BEFORE THE OFFICE OF STATE ADMINISTRATIVE HEARINGS STATE OF GEORGIA

JIMMY FREELS, a minor by and through DAVID FREELS, his father,

Petitioner,

ADMINISTA

DOCKET NUMBER: v.

OSAH-DCH-LOC-0615259-44-Teate

DEPARTMENT OF COMMUNITY

HEALTH.

Respondent.

INITIAL DECISION

I. Introduction

In response to adverse agency action on November 23, 2005, Petitioner requested a hearing that was held on June 15, 2006. The record remained open until July 31, 2006, for the parties to file written closing briefs, proposed findings of fact and conclusions of law, and responses thereto.2 For reasons indicated, Respondent's determination is REVERSED.

By joint stipulation and amendment of the proposed pre-hearing order that was filed on March 13, 2006, the pleadings, transcripts of hearings, and all other papers of record in the matter of Jimmy Freels v. Georgia Department of Community Health, Division of Medical Assistance, OSAH Docket No. OSAH-DMA-00-14208-44-KUS are fully incorporated into the present action by reference and may be used and relied upon by the judge or the parties in presentation and resolution of this matter. Such reference may be denoted hereinafter by "prior record."

II. Findings of Fact

- 1. The Petitioner is a qualified Medicaid recipient who is an eligible recipient under the age of 21 entitled to early and periodic screening, diagnostic, and treatment (EPSDT) services. He is afflicted with spastic quadriplegia, a condition of spasticity or stiffness of all four limbs that is one of the more severe forms of cerebral palsy (CP). This condition is a mid-brain injury causing deficits in speech and motor function. (Pre-hearing order Stipulation; Testimony of Petitioner's father regarding current age: Testimony of Dr. Miller regarding diagnosis).
- 2. Inasmuch as CP is not currently curable, the goal of typical treatment protocol for a child with CP is to maximize the child's potential for function. Typical therapies may include physical therapy,

² The original closure date was extended at the parties' request per order on June 30, 2006.

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Respondent received Petitioner's appeal on January 5, 2006, and the matter was referred to the Office of State Administrative Hearings (OSAH) on January 25, 2006. A hearing was initially scheduled for March 21, 2006, and then continued at the parties' request to June 15, 2006.

occupational therapy, speech therapy, medications such as baclofen or botox injections, adaptive orthopedic appliances and corrective orthopedic surgeries. (Testimony of Dr. Miller).

- 3. Hyperbaric Oxygen Therapy (HBOT) is a procedure that allows patients to breath one hundred percent oxygen while in a compressed air chamber. Although HBOT is routinely recognized and generally approved as a therapy in a number of medical conditions such as wounds, burns, and certain neurological, orthopedic and emergency conditions, there is controversy among professionals whether or not HBOT should be applied in the treatment of children with CP. Much of the controversy centers on the lack of double-blind studies on its efficacy in treating CP children. Such double-blind studies create a high degree of reliability in the medical profession; however, the practice of medicine does not consist entirely of treatments that result from double-blind studies. Clinical experience and "off label" uses of drugs and other treatments is not uncommon. Medications such as baclofen or botox injections are such "off label" uses in the treatment of CP. (Testimony of Dr. Carroll; Testimony of Dr. Berenson; Testimony of Dr. Miller; Testimony of Dr. Harch; Testimony of Dr. Marois; and Testimony of Dr. Uzler).
- 4. The Petitioner underwent 42 Hyperbaric Oxygen Therapy (HBOT) treatments between May 1999 and July 1999. SPECT-scan images were taken of the Petitioner's brain on May 14, 1999, immediately prior to his first HBOT treatment, and June 15, 1999, immediately following his twenty-first HBOT treatment to measure the difference in regional brain function. The SPECT-scans demonstrated a significant improvement in brain blood flow and metabolism. (Prior record).
- 5. Throughout, Petitioner's larger treatment protocol has included patterning, speech therapy, occupational therapy and physical therapy. However, Petitioner's father opines that the greatest improvement, "the biggest leap" occurred in his speech, language and cognition in May and June of 1999, after the first 42 HBOT treatments that he received. (Testimony of Petitioner's father).
- 6. Prior to the first request in 1999 and ongoing thereafter, the Petitioner has requested Medicaid reimbursement for Hyperbaric Oxygen Therapy (HBOT) to correct or ameliorate his spastic quadriplegia. In its last denial of this request under the legal standard enunciated by the superior court and affirmed by the Georgia Court of Appeals, Respondent has denied the Petitioner's request, citing as its rationale that "no tangible, verifiable evidence can be found showing that HBOT meets the 'correct or ameliorate' standard of 'early and periodic screening, diagnostic and treatment services' for cerebral palsy as set forth in 42 U.S.C. § 1396d(r)(5)."
- 7. Since the last adjudication in 2000, Petitioner continues to receive speech therapy, occupational therapy and physical therapy. Currently, such therapies, as well as daily assistance from a paraprofessional to assist him due to his very limited motor capabilities, are provided incident to his individualized educational plan (IEP). For three years, Petitioner has participated in swimming activities and for a couple of years he has participated in wheelchair football and wheelchair hockey. (Testimony of Petitioner's father).

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- 8. Subsequent to the last adjudication in 2000,³ Petitioner has presented new evidence to demonstrate that HBOT can, has, and continues to correct and ameliorate his CP and associated symptoms. (Testimony of Dr. Harch; Testimony of Dr. Uszler; and Testimony of Dr. Marois; Petitioner's Exhibits 1, 2, and 3).
- 9. The Petitioner underwent additional treatment from Dr. Paul Harch in 2004. Dr. Harch is an expert in Emergency Medicine and in hyperbaric medicine. The Petitioner underwent a SPECT-scan on April 5, 2004, received HBOT, then underwent another SPECT-scan on April 6, 2004. Dr. Harch testified concerning the results of this testing and treatment and concluded that the SPECT-scan showed improvement and the Petitioner showed immediate improvement in his clinical condition as he was very talkative, had reduced lower extremity spasticity, and improvement in right upper extremity function. Dr. Harch also concluded that since a single HBOT treatment favorably changed brain blood flow and metabolism, the Petitioner would benefit from additional HBOT. (Testimony of Dr. Harch).
- 10. The Petitioner presented evidence from Dr. Michael Uszler, a physician Board Certified in Nuclear Medicine, with 23 years experience reading and reviewing SPECT-scan images. Dr. Uszler testified that SPECT-scan images demonstrate regional brain function, and changes in regional brain function. Dr. Uszler testified SPECT-scans demonstrate improved regional brain function with medical therapies, including HBOT. The test can be used for evaluating changes in regional brain function before and after a course of therapy. Dr. Uszler reviewed the two SPECT-scan images from 1999 and observed a correction and amelioration of regional brain function from the first to the second scan. Dr. Uszler reviewed the two SPECT-scan images from 2004 and concluded there was correction and amelioration of regional brain function from the first to the second scan. (Testimony of Dr. Uszler).
- 11. Respondent presented evidence from Dr. Gary Miller, who testified that until performing a literature review on HBOT following the Respondent's denial, he had not performed any significant research into the use of HBOT for pediatric CP patients. Dr. Miller relied on an Agency for Healthcare Research and Quality (AHRQ) literature review, based heavily on a report called the "Collet Study." Dr. Miller concluded from his review of this literature that there was no proof of the efficacy of HBOT for the treatment of pediatric CP patients. Dr. Miller's testimony was consistent and did not differ substantially in substance from that of Drs. Carroll and Berenson in the prior proceeding. All three of Respondent's witnesses view the matter from the perspective of child neurologists. (Testimony of Dr. Miller; prior testimony of Drs. Carroll and Benson).
- 12. In rebuttal to this testimony, Petitioner introduced evidence from Dr. Pierre Marois, a physician specializing in pediatric Physical Medicine and Rehabilitation who has more than 50,000 consultations in CP and actively follows more than 1,500 children with that diagnosis. Dr. Marois is

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³ In the adjudication over similar issues in 2000, the administrative law judge concluded that the Petitioner could only offer non-conclusive speculation by his medical expert that increased blood flow resulting from HBOT treatments has improved his function and that the evidence was inconclusive to demonstrate observed improved function was attributable to HBOT,

⁴ AHRQ is a division of the United States Department of Health and Human Services.

one of the authors of the Collet Study. Dr. Marois concluded the study demonstrated that all individuals who received HBOT in the study experienced statistically significant improvement measured by objective means and that the data demonstrated that HBOT corrects and ameliorates the underlying condition causing CP. (Testimony of Dr. Marois).

13. The Petitioner is now enrolled in public school, in regular classes, and actively involved in extracurricular activities. The Petitioner has experienced functional improvement and his father opines that he needs additional HBOT in addition to his routine therapies. (Testimony of Petitioner's father).

III. Conclusions of Law

- 1. "Medicaid is a state-administered program to provide payment for medical services to clients of certain public assistance programs and other needy individuals at the state's option." ABC Home Health Services, Inc. v. Georgia Department of Medical Assistance, 211 Ga.App. 461 (1993). The Medicaid program is governed by a federal statute and federal regulations. See 42 U.S.C. § 1396a and 42 C.F.R. §§ 435.110 to 435.340. The federal government has established "state plan" requirements defining the parameters within which the states may administer the program. 42 U.S.C. § 1396 (a).
- 2. The legal standard in this case is governed by Georgia Department of Community Health v. Freels, 258 Ga. App. 446, 576 S.E.2d 2 (2002) and the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) provisions of the Medicaid Statute, codified at 42 U.S.C. §§ 1396d(a) & 1396d(r)(1-5). Section 1396d(a)(4)(B) requires participating states to provide EPSDT services to Medicaid eligible recipients under the age of 21. Section 1396d(r)(1-5) lists the services States must provide as part of their responsibility under the Medicaid program. Included is § 1396d(r)(5) which mandates that States participating in the Medicaid program include "[s]uch other necessary health care, diagnostic services, treatment and other measures described in subsection (a) of this section to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services, whether or not such services are covered under the State plan." (Emphasis added).
- 3. In considering relevant Medicaid law, the Georgia Court of Appeals stated that "instead of requiring proof that HBOT is the accepted standard medical practice, or that it meets the definition of medical necessity reserved for adult Medicaid recipients, the [Department] should have focused its inquiry on whether HBOT was necessary to correct or ameliorate [the Petitioner's] physical condition." Georgia Department of Community Health v. Freels, 258 Ga.App. at 450.⁵ Merriam-

⁵ After a prior adverse Initial Decision subsequently became Respondent's final decision, Petitioner appealed or
February 28, 2001 to the Superior Court of DeKalb County, Georgia in Jimmy Freels v. Georgia Department of
Community Health, Civil Action File No. 2001CV32734. That Superior Court reversed the Final Decision inasmuch as
the Department applied the wrong legal standard by focusing on whether HBOT was an accepted treatment that was
medically necessary. According to the superior court, the proper inquiry was whether HBOT was necessary "to correct or
ameliorate a physical or mental defect or condition" regardless of whether it is an accepted medical practice. Respondent
appealed the superior court ruling to the Georgia Court of Appeals in Georgia Department of Community Health Health

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Webster Online Dictionary indicates that "ameliorate" as a verb in it its transitive form denotes "to make better or more tolerable" and that in its intransitive form it denotes "to grow better," with a synonym word being "improve."

- 4. The burden of proof in matters of public assistance is routinely upon the applicant for matters involving applications for benefits and is routinely upon the agency for matters involving agency action reducing, suspending, or terminating a benefit. Ga. Comp. R. & Regs., r. 616-1-2-.07(1)(d) (2004). In the case at hand, Petitioner is a recipient of public assistance whose request for specified services has been denied. As such, the denial may be alternatively viewed as an application for a benefit or a suspension of a service that would otherwise be provided. Even so, and assuming that the matter could be clearly resolved as either an application for benefits or as a reduction, suspension or termination of such benefits, the ALJ is authorized to place the burden on either party as the law or justice requires. In the interest of justice, the ALJ made a clear election to place the burden on Respondent and communicated such intention to the parties without objection. Ga. Comp. R. & Regs., r. 616-1-2-.07(2) (2004). With the prior record evidence and with the new testimony of Dr. Miller, Respondent met its initial burden of proof shifting the burden to Petitioner to rebut Respondent's prima facie case. Petitioner met this burden of rebuttal with credible testimony from Dr. Marois, Dr. Uszler and new testimony from Dr. Harch.
- 5. As in most civil matters, the standard of proof is a preponderance of the evidence. See Ga. Comp. R. & Regs., r. 616-1-2-.(4) (2004). Three child neurologist supported Respondent's position. A specialist in pediatric Physical Medicine and Rehabilitation, a specialist in emergency medicine and HBOT, and a specialist in Nuclear Medicine supported Petitioner's side. Weighing the evidence presented, Petitioner's arguments are more cross-disciplinary and persuasive than those presented by Respondent. Given that the standard is "corrective or ameliorative," there is a preponderance of the evidence that the HBOT treatments were necessary to correct or ameliorate Petitioner's physical condition.

Decision

Respondent's denial of Petitioner's request for reimbursement of HBOT treatment is REVERSED and the Respondent is hereby ORDERED to honor the Petitioner's request for reimbursement for HBOT.

SO ORDERED, this 9th day of August 2006.

Steven/W. Teate

Administrative Law Judge

258 Ga. App. 446 (2002) that affirmed the superior court decision to the extent that it was affected by error of law and reversed to the extent the superior court had rejected testimony from Dr. Carroll and Dr. Berenson, two of Respondent's witnesses. The Georgia Court of Appeals remanded the matter for subsequent review under the standard articulated. Incident to such a review, Respondent again denied Petitioner's claim on November 23, 2005, and Petitioner filed the current appeal.

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