UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

W.B., by and through his father and legal guardian, David B., and A.W., by and through her mother and legal guardian, Brittany C., on behalf of themselves and all others similarly situated,

Plaintiffs,

v. Case No.:

SIMONE MARSTILLER, in her official capacity as Secretary for the FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION,

Defendant.

CLASS ACTION COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

I. PRELIMINARY STATEMENT

1. Plaintiffs W.B. and A.W. are children with multiple medically complex conditions who sought coverage of specialty medical services under Florida's Medicaid program. Defendant denied those requests based on a standard of medical necessity that conflicts with the coverage standard for children's services required by federal Medicaid law.

2. Title XIX of the Social Security Act (the Medicaid Act) mandates coverage of "early and periodic screening, diagnostic and treatment services" for

Medicaid-enrolled children (EPSDT). 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(4)(B). Under EPSDT, states must provide all Medicaid-covered services necessary to "correct or ameliorate" physical or mental conditions of Medicaid beneficiaries under age 21. *Id.; id.* § 1396d(r)(5)

3. Defendant's coverage standard, which is set forth in Fla. Admin. Code R. 59G-1.010, is more restrictive than what is allowed for under EPSDT. Application of this standard has resulted in improper denial of Medicaid-covered services that W.B. and A.W. need to correct and ameliorate their medical conditions.

4. W.B. and A.W. bring this class action against Defendant, Simone Marstiller, in her official capacity as the Secretary of the Florida Agency for Health Care Administration (AHCA or the Agency) to enforce their right to have the correct standard for Medicaid coverage apply to them and to all Medicaid beneficiaries under age 21.

II. JURISDICTION

5. Jurisdiction is conferred on this Court by 28 U.S.C. § 1331, which provides for original jurisdiction over all civil suits involving questions of federal law, and 28 U.S.C. §§ 1343(3) and (4), which grant this Court original jurisdiction in all actions authorized by 42 U.S.C. § 1983 to redress the deprivation under color

of State law of any rights, privileges, or immunities guaranteed by the U.S. Constitution and Acts of Congress.

6. Plaintiffs seek declaratory, injunctive, and other appropriate relief, pursuant to 28 U.S.C. §§ 2201 and 2202; Fed. R. Civ. P. 23, 57 and 65; and 42 U.S.C. § 1983.

7. Pursuant to 28 U.S.C. § 1391(b), venue is proper as Plaintiffs W.B. and A.W. reside in the district and a substantial part of the events or omissions giving rise to their claims also occurred in the district.

III. PARTIES

8. Plaintiff, W.B., is a one-year-old boy diagnosed with a rare genetic disorder known as CHARGE syndrome. He is enrolled in Florida's Medicaid program. W.B. resides in St. Augustine, St. Johns County, Florida with, David B., his father and legal guardian.

9. Plaintiff, A.W., is an 11-year-old girl who has significant disabilities. She is enrolled in Florida's Medicaid program. She resides in Jacksonville, Duval County, Florida with Brittany C., her mother and legal guardian.

10. Defendant, Simone Marstiller, is sued in her official capacity as the Secretary of AHCA, which is the single state agency responsible for the administration of Florida's Medicaid program. 42 U.S.C. § 1396a(a)(5); 42 C.F.R. § 431.10; Fla. Stat. § 20.42.

11. Secretary Marstiller directs and oversees all department programs, including Florida's Medicaid program. Fla. Stat. §§ 20.42, 409.902(1). Secretary Marstiller is responsible for ensuring that the operation of the Florida Medicaid program complies with the Medicaid Act and its implementing regulations. Secretary Marstiller is based, and her Agency is headquartered in Tallahassee, Leon County, Florida.

IV. CLASS ALLEGATIONS

12. Plaintiffs bring this class action on behalf of themselves and all other individuals similarly situated in the State of Florida pursuant to Rule 23(a) and (b)(2) of the Federal Rules of Civil Procedure.

13. The Plaintiffs bring this case as a statewide class action on behalf of:

> All Florida Medicaid beneficiaries under age 21 who have been or will be required to establish their need for Medicaid services under Defendant's standard for medical necessity set forth in Fla. Admin. Code R. 59G-1.010.

14. The requirements of Rule 23(a) and (b)(2) of the Federal Rules of Civil Procedure are met for the following reasons:

a. The class is so numerous that joinder of all members is impracticable. As of March 31, 2021, there were 2,366,388 children under age 21 enrolled in Florida's Medicaid program and entitled to EPSDT services.

b. The claims of the named Plaintiffs and putative class raise common questions of law and fact. The question of law common to the class is whether Defendant's medical necessity standard is more restrictive than and violates the coverage standard mandated by the EPSDT provisions of the federal Medicaid Act. Common questions of fact include whether the Defendant is applying its adopted standard to Medicaid-enrolled children under age 21, rather than the Medicaid Act's broader standard requiring coverage of services that "correct or ameliorate" illnesses or conditions.

c. The claims of the Plaintiffs are typical of the claims of the class in that the individual Plaintiffs and members of the class are all under 21 years old and are required to establish eligibility for Medicaid services pursuant to Fla. Admin. Code R. 59G-1.010.

d. The representative Plaintiffs will fairly and adequately protect the rights of the class because they suffer from the same deprivation as the other class members and have been denied the same federal right that they seek to enforce on behalf of those other class members.

e. The Plaintiffs' interests in obtaining injunctive relief for the violations of their rights and privileges are consistent with and not antagonistic to those of any person within the class.

f. The interests of the class will be adequately protected as Plaintiffs are represented by attorneys with experience in Medicaid class action litigation.

15. Defendant has acted on grounds generally applicable to the class by violating provisions of the federal Medicaid Act thereby making it appropriate for declaratory and injunctive relief on behalf of the class under Rule 23(b)(2) of the Federal Rules of Civil Procedure.

V. LEGAL FRAMEWORK AND FACTUAL ALLEGATIONS COMMON TO THE CLASS

A. Medicaid Framework

16. The Medicaid Act, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396w-5, establishes a medical assistance program cooperatively funded by the federal and state governments.

17. Medicaid is designed to "enabl[e] each State, as far as practicable...to furnish (1) medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other

services to help such families and individuals attain or retain capability for independence and self-care....” 42 U.S.C. § 1396-1.

18. States are required to administer Medicaid in “the best interests of recipients.” 42 U.S.C. § 1396a(a)(19).

19. The Centers for Medicare & Medicaid Services (CMS) of the United States’ Department of Health and Human Services administers Medicaid at the federal level. CMS’s rules and regulations are set forth in 42 C.F.R. §§ 430.0-456.725 and in the CMS State Medicaid Manual.

20. A state’s participation in Medicaid is voluntary. Once a state elects to participate, it must adhere to the requirements established by the United States Constitution, the Medicaid Act, and the rules promulgated by CMS. 42 U.S.C. § 1396-1; 42 C.F.R. § 430.12.

21. Under federal Medicaid regulations, states participating in the Medicaid program:

> must provide that the State will pay for services furnished in another State to the same extent that it would pay for services furnished within its boundaries if the services are furnished to a beneficiary who is a resident of the State, and any of the following conditions is met…[t]he State determines, on the basis of medical advice, that the needed medical services, or necessary supplementary resources, are more readily available in the other State….

42 C.F.R. § 431.52.

B. The Medicaid Act's EPSDT Mandate

22. The federal Medicaid statute's EPSDT provisions establish requirements for participating states to provide services for children that differ from the standards that apply to covering services for adults.

23. Federal law requires states to provide certain mandatory benefits and services. For Medicaid-eligible children under 21, state Medicaid programs must provide "early and periodic screening, diagnostic and treatment services." *See* 42 U.S.C. §§ 1396a(a)(10)(A), 1396a(a)(43), 1396d(a)(4)(B), and 1396d(r).

24. The Medicaid Act's EPSDT provisions require that any of the services described in 42 U.S.C. § 1396d(a) must be provided when they are "necessary health care, diagnostic services, treatment and other measures…to *correct or ameliorate* defects and physical and mental illnesses and conditions…regardless of whether or not such services are covered" for adults. *Id*. § 1396d(r)(5) (emphasis added).

25. Services that fall under 42 U.S.C. § 1396d(a) include outpatient hospital services and home health care services (including medical equipment and supplies). *See* 42 U.S.C. §§ 1396d(a)(2)(A) & (a)(7); 42 C.F.R. § 440.70(b)(3) (regulating home health services); *see also* Fla. Stat. § 409.905(4).

26. A service will "correct or ameliorate" the child's condition if it corrects, compensates for, improves a condition, or prevents a condition from

worsening, even if the condition cannot be prevented or cured. U.S. Dep't of Health & Human Servs., Ctrs. for Medicare & Medicaid Servs. (CMS), *EPSDT: A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents* at 10 (June 2014) (CMS, EPSDT Guide).[1]

27. While states are "permitted (but not required) to set parameters that apply to the determination of medical necessity in individual cases…those parameters may not contradict or be more restrictive than the federal [EPSDT] statutory requirement." *Id.* at 23.

28. For example, a state "may cover services in the most cost effective mode," but the state must ensure that "the less expensive service is *equally effective* and actually available." *Id.* at 25 (emphasis added).

29. Furthermore, "a state may not deny medically necessary treatment to a child based on cost alone" and "[t]he child's quality of life must also be considered." *Id.*

30. States must also consider and give weight to the opinions of a beneficiary's treating professional. Both the treating professional and the state have a role to play in evaluating whether a service is necessary to correct or ameliorate a child's condition. *Id.* at 24. The state cannot dismiss the treating professional's

[1] The CMS EPSDT Guide can be accessed at: *https://www.medicaid.gov/sites/default/files/2019-12/epsdt_coverage_guide.pdf.*

recommendation without consideration and, where there is a disagreement, must decide, based on the evidence, whether the service should be covered. *Id.*

C. Florida's Medicaid Program

i. Administration of Florida's Medicaid Program

31. Florida participates in the Medicaid program and therefore must meet the requirements of the federal Medicaid Act and implementing regulations. Fla. Stat. §§ 409.901-.9205; 42 U.S.C. § 1396-1; 42 C.F.R. § 430.12.

32. As the single state agency in Florida ultimately responsible for the oversight of the State's entire Medicaid program, AHCA is responsible for determinations of whether a requested Medicaid service is medically necessary. Fla. Stat. § 409.902(1).

33. The Florida Medicaid program does not itself provide health care services directly to enrollees, nor does it provide those enrollees with money to purchase health care services directly. Rather, Florida's Medicaid program is a vendor payment program wherein Defendant, or managed care organizations (MCOs) with whom Defendant contracts, reimburse participating providers for the services they provide to enrollees.

34. Florida's Medicaid program provides health care to beneficiaries one of two ways: on a Fee-For-Service (FFS) basis or through MCOs paid on a per-

member-per-month capitation basis, referred to in Florida law as "managed care plans."[2] Fla. Stat. §§ 409.962(10), 409.966, .967, .968, .971.

35. For those Medicaid beneficiaries enrolled in FFS, Defendant contracts with a Quality Improvement Organization (QIO) called eQHealth Solutions, Inc. (eQHealth) to evaluate whether a service should be covered by Medicaid.

36. When AHCA, or one of its contractors, denies, reduces, or terminates a Medicaid service, the Medicaid beneficiary is entitled to a hearing with AHCA's Office of Fair Hearings. *See* 42 C.F.R. § 431.220; 42 C.F.R. § 438.408(f); Fla. Admin. Code R. 59G-1.100.

ii. Florida's Medical Necessity Standard

37. To evaluate whether a Medicaid beneficiary is entitled to coverage of a service, Defendant, in Florida's administrative code, defines "medically necessary" and "medical necessity" as follows:

> The medical or allied care, goods, or services furnished or ordered must meet the following conditions:
>
> - Be necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain
>
> - 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

> - Be consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational
>
> - 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
>
> - Be furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider
>
> 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 R. 59G-1.010 (incorporating by reference the provisions of the Florida Medicaid Definitions Policy, August 2017).

38. All conditions set forth in Defendant's standard of medical necessity must be met before Florida Medicaid coverage will be authorized. *See* Fla. Admin. Code R. 59G-1.035(6) ("In order for the health service to be covered under the Florida Medicaid program, it must also meet all other medical necessity criteria as defined in subsection 59G-1.010….").

39. Under Defendant's standard, a service will not be covered by the Medicaid program, unless it is, among other things, "necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain." Fla. Admin. Code R. 59G-1.010.

40. In comparison, the federal EPSDT provisions require only that a requested service be necessary to "correct or ameliorate" a child's illness, disability, or other health condition. 42 U.S.C. § 1396d(r)(5).

41. The Medicaid Act does not allow the Defendant to require that an illness be significant or that pain be severe for treatment to be covered. Thus, the first prong of Defendant's standard of medical necessity incorporates coverage criteria that is more restrictive than what is allowed under EPSDT.

42. Defendant's medical necessity standard requires that the requested service "be furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider." *Id.*

43. The federal Medicaid EPSDT provisions do not authorize the Defendant to consider "convenience" as a factor in evaluating whether Medicaid coverage is required and, instead "encompasses a more expansive view, allowing for services that sustain or support, as opposed to actually treating the disability." *C.F. v. Dep't of Children and Families*, 934 So.2d 1, 6 (Fla. 3d DCA 2005).

44. Florida's state courts have repeatedly found that Defendant's standard for deciding whether a service is medically necessary for an EPSDT-eligible child excludes coverage of services needed to ameliorate a condition or prevent a condition from worsening.

45. In 2005, the court in *C.F.* reversed the state's decision to deny services to an EPSDT-eligible child finding that the state "improperly applied a more restrictive standard of 'medical necessity' [Fla. Admin. Code R. 59G-1.010] than that outlined by federal Medicaid law." *Id.*

46. In February 2012, *I.B. v. Agency for Health Care Admin.*, 87 So.3d 6, 8-10 (Fla. 3d DCA 2012) reversed the Defendant's decision denying coverage for services needed by an EPSDT-eligible child, finding that the Defendant "relied upon an incorrect and inapplicable rule [Fla. Admin. Code R. 59G-1.010] to determine medical necessity."

47. In August 2012, *E.B. v. Agency for Health Care Admin.*, 94 So.3d 708, 708-709 (Fla. 4th DCA 2012), reversed the Defendant's decision denying home health care to an EPSDT-enrolled child due to the failure "to consider the federal early, periodic, screening, diagnostic and treatment ("EPSDT") standard in making its determination as to which services requested by E.B. were covered by the Medicaid…Program."

48. Thereafter, Defendant wrote an internal memo, dated August 5, 2014, to justify its requirement that requested Medicaid services for children be evaluated under the same medical necessity standards that the State applies to adults. *See* AHCA, "Summary Memorandum: Medical Necessity as a Limitation on Medicaid Services, Including EPSDT" (AHCA EPSDT Memo) (Ex. 1, hereto).

49. The AHCA EPSDT Memo recites Defendant's standard of medical necessity in Fla. Admin. Code R. 59G-1.010 and then sets forth that "states may place limits on Medicaid state plan services, including EPSDT services…based on the state's definition of 'medical necessity.'" (Ex. 1, p. 10).

50. The AHCA EPSDT Memo states that it is an erroneous legal position to hold that the medical necessity standard is different for children and adults. (Ex. 1, p. 12).

51. The AHCA EPSDT Memo states that "a treating physician's opinion regarding the medical necessity of a service is not dispositive or accorded deference." (Ex. 1, p. 10).

52. The AHCA EPSDT Memo provides that coverage decisions can consider the "convenience" prong of Fla. Admin. Code R. 59G-1.010 with one unexplained exception—private duty nursing. (Ex. 1, p. 11-12).

53. In October 2020, *Q.H. v. Sunshine State Health Plan*, 307 So.3d 1, 14 (Fla. 4th DCA 2020), the court found that the Defendant erroneously applied "the 'overly restrictive' standard of medical necessity set forth in the Florida Administrative Code, rather than the more expansive EPSDT standard of whether the treatment was necessary to 'correct or ameliorate' the child's condition."

54. At Defendant's guidance and direction, eQHealth applies Defendant's medical necessity standard when evaluating all requests for Medicaid coverage,

including for beneficiaries under age 21. *See* Fla. Admin. Code R. 59G-1.053 (in discussing QIO review, the rule defines medical necessity as set forth in Fla. Admin. Code R. 59G-1.010 and then states "…services for recipients under the age of 21 years exceeding the coverage described within a policy or the associated fee schedule may be approved, *if medically necessary*) (emphasis added).

55. Defendant's contracts with the MCOs require that the MCOs apply Defendant's medical necessity standard when evaluating all requests for Medicaid coverage, including for beneficiaries under age 21. *See* AHCA, Statewide Medicaid Managed Care Program, 2018-2023 Model Health Plan Contract, Attachment II, Core Provisions at 18, 63 & 78, accessed at: *https://ahca.myflorida.com/medicaid/statewide_mc/pdf/Contracts/2020-10-01/Attachment_II_Core_Contract_Provisions_2020-10-01.pdf*.

56. If a beneficiary elects a fair hearing to review the denial, reduction, or termination of a requested service, AHCA hearing officers apply the medical necessity standard set forth in Fla. Admin. Code R. 59G-1.010 to determine whether the decision was proper. *See* Fla. Admin. Code R. 59G-1.053.

57. Defendant includes the AHCA EPSDT memo in its training to hearing officers.

58. The AHCA EPSDT memo is included as part of Defendant's record on appeals challenging adverse coverage decisions for children under age 21,

including in the denial of A.W.'s specialty medical bed as discussed in paragraphs 102 to 131 infra.

VI. FACTS AND ALLEGATIONS OF PLAINTIFFS

A. Plaintiff W.B.

59. Plaintiff W.B. lives in his family home in St. Augustine, Florida with his father, David B., his mother Stacy B., and his brothers, J.D.B. (8 years old) and C.B. (6 ½ years old).

60. W.B. is a one-year-old boy diagnosed with a genetic disorder known as CHARGE syndrome; it presents in less than one out of 10,000 live births in the U.S.

61. The "CHARGE" in CHARGE syndrome is an acronym for the conditions that occur in children diagnosed with the syndrome: **Colobomas** (tissue that normally occurs in or around the eye is missing at birth), **Heart** defects, **Atresia** of the nasal choanae (congenital narrowing of the nasal cavity that causes difficulty breathing), **Retardation** of development, **Genitourinary** abnormalities (abnormalities of the genital and urinary organs), and **Ear** and hearing anomalies.

62. W.B.'s CHARGE syndrome diagnosis results in multiple congenital anomalies including colobomas, nasal choanae, right facial palsy, a soft larynx that partially obstructs his airway, concerns for immunodeficiency, hypoparathyroidism (low production of parathyroid hormone that causes abnormally low calcium levels

in blood leading to muscle aches or cramps, seizures, kidney dysfunction, fatigue, and other symptoms), dysphagia, GERD, and developmental delay.

63. W.B. uses a gastronomy tube (g-tube) for his nutritional needs. He attends a Prescribed Pediatric Extended Care center during the day that provides nursing services, personal care, and developmental therapies.

64. A child diagnosed with CHARGE syndrome will be followed on average by 17 different medical specialists and will need to undergo more than a dozen surgical procedures before the age of 10 years old. Accordingly, as symptoms specific to CHARGE syndrome present, the timing and identification of medical interventions are critical to ameliorating the impact of the syndrome on a child.

65. W.B. is enrolled in the Florida MCO known as the Children's Medical Services Health Plan or the CMS Plan. The CMS Plan is administered by WellCare Health Plans, Inc.

66. W.B.'s primary care physician, Dr. Stephanie Carlin, is an assistant professor with the Department of Pediatrics, Division of Community and Societal Pediatrics with the University of Florida Health, Jacksonville (UFHealth Jacksonville).

67. Dr. Carlin practices at UFHealth Jacksonville's Bower Lyman Center for Medially Complex Children (the Center). The Center provides a coordinated

family-focused medical home for children ages 0-21 with complex medical conditions.

68. Dr. Carlin determined that W.B. needs care provided by an out-of-state specialty clinic called the CHARGE Center, which is run by the Cincinnati Children's Hospital (the CHARGE Center).

69. Dr. Carlin made this determination because W.B.'s diagnosis is so rare that the treatment specialists in Florida do not have the requisite expertise to evaluate W.B.'s condition and coordinate ongoing treatment interventions to prevent negative clinical outcomes caused by disjointed and varied plans of care developed by subspecialists who do not have expertise in CHARGE.

70. For example, W.B. failed his most recent swallow study in Florida and continues to struggle with his secretions leading to respiratory distress and chronic lung disease. It is the opinion of W.B.'s Ear, Nose, and Throat (ENT) specialist, Dr. Andrew R. Simonsen, that only the CHARGE Center will be able to evaluate W.B.'s swallowing issues to devise a plan locally to address this health condition.

71. The CHARGE Center is a one-of-a-kind facility in the U.S. that uses a multidisciplinary approach to coordinate care among multiple specialists, all who have specific, up-to-date expertise in treating CHARGE syndrome, including

genetics, ophthalmology, cardiology, plastic surgery, and ENT. There are no similar clinics in Florida.

72. The CHARGE Center combines an aerodigestive evaluation -- a comprehensive multidisciplinary approach that involves pulmonology, gastroenterology, and ENT – with a CHARGE evaluation to create a comprehensive plan of care.

73. The CHARGE Center designs their plans of care to ensure that the treatment interventions, as evaluated and determined by experts in the condition, are timed correctly which, in turn, optimizes the treatment outcomes for the child. The CHARGE Center's continued plan of care can then be executed locally so the child will have better outcomes throughout the ongoing course of their treatment.

74. Coordination also ensures that certain encounters, like anesthesia or blood draws that are a part of the initial evaluation and treatment at the CHARGE Center, are scheduled and timed to minimize stress and health risks to the child. For example, if the child requires multiple surgeries as part of the initial evaluation at the CHARGE Center, the surgeries are scheduled at the same time so that anesthesia, a procedure that carries risk especially to young children, only needs to be administered once.

75. The CHARGE Center regularly bills out of state Medicaid programs for its outpatient hospital services.

76. Under the CHARGE Center's proposal, W.B. would receive care at the CHARGE Center for approximately one week while staying in Cincinnati, Ohio.

77. W.B.'s care at the CHARGE Center would be led by Dr. Catherine Hart, an ENT who specializes in treating CHARGE syndrome. Dr. Hart would work closely with specialists in pulmonology and gastroenterology to evaluate W.B.'s ongoing treatment needs and establish a plan of care to be implemented by his physicians in Florida.

78. The coordination between specialists during the weeklong period also allows visits, testing, and evaluations completed at the CHARGE Center to be done in a sequence that minimizes the treatment risks to W.B. by consolidating anesthesia events and blood draws.

79. W.B. will undergo multiple surgeries during this evaluation at the CHARGE Center including microlarnygoscopy, bronchoscopy, esophagogastroduodenoscopy, and nasal dilation.

80. W.B.'s evaluations will also include a swallow study, chest x-ray, auditory brainstem response test for hearing, anesthesia consultation, and a cardiology consultation.

81. Since birth, W.B. has had three emergency room visits, four hospital admissions, and three admissions for observation due to complications that Dr. Carlin believes can only be ameliorated by treatment at the CHARGE Center.

82. Dr. Carlin's opinion is that W.B. may experience long-term developmental setbacks if he does not receive the streamlined treatment and care planning at the CHARGE Center from physicians who specialize in the syndrome.

83. Members of W.B.'s Florida aerodigestive team including W.B.'s ENT, Dr. Simonsen, and his pulmonologist, Dr. Gerardo Vazquez Garcia, both state that they do not have the specialized expertise needed to treat CHARGE syndrome and W.B.'s admission to the CHARGE Center is medically necessary because there are no ENTS or pulmonologists located in Florida with the requisite expertise.

84. W.B.'s family is committed to W.B. receiving the care he needs to ameliorate his rare condition even if they must travel outside of Florida. Treatment outside of Florida at the CHARGE Center will be a significant obligation for W.B. and his family requiring disruption of their daily lives. W.B.'s parents are prepared to take leave from work and to arrange for the care of their other children to travel with W.B. to Ohio and actively participate in his care.

85. Since September 2020, Dr. Carlin has requested, and Defendant has denied, coverage of treatment at the CHARGE Center to address W.B.'s medical needs.

86. In September 2020, the CMS Plan, acting on behalf of Defendant, denied coverage of outpatient hospital services at The CHARGE Center.

87. The CMS Plan applied Defendant's medical necessity standard to evaluate W.B.'s request for treatment at the CHARGE Center stating:

> We made our decision because: We determined that your requested services are not medically necessary because the services do not meet the reason(s) checked below: (See Rule 59G-1.010)
>
> *Must be able to be 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,
> *Must be furnished in a manner not primarily intended for the convenience of the recipient, caretaker, or provider. (The convenience factor is not applied to the determination of the medically necessary level of private duty nursing (PDN) for children under the age of 21.)"

88. The CMS Plan further justified its denial on the basis that:

> "we received a request to authorize treatment for your child with an out of network provider, Dr. Catherine Hart at Cincinnati Children's Hospital. We did not approve the request for authorization because out of network services are not a covered benefit when services are available within your plan. This service can be provided by one of the following in network providers…."

89. On October 15, 2020, Dr. Carlin's office filed an appeal on behalf of W.B. requesting that the CMS Plan overturn its denial and authorize treatment at the CHARGE Center.

90. Dr. Carlin's office responded to the CMS Plan denial and, specifically, its finding that W.B. can be served by individual in-network providers by stating:

> "there are no CHARGE centers in network that have a multidisciplinary team of providers who specialize in CHARGE. [W.B.] has had a complicated clinical course and his care would benefit from a multidisciplinary team approach to ensure that we are maximizing his care locally."

91. On November 13, 2020, CMS sent Dr. Carlin's office a second denial affirming its first decision.

92. The second CMS Plan denial states:

> On November 11, 2020, after consideration of the information you provided to…[CMS]…in support of your plan appeal…[CMS]…hereby Denies your plan appeal. As a result, you will not receive service, effective 11/11/20.
>
> The facts we used to make our decision are: We have doctor's [sic] who can see and manage your condition. The reasons for this decision are based on a set of standards. This included Wellcare Health Plans, Inc. Find A provider Website Member Benefit."

93. Defendant adopts CMS plan denials.

94. The CMS Plan denied W.B.'s request on the basis that treatment at the CHARGE Center was not "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."

95. In evaluating W.B.'s request under Defendant's standard, and specifically whether treatment with in-network providers is "equally effective," the CMS Plan did not consider Dr. Carlin's opinion that specialists in-network with the CMS plan were insufficient to meet W.B.'s treatment needs because they do not have expertise in CHARGE.

96. The CMS plan did not explain why the services it offers are equally effective to treatment at the CHARGE Center or how those services would correct or ameliorate W.B.'s documented healthcare needs.

97. The CMS Plan also denied W.B.'s request under Defendant's medical necessity standard requiring that the service "must be furnished in a manner not primarily intended for the convenience of the recipient, caretaker, or provider."

98. Rather than acknowledge the ample evidence presented by Dr. Carlin justifying W.B.'s need for specialized treatment at the CHARGE Center, which is not convenient for anyone, and explaining why, in the opinion of the CMS Plan, the requested treatment would not correct or ameliorate W.B.'s condition, the CMS Plan relied on Defendant's medical necessity standard to deny the request.

99. In its denials to W.B., the CMS Plan did not use or reference EPSDT or its "correct or ameliorate" standard to evaluate W.B.'s request.

100. By failing to evaluate W.B.'s request for coverage under the EPSDT standard, Defendant fails to discharge its duty under federal Medicaid law to provide all benefits or services for Medicaid beneficiaries under age 21 that are "necessary to correct or ameliorate defects and physical and mental illnesses and conditions…."

101. Defendant continues to deny W.B.'s requests for Medicaid to provide treatment at the CHARGE Center as prescribed by his treating professionals.

B. Plaintiff A.W.

102. Plaintiff A.W. (11 years old) lives in her family home in Jacksonville, Florida with her mother, Brittany C., her father Antonio W., and her sibling, A.W. (7 years old).

103. A.W. (11 years old) was born premature at 24 weeks of gestation and is a medically complex child. A.W. is diagnosed with quadriplegic cerebral palsy, global developmental delay, muscle spasticity, partial epilepsy with impairment of consciousness, neuromuscular scoliosis, cortical visual impairment, spastic hip dislocation, dysphagia causing pulmonary aspiration with swallowing (difficult or improper swallowing that leads to the inhalation of foreign material into the lower airway), obstructive sleep apnea syndrome, and gastroesophageal reflux disease.

104. A.W. is non-verbal, is incontinent of bowel and bladder, is non-ambulatory and requires either a two-person lift or a Hoyer lift (medical equipment that assists a caregiver in transfers). A.W. uses a wheelchair for all mobility purposes.

105. A.W. uses a g-tube for administration of nutrition and medication. The g-tube has extended tubing. Her g-tube feeding schedule includes enteral feeds continuously at night.

106. A.W. is a high risk for falling out of bed. A.W.'s developmental delay means that she does not understand how to protect herself from falls. Due to her inability to ambulate, she cannot physically protect herself from falls.

107. A.W. has previously fallen out of bed. As recently as May 6, 2021, A.W. fell out of bed and was found hanging by her foot with her face pressed up against the wall.

108. A.W.'s treating physician is Dr. Stephanie Carlin.

109. Dr. Carlin prescribed for A.W. a specialty medical bed, which is a piece of medical equipment.

110. The specialty medical bed prescribed by Dr. Carlin is called a Dream Series bed.

111. The Dream Series bed is an enclosed bed with a manual adjustable head, an IV pole, and access ports built into the foot and headboards for routing of medical tubing.

112. The bed is built with an unbroken perimeter between the supportive mattress and the frame to reduce gaps and openings that lead to entrapment. The bed was specifically designed to eliminate the risk of entrapment posed by a traditional hospital bed.

113. The bed's enclosure door can be operated with one hand maximizing caregiver access.

114. A.W.'s scoliosis requires a supportive mattress and bedframe that will alleviate pressure along her spine. The Dream Series bed has the supportive mattress and frame that A.W.'s condition requires, while a hospital bed does not.

115. A.W.'s seizures and extreme spasticity can cause her to fall out of bed involuntarily or become entrapped between the frame of a traditional hospital bed and its mattress or within the opening of a hospital bed's siderails. She is unable to free herself if she becomes entrapped and she cannot call out for help. The Dream Series bed's unbroken perimeter, which minimizes gaps between the frame and enclosure, prevents A.W. from falling out and from becoming entrapped.

116. A.W.'s various health conditions create a risk for aspiration, chronic coughing, recurrent pneumonia, and choking. The adjustable head of the Dream Series bed will alleviate her symptoms and minimize her risk for aspiration.

117. A.W. relies on caregivers to physically assist with all activities of daily living, including toileting and transferring. The Dream Series bed is designed so the high sides (which prevent falls) can be raised and lowered, and the doors can be unlatched or secured with minimal effort. This ensures that A.W.'s caregivers can always access her quickly.

118. A.W.'s g-tube has previously been found with the tubing wrapped around her neck, a concern that is heightened by the fact that A.W. uses her g-tube for continuous enteral feeds at night. If the g-tube becomes wrapped around A.W.'s neck, she is unable to free herself and she cannot call for help. The Dream Series bed is designed with a special outlet to route the extension tubing, thereby mitigating this danger.

119. On February 24, 2020, eQHealth, acting on behalf of Defendant, issued a notice to A.W. that denied coverage of the Dream Series bed prescribed by Dr. Carlin.

120. The February 24th notice states:

> The request for service is denied in whole or in part because they [sic] are not medically necessary as defined in Rule 59G-1.010(166), Florida Administrative Code.

> Specifically, the requested services are not medically necessary under the following standards:
>
> Individualized, specific, and consistent with the symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the patient's needs.

121. The February 24th denial further states that:

> The clinical information provided does not support Medicaid's medical necessity definition. The patient is a 10 year old with CP who is non-ambulatory, non-verbal, and has GT and the request is for a specialty bed. The request is excessive because a hospital bed should suffice. A specialy [sic] bed was previously denied last November.

122. On March 2, 2020, A.W.'s mother requested an administrative fair hearing to challenge eQHealth's February 24th denial of the specialty bed for A.W.

123. On May 6, 2020, an AHCA hearing officer issued a final order, which upheld eQHealth's denial and found that a specialty bed is not medically necessary for A.W.

124. In the "Conclusions of Law" section of AHCA's final order, the hearing officer relies on the medical necessity standards in Fla. Admin. Code R. 59G-1.010 to affirm eQHealth's denial, concluding that "Petitioner did not show that a specialty bed is individualized, specific, and consistent with the symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the Petitioner's needs."

125. AHCA's hearing order adopts the opinion of eQHealth's medical director, Dr. Rakesh Mittal, finding that a traditional "hospital bed is sufficient to meet A.W.'s needs because it is height adjustable, inclines, has stable rails, and can be used with thick foam padding to protect [A.W.]"

126. The hearing officer did not address Dr. Carlin's concerns about why a traditional bed was insufficient to meet A.W.'s needs, *e.g.*, that A.W. risks becoming entrapped between the mattress and side rails of a hospital due to her spasticity and seizures.

127. In contrast, EPSDT requires that some deference be accorded to the treating physician's opinion and, where there is a disagreement, the final decision should be based on the evidence. The hearing officer, however, did not consider the evidence of Dr. Carlin's testimony or otherwise accord her opinion deference.

128. The hearing officer's opinion does not discuss whether the foam padding used with a traditional medical bed is an equally effective alternative to the supportive mattress used with A.W.'s requested specialty medical bed. In contrast, EPSDT requires that the state evaluate whether a less expensive service, like a hospital bed, is equally effective to the requested service. *Id.*

129. Because the hearing officer relied on Defendant's medical necessity standard to evaluate the Medicaid coverage for A.W.'s requested benefit – rather than evaluate the coverage under the EPSDT standard – Defendant denied A.W.

the care and treatment necessary to correct or ameliorate her conditions in violation of federal Medicaid law.

130. By failing to evaluate A.W.'s request for coverage under the EPSDT standard, Defendant fails to discharge its duty under federal Medicaid law to provide all benefits or services for Medicaid beneficiaries under age 21 that are "necessary to correct or ameliorate defects and physical and mental illnesses and conditions…."

131. Defendant continues to deny A.W.'s requests for Medicaid to provide a specialty medical bed as prescribed by her treating professionals.

VII. CAUSE OF ACTION: Violation of the Medicaid Early and Periodic Screening, Diagnostic and Treatment Provisions

132. Plaintiffs incorporate and re-allege paragraphs 1 through 131 as if fully set forth herein.

133. In violation of the EPSDT provisions of the Medicaid Act, 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(4)(B), 1396a(a)(43)(C), and 1396d(r)(5), the Defendant is failing to decide requests for medical services on behalf of Plaintiffs and all other similarly situated Florida Medicaid beneficiaries under the age of 21 in accordance with the Medicaid Act's EPSDT "correct or ameliorate" standard and to provide Plaintiffs and all other similarly situated Florida Medicaid beneficiaries under the age of 21 with services and benefits necessary to correct or ameliorate their health conditions.

VIII. REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court:

A. Certify this action as a class action pursuant to Fed. R. Civ. P. 23;

B. Issue a declaratory judgment pursuant to 28 U.S.C. § 2201 and Fed. R. Civ. P. 57 that Defendant's application of its medical necessity standard set forth in Fla. Admin. Code R. 59G-1.010 to beneficiaries under 21 violates the EPSDT requirements in federal Medicaid law;

C. Grant a preliminary and permanent injunction directing Defendant to evaluate Medicaid coverage for W.B. and A.W.'s requested services under a standard of medical necessity that comports with federal Medicaid law and prohibit Defendant from denying the medically necessary services;

D. Grant a permanent injunction directing Defendant to:

1) Cease applying its standard of medical necessity under Fla. Admin. Code R. 59G-1.010 for named Plaintiffs and all Medicaid beneficiaries under age 21; and

2) Adopt a medical necessity standard for beneficiaries under age 21 that comports with federal Medicaid law.

E. Retain jurisdiction over this action to ensure Defendants' compliance with the mandates of the Court's Orders;

F. Award to Plaintiff the costs and reasonable attorney fees pursuant to 42 U.S.C. § 1988; and,

G. Order such other relief as this Court deems just and equitable.

Respectfully submitted this 6th day of August 2021.

Plaintiffs by their Attorneys,

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