IN THE
UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

A.M.T., by his mother and next friend Karla T., *et al.*,	)	
Plaintiffs,	)	
vs.	)	No. 1:10-cv-0358-SEB-TAB
ANNE WALTERMANN MURPHY, *et al.*,	)	
Defendants.	)	

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION[1]

INTRODUCTION

In an oft-cited opinion, the Fourth Circuit Court of Appeals has characterized the statutory and regulatory framework for the Medicaid program as representing "among the most completely impenetrable texts within human experience." *Rehab. Ass'n of Virginia v. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994). Although the present case concerns the nuances of federal Medicaid law, the questions that it presents are actually quite simple. The plaintiffs are all seriously disabled children for whom therapy services have been prescribed by their treating physicians in order to ward against or otherwise prevent significant regression in their conditions. Notwithstanding both these recommendations and the indisputable fact that the plaintiffs will lose physical and intellectual function absent the continuation of these therapies, the Indiana Family and Social Services Administration has begun refusing to provide Medicaid

[1] On March 25, 2010, the plaintiffs filed their Motion for Class Certification (R. Doc. 10). Briefing on this issue is proceeding, and it is anticipated that this Motion will be fully briefed in advance of the preliminary injunction hearing presently scheduled for May 28, 2010. In the event that the Court grants the plaintiffs' request for class certification, the plaintiffs request that any preliminary injunction inure to the benefit of the class as well.

payment for therapies for longer than two (2) years (absent certain circumstances) or for therapies that it considers "maintenance"—that is, therapies intended to prevent *re*gression in a patient's condition rather than therapies intended to enable or cause significant *pro*gression. *See* IND. ADMIN. CODE tit. 405, r. 5-22-6(b)(6),(7). This case therefore presents two (2) legal issues for resolution:

- Whether a State may refuse to provide Medicaid payment for services to children when those services have been recommended as medically necessary by their treatment providers.

- Whether a State must provide Medicaid payment for therapy services to disabled children when those services are necessary to prevent significant regression in the children's functional state or in their ability to complete their activities of daily living.

The Seventh Circuit has previously recognized that "in the context of individuals under the age of twenty-one . . . a state's discretion to exclude services deemed 'medically necessary' by a . . . provider has been circumscribed by the express mandate of [federal Medicaid law]." *Collins v. Hamilton*, 349 F.3d 371, 376 n.8 (7th Cir. 2003). And the notion that a state may refuse to provide Medicaid payment for therapy services to disabled children simply because those services are only necessary to prevent substantial regression in their conditions flies in the face of the broad coverage that federal Medicaid law ensures will be available for minors.[2]

[2] As noted immediately above, at issue in this case are two (2) policies of the State: (a) that forbidding the provision of Medicaid payment for therapies for longer than two (2) years, s*ee* IND. ADMIN. CODE tit. 405, r. 5-22-6(b)(6); and (b) that forbidding the provision of Medicaid payment for so-called "maintenance therapy," *see* IND. ADMIN. CODE tit. 405, r. 5-22-6(b)(7). However, because the former (two-year) regulation also limits therapies that do not result in "a significant change in medical condition," in actuality this regulation appears to be co-extensive with the State's prohibition on Medicaid payment for "maintenance therapy." Each of these regulations is therefore treated together throughout this brief under the nomenclature for "maintenance therapy." Additionally, although the State's two-year limit appears to possess a potential exception for juveniles, *see id.*, no such exception exists concerning the provision of "maintenance therapy," *see* IND. ADMIN. CODE tit. 405, r. 5-22-6(b)(7). In this vein, it is possible that an injunction prohibiting the enforcement of the "maintenance therapy" regulation will render the "two-year" regulation obsolete. Moreover, any exception to the "two-year" regulation

Given that the plaintiffs are likely to prevail on the merits of their claims and that they will suffer irreparable harm absent immediate relief, a preliminary injunction enjoining the agency from enforcing either challenged provision of the Indiana Administrative Code against children should issue.

STATEMENT OF FACTS

It is anticipated that the following facts will be adduced during the preliminary injunction hearing in this cause (which is presently scheduled for May 28, 2010):

I. FACTS CONCERNING THE STATE'S PRACTICES OR POLICIES

The Indiana Family and Social Services Administration, through its Office of Medicaid Policy and Planning, is responsible for the operation of, *inter alia*, the Medicaid program in Indiana.

A Medicaid enrollee who desires to receive Medicaid payment for certain services—including, *inter alia*, physical therapy, occupational therapy, respiratory therapy, and speech pathology (collectively, "therapies")—must obtain approval for these services from the Medicaid agency before receiving Medicaid payment for these services. This is a process known as "prior authorization." A request for prior authorization is submitted on behalf of a Medicaid enrollee by the provider that will provide the services to the Medicaid enrollee. Once such a request is submitted on behalf of a Medicaid enrollee, it will be approved, denied, or modified by the Medicaid agency. The Medicaid agency has contracted with two (2) companies to issue decisions on prior authorization requests. These companies are Advantage Health Solutions, Inc,

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is limited to those Medicaid recipients who are under eighteen (18) years of age, s*ee* IND. ADMIN. CODE tit. 405, r. 5-22-6(b)(6), whereas expansive Medicaid coverage for EPSDT-eligible children exists until the child's twenty-first (21st) birthday, *see* 42 U.S.C. § 1396a(a)(10)(A); 42 U.S.C. § 1396d(4)(B). Thus, some members of the putative class are automatically ineligible for any potential exception to the "two-year" rule, and for these persons the two (2) regulations at issue appear to be more-or-less co-extensive with one another.

and MDWise, Inc., and these companies both therefore operate as agents of the Medicaid agency.[3]

Based on the terms of explicit state regulations, the Medicaid agency and its contractors refuse to approve therapies for more than two (2) years from the initiation of the therapy, unless there is a significant change in medical condition requiring longer therapy.[4] The Medicaid agency and its contractors also refuse to approve so-called "maintenance therapy," which is defined as "therapy addressing chronic medical conditions where further progress can no longer be expected or where progress is minimal in relation to the time needed in therapy to achieve that progress."[5] Thus, "maintenance therapy" is, in essence, therapy designed to prevent an individual from regressing to a lesser functional state rather than therapy designed to enable an individual to progress to a better functional state. Although the Medicaid agency may approve therapies for longer than two (2) years for a Medicaid recipient under the age of eighteen (18) on a case-by-case basis, it will not do so if it determines that the therapies requested qualify as "maintenance therapy."[6]

The Medicaid agency enforces both of these policies even when the requested therapies have been recommended and/or prescribed by a Medicaid enrollee's physician or other licensed practitioner of the healing arts within the scope of their practice under Indiana law. Indeed,

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[3] For Indiana's regulations detailing the prior authorization process, see IND. ADMIN. CODE tit. 405, r. 5-3-1, *et seq.*

[4] *See* IND. ADMIN. CODE tit. 405, r. 5-22-6(b)(6) ("Therapy for rehabilitative services will be covered for a recipient no longer than two (2) years from the initiation of the therapy unless there is a significant change in medical condition requiring longer therapy. Habilitative services for a recipient under eighteen (18) years of age may be prior authorized for a longer period on a case-by-case basis.).

[5] *See* IND. ADMIN. CODE tit. 405, r. 5-22-6(b)(7) ("Maintenance therapy is not a covered service."); *see also* IND. ADMIN. CODE tit. 405, r. 5-22-1(5) (defining "maintenance therapy").

[6] These prohibitions are detailed in a portion of the Medicaid agency's policy manual, which was attached to the plaintiffs' Class Action Complaint for Declaratory and Injunctive Relief (filed Mar. 25, 2010), as Exhibit 1.

because a prior authorization request must be submitted on a Medicaid enrollee's behalf by his or her physician or other licensed practitioner of the healing arts within the scope of their practice under Indiana law, each prior authorization request for therapies has necessarily been recommended and/or prescribed by these individuals. Minors for whom therapies have been recommended and/or prescribed will oftentimes have chronic medical conditions and/or serious disabilities that hinder their ability to function or develop. For these individuals, because of their age it is difficult and oftentimes impossible to determine whether and when they have reached their best possible functional state. However, even if they have reached their best possible functional state, therapies are generally necessary in order to prevent regression. A minor for whom therapies have been recommended and/or prescribed and who possesses a chronic medical condition and/or serious disability that hinders his or her ability to function or develop will likely lose the ability to walk, crawl, roll over, stretch, or assist their caretakers with their activities of daily living if these therapies are stopped. In many cases, if therapies are stopped the minor will require one (1) or more surgeries (which will likely be paid for by the Medicaid agency).

Thus, regardless of whether therapies for minors are capable of advancing an individual to a higher functional state, they are certainly preventative in nature and are necessary to prevent these individuals from regressing to a worse functional state.

II. FACTS CONCERNING THE NAMED PLAINTIFFS

Each of the named plaintiffs is a seriously disabled child. Both A.M.T. (who is seven) and J.M.G. (who is twelve) have a primary diagnosis of cerebral palsy. J.J.M. (who is nine) has a primary diagnosis of Pyruvate Carboxylase Deficiency Type II ("PCD Type II"), which is a type of mitochondrial metabolic myopathy and, like cerebral palsy, a condition that hinders his ability to develop and to function, and that results in his being medically fragile. As a result of

their conditions, the named plaintiffs each have significant functional limitations. A.M.T., on the one hand, is capable of walking although he cannot yet run. J.J.M. cannot walk, although he is capable of rolling over, stretching his legs, and engaging in other movements that would be considered rudimentary for a child without disabling conditions. And J.M.G. can stretch out and assist his parents or caretakers somewhat with transfers, but cannot so much as crawl short distances.

The named plaintiffs are all Medicaid enrollees who are eligible for EPSDT services as a result of their age. For several years, the plaintiffs have received Medicaid payment for therapies prescribed by their treatment physicians: A.M.T. has received one (1) hour-long session of physical therapy and one (1) hour-long session of occupational therapy each week for the past seven (7) years; J.J.M. has received three (3) hour-long sessions of physical therapy and one (1) hour-long session of occupational therapy each week for the past six (6) years; and J.M.G. has also received two (2) hour-long sessions of physical therapy and one (1) hour-long session of occupational therapy each week for several years.

In late 2009 or early 2010, prior authorization requests were submitted on behalf of each of the named plaintiffs in order to continue their therapies at their current rate. These requests were submitted by the plaintiffs' providers after these providers prescribed or otherwise recommended this rate of therapies for each of the named plaintiffs. Each of these requests, however, was denied in substantial part. According to the denial notice received by A.M.T., "[t]he requested services would not [b]e restorative of an im[p]airment in function caused by an acute change in the pati[en]t's medical condition, and maintenance therapy is noncoverable per IAC guidelines." According to the denial notice received by J.J.M., "[r]ehabilitative therapies will be covered for no longer then [*sic*] two (2) years except when there is a significant change in

the recipient's condition necessitating additional therapies" and that the therapies had already "been provided for at least two (2) years with minimal documented change in [J.J.M.'s] condition." And according to the denial notice received by J.M.G., the requested services were denied as a result of 405 IAC 5-22-6(b)(6) and 405 IAC 5-22-6(b)(7).[7]

However, without the continuation of the requested therapies, the plaintiffs can expect significant regression in their conditions and in their functional states. This regression will include the loss of muscle function and the shortening of tendons. A.M.T. will begin having difficulty walking. J.J.M., in turn, will begin having trouble rolling over, stretching on his own, participating in his educational activities, and otherwise functioning. And J.M.G., for his part, will begin having trouble stretching on his own, assisting his parents and caregivers in his daily care, and otherwise functioning. The unnamed members of the putative class can expect similar losses in their ability to function that would not occur if their therapies were continued at their previous rates. In this manner, the prescribed therapies—even if those therapies are considered "maintenance therapies" within the meaning of the Indiana Administrative Code—are medically necessary for each of the plaintiffs and each of the members of the putative class.

PRELIMINARY INJUNCTION STANDARD

The standard in the Seventh Circuit for the granting of a preliminary injunction is clear. In order to determine whether a preliminary injunction should be granted, the Court weighs several factors:

> (1) whether the plaintiff has established a prima facie case, thus demonstrating at least a reasonable likelihood of success at trial;

[7] The denial notices received by each of the named plaintiffs were attached the plaintiffs' Class Action Complaint for Declaratory and Injunctive Relief (filed Mar. 25, 2010), as Exhibits 2 through 4, respectively.

(2) whether the plaintiff's remedies at law are inadequate, thus causing irreparable harm pending the resolution of the substantive action if the injunction does not issue;

(3) whether the threatened injury to the plaintiff outweighs the threatened harm the grant of the injunction may inflict on the defendant; and

(4) whether, by the grant of the preliminary injunction, the public interest would be disserved.

See, e.g., *Baja Contractor, Inc. v. City of Chicago*, 830 F.2d 667, 675 (7th Cir. 1987). The heart of this test, however, is "a comparison of the likelihood, and the gravity of two types of error: erroneously granting a preliminary injunction, and erroneously denying it." *Gen. Leaseways, Inc. v. Nat'l Truck Leasing Ass'n*, 744 F.2d 588, 590 (7th Cir. 1984). After weighing these factors, it is clear that a preliminary injunction should issue in this case.

ARGUMENT

I. LIKELIHOOD OF SUCCESS ON THE MERITS

A. Background to the Medicaid Program

Medicaid is a cooperative federal-state program through which the federal government provides financial aid to states that furnish medical assistance to eligible low-income individuals. *See* 42 U.S.C. § 1396, *et seq.*; *Atkins v. Rivera*, 477 U.S. 154, 156 (1986). Although state participation is voluntary, states electing to participate in the program are required to comply with certain statutory requirements imposed by federal law, as well as with regulations promulgated by the United States Department of Health and Human Services. *See Evergreen Presbyterian Ministries, Inc. v. Hood*, 235 F.3d 908, 915 (5th Cir. 2000). To qualify for federal assistance, therefore, "a state must submit to the [federal government] and have approved a 'state plan' for 'medical assistance' that contains a comprehensive statement describing the nature and scope of the state's Medicaid program." *S.D. ex rel. Dickson v. Hood*, 391 F.3d 581, 586 (5th

Cir. 2004) (citations omitted). Among other things, the state plan must establish "a scheme for reimbursing health care providers for the medical assistance provided to eligible individuals." *Wilder v. Virginia Hosp. Ass'n*, 496 U.S. 498, 502 (1990).

The Medicaid Act defines "medical assistance" as "payment of part or all of the cost of . . . care and services" included in an enumerated list of twenty-seven (27) general categories of assistance. 42 U.S.C. § 1396d(a); *see also, e.g.*, *S.D.*, 391 F.3d at 586. Some of the categories of assistance are mandatory and must be included within a state's Medicaid plan, whiles others are optional and may be included at the discretion of the state. *See* 42 U.S.C. § 1396a(a)(10)(A). One of the mandatory service categories is "early and periodic screening, diagnostic, and treatment services" ("EPSDT services") for individuals who are under the age of twenty-one (21). *See* 42 U.S.C. § 1396a(a)(10)(A); 42 U.S.C. § 1396d(4)(B).

EPSDT services are defined to include all "necessary health care, diagnostic services, treatment, and other measures described in subsection (a) of [42 U.S.C. § 1396d] 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). Among the services enumerated in 42 U.S.C. § 1396d(a) are the following:

a. Physical therapy and related services. 42 U.S.C. § 1396d(a)(11).

b. Other diagnostic, screening, preventative, and rehabilitative services, including any medical or remedial services (provided in a facility, a home, or other setting) recommended by a physician or other licensed practitioner of the healing arts within the scope of their practice under State law, for the maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level. 42 U.S.C. § 1396d(a)(13).

Thus, "EPSDT is a comprehensive child health program designed to assure the availability and accessibility of health care resources for the treatment, correction, and amelioration of the unhealthful conditions of individual Medicaid recipients under the age of twenty-one." *S.D.*, 391

F.3d at 586. One of the principal goals of the program is to "assure that health problems found are diagnosed and treated early, before they become more complex and their treatment more costly." *Id.* (citation and alteration omitted). In this manner, in the context of the EPSDT program, "there is a very strong inference to be inclusive rather than exclusive." *Ekloff v. Rogers*, 443 F.Supp.2d 1173, 1180–81 (D. Ariz. 2006).

B. The Seventh Circuit has already decided definitively that Indiana does not have discretion to refuse Medicaid payment for services deemed necessary by an EPSDT provider, and the plaintiffs are therefore exceedingly likely to prevail on the merits of their claims.

It cannot be seriously disputed in this case that therapies have been prescribed or otherwise recommended for each of the plaintiffs by their treating physicians in an amount greater than that which was approved for Medicaid payment by the Indiana Family and Social Services Administration. Indeed, the policy at issue in this case prohibits any payment for therapies that are deemed "maintenance" in nature—therapies designed to prevent regression in the plaintiffs' conditions—notwithstanding the recommendations of the plaintiffs' physicians or their therapists.[8]

As noted above, among the EPSDT services for which Medicaid payment must be provided are "diagnostic, screening, preventative, and rehabilitative services . . . *recommended by a physician or other licensed practitioner of the healing arts within the scope of their practice under State law*, for the maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level." 42 U.S.C. § 1396d(a)(13) (emphasis added); *see also* 42 U.S.C. § 1396d(r). In interpreting this statute, the Seventh Circuit has held explicitly that "in the context of individuals under the age of twenty-one subject to EPSDT services, a state's

[8] As noted above, the two (2) regulations at issue in this case are treated together throughout this brief under the nomenclature for "maintenance therapy." *See supra* note 2.

discretion to exclude services deemed 'medically necessary' by an EPSDT provider has been circumscribed by the express mandate of the statute." *Collins v. Hamilton*, 349 F.3d 371, 376 n.8 (7th Cir. 2003) (internal citation omitted). In other words, the only person who may properly determine the appropriateness of a given treatment or service for an EPSDT-eligible individual (as the plaintiffs in the present case quite clearly are) is, unsurprisingly, that individual's provider.[9]

In *Collins*, a class of disabled children filed suit against officials from the Indiana Family and Social Services Administration challenging the agency's failure to provide long-term residential treatment in psychiatric residential treatment facilities (PRTF) for EPSDT-eligible children. *See id.* at 372. The Seventh Circuit framed the issues to be decided as follows:

> The question in this case is whether Indiana is required to provide Medicaid coverage to eligible individuals under the age of twenty-one for placement in long-term PRTFs, or whether Indiana's obligations under Medicaid are limited to coverage of the acute treatment options currently available in its inpatient psychiatric hospitals. Essentially, the issue boils down to whether Indiana's exclusion of PRTFs encompasses 'necessary' medical services and whether a state has the discretion to make such exclusions under the Act[.]

Id. at 373–74. After rejecting the State's position it was not required to cover long-term placement and that such placement could not be medically necessary, the *Collins* court explicitly found "that Indiana is required to fund the cost of placement in a PRTF if it is deemed 'medically necessary' *by an EPSDT screening*." *Id.* at 376; *see also id.* at 376 n.8 (quoted *supra*).

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[9] Insofar as *Collins* was decided against the Indiana Family and Social Services Administration—the defendants at present—the State is likely barred by the doctrine of collateral estoppel from insisting that it possesses discretion to refuse Medicaid payment for services deemed necessary by an EPSDT provider. *See, e.g.*, *H-D Michigan, Inc. v. Top Quality Serv., Inc.*, 496 F.3d 755, 760 (7th Cir. 2007) (reiterating the established test for determining when an issue is precluded by collateral estoppel, whereby (a) the issue sought to be precluded must have been actually litigated in prior litigation, (b) the determination of the issue must have been essential to the final judgment in the prior litigation, (c) the party against whom estoppel is invoked must have been fully represented in the prior action, and (d) the issue sought to be precluded must be the same as that involved in the prior litigation).

This holding—that the responsibility for determining the propriety of services for EPSDT-eligible children rests with their actual providers—is also supported by the holdings of other courts. In *Pediatric Specialty Care, Inc. v. Arkansas Department of Human Services*, 293 F.3d 472 (8th Cir. 2002), for instance, the Eighth Circuit interpreted the same statutory backdrop as it related to a State's proposed cuts in EPSDT services resulting from a budgetary shortfall. As in *Collins*, the court held explicitly that a state has no discretion to deny services recommended or otherwise prescribed by the treatment provider of an EPSDT-eligible child. Said the court: "We affirm the district court's decision to the extent that it holds that a Medicaid eligible individual has a federal right to early intervention day treatment *when a physician recommends such treatment*." *Id.* at 480 (emphasis added). Thus,

> after [clinical staff] perform a diagnostic evaluation of an eligible child, if the . . . physician prescribes early intervention day treatment as a service that would lead to the maximum reduction of medical and physical disabilities and restoration of the child to his or her best possible functional level, the [State] must reimburse the treatment.

Id. In the words of another district court, "if a competent and credible diagnosis shows that a child requires a specific treatment, courts will find that the state has an obligation to provide it." *Rosie D. v. Romney*, 410 F.Supp.2d 18, 29 (D. Mass. 2006).

This, once again, is hardly surprising. For one, it is entirely in keeping with the "broad mandate of the EPSDT program" that has been made "abundantly clear." *Smith v. Benson*, __ F.Supp.2d __, 2010 WL 1404066, at *4 (S.D. Fla. Jan. 28, 2010); *see also, e.g.*, *Parents' League for Effective Autism Servs. v. Jones-Kelley*, 339 Fed. Appx. 542, 549 (6th Cir. 2009) (noting that judicial decisions must "comport with the broad coverage afforded under the EPSDT mandate"); *Katie A. v. Los Angeles County*, 481 F.3d 1150, 1154 (9th Cir. 2007) (noting that "[t]he EPSDT obligation is . . . extremely broad"); *Ekloff*, 443 F.Supp.2d at 1180–81 (noting that, in the context

of EPSDT services, "there is a very strong inference to be inclusive rather than exclusive"); *Rosie D.*, 410 F.Supp.2d at 25 (noting that "[a]s broad as the overall Medicaid umbrella is generally, the initiatives aimed at children are far more expansive"). Moreover, this interpretation of the EPSDT provisions is supported by the legislative history of these provisions: as this history makes clear, "Medicaid [was intended to] cover any medically necessary services identified as necessary through the EPSDT program." 135 Cong. Rec. S6900 (June 19, 1989) (statement of Sen. Chafee). And finally, this may be viewed as simply the codification of the age-old principle that a treating physician is in the best position to assess the needs of his or her patient. *See, e.g.*, *Capizanno v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006); *Gossage v. U.S.*, 91 Fed. Cl. 101, 107 (Fed. Cl. 2010).

That is precisely the case here, and, once again, controlling authority indicates that "a state's discretion to exclude services deemed 'medically necessary' by an EPSDT provider has been circumscribed by the express mandate of the statute." *Collins*, 349 F.3d at 376 n.8. In this case, the facts adduced at the preliminary injunction hearing will demonstrate that the therapy services at issue have been found medically necessary by the plaintiffs' treatment providers and have therefore been recommended or prescribed. Indeed, the very nature of Indiana's prior authorization program ensures that any requested service is first recommended by an individuals' providers. *See* IND. ADMIN. CODE tit. 405, r.5-3-5(a) (requiring that, upon seeking approval for a given service, a provider submit "[w]ritten evidence of physician involvement and personal patient evaluation" as well as "a current plan of treatment and progress notes, as to the necessity, effectiveness, and goals of therapy services"). As such, the State's reliance on two (2) provisions of the Indiana Administrative Code to refuse or otherwise limit requested therapies on behalf of the plaintiffs and the putative class is in violation of federal Medicaid law.

C. Even if the State were to possess discretion to refuse physician-recommended services to EPSDT-eligible children, the refusal to provide Medicaid coverage for so-called "maintenance therapy" conflicts squarely with federal Medicaid law.

Even were this Court to conclude that the State possesses discretion under federal Medicaid law to refuse payment for prescribed therapies on behalf of EPSDT-eligible children, the State's use of the two (2) challenged provisions of the Indiana Administrative Code suffers from a more fundamental fallacy. That is, the State has decided that it will not provide Medicaid payment for what it refers to as "maintenance therapy." IND. ADMIN. CODE tit. 405, r. 5-22-6(b)(7). This is therapy that the State determines "addresses chronic medical conditions where further progress can no longer be expected or where progress is minimal in relation to the time needed in therapy to achieve that progress." IND. ADMIN. CODE tit. 405, r. 5-22-1(5). And, although an ostensible exception to its rule that therapies will not be provided for more than two (2) years exists for children under eighteen (18) years of age, *see* IND. ADMIN. CODE tit. 405, r. 5-22-6(b)(7), the prohibition on the provision of "maintenance therapy" has no exceptions. This is so even when so-called "maintenance therapy" is necessary in order to ward against significant regression in a patient's functional state. The legal issue, therefore—in its simplest terms—is whether federal Medicaid law requires a participating state to provide Medicaid payment for therapy services for children when those services are necessary in order to prevent a patient's regression even when substantial further progression may not be likely. The answer is a resounding "yes."

The Medicaid Act specifically requires participating states to cover medical care specified in 42 U.S.C. § 1396d(a) for minors when that care has been prescribed by a physician or licensed practitioner of the healing arts "to correct or ameliorate defects and physical and mental illnesses and conditions." 42 U.S.C. § 1396d(r)(5). Thus, the analysis of whether the

State is required to provide Medicaid payment for physical therapy, occupational therapy, respiratory therapy, and speech pathology even when those services are only necessary to be prevent against the regression in a child's condition may proceed in two (2) parts: *first*, these services must fall within the ambit of the second clause of 42 U.S.C. § 1396d(r)(5) and be for the purpose of "correcting or ameliorating" a defect, illness, or condition; *and second*, these therapies must fall within the ambit of one of the services detailed in 42 U.S.C. § 1396d(a). In the present case, it is clear that both requirements are met.[10]

1. The "Correct or Ameliorate" Provision – 42 U.S.C. § 1396d(r)(5)

Section 1396d(r)(5) of the Medicaid Act requires the provision of Medicaid payment on behalf of EPSDT-eligible children for all "necessary health care, diagnostic services, treatment, and other measures described in subsection (a) of [42 U.S.C. § 1396d] 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." The question, therefore, is whether "maintenance therapy"—by preventing or retarding medical and functional regression—corrects or ameliorates the defects and physical and mental illnesses of the plaintiffs, or whether this language bespeaks only therapies designed to enable significant progression in a Medicaid recipient's medical condition. Initially, it deserves reiteration that, in the context of EPSDT services, "there is a very strong inference to be inclusive rather than exclusive." *Ekloff*, 443 F.Supp.2d at 1180–81.

[10] The EPSDT mandate also requires that the services at issue be prescribed or otherwise recommended by a patient's physician or other licensed practitioner of the healing arts. 42 U.S.C. § 1396d(r)(5). Given that, as noted above, the prior authorization requirement in Indiana ensures that all requested services will be recommended by a patient's treatment providers, this requirement is clearly met in this case, and the State may not seriously contend to the contrary.

Moreover, the precise issue presented by this case was resolved in both *Collins v. Hamilton*, *supra*, and *Ekloff*. According to the district court in *Collins*,

> [t]he Medicaid Act specifically directs the State to "ameliorate" mental illnesses in children. "Ameliorate" is defined as "to make better or more tolerable." There is no time limitation evident in this definition. Required treatment includes anything which is to make a condition, even a long-term condition like mental illness, more tolerable.

Collins v. Hamilton, 231 F.Supp.2d 840, 848–49 (S.D. Ind. 2002), *aff'd*, 349 F.3d 371 (7th Cir. 2003) (Young, J.) (quoting WEBSTER'S SEVENTH NEW COLLEGIATE DICTIONARY (1963)). Continued the court, in words entirely apposite to the present case: "the State has decided that these children are 'lost causes' and it is not feasible to treat these children. In other words, they are 'too disabled' for treatment. The court does not believe that this was the intent of Congress in enacting the federal Medicaid Act." *Id.* at 849. On appeal, the Seventh Circuit agreed. Addressing the State's argument that long-term placements cannot "improve" a patient's condition, the court "s[aw] no reason why residential treatment, even if long-term, cannot consist of 'active treatment' that 'improves or ameliorates' a patient's condition." *Collins*, 349 F.3d at 375–76.

The *Ekloff* court relied on Judge Young's decision in *Collins* to reach a similar conclusion. The question in that case was whether the EPSDT provisions required a state participating in the Medicaid program to provide payment for incontinence briefs "for preventative purposes." 443 F.Supp.2d at 1179. Although the disabled children in *Ekloff* did not currently suffer from "skin breakdown," these briefs were necessary "in order to avoid skin breakdown and infection and to enable [the children] to participate in social, community, therapeutic and educational activities." *Id.* at 1175. Held the court:

> Webster's Dictionary defines "ameliorate" as "to make better or more tolerable." Clearly, the incontinence briefs are meant to make the children's condition better

> or more tolerable by preventing skin breakdown. The briefs are used to not only prevent future pain from open skin sores but to facilitate and maximize their daily opportunities as well as to make their condition as tolerable as possible by not forcing them to suffer the needless pain of skin sores. This seems to be the very essence of what Congress had intended in their Medicaid statute.

Id. at 1180. The court in *Ekloff* thus, explicitly and with no equivocation whatsoever, rejected the state's argument that the "correct or ameliorate" provision only requires participating states "to cover services that correct or improve actually existing defects and conditions and . . . does not require preventative measures." *Id.* at 1181. This extremely narrow reading of 42 U.S.C. § 1396d(r)(5) cannot not be squared with the language of the statute, prior case law, or legislative history. *Id.*

The present case is on all fours with both *Collins* and *Ekloff*. The Indiana Family and Social Services Administration has determined that it will not provide Medicaid payment for therapy services that are necessary "only" to maintain a disabled child's current functional state. However, without these services, the plaintiffs and the members of the putative class will lose significant functionality, will lose the ability to assist in their activities of daily living, and will likely require multiple surgeries—almost certainly paid for by the Medicaid program—in order to cure injuries caused by the absence of therapy services. Given that one of the principal goals of the EPSDT program is to "assure that health problems found are diagnosed and treated early, before they become more complex and their treatment more costly," *S.D.*, 391 F.3d at 586 (citation and alteration omitted), this cannot be so.[11]

[11] The "correct or ameliorate" provision of the Medicaid Act—42 U.S.C. § 1396d(r)(5)—cannot be read to preclude the provision of Medicaid payment for so-called "maintenance therapy" for an additional reason. The first clause of that section requires the coverage of "[s]uch other necessary health care, diagnostic services, treatment, and other measures described in" 42 U.S.C. § 1396d(a). Given that one of these services for which coverage must be provided is "preventative . . . services, including any medical or remedial services . . . for the maximum reduction of physical or mental disability," 42 U.S.C. § 1396d(a)(13), the EPSDT provision is

2. The Services Described in 42 U.S.C. § 1396d(a)

Given that the "maintenance therapy" at issue in this case must be deemed to "correct or ameliorate defects and physical and mental illnesses and conditions," the next issue to be resolved is whether these therapy services consitute "[s]uch other necessary health care, diagnostic services, treatment, and other measures described in [42 U.S.C. § 1396d(a)]." *See* 42 U.S.C. § 1396d(r)(5). The services at issue in this case are covered by three (3) separate provisions of 42 U.S.C. § 1396d(a).

a. Physical Therapy and Related Services – 42 U.S.C. § 1396d(a)(11)

First, federal Medicaid law requires the coverage of "physical therapy and related services." *See* 42 U.S.C. § 1396d(a)(11). The State's prohibition on the provision of "maintenance therapy," however, encompasses occupational, physical, and respiratory therapy, as well as speech pathology. *See* IND. ADMIN. CODE tit. 405, r. 5-22-6. Clearly physical therapy is covered by 42 U.S.C. § 1396d(a)(11). The issue as to occupational therapy, respiratory therapy, and speech pathology, however, requires a determination as to what constitutes a "related service" under that provision.

However, an answer to this question may be gleaned from federal regulations, which specify that, at the very least, occupational therapy and speech pathology qualify as a service related to physical therapy. *Meyers v. Reagan*, 776 F.2d 241, 243–44 (8th Cir. 1985) (relying on 42 C.F.R. § 440.110); *see also William T. v. Taylor*, 465 F.Supp.2d 1267, 1287 (N.D. Ga. 2000) (noting that speech pathology services "are included in the statutory 'physical therapy and related services' category"); *Fred C. v. Texas Health & Human Servs. Comm'n*, 988 F.Supp.

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rendered meaningless in part if "maintenance therapy" is deemed non-coverable. Clearly, courts must "avoid interpreting a statute in a way that renders a word or phrase redundant or meaningless." *E.g.*, *United States v. Berkos*, 543 F.3d 392, 396 (7th Cir. 2008).

1032, 1034–35 (W.D. Tex. 1997) (noting that "services with speech hearing and language disorders" are included within the "related services" provision of 42 U.S.C. § 1396d(a)(11)) (citing *Meyers*, 776 F.2d at 243–44); *Hunter v. Chiles*, 944 F.Supp. 914, 919 (S.D. Fla. 1996) (same) (citing *Meyers*, 776 F.2d at 243–44).[12]

b. Respiratory Care Services – 42 U.S.C. § 1396d(a)(20)

Second, as noted immediately above, the State's prohibition on providing Medicaid coverage for "maintenance therapy" encompasses physical therapy, occupational therapy, respiratory therapy, and speech pathology. Three (3) of these services—physical therapy, occupational therapy, and speech pathology—are included within the "physical therapy and related services" category of 42 U.S.C. § 1396d(a)(11). *See* 42 C.F.R. § 440.110. While respiratory therapy is not included within this provision, federal Medicaid law explicitly (and separately) requires the coverage of "respiratory care services." 42 U.S.C. § 1396d(a)(20). These are services "provided by a respiratory therapist or other health care professional trained in respiratory therapy." 42 U.S.C. § 1396a(e)(9)(C). Clearly respiratory therapy, as that term is used in Title 405, rule 5-22-6 of the Indiana Administrative Code, is included within this provision.

c. Preventative and Rehabilitative Services – 42 U.S.C. § 1396d(a)(13)

And finally, federal Medicaid law also requires the coverage of

> other diagnostic, screening, preventative, and rehabilitative services, including any medical or remedial services (provided in a facility, a home, or other setting) recommended by a physician or other licensed practitioner of the healing arts

[12] "Physical therapy" is defined only as "services prescribed by a physician or other licensed practitioner of the healing arts within the scope of his or her practice under State law and provided to a recipient by or under the direction of a qualified physical therapist." 42 C.F.R. § 440.110(a). "Occupational therapy" is defined in nearly identical terms. *See* 42 C.F.R. § 440.110(b). The utter lack of qualification in these definitions is also strong evidence that the services at issue in this case must be covered under the Medicaid program.

> within the scope of their practice under State law, for the maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level.

42 U.S.C. § 1396d(a)(13). "Preventative services"—as that term is used in this statute—refers to services provided by a licensed practitioner of the healing arts in order to (a) prevent disease, disability, or other health conditions or their progression; (b) prolong life; or (c) promote physical and mental health and efficiency." 42 C.F.R. § 440.130(c). Certainly, so-called "maintenance therapy" is, at the very least, intended to prevent the progression of disabilities and promote physical and mental health. For this reason as well, the therapies at issue in this case must be covered by the State.

This reading is buttressed by the legislative history of the EPSDT statute. In testifying before the House Ways and Means Committee, the Secretary of the Department of Health, Education, and Welfare (now the Department of Health and Human Services) stated as follows:

> In low-income areas, we estimate that six out of every ten children who suffer from one or more chronic conditions are not receiving any treatment.
>
> * * *
>
> In most instances, this complete loss is unnecessary and *preventable*.

Mitchell v. Johnston, 701 F.2d 337, 347 (5th Cir. 1983) (quoting Hearings Before the Committing on Ways & Means Regarding H.R. 57-10, at 189–91 (testimony of Secretary John Gardner)) (emphasis in *Mitchell*). Although the latter portion of Secretary Gardner's testimony specifically concerned preventative dental care, these statements are equally applicable to the present care and are powerful evidence that Congress sought to ensure the coverage of treatment and other care directed toward even chronic medical conditions. It is this treatment that is not covered by the State at present. *See* IND. ADMIN. CODE tit. 405, r. 5-22-1(5) (defining "maintenance therapy," in part, as "therapy addressing chronic medical conditions").

The district court in *Parents League for Effective Autism Services (PLEAS) v. Jones-Kelley*, 565 F.Supp.2d 905 (S.D. Ohio 2008), *aff'd*, 339 Fed. Appx. 542 (6th Cir. 2009), thus addressed an issue nearly identical to the issue presented by this case. In that case, the plaintiffs challenged the refusal of Ohio's Medicaid agency to cover certain mental health services recommended for children with autism. *Id.* at 907, 909–10. That is, the agency in that case decided that the services at issue were "not generally 'habilitative' because the services [we]re not 'restoring' any skills that the child previously had," and that they therefore did not fall within the ambit of 42 U.S.C. § 1396d(a)(13). *Id.* at 916. After first detailing the "extremely broad EPSDT obligation" on states, *id.* at 912, the district court soundly rejected this notion:

> [The d]efendants have cited no authority for their restrictive interpretation that "remedial and medical services" are covered only if they are "rehabilitative." . . . Given the expansive requirements of the EPSDT mandate, the Court finds no basis for such a restrictive reading of the statute.
>
> Moreover, section (a)(13) also requires that State's [*sic*] provide "preventative services" which are defined as: services provided by a physician or other licensed practitioner of the healing arts within the scope of his practice under state law to: 1) prevent disease, disability, and other health conditions or their progression; 2) prolong life; and 3) promote physical and mental health and efficiency. Thus, the services . . . may well be "preventative" as well as "rehabilitative."

Id. at 916. This conclusion—that "the services required by the EPSDT mandate are more broad than [the d]efendants would suggest"—was also supported by case law. *Id.* at 916–17 (citing *Rosie D. v. Romney*, 410 F.Supp.2d 18 (D. Mass 2006), *S.D. v. Hood*, 391 F.3d 581 (5th Cir. 2004), and *Pediatric Specialty Care, Inc. v. Arkansas Dep't of Human Servs.*, 443 F.3d 1005 (8th Cir. 2006)).[13]

[13] On appeal, the Sixth Circuit affirmed the district court's decision in *PLEAS*. 339 Fed. Appx. 542 (6th Cir. 2009). In so doing, it focused on the mandate of 42 U.S.C. § 1396d(a)(13) that rehabilitative services be covered, and did not venture into the mandate that preventative services also be covered. However, the court soundly rejected the state agency's contention that the

Indeed, the "maintenance therapy" at issue in this case has as its very root the word "maintain," which is defined to include "preserve from failure or decline" and "to keep in an existing state." *See* WEBSTER'S SEVENTH NEW COLLEGIATE DICTIONARY 509 (1972). The clear implication is, to put it crassly, that something bad will happen absent these services. In the case of the plaintiffs and the members of the putative class, this "something bad" is significant regression in their conditions, the loss of functionality and the ability to assist in their activities of daily living, the deterioration of muscles and tendons, and the potential need for multiple surgeries that would not otherwise be required. At the very least, the therapies at issue in this case qualify as "preventative services" under 42 U.S.C. § 1396d(a)(13), and must therefore be covered pursuant to the State's EPSDT obligation. The plaintiffs are therefore exceedingly likely to prevail on the merits of their legal claims.

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services at issue need only be provided to return an individual to a previously possessed functional level, concluding as follows:

> *First,* § 1396d(a)(13) reflects the extremely broad EPSDT obligation. [The d]efendants' reading of § 1396d(a)(13) to cover only services that restore a child to a prior skill level would arguably mean that no child who is born with a disability[] could ever receive rehabilitative services. Such an outcome arguably does not comport with the broad coverage afforded under the EPSDT mandate.
>
> *Second*, cases from other circuits have concluded that § 1396d(a) covers services that are arguably similarly to the [therapies at issue.]
>
> *Third,* no administrative interpretations of § 1396d(a)(13) appear to clarify or restrict the provision in the way suggested by the defendants.

339 Fed. Appx. at 549. The Eighth Circuit in *Pediatric Specialty Care* reached a similar conclusion, *see* 293 F.3d at 480–81 (concerning early intervention day treatment), and the Seventh Circuit in *Collins* gave short shrift to the State's argument the long-term residential placement at issue could not "improve" a patient's condition, *see* 349 F.3d at 375–76. For the same reasons described above (concerning the "correct or ameliorate" provision of federal Medicaid law) the services presently at issue also qualify as "rehabilitative services" within the meaning of 42 U.S.C. § 1396d(a)(13)—and clearly they are designed to ensure the "maximum reduction of physical or mental disability" and to maintain individuals' "best possible functional level."

II. IRREPARABLE HARM FOR WHICH NO ADEQUATE REMEDY AT LAW EXISTS

Next, the harm that the plaintiffs will suffer absent a preliminary injunction in this cause will be dramatic. After all, this case concerns the provision of therapy services that enable disabled children to maintain their highest degree of functionality. These services permit the plaintiffs to assist their parents or other caretakers with transfers, bathing, toileting, and all forms of mobility. Absent the provision of these services, the plaintiffs can expect significant regression in their conditions, including the potential for multiple surgeries and substantial loss of function. There is no other remedy for these consequences.

For these reasons, it is clear that "[i]n cases alleging that a state law violates the federal Medicaid statute and requesting injunctive relief"—as this case does—"irreparable harm nearly always follows a finding of success on the merits." *Smith v. Benson*, __ F.Supp.2d __, 2010 WL 1404066, at *11 (S.D. Fla. Jan. 28, 2010) (citing numerous cases). Thus, "Medi[caid] recipients may demonstrate a risk of irreparable injury by showing that enforcement of a proposed rule 'may deny them needed medical care.'" *Indep. Living Ctr. of Southern California, Inc. v. Maxwell-Jolly*, 572 F.3d 644, 658 (9th Cir. 2009) (citation omitted); *see also, e.g.*, *Massachusetts Ass'n of Older Americans v. Sharp*, 700 F.2d 749, 753 (1st Cir. 1983) ("Termination of benefits that causes individuals to forego . . . necessary medical care is clearly irreparable injury.") (citations omitted). This line of cases is entirely on par with the present case, and it is clear that the plaintiffs will suffer irreparable injury without the issuance of a preliminary injunction.

III. BALANCING OF HARMS

The balancing of harms likewise weighs in favor of the plaintiffs. Without an injunction, the plaintiffs will be faced with an ongoing violation of the Medicaid Act and with the ongoing inability to access necessary medical care. Because they have demonstrated a substantial

likelihood of success on the merits of their claim, "no substantial harm to others can be said to inhere in its enjoinment." *See, e.g.*, *Déjà vu of Nashville, Inc. v. Metro. Gov't of Nashville*, 274 F.3d 377, 400 (6th Cir. 2001); *Connection Distrib. Co. v. Reno*, 154 F.3d 281, 288 (6th Cir. 1998). On the other hand, an injunction will merely force the State to conform its conduct to legal norms and the requirements of federal law. A governmental entity cannot claim that requiring it to comply with controlling law is harmful. The balance of harms therefore favors the issuance of equitable relief.

IV. PUBLIC INTEREST

Finally, it is "always in the public interest to prevent violation of a party's constitutional rights." *Déjà vu of Nashville*, 274 F.3d at 400 (quoting *G & V Lounge, Inc. v. Michigan Liquor Control Comm'n*, 23 F.3d 1071, 1079 (6th Cir. 1994)). The same may be said of the plaintiffs' federal rights under the Medicaid Act. After all, "there is a robust public interest in safeguarding access to medical care for those eligible for Medicaid, whom Congress has recognized as 'the most needy in the country.'" *Indep. Living Ctr.*, 572 F.3d at 659 (citing *Schweiker v. Hogan*, 457 U.S. 569, 590 (1982)). Thus, the public interest is served by the enforcement of the Medicaid Act.

THE INJUNCTION SHOULD ISSUE WITHOUT BOND

Finally, Rule 65(c) of the Federal Rules of Civil Procedure states that no preliminary injunction should issue except until security is given in an amount deemed proper by the court. *See* FED. R. CIV. P. 65(c). Nonetheless, the amount of security required—and, indeed, whether security should be required at all—rests soundly in the discretion of the trial court. *See Scherr v. Volpe*, 466 F.2d 1027, 1035 (7th Cir. 1972). Thus, despite the language of the federal rule, appropriate circumstances excuse the issuance of a preliminary injunction without a bond. *See,*

e.g., *Wayne Chemical, Inc. v. Columbus Agency Serv. Corp.*, 567 F.2d 692, 701 (7th Cir. 1977). In determining whether a bond should be required, courts look to various factors: the possible loss to the enjoined party; the hardship a bond would impose on the applicant; and the impact of a bond on the enforcement of federal rights. *See Smith v. Bd. of Election Comm'rs for the City of Chicago*, 591 F.Supp. 70, 72 (N.D. Ill. 1984) (citing *Crowley v. Local No. 82*, 679 F.3d 978, 1000 (1st Cir. 1982)).

This case represents a challenge by seriously disabled juvenile Medicaid recipients to various standards governing the provision of services that have been implemented by a state agency with an annual budget in the billions of dollars. *See* Indiana Budget Agency, 2009–11 Budget, available at http://www.in.gov/sba/2543.htm (last visited Apr. 12, 2010). As noted above, Congress has declared the Medicaid population to be "the most needy in the country." *Schweiker*, 457 U.S. at 590. Of course, the sub-set of the Medicaid population consisting of seriously disabled children is even more needy. To require a bond in the present case would be to condition the exercise of the plaintiff's federal rights to adequate medical care on their financial status. Therefore, no bond should be required.

CONCLUSION

For the foregoing reasons, the State should be preliminary enjoined from enforcing the challenged provisions of the Indiana Administrative Code against EPSDT-eligible children for whom therapy services have been prescribed or otherwise recommended by their treatment professionals. In the event that the Court grants the plaintiffs' request for class certification, the preliminary injunction should inure to the benefit of the class as well.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby verify that on this 16th day of April, 2010, a copy of the foregoing was filed electronically with the Clerk of this Court. This filing may be accessed through the Court's electronic system. This filing was served on the following parties by operation of the Court's electronic system:

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