BEFORE THE
OFFICE OF ADMINISTRATIVE HEARINGS
STATE OF CALIFORNIA

In the Matter of: CLAIMANT, and INLAND REGIONAL CENTER, Service Agency.	OAH No. 2017030733

DECISION

Adam L. Berg, Administrative Law Judge, Office of Administrative Hearings (OAH), State of California, heard this matter in San Bernardino, California, on January 29, 2018.

Jennifer Cummings, Program Manager, Fair Hearings and Legal Affairs, represented Inland Regional Center (IRC).

Claimant's mother represented claimant.

The matter was submitted on January 29, 2018.

ISSUES

Should claimant's appeal of IRC's determination that it will not fund a compounded vitamin regimen prescribed by claimant's neurologist be dismissed because claimant failed to timely file a Fair Hearing Request?

Should IRC fund a compounded vitamin regimen prescribed by claimant's neurologist?

FACTUAL FINDINGS

BACKGROUND

1. Claimant is a 20-year-old conserved male who is eligible for regional center services based on a diagnosis of autism spectrum disorder. At an Individualized Program Plan (IPP) meeting held on June 23, 2016, claimant's mother, who is his conservator, requested IRC pay for a "vitamin cocktail" [1] prescribed by claimant's neurologist for claimant's suspected Mitochondrial Disease.[2]

2. On December 20, 2016, IRC sent claimant's mother a Notice of Proposed Action and attached letter denying claimant's request for IRC to fund a compounded vitamin regimen to treat claimant's Mitochondrial Disease. IRC determined the vitamins to be a non-evidence-based and experimental treatment, which has not been clinically determined or scientifically proven to be effective or safe, and the funding request was not directed toward alleviating claimant's developmental disability. Alternatively, IRC noted that the vitamins could be purchased over-the-counter at claimant's expense. The letter informed claimant that if he disagreed with the decision, he could file a Fair Hearing Request within 30 days of receipt of the letter.

3. IRC sent the Notice of Proposed Action and attached letter by certified mail, which was received by claimant's father on December 23, 2016.

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[1] The vitamin cocktail prescribed by claimant's neurologist, and compounded at a specialty pharmacy, contains coenzyme Q-10, ascorbic acid, riboflavin, thiamine hydrochloride, alpha lipoic acid, and vitamin B succinate.

[2] Mitochondrial Disease is a chronic genetic disorder that can cause physical, developmental, or cognitive disabilities.

4. On March 10, 2017, IRC received claimant's Fair Hearing Request appealing IRC's decision to deny claimant's request to fund the compounded vitamins.

5. IRC forwarded the Fair Hearing Request to OAH and simultaneously filed a motion to dismiss. IRC claimed that the Fair Hearing Request should be dismissed because it was not filed within 30 days of receipt of the Notice of Action as required under Welfare and Institutions Code section 4710.5, subdivision (a).

6. Claimant's mother filed an opposition to the motion to dismiss, claiming that IRC delayed making a decision until it knew she would be out of the country, thus the time to appeal should be equitably tolled. Additionally, she claimed she requested that IRC re-issue its decision so that she could timely appeal. She claimed IRC advised her that if she submitted additional information, and IRC did not change its position regarding funding, IRC would issue a new Notice of Proposed Action that claimant could appeal.

7. On March 15, 2017, Presiding Administrative Judge Walker denied IRC's motion to dismiss without prejudice so the issue could be decided at hearing.

8. On April 4, 2017, an informal meeting was held between IRC, claimant's mother and claimant's then authorized representative, Peter Attwood. In a letter dated April 5, 2017, IRC maintained its decision to deny funding for the compounded vitamin because generic funding resources have not been exhausted and the vitamins are considered to be an experimental treatment. According to the letter, IRC discussed the need for claimant to appeal the denial of coverage by his private insurance and Medi-Cal's to the Department of Managed Health Care or the Department of Insurance.

IRC'S EVIDENCE

9. Beth Scott is claimant's Consumer Services Coordinator and has held this position at IRC for 11 years. She met with claimant's mother in June 2016 for claimant's annual IPP meeting. At this time, claimant's mother requested IRC fund the

compounded vitamins claimant's neurologist prescribed to claimant. Ms. Scott requested that claimant's mother provide supporting documentation for the request and she would forward the request to IRC's clinical review team for review. Additionally, Ms. Scott arranged for claimant's mother to meet with IRC's pharmaceutical consultant, Dr. Kvaveh Kokabi.

10. Dr. Kokabi has been IRC's pharmaceutical consultant for the past four years. He received his Doctor of Pharmacy degree from the University of Southern California in 2008 and a Master of Science in Biochemistry and Molecular Biology from the University of California, Los Angeles in 2002. He is a licensed pharmacist in California and works as a clinical pharmacist. Dr. Kokabi met with claimant's mother on or about August 29, 2016, to discuss all of the medications that claimant was taking, including the vitamin regimen. Dr. Kokabi authored a report dated September 10, 2016, which was forwarded to claimant's mother for her review.

11. On November 9, 2016, Ms. Scott emailed claimant's mother inquiring if she had reviewed the report and still wanted Ms. Scott to move forward with the request. Claimant's mother responded that she was not happy with the report because Dr. Kokabi did not reference a letter provided by claimant's neurologist. Ms. Scott responded on November 16, 2016, stating that claimant's mother could put her concerns in a letter that would be reviewed in evaluating the request. Ms. Scott closed by saying, "Please let me know if I can just move forward on this request." On December 1, 2016, claimant's mother emailed Ms. Scott listing numerous reasons why she believed that Dr. Kokabi's report was deficient.

12. Dr. Kokabi testified that insurance plans generally do not fund vitamins, with the exception of prenatal vitamins. He does not believe that the compounded vitamins prescribed to claimant are widely known or an accepted and proven practice for treatment of Mitochondrial Disease. He noted that the U.S. Food and Drug

Administration (FDA) has limited authority to regulate dietary supplements. Thus, although the prescribed vitamins are prepared at a compounding pharmacy, the vitamins themselves are not subject to any greater FDA review than over-the-counter vitamins. Dr. Kokabi emphasized that his role was not to make a determination as to whether the compounded vitamin regimen was appropriate for claimant, and he recommended claimant to continue to take the product as ordered by his neurologist so long as there are benefits and no adverse effects. However, he did not believe that the vitamin regimen has been clinically determined or scientifically proven to be effective or a general physician practice.

13. Wasima Alvi has been IRC's Clinical Services Manager for the past five years. In that role, she supervises all of IRC's clinical staff, including physicians and psychologists. Ms. Alvi reviewed claimant's request and determined that the vitamin regimen was an experimental treatment that has not been scientifically proven and recommended denial of the request. She noted that IRC is prohibited from funding experimental treatments that have not been scientifically proven to be safe and effective.

14. Mr. Garcia is a program manager at IRC responsible for supervising consumer services coordinators, including Ms. Scott. After receiving claimant's mother's response to Dr. Kokabi's report, Mr. Garcia notified claimant's mother by letter dated December 20, 2016, that IRC was denying claimant's request to fund the vitamin cocktail. Mr. Garcia testified that he notified claimant of IRC's decision within five days as required by law.

15. Valerie Mosher is a registered dietician and has consulted for IRC for the past nine years. Ms. Mosher testified that the best source of vitamins is from natural food because the body is better able to process the nutrients

16. IRC's Purchase of Service Policy, which has been approved by the Department of Developmental Services, contains provisions for funding medical and diagnostic requests. Under the policy, IRC may purchase medical or dental services after private and generic sources have been exhausted. All requests must be accompanied by a copy of the denial from Medi-Cal or private health insurance. Under the policy, IRC is unable to 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."

CLAIMANT'S EVIDENCE

17. Claimant's mother testified that she was out of the country when IRC sent her the denial letter. She believed IRC delayed making a decision for months and waited until she was out of the country to issue a decision. Although her husband received IRC's denial letter, he did not open it and she did not see it until her return. Because the appeal period passed, she requested IRC to re-issue its decision so she could timely appeal. IRC refused to re-issue the denial so she filed the Fair Hearing Request. However, IRC also advised her to submit additional information in support of her request. She believed that IRC took so long in making a decision she did not want to have to wait for them to submit a new denial.

18. Claimant's mother testified that the vitamin regimen has resulted in significant improvements of claimant's symptoms and behavior. Claimant has been seeing a neurologist, Dr. Margaret Bauman, for four years, who prescribed the vitamin regimen. Claimant had to stop taking the vitamins because his family could not afford the cost. Claimant's mother observed behavioral changes following claimant's termination of the vitamin regimen, which included an increase in tantrums and poor behavior. Once he returned to taking the vitamins his behavior improved.

19. Claimant's mother appealed the denial of coverage by her insurance carrier and Medi-Cal. Although the status of her appeals to both entities was not entirely clear, claimant's mother believed that her request for a hearing was rejected because Medi-Cal does not cover vitamins in any circumstance. Claimant submitted a position statement from the Department of Health Care Services in response to claimant's appeal regarding the denial of payment for the vitamin regimen. The position statement notes that under Medi-Cal Update Pharmacy Bulletins, multivitamin supplements, unless defined and described in the Contract Drugs List of the Medi-Cal Pharmacy Manual, are not a covered benefit. Claimant's mother said claimant is no longer covered by a private insurer as of the beginning of the year.

20. Claimant submitted a letter dated June 20, 2016, from Margaret Bauman, M.D., a California licensed physician and Associate Professor at Boston University School of Medicine, addressed to claimant's insurance company. The letter is summarized as follows: Dr. Bauman is claimant's neurologist and she requested reconsideration of the decision to deny coverage of the vitamin regimen she prescribed to address claimant's "low stamina and low energy." Based on his blood work, claimant has a "probable" mitochondrial disorder, which can only be confirmed through a muscle biopsy. Since starting the vitamins, claimant has had "improved behavior, social engagement and speech." Dr. Bauman stated that the fact the vitamins could be purchased over-the-counter did not justify denial because they are food products without FDA oversight. "When I prescribe these vitamins it is for a specific need with a specific dosage that cannot be guaranteed by food products." Finally, if the vitamins were purchased individually, it would be unreasonable for a person with significant disabilities to tolerate taking so many pills.

21. Claimant submitted additional letters from Dr. Bauman dated February 9, 2017, and July 21, 2017, addressed to IRC and claimant's insurance respectively, which

were generally similar in content. The letters are summarized as follows: Claimant has been diagnosed with mitochondrial disorder. The vitamin cocktail claimant receives contains substances recommended by the Mitochondrial Medicine Society as cited in a review article published in *Genetics in Medicine*. Claimant has received the cocktail for over a year, which has improved his physical stamina and attentional focus and has decreased his disruptive behaviors. Dr. Bauman disagreed with IRC's conclusion that it is non-evidence based or experimental. Although she admitted more research is needed, she believes the Mitochondrial Society Consensus statement recommends most of the substances and in her clinical judgment, they "are medically indicated based on his well-documented positive response to these products." She concluded that failure to fund the cocktail" runs the substantial risk of serious developmental regression, and would border on medical malpractice."

22. Claimant submitted a letter from her primary care physician, Nancy Rodriguez Fernando, D.O. Dr. Rodriguez Fernando merely stated that Dr. Bauman believes that claimant requires the vitamins and, they should be properly compounded to ensure correct dosages.

23. Claimant submitted an article entitled "Diagnosis and management of mitochondrial disease: a consensus statement from the Mitochondrial Medicine Society" published in the September 2015 edition of *Genetics in Medicine*. The purpose of the article was to review the literature regarding mitochondrial disease and to provide recommendations for optimal diagnosis and treatment. Although the study recommended vitamins for patients with a diagnosis of mitochondrial disease, the authors noted that vitamin therapies "are not standardized and multiple variations of treatments exist." Furthermore, the article noted, "few trials have explored the clinical effects of these treatments. There is a general lack of consensus regarding which agents should be used."

LEGAL CONCLUSIONS

BURDEN OF PROOF

1. In a proceeding to determine whether an individual is eligible for services, the burden of proof is on the claimant to establish by a preponderance of the evidence that IRC should fund the requested service. (Evid. Code, §§ 115, 500; *McCoy v. Bd. of Retirement* (1986) 183 Cal.App.3d 1044, 1051-1052.)

THE LANTERMAN ACT

2. The Legislature enacted a comprehensive statutory scheme known as the Lanterman Developmental Disabilities Services Act (Welf. & Inst. Code, § 4500 et seq.) 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. 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 and to lead more independent and productive lives in the community. (*Assn. for Retarded Citizens v. Dept. of Developmental Services* (1985) 38 Cal.3d 384, 388.)

3. Welfare and Institutions Code section 4501 outlines the state's responsibility for persons with developmental disabilities and the state's duty to establish services for those individuals.

4. The Department of Developmental Services (DDS) is the public agency in California responsible for carrying out the laws related to the care, custody and treatment of individuals with developmental disabilities under the Lanterman Act. (Welf. & Inst. Code, § 4416.) In order to comply with its statutory mandate, DDS contracts with private non-profit community agencies, known as "regional centers," to provide the

developmentally disabled with "access to the services and supports best suited to them throughout their lifetime." (Welf. & Inst. Code, § 4620.)

5. Welfare and Institutions Code section 4512, subdivision (b) defines "services and supports" as:

> [S]pecialized 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 independent, productive, normal lives. The determination of which services and supports are necessary for each consumer shall be made through the individual program plan process. The determination shall be made on the basis of the needs and preferences of the consumer or, when appropriate, the consumer's family, and shall include consideration of a range of service options proposed by individual program plan participants, the effectiveness of each option in meeting the goals stated in the individual program plan, and the cost-effectiveness of each option . . . Nothing in this subdivision is intended to expand or authorize a new or different service or support for any consumer unless that service or support is contained in his or her individual program plan.

6. A regional center's responsibilities to its consumers are set forth in Welfare and Institutions Code sections 4640-4659.

7. Welfare and Institutions Code section 4646 requires that the Individual Program Plan and the provision of the services and supports be centered on the individual with developmental disabilities and take into account the needs and preferences of the individual and the family. Further, the provisions of services must be effective in meeting the IPP goals, reflect the preferences and choices of the consumer, and reflect the cost-effective use of public resources.

8. Welfare and Institutions Code section 4648, subdivision (a)(16), provides,

> [R]egional 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. Experimental treatments or therapeutic services include experimental medical or nutritional therapy when the use of the product for that purpose is not a general physician practice. . . .

9. Welfare and Institutions Code section 4659, subdivision (c), provides that regional centers regional centers shall not purchase any service that would otherwise be available from Medi-Cal, private insurance, or a health care service plan when a consumer or a family meets the criteria of this coverage but chooses not to pursue that coverage. Subdivision (d)(1) provides a regional center may not purchase medical or dental services for a consumer three years of age or older unless the regional center is provided with documentation of a Medi-Cal, private insurance, or a health care service plan denial and the regional center determines that an appeal by the consumer or family of the denial does not have merit.

10. Welfare and Institutions Code section 4434, subdivision (d), provides that the department shall review new or amended purchase-of-service policies prior to implementation by the regional center to ensure compliance with statute and regulation. The department shall take appropriate and necessary steps to prevent regional centers from utilizing a policy or guideline that violates any provision of the Lanterman Act or any regulation adopted thereunder.

11. Welfare and Institutions Code section 4646.4, subdivision (a), requires regional centers to establish an internal process that ensures adherence with federal and state law and regulation, and when purchasing services and supports, ensures conformance with the regional center's purchase of service policies.

12. In implementing Individual Program Plans, regional centers are required to first consider services and supports in natural community, home, work, and recreational settings. (Welf. & Inst. Code, § 4648, subd. (a)(2).) Services and supports shall be flexible and individually tailored to the consumer and, where appropriate, his or her family. (*Ibid.*) A regional center may, pursuant to vendorization or a contract, purchase services or supports for a consumer in order to best accomplish all or any part of the Individual Program Plan. (Welf. & Inst. Code, § 4648, subd. (a)(3).)

13. The regional center is also required to consider generic resources and the family's responsibility for providing services and supports when considering the purchase of regional center supports and services for its consumers. (Welf. & Inst. Code, § 4646.4.)

14. Welfare and Institutions Code section 4710, subdivision (b), provides that "adequate notice" must be sent "no more than five working days after the agency makes a decision without the mutual consent of the recipient or authorized representative, if any, to deny the initiation of a service or support requested for inclusion in the

individual program plan." Section 4701 outlines the requirements contained in the written notice in order to constitute "adequate notice."

15. Welfare and Institutions Code section 4710.5, subdivision (a), provides that a consumer or the consumer's representative who is dissatisfied with any decision or action of the service agency must file a request for a fair hearing within 30 days after notification of the decision or action complained of.

IRC'S MOTION TO DISMISS

16. On December 20, 2016, IRC sent claimant a Notice of Proposed Action and attached letter denying the request for funding of the vitamin cocktail. This was received by claimant's father on December 23, 2016. Claimant contends that IRC delayed making this decision for several months, and sent the denial notice when IRC knew that claimant's mother would be out of the country. However, there was no evidence that IRC failed to comply with Welfare and Institutions Code section 4710, subdivision (b), which requires IRC to send notice to claimant's representative within five days of its decision to deny a requested service. In two emails sent by Ms. Scott to claimant's mother in November 2016, Ms. Scott inquired with claimant's mother if she had reviewed the pharmacist's report and asked claimant's mother if Ms. Scott should forward the request for decision. On December 1, 2016, claimant's mother emailed Ms. Scott to express her disapproval of Dr. Kokari's report, which indicates her knowledge that IRC had not yet rendered a decision on the claim. There was no evidence that IRC was dilatory in rendering a decision or intentionally waited for claimant's mother to leave the country before issuing its decision.

17. Claimant failed to timely file a notice of appeal within 30 days of receipt of the decision. Although claimant's mother contends she was out of the country, the fact that she failed to make arrangements to be able to address any mail she received during

this time was not excusable neglect that would justify any equitable tolling. On these grounds, claimant's appeal should be dismissed.

However, claimant's mother also requested IRC re-issue its decision so that she could timely file a Fair Hearing Request. IRC presented her with two options in response: file a fair hearing request for the December 20, 2016, denial (which may be dismissed as untimely) or submit the February 2017 letter from Dr. Bauman, which IRC would consider, and then issue a new Notice of Action based on this new evidence. Although claimant elected to file a Fair Hearing Request challenging the original denial, she did submit the February 2017 letter to IRC for its consideration. Moreover, during the informal meeting in April 2017, IRC raised the issue of whether claimant had adequately exhausted his appeal rights challenging his health insurer and Medi-Cal's denial of coverage. Claimant subsequently submitted evidence that, at the very least, showed appeals to claimant's health insurer and Medi-Cal were pending, but futile.

Thus, some of the material submitted did not even exist at the time of the original denial in December 2016, and this new material was directly related to some of the reasons claimed by IRC as its basis for denial. Therefore, it is found that at least some of the submitted material must be considered "new" to the process; the fact that the material did not cause IRC to change its decision is of no importance in that regard. Because at least some of the material submitted by claimant's mother had not been previously reviewed by IRC, and because IRC had considered the material and informed claimant's mother that it would not be changing its original decision, claimant's appeal need not be dismissed for lack of timeliness. Instead, it may be considered as an appeal not from IRC's original decision to deny the service, but from its later decision affirming that denial based on the additional evidence. Accordingly, jurisdiction is established to proceed in this matter and IRC's motion to dismiss is denied.

EVALUATION OF CLAIMANT'S REQUEST

18. In denying claimant's request, IRC claimed that the funding request was not directed toward claimant's developmental disability. While true that the vitamin compound is being prescribed for treatment of suspected Mitochondrial Disease, and not autism spectrum disorder, the Lanterman Act requires that the services or support alleviate a developmental disability or be directed toward the physical habilitation of a person with a developmental disability. (Welf. & Inst. Code, § 4512, subd. (b).) Thus, so long as the services and supports alleviate developmental disability or assist in the habilitation of a person with a developmental disability, they fall within the ambit of the Lanterman Act.

19. IRC's claim that claimant did not exhaust all funding resources is not a bar for IRC to provide funding. Claimant did seek coverage from his health insurer and Medi-Cal, which it denied. Medi-Cal's policies clearly indicate that vitamins are not covered, regardless of any medical necessity. Thus, claimant does not have a prima facie basis to appeal Medi-Cal's decision, and because the appeal would be futile, IRC is not barred from purchasing medical services on this basis. (Welf. & Inst. Code, § 4659, subd. (d)(1).)

20. However, under the Lanterman Act, IRC "must adhere to federal and state laws and regulations" and must purchase services and supports pursuant to the purchase of service policies. (Welf. & Inst. Code, § 4646.4, subd. (a).) IRC is prohibited by law from purchasing experimental treatments, which include experimental medical or nutritional therapy when the use of the product for that purpose is not a general physician practice, which have not been clinically determined or scientifically proven to be effective or safe or for which risks and complications are unknown. (Welf. & Inst. Code, § 4648, subd. (a)(16).) This prescription is mirrored in IRC's purchase of service policies approved by the Department. Consequently, claimant has the burden of proving

that the vitamin regimen prescribed by his neurologist is not experimental and has been clinically or scientifically proven to be effective and safe.

In support of her position, claimant's mother offered a letter from claimant's prescribing physician, Dr. Bauman. Although Dr. Bauman contends that claimant's stamina, focus, and behavior have improved since taking the vitamin regimen, Dr. Bauman offered little in the way of evidence to establish that vitamins have been scientifically or clinically proven to be effective treatments for Mitochondrial Disease. Indeed, she relies on a single article that itself notes that few trials have been conducted and there is a lack of consensus as to which vitamins should be used. Whether or not the vitamin regimen is appropriate or beneficial for claimant is an issue solely between claimant and claimant's doctors. The efficacy of the vitamin regimen in treating claimant is not at issue; the issue is whether the use of the vitamin regimen is needed to alleviate the conditions of the developmental disability that renders claimant eligible for regional center services. Claimant did not present sufficient evidence to establish that the vitamin regimen is not experimental or has been clinically or scientifically proven to be effective for reasons that would render it an appropriate service or support eligible for purchase by a regional center under the Lanterman Act.

Claimant's mother's testimony was credible, heartfelt, and sincere. It is clear that she only wants the best treatment for her son, and she believes that the vitamin regimen has been effective in improving the quality of his life. However, for the reasons discussed above, IRC is simply not authorized under the Lanterman Act to fund this treatment.

ORDER

Claimant's appeal from IRC's determination that it will not fund the requested compounded vitamin regimen is denied.

DATED: February 9, 2018

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ADAM L. BERG

Administrative Law Judge

Office of Administrative Hearings

NOTICE

This is the final administrative decision. Both parties are bound by this decision. Either party may appeal this decision to a court of competent jurisdiction within ninety days.