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,

Case No.: 3:21-cv-771-MMH-PDB

v.

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

Defendant.
_____/

PLAINTIFFS' SUPPLEMENTAL BRIEF IN SUPPORT OF PLAINTIFFS' MOTIONS FOR PRELIMINARY INJUNCTION

Pursuant to the Court's Order dated August 9, 2021 (Dkt. 8), Plaintiffs submits this supplemental brief in support of Plaintiff A.W.'s Motion for Preliminary Injunction (Dkt. 4) and Plaintiff W.B.'s Motion for Preliminary Injunction (Dkt. 5). In support, Plaintiffs state as follows:

1. On August 6, 2021, along with a Class Action Complaint for Declaratory and Injunctive Relief (Dkt. 1) and Motion for Class Certification (Dkt. 3), Plaintiffs filed two separate motions for preliminary injunction entitled: A.W.'s

Motion for Preliminary Injunction (Dkt. 4) and W.B.'s Motion for Preliminary Injunction (Dkt. 5) (collectively, "the Motions for Preliminary Injunction"). The Motions for Preliminary Injunction did not include a statement about the security required pursuant to Fed. R. Civ. P. 65(c). The Motions also did not include proposed orders.

2. Also on August 6, 2021, pursuant to Local Rule 6.02(b), counsel for Plaintiffs emailed a copy of the Complaint, Motion for Class Certification, and the Motions for Preliminary Injunction to Andrew Sheeran, Chief Litigation Counsel, Office of General Counsel at the Agency for Health Care Administration.

3. On August 9, 2021, this Court entered an Order directing Plaintiffs to (1) promptly file supplements to the Motions for Preliminary Injunction including "a precise and verified explanation of the amount and form of the required security which must be posed pursuant to Rule 65(c) [of the Fed. R. Civ. P.] as well as a 'proposed order' " and (2) "promptly effect service of process on Defendant and to file a notice with the Court advising that service has been accomplished."

4. Regarding the security to be posed with the Motions for Preliminary Injunction, while Fed. R. Civ. P. 65(c) requires that an applicant for a preliminary injunction provide security against the potential effects of a wrongly issued injunction, it is well-established that "the amount of security required by the rule is a matter within the discretion of the trial court...." *BellSouth Telecommunications,*

Inc. v. MCIMetro Access Transmission Servs., LLC, 425 F.3d 964, 971 (11th Cir. 2005) (quoting *City of Atlanta v. Metro. Atlanta Rapid Transit Auth.*, 636 F.2d 1084, 1094 (5th Cir. Unit B 1981)). The Court may elect to require no security at all. *Id*. In addition, relevant to the instant case, public interest litigation is a recognized exception to the bond requirement. *See Vigue v. Shoar*, No. 3:19-CV-186-J-32JBT, 2019 WL 1993551, at *3 (M.D. Fla. May 6, 2019) (citing *City of Atlanta v. Metropolitan Atlanta Rapid Transit Authority*, 636 F.2d 1084, 1094 (5th Cir. 1981) ("[P]ublic-interest litigation [constitutes] an area in which the courts have recognized an exception to the Rule 65 security requirement.")). Therefore, Plaintiffs respectfully request that the Court waive the bond requirement on the basis that the matter of security is entirely within the Court's discretion and, additionally, the instant case involves public interest litigation.

5. Regarding the proposed orders for the Motions for Preliminary Injunction, Plaintiffs file the proposed orders as Exhibit 1 and 2 to this Motion to Supplement.

6. Finally, regarding service of process on Defendant, formal service of the Complaint, Motion for Class Certification, and the Motions for Preliminary Injunction was effected on August 10, 2021. Proof of that service is filed contemporaneous to this motion. As stated above, counsel for Plaintiffs also

provided a copy of these documents via email to AHCA Office of General Counsel on August 6, 2021.

Respectfully submitted this 11th day of August 2021.

Plaintiffs by their Attorneys,

/s/ Katy DeBriere
Katherine DeBriere
Lead Counsel

Fla. Bar No.: 58506
Florida Health Justice Project
126 W. Adams Street
Jacksonville, FL 32202
Telephone: (904) 356-8371, ext. 333
Facsimile: (904) 356-8780
debriere@floridahealthjustice.org

CERTIFICATE OF SERVICE

I hereby certify that on August 11, 2021, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system. I further certify that I mailed the foregoing document by first-class mail to the following non-CM/ECF participant:

Simone Marstiller, Secretary
Agency for Health Care Administration
2727 Mahan Dr.
Tallahassee, FL 32308
(888) 419-3456

/s/ Katy DeBriere
Katherine DeBriere

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

W.B., by and through his Next Friend, David Bilotta, and A.W., by and through her Next Friend, Brittany Cunningham on behalf of herself and all others similarly situated,

Plaintiff,

Case No.: 3:21-cv-771-MMH-PDB

v.

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

Defendant.
_____/

PROPOSED ORDER ON PLAINTIFF A.W.'S MOTION FOR PRELIMINARY INJUNCTION

This matter is before the Court on Class Member A.W.'s Motion for Preliminary Injunction. This is an action for injunctive and declaratory relief in which Plaintiff A.W. claims the Defendant is violating her rights under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) provisions of the Medicaid Act, 42 U.S.C. §§ 1396a(a)(43) & 1396d(r). A.W., an eleven-year-old girl with significant complex medical conditions and disabilities, seeks a Preliminary Injunction against Defendant regarding Defendant's denial of a specialized bed.

Before a court will grant preliminary injunctive relief, the moving party must establish that: (1) "it has substantial likelihood of success on the merits," (2) it will suffer irreparable injury if the relief is not granted, (3) the threatened injury outweighs the harm the relief may inflict on the non-moving party, and (4) entry of relief "would not be adverse to the public interest." *KH Outdoor, LLC v. City of Trussville*, 458 F.3d 1261, 1268 (11th Cir. 2006). "Of these four requisites, the first factor, establishing a substantial likelihood of success on the merits, is most important...." *ABC Charters, Inc. v. Bronson*, 591 F. Supp. 2d 1272, 1294 (S.D. Fla. 2008).

First, Plaintiff must establish a substantial likelihood of success on the merits. The Medicaid Act mandates that states that participate in the Medicaid program provide EPSDT services to Medicaid-eligible children under age 21. 42 U.S.C. §§ 1396a(a)(43) & 1396d(r). Under EPSDT, children must receive all services and treatments covered by the Medicaid Act necessary to "correct or ameliorate" any physical and mental illnesses and conditions discovered during a screen. 42 U.S.C. §1396d(r)(5); *see also Pittman v. Sec'y, Fla. Dep't of Health & Rehab. Servs.*, 998 F.2d 887, 889 (11th Cir. 1993). The state must provide any service covered by EPSDT "whether or not such services are covered under the state plan." *Id.* In other words, 42 C.F.R. §1396d(r)(5) requires that participating states must "cover every type of health care or service necessary for EPSDT corrective or ameliorative

purposes that is allowable under §1396d(a)." *Moore v. Reese*, 637 F.3d 1220, 1233-34 (11th Cir. 2011). Medicaid services "ameliorate" a condition when they maintain or improve a child's health or when they prevent a condition from worsening or prevent the development of additional health problems. *See* U.S. Dep't of Health & Human Servs., Ctrs. for Medicare & Medicaid Servs., *EPSDT – A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents* at 10 (June 2014).

Here, A.W. has shown that Defendant breached her duty under the federal Medicaid Act to provide A.W. with durable medical equipment, in this case a specialized bed, sufficient to ameliorate her conditions. In denying the A.W.'s request, Defendant relied on its own medical necessity standard set forth in Fla. Admin. Code R. 59G-1.010 which sets parameters that contradict and are more restrictive than what is allowed for under EPSDT. *See C.F. v. Department of Children and Families*, 934 So. 2d 1, 7 (Fla. 3d DCA 2005) (in evaluating whether a state agency correctly analyzed a child's need for Medicaid services under Fla. Admin. Code R. 59G-1.010, the court held that the agency "incorrectly used more restrictive definitions of 'medical necessity'…than federal law requires"); *see also*, *Q.H. v. Sunshine State Health Plan*, 307 So.3d 1, 14 (Fla. 4th DCA 2020) (finding that the state "erred in applying the 'overly restrictive' definition 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'"); *see also*, *I.B. v. Agency for Health Care Admin.*, 87 So.3d 6, 8-10 (Fla. 3d DCA 2012); *E.B. v. Agency for Health Care Admin.*, 94 So.3d 708, 708-709 (Fla. 4th DCA 2012).

A.W.'s treating professionals prescribed the durable medical equipment,[1] known as the "Dream Series" bed, because (1) A.W.'s scoliosis requires a bed that has a supportive mattress and bed frame; (2) A.W.'s developmental delay, seizures, and spasticity place her at risk for falling out of bed or becoming entrapped between the mattress and frame of a traditional hospital bed and side rails; (3) A.W.'s caregivers must have easy and quick access to A.W. while providing A.W. full assistance with her activities of daily living which requires a bed that can be raised and lowered as well as has sides that can be unlatched or secured with minimal effort; (4) A.W. risks aspiration which requires a bed with an adjustable head; and (5) A.W. risks becoming entangled in her g-tube extension tubing thus requiring a bed that has a special port to route the tubing.

Rather than assess whether the Dreams Series bed is medically necessary according to EPSDT's broad standard, Defendant instead evaluated A.W.'s request under its more stringent standard. In applying this more stringent standard, Defendant did not accord any weight or deference to the concerns of A.W.'s treating professionals. Most significantly, in finding that a traditional hospital bed

[1] Durable medical equipment is listed under 42 C.F.R. §1396d(a)(2)(A).

is sufficient to meet A.W.'s needs, Defendant ignored the treating professionals' opinion that a traditional hospital bed may lead to A.W.'s entrapment and serious injury. And, while both the state and treating physician have a role to play in determining medical necessity, states are "not empowered to act as the 'final arbiter' of medical necessity to arbitrarily ignore the reasons given in the treating physician's recommendation of…[medical services]." *M.H. v. Berry*, No. 15-cv-1427 TWT; 2021 WL 1192938 *6 (N.D. Ga. March 29, 2021). Defendant's decision to deny A.W. the Dream Bed and the reasons given for that decision do not comport with the EPSDT mandate. Accordingly, A.W. has shown a substantial likelihood of success on the merits

Second, A.W. must establish irreparable injury if relief is not granted. A.W.'s treating professionals have requested that Medicaid provide A.W. with a Dream Series bed. Without prompt access to this necessary benefit, A.W.'s health and well-being are in jeopardy. As stated by A.W.'s pediatrician, the benefit is necessary to "reduce the risk of injuries at bedtime." Thus, Defendant's denial of this medically necessary benefit to A.W. subjects her to irreparable harm. *See K.G. ex rel. Garrido v. Dudek*, 839 F. Supp. 2d 1254, 1278 (S.D. Fla. 2011); *Edmunds v. Levine*, 417 F. Supp. 2d 1323, 1342 (S.D. Fla. 2006) (citing *Cramer v. Chiles*, 33 F. Supp. 2d 1342, 1349 (S.D. Fla. 1999)); *see also*, O.*B. v. Norwood*, 170 F. Supp. 3d 1186, 1196 (U.S.D.C. N.D. Ill. 2016).

Third, A.W. must establish that the threatened injury outweighs the harm the relief may inflict on the non-moving party. Here, the balance of harms clearly lies in A.W.'s favor. Defendant is obligated by the Medicaid Act to promptly provide A.W. with all the necessary care she needs to correct or ameliorate her illnesses and conditions, and entry of a preliminary injunction will not harm Defendant. Instead, it simply demands that Defendant meet an obligation under which she is already subject to pursuant to federal Medicaid law. In contrast, the harm to A.W. if an injunction is not issued is evident and clearly outweighs any harm to Defendant. *See K.G.*, 839 F. Supp. 2d at 1268.

Fourth, A.W. must establish that entry of relief would not be adverse to the public interest. Granting a preliminary injunction will serve the public interest in upholding the law and enforcing the mandates of the Medicaid Act. *See K.G.* at 1280.

Finally, the security required by Fed. R. Civ. P. 65(c) is a matter within the discretion of the Court. *BellSouth Telecommunications, Inc. v. MCIMetro Access Transmission Servs., LLC*, 425 F.3d 964, 971 (11th Cir. 2005) (citations omitted). The Court may elect to require no security at all. *Id*. Public interest litigation such as this case is a recognized exception to the bond requirement. *Vigue v. Shoar*, No. 3:19-CV-186-J-32JBT, 2019 WL 1993551, at *3 (M.D. Fla. May 6, 2019) (citations omitted). Accordingly, the Court waives the security required by Fed. R. Civ. P. 65(c) because this matter involves public interest litigation.

For the reasons discussed above, the Court finds that A.W. has established all the requirements for the entry of a preliminary injunction. A.W.'s Motion for a Preliminary Injunction is **GRANTED**. Defendant is hereby enjoined from applying its medical necessity standard set forth in Fla. Admin. Code R. 59G-1.010 to A.W.'s request for a specialty medical bed and is ordered to evaluate A.W.'s request pursuant to the correct or ameliorate standard required by the EPSDT provisions of the federal Medicaid Act.

SO ORDERED, this ___ day of _____ 2021.

_____
Honorable Marcia Morales Howard
United State District Judge

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

W.B., by and through his Next Friend, David Bilotta, and A.W., by and through Her Next Friend, Brittany Cunningham on behalf of herself and all others similarly situated,

Plaintiff,

Case No.: 3:21-cv-771-MMH-PDB

v.

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

Defendant.
_____/

PROPOSED ORDER ON PLAINTIFF W.B.'S MOTION FOR PRELIMINARY INJUNCTION

This matter is before the Court on Plaintiff W.B.'s Motion for Preliminary Injunction. This is an action for injunctive and declaratory relief in which Plaintiff W.B. claims the Defendant is violating his rights under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) provisions of the Medicaid Act, 42 U.S.C. §§ 1396a(a)(43) & 1396d(r). W.B., a one-year-old boy diagnosed with a rare genetic disorder known as CHARGE Syndrome, seeks a Preliminary Injunction

against Defendant regarding Defendant's denial of specialty, out-of-state, outpatient hospital services.

Before a court will grant preliminary injunctive relief, the moving party must establish that: (1) "it has substantial likelihood of success on the merits," (2) it will suffer irreparable injury if the relief is not granted, (3) the threatened injury outweighs the harm the relief may inflict on the non-moving party, and (4) entry of relief "would not be adverse to the public interest." *KH Outdoor, LLC v. City of Trussville*, 458 F.3d 1261, 1268 (11th Cir. 2006). "Of these four requisites, the first factor, establishing a substantial likelihood of success on the merits, is most important...." *ABC Charters, Inc. v. Bronson*, 591 F. Supp. 2d 1272, 1294 (S.D. Fla. 2008).

First, Plaintiff must establish a substantial likelihood of success on the merits. The Medicaid Act mandates that states that participate in the Medicaid program provide EPSDT services to Medicaid-eligible children under age 21. 42 U.S.C. §§ 1396a(a)(43) & 1396d(r). Under EPSDT, children must receive all services and treatments covered by the Medicaid Act necessary to "correct or ameliorate" any physical and mental illnesses and conditions discovered during a screen. 42 U.S.C. §1396d(r)(5); *see also Pittman v. Sec'y, Fla. Dep't of Health & Rehab. Servs.*, 998 F.2d 887, 889 (11th Cir. 1993). The state must provide any service covered by EPSDT "whether or not such services are covered under the state plan." *Id.* In other

words, 42 C.F.R. §1396d(r)(5) requires that participating states must "cover every type of health care or service necessary for EPSDT corrective or ameliorative purposes that is allowable under §1396d(a)." *Moore v. Reese*, 637 F.3d 1220, 1233-34 (11th Cir. 2011). Medicaid services "ameliorate" a condition when they maintain or improve a child's health or when they prevent a condition from worsening or prevent the development of additional health problems. *See* U.S. Dep't of Health & Human Servs., Ctrs. for Medicare & Medicaid Servs., *EPSDT – A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents* at 10 (June 2014).

Here, W.B. has shown that Defendant breached her duty under the federal Medicaid Act to provide W.B. with specialty outpatient medical services at the CHARGE Center, a one-of-a-kind facility located at Cincinnati Children's Hospital. In denying the request, Defendant relied on its own medical necessity standard set forth in Fla. Admin. Code R. 59G-1.010 which sets parameters that contradict and are more restrictive than what is allowed for under EPSDT. *See C.F. v. Department of Children and Families*, 934 So. 2d 1, 7 (Fla. 3d DCA 2005) (in evaluating whether a state agency correctly analyzed a child's need for Medicaid services under Fla. Admin. Code R. 59G-1.010, the court held that the agency "incorrectly used more restrictive definitions of 'medical necessity'…than federal law requires"); *see also*, *Q.H. v. Sunshine State Health Plan*, 307 So.3d 1, 14 (Fla. 4th DCA 2020) (finding that the state "erred in applying the 'overly restrictive'

definition 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' "); *see also*, *I.B. v. Agency for Health Care Admin.*, 87 So.3d 6, 8-10 (Fla. 3d DCA 2012); *E.B. v. Agency for Health Care Admin.*, 94 So.3d 708, 708-709 (Fla. 4th DCA 2012).

W.B.'s treating professionals prescribed the outpatient medical services[1] at the CHARGE Center because the Center uses a multidisciplinary approach to coordinate care among subspecialists who have specific, up-to-date expertise in treating CHARGE Syndrome. In his short life, W.B., whose genetic disorder appears in only 1 in 10,000 live births, has been hospitalized over half a dozen times. His local treatment team is adamant that without care from the specialists at the CHARGE Center, W.B.'s will likely have poor clinical outcomes including further hospitalizations and developmental setback.

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[1] Outpatient medical services are listed under 42 C.F.R. §1396d(a)(7).

Additionally, under federal Medicaid regulations, states participating in the Medicaid program:

> "must provide 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.

Rather than assess whether care at the CHARGE Center is medically necessary according to EPSDT's broad standard, Defendant instead evaluated W.B.'s request under its more stringent standard. In applying this more stringent standard, Defendant did not accord any weight or deference to the concerns of W.B.'s treating professionals. Most significantly, Defendant ignored the opinion of W.B.'s pediatrician, Dr. Stephanie Carlin, that there were no specialty centers in Florida with expertise in treating CHARGE Syndrome. While both the state and treating physician have a role to play in determining medical necessity, states are "not empowered to act as the 'final arbiter' of medical necessity to arbitrarily ignore the reasons given in the treating physician's recommendation of…[medical services]." *M.H. v. Berry*, No. 15-cv-1427 TWT; 2021 WL 1192938 *6 (N.D. Ga. March 29, 2021).

Furthermore, Defendant, in relying on its own standard of medical necessity, violated EPSDT when she required W.B. to prove that his care at the CHARGE Center was not meant as a matter of convenience for him, his parents, or his providers. Defendant cannot graft on an additional requirement – outside whether the service is necessary to correct or ameliorate W.B.'s health condition – in determining whether W.B. is entitled to a Medicaid service. *See Jackson v. Millstone*, 801 A.2d 1034, 1049 (Md. 2002)*; M.H.,* 2021 WL 1192938 at *7 (finding that the state should determine whether a service is "medically

necessary…based on whether a service is medically necessary to correct or ameliorate a beneficiary's condition" and not "based upon non-medical criteria"). Defendant's decision to deny W.B.'s care at the CHARGE Center and the reasons given for that decision do not comport with the EPSDT mandate. Accordingly, W.B. has shown a substantial likelihood of success on the merits.

Second, W.B. must establish irreparable injury if relief is not granted. W.B.'s treating professionals have requested that Medicaid approve W.B.'s course of evaluation and treatment at the CHARGE Center. Without prompt access to this necessary benefit, W.B.'s health and well-being are in jeopardy. As stated by W.B.'s pediatrician, the care is necessary so W.B. can avoid long-term developmental setbacks; a sentiment echoed by W.B.'s other treating physicians. Thus, Defendant's denial of this medically necessary benefit to W.B. subjects him to irreparable harm. *See K.G. ex rel. Garrido v. Dudek*, 839 F. Supp. 2d 1254, 1278 (S.D. Fla. 2011); *Edmunds v. Levine*, 417 F. Supp. 2d 1323, 1342 (S.D. Fla. 2006) (citing *Cramer v. Chiles*, 33 F. Supp. 2d 1342, 1349 (S.D. Fla. 1999)); *see also*, O.*B. v. Norwood*, 170 F. Supp. 3d 1186, 1196 (U.S.D.C. N.D. Ill. 2016).

Third, W.B. must establish that the threatened injury outweighs the harm the relief may inflict on the non-moving party. Here, the balance of harms lies in W.B.'s favor. Defendant is obligated by the Medicaid Act to promptly provide W.B. with all the necessary care he needs to correct or ameliorate his illness and condition, and

entry of a preliminary injunction will not harm Defendant. Instead, it simply demands that Defendant meet an obligation under which she is already subject to pursuant to federal Medicaid law. In contrast, the harm to W.B. if an injunction is not issued is evident and clearly outweighs any harm to Defendant. *See K.G.*, 839 F. Supp. 2d at 1268.

Fourth, W.B. must establish that entry of relief would not be adverse to the public interest. Granting a preliminary injunction will serve the public interest in upholding the law and enforcing the mandates of the Medicaid Act. *See K.G.* at 1280.

Finally, the security required by Fed. R. Civ. P. 65(c) is a matter within the discretion of the Court. *BellSouth Telecommunications, Inc. v. MCIMetro Access Transmission Servs., LLC*, 425 F.3d 964, 971 (11th Cir. 2005) (citations omitted). The Court may elect to require no security at all. *Id*. Public interest litigation such as this case is a recognized exception to the security requirement. *Vigue v. Shoar*, No. 3:19-CV-186-J-32JBT, 2019 WL 1993551, at *3 (M.D. Fla. May 6, 2019) (citations omitted). Accordingly, the Court waives the security required by Fed. R. Civ. P. 65(c) because this matter involves public interest litigation

For the reasons discussed above, the Court finds that W.B. has established all the requirements for the entry of a preliminary injunction. W.B.'s Motion for a Preliminary Injunction is **GRANTED**. Defendant is hereby enjoined from applying its medical necessity standard set forth in Fla. Admin. Code R. 59G-1.010 to W.B.'s

request for outpatient hospital services at the CHARGE Center and is ordered to evaluate W.B's request pursuant to the correct or ameliorate standard required by the EPSDT provisions of the federal Medicaid Act.

SO ORDERED, this ___ day of _____ 2021.

_____
Honorable Marcia Morales Howard
United State District Judge