IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

STEVEN HILTIBRAN, et al.	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case no. 10-4185-CV-C-NKL
	)	
RONALD J. LEVY, et al.	)	
	)	
Defendants.	)	

SUGGESTIONS IN OPPOSITION TO MOTION
FOR PRELIMINARY INJUNCTION

Defendants, for their Suggestions in Opposition to Plaintiff's Motion for Preliminary Injunction (Doc. #5), state as follows:

Whether a preliminary injunction should issue involves four factors: (1) the threat of irreparable harm to the movant; (2) the state of the balance between this harm and the injury that granting the injunction will inflict on other parties litigant; (3) the probability that movant will succeed on the merits; and (4) the public interest. *Vonage Holdings Corp. v. Nebraska Public Service Comm'n,* 564 F.3d 900, 904 (8th Cir. 2009) (citing *Dataphase Sys., Inc. v. C L Systems, Inc*., 640 F.2d 109, 114 (8th Cir.1981)). A preliminary injunction is "an extraordinary remedy." *Watkins, Inc. v. Lewis*, 346 F.3d 841, 844 (8th Cir. 2003). A district court has broad discretion when ruling on preliminary injunction requests. *CDI Energy Services v. West River Pumps, Inc.*, 567 F.3d 398, 401 (8th Cir. 2009). The party seeking the injunction has "the complete burden of proving that a preliminary injunction should be granted." *Gelco Corp. v. Coniston Partners*, 811 F.2d 414, 418 (8th Cir. 1987).

Here, the Motion for Preliminary Injunction seeks to change the status quo that has existed for years. Plaintiffs want this Court to order the Department to provide them, through

Medicaid, adult incontinence briefs. Plaintiffs' claim that the State of Missouri should cover adult incontinence briefs under Medicaid as "durable medical equipment," as a "medical necessity," or under Home Health Services. If the State does not cover adult incontinence briefs under any of these sections, then Plaintiffs claim that the failure to do so violates the Americans with Disabilities Act (ADA) and the Rehabilitation Act of 1973 (RA).

The State of Missouri is in compliance with federal Medicaid law. There is no need for a preliminary injunction, and the factors for a preliminary injunction have not been met.

1. Plaintiffs have not shown a likelihood of success on the merits.

While Plaintiffs claim that the State of Missouri must provide adult incontinence briefs, the Medicaid statutes and regulations do not automatically require any state to provide incontinence briefs, with the exception of a requirement that they be provided to those between the ages of four and twenty years of age. Missouri, like every state, is permitted to select certain optional items to provide, and adult incontinence briefs are just such an optional item.

Plaintiffs have failed to demonstrate that they are likely to succeed on the merits. While Plaintiffs want a complete alteration in the way that the State handles adult incontinence briefs, the applicable law does not require what Plaintiffs want and seek in this suit.

A. Adult Incontinence briefs are not Durable Medical Equipment

Plaintiffs assert that Missouri's current durable medical equipment (DME) policy is invalid because it does not meet the "reasonable standards" provisions required by the Medicaid Act, 42 U.S.C. § 1396(a)(17). That statute requires that a state must ensure that each provided service is covered in "sufficient . . . amount, duration, and scope to reasonably achieve its purpose." 42 C.F.R. § 440.230(b). The state may not impose arbitrary limitations on required services "solely because of the diagnosis, type of illness, or condition." 42 C.F.R. § 440.230(c).

It should be noted that under the Medicaid statutes, participating states are required to provide certain services and benefits, but are also permitted to make certain elections and cover only certain items. DME is one area where states are permitted to customize their individual state plans to provide coverage, through what items they choose to cover. Indeed, states are not required to cover DME at all. *See* 42 U.S.C. §1396a(a)(10)(D); *Lankford v. Sherman*, 451 F.3d 496, 504 (8th Cir. 2006) ("DME is an optional service under the Medicaid Act").

Plaintiffs rely heavily on an Eighth Circuit decision concerning Missouri's DME program, *Lankford v. Sherman*, 451 F.3d 496 (8th Cir. 2006). Therein, the court considered a preliminary injunction brought to enjoin changes to the DME program, and recognized that, "[w]hile optional DME programs are not explicitly subject to [the reasonable standards] requirements, CMS (the agency that administers Medicaid) maintains that the reasonable-standards provisions apply to all forms of medical assistance, including a state's provision of DME." 451 F.3d at 506.

Lankford also held that "[b]ecause Missouri has elected to cover DME as an optional Medicaid service, it cannot arbitrarily choose which DME items to reimburse under its Medicaid policy." *Id.* at 511. Moreover, the state is required to have a "meaningful procedure for requesting non-covered items." *Id.* at 512. The *Lankford* court recognized that the state's exceptions process for requesting non-covered DME items did not provide a real process by which plaintiffs could obtain these items. For this reason, the court held that the plaintiffs had demonstrated a likelihood of success on the merits of their preliminary injunction claims.

Like the plaintiffs in *Lankford*, the Plaintiffs herein contend that the exceptions process is unavailable to them because there are no circumstances under which DSS will consider adult incontinence briefs to be medically necessary. Plaintiffs argue that Missouri must use a medical

necessity standard to determine which medical supplies are covered under the DME program. Some cases have approved of these types of claims. *Esteban v. Cook*, 77 F. Supp. 2d 1256 (S.D. Fla. 1999) (requiring wheelchairs and holding that state may not "arbitrarily or unreasonably" deny medical equipment "entirely on the basis of age"); *Bell v. Agency for Health Care Admin.*, 768 So. 2d 1203 (Fla. App. 2000) (exclusion of medical equipment and supplies for individuals age 21 and over was arbitrary and unreasonable). Indeed, a court struck down a state's exclusion of adult incontinence briefs under the "reasonable standards" requirement. *Bristol v. R.I. Dep't of Human Serv.*, 1997 WL 839884, C.A. No. 95-6605 (R.I. Super. Ct. Jan. 30, 1997).

In *Lankford*, Missouri acknowledged that the state statute requires coverage of all medically necessary DME. "The [state] legislation is consistent with Medicaid's reasonable standards requirement. By its terms it covers all medically necessary items of DME." Defendants' Response to Court's Order of March 2, 2007, in *Lankford* (attached as Ex. 24 to plaintiffs' complaint). The legislation, as passed, requires payment for "[p]rescribed medically necessary durable medical equipment." Mo. Rev. Stat. § 208.152.1(19).

But the difference between this case, and *Lankford* and the other cited cases, lies in Missouri's definition of DME and medical supplies. Missouri, like all states, is permitted to define what constitutes DME and medical supplies. The distinction is fatal to Plaintiffs' claims. Missouri's definition of DME is "equipment that can withstand repeated use." 13 C.S.R. 70-60.010. Missouri does not provide medical *supplies* as part of the DME program for adult participants—Missouri only provides medical *equipment*.[1] Incontinence briefs cannot withstand

[1] In *Lankford*, the plaintiffs objected that the DME program did not meet reasonable standards because the DME program provided certain equipment, but did not provide all of the parts necessary to make the equipment useable (e.g., electric wheelchairs were covered while batteries were not). Those claims are distinguishable from Plaintiffs' claims in this case. Here, Plaintiffs

repeated use—they are specifically designed to be single-use items. As such, adult incontinence briefs are not covered as DME.

Whether adult incontinence briefs are medical supplies or are personal hygiene items does not change the outcome. Missouri has not elected under Medicaid to provide medical supplies thorough the DME program, and thus can exclude adult incontinence briefs from coverage because they do not meet the definition of durable medical equipment.

The reason why states are required to cover adult incontinence briefs for children ages four thorough twenty is simple—the federal government requires it. The federal program, the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services, requires that each state plan provide EPSDT health care and services as a mandatory category of medical assistance. It requires that states provide all services deemed to be medically necessary to correct or ameliorate a defect, illness, or condition identified by screening. Thus, a state must provide any service that a state is permitted to cover regardless of whether the state's plan otherwise provides or elects to provide that service. *See S.D. v. Hood*, 391 F.3d 581 (5th Cir. 2004); *Eckloff v. Rodgers*, 443 F. Supp. 2d 1173 (D. Ariz. 2006); *Smith v. Benson*, No. 09-21543-CIV, 2010 WL 1404066 (S.D. Fla. Jan. 28, 2010).

In short, as part of its Medicaid program, Missouri (like all states) is required by the EPSDT program to provide services and items (including medical supplies) for those under 21 years of age. However, that program does not require that states provide identical services to those over twenty-one years of age. Here, all of the Plaintiffs are well over twenty-one years of age, and do not qualify for the EPSDT program.

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do not allege that they need incontinence briefs to make their equipment functional; they allege that an entire additional category (medical supplies) should be covered under the DME program.

Thus, Plaintiffs are not likely to succeed on the merits of their claim that Missouri is required to provide incontinence briefs under the DME program. Missouri's election not to provide medical supplies under the DME program is within the state's discretion in providing an option service. Moreover, Plaintiffs argue that the only test for whether something should be provided is medical necessity. This argument ignores the discretion available to states to define the covered services in optional areas of care. Missouri's definition of DME to include equipment but not supplies meets the "reasonable standards" requirement of the Medicaid Act.

B. Plaintiffs are not entitled to home health services

Plaintiffs allege that Missouri's policy violates the requirement that the state's Medicaid program provide "home health services" including "[m]edical supplies, equipment, and appliances suitable for use in the home." 42 C.F.R. § 440.70(b)(3).

In Missouri, all Medicaid recipients are categorically needy. The Medicaid Act provides that the categorically needy are entitled to nursing facility services for individuals 21 years of age or older. 42 U.S.C. §§ 1396(a)(10)(A); 1396(a)(4)(A). For those entitled to nursing facility services, the state must provide "home health services."

The provision of home health services is a "mandatory" service for the categorically needy. Plaintiffs argue that adult incontinence briefs are a "medical supply," and therefore must be provided as part of the home health services program. Moreover, Plaintiffs note that adult incontinence briefs are treated as a medical supply for Medicaid recipients age four through twenty and that other states consider adult incontinence briefs to be medical supplies. Plaintiffs also allege that adult incontinence briefs are considered medical supplies for purposes of determining the daily rate for nursing facility care.

What Plaintiffs do not, and cannot, allege is that they qualify for home health services under Missouri's plan. Although home health services are a "mandatory" service, individual

states may impose controls on utilization (*i.e.*, the state may limit the amount, scope, and duration). In other words, the state may limit the number of times a service may be provided and the period over which it can be provided.[2] In Missouri, home health services are used to provide services for temporary recovery from specific, episodic health incidents. Generally, home health services are ordered for patients returning home from the hospital or recovering from a specific condition. The service is limited to a maximum of 100 home visits per year (13 C.S.R. 70-90.010(6)), requires a plan of care prescribed by a physician every 60 days (13 C.S.R. 70-90.010(1)(C)), and is not intended to be a substitute for institutional care. In particular, home health services provides "non-routine supplies identified as specific and necessary to the delivery of a participant's nursing care and prescribed in the plan of care." 13 C.S.R. 70-90.010(4).

Plaintiffs have ongoing conditions requiring continuing care; these are not the type of episodic health conditions for which home health services would be appropriate under Missouri's plan. Plaintiffs allege that they expect to continue to require adult incontinence briefs for the indefinite future, perhaps for their entire lives. Services of this type are not covered by Missouri's home health services plan. Thus, plaintiffs have not demonstrated a likelihood of success on this claim because plaintiffs lack standing to raise this claim.[3]

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[2] Under this provision, a participant "entitled" to nursing facility care is not the same as "eligible" for nursing facility care. In other words, to qualify for home health services, it is not required that a participant meet the level-of-care criteria for nursing facility care. Under Missouri's plan, all plan participants have access to home health services if they have an appropriate injury or illness for which a physician prescribes home health services, regardless of whether the participant would otherwise qualify for institutional care. Thus, plaintiffs' allegations that they meet the level-of-care criteria for nursing facility care are not determinative of whether those plaintiffs meet the requirements for home health services under Missouri's plan.

[3] The Court need not address the question of whether home health services would ever cover adult incontinence briefs because these plaintiffs have not demonstrated that they qualify for home health services.

C. Plaintiffs have failed to state a violation of the ADA or RA

Plaintiffs' final argument is that Missouri's policy violates Title II of the ADA and Section 504 of the Rehabilitation Act. The claim is that Missouri's policy has the effect of forcing disabled plaintiffs into institutional care settings and that such segregation of incontinent disabled persons into institutions is a violation of the goals of the ADA and Section 504.

The "integration mandate" of the ADA and Section 504 requires states to ensure that services are administered to people with disabilities in the most integrated setting appropriate to their needs. In *Olmstead v. L.C.*, 527 U.S. 581 (1999), the Supreme Court analyzed these provisions and held that "unjustified isolation" is "properly regarded as discrimination based on disability." 527 U.S. at 597. The court interpreted the integration mandate to require that persons with disabilities be served in the community rather than in institutions when community placement is appropriate, the transfer from institutional care to a less restrictive setting is not opposed by the affected individual, and the state cannot demonstrate a fundamental alteration of its programs and services. *Id.* at 587, 591-92, 602-03.

Plaintiffs here allege that by covering adult incontinence briefs for individuals in institutions, but refusing to provide such coverage for individuals in home care settings, Missouri is violating the integration mandate. And, as noted previously, Missouri's long-standing Medicaid program, approved by the CMS has not covered adult incontinence briefs for those over twenty-one (and outside of the EPSDT program). Plaintiffs claim that "the *only* way Plaintiffs can receive the services they need is to move to a nursing home or other such institution." (Pl. Br. 19. (Emphasis original).) This argument ignores the fact that Missouri has waiver programs designed to help prevent institutionalization. Through these waivers, Missouri

does provide adult incontinence briefs as special medical supplies.[4] Under Medicaid, states are permitted to elect to provide certain items through waiver programs, such as special medical supplies, including adult incontinence briefs. See, §1916(c) of the Social Security Act. Plaintiffs do not allege whether they have applied for available waiver programs. Nonetheless, to the extent that one of these plaintiffs actually faces institutionalization because of inability to obtain adult incontinence briefs, it is likely that the plaintiff would qualify for a waiver program that would provide such coverage.

Finally, it should not be overlooked that Missouri's program is based on a State Plan, and that the Plan has to be reviewed and approved by the CMS, the federal agency that reviews such requests for compliance with federal laws governing the program. Here, CMS approved Missouri's State Plan. CMS's approval of a State Plan amendment is entitled to deference. *Pharm. Research and Mfrs. of Am. v. Thompson*, 362 F.3d 817, 821-22 (D.C. Cir. 2004).

2. Plaintiffs have not shown irreparable harm to themselves.

Plaintiffs claim that a loss of Medicaid benefits constitutes irreparable harm, citing a number of cases. But unlike those cases, Plaintiffs are not threatened with a loss of existing Medicaid benefits, nor is Missouri changing its program or benefits.

Instead, Plaintiffs are requesting a change to the state Medicaid program as currently administered, to require coverage of an item not currently covered. Continuation of a long-standing policy for the duration of this litigation is not irreparable harm. In addition, Plaintiffs may qualify for waiver programs that provide incontinence briefs as special medical supplies.

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[4] Adult incontinence briefs are available as special medical supplies under the Community Support Waiver and the Comprehensive Waiver through the Department of Mental Health, through the Physical Disabilities Waiver, the Prevention Waiver (scheduled to begin on October 1, 2010), the Independent Living Waiver, and through the AIDS Waiver programs.

Because Plaintiffs have not applied for these programs, it is not clear whether they would be admitted to the programs. Nonetheless, the fact that Plaintiffs have failed to exhaust the available options under the existing plan counsels against changing the status quo.

If Plaintiffs fail to demonstrate irreparable harm, that is "an independently sufficient ground upon which to deny a preliminary injunction." *Watkins, Inc. v. Lewis*, 346 F.3d 841, 844 (8th Cir. 2003). Thus, "[o]nce a court determines that the movant has failed to show irreparable harm absent the injunction, the inquiry is finished and the denial of the injunctive request is warranted." *Gelco Corp. v. Coniston Partners*, 811 F.2d 414, 420 (8th Cir. 1987); *Taxpayers' Choice Vol. Comm. v. Roseau County Bd of Com'rs*, 903 F. Supp. 1301, 1308 (D. Minn. 1995).

3. There is harm to the State and the public interest will not be served.

Plaintiffs' suit changes the status quo, and injunction requires the State to pay for briefs. It is expected that testimony at the preliminary injunction hearing will demonstrate that the yearly cost to the state could be significant to provide briefs to all.

As to the public interest, Missouri courts have noted that the state has a compelling governmental interest in carrying out the Medicaid program. *Rolla Manor v. Dep't of Social Services, Div. of Med. Services*, 865 S.W.2d 812, 815 (Mo. App. S.D. 1993)("purpose under Medicaid…is to provide reasonable reimbursement ...while incorporating cost containment measures"); *Couch v. Division of Family Services*, 795 S.W.2d 91, 93 (Mo. App. W.D. 1990). The public interest is better served by the status quo until this litigation is concluded.

Moreover, an injunction here would require Missouri to bear the administrative burdens associated with amending its State Plan. *See* 42 C.F.R. §§ 430.12-.20. The state should not be required to take on such burdens before this Court has finally resolved Plaintiffs' claims. *National Assoc. of Chain Drug Stores v. Schwarzenegger*, 2010 WL 1506928 (9th Cir. Apr. 15, 2010) (affirming denial of preliminary injunction where plaintiffs demanded change in

reimbursement rates and noting that "regardless of the [plaintiffs'] likelihood of success on the merits of their claims, they are not entitled to the preliminary injunction that they seek.").

CONCLUSION

This Court should deny Plaintiffs a preliminary injunction. Plaintiffs have failed to demonstrate that the *Dataphase* factors justify a preliminary injunction at this time.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify on this 30th day of September, 2010, the foregoing was filed electronically with the Clerk of the Court, and was served by operation of ECF system on the following:

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