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.
_____/

RESPONSE TO MOTION FOR CLASS CERTIFICATION

Pursuant to Federal Rule of Civil Procedure 23 ("Rule 23"), 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 response in opposition to the motion for class certification (the "Motion") filed by Plaintiffs W.B., by and through his father and legal guardian, David B. ("W.B."), and A.W., by and through her mother and legal guardian, Brittany C. ("A.W.") (collectively, "Plaintiffs"), on behalf of themselves and all others similarly situated.

INTRODUCTION

Plaintiffs have filed a Complaint alleging that AHCA has violated the early and periodic screening and diagnostic treatment ("EPSDT") provisions of the Medicaid Act, 42 U.S.C. § 1396 et seq. The gravamen of the Complaint is that AHCA has adopted a definition of "medical necessity" as a utilization control mechanism that, in some respects, is more restrictive than the EPSDT provisions allow, and, consequently, in some instances, services that should be authorized under the EPSDT provisions of the Act are being unlawfully denied because of some portions of the definition. *See generally* 42 U.S.C. § 1396d(r)(5).

To address the problem alleged in the Complaint, Plaintiffs request that this Court certify a class that can best be described as sprawling, consisting 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 as set for in Fla. Admin. Code R. 59G-1.010.

D.E. 1, p.4. If certified, this class would include every one of approximately 2.4 million Medicaid-enrolled children (under age 21) merely because, in Plaintiffs' view each Medicaid-enrolled child subject to AHCA's medical necessity definition has been or one day will be denied EPSDT services for reasons that are unlawful under the Act. Consequently, the Complaint seeks an order globally 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.

There is no meaningful way to identify the proposed class, much less determine issues such as standing, numerosity, commonality, and typicality. This is because, contrary to the broad relief requested, as Plaintiffs acknowledge in the Complaint, the Act, its implementing regulations, and binding Eleventh Circuit precedent construing them all make clear that AHCA is permitted to develop a medical necessity definition as a utilization control measure applicable to EPSDT services, and therefore its existence, in and of itself, is not unlawful. Further, AHCA's medical necessity definition has a number of components, each of which can serve as an independent basis for the denial of services, and Plaintiffs implicitly acknowledge that at least some of these components are acceptable.

Accordingly, simply being "subject to" AHCA's medical necessity definition as it relates to EPSDT services is not, and cannot, be the hallmark of a certifiable class. Rather, it is the alleged harms stemming from the definition—denials for reasons inconsistent with the Act—that are actionable. However, apart from the Plaintiffs, the Motion presents no support for the proposition that any Medicaid-enrolled children have even been denied (or will ever be denied) EPSDT services based on the portions of the medical necessity definition that Plaintiffs assert to be unlawful. Moreover, the class would necessarily be comprised of an unidentified

number of children who were denied (or will be denied) services for a myriad of reasons, including reasons that are indisputably permissible under the Act and reasons that have nothing to do with medical necessity, and this would unavoidably require highly-fact intensive individualized inquiries to determine which of the millions of children actually belong in the class.

Apart from the patent, unmanageable overbreadth of the class Plaintiffs seek to certify, there are a series of reasons why the Motion should be denied. First, class certification is unnecessary for the relief requested. If Plaintiffs were able to establish that AHCA's definition of medical necessity is irreconcilable with the EPSDT provisions of the Act, one plaintiff with standing could establish the invalidity of the definition. Thus, there is no need for the Court and the parties to endure the complexities and expense associated with class litigation.

Second, the named Plaintiffs lack Article III standing. As established below and in AHCA's contemporaneously filed Motion to Dismiss, the specific harms alleged in the Complaint have been remedied—the equipment and services sought by the Plaintiffs have been provided—and all that remains is a generalized grievance with the medical necessity definition without any allegations of ongoing harm sufficient to constitute a concrete and particularized injury-in-fact.

Third, Plaintiffs have not, and cannot, demonstrate compliance with the Rule 23 requirements. Plaintiffs have failed to meet their burden of showing that a class

comprised of all Medicaid-enrolled children who by virtue of being subject to AHCA's medical necessity definition have been or will be denied EPSDT services. The class is not ascertainable because identifying the class members requires extensive individualized assessments with respect to members who have already been denied EPSDT services for reasons Plaintiffs contend to be unlawful, and, presumably, a crystal ball for members who will be denied EPSDT services in the future. Plaintiffs fail to propose a meaningful mechanism for discerning either group. The mechanism Plaintiffs do propose for ascertaining the class is both underinclusive, because it does not address denials that were not appealed or those class members who Plaintiffs speculate "will be" denied services in the future based on medical necessity, and overinclusive, because it includes denials based on portions of AHCA's medical necessity definition that Plaintiffs implicitly concede are valid.

Additionally, the proposed class lacks commonality and typicality. The alleged "glue" that holds the broad class together—a definition of medical necessity that has or will result in impermissible EPSDT denials—cannot be unlawful as to every Medicaid-enrolled child, and evaluating which children fall into the class is inherently a fact-intensive, individualized assessment. Because AHCA's application of the medical necessity definition is highly individualized based on the needs of the child, there is no common injury applicable to every Medicaid-enrolled child

stemming from the definition. As such, the proposed class does not share a common contention that is capable of class-wide resolution.

Any one of these reasons is sufficient in and of itself to require denial of class certification, and for these reasons, AHCA requests that the Motion be denied.

BACKGROUND

I. Medical Necessity Under the Medicaid Act

Under the Medicaid Act, participating states must provide EPSDT services for Medicaid-enrolled children under the age of 21. Of central importance to this case, the core EPSDT provision of the Act requires participating states to provide Medicaid-enrolled children "[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…." 42 U.S.C. § 1396d(r)(5).

The central premise of the Complaint is that certain portions of AHCA's medical necessity definition are irreconcilable with the "correct or ameliorate" standard in 42 U.S.C. § 1396d(r)(5). However, and as more fully developed in AHCA's contemporaneously filed motion to dismiss, Plaintiff's argument relies on a fundamental misreading of this statute, as the statute unambiguously limits AHCA's requirement to authorize services to those that are "necessary," and the Medicaid Act and its implementing regulations grant AHCA broad discretion to

define medical necessity. *See* 42 U.S.C. § 1396a(a)(17) (requiring states to provide reasonable standards for determining eligibility that are consistent with the Act); 42 C.F.R. § 440.230(d) (recognizing authority of states to place medical necessity limitations on EPSDT services); *see also* Centers for Medicare & Medicaid Servs. ("CMS"), U.S. Dep't of Health & Human Servs., State Medicaid Manual, ch.1, §§ 5110, 5122 (stating states may adopt reasonable limitations on EPSDT services, including medical necessity determinations); CMS, U.S. Dep't of Health & Human Servs., EPSDT: A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents, 23-24 (June 2014) (same).

II. Florida's Medical Necessity Standard

Florida law provides that AHCA "shall pay for early and periodic screening and diagnosis of a recipient under age 21 to ascertain physical and mental problems and conditions and all services determined by the agency to be medically necessary for the treatment, correction, or amelioration of these problems and conditions. . . ." *See* § 409.905(2), Fla. Stat. Florida's definition of medical necessity is comprised of five separate components. *See* Rule 59G-1.010, Fla. Admin. Code.

First, the service must be "necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain." *Id*. Second, the service must 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." *Id.* Third, the service must be "consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational." *Id.* Fourth, the service must 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." *Id.* And finally, the service must be "furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider." *Id.* The definition further provides that "[t]he 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." *Id*. (emphasis added).

As noted above, each of these components can serve as an independent basis for the denial of services. Further, Plaintiffs do not challenge the second, third, or fourth components of the definition.

There are several contexts in which AHCA, or entities implementing Florida's Medicaid program on behalf of or in concert with AHCA, utilize the medical necessity definition for EPSDT service determinations. Most Medicaid participants are required to enroll in a managed Medicaid assistance ("MMA") plan, provided by a managed care organization ("MCO"). The MCOs contract with AHCA to deliver managed care to their enrollees, which includes the authority to make medical

necessity determinations in accordance with Florida law and AHCA's regulations.

Medicaid recipients not required to enroll in an MMA plan receive their services on a fee-for-service ("FFS") basis, and AHCA contracts with eQHealth Solutions Florida Inc. ("eQHealth"), a quality improvement organization ("QIO"), to review authorization requests and make medical necessity determinations.

III. The Named Plaintiffs

There are two named plaintiffs in this action: W.B. and A.W. The similarities between W.B. and A.W. are limited: (1) they are both Medicaid-enrolled children who were initially denied coverage of certain specialty medical services; (2) neither W.B. nor A.W. fully utilized AHCA's established administrative procedures for challenging allegedly improper denials of authorization for services;[1] and (3) both W.B. and A.W. were ultimately approved for the services that formed the basis for their stated injuries in the Complaint. That is where the similarities end, and, of particular significance, W.B. and A.W. were initially denied the services previously at issue under unrelated components of the medical necessity definition.

[1] Whether Medicaid enrollees receive services on an FFS basis or through an MMA plan, they are provided with a grievance and appeal process. Upon receipt of an adverse benefit determination the Medicaid enrollee may appeal the decision to the MCO or QIO directly. If any part of the initial adverse benefit determination is upheld after this initial appeal, the Medicaid enrollee may ask for a Medicaid fair hearing conducted by AHCA ("Fair Hearing"). *See* § 409.285, Fla. Stat. After which, if the Medicaid enrollee believes the hearing officer erroneously affirmed the denial of an authorization request, he or she has the right to appeal the decision to a Florida intermediate appellate court. *See* § 120.68, Fla. Stat. Here, W.B. did not pursue a merits-based Fair Hearing determination, *see* Ex. "A," and A.W. did not exercise her appellate rights and thus allowed the hearing officer's order to become final.

A. W.B.

W.B. is a one-year-old child enrolled in the Children's Medical Services Health Plan, an MMA plan administered by WellCare Health Plans, Inc. ("WellCare"). W.B. has a condition known as CHARGE syndrome, and his alleged injury was based on a request for treatment at a specialty facility operating in Cincinnati Children's Hospital, an out of state, out of network provider. D.E. 5-2; D.E. 5-4. WellCare initially denied the request because it determined that the treatment was not medically necessary 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 was 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. "B."

B. A.W.

A.W. is an eleven-year-old child diagnosed with significant medical conditions whose alleged injury was premised on the denial of a requested specialty piece of durable medical equipment, a specialty bed. D.E. 4-2; D.E. 4-6. A.W. is an FFS Medicaid recipient, and, accordingly, the request was submitted to AHCA's

QIO, eQHealth, which initially denied the request on medical necessity grounds because it determined that the specialty bed was not individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness under treatment and was in excess of the patient's needs. *Id.* eQHealth has since approved the specialty bed for A.W. *See* Ex. "C."

IV. The Proposed Class

As provided above, the Plaintiffs propose a class that would include every Medicaid-enrolled child in Florida, under 21, as they define the proposed class as "[a]ll Florida Medicaid beneficiaries under age 21 who have been or will be required to establish their need for Medicaid services under [AHCA's] standard for medical necessity, . . ." D.E. 1, p.4, because, in their view, each Medicaid-enrolled child has or will have EPSDT services denied based on application of the medical necessity definition. *See* D.E. 3, p.16. However, the Motion does not present any evidence demonstrating that an appreciable number of Medicaid-enrolled children have had EPSDT services denied, let alone that any are planning to request services that will be denied, based on the allegedly impermissible portions of the definition.

To the contrary, the Motion refers to "thousands of low-income children in Florida [that] are subject to Defendant's medical[] necessity standard resulting in denials of EPSDT services," *Id.* at p.14, and cites to the 1,317 Fair Hearing requests AHCA received regarding services for children under age 21 in fiscal year 2019-

2020. *Id*. While 1,317 could be an underestimate of actual denials, it would represent less than .06 percent of a proposed class inclusive of nearly 2.4 million Medicaid-enrolled children. *See id*. What's more, at least some portion of that .06 percent almost certainly includes appeals of denials premised on the prongs of AHCA's medical necessity definition Plaintiffs do not challenge. Even assuming the number of Medicaid-enrolled children that have or will be adversely affected by the allegedly invalid components of the medical necessity definition is in the "thousands," that number is just a very small fraction of the proposed class.

V. The Proposed Remedy

To match the sprawling class, the Complaint seeks an equally broad remedy: an order enjoining AHCA from applying its definition of medical necessity to EPSDT services and requiring AHCA to adopt a new definition of medical necessity. D.E. 1, p.33; D.E. 3, p.19 ("[T]he remedies sought by the named plaintiffs are the same remedies that would benefit class members: an injunction requiring Defendant to modify its medical necessity standard, as applied to children under age 21, in a manner that comports with EPSDT."). Plaintiffs seek to invalidate the definition *in toto* as applied to EPSDT services, notwithstanding the fact that Plaintiffs only take issue with two of its five prongs:[2] the requirements that the service be "necessary to

[2] Plaintiffs also indirectly attack the portion of the medical necessity definition which provides that "[t]he 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

protect life, to prevent significant illness or significant disability, or to alleviate severe pain," and that the service "be furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider." By omitting any discussion of the other prongs of the definition, Plaintiffs implicitly concede that those provisions comply with federal law.[3]

STANDARD OF REVIEW

A party seeking class certification has the burden of proof to establish all requirements of Rule 23, and any doubts concerning whether the standard has been satisfied must be resolved against the party seeking certification. *Brown v. Electrolux Home Prod., Inc.*, 817 F.3d 1225, 1233 (11th Cir. 2016). "All else being equal, the presumption is against class certification because class actions are an exception to our constitutional tradition of individual litigation." *Id.*

While the decision to grant or deny class certification lies within the discretion

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necessity or a covered service." However, Plaintiffs' principal complaint is not with the definition itself but with a 2017 memorandum issued by AHCA summarizing the concept of medical necessity as a limitation on Medicaid services, including EPSDT. *See* D.E. 1-1. Plaintiffs do not acknowledge that the definition merely precludes a provider's prescription from itself constituting a controlling medical necessity determination and, instead, assert that the memorandum goes farther and dictates that provider recommendations are to be completely ignored. While Plaintiffs have incorrectly interpreted this memorandum, the more important point is that Plaintiffs do not assert that the portion of definition itself—"[t]he 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—violates federal law. As such, Plaintiffs' challenge to this memorandum bears no relationship to the relief they seek in the case.

[3] As discussed in AHCA's motion to dismiss, there can be no serious contention otherwise, as these prongs of the medical necessity definition are clearly contemplated by federal guidance implementing the Medicaid Act.

of the district court, *Armstrong v. Martin Marietta Corp*., 138 F.3d 1374, 1386 (11th Cir. 1998), that discretion is not unfettered and requires the court to perform a "rigorous analysis" to determine whether the party seeking class certification "in fact" affirmatively demonstrated its compliance with the requirements of Rule 23. *Brown*, 817 F.3d at 1233. Moreover, if the Court has reservations about whether the Rule 23 requirements have been met, it should refuse to grant certification until any and all doubts have been resolved. *Landeros v. Pinnacle Recovery, Inc*., 692 F. App'x 608, 611 (11th Cir. 2017) (citing *Brown*, 817 F.3d at 1233-34).

LEGAL ARGUMENT

I. Class Certification Is Inappropriate Under Rule 23(b)(2).

Plaintiffs seek class certification under Rule 23(b)(2), which provides that a class can be certified for purposes of a request for declaratory or injunctive relief only if "the party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole." Fed. R. Civ. P. 23(b)(2). This Court should exercise its discretion in favor of denying the Motion because class relief is not necessary or appropriate in this case.

The appropriateness of the class mechanism for achieving the requested injunctive relief is a proper consideration under Rule 23(b)(2). *See M.R. v. Bd. of Sch. Comm'rs of Mobile Cty*., 286 F.R.D. 510, 518 (S.D. Ala. 2012) (collecting

cases).[4] "Where the members of the proposed class would benefit from the relief sought by the individual plaintiffs even if no class were certified, [district] courts often find that the burdens outweigh the benefits and that class certification is properly denied as inappropriate." *M.R.*, 286 F.R.D. at 518. That is, class-based relief is not appropriate in circumstances where an injunction for the individual plaintiffs would amount to exactly the same relief as an injunction for an entire class. *Id*; *see also Arnett v. Strayhorn*, 515 F. Supp. 2d 690, 698 (W.D. Tex. 2006), *aff'd sub nom. Arnett v. Combs*, 508 F.3d 1134 (5th Cir. 2007) (noting that class actions exist for the purpose of judicial economy, and if no useful purpose would be served through a class action, class certification should be denied).

For example, in *United Farmworkers of Florida Housing Project, Inc. v. City of Delray Beach*, 493 F.2d 799 (5th Cir. 1974),[5] in a challenge to a municipality's

[4] *See also Dionne v. Bouley*, 757 F.2d 1344, 1356 (1st Cir. 1985) (holding class certification may be denied where there is no meaningful benefit); *Galvan v. Levine*, 490 F.2d 1255, 1261 (2d Cir. 1973) (holding class certification was unnecessary formality when state defendant made clear that it understood that the judgment would run to the benefit of not only the named plaintiffs, but also all others similarly situated); *Gayle v. Warden Monmouth Cty. Corr. Inst*., 838 F.3d 297, 310 (3d Cir. 2016) (holding necessity is not a freestanding requirement of class certification, but that it may be a relevant consideration as to appropriateness); *Sandford v. R. L. Coleman Realty Co*., 573 F.2d 173, 178 (4th Cir. 1978) (holding class certification was unnecessary in order to give the plaintiffs the injunctive relief they requested); *Craft v. Memphis Light, Gas & Water Div*., 534 F.2d 684, 686 (6th Cir. 1976), *aff'd*, 436 U.S. 1, 98 S. Ct. 1554 (1978) (same); *James v. Ball*, 613 F.2d 180, 186 (9th Cir. 1979), *reversed on other grounds, Ball v. James*, 451 U.S. 355, 101 S. Ct. 1811 (1981) (same); *Kansas Health Care Ass'n, Inc. v. Kansas Dep't of Soc. & Rehab. Servs*., 31 F.3d 1536, 1548 (10th Cir. 1994) (same).

[5] *In Bonner v. City of Prichard, Alabama*, 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc), the Eleventh Circuit adopted as binding precedent all decisions of the former Fifth Circuit handed down prior to October 1, 1981.

refusal to permit a proposed housing project to connect to existing water and sewer systems, a Fifth Circuit panel affirmed the district court's refusal to certify as a class the farmworkers for whose benefit the litigation was conducted because, with or without class certification, "the decree to which they are entitled is the same." *Id*. at 812. Because the relief sought would benefit all persons "subject to the practice under attack," the panel concluded that certification of a class was unnecessary. *Id*.

Similarly, in *Access Now Inc. v. Walt Disney World Co*., 211 F.R.D. 452 (M.D. Fla. 2001), a court in the Middle District of Florida concluded that class certification was not necessary because "[t]he Plaintiffs are only seeking injunctive relief which, if granted, would necessarily benefit all other potential class members," and therefore the "complexity and expense of a class action" was not necessary in the case. *Id*. at 455; *see also Madera v. Lee*, No. 1:18-CV-152-MW/GRJ, 2019 WL 1054671, at *1 (N.D. Fla. Mar. 5, 2019) (denying class certification because class was not necessary); *Hall v. Burger King Corp*., No. CIV A.890260CIVKEHOE, 1992 WL 372354, at *11 (S.D. Fla. Oct. 26, 1992) (same); *Thompson v. Merrill*, No. 2:16-CV-783-ECM, 2020 WL 411985, at *5 (M.D. Ala. Jan. 24, 2020) (same).

Here, Plaintiffs' requested relief does not warrant class certification for similar reasons. Plaintiffs' request for a permanent injunction directing AHCA to "[c]ease 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

"[a]dopt a medical necessity standard for beneficiaries under age 21 that comports with federal Medicaid law," D.E. 1, p.33, if granted, would benefit all similarly-situated individuals, regardless of whether they are putative class members. If this Court were to craft an order finding that AHCA's definition of medical necessity is more restrictive than federal law permits, even in the context of litigation between AHCA and just one plaintiff, then Plaintiffs will have achieved exactly the requested relief they are seeking—AHCA would have to cease applying its definition of medical necessity and adopt a new rule in accordance with the Court's finding.

II. The Named Plaintiffs Lack A Concrete Injury.[6]

"[A]ny analysis of class certification must begin with the issue of standing." *Griffin v. Dugger*, 823 F.2d 1476, 1482 (11th Cir. 1987). A named plaintiff with standing to bring the claims of the class is a prerequisite to class certification. *AA Suncoast Chiropractic Clinic, P.A. v. Progressive Am. Ins. Co.*, 938 F.3d 1170, 1174 (11th Cir. 2019). Additionally, at least at trial, every class member individually must demonstrate standing. *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2207-08 (2021) (considering standing in the class action context, stating that "standing is not dispensed in gross; rather, plaintiffs must demonstrate standing for each claim that they press and for each form of relief that they seek," and reversing judgment in

[6] The issue of standing is more fully briefed in AHCA's motion to dismiss the Complaint. The reasons that require dismissal of the Complaint similarly require denial of the Motion.

favor of those class members who did not demonstrate a concrete injury in fact).

The Motion alleges that the named Plaintiffs have standing because they "suffer the concrete and particularized injury of (1) [AHCA] denying their request to provide a Medicaid service based on an erroneous standard of medical necessity, and (2) because of [AHCA's] denial, they were denied care necessary to correct or ameliorate their conditions placing their health at risk." D.E. 3, p.12. However, these concrete and particularized injuries no longer present a live controversy for which this Court can order relief because Plaintiffs have received the requested services and equipment. As such, neither the named Plaintiffs nor the proposed class, as defined, continue to suffer from or face any imminent risk of a concrete, particularized injury. Rather, the only remaining live controversy is a generalized grievance related to a statutory violation not tied to any specific harm, which, as a matter of law cannot support Article III standing.[7]

[7] As indicated above, there is a related question as to whether the definition of the proposed class, by virtue of its overbreadth, could ever pass Article III standing muster. As the court in *Cordoba* noted, "there is a meaningful difference between a class with a few members who might not have suffered an injury traceable to the defendants and a class with potentially many more, even a majority, who do not have Article III standing." *Cordoba*, 942 F.3d at 1277. Although the panel of the Eleventh Circuit in *Cordoba* declined to adopt a rule that an overbroad class presented an issue of standing at the class certification stage, and instead resolved the issue pursuant to Rule 23(b)(3), the instruction was clear: "if a class is overbroad in this way, there is a compelling reason to redefine it more narrowly." *Id.* at 1276 (quotations and citations omitted); *see also Conigliaro v. Norwegian Cruise Line Ltd.*, No. 05-21584-CIV, 2006 WL 7346844, at *3 (S.D. Fla. Sept. 1, 2006) ("[T]he proposed class description must not be so broad as to include individuals who are without standing to maintain the action on their own behalf") (internal quotation marks omitted). Here, the proposed class definition is legally insufficient because the putative class includes individuals who, under binding Supreme Court precedent, would not have standing to sue on their own and could not be afforded relief under any circumstances. Plaintiffs' proposed class

III. The Class Is Not Ascertainable.

In addition to concerns raised above, the Motion is due to be denied because the proposed class fails the requirement that it must be "adequately defined and clearly ascertainable." *AA Suncoast,* 938 F.3d at 1174. Importantly, if the court must engage in individualized determinations to ascertain class membership, the class should not be certified. *Stalley v. ADS Alliance Data Sys., Inc*., 296 F.R.D. 670, 678 (M.D. Fla. 2013). Identification of the class should be manageable and should not require much, if any, individual inquiry. *Bussey v. Macon Cnty. Greyhound Park, Inc*., 562 F. App'x 782, 787 (11th Cir. 2014) (quoting *Newberg on Class Actions* § 3.3 p. 164 (5th ed. 2012)).

For example, in *Jamie S. v. Milwaukee Public Schools*, 668 F.3d 481 (7th Cir. 2012), a Seventh Circuit panel vacated a class-certification order, where the initial proposed class was "all school age children with disabilities who reside in the Milwaukee Public School District boundaries and who are or may be eligible for special education and related services under IDEA and Wisconsin law," but was ultimately narrowed to "students eligible to receive special education from MPS' 'who are, have been or will be' denied or delayed entry into or participation in the IEP process." *Id*. at 485. The court found that both the initial proposed class and the

necessarily includes class members that have not been harmed in any way by the portions of the definition that are alleged to be invalid.

certified class were "fatally indefinite" because they "sought to lump together thousands of disparate plaintiffs" and required fact-intensive, individualized inquiries. *Id*. at 493-96.

The rationale of a sister court in *A.R. v. Dudek*, No. 12-60460-CIV, 2016 WL 3766139 (S.D. Fla. Feb. 29, 2016), *aff'd sub nom. A.R. by & through Root v. Sec'y Fla. Agency for Health Care Admin*., 769 F. App'x 718 (11th Cir. 2019), is also instructive here. *Id.* at *1. There, the plaintiffs sought to certify a class comprised of "[a]ll current and future Medicaid recipients in Florida under the age of 21, who are (1) institutionalized in nursing facilities, or (2) medically complex or fragile and at risk of institutionalization in nursing facilities." *Id.* at *1. The magistrate judge, whose report and recommendation was adopted in relevant part, found that the proposed class was too broad and amorphous. *A.R. v. Dudek*, No. 12-60460-CIV, 2015 WL 11143082, at *5 (S.D. Fla. Aug. 7, 2015), *report and recommendation adopted in part, rejected in part*, No. 12-60460-CIV, 2016 WL 3766139 (S.D. Fla. Feb. 29, 2016), *aff'd sub nom. A.R. by & through Root v. Sec'y Fla. Agency for Health Care Admin*., 769 F. App'x 718 (11th Cir. 2019).

With respect to overbreadth, the magistrate judge found that "Plaintiffs' definition is over inclusive because it includes children who are unharmed by the policies alleged to be causing institutionalization and, thus, lack standing." *Id*. at *5. Additionally, the magistrate judge found that the proposed class impermissibly

required a fact-intensive inquiry. *Id*. The district judge agreed with the magistrate judge's reasoning and conclusions with respect to ascertainability of the proposed class and added the additional comment that because "Plaintiffs offer[ed] no objective measure by which to gauge the persons included within the class," "the proposed class definition is not sufficiently ascertainable as required by the Eleventh Circuit." *A.R.* 2016 WL 3766139, at *1.

Here, the proposed class suffers from the same ascertainability deficiencies at issue in *Jamie S.* and *A.R.* There is simply no meaningful way to determine which Medicaid-enrolled children have been or will be denied EPSDT services, under the challenged portions of AHCA's medical necessity definition (for reasons that are incongruous with the EPSDT provisions of the Medicaid Act) without the individual review of millions of records.

Plaintiffs contend that the class is ascertainable because "MCOs must report monthly to Defendant a summary of all Medicaid appeals including whether the appeal is EPSDT related," and therefore "Defendant thus has a mechanism to identify every Medicaid beneficiary under age 21 who was refused coverage of a requested benefit due to the application of Defendant's medical necessity standard." D.E. 3, p.22. But this mechanism is both overinclusive and underinclusive. The mechanism is underinclusive because it is limited to identification of children who actually *were* refused coverage of a requested benefit and completely ignores those

class members Plaintiffs speculate will be wrongfully denied EPSDT services in the future. It is also underinclusive because it fails to account for Medicaid recipients who, like A.W., are not enrolled in an MCO. Additionally, Plaintiffs' proposed mechanism is overinclusive because it encompasses denials based on reasons other than medical necessity as well as denials based on the unchallenged prongs of the medical necessity definition.

IV. The Putative Class Does Not Satisfy the Requirements of Rule 23(a).

The foregoing reasons independently demonstrate why the Court should deny the Motion, however, the Court should also deny the Motion because it fails to satisfy the "commonality" and "typicality" requirements of Rule 23(a). *See AA Suncoast*, 938 F.3d at 1174 (holding party seeking to certify class must prove numerosity, commonality, typicality, and adequacy of representation).[8]

Rule 23(a) requires a plaintiff who seeks to represent a class show that "there are questions of law or fact common to the class." Fed. R. Civ. P. 23(a). Thus, where resolution of claims depends on individualized facts and circumstances class certification is inappropriate. *Vega v. T-Mobile USA, Inc.*, 564 F.3d 1256, 1272 (11th Cir. 2009). In *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338 (2011), the Supreme

[8] Plaintiffs' allegations as to numerosity are also largely conclusory. *See Vega v. T-Mobile USA, Inc.*, 564 F.3d 1256, 1268 (11th Cir. 2009) (district court abused its discretion by relying on speculation to establish numerosity in the absence of evidence in the record); *Hunter v. Cook*, No. 1:08-CV-2930-TWT, 2012 WL 12831938 (N.D. Ga. Aug. 2, 2012) (denying class certification because plaintiffs did not produce any evidence as to the number of individuals who were affected by the policies at issue).

Court explained the that the "commonality requirement" was more than a simple shared question of law or even a shared violation of the same provision of law. *Id.* at 350. Commonality requires substantially more:

> Quite obviously, the mere claim by employees of the same company that they have suffered a Title VII injury, or even a disparate-impact Title VII injury, gives no cause to believe that all their claims can productively be litigated at once. Their claims must depend upon a common contention … That common contention, moreover, must be of such a nature that it is capable of classwide resolution—which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke.

Id.

For example, in *Truesdell v. Thomas*, 889 F.3d 719 (11th Cir. 2018), an Eleventh Circuit panel affirmed the denial of class certification in an action involving a law enforcement officer's alleged misuse of Florida's driver and vehicle identification database to access the personal information of thousands of individuals. *Id.* at 722. The Court noted that at least some of the officer's access was alleged to be legitimate, and thus the district court correctly found that the defendant-appellee's proposed class lacked typicality and commonality because the "reasons for accessing each putative class member's personal information may vary for each class member." *Id*. at 726 (quotation omitted).

Typicality, like commonality, focuses on whether a sufficient nexus exists between the legal claims of the named class representatives and those of individual class members. *Prado-Steiman ex rel. Prado v. Bush*, 221 F.3d 1266, 1278 (11th Cir.

2000). While commonality relates to the characteristics of the class as a whole, typicality refers to how the named plaintiffs relate to the class. *Id*. Much like commonality, there can be no typicality where the court must consider individualized factors to determine whether relief is warranted. *Vega*, 564 F.3d at 1276. Moreover, "[w]ithout individual standing to raise a legal claim, a named representative does not have the requisite typicality to raise the same claim on behalf of a class." *Prado-Steiman*, 221 F.3d at 1279; *see also Hines v. Widnall*, 334 F.3d 1253, 1258 (11th Cir. 2003) (affirming denial of class certification because plaintiffs sought to represent a class that was "far too broad," and, therefore, the named plaintiffs did not meet the typicality requirement of Rule 23).

For example, in *Prado*, an Eleventh Circuit panel vacated a class certification order with instructions to the district court to ensure that at least one of the named class representatives possessed the requisite typicality and standing to bring each of the class's legal claims. 221 F.3d at 1267. The panel noted that a class including "[a]ll persons with developmental disabilities who are presently receiving Home and Community–Based Waiver Services or who are eligible to receive Home and Community–Based Waiver Services, or who would receive or be eligible for Home and Community–Based Waiver Services in the future," was too broad and that class certification was inappropriate because "there [were] sharp differences amongst class subgroups in the type of conduct challenged and the type of injury suffered."

Id. at 1270, 1281. The court concluded, "Plaintiffs have not demonstrated that the claims of the named class representatives possess the requisite typicality with the claims of the class at large, or that the named class representatives possess standing to raise all of the class's claims." *Id*. at 1283; *see also Griffin*, 823 F.2d at 1484 (holding district court erred when it certified class testing claim when plaintiff suffered no injury as a result of defendant's testing requirements).

Here, Plaintiffs allege "[a]ll members of the proposed class have suffered or will suffer the same harms; Defendant is denying class members Medicaid services based on its restrictive medical necessity standard rather than afford them the opportunity to prove medical necessity in accordance with EPSDT's broader criteria." D.E. 3, p.16. But this contention relies on the dubious premise that *all* Medicaid-enrolled children have been or one day will be denied EPSDT services on the basis of portions of the medical necessity definition Plaintiffs allege to be invalid, and the Motion does not assert any facts that would support this conclusion.

Further, the "same harms" Plaintiffs allege to exist between the putative class members are, in fact, widely divergent. The mere existence of AHCA's general medical necessity definition does not warrant class certification, because simply applying medical necessity limitations to EPSDT services, in and of itself, is not unlawful. Moreover, AHCA's application of its "medical necessity" definition is highly individualized and, consequently, does not affect all Medicaid-enrolled

children in the same way. Much like in *Truesdell*, there are circumstances in which AHCA properly applies (or will apply) its definition of medical necessity to EPSDT services in a manner that Plaintiffs would concede to be completely valid.

Thus even assuming Plaintiffs state a claim for relief and correctly identify the relevant standards, Plaintiffs' claims do not raise a question that is susceptible to one common class-wide answer. For any given class member, there are too many intervening issues relevant to the question of whether AHCA's medical necessity definition is narrower than federal law permits, including: (1) whether the class member was denied services based on medical necessity; (2) the reasoning supporting the medical necessity determination, i.e. what prong of the definition was applied; (3) whether that reasoning is supported by or at odds with the requirements of the EPSDT provisions of the Act; (4) whether the class member challenged the denial of services based on medical necessity and whether the denial was affirmed because of necessity; and (5) how each of these questions applies to unidentified future requests for EPSDT services. Attendant to each of these questions is a series of fact-intensive inquiries that are not appropriate for class-wide adjudication.

Indeed, the named Plaintiffs themselves do not even share a common injury, and, relatedly are not typical of the proposed class, because they were denied EPSDT services for different, individualized reasons, and, thus, whether the application of AHCA's medical necessity was in violation of the EPSDT provisions of the Act

cannot be answered in one broad stroke. As stated above, AHCA's definition of "medical necessity" is comprised of five prongs, each of which can form an independent basis for denial of a service. The record evidence demonstrates that A.W. was denied services based on the second prong of AHCA's medical necessity definition—the requirement that the service 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. D.E. 4-3. However, the Complaint does not challenge this component of AHCA's definition of medical necessity, which begs the question of what class of plaintiffs A.W. purports to represent.

Further, as Plaintiffs recognize in the Complaint, W.B. was denied services based on prong four of AHCA's medical necessity definition—that the service be reflective of the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available statewide—and prong five—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. 5-7. But the allegations of the Complaint apparently only challenge the latter standard.[9] Moreover, while Plaintiffs allege that the application of prong five to W.B. was unlawful under the EPSDT provisions of the Act, it does not

[9] With respect to prong four, as stated in the Motion, what Plaintiffs are really challenging with respect to W.B. is the application of AHCA's cost-effectiveness standard, not that the requirement is facially violative of the Medicaid Act. *See* D.E. 3, p.9.

necessarily follow that the application of prong five to all Medicaid-enrolled children will be similarly unlawful. For example, application of prong five could result in an approval for one child; or the circumstances could be such that the EPSDT provisions of the Act would also mandate a denial.

In addition to challenging the fifth prong of AHCA's medical necessity definition, Plaintiffs also challenge the first prong of the definition—the requirement that a service be necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain. D.E. 1 at ¶ 41. However, there are no named plaintiffs who were denied services based on this requirement. Thus, there is no named plaintiff that is "typical" of this harm, nor is there a named plaintiff that has standing to assert this type of injury.

In support of its commonality argument, Plaintiffs rely on *M.H. v. Berry*, No. 1:15-CV-1427-TWT, 2017 WL 2570262 (N.D. Ga. June 14, 2017); however, the case is easily distinguished. There, the putative class included approximately 763 members. *Id*. at *4. This stands in stark contrast to the proposed class here of approximately 2.4 million Medicaid-enrolled children. By comparison, the class in *M.H*. was ascertainable and well-defined. Additionally, the alleged shared commonality between the class members in *M.H.* was much more suitable for class-resolution. At issue was the policies the state of Georgia applied in setting the number of skilled-home nursing hours. *Id.* at *2. There is a significant difference

between a challenge to policies regarding the determination of the number of medically necessary nursing hours, and the application of a general medical necessity definition to all EPSDT services. The former takes for granted that the service will be provided, and the only question is in what amount, the latter does not and could result in an approval, a denial that is consistent with the Act, or a denial that is inconsistent with the Act. Thus, here, unlike in *M.H.*, the sharp differences amongst the proposed class members in the type of conduct challenged and the type of injury suffered precludes this Court from finding that the proposed class satisfies the requirements of Rule 23.

DATED this 30th day of September, 2021.

Respectfully submitted,

/s/ *Erik M. Figlio*
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Florida Bar No.: 0745251
Alexandra E. Akre
Florida Bar No.: 0125179
Ausley McMullen
123 South Calhoun Street (32301)
Post Office Box 391
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Facsimile No.: (850) 222-7560
rfiglio@ausley.com
csullivan@ausley.com

ATTORNEYS FOR DEFENDANT

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

STATE OF FLORIDA
AGENCY FOR HEALTH CARE ADMINISTRATION
OFFICE OF FAIR HEARINGS

W.B. C/O DAVID B[redacted]

PETITIONER, **AHCA Case No.: [redacted]**

vs.

CHILDREN'S MEDICAL SERVICES,

RESPONDENT.
_____/

FINAL ORDER OF DISMISSAL

The Fair Hearing request in this case was made by David B[redacted] ("Complainant") on January 8, 2021. Complainant is a third party and not the purported Recipient, W.B.

Rule 59G-1.100(7)(c)(1), Florida Administrative Code ("F.A.C."), requires any person requesting a Fair Hearing on behalf of a Recipient or seeking to represent a Recipient in a Fair Hearing to provide and maintain with the Office a written authorization signed by the Recipient or by a person with legal authority to act on behalf of the Recipient. Failure to file a Designation of Authorized Representative ("DAR") constitutes grounds for dismissal of a Fair Hearing request pursuant to Rule 59G-1.100(9)(b)(4), F.A.C.

The Office of Fair Hearings ("Office") provided an Acknowledgement of Third Party Fair Hearing Request ("Acknowledgement") to Complainant at their address of record on January 12, 2021. The Acknowledgment advised Complainant of the DAR requirement under Rule 59G-1.100(7)(c)(1), F.A.C. Also included with the Acknowledgement was a sample DAR form with instructions for completion and submittal. The Office did not receive a response.

On January 20, 2021, the undersigned issued an Order to Show Cause ("Order") why the third party hearing request should not be dismissed for failure to comply with Rule 59G-1.100(7)(c)(1), F.A.C. Included with the Order was another copy of the sample DAR form with instructions. The Order notified Complainant that failure to comply with the rule requirement on or before February 1, 2021, would result in dismissal of the case. Again, the Office did not receive a response.

Dismissal of this case is without prejudice to refile within applicable time limits.

IT IS HEREBY ORDERED AND ADJUDGED THAT:

The case is dismissed without prejudice, and is now closed.

DONE AND ORDERED this 9th day of February, 2021, in Tallahassee, Leon County, Florida.

James W. Earl
21-FH0083
2021.02.09 10:20:47 -05'00'

JAMES W. EARL, Hearing Officer
Agency for Health Care Administration
Office of Fair Hearings
2727 Mahan Drive, Mail Stop # 11
Tallahassee, FL 32308-5407
Office: (850) 412-3649
Fax: (850) 487-1423
E-mail: OfficeOfFairHearings@ahca.myflorida.com

NOTICE OF A RIGHT TO JUDICIAL REVIEW

A PARTY WHO IS ADVERSELY AFFECTED BY THIS FINAL ORDER IS ENTITLED TO JUDICIAL REVIEW, WHICH SHALL BE INSTITUTED BY FILING THE ORIGINAL NOTICE OF APPEAL WITH THE AGENCY CLERK OF AHCA, AND A COPY, ALONG WITH THE FILING FEE PRESCRIBED BY LAW, WITH THE DISTRICT COURT OF APPEAL IN THE APPELLATE DISTRICT WHERE THE AGENCY MAINTAINS ITS HEADQUARTERS OR WHERE A PARTY RESIDES. REVIEW PROCEEDINGS SHALL BE CONDUCTED IN ACCORDANCE WITH THE FLORIDA APPELLATE RULES. THE NOTICE OF APPEAL MUST BE FILED WITHIN 30 DAYS OF THE RENDITION OF THE ORDER TO BE REVIEWED.

COPIES FURNISHED TO:

W.B. c/o David B[redacted]
[redacted]
[redacted]

Children's Medical Services
CMSPlanContract@flhealth.gov

AHCA Medicaid Hearing Unit
MedicaidHearingUnit@ahca.myflorida.com

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