IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

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

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.

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

Defendant.
_____/

MOTION TO DISMISS

Pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure and Local Rule 3.01, Defendant Simone Marstiller, in her official capacity as Secretary for the Florida Agency for Health Care Administration ("AHCA"), files this Motion to Dismiss the Complaint, filed by Plaintiffs W.B. and A.W., on behalf of themselves and all other similarly situated individuals ("Plaintiffs"), and incorporated memorandum of law. Plaintiffs are minors enrolled in Florida's Medicaid program administered by AHCA, and, as such, are eligible for services

under the Early and Periodic Screening, Diagnostic and Treatment ("EPSDT") provisions of the Medicaid Act,[1] 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(4)(B), 1396a(a)(43)(C), and 1396d(r)(5). Plaintiffs have filed a Complaint alleging that AHCA has violated these provisions of the Act because Plaintiffs, and other Medicaid-enrolled children, may have been—or may one day be—improperly denied EPSDT services as a result of AHCA's decision to refuse to authorize services not deemed medically necessary under its codified definition of "medical necessity."

The Complaint should be dismissed on Article III standing grounds because Plaintiffs lack a concrete, particularized injury. Plaintiffs' only concrete alleged harms have been remediated (i.e., the specific services the Complaint alleges were improperly denied have been authorized), and all that remains is a general grievance with AHCA's definition of "medical necessity" as it applies to unidentified past and future requests for services under the EPSDT provisions of the Act.

Indeed, although Plaintiffs seek to certify a class that may include millions of Medicaid-enrolled children, the Complaint contains no concrete examples of how the "medical necessity" definition prevents Plaintiffs or any members of the putative class from obtaining services in the manner they allege violates federal law, apart from the two denials of requests for services that are now approved. Without more,

[1] 42 U.S.C. § 1396 et seq. (the "Medicaid Act" or the "Act").

Plaintiffs' indefinite challenge to the "medical necessity" definition falls squarely within the category of generalized grievances that the United States Supreme Court and Eleventh Circuit have ubiquitously held to fail the jurisdictional "case" or "controversy" threshold of Article III, section 2 of the United States Constitution.

The Complaint should also be dismissed for failure to state a claim upon which relief can be granted because the Complaint's allegations fail to demonstrate that AHCA's definition of medical necessity is inherently inconsistent with the Medicaid Act. The Act confers broad discretion on the states to develop their Medicaid programs both generally and specifically with respect to the development of "medical necessity" definitions as utilization control mechanisms. AHCA has adopted its five-prong medical necessity definition in accordance with this grant of discretion, and there is nothing unreasonable or violative of federal law with respect to any part of it.

While Plaintiffs acknowledge that states are permitted "to set parameters that apply to the determination of medical necessity," D.E. 1, ¶ 27 (quotation omitted), Plaintiffs contend that some services that should be authorized under the EPSDT provisions of the Act are being unlawfully denied because of AHCA's medical necessity definition. According to Plaintiffs, an EPSDT provision, section 1396(r)(5), contains a broad requirement that Medicaid-enrolled children receive any service necessary to "correct or ameliorate" illnesses and conditions and

precludes AHCA from relying upon its medical necessity definition with respect to EPSDT services. However, Plaintiffs do not meaningfully acknowledge that section 1396(r)(5) expressly authorizes states to include only those EPSDT services that are "***necessary***" to "correct or ameliorate" illnesses and conditions. And, as provided above, the Medicaid Act entrusts AHCA to set the parameters for what is "necessary."

Plaintiffs' arguments are irreconcilable with the Centers for Medicare and Medicaid Services ("CMS") implementing regulations, which specifically authorize states to "place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures," 42 C.F.R. § 440.230(d), and binding Eleventh Circuit precedent, *see Moore ex rel. Moore v. Reese*, 637 F.3d 1220 (11th Cir. 2011), which holds the same. In sum, Plaintiffs' contention that AHCA's medical necessity definition is facially inconsistent with the EPSDT provisions of the Medicaid Act is wrong as a matter of law. And Plaintiffs do not allege any concrete examples of how they believe AHCA is relying on its medical necessity definition in a manner that denies services to Medicaid-enrolled children that the EPSDT provisions of the Act require AHCA to authorize.

For these reasons, the Complaint should be dismissed for lack of subject matter jurisdiction or for failure to state a claim upon which relief can be granted.

BACKGROUND

I. The Medicaid Act

Medicaid is a cooperative medical assistance program, pursuant to which, states devise and fund their own medical assistance programs, subject to the requirements of the Medicaid Act. Under the Act, participating states must provide EPSDT services for Medicaid-enrolled children under the age of twenty-one. Of particular significance here, the EPSDT provisions of the Act require states to provide children, among other things, "[s]uch other necessary health care, diagnostic services, treatment, and other measures described in [§1396d(a)] 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).

The Medicaid Act and its implementing regulations do not define what is "necessary" to "correct or ameliorate" medical conditions, but rather grant the authority to the states to set reasonable standards for the terms "necessary" and "medical necessity." *See* 42 U.S.C. § 1396a(a)(17) (requiring states to provide reasonable standards for determining the extent of medical assistance that are consistent with the Medicaid Act); 42 C.F.R. § 440.230(d) (authorizing states to limit services on the basis of medical necessity or to employ other utilization control procedures).

To that end, CMS has published guidance documents explaining the contours of medical necessity and permissible limitations on the same, including the State Medicaid Manual, a manual outlining official interpretations of the law and regulations,[2] and the EPSDT: A Guide for States, a guide that compiles various EPSDT policy statements that CMS has issued over the years.[3]

The State Medicaid Manual provides that states have "the flexibility within the Federal statute and regulations to design an EPSDT program." State Medicaid Manual, § 5010. This includes placing reasonable "appropriate limits" on EPSDT services based on medical necessity. *Id*. at §§ 5110, 5122. For example, states have no obligation under the EPSDT to provide any items or services that are not safe and effective, or which are considered experimental. *Id*. at § 5122.

The EPSDT Guide provides similar instruction:

> Services that fit within the scope of coverage under EPSDT must be provided to a child only if necessary to correct or ameliorate the individual child's physical or mental condition, i.e., only if "medically necessary."
>
> ***
>
> States may adopt a definition of medical necessity that places tentative limits on services pending an individualized determination by the state,

[2] *See* CMS, U.S. Dep't of Health & Human Servs., State Medicaid Manual, ch.1, § B.1, hereinafter, the "State Medicaid Manual."
[3] *See* CMS, U.S. Dep't of Health & Human Servs., EPSDT: A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents, 23 (June 2014), hereinafter, the "EPSDT Guide."

> or that limits a treating provider's discretion, as a utilization control, but additional services must be provided if determined to be medically necessary for an individual child.

EPSDT Guide, at 23-24. The EPSDT Guide includes examples of permissible "medical necessity" limitations, including prior authorizations, prohibitions on experimental treatments, and consideration of cost-effectiveness. *Id*. at 24-25. The EPSDT Guide explains "a state need not make services available in every possible setting as long as the services are reasonably available through the settings where the service is actually offered." *Id*.

II. Florida's "Medical Necessity" Definition

As explicitly contemplated by the Medicaid Act and its implementing regulations, Florida has incorporated a medical necessity standard as a condition for Medicaid services, including EPSDT services. *See* § 409.905(2), Fla. Stat. Section 409.905(2), Florida Statutes, provides that AHCA shall pay for all EPSDT services "determined by the agency to be medically necessary for the treatment, correction, or amelioration of these problems and conditions." *Id*.

AHCA's definition of "medically necessary" is promulgated in Rule 59G-1.010, Florida Administrative Code, and applies generally to Medicaid services, including EPSDT services. The definition provides:

> 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.

See Rule 59G-1.010, Fla. Admin. Code.

III. The Named Plaintiffs

The Complaint alleges specific harms suffered by two named plaintiffs, A.W. and W.B., i.e., denials of services that Plaintiffs allege should have been authorized but were wrongly denied as a result of AHCA's definition of medical necessity. D.E. 1, ¶ 1. As stated in the Complaint, W.B. is a one-year-old child enrolled in the Children's Medical Services Health Plan, a Managed Medicaid Assistance program

administered by WellCare Health Plans, Inc. ("WellCare").[4] *Id*. at ¶ 65. W.B. is diagnosed with a condition known as CHARGE syndrome. *Id*. at ¶ 60. W.B.'s medical provider requested approval for services at an out of state facility from WellCare. *Id*. at ¶ 68. Initially, WellCare denied W.B.'s request because the services (1) did not meet 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 (2) were not furnished in a manner not primarily intended for convenience of the recipient, caretaker, or provider. D.E. 5-7. Ultimately, however, the WellCare Medical Director overturned the original medical necessity determination and authorized the requested services. *See* Ex. "A."

A.W. is an eleven-year-old, medically-complex child diagnosed with significant medical conditions who receives services reimbursed by AHCA on a fee-for-service ("FFS") basis. D.E. 1, ¶¶ 103, 119. A.W.'s medical provider requested a specialty medical bed from eQHealth Solutions Florida Inc. ("eQHealth"), a quality improvement organization ("QIO") contracted by AHCA to make medical necessity determinations for FFS Medicaid recipients. *Id.* at ¶ 109. eQHealth initially denied A.W.'s request because it determined that the specialty bed was not individualized,

[4] The majority of Medicaid recipients in Florida receive their medical services through a managed medical assistance ("MMA") plan provided by a managed care organization ("MCO") operating pursuant to a contract with AHCA. The MCOs have the authority to make medical necessity determinations in accordance with Florida law and AHCA's regulations. Medicaid recipients that are not required to enroll in an MMA receive services on a fee-for-service ("FFS") basis.

specific, and consistent with symptoms or confirmed diagnosis of the illness under treatment and was in excess of the patient's needs. *Id.* at ¶ 35; D.E. 4-6. The eQHealth Medical Director ultimately overturned the original medical necessity determination and the specialty bed for A.W. has now been approved. *See* Ex. "B."

In sum, the services sought by the named Plaintiffs have now been provided. Accordingly, none of the Complaint's allegations demonstrate the existence of an ongoing concrete injury being suffered by the Plaintiffs, and no concrete injury is alleged with respect to any of the other members of the putative class.

LEGAL ARGUMENT

I. The Complaint Should be Dismissed for Lack of Standing as it Fails to Allege a Live, Particularized Injury In Fact.

It is well-established that the federal courts lack jurisdiction over plaintiffs who lack Article III standing. *Stalley ex rel. U.S. v. Orlando Reg'l Healthcare Sys., Inc.*, 524 F.3d 1229, 1232 (11th Cir. 2008) (noting that a dismissal for lack of standing has the same effect as a dismissal for lack of subject matter jurisdiction). Critically, it is not enough that the complaint set forth facts from which the court could imagine the existence of Article III standing. *Miccosukee Tribe of Indians of Fla. v. Fla. State Athletic Comm'n,* 226 F.3d 1226, 1229 (11th Cir. 2000). Rather, the complaint must "clearly and specifically" plead facts to demonstrate Article III standing. *Id*. at 1230. When assessing standing the Court may consider extrinsic material such as affidavits, or, like here, the indisputable fact that the named

Plaintiffs' alleged concrete harms have been resolved. *See Stalley*, 524 F.3d at 1233.

To demonstrate standing, the plaintiff must show, as an irreducible, jurisdictional minimum: (1) an injury in fact; (2) that is causally connected to the defendant's actions; and (3) that is redressable by a favorable decision. *Kennedy v. Floridian Hotel, Inc.*, 998 F.3d 1221, 1229 (11th Cir. 2021). To demonstrate an injury-in-fact the plaintiff must show an injury that is (1) concrete and particularized; and (2) actual and imminent, not speculative or hypothetical. *Id.*

Additionally, a plaintiff seeking injunctive relief—as is the case here—must demonstrate a real and immediate threat of future injury. *Id.* This means that the anticipated injury is substantially likely to actually occur within some fixed period of time in the future. *Corbett v. Trans. Sec. Admin.*, 930 F.3d 1225, 1233 (11th Cir. 2019), *cert. denied*, 140 S. Ct. 900 (2020); *see also Fla. Health Scis. Ctr., Inc. v. Sec'y, U.S. Dep't of Health & Hum. Servs.*, 844 F. App'x 217, 220 (11th Cir. 2021) (stating an injury is not imminent if it depends on attenuated possibilities).

Importantly, an alleged statutory violation without a resulting concrete harm is not sufficient to satisfy Article III standing. *See TransUnion LLC v. Ramirez*, --, U.S. --, 141 S. Ct. 2190 (2021). Specifically, "[u]nder Article III, an injury in law is not an injury in fact. Only those plaintiffs who have been concretely harmed by a defendant's statutory violation may sue that private defendant over that violation in federal court." *Id.* at 2205. In *Muransky v. Godiva Chocolatier, Inc.*, 979 F.3d 917

(11th Cir. 2020), an Eleventh Circuit panel summarized the relevant inquiry:

> [W]e consider two things when we evaluate whether concrete harm flows from an alleged statutory violation—and thus whether the plaintiff has standing. First, we ask if the violation itself caused harm, whether tangible or intangible, to the plaintiff. If so, that's enough. If not, we ask whether the violation posed a material risk of harm to the plaintiff. If the answer to both questions is no, the plaintiff has failed to meet his burden of establishing standing.

Id. at 928.

So, for example, in *L.M.P. on behalf of E.P. v. School Board of Broward County, Florida*, 879 F.3d 1274 (11th Cir. 2018), an Eleventh Circuit panel found that a challenge to a school district's policy as violative of federal law failed for lack of standing. *Id*. at 1276. The court concluded that, even if the school district violated the Individuals with Disabilities Education Act by having a predetermined policy of not considering certain methodologies in a child's individualized education plan, the plaintiffs did not have standing to challenge the policy because they did not suffer a concrete and particularized harm in connection with the policy. *Id*. at 1282.

Similarly, in *Wood v. Raffensperger*, 981 F.3d 1307 (11th Cir. 2020), an Eleventh Circuit panel rejected a citizen's constitutional challenge to Georgia's election laws because he failed to allege a particularized grievance with the law:

> [The Plaintiff/Appellant] bases his standing on his interest in 'ensur[ing that] . . . only lawful ballots are counted.' **An injury to the right to require that the government be administered according to the law is a generalized grievance. And the Supreme Court has made clear that a generalized grievance, no matter how sincere, cannot support standing.**

Id. at 1314 (emphasis added) (citations and quotations omitted); *see also Banks v. Sec'y of Health & Hum. Servs.*, No. 21-11454, 2021 WL 3138562, at *2 (11th Cir. July 26, 2021) (rejecting argument that violation of statutory right to Medicare coverage is sufficient to confer standing).

Relatedly, because Article III limits federal courts to deciding cases and controversies, federal courts lack jurisdiction when there is no longer any live controversy. *See In re Checking Acct. Overdraft Litig.*, 780 F.3d 1031, 1039 (11th Cir. 2015) (holding named plaintiffs lacked standing to bring class action because plaintiffs had already received a favorable decision with respect to the alleged controversy). "'[I]f events that occur subsequent to the filing of a lawsuit or an appeal deprive the court of the ability to give the plaintiff or appellant meaningful relief, then the case is moot and must be dismissed.'" *C.V. by & through Wahlquist v. Senior*, No. 12-60460-CIV, 2017 WL 2730397, at *6 (S.D. Fla. Mar. 22, 2017) (quoting *Soliman v. U.S. ex rel. INS*, 296 F.3d 1237, 1242 (11th Cir. 2002)).

For example, in *A.R. by & through Root v. Secretary Florida Agency for Health Care Administration*, 769 F. App'x 718 (11th Cir. 2019), an Eleventh Circuit panel held that a district court properly dismissed three named plaintiffs because one plaintiff had moved out of state and, as such, would not be subject to the policies at issue, while the other two had aged out of the challenged program at issue. *Id.* at 727, n.7. The panel concluded that because the three individuals "lack[ed] a legally

cognizable interest in the outcome . . .the district court did not err in dismissing them from the case." *Id*. (quotation omitted). Further, because there were no remaining plaintiffs who were subject to the policy at issue, the panel held that the district court properly dismissed count five of the complaint because there were no remaining plaintiffs that had standing to bring the claim. *Id*. at 727.

Of greatest similarity to this case is *Summer H. v. Fukino*, No. CIV09-00047SOM/BMK, 2009 WL 1249306 (D. Haw. May 6, 2009), in which a district court judge dismissed for lack of standing a challenge to Hawaii's proposed 15 percent cut to Medicaid benefits as violative of EPSDT requirements. *Id*. at *1. With respect to one named plaintiff the court held that, after the state had agreed that no cuts to services were appropriate, he lacked an injury in fact and dismissed his claims. *Id*. at *6. The court held that two other named plaintiffs lacked standing because they were in the process of appealing the state's proposed cuts to their services and had suffered no reductions in services. *Id.* at *6-*7. The court also held that other named plaintiffs failed to demonstrate an actual cut in EPSDT benefits and therefore lacked standing. *Id*. at *8.

The Eleventh Circuit panel opinion in *A.R.* and order in *Summer H.* should instruct the result here. As with the plaintiffs in *A.R.* and *Summer H*., the alleged concrete and particularized injuries suffered by the named Plaintiffs have been indisputably remedied. There is no live controversy related to a concrete injury

stemming from AHCA's alleged violation of the Medicaid Act that this Court could redress. What remains is a generalized grievance with AHCA's definition of medical necessity without any accompanying injury-in-fact.

Moreover, the Complaint does not allege that AHCA's definition of medical necessity poses an immediate, material risk of harm to the named Plaintiffs. Indeed, the Complaint is silent as to any alleged future concrete, particularized harm that Plaintiffs might suffer as a result of AHCA's medical necessity definition. And it is not this Court's role to imagine possible scenarios under which Article III standing for the named Plaintiffs could materialize. At best, any material risk to Plaintiffs depends on a series of attenuated possibilities including, but not necessarily limited to (1) a request for another service by a named Plaintiff; (2) a denial by the relevant MCO or QIO based on a medical necessity determination, which is inconsistent with the Medicaid Act;[5] (4) an unsuccessful initial appeal to the MCO or QIO by the named Plaintiff; and (5) the inability of the parties to reach informal resolution without Court intervention. This is not the type of real and immediate, concrete

[5] It is worth reemphasizing that the existence of AHCA's medical necessity definition in and of itself does not result in a concrete, particularized injury. Again, Plaintiffs do not dispute that AHCA is entitled to adopt a definition of medical necessity to limit the provision of EPSDT services, rather, the injury Plaintiffs allege is a denial of EPSDT services based on those portions of AHCA's medical necessity definition that are more restrictive than the Medicaid Act. As discussed below, this argument is without merit. In any event, the relevant inquiry is not "will another Medicaid-enrolled child be denied EPSDT services based on medical necessity," but rather, "will another Medicaid-enrolled child be denied EPSDT services based on the application of AHCA's medical necessity in a manner that is more restrictive that the Medicaid Act permits."

threat of future injury necessary to support Article III standing.

II. The Complaint Fails To State A Cause Of Action Because AHCA'S Definition of Medical Necessity Does Not Violate Federal Law.

The central premise of the Complaint is that AHCA's definition of medical necessity is invalid as it applies to the provision of EPSDT services because it is more restrictive than what federal law allows. For relief, the Complaint seeks an order from this Court enjoining AHCA from applying its medical necessity definition for EPSDT service determinations, and compelling AHCA to adopt a new definition of medical necessity for the same. In other words, this action is akin to a facial challenge to AHCA's medical necessity definition—by virtue of the relief Plaintiffs seek, the necessary implication of Plaintiffs' argument is that there is no set of circumstances in which AHCA's medical necessity definition can be applied to the millions of Medicaid-enrolled children that are eligible for EPSDT services.

But the Complaint does not allege any facts that would suggest that AHCA's medical necessity definition is violative of federal law in *every* set of circumstances. And even more importantly for purposes of this Motion, the Complaint fails to demonstrate how there is *anything* irreconcilable as a matter of law between the definition and the EPSDT provisions of the Medicaid Act, which must be the standard given the class Plaintiffs seek to certify and the relief they seek.

Instead, in an attempt to state a claim against AHCA, Plaintiffs read critical words out of the statute on which they rely. The centerpiece of Plaintiffs' argument

is a specific section of the Medicaid Act relating to EPSDT services—42 U.S.C. § 1396(r)(5)—which requires state Medicaid programs to provide "[s]uch other necessary health care, diagnostic services, treatment, and other measures described in [§ 1396d(a)] 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." Plaintiffs contend that the "correct or ameliorate" standard in section 1396(r)(5) requires a robust authorization of services beyond what AHCA's medical necessity definition allows.

But the fundamental flaw in Plaintiffs' argument is its failure to recognize that section 1396(r)(5) on its face only requires states to cover EPSDT services to the extent they are "necessary," and there is no definition of what is "necessary" to "correct or ameliorate" medical conditions under federal law. *See Moore*, 637 F.3d at 1232. In other words, accepting Plaintiffs' argument would require the Court to, among other things, read "necessary" out of section 1396(r)(5) entirely.

In reality, the Medicaid Act and its implementing regulations expressly grant the states the authority to set reasonable standards for the terms "necessary" and "medical necessity," so long as any limitations are reasonable and otherwise do not undermine the purpose and intent of the Medicaid Act. *See* 42 U.S.C. § 1396a(a)(17); *Moore*, 637 F.3d at 1232. There can be no real dispute that a state "may place appropriate limits on a service based on such criteria as medical necessity or on

utilization control procedures." 42 C.F.R. § 440.230(d).

The CMS guidance documents confirm the states' primary role in defining the parameters of medical necessity in the context of EPSDT services. For example, the State Medicaid Manual provides that states may place "appropriate limits," such as medical necessity requirements, on EPSDT services. State Medicaid Manual, §§ 5110, 5122. Pursuant to the State Medicaid Manual, these "appropriate limits" include limitations on services that are not safe, that are not effective, or that are considered to be experimental. *Id*. at § 5122. The EPSDT Guide provides similar guidance, reiterating that states have broad discretion in defining what "medically necessary" means, and that they may place limits on EPSDT services based on medical necessity. *See* EPSDT Guide, at 23-25. Like the State Medicaid Manual, the EPSDT Guide lists prohibitions on experimental treatments and consideration of cost-effectiveness as acceptable medical necessity limitations. *Id*. It should not be lost on the Court that these are some of the very limitations AHCA has adopted as part of its medical necessity definition. *See* Rule 59G-1.010, Fla. Admin. Code.

Given its expansive language, some authorities (and indeed, Plaintiffs in this case) have interpreted the EPSDT provision of the Medicaid Act, § 1396d(r)(5), as eliminating the states' discretion in providing EPSDT services. *Cf. Moore*, 637 F.3d at 1230 (reversing district court for misconstruing states' role). But that interpretation of the Act was unambiguously rejected by an Eleventh Circuit panel

in *Moore*, and, accordingly, binding precedent dictates that "even if a category of medical services or treatments is mandatory under the Medicaid Act, participating states must provide those medical services or treatments for Medicaid recipients only if they are 'medically necessary.'" 637 F.3d at 1233. Further, "the Medicaid Act endows participating states with broad discretion to fashion standards for determining the extent of medical assistance, so long as such standards are reasonable and congruous with the purposes of the Act." *Id*. at 1244.

After reviewing the Medicaid statutes, regulations, manuals, and precedents, the *Moore* panel identified six guiding principles related to EPSDT services. *Id*. at 1255. First, a state is only required to provide EPSDT services if those services are medically necessary to correct or ameliorate his or her condition. *Id*. Second, states are required to adopt reasonable standards for determining eligibility for, and the extent of, Medicaid services that are consistent with the objectives of the EPSDT program. *Id*. Third, states may adopt a definition of medical necessity that limits a provider's discretion and may even limit the provision of required Medicaid services, as long as those limitations do not discriminate based on the type of medical condition. *Id*. Fourth, and relatedly, a private provider's opinion on medical necessity is not dispositive. *Id.* Fifth, a state may limit the amount, duration, and scope of EPSDT services and states are not required to provide medically unnecessary but desirable EPSDT services. *Id*. Sixth, a state may place limits on

EPSDT services, including medical necessity criteria, and can review the medical necessity of a service prescribed by a medical provider on a case-by-case basis. *Id.*

Applying these principles, the *Moore* court found that any facial challenge to Georgia's medical necessity standard as applied to EPSDT services would not survive because it was not per se unreasonable and simply reflected Georgia's exercise of its discretionary authority. *Id*. at 1257. The court construed the plaintiff's challenge to the standard as an as-applied challenge and held that the district court erred in granting summary judgment for the plaintiff and "too narrowly limiting" the state's role in determining medical necessity. *Id*. at 1257-58.

A similar result should follow here. Plaintiffs cannot state a cause of action because AHCA's definition of medical necessity is not a *per se* unreasonable or an invalid exercise of its discretion under the Medicaid Act. Consistent with the authorities set forth above, Florida has incorporated a medical necessity standard as a condition for EPSDT services that is plainly permissible under federal law.

Simply stated, the central contention of the Complaint—that the EPSDT "correct or ameliorate" standard can be divorced from the concept of medical necessity—cannot be reconciled with the CMS guidance documents and binding Eleventh Circuit precedent discussed above. For example, an experimental treatment may "correct" a certain condition, but the State Medicaid Manual and EPSDT Guide expressly provide that a state is under no obligation to provide any experimental

services, i.e., such services are not medically necessary. State Medicaid Manual, at § 5122; EPSDT Guide, at 24. Likewise, a desirable treatment may "ameliorate" a certain condition but binding Eleventh Circuit precedent instructs that a state is not required to provide desirable but medically unnecessary services. *Moore*, 637 F.3d at 1255. Similarly, a certain treatment or service may generally correct or ameliorate a condition, but an individualized case-by-case determination may demonstrate that, in fact, the service is not medically necessary for a particular child. *Id*.

The Complaint specifically challenges two prongs of AHCA's five-pronged definition of medical necessity outlined above.[6] The necessary implication is that Plaintiffs recognize the validity of the remaining three prongs, which include requirements that the service at issue be (1) 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; (2) consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational; and (3) reflective of the level of service that can be safely furnished, and for which no equally effective and more conservative or less

[6] In 2017 AHCA issued a memorandum summarizing the concept of medical necessity as a limitation on Medicaid services, including EPSDT, *see* D.E. 1-1, and Plaintiffs rely on this memorandum—as opposed to the text of the rule itself—for the false proposition that AHCA believes the opinions of treating providers are to be completely ignored See D.E. 1, ¶ 51. While Plaintiffs have clearly misconstrued the meaning and effect of the memorandum, the more important point is that Plaintiffs' quibble is with the memorandum, not the rule. Notwithstanding this, Plaintiffs seek to sweepingly enjoin the rule defining medical necessity, not this memorandum.

costly treatment is available statewide. In any event, as the CMS guidelines make unambiguously clear, these limitations are consistent with federal law. *See, e.g.*, State Medicaid Manual, at § 5122*; EPSDT Guide,* at 23-25.

With respect to the remaining two prongs of the definition, Plaintiffs are simply wrong as a matter of law. The Complaint alleges that the requirement that a service "be necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain," is inconsistent with the federal EPSDT provision that authorizes services necessary to "correct or ameliorate" a child's illness, disability, or other health condition. D.E. 1, ¶¶ 39-40. However, as provided above, Plaintiffs have misread the term "necessary" out of the provision upon which they rely. AHCA is only required to authorize services *necessary* to correct or ameliorate illnesses and conditions, and, further, has broad discretion to determine what "necessary" means. Pursuant to this discretion, AHCA determined that services were only "medically necessary" to protect life, to prevent significant illness or significant disability, or to alleviate severe pain. This is a reasonable requirement that is entirely consistent with federal law and regulations. Indeed, the Complaint fails to provide a single example of a factual circumstance in which this prong could violate federal law, much less meaningfully allege that the requirement is *per se* unreasonable or inconsistent with the EPSDT provisions of the Medicaid Act.

The Complaint also challenges AHCA's requirement that the service "be

furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider," D.E. 1, ¶ 42, and states that "federal Medicaid EPSDT provisions do not authorize the Defendant to consider 'convenience' as a factor." *Id*. at ¶ 43. Again, this misconstrues the relevant standard. The Medicaid Act expressly permits AHCA to consider whatever factors it deems appropriate for determining medical necessity, with the only limitations being reasonableness and consistency with the purpose of the Act. There is nothing inherently unreasonable or inconsistent with AHCA's consideration of convenience, rather, the consideration is entirely compatible with *Moore*'s instruction that states are free to limit desirable but medically unnecessary EPSDT services.[7]

CONCLUSION

For the foregoing reasons, AHCA respectfully request that the Plaintiffs' Complaint be dismissed.

DATED this 30th day of September, 2021.

[7] The Complaint cites a series of decisions of Florida intermediate appellate courts, which they assert demonstrate judicial recognition of a fundamental problem with AHCA's medical necessity definition. The reality, however, is that each of these cases involved the consideration of individual factual circumstances. *See, e.g.*, *Moore*, 637 F.3d at n.66 (explaining the salient factors at issue in *C.F. v. Department of Children & Families*, 934 So.2d 1 (Fla. 3d DCA 2005)); *I.B., ex rel. R.B. v. State, Agency for Health Care Admin*., 87 So. 3d 6, 9 (Fla. 3d DCA 2012) (holding hearing officer should have applied rule governing personal care assistance rather than skilled nursing medical necessity standard); *E.B. v. Agency for Health Care Admin*., 94 So. 3d 708 (Fla. 4th DCA 2012) (considering reduction in duration of home health aide services). And, in any event, and more importantly, decisions of state intermediate appellate courts interpreting federal law are not binding on this Court. *See Gallardo by & through Vassallo v. Dudek*, 977 F.3d 1366, 1367 (11th Cir. 2020). By contrast, the *Moore* decision is binding, and forecloses Plaintiffs' claims.

Respectfully submitted,

/s/ *Erik M. Figlio*
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Alexandra E. Akre
Florida Bar No.: 0125179
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123 South Calhoun Street (32301)
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ATTORNEYS FOR DEFENDANT

LOCAL RULE 3.01(g) CERTIFICATION

Pursuant to Local Rule 3.01(g), counsel for AHCA has conferred in good faith with counsel for Plaintiffs' counsel via telephonic conference and Plaintiffs' counsel opposes the motion.

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing has been filed electronically via the CM/ECF System on this 30th day of September, 2021.

/s/ *Erik M. Figlio*
Erik M. Figlio

Children's Medical Services Health Plan
Operated by WellCare

Fax Cover Sheet

From:	Children's Medical Services Health Plan	To:	CINCINNATI CHILDRENS HOSPITAL MEDICAL CE
Sender's Fax #:	(877) 892-8215	Recipient's Fax #:	(513) 636-0764
Pages (Including cover page):	3	Date:	08/18/2021
Subject:	Approved		

Message:

Please see attached request for additional information.

WellCare Health Plans, Inc. | P.O. Box 31370 | Tampa, FL 33631-3370

Children's Medical Services Health Plan
Operated by WellCare

P.O. Box 31370
Tampa, FL 33631-3370

08/18/2021

RE: Authorization Determination

Dear Provider:

The request submitted by CINCINNATI CHILDRENS HOSPITAL MEDICAL CE 914 for W[redacted] B[redacted], has been approved**.**

Authorization Number:	[redacted]
Authorization:	Consultation and treatment
Place of Service:	On Campus-Outpatient Hospital
Treating Provider:	PHILIP PUTNAM, MD 683239
Facility:	CINCINNATI CHILDRENS HOSPITAL MEDICAL CE 914
	This approval is for the original denial being overturned and approved by the Medical Director.
Service Details:	Consult and Treat

Effective Date	Expiration Date	Code	Description	Quantity
08/18/2021	10/17/2021	43239	EGD BIOPSY SINGLE/MULTIPLE	1
08/18/2021	10/17/2021	99205	OFFICE/OUTPATIENT VISIT NEW	1

Please notify the member of this authorization determination.

If you are the requesting provider, please ensure that the treating provider and/or facility is aware of this information. The health plan does not coordinate these services.

Children's Medical Services Health Plan
Operated by WellCare

If you are the treating provider, please communicate treatment status and care outcome to the member's primary care physician on a periodic basis.

Obtaining authorization does not guarantee payment, but rather only confirms whether a service meets WellCare's determination criteria at the time of the request. WellCare retains the right to review benefit limitations and exclusions, beneficiary eligibility on the date of service, the medical necessity of services, and correct coding and billing practices.

Claims submitted for payment should include all necessary, complete and compliant data including the authorization number, CPT and ICD-10 codes.

To all MEDICARE providers: Members may be responsible for a sum of copays when receiving certain diagnostic services in addition to a consult or procedure, depending on how your office bills for those services.

Sincerely,

Children's Medical Services Health Plan

eQHealth Solutions - Florida Division
5431 E. Beaumont Blvd.
Suite 5431
Tampa, FL 33634

Date of Notice: 9/22/2021
Review Complete Date: 9/21/2021
Review Request Date: 9/21/2021
Billing Provider & Number: 100894700
UNITED SEATING AND MOBILITY, LLC
Setting: DME
Requested By: Phyllis Boudreux
Doctor's & Number: 276059200
CARLIN STEPHANIE A
Recipient Name: [redacted]
Recipient's Medicaid Number: [redacted]
Admit Date: [redacted]

ADMINISTRATOR
UNITED SEATING AND MOBILITY, LLC
2580 COUNTY ROAD 220 STE 1
MIDDLEBURG, FL 32068-6532

NOTICE OF OUTCOME

Dear ADMINISTRATOR:

eQHealth Solutions is the Quality Improvement Organization contracted with the Florida Agency for Health Care Administration (AHCA) to review DME services provided to Medicaid recipients in the State of Florida. Under this contract, experienced nurses and physicians assure that Medicaid medical care meets medical necessity guidelines.

We received a request for review of the equipment and/or supplies listed below for the above referenced patient to determine if such services are appropriate.

Prior Authorization Number	Equipment Code	Effective Begin Date	Effective Thru Date	Total Units
5021265620	E1399	9/21/21	12/31/21	1

A physician reviewed the request and based on the information submitted to us the following items have been approved. Our decision includes the number of units approved or denied in the "Total Units" column.

Code	Description	From	Thru	Total Units		Rental Type If Rented	*Payment for Manually Priced Items
E1399	Specialized Medical Equipment/Supplies	9/21/21	12/31/21	Approved	1		11,040.47
				Denied	0		

* See Fee Schedule for payment amounts for any requested codes that are not manually priced.

Please be aware that this eQHealth Solutions certification determination does not guarantee Medicaid payment for services. Eligibility for and payment of Medicaid services are subject to all terms and conditions and limitations of the Medicaid Program.

If you have any questions or need additional information, you may contact customer service at 1-855-444-3747.

Sincerely,

Medical Director
Chris Kunis, MD

649 DME OP Outcome

52163993