UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 11-20684-CIV-LENARD/O'SULLIVAN

K.G., by and through his next friend, ILIANA GARRIDO, I.D., by and through his next friend, NILDA RIVERA, and C.C., by and through his next friend, RACHELLE CRAWFORD,

Plaintiffs,

v.

ELIZABETH DUDEK, in her official capacity as Secretary, Florida Agency for Health Care Administration,

Defendant.
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AMENDED PERMANENT INJUNCTION ORDER

THIS CAUSE is before the Court following a four-day bench trial. Plaintiffs K.G., I.D., and C.C., by and through their next friends, Iliana Garrido, Nilda Rivera, and Rachelle Crawford, respectively, brought suit against Defendant Elizabeth Dudek, in her official capacity as Secretary, Florida Agency for Health Care Administration ("AHCA" or "the Agency"). Plaintiffs seek, inter alia, a permanent injunction ensuring that Medicaid-eligible minors under the age of 21 in Florida who have been diagnosed with autism or Autism Spectrum Disorder ("ASD") receive Medicaid coverage for medically necessary behavioral

health services, including Applied Behavioral Analysis ("ABA").[1] (See First Am. Compl., D.E. 63, at 11-12.) Florida's Medicaid program does not cover ABA or any community behavioral health services to treat autism or ASD. See FLA. ADMIN. CODE ANN. r. 59G-4.050 (incorporating by reference The Florida Medicaid Community Behavioral Health Services Coverage and Limitations Handbook); see also The Florida Medicaid Community Behavioral Health Services Coverage and Limitations Handbook Rule 2-1-4, D.E. 63-1, at Exhibit A (stating that "Medicaid does not pay for community behavioral health services for treatment of autism").[2] Plaintiffs argue that Defendant's rule regarding behavioral health services violates the federal Medicaid Act that requires certain services be provided to Medicaid recipients under the age of 21 and violates the federal Medicaid Act's comparability requirement. Defendant argues that the Medicaid Act does not require states to cover ABA because ABA is not a "rehabilitative service[] . . . for the maximum reduction of physical or

[1]Although Plaintiffs requested in their First Amended Complaint that the injunctive relief apply to all "medically necessary behavioral health services," the evidence and argument at trial focused only on ABA. Therefore, this injunction applies only to ABA.

[2]The "Service Exclusions" section in Rule 2-1-4 states as follows:

> Medicaid does not pay for community behavioral health services for treatment of autism, pervasive developmental delay, non-emotional or non-behavioral based developmental disability, or mental retardation.
>
> Services are not considered to be medically reasonable when the recipient has an organic brain disorder (dementia or delirium) or other psychiatric or neurological conditions that have produced a cognitive deficit severe enough to prohibit benefit to the recipient.

The Florida Medicaid Community Behavioral Health Services Coverage and Limitations Handbook, Rule 2-1-4.

mental disability and restoration of an individual to the best possible functional level." See 42 U.S.C. § 1396d(a)(13). Defendant further argues that even if ABA could be covered under § 1396d(a)(13), the State of Florida still is not required to cover ABA under its Medicaid plan because AHCA has reasonably determined that ABA is experimental and not medically necessary for children with autism and ASD. Finally, Defendant argues that the process AHCA used to determine that ABA is experimental was not arbitrary and capricious.

Plaintiff K.G. filed his Complaint on February 28, 2011. (D.E. 1.) On March 10, 2011, Plaintiff K.G. filed his First Amended Motion for Preliminary Injunction. (D.E. 10.) Magistrate Judge John J. O'Sullivan held a hearing on the motion July 18, 2011 (see D.E. 36, 44, 57) and issued a report recommending the Court grant the motion (D.E. 45). On November 1, 2011, the Court adopted the Report and Recommendation of Magistrate Judge O'Sullivan and directed Defendant to "provide Medicaid coverage for K.G.'s ABA therapy as prescribed by his treating physician." (Preliminary Injunction Order, D.E. 74.) The Court denied Defendant's motion for reconsideration (D.E. 82) of the Court's Preliminary Injunction Order on February 10, 2012 (D.E. 97).

On September 12, 2011, Plaintiff K.G. filed his First Amended Complaint, in which I.D. and C.C. were added as Plaintiffs. (D.E. 63.) Because I.D. and C.C. were added as Plaintiffs after Plaintiff K.G. filed his motion for a preliminary injunction and the Magistrate Judge issued his Report and Recommendation on Plaintiff K.G.'s motion, Plaintiffs I.D. and C.C. were not included in the Court's Preliminary Injunction Order.

On October 21, 2011, the Parties cross-moved for summary judgment. (D.E. 70, 72.) The Court denied the Parties' motions on March 7, 2012, concluding that "because the question of whether the Agency was reasonable in its determination that ABA is experimental is a fact-intensive inquiry, and because material issues of fact exist regarding the efficacy of ABA and whether ABA is medically necessary, summary judgment must be denied." (D.E. 105.)

The Court held a bench trial from March 20 through March 23, 2012. At trial, Plaintiffs called the following fact witnesses: Iliana Garrido, Plaintiff K.G.'s mother; Alexander Lorenzo, ABA provider to Plaintiff K.G.; and Dr. Roberto Lopez Alberola, Division Chief of Pediatric Neurology at Jackson Memorial Hospital in Miami, Florida, Associate Professor at the University of Miami Miller School of Medicine, and Plaintiff C.C.'s treating neurologist. Plaintiffs presented the transcripts of the deposition testimony for three additional fact witnesses: Michael Bolin, AHCA administrator in the Bureau of Medicaid Services; Darcy Abbot, AHCA administrator in the Bureau of Medicaid Services; and Karen Chang, Senior Management Analyst Supervisor for AHCA. In addition, Plaintiffs called three expert witnesses: Dr. Elza Vasconcellos, Director of the Autism Clinic, the Headache Center and Co-Director of the Neurogenetics Clinic at the Miami Children's Hospital in Miami, Florida, and the treating neurologist for Plaintiffs K.G. and I.D.; Dr. James Mulick, Professor in both the Department of Psychology and in the Department of Pediatrics at Ohio State University and a psychologist at The Children's Hospital in

Columbus, Ohio;[3] and Dr. Jon Bailey, Professor Emeritus in the Department of Psychology at Florida State University and former editor of the Journal of Applied Behavior Analysis.

Defendant called Elizabeth Kidder, the AHCA Deputy Secretary for Medicaid, as the agency representative for AHCA. In addition, Defendant presented videotaped deposition testimony of its two expert witnesses: Dr. Robert Moon, the Chief Medical Officer and Deputy Commissioner Health Systems of the Alabama Medicaid Agency, and Dr. Alison Little, Evidence and Policy Advisor for the Center of Evidence-based Policy at Oregon Health and Science University.[4]

To obtain a permanent injunction, Plaintiffs must show by a preponderance of the evidence the following four factors: "(1) that [they have] prevailed in establishing the violation of the right asserted in his complaint; (2) there is no adequate remedy at law for the violation of this right; (3) irreparable harm will result if the court does not order injunctive relief; and (4) if issued, the injunction would not be adverse to the public interest." Thomas v. Bryant, 614 F.3d 1288, 1317 (11th Cir. 2010); eBay Inc. v. MercExchange, L.L.C., 547

[3]Dr. Mulick specializes in early childhood, developmental disabilities, behavioral assessment of drug action and habit disorders.

[4]Defendant's expert disclosures in this case were due by August 15, 2011. (D.E. 30.) On August 11, 2011, the Court granted Defendant's motion for an extension of time to comply with this deadline and provided Defendant until August 29, 2011 to furnish Plaintiffs with an expert witness list and summaries. (D.E. 56.) Defendant did not provide any expert witness lists or summaries to Plaintiffs within this deadline. On December 2, 2011, Defendant filed a motion to disclose expert witnesses out of time and extend the deadline for expert discovery. (D.E. 83.) Over Plaintiffs' objections, the Court granted Defendant's motion on February 10, 2012. (D.E. 96.)

U.S. 388, 391 (2006); Sheely v. MRI Radiology Network, P.A., 505 F.3d 1173, 1182 n.10 (11th Cir. 2007) (stating that "[w]hether a permanent injunction is appropriate . . . turns on whether the plaintiff can establish by a preponderance of the evidence that this form of equitable relief is necessary").

Based on the following facts that were established at trial through testimony and exhibits and facts that were stipulated by the Parties in their Amended Joint Pretrial Stipulation (D.E. 98-1), and based on the following conclusions of law, the Court finds that a permanent injunction shall be issued for the following reasons:[5]

The State of Florida has chosen to participate in the federal Medicaid program and therefore "must comply with federal statutory and regulatory requirements." Moore ex rel. Moore v. Reese, 637 F.3d 1220, 1232 (11th Cir. 2011). Under the federal Medicaid act, states must provide "early and periodic screening, diagnostic, and treatment services" ("EPSDT") for Medicaid-eligible children under the age of 21. 42 U.S.C. § 1396a(a)(10)(A); 42 U.S.C. § 1396d(a)(4)(B).

K.G., I.D., and C.C. are minors under the age of 21 who, due to their disabling conditions and their parents' income levels, are Florida Medicaid recipients. During EPSDT screens,[6] K.G., I.D., and C.C. were all diagnosed with autism or Autism Spectrum Disorder

[5]The Court also incorporates all the factual findings and conclusions of law that the Court stated orally following trial on March 23, 2012 into this Permanent Injunction Order.

[6]EPSDT screens include any visit to a physician (including family-initiated visits) to determine if the child has a condition requiring further assessment, diagnosis or treatment. (Memorandum from Christine Nye, Director, federal Health Care Financing Administration

("ASD") and were all prescribed ABA by their treating neurologists. Autistic disorder, the full-blown condition, is one of five disorders falling under the umbrella of Autism Spectrum Disorder.[7] Autism is a complex neurodevelopmental disability that generally appears during the first three years of life and impacts the normal development of the brain, resulting in impairments of social interaction, verbal and non-verbal communication, leisure or play activities, and learning.[8] [9] ABA is a type of early intensive behavioral interaction ("EIBI")

Medicaid Bureau (Apr. 12, 1991), D.E. 21-5.)

[7]There is a movement away from using the term "autism" in and of itself to using the term "autistic spectrum disorder" which includes Pervasive Developmental Disorder ("PDD"). Autism and ASD are listed in the American Psychiatric Association's Diagnostic and Statistical Manual IV ("DSM-IV"), and the International Classification of Diseases ("ICD"). The DSM-IV, which is currently the valid classification system for diagnosis, lists Pervasive Developmental Disorder and the five subcategories including autism. The DSM V, unless it changes prior to its final adoption, will have only the term Autism Spectrum Disorder ("ASD"), and it will subsume all the subtypes listed under PDD. (Am. Joint Pretrial Stipulation, D.E. 98-1, at page 6, ¶¶ 28-32.)

[8]Federal regulations state the following as a definition for autism:

> Autism means a developmental disability significantly affecting verbal and nonverbal communication and social interaction, generally evident before age three, that adversely affects a child's educational performance. Other characteristics often associated with autism are engagement in repetitive activities and stereotyped movements, resistence to environmental change or change in daily routines, and unusual responses to sensory experiences.

34 C.F.R. § 300.8(c)(1)(i).

[9]The Parties stipulated that Plaintiffs K.G., I.D., and C.C. developed normally as infants, but their behavior changed as they became toddlers. K.G. "began exhibiting aggressive, antisocial behaviors, lost all previously acquired vocabulary, and stopped eating solid table food." I.D. "began exhibiting odd behaviors such as screaming, not playing with others, and sensitivity to loud noises." C.C. "stopped socializing and being affectionate with family, became aggressive, walked on his toes, had tantrums, did not cope well with new environments, and developed sensitivity to loud noises." (See Am. Joint Pretrial Stipulation, D.E. 98-1, at pages 4-

health service that uses a structured one-on-one program to treat the behavioral problems associated with autism and ASD.[10]

Because Plaintiffs' conditions were discovered during EPSDT screens, the State of Florida is required to provide the children with any service described in 42 U.S.C. § 1396d(a) that is necessary to correct or ameliorate the children's conditions, whether or not the service is covered for adults under the State's Medicaid plan. 42 U.S.C. § 1396d(r)(5)[11]; Moore, 637 F.3d at 1233-34; Smith v. Benson, 703 F. Supp. 2d 1262, 1269 (S.D. Fla. 2010); Rosie D.

5, ¶¶ 8-22.)

In the Court's Preliminary Injunction Order, the Court ordered Defendant to provide Medicaid coverage for K.G.'s ABA therapy, as prescribed by his treating physician. Iliana Garrido, K.G.'s mother, testified that K.G. started receiving 15 hours per week of ABA therapy in February 2012. Before K.G. received ABA therapy, his behavioral problems included "outbursts, extreme aggression, kicking, hitting, throwing objects, hurting himself by banging his head against the wall, biting and scratching himself, poor eye contact, extreme irritability, hyperactivity, incessant screaming, frequent tantrums, and isolating himself from others." (Am. Joint Pretrial Stipulation, at page 4, ¶ 11.) After only one month of ABA therapy, Garrido testified that K.G. "has changed very much." K.G. is "smiling," "sleep[ing] better," and "being less aggressive" and "more sociable." Garrido also testified that K.G. is "learning how to communicate" and that he "says hello to people" and "can say words and sentences." Alexander Lorenzo, K.G.'s ABA provider, testified that he "has seen significant progress since the initial assessment." In particular, Lorenzo testified that K.G. "is able to provide better eye contact, "is able to follow instructions in different situations," "is labeling items in his environment," and is "engaging in minimal but more than before conversation with his therapist and his mother."

[10]This definition was stipulated to by the Parties in their Amended Joint Pretrial Stipulation, Docket Entry 98-1. Dr. Bailey testified that ABA is also called Intensive Behavioral Intervention ("IBI") therapy or the Lovaas method.

[11]This EPSDT mandate requires the State to provide to Medicaid-eligible minors "[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." 42 U.S.C. § 1396d(r)(5) (emphasis added).

v. Romney, 410 F. Supp. 2d 18, 26 (D. Mass. 2006). Thus, in determining if AHCA's decision not to cover ABA for children with autism and ASD violates the EPSDT provisions in the Medicaid Act, this statutory framework presents two questions: (1) is ABA among those services which can be covered under 42 U.S.C. § 1396d(a), and (2) is ABA necessary to correct or ameliorate an illness or condition for a Medicaid recipient under age 21?

ABA falls within the scope of 42 U.S.C. § 1396d(a)(13).[12] The services under this provision are as follows:

> other diagnostic, screening, preventive, and rehabilitative services, including any medical or remedial services (provided in a facility, a home, or other setting) recommended by a physician or other licensed practitioner of the healing arts within the scope of their practice under State law, for the maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level[.]

42 U.S.C. § 1396d(a)(13) (emphasis added). Federal regulations define "rehabilitative services" as:

> any medical or remedial services recommended by a physician or other licensed practitioner of the healing arts, within the scope of his practice under State law, for maximum reduction of physical or mental disability and restoration of a recipient to his best possible functional level.

42 C.F.R. § 440.130(d) (emphasis added). Plaintiffs have established beyond all doubt

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[12]In the alternative, ABA may fall within the scope of 42 U.S.C. § 1396d(a)(6). The services under this provision are "medical care, or any other type of remedial care recognized under State law, furnished by licensed practitioners within the scope of their practice as defined by State law." 42 U.S.C. § 1396d(a)(6). Plaintiffs' experts Dr. Elza Vasconcellos, Dr. James Mulick, and Dr. Jon Bailey all testified that ABA is a medical service. Dr. Bailey testified that Florida law does not require ABA practitioners to be licensed, but that ABA practitioners are certified by an independent nonprofit organization called the Behavioral Analyst Certification Board. See FLA. ADMIN. CODE R. 65G-4.003 (describing certification as a behavior analyst).

through testimony and exhibits at trial that ABA is necessary to restore children with autism or ASD to the normal trajectory of development that all children have through the first twelve years of life. Dr. Mulick testified as follows:

> The rate of connections in the human brain accelerates from birth to about age 6, continues to increase as children reach about the age of 12, remains at a high level. . . . And that is why certain kinds of learning establishing the neural network, if they don't occur early in life, they're simply not going to occur or not going to occur easily.

Dr. Mulick further testified that the purpose of ABA is to restore autistic children to their normal rate of development. Dr. Lopez Alberola testified that ABA restores autistic children's functional capacity to "develop normally and continue in the normal pattern of human development." Dr. Vasconcellos testified that ABA restores children to their normal potential by "restor[ing] them back to the curve of the developmental milestones that they had before the autism started[,] . . . similar as what you expect for normal development in childhood." As to the Plaintiffs in this case, Dr. Lopez Alberola, C.C.'s treating neurologist, and Dr. Vasconcellos, K.G. and I.D.'s treating neurologist, clearly established that ABA would restore K.G., I.D., and C.C. to their best possible functional levels. Other courts have interpreted 42 U.S.C. § 1396d(a)(13) to mean that "if a licensed clinician finds a particular service to be medically necessary to help a child improve his or her functional level, this service must be paid for by a state's Medicaid plan pursuant to the EPSDT mandate." Parents League for Effective Autism Servs. v. Jones-Kelley, 565 F. Supp. 2d 905, 915 (S.D. Ohio 2008), aff'd, 339 F. App'x 542, 544 (6th Cir. 2009); Rosie D., 410 F. Supp. 2d at 26;

see also Collins v. Hamilton, 349 F.3d 371, 375 (7th Cir. 2003); John B. ex rel. L.A. v. Menke, 176 F. Supp. 2d 786, 800 (M.D. Tenn. 2001); Pediatric Specialty Care, Inc. v. Ark. Dep't of Health & Human Servs., 293 F.3d 472, 480-81 (8th Cir. 2002).

Although the EPSDT statutory provision uses the term "necessary," the Medicaid Act does not define the term. See generally 42 U.S.C. § 1396d. Instead, the Medicaid Act and its implementing regulations grant states the authority to set reasonable standards for the terms "necessary" and "medical necessity." See 42 U.S.C. § 1396a(a)(17); 42 C.F.R. § 440.230(d); see also Rush v. Parham, 625 F.2d 1150, 1154-55 (5th Cir. 1980).[13] States are not required to pay for services that are not medically necessary. See Rush, 625 F.2d at 1155. "'Experimental forms of treatment, i.e., treatment not generally recognized as effective in the medical community'" is "an example of a service the state is not required to pay for because it is not medically necessary." Moore, 637 F.3d at 1248 n.48 (quoting Rush, 625 F.2d at 1154-55). However, "a 'state may not arbitrarily deny or reduce the amount, duration, or scope of a required service . . . solely because of the diagnosis, type of illness, or condition.'" Rush, 625 F.2d at 1157 n.12 (quoting 42 C.F.R. § 440.230(c)(1)).[14]

ABA is "medically necessary" and is not "experimental" as defined under Florida administrative law and federal law. See FLA. ADMIN. CODE ANN. r. 59G-1.010(166)(a)3

[13]In Bonner v. City of Prichard, 661 F.2d 1206, 1209 (11th Cir. 1981), the Eleventh Circuit adopted as binding precedent all decisions handed down by the former Fifth Circuit before October 1, 1981.

[14]This provision will be further discussed in the Court's forthcoming order on the declaratory judgment.

(defining "medical necessity")[15]; FLA. ADMIN. CODE ANN. r. 59G-1.010(84)(a)3 (defining "experimental" and "reliable evidence")[16]; Rush, 625 F.2d 1154-58 (setting forth guidelines

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[15]The definition for "medically necessary" states in its entirety:

> (166) "Medically necessary" or "medical necessity" means that the medical or allied care, goods, or services furnished or ordered must:
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> (a) Meet the following conditions:
>
> 1. Be necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain;
>
> 2. Be individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the patient's needs;
>
> 3. Be consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational;
>
> 4. Be reflective of the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available; statewide; and
>
> 5. Be furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.
>
> (b) "Medically necessary" or "medical necessity" for inpatient hospital services requires that those services furnished in a hospital on an inpatient basis could not, consistent with the provisions of appropriate medical care, be effectively furnished more economically on an outpatient basis or in an inpatient facility of a different type.
>
> (c) The fact that a provider has prescribed, recommended, or approved medical or allied care, goods, or services does not, in itself, make such care, goods or services medically necessary or a medical necessity or a covered service.

FLA. ADMIN. CODE ANN. r. 59G-1.010(166).

[16]The State's complete definitions of "experimental" and "reliable evidence" are as follows:

for determining whether a treatment is "experimental")[17]; Moore, 637 F.3d at 1248 n.48.

> (84) "Experimental" or "Experimental and clinically unproven" or "Investigational" as related to drugs, devices, medical treatments or procedures means:
>
> (a)1. The drug or device cannot be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and approval for marketing has not been given at the time the drug or device is furnished; or
>
> 2. Reliable evidence shows that the drug, device or medical treatment or procedure is the subject of on-going phase I, II, or III clinical trials or under study to determine its maximum tolerated dose, its toxicity, its safety, its efficacy, or its efficacy as compared with the standard means of treatment or diagnosis; or
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> 3. Reliable evidence shows that the consensus among experts regarding the drug, device, or medical treatment or procedure is that further studies or clinical trials are necessary to determine its maximum tolerated dose, toxicity, safety, or efficacy as compared with the standard means of treatment or diagnosis.
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> 4. The drug or device is used for a purpose that is not approved by the FDA.
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> (b) Reliable evidence shall mean only published reports and articles in the authoritative medical and scientific literature; the written protocol or protocols used by the treating facility or the protocol(s) of another facility studying substantially the same drug, device or medical treatment or procedure; or the written informed consent used by the treating facility or by another facility studying substantially the same drug, device or medical treatment or procedure.

FLA. ADMIN. CODE ANN. r. 59G-1.010(84).

[17]The former Fifth Circuit defined "experimental treatment" as "treatment not generally recognized as effective by the medical profession." Rush, 625 F.2d at 1155. In addition, the Court set forth the following guidelines for determining whether a medical service is "experimental":

> The clearest articulation of the considerations that go into determining whether a particular service is experimental is found in a letter Medicare uses to explain to its clients why a service is ineligible for reimbursement:
>
> In making such a decision (whether to provide payment for a particular service), a basic consideration is whether the service has come to be generally accepted by

The role of the Court is to decide whether AHCA's determination that ABA is experimental was reasonable. See Rush, 625 F.2d at 1157 (remanding to the district court to decide "whether [the state's] determination that transsexual surgery is experimental is reasonable"); see also Miller v. Whitburn, 10 F.3d 1315, 1321 (7th Cir. 1993) (stating that "the district court may decide only whether [the state's] determination that the liver-bowel transplant procedure is experimental is reasonable" (citing Rush, 625 F.2d at 1157)).

Based on the testimony and exhibits at trial, the Court finds that the determination by AHCA that ABA is experimental was arbitrary, capricious, and unreasonable both in its process and in its conclusion. Elizabeth Kidder, the AHCA Deputy Secretary for Medicaid, testified that AHCA has a standard process for determining whether a certain treatment or service should be covered under the State's Medicaid plan, and that AHCA did not follow this standard process when determining not to cover ABA. Kidder testified that AHCA's standard practice involves assigning a treatment to an analyst and a registered nurse to research the treatment, and the analyst and nurse review published, peer-reviewed literature on the treatment, as well as whether other entities are covering the service (e.g., other state

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> the professional medical community as an effective and proven treatment for the condition for which it is being used. If it is, Medicare may make payment. On the other hand, if the service or treatment is not yet generally accepted, is rarely used, novel or relatively unknown, then authoritative evidence must be obtained that it is safe and effective before Medicaid may make payment.

Id. at 1156 n.11 (quoting Enclosure # 2 to Intermediary Letters Nos. 77-4 & 77-5, (1976 Transfer Binder) Medicare & Medicaid Guide (CCH) P 28,152 (1976)) (emphasis added).

Medicaid programs,[18] Medicare, and commercial insurance plans[19]). In addition, Michael Bolin, an AHCA employee, testified that as part of its standard practice AHCA "routinely" consults with physicians for a "clinical evaluation of the data." After the analyst and nurse have finished this research, the analyst puts their findings in a memorandum that is reviewed by four to five levels of administrators up the chain of command before being adopted by the Agency. Kidder testified that this standard practice was in place when AHCA decided that ABA was experimental, but ABA did not go through this process. Instead, after Plaintiff K.G. filed the Complaint in this Court on February 28, 2011, Roberta Bradford, the then AHCA Deputy Secretary for Medicaid, determined that ABA was experimental by reviewing the following material: a meta-analysis[20] by Spreckley and Boyd published in the Journal of Pediatrics, a meta-analysis by Ospina published in PloS ONE, and the TEC Report. The TEC Report was funded by Blue Cross and Blue Shield Association, a federation of 38 health insurance organizations and companies in the United States, and Kaiser Permanente, a

[18]Defendant's expert witness, Dr. Robert Moon, who is the Chief Medical Officer and Deputy Commissioner Health Systems of the Alabama Medicaid Agency, stated that he "may know of a few [state Medicaid programs] that do [cover ABA]."

[19]The Court notes that commercial health insurance plans and health maintenance organizations in Florida are required to provide coverage of ABA to children under the age of eighteen who are diagnosed with Autism Spectrum Disorder. FLA. STAT. §§ 627.6686, 641.31098.

[20]Dr. Bailey testified that a meta-analysis is "a very sophisticated statistical approach," where the researchers look at many studies and "compare individual subject data in one study with a bunch of other studies that may have collected similar but not exactly the same data." Dr. Bailey further testified that meta-analysis is considered "the state of the art" that is "above a simple review of the data" because "a review is simply an analysis by one or more authors of their opinions of the status of the research, whereas meta-analysis is quantitative."

nonprofit health plan service.[21] This material was provided to Bradford by AHCA's legal counsel. No analyst and/or nurse in AHCA was assigned to research ABA, no analyst ever reviewed any "published reports and articles in the authoritative medical and scientific literature" about ABA, and no memorandum regarding ABA was ever prepared by an analyst and reviewed by the four to five levels of management in AHCA. See FLA. ADMIN. CODE ANN. r. 59G-1.010(84)(b) (defining "reliable evidence"). No one in AHCA reviewed whether ABA was covered by other states' Medicaid programs, Medicare, or commercial insurance plans. No one in AHCA consulted with a physician about ABA. After reviewing only these three reports, Bradford alone determined that ABA is experimental.

Kidder replaced Bradford in August 2011. The week before her deposition in this case, Kidder asked for the file of materials that Bradford reviewed in making her determination that ABA is experimental. Kidder testified that she wanted to see if she could "replicate [Bradford's] conclusion" by using the materials Bradford used. In addition to the Spreckley and Boyd meta-analysis, Ospina meta-analysis, and TEC Report, Kidder reviewed

[21]Blue Cross Blue Shield Association founded the Technology Evaluation Center ("TEC"), which produces assessments for their clients. The descriptions of Blue Cross Blue Shield Association and Kaiser Permanente were found on their respective websites.

the Hayes Report[22] and the AHRQ Report, also referred to as the Warren study.[23] Kidder

[22]As set forth in the Parties' Amended Joint Pretrial Stipulation, Hayes, Inc. ("Hayes") is a for-profit health technology assessment company. AHCA pays $60,949.00 per year to Hayes for access to Hayes' database of health technology assessments. Dr. Bailey testified that the Hayes assessments "appear to be available only to organizations that subscribe to them" and are "not in the public domain." The assessments contain the following disclaimer on each page: "This report is intended to provide research assistance and general information only. It is not intended to be used as the sole basis for determining coverage policy."

The Hayes assessments involve reviews of published literature on a given service, but as Dr. Alison Little, Defendant's expert, testified, the Hayes assessments are not original research. Dr. Bailey testified that Hayes "create[s] categories of studies and then summarize[s] the findings and then critique[s] the methodology," which is "quite different" from a "systematic meta-analysis" which involves "looking at the methodology and actually making comparisons from one article to the other."

The assessments also include an evaluation by Hayes of the evidence in the form of a "Hayes Rating" – a grade of A, B, C, D1, or D2. Dr. Bailey testified that this rating system seemed "subjective" because Hayes does not state a rubric for its rating system. Dr. Bailey contrasted the Hayes rating system to the rating system used by the Oxford Centre for Evidence-Based Medicine, which Dr. Bailey testified is well-established, international, and quantitative. Dr. Bailey further testified that in contrast to Hayes, the Oxford Centre specifies why a treatment receives a certain rating.

Hayes assessed ABA in its report titled Intensive Behavioral Intervention Therapy for Autism (the "Hayes Report") and gave ABA a Hayes rating of "C," indicating "potential but unproven benefit." Dr. Bailey testified that he was "amazed" that ABA received a "C" rating because ABA is "described as being the therapy of choice." Dr. Little also agreed that most of the underlying studies in the Hayes Report found improvement in children treated with ABA as compared with other treatments, and that the Hayes Report did not cite to any study that concluded that ABA was ineffective or experimental.

With regard to Hayes' review of the literature, Dr. Little agreed that Hayes did not review every study on ABA that had been done over the past forty to fifty years. In particular, Hayes excluded studies with fewer than ten individuals because, in Dr. Little's opinion, "they are so susceptible to bias" and "they are too small to draw conclusions from." Dr. Bailey testified that Hayes did a "selective review of the literature." In particular, Dr. Bailey testified that Hayes omitted studies with "single-subject design," where ABA researchers use small groups of subjects (i.e., four to eight subjects) and each subject is used as his own control "so by the end of the study, [the researchers] are able to tell you what works with individual children." Dr. Bailey further testified that Hayes gives great weight to randomized, control trials, but that those trials are "not appropriate for the vast majority of ABA research" because it is "hard to find enough

read only the summary of the Hayes Report, which included the analyses of the three reports previously reviewed by Bradford and read by Kidder, and four additional meta-analyses, which Kidder chose not to read. Kidder admitted that out of the four meta-analyses she chose not to read, the Hayes summary stated that three meta-analyses concluded that ABA results in beneficial improvement in outcomes and suggested that the treatment should be considered a therapy of choice and the other concluded that ABA is an effective therapy for a sub-population of children with autism. In addition, Kidder read only the executive summary of the AHRQ Report, and she did not read the 100 pages in the AHRQ Report that addressed ABA. Again, AHCA completely failed to follow its own standard procedures.

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autistic children that come close to having approximately the same age and other relevant variables" and because it would be "unethical to give [the control group] no treatment, especially since the treatment involves about a year and that's going to be a year lost for those children." Kidder testified that she did not consult with any member of the medical community to determine whether Hayes' decision to exclude studies with fewer than ten participants was valid.

[23]ARHQ is the Agency for Healthcare Research and Quality, a federal agency within the United States Department of Health and Human Services. Dr. Bailey testified that no one in AHRQ actually wrote the AHRQ Report; instead, AHRQ "commissioned this report from a group" and Zachary Warren of Vanderbilt University actually wrote the report. The AHRQ Report contains a disclaimer that "no statement in this report should be construed as an official position of AHRQ or the U.S. Department of Health and Human Services." Although a draft of the AHRQ was peer-reviewed and made available for public comment, Dr. Bailey testified that because neither he nor his professional colleagues had ever heard of the AHRQ Report, "it must have been peer-reviewed by a different group, but not ABA."

Dr. Bailey testified that the AHRQ Report is "very similar" to the Hayes Report because they used similar selection criteria in the studies they reviewed and were similar in their critiques of "what they considered to be methodological problems." Dr. Bailey believes that the AHRQ Report "miss[es] the bigger picture . . . , which is that these are important studies and they show significant effects." Furthermore, Dr. Bailey testified that like Hayes, AHRQ excluded studies with fewer than ten participants.

No analyst and/or nurse in AHCA ever reviewed any "reliable evidence"[24] about ABA, no one assessed whether ABA was covered by other states' Medicaid programs, Medicare, or commercial insurance, no one consulted with any physician about ABA, and no memorandum regarding ABA was ever prepared by an analyst and reviewed by AHCA's management. Instead, Kidder took on the role of analyst for the purpose of this litigation, and upon a cursory review of these materials, decided that ABA was experimental.

Testimony from Dr. Bailey established that almost all of the materials relied upon by Bradford and Kidder are not "reliable evidence" as defined under Florida law. Under Florida law,

> Reliable evidence shall mean only published reports and articles in the authoritative medical and scientific literature; the written protocol or protocols used by the treating facility or the protocol(s) of another facility studying substantially the same drug, device or medical treatment or procedure; or the written informed consent used by the treating facility or by another facility studying substantially the same drug, device or medical treatment or procedure.

FLA. ADMIN. CODE ANN. r. 59G-1.010(84)(b) (emphasis added). The TEC Report, Hayes Report, and the AHRQ Report are not peer-reviewed and have not been published "in the authoritative medical and scientific literature." See id. The Spreckley and Boyd meta-analysis (which was also used in the Hayes Report) was published in the Journal for Pediatrics, which would ordinarily be considered "reliable evidence." See id. However, Dr. Bailey testified that the Spreckley and Boyd meta-analysis made a clear error in its evaluation

[24] See FLA. ADMIN. CODE ANN. r. 59G-1.010(84)(b).

of the Sallows and Graupner study. Dr. Bailey cited to a letter to the editors of the Journal of Pediatrics from Smith, Eikeseth, Sallows, and Graupner, and Dr. Bailey testified that the authors stated that Spreckley and Boyd misrepresented the findings in the Sallows and Graupner study. Dr. Bailey further testified that the authors claimed that removing the mischaracterized Sallows and Graupner study from the Spreckley and Boyd meta-analysis would show that ABA yields significant findings on three of the four outcome measures in the meta-analysis. The Hayes Report did not mention this letter to the editor. It was also not included in the materials Bradford reviewed and turned over to Kidder, and Kidder did not review the subsequent discourse published in the Journal of Pediatrics. Dr. Bailey testified that this letter to the editor of the Journal of Pediatrics exemplified the peer-review process, whereby studies get published in the public domain and everyone in the field may examine them and respond.[25] Kidder testified that she did not review this letter to the editor. It is

[25]Dr. Bailey testified that the peer-review process for publication in the scientific and medical literature is a "painstaking process" and it "takes months to review" an article. Dr. Bailey further testified,

> Articles go back and forth to the authors requesting more information often. And ultimately, the peer-review process establishes the quality level of research at that moment in time. Now, the quality level standard may change over time as new research is done. And so the goal of the associate editor and the editor and reviewers is to stay in constant touch with whatever changes might occur in the standards of science. [Therefore,] the peer-review process represents what the scientist[s] who do the research think . . . .

Additionally, Dr. Bailey testified that when he served as editor of the Journal of Applied Behavioral Analysis, eighty-five percent of the submitted articles were rejected and that such strict scrutiny exemplifies the exacting standards and high reputation of the journals in the literature.

reasonable to infer that if AHCA had followed its standard practice for making coverage decisions in this case, an analyst may have found this letter in his or her survey of the "published reports and articles in the authoritative medical and scientific literature." See FLA. ADMIN. CODE ANN. r. 59G-1.010(84)(b). Dr. Bailey further testified that the Ospina meta-analysis made the same mistake as the Spreckley and Boyd meta-analysis.

In addition, AHCA did not comply with the definition of "experimental" under Florida law when determining that ABA is experimental. Florida's definition of "experimental" states, in relevant part:

> Reliable evidence shows that the consensus among experts regarding the drug, device, or medical treatment or procedure is that further studies or clinical trials are necessary to determine its maximum tolerated dose, toxicity, safety, or efficacy as compared with the standard means of treatment or diagnosis.

FLA. ADMIN. CODE ANN. r. 59G-1.010(84)(a)3 (emphasis added).[26] Kidder testified that she did not compare ABA to any other treatment as required by Florida law, that ABA is "the only treatment out there," and that she felt that further studies were necessary to determine ABA's maximum efficacy. Kidder further testified that ABA may even be the standard of care for autism and ASD. In essence, Kidder testified she only applied the first prong of the definition, and never made a comparative analysis because ABA either is the standard of care or there is no standard of care.

Dr. Vasconcellos, Dr. Bailey, and Dr. Mulick all testified that ABA is the standard means of treatment for autism and ASD. Dr. Vasconcellos testified that she prescribes ABA

[26]Florida's complete definition of "experimental" is set forth in footnote 16, supra.

to all of her autistic patients and believes it would be medical malpractice not to prescribe ABA for a child with autism. Dr. Bailey testified that "we know ABA works. It's been well-established. It's accepted in the medical community." Furthermore, Dr. Mulick testified that the consensus in the medical community is that ABA has been the standard means of treatment for children with autism and ASD since the 1990's, evidenced by consensus statements from the following sources: Centers for Medicare and Medicaid Services, United States Surgeon General Schachter, the Center for Disease Control and Prevention, the National Institute for Child Health and Human Development, the National Institute for Neurological Disorders and Stroke, the National Institute for Mental Health, the American Society of Child and Adolescent Psychiatry, the American Academy of Pediatrics, and the American Psychological Association. Kidder testified that she did not consider any of these consensus statements when determining the standard means of treatment for autism. In sum, the Court finds that AHCA's failure to follow its own unwritten but formal standard practice for making treatment coverage decisions, failure to apply Florida's definition for "experimental," and failure to use "reliable evidence" as defined by Florida law, was unreasonable, arbitrary, and capricious.[27]

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[27]In addition, the Court notes that in 2008, the Florida legislature authorized AHCA "to seek federal approval through a Medicaid waiver or a state plan amendment for the provision of occupational therapy, speech therapy, physical therapy, behavior analysis, and behavior assistant services to individuals who are 5 years of age and under and have a diagnosed . . . autism spectrum disorder." The Florida legislature ordered AHCA to "submit an annual report beginning on January 1, 2009, to the President of the Senate, the Speaker of the House of Representatives, and the relevant committees of the Senate and the House of Representatives regarding progress on obtaining federal approval and recommendations for the implementation

The "reliable evidence," as defined by Florida law, conclusively shows that ABA is not "experimental." Plaintiffs have established through their expert witnesses that there exists in the medical and scientific literature a plethora of peer-reviewed meta-analyses, studies, and articles that clearly establish ABA is an effective and significant treatment to prevent disability and restore developmental skills to children with autism and ASD. Dr. Bailey testified that the four peer-reviewed meta-analyses listed at the end of the Hayes Report (two by Eldevik, one by Reichow, and one by Virues-Ortega) show that ABA is effective though they received scarce attention in the Hayes summary report. These meta-analyses included findings of large to moderate changes in IQ, intensive ABA intervention leads to positive medium to large effects in terms of intellectual functioning, language development, acquisition of daily living skills, and social functioning in children with autism and ABA is the treatment of choice. Dr. Bailey further testified about three additional studies (by Dawson, Zachor, Smith) that show that ABA is effective. For example, Dr. Bailey testified that the Zachor study is "well-conducted," "well-respected," "highly cited," and "published in a good journal . . . with peer review," and that the study concluded that the children receiving ABA "showed significantly greater improvements" than those children in the eclectic group. Further, Dr. Bailey stated that AHRQ did not acknowledge the significance of the Zachor study or its findings. Dr. Bailey testified that he is aware of 25 to 30 reviews of the literature and an additional 30 to 50 meta-analyses showing that ABA

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of these home and community-based services." FLA. STAT. § 409.906(26). Kidder testified that AHCA never complied with this directive.

has been proven effective for children with autism. Notably, all the experts that testified for Plaintiffs and Defendant stated that they have never seen a study in the peer-reviewed literature where the authors concluded that ABA was ineffective as a treatment for children with autism or a study that characterized ABA as experimental.

Based on the foregoing, the Court finds that Plaintiffs have clearly established that Florida's exclusion of ABA for Medicaid-eligible minors diagnosed with autism or ASD violates the broad EPSDT mandate in the federal Medicaid Act. Regarding the remaining factors for a permanent injunction, the Court first finds that there is no adequate remedy at law for the violation of this right. Second, there would be irreparable injury to Plaintiffs and all Medicaid-eligible minors in Florida who have been diagnosed with autism or ASD if these children do not receive ABA pursuant to this injunction. If these children do not receive ABA in the primary years of development up to age 6 and then to 12 years of age, the children may be left with irreversible language and behavioral impairments. As Dr. Lopez Alberola testified:

> There are certain windows of opportunity in normal development that if these windows are missed, they will be forever gone, at which point no matter how much therapy the child is exposed to, the damage has already been done and it is potentially irreparable. . . . Specifically, the child may be left language impaired, the child may be left with significant behavioral impairment, non-functioning, non-integrated member of society. . . . [I]f the child is not speaking by 7 years of age, the chances of the child ever developing language pretty much after 7 years of age is next to none.

Dr. Mulick expressed similar concerns, testifying:

> [If] certain kinds of learning establishing the neural network . . . don't occur

> early in life, they're simply not going occur or not going to occur easily. For example, no one has learned to talk a human language or communicate with a human language past the age of 12.

K.G. is already 6 years old, C.C. is 5 years old, and I.D. is 3 years old. Dr. Vasconcellos testified that starting ABA at 4 years old is "late." Therefore, it is imperative that autistic children in Florida receive ABA immediately to prevent irreversible harm to these children's health and development.

Finally, regarding the public interest element, "[i]ssuance of an injunction to enforce the federal Medicaid Act is without question in the public interest." Edmonds v. Levine, 417 F. Supp. 2d 1323, 1342 (S.D. Fla. 2006). Furthermore, the Court finds that paying for the cost of ABA for autistic children will ultimately save public funds. Dr. Mulick testified that autistic children who do not receive ABA become "totally dependent on the community and state and the Federal Government for support. They receive Social Security support, domiciliary care. They often become injured and require . . . expensive medical interventions." Therefore, the Court finds Plaintiffs have satisfied by a preponderance of the evidence the four factors necessary to be granted a permanent injunction.

Accordingly, it is hereby **ORDERED AND ADJUDGED** that:[28]

1. As of 10:50 a.m. on March 26, 2012, Defendant is enjoined from enforcing Florida Behavioral Health Rule 2-1-4 as it relates to autism, Autism Spectrum Disorder, and Applied Behavioral Analysis treatment.

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[28]The Court will address Plaintiffs' claims regarding a declaratory judgment in a forthcoming Order.

2. As of 10:50 a.m. on March 26, 2012, the State of Florida is hereby ordered to provide, fund, and authorize Applied Behavioral Analysis treatment to Plaintiffs K.G., I.D., and C.C., as well as to all Medicaid-eligible persons under the age of 21 in Florida who have been diagnosed with autism or Autism Spectrum Disorder, as prescribed by a physician or other licensed practitioner.

3. Defendant shall notify all community behavioral health services providers enrolled in the Medicaid program that ABA is now a covered service for children who have been diagnosed with autism or Autism Spectrum Disorder.

4. Defendant shall notify all physicians enrolled in the Medicaid program who may provide EPSDT screens that ABA is now a covered service for children who have been diagnosed with autism or Autism Spectrum Disorder.

5. Defendant shall designate an authorization code for ABA treatment and notify all persons in listed in numbers 3 and 4 of such designation.

6. Defendant shall take whatever additional steps are necessary for the immediate and orderly administration of ABA treatment for Medicaid-eligible persons under the age of 21 who have been diagnosed with autism or Autism Spectrum Disorder.

7. Defendant shall certify in an affidavit filed with the Court within seven (7) calendar days that numbers 3 through 6 of this Order have been accomplished.

DONE AND ORDERED in Chambers at Miami, Florida at 10:50 a.m. this 26th day of March, 2012.

JOAN A. LENARD
UNITED STATES DISTRICT JUDGE