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.
_____/

DECLARATORY JUDGMENT

Pursuant to the Mandate of the United States Court of Appeals for the Eleventh Circuit (D.E. 185), the Court enters the following Declaratory Judgment.

THIS COURT ISSUED AN ORDER on May 22, 2012 directing the parties to provide a Status Report regarding their respective positions on a declaratory judgment. The Court has reviewed the parties' Status Reports, along with the relevant record and relevant Medicaid law. The Court specifically reviewed EPSDT provisions of the Medicaid statute requiring that a state must cover those services which are described in 42 U.S.C. § 1396d(a) and which are necessary to correct or ameliorate an illness or condition for Medicaid recipients under age 21. See 42 U.S.C. §§ 1396a(a)(10)(A),

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1396d(a)(4)(B), 1396d(r)(5). See also 42 U.S.C. § 1396a(a)(43). The Court also reviewed Medicaid's comparability provisions requiring that services must be equal in amount, duration, and scope for all categorically needy recipients and prohibiting states from arbitrarily denying a required service to otherwise eligible recipients "solely because of the diagnosis, type of illness, or condition." See 42 U.S.C. § 1396a(a)(10)(B)(i); 42 C.F.R. §§ 440.230(c), 440.240(b)(1).

Having reviewed the parties' Status Reports, along with the record and relevant Medicaid law, Plaintiffs' requested declaratory relief with respect to Medicaid's EPSDT and Comparability requirements is GRANTED and DECLARATORY JUDGMENT[1] is entered against the Defendant.

Regarding EPSDT, it is DECLARED and ADJUDGED:

1. The Medicaid Act requires that states must provide for early and periodic screening, diagnostic and treatment (EPSDT) services for recipients under age 21. See 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(4)(B).

2. EPSDT includes healthcare, diagnostic services, treatment and other measures which are described in one of the subsections in § 1396d(a) and which are necessary to "correct or ameliorate" physical and mental conditions discovered by screening services. See 42 U.S.C. § 1396d(r)(5).

[1] This Order Granting Declaratory Judgment also incorporates all of the factual findings and conclusions of law in the First Amended Permanent Injunction Order, D.E. 123 (with the exception of those findings pertaining to Plaintiffs' irreparable injury and lack of adequate remedy at law). This Order also incorporates the factual findings and conclusions of law the Court stated orally on March 23, 2012.

3. The Medicaid Act requires that states must arrange for (directly or through referral to appropriate agencies, organizations, or individuals) corrective treatment." 42 U.S.C. § 1396a(a)(43)(C).

4. Applied Behavior Analysis ("ABA") is among those services described in 42 U.S.C. § 1396d(a).

5. ABA falls within the scope of 42 U.S.C. § 1396d(a)(13). 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.

6. ABA falls within the federal regulation's definition of "rehabilitative services" at 42 C.F.R. § 440.130(d).

7. ABA is a medical service.

8. Coverage of ABA to treat children with ASD is required for Florida commercial health insurance plans and health maintenance organizations, as well as for federal employee health benefits plans.

9. The Plaintiffs, Medicaid recipients under age 21, suffer from Autism Spectrum Disorders discovered during EPSDT screens.

10. "Autism Spectrum Disorder" is a commonly used umbrella term for several disorders. See D.E. 98-1 at 6 ¶¶ 28-29. Per the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR), the umbrella term is "Pervasive

Developmental Disorders" (PDD), and the five diagnoses under the umbrella are (1) Autistic Disorder, (2) Rett's Disorder, (3) Childhood Disintegrative Disorder, (4) Asperger's Disorder, and (5) Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS). Under the current proposed revision to the DSM (DSM-V), the umbrella term used will be "Autism Spectrum Disorder" (ASD).

11. The Plaintiffs' treating pediatric neurologists prescribed ABA.

12. ABA is prescribed in order to provide children with ASD with the maximum reduction of their disability.

13. ABA is prescribed in order to restore children with ASD to their best possible functional levels.

14. ABA would restore Plaintiffs to their "best possible" functional levels.

15. There is a devastating difference in outcomes for ASD patients with Medicaid (who do not receive ABA coverage) compared to those covered by commercial insurance who do receive ABA.

16. ABA is necessary to correct or ameliorate the condition of Autism Spectrum Disorder.

17. ABA is "medically necessary" and is not "experimental" as defined under Florida administrative law and federal law. See FLA. ADMIN. CODE r. 59G-1.010(166)(a)(3); FLA. ADMIN. CODE ANN. r. 59G-1.010(84)(a)(3); Rush v. Parham, 625 F.2d 1150, 1154-58 (5th Cir. 1980); Moore v. Reese, 637 F.3d 1220, 1248 n. 48 (11th Cir. 2011).

18. Florida law'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 <u>as compared with the standard means of treatment</u> or diagnosis.

FLA. ADMIN. CODE ANN. r. 59G-1.010(84)(a)(3) (emphasis added).

19. ABA is indisputably considered by the medical community to be the standard means of treatment for children with ASD.

20. ABA is indisputably considered proven and effective by the medical community.

21. There is a plethora of medical and scientific literature including peer-reviewed meta-analyses, studies, and articles conclusively showing that ABA is a proven and effective treatment to prevent disability and restore developmental skills to children with autism and ASD.

22. The Florida definition of "experimental" further defines "reliable evidence" as:

> [O]n1y 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).

23. "Reliable evidence" as defined by FLA. ADMIN. CODE r. 59G-1.010(84)(b) conclusively shows that ABA is not "experimental."

24. Defendant's determination that ABA is experimental was not reasonable.

25. It is unreasonable to solely consider large-scale randomized controlled trials when evaluating ABA's efficacy because these trials are not appropriate or feasible for the vast majority of ABA research involving children with ASD, and it is unethical to have a control group, i.e., a group of children not getting ABA therapy.

26. Defendant's determination that ABA is experimental was arbitrary and capricious.

27. A state violates the Medicaid Act by excluding a service for recipients under age 21 which: 1) can be covered under 42 U.S.C. § 1396d(a); and 2) is necessary to correct or ameliorate the recipients' illness or condition. See 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(4)(B), 1396d(r)(5); D.E. 123 at 9.

28. The Defendant violated EPSDT provisions of the Medicaid Act by excluding coverage of Applied Behavior Analysis (ABA) for Medicaid-eligible recipients under 21 with ASD because ABA can be covered under 42 U.S.C. § 1396d(a)(13) and is necessary to correct or ameliorate their condition. See 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(4)(B), 1396d(r)(5).

29. This declaration does not eliminate the Defendant's authority to make individual medical necessity determinations, in accordance with governing law and regulations.

Regarding Comparability, it is DECLARED and ADJUDGED:

30. The Plaintiffs, who receive SSI and Medicaid, are "categorically needy." See 42 U.S.C. § 1396a(a)(10)(i).

31. The Plaintiffs suffer from Autism Spectrum Disorders ("ASD").

32. "Autism Spectrum Disorder" is a commonly used umbrella term for several disorders. See D.E. 98-1 at 6 ¶¶ 28-29. Per the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR), the umbrella term is "Pervasive Developmental Disorders" (PDD), and the five diagnoses under the umbrella are (1) Autistic Disorder, (2) Rett's Disorder, (3) Childhood Disintegrative Disorder, (4) Asperger's Disorder, and (5) Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS). Under the current proposed revision to the DSM (DSM-V), the umbrella term used will be "Autism Spectrum Disorder" (ASD).

33. Autism and Pervasive Developmental Delay ("PDD") are mental health diagnoses listed in the American Psychiatric Association's Diagnostic and Statistical Manual-IV (DSM), and the International Classification of Diseases (ICD).

34. The Plaintiffs were prescribed Applied Behavior Analysis (ABA) to treat their ASD.

35. ABA is a type of early intensive behavioral intervention health service used to treat the behavioral problems associated with ASD.

36. ABA is the type of behavioral health service that is medically necessary to treat ASD.

37. ABA is the standard behavioral treatment for ASD.

38. The Defendant's Rule describing Medicaid coverage of behavioral health services is at Rule 59G-4.050 ("the Rule"), Florida Administrative Code, which incorporates by reference The Florida Medicaid Community Behavioral Health Services Coverage and Limitations Handbook.

39. The Rule provides coverage of behavioral health services to treat certain mental and behavioral health diagnoses in the DSM and ICD.

40. The Rule excludes coverage of community behavioral health services to treat ASD, including Autism and PDD, and provides no exception for recipients under 21.

41. Under Defendant's Rule, categorically needy children with certain DSM/ICD diagnoses (e.g., depression, schizophrenia) can get behavioral health services that are medically necessary to treat their condition while categorically needy children with ASD cannot get medically necessary behavioral services to treat their condition.

42. The Rule violates 42 U.S.C. § 1396a(a)(10)(B)(i) and 42 C.F.R. § 440.240(b)(1) because the Defendant's behavioral health services are not equal in amount, duration or scope for all categorically needy recipients.

43. The Rule violates 42 C.F.R. § 440.230(c) because the Defendant arbitrarily denied a required service to otherwise eligible recipients "solely because of the diagnosis, type of illness, or condition."

44. This declaration does not eliminate the Defendant's authority to make individual medical necessity determinations, in accordance with governing law and regulations.

DONE AND ORDERED in Chambers at Miami, Florida this 5th day of November, 2013.

Joan A. Lenard

JOAN A. LENARD
UNITED STATES DISTRICT JUDGE