categories.

SDRC's Evidence

TESTIMONY OF ALYSSA DELAGNES

8. The following is a summary of the testimony of Alyssa Delagnes. Ms. Delagnes is an SDRC SDP Program Manager. She holds a bachelor's degree in psychology with a minor in disability studies. Ms. Delagnes has been working for SDRC for approximately eight years.

9. Ms. Delagnes described the SDP as an alternate way of receiving regional center services. The budget of money provided to a claimant for services is the same amount under SDP as it would be under the traditional services model. SDP participants develop a spending plan and are not required to use regional center vendor providers. However, service providers used by SDP participants must meet the criteria set forth in the Lanterman Act. The Lanterman Act prohibits funding for experimental treatments. Further, all SDP services must be compliant with the Federal Home Community Based Services Waiver program (HCBS waiver). A service must fit under one of the SDP service code definitions to be eligible under the HCBS waiver.

10. Ms. Delagnes testified that the July 8, 2024, DDS directive provides specific guidance on what can and cannot be purchased or funded under the SDP (July 2024 DDS directive). Per the July 2024 DDS directive, SDP funds can only be used for goods and services that "have been approved by the federal Centers for Medicare and Medicaid Services" and cannot be funded by other sources, such as Medi-Cal or In-Home Supportive Services. The July 2024 DDS directive's "Enclosure A" also addresses

the use of participant-directed services and experimental treatments, stating that "experimental or prohibited treatments shall not be provided."

TESTIMONY OF MELISSA MELGAR

11. The following is a summary of the testimony of Melissa Melgar, SDRC's Coordinator of Behavior Services. Ms. Melgar has a bachelor's degree in psychology, and a master's degree in clinical psychology. She has over 16 years of experience in the field and has been with SDRC for almost eight years.

12. Ms. Melgar testified that Jon Pak, the Executive Director of Brain Balance of Greater San Diego, previously applied for vendorization with SDRC. The application for vendorization was denied and subsequently appealed. Ms. Melgar authored SDRC's Vendor Appeal Position statement (appeal statement), dated June 6, 2023, which addressed SDRC's concerns regarding Brain Balance.

13. One concern addressed in the appeal statement was the qualification of providers presented to SDRC having lack of experience and education in developmental disabilities. Mr. Pak's resume displayed experience primarily in business and finance. Another resume reviewed indicated study in exercise physiology. Neither resume indicated education or experience with developmental disabilities. No staff backgrounds provided were specific to developmental disabilities. There were no staff requirements for training in developmental disabilities or autism.

14. Another concern expressed in the appeal statement, which Ms. Melgar reiterated in her testimony, was that "published materials on Brain Balance involve testimonials, self-reports, and low-quality research studies lacking in scientific rigor." To qualify as an approved SDP service, the service must be evidence-based and not experimental.

15. Ms. Melgar testified that evidence-based practice involves the use of scientifically rigorous research, per Welfare and Institutions Code section 4686.2, subdivision (c)(3). Ms. Melgar testified that scientific rigor is defined by the National Institute of Health as:

> The strict application of the scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation and reporting of results. This includes full transparency in reporting experimental details so that others may reproduce and extend the findings.

16. Brain Balance provided SDRC a publication, also available on their website, entitled "Brain Balance Outcomes: Research and Studies" containing information regarding recent research and studies on the Brain Balance program. The Brain Balance research publication listed 37 source references in its endnotes. Ms. Melgar testified that she reviewed each of the 37 source references and provided a detailed chart of her findings.

17. Ms. Melgar testified that seven of the 37 source references are discussed in the Brain Balance research publication itself. The other 30 source references are not specifically on Brain Balance. The other 30 source references may have looked at a component of the Brain Balance program, but not the Brain Balance treatment program as a whole.

18. Regarding the seven research studies that did address Brain Balance specifically, Ms. Melgar testified that there were significant shortcomings with these studies. First, none of the seven studies had randomized control trials. Second, Brain Balance was involved in all seven studies, with six of the seven studies co-authored by

Rebecca Jackson, who is employed by Brain Balance, and the other study receiving consulting fees from Brain Balance. Third, five of the seven studies used retrospective data analysis, using existing Brain Balance data, which did not allow for a true control group. Fourth, parent surveys were used as the measurement tool in some of the research studies, which is not a reliable indicator of progress actually made.

19. Ms. Melgar testified that none of the seven research studies that did address Brain Balance specifically addressed autism, for which claimant is eligible for regional center services. One of the seven studies was conducted only on children with attention-deficit/hyperactivity disorder (ADHD) and five of the seven studies had no diagnostic criteria at all. One study had a high dropout rate of 59 percent and others had a small sample size or the sample size was unknown.

20. Ms. Melgar testified regarding a 2021 University of Kansas, Department of Applied Behavioral Science study that examined Brain Balance and determined it was not evidence-based. The study found that many of the treatment components used by Brain Balance lack empirical evidence, such as the use of specialized earphones and glasses, nutritional interventions and sensory integration training. Ms. Melgar pointed out there is acceptable sensory integration used in addressing autism, which is evidence-based, but this was not what was utilized by Brain Balance.

21. Ms. Melgar also testified regarding a review of the Brain Balance program by a Wisconsin Department of Health Services advisory committee (Wisconsin committee). The program was initially reviewed in April 2012 and re-reviewed in 2015 and 2018 to determine if Brain Balance treatment was a proven and effective treatment for individuals with autism spectrum disorder and/or other developmental disabilities. The Wisconsin committee that reviewed Brain Balance in 2015 deemed Brain Balance treatment as "Level 4," meaning there is insufficient evidence and it is

experimental treatment. The Wisconsin committee deemed Brain Balance treatment as experimental based, in part, on there not being "at least one high quality study that demonstrates experimental control and favorable outcomes of treatment package."

22. Ms. Melgar testified that she visited a Brain Balance facility and testified regarding her visit in another OAH matter. She read her prior testimony at this hearing, describing the facility as "clinically unusual." Ms. Melgar was asked to remove her shoes upon arrival. She was provided various sensory stimulation devices and glasses with blinking lights. She noted that some computers at the facility had eye tracking software. Ms. Melgar testified that the services offered by Brain Balance were not services seen in the treatment of autism. She testified that the Brain Balance site did not appear to a facility designed to provide services and support to alleviate disability as described in Welfare and Institutions Code section 4512, subdivision (b).

23. Ms. Melgar reviewed the decisions in three other OAH matters regarding Brain Balance funding, as well as the prior OAH decision for the matter in which she testified. Ms. Melgar testified that she reviewed the expert testimony in the other matters and her position is consistent with what other regional center experts have concluded and what OAH has determined—Brain Balance is not evidence-based and therefore cannot be funded by SDRC.

24. Ms. Melgar testified regarding the California Evidence-Based Clearinghouse (CEBC) Scientific Rating Scale, which evaluates practices based on available research evidence. Ms. Melgar testified that Brain Balance is most like the "NR" category, meaning it could not be rated on the CEBC Scientific Rating Scale.

SDRC'S DOCUMENTARY EVIDENCE

25. SDRC presented 29 documents, all of which were received into evidence. Some of SDRC's supporting documents are discussed in more detail below.

26. SDRC provided a Brain Balance publication, entitled "Brain Balance Outcomes: Research and Studies" containing information regarding recent research and studies on the Brain Balance program. SDRC provided a summary prepared by SDRC of the research studies cited in the Brain Balance booklet, which included information regarding who was studied, the intervention addressed, and SDRC's concerns with the results of each of the cited studies.

27. SDRC provided Brain Balance vendor appeal documents as follows: May 3, 2023, letter from Jon Pak, Executive Director of Brain Balance of Greater San Diego to Mark Klaus, Executive Director of SDRC "re: Appeal to denied vendor application," SDRC's Vendor Appeal Position Statement dated June 6, 2023, and June 26, 2023, letter from Neil Kramer, SDRC Executive Director Designee to Jon Pak regarding vendorization appeal decision. These documents address Brain Balance's position regarding its qualifications for vendorization, SDRC's position regarding the reasons it did not support vendorization for Brain Balance, and SDRC's denial of Brain Balance's appeal for vendorization.

28. SDRC provided articles and publications entitled "Evidence-based practices in the field of intellectual and developmental disabilities: An international consensus approach," published in 2010, "Addressing Rigor in Scientific Studies" dated August 10, 2023, "Evidence-Based Practices for Children, Youth, and Young Adults with Autism," published in 2020. These publications address evidence-based practices and scientific rigor.

29. SDRC provided a University of Kansas study, authored by Katherine A. Johnson, MS, BCBA, LBA, Catherine L. McHugh, MA, BCBA, LBA, and Thomas Zane, PhD, BCBA-D, published on the Association for Science in Autism Treatment (ASAT) website addressing whether Brain Balance is science based. The authors concluded that Brain Balance lacked empirical evidence and was not supported by scientific research.

30. SDRC provided a Wisconsin Department of Health Services Autism and Developmental Disabilities Treatment Intervention Advisory Committee re-review of the Brain Balance program and whether it was "a proven and effective treatment for individuals with autism spectrum disorder and/or other developmental disabilities," dated January 30, 2015. The Wisconsin review committee concluded that Brain Balance could not be considered a proven and effective treatment given the lack of research evidencing its use or effectiveness.

31. SDRC provided the DDS directive regarding SDP and goods and services dated July 8, 2024, SDP service definitions, and excerpts from Welfare and Institutions Code. The documents address allowable purchases and funded services under the SDP.

32. SDRC provided four OAH decisions addressing the issue of Brain Balance funding. SDRC requested judicial notice be taken of these decisions. The decisions were admitted into evidence and were considered for argument only, as they are not binding, nor do they have any precedential authority in this matter.

Claimant's Evidence

TESTIMONY OF CLAIMANT'S FATHER

33. The following is a summary of the testimony of claimant's father.

34. Claimant's father disagrees with SDRC's position that Brain Balance is experimental. Brain Balance research has been peer reviewed in various reputable scientific journals. SDRC is subjectively defining Brain Balance as experimental.

35. Claimant's father asserted that Brain Balance does not need to be evidence-based for approval. He argued Welfare and Institutions Code section 4648, subdivision (a)(17) only requires services to be safe, not that they be evidence-based.

36. Further, the HCBS waiver does not define allowable services strictly by service codes but includes community supports that are safe. Brain Balance aligns with specialized therapeutic services and is designed to meet various goals, including promoting independence.

37. Claimant is at home with family support. Brain Balance services are necessary to address sensory and other challenges not otherwise effectively addressed. Brain Balance addresses core developmental disability symptoms and offers tailored programming that is "clearly aligned" with the needs of claimant. Claimant has a right to services that meet his needs, and provide for the least restrictive placement. Claimant has not been able to access the services Brain Balance offers from other sources and his school-based services are not able to meet claimant's needs.

38. Claimant's father addressed the issue of Brain Balance's research, specifically that one of the seven studies that addressed Brain Balance was conducted

only on children with ADHD, not autism. Claimant's father testified that claimant has both diagnoses, and it is not the diagnosis itself that should be addressed, but the needs in claimant's IPP. Further, Brain Balance funding research is not unusual; historically, most research is funded by the organization developing it. Finally, SDRC argues that Brain Balance is not "backed by real science," but the University of Kansas study they provided was not scientifically peer reviewed.

39. Claimant's father also addressed the qualifications of the Brain Balance staff, testifying that John Pak has a master's degree in education, as does each program director. These staff members are trained within their scope of practice.

40. The prior OAH decisions that SDRC noted addressed Brain Balance and concluded it could not be funded did not prove Brain Balance was experimental; rather, those decisions support SDRC's overly restrictive interpretation of what can be funded. Further, this case must be evaluated on its own merits.

41. Claimant's father also pointed to the fact that the Arizona Empowerment Scholarship Account (ESA) Program funds Brain Balance services. On cross-examination, claimant's father was asked if he understood that the Arizona ESA program was a private school, educational services funding program, to which he responded he did not understand the relevance of the question.

42. During cross-examination, claimant's father stated he was not aware of any new research on Brain Balance that was not mentioned at the hearing.

CLAIMANT'S DOCUMENTARY EVIDENCE

43. Claimant presented eight documents, all of which were received into evidence. Some of claimant's supporting documents are discussed in more detail below.

44. Claimant submitted a position statement setting forth claimant's father position as to why claimant's appeal should be granted. Claimant's father's arguments in support of granting the appeal include that Brain Balance is supported by peer-reviewed research in reputable scientific journals and satisfies the requirements of Welfare & Institutions Code section 4648, subdivision (a)(17), "which prohibits only services that are experimental, unsafe, or not scientifically proven." Claimant's father points to Brain Balance being funded by the Arizona ESA program, a state-administered education initiative, as evidence that Brain Balance is "recognized in public policy" and "not fringe or speculative." Claimant's father argues that Brain Balance services are necessary and that under Welfare & Institutions Code section 4685, subdivision (c)(1) and subdivision (c)(2), regional centers are required to provide individualized services when standard services are not sufficient.

45. Claimant submitted a letter dated February 23, 2025, from Joseph Tulagan, M.D., claimant's pediatrician. Dr. Tulagan supported claimant's participation in Brain Balance as claimant "continues to experience significant challenges with sensory processing, motor coordination, and adaptive life skills" and Brain Balance "targets areas not fully addressed in traditional therapies" by "integrating sensory-motor training, cognitive development, and emotional regulation." Dr. Tulagan lists one or two sentence findings from "studies from reputable institutions" that support the effectiveness of Brain Balance and which he opines "suggest that Brain Balance is a

legitimate and evidence-supported program" and that classifying it as "experimental" may be inaccurate.

The information provided by Dr. Tulagan are brief descriptions of studies. His descriptions do not identify 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 autism or intellectual disability. Further, Dr. Tulagan states that Brain Balance targets areas not fully addressed in traditional therapies but does not identify with specificity what areas are not fully addressed in traditional therapies. Given these issues, Dr. Tulagan's letter in support of Brain Balance services for claimant is given less weight.

46. Claimant submitted additional documents setting forth his arguments with respect to the Arizona ESA program, his response to SDRC "misrepresentations" regarding issues such as Brain Balance staff qualifications and scientific standards, rebuttals to SDRC claims such as Brain Balance being experimental and not evidence-based, argument in response to recent denials of funding for Brain Balance, his response to critiques of Brain Balance from organizations such as ASAT, and providing testimonials as to Brain Balance's effectiveness.

LEGAL CONCLUSIONS

Purpose of the Lanterman Act

1. The legislature enacted a comprehensive statutory scheme known as the Lanterman Developmental Disabilities Act (Lanterman Act), set forth in Welfare and Institutions Code section 4500 et seq., to meet the needs of each person with developmental disabilities, regardless of that person's degree of handicap or age, and

at each stage of that person's life. The purpose of the statutory scheme is twofold: To prevent or minimize the institutionalization of developmentally disabled persons and their dislocation from family and community, and to enable them to approximate the pattern of everyday living of nondisabled persons of the same age in order to lead more independent and productive lives in the community (*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, fn. 5.) In this case, claimant bears the burden to prove his SDP spending plan should include funding for Brain Balance.

3. The standard by which each party must prove those matters is the "preponderance of the evidence" standard. (Evid. Code, § 115.)

4. 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.)

Applicable Statutory Authority

5. Welfare and Institutions Code section 4512, subdivision (b), states:

> Services and supports for persons with developmental disabilities means specialized services and supports or

> special adaptations of generic services and supports directed toward the alleviation of a developmental disability or toward the social, personal, physical, or economic habilitation or rehabilitation of an individual with a developmental disability, or toward the achievement and maintenance of an independent, productive, and normal life....

6. Welfare & Institutions Code section 4648, subdivision (a)(17), provides in part: "regional centers shall not purchase experimental treatments, therapeutic services, or devices that have not been clinically determined or scientifically proven to be effective or safe or for which risks and complications are unknown."

7. Welfare & Institutions Code section 4685, subdivision (c)(1), provides in part:

> The department and regional centers shall give a very high priority to the development and expansion of services and supports designed to assist families that are caring for their children at home, when that is the preferred objective in the individual program plan.

8. Welfare & Institutions Code section 4685, subdivision (c)(2), provides in part:

> When children with developmental disabilities live with their families, the individual program plan shall include a family plan component which describes those services and supports necessary to successfully maintain the child at

> home. Regional centers shall consider every possible way to assist families in maintaining their children at home, when living at home will be in the best interest of the child, before considering out-of-home placement alternatives.

9. Welfare and Institutions Code section 4686.2, subdivision (d)(3), defines "evidence-based practice" as follows:

> a decision-making process that integrates the best available scientifically rigorous research, clinical expertise, and individual's characteristics. Evidence-based practice is an approach to treatment rather than a specific treatment. Evidence-based practice promotes the collection, interpretation, integration, and continuous evaluation of valid, important, and applicable individual- or family-reported, clinically-observed, and research-supported evidence. The best available evidence, matched to consumer circumstances and preferences, is applied to ensure the quality of clinical judgments and facilitates the most cost-effective care.

10. Welfare and Institutions Code section 4685.8, subdivision (c)(6), provides that SDP can fund services and supports only if they are approved for funding by Medicare and Medicaid Services.

Evaluation

11. Claimant did not prove by a preponderance of the evidence that the treatment provided by Brain Balance has been clinically determined or scientifically

proven to be effective for the treatment or remediation of claimant's qualifying disabilities. As a result, it is experimental and SDRC is prohibited from funding Brain Balance services.

12. SDRC is prohibited by the Lanterman Act from funding therapies that have not been clinically determined or scientifically proven to be effective for the treatment or remediation of developmental disabilities. The legislature enacted this prohibition not only to safeguard taxpayers from the wasteful spending of public funds, but also to protect consumers and their parents from the false hope of therapies that have not been established to meet the claims made by some of their practitioners.

13. There was inadequate support presented at hearing for the effectiveness of the treatment provided by Brain Balance. The testimony by SDRC's witnesses and publications they cited showed there is insufficient testing of Brain Balance treatments as there is a lack of reliability and credibility in the studies that reference Brain Balance.

14. Claimant's argument that Brain Balance is not experimental is unpersuasive. Brain Balance research having been "peer reviewed in various reputable scientific journals" does not make it non-experimental. Peer review and publication alone are not enough.

15. Claimant's argument that Welfare and Institutions Code section 4648, subdivision (a)(17), does require Brain Balance to be CEBC misstates the law. While the term "evidence-based" is not specifically used in Welfare & Institutions Code section 4648, subdivision (a)(17), it does provide that experimental treatments and therapeutic services cannot be purchased if they "have not been clinically determined or

scientifically proven to be effective or safe." Evidence-based practice ensures this standard is met.

16. It was clear from claimant's father's testimony that he wants what is best for his son and genuinely believes that Brain Balance benefited his son in ways other services to date have not. Claimant's father expressed that claimant has not been able to access the services that Brain Balance offers from other sources and claimant's school-based services are not able to meet claimant's needs. However, resorting to unproven services such as Brain Balance to address claimant's needs is not the solution, at least not as part of regional center services. As a public program designed to serve a large population, regional centers must ensure the services they fund are in strict compliance with all legal restrictions and requirements. The evidence supports that Brain Balance is experimental and for this reason, SDRC is precluded from funding Brain Balance.

17. Based on all the above, SDRC's decision to deny claimant's request to fund Brain Balance services through claimant's SDP spending plan must be upheld.

ORDER

Claimant's appeal of San Diego Regional Center's decision denying claimant's request to fund Brain Balance services through claimant's Self-Determination Program is denied. San Diego Regional Center may not fund Brain Balance services for claimant.

DATE: April 10, 2025

MICHELLE C. HOLLIMON
Administrative Law Judge
Office of Administrative Hearings

BEFORE THE
DEPARTMENT OF DEVELOPMENTAL SERVICES
STATE OF CALIFORNIA

In the Matter of:

Claimant

OAH Case No. 2024120928

Vs**.**

DECISION BY THE DIRECTOR

San Diego Regional Center

Respondent.

ORDER OF DECISION

On April 10, 2025, an Administrative Law Judge (ALJ) at the Office of Administrative Hearings (OAH) issued a Proposed Decision in this matter.

Given the unique circumstances of the case, the Proposed Decision is adopted by DDS as its Decision in this matter. The Order of Decision, together with the Proposed Decision, constitute the Decision in this matter.

This is the final administrative Decision. Each party is bound by this Decision. Either party may request a reconsideration pursuant to 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.

Attached is a fact sheet with information about what to do and expect after you receive this decision, and where to get help.

IT IS SO ORDERED on this day May 7, 2025

Original signed by:

Pete Cervinka, Director