UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

STEVEN HILTIBRAN, by and through his mother and guardian, Debra Burkhart; NICHOLAS TATUM, by and through his mother and next friend, Stacy Tatum; RONALD COONTZ, by and through his mother and guardian, Patricia Coontz; and NENA HAMMOND, Plaintiffs, v. RONALD J. LEVY, in his official capacity as Director of the Missouri Department of Social Services; and IAN McCASLIN, M.D., in his official capacity as Director of the MO HealthNet Division, Defendants.	)	Case No. 10-4185-CV-C-NKL

PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

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PRELIMINARY STATEMENT

Plaintiffs are low-income Missouri residents who receive their health services through Missouri's Medicaid program, known as MO HealthNet. Plaintiffs suffer from a range of disabilities, including severe cerebral palsy, psychosis, scoliosis, static encephalopathy (permanent brain damage), seizure disorder, liver disease, and mental retardation. As a result of their disabilities, Plaintiffs have no bladder or bowel control; they are incontinent. Plaintiffs' physicians have determined that incontinence briefs are medically necessary to prevent skin breakdowns and infections and to maintain Plaintiffs' ability to live in the community. The Department of Social Services, which administers the Missouri Medicaid program, has refused Plaintiffs' claims on grounds that their incontinence briefs are personal hygiene items.

Defendants have promulgated a regulation, 13 C.S.R. § 70-60.010, and policy that cover incontinence briefs needed by recipients who are under age 21. Defendants' policy also covers incontinence briefs as necessary supplies for individuals over age 20 if they live in institutional settings, such as nursing homes. As a result of these policies, three of the plaintiffs lost Medicaid coverage of their incontinence supplies upon turning 21, and all will go without the prescribed adult diapers unless they go into a nursing home. Plaintiffs face a high likelihood of hospitalizations to address infections and may be forced into nursing homes in order to receive these necessary supplies.

Plaintiffs seek declaratory and injunctive relief to enjoin Defendants from denying Medicaid coverage of their medically necessary incontinence supplies and thereby violating federal Medicaid and disability discrimination mandates. Plaintiffs seek a fair process by which they can establish the medical necessity of adult diapers, just as three of them did before they reached 21 years of age.

BACKGROUND ON THE MEDICAID PROGRAM

Congress created the Medicaid program in 1965 by adding Title XIX to the Social Security Act, 42 U.S.C. §§ 1396-1396w-2 (hereinafter "the Act"). The purpose of Medicaid is to enable each State, as far as practicable, to furnish "rehabilitation and other services to help … [low-income] … families and individuals attain or retain capability for independence or self-care." 42 U.S.C. § 1396-1.

State participation in Medicaid is optional. However, a state that chooses to participate, and thereby receive federal matching funds for program expenditures, "must comply with requirements imposed both by the Act itself and by the Secretary of Health and Human Services." Schweiker v. Gray Panthers, 453 U.S. 34, 37 (1981); see also Lankford v. Sherman, 451 F.3d 496, 504 (8th Cir. 2006); Weaver v. Reagen, 886 F.2d 194, 197 (8th Cir. 1989).

Missouri participates in the Medicaid program and accepts federal matching funds for its program expenditures. During fiscal years 2010 and 2011, the State will receive enhanced federal funding as a result of the American Recovery and Reinvestment Act of 2009 (ARRA), Pub. L. No. 111-5, § 5001 (Feb. 17, 2009). The federal government will pay more than 70 cents of each dollar spent on Medicaid services in Missouri, including more than 74 cents of each dollar for the second quarter of fiscal year 2010. 75 Fed. Reg. 22807-2208 (April 30, 2010). Without the enhanced funding from ARRA, the federal government would normally pay more than 64 cents of each dollar spent on Medicaid services in Missouri. Id.

Medicaid is not available to everyone who is poor. Rather, it only covers certain groups of needy individuals, with almost all of those groups being listed or referenced in

42 U.S.C. § 1396a(a)(10)(A). Missouri must cover some of the groups listed in § (10)(A) and has the option to cover additional groups. The groups that a state must cover, referred to in Medicaid parlance as the "categorically needy," include individuals who are aged, blind, or disabled, working disabled individuals, and children and pregnant women who meet federal poverty level standards. Id. at § 1396a(a)(10)(A)(i). All Missouri Medicaid recipients are "categorically needy." Lankford, 451 F.3d at 504. When it enacted Medicaid, Congress stated that categorically needy people "are the most needy in the country and it is appropriate for medical care costs to be met, first, for these people." H.R. Rep. No. 213, 89th Cong., 1st Sess; S. Rep. No. 404, 89th Cong., 1st Sess., Pt. 1, reprinted in 1965 U.S.C.C.A.N. 2020-21.

MISSOURI'S INCONTINENCE SUPPLIES POLICY

Missouri provides coverage of incontinence briefs through its durable medical equipment (DME) program. Missouri law requires Defendants to cover all *medically necessary* DME "using best medical evidence and care and treatment guidelines, consistent with national standards to verify medical need." Mo Rev. Stat. § 208.152.1(19). The State has promulgated a regulation governing its DME program. 13 C.S.R. § 70-60.010. This regulation does not list the specific DME items that the State will cover but rather incorporates by reference the DME Provider Manual and Provider Bulletins, which specifically describe the DME covered by the MO HealthNet Division. 13 C.S.R. § 70-60.010(6); see also 13 C.S.R. § 70-60.010(2) ("Covered services are limited as specified in the DME provider manual and bulletins.").

Defendants have promulgated Provider Manual and Bulletin provisions regarding coverage of incontinence briefs.[1] Under these policies, Missouri covers incontinence briefs for individuals aged four through twenty years when these supplies are determined to be medically necessary through a prior authorization process. When an individual becomes 21 years old, however, the Missouri Medicaid program considers incontinence briefs to be "personal hygiene" or non-medical items.[2] Unless the individual is living in or goes into an institution, the supplies are no longer covered, even if the State's prior authorization process previously determined that these services were medically necessary.

ARGUMENT

I. STANDARD FOR PRELMINARY RELIEF

Injunctive relief is "an equitable remedy shaped to right an ongoing wrong." Kohl v. Woodhaven Learning Ctr., 865 F.2d 930, 934 (8th Cir. 1989). There are four factors that this Court must consider in determining whether to grant preliminary relief: "(1) the probability of success on the merits, (2) the threat of irreparable harm to the movant, (3) the balance between the harm and the injury that granting the injunction will inflict on other parties, and (4) the public interest." Lankford, 451 F.3d at 503 (citing

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[1] Missouri Durable Medical Equipment Provider Manual, § 13.22.B, at http://manuals.momed.com/collections/collection_dme/Durable_Medical_Equipment_Section13.pdf; DSS, Provider Bulletin Vo. 31, No. 52, March 6, 2009 ("DME Provider Bulletin"), at http://www.dss.mo.gov/mhd/providers/pdf/bulletin31-52_2009mar06.pdf (Ex. 5 and 6).

[2] Defendants' policy is summarized in recent correspondence from the Special Counsel for the Missouri Department of Social Services: "Incontinence supplies are *non-covered for adults* through MO HealthNet's DME program. Diapers are considered a *personal hygiene item*, not an essential medical item, and have never been a covered service for adults" in Missouri. Allen Letter, February 23, 2010 (Ex. 1) (emphasis added).

Dataphase Sys. v. C L S ys., Inc., 640 F.2d 109, 114 (8th Cir. 1981); see also Winter v. Natural Res. Def. Council, 129 S.Ct. 365 (2008). Plaintiffs meet all these factors.

II. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS OF THEIR CLAIMS.

A. Defendants' Regulation and Policy Likely Violate the "Reasonable Standards" Requirement.

The Medicaid Act requires a participating state to em ploy "reasonable standards…for determining…the extent of medical assistance under the plan which…are consistent with the ob jectives of this s ubchapter." 42 U.S. C. § 1396a(a)(17). See Wisconsin Dept of He alth and Fam ily Serv. v. Blum er, 534 U.S. 473, 479 (2002); Schweiker v. Gray Panthers, 453 U.S. 34, 36-37 (1981); Herweg v. Ray, 455 U.S. 265 (1982); Lankford v. Sherman, 451 F.3d at 506 (noting that while "a state has considerable discretion to fashion m edical assistance under its Medicaid plan, this discretion is constrained by the reasonable-standards requirement").

The primary objective of Medicaid is "to furnish medical assistance to individuals whose income and resources are insufficient to meet the cost of necessary m edical services," Beal v. Doe, 432 U.S. 438, 444-45 (1977), and to furnish rehabilitation and other services to help such individual "attain or retain capability for independence or self-care." 42 U.S.C. § 1396-1. See also Weaver, 886 F.2d at 198 (citing Beal and stating, "[t]his provision [(a)(17)] has been interpre ted to requ ire that a state Med icaid plan provide treatment that is deem ed 'medically necessary' in order to c omport with the objectives of the Act"); Lankford, 451 F.3d at 511 ("[A] state's *failure to p rovide Medicaid coverage for non-experimental, medically necessary services within a covered*

Medicaid category is per se unreasonable and inconsistent with the stated goals of Medicaid.") (emphasis added).[3]

The "reasonable standards" requirement applies to coverage of medical equipment and supplies. See Lankford, 451 F.3d at 510 ("[T]he federally funded DME program must comply with Medicaid's reasonable standards requirement, and its implementing regulations."). Moreover, "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." Id. at 508 (emphasis added).[4] Thus, courts have struck down state Medicaid policies that restrict access to medical equipment and supplies as violations of "reasonable standards." See id. at 511-12; Esteban v. Cook, 77 F. Supp. 2d 1256, 1262 (S.D. Fla. 1999); Bell v. Agency for Health Care Admin., 768 So.2d 1203, 1204 (Fla. Ct. App. 2000).

1. Missouri's Regulation and Policy Employ Unreasonable Standards by Imposing Standards that are More Restrictive than Medical Necessity.

Missouri's incontinent supplies policy violates the reasonable standards requirement because it denies access to medically necessary incontinence supplies to anyone over the age of 20 who is not institutionalized but is living in his or her home.

[3] A state Medicaid program employs reasonable standards when it ensures that each provided service is covered in "sufficient…amount, duration, and scope to reasonably achieve its purpose." 42 C.F.R. § 440.230(b); Lankford, 451 F.3d at 506; McNeill-Terry v. Roling, 142 S.W.3d 828, 834 (Mo. App. 2004). Furthermore, it may not impose arbitrary limitations on required services, such as medical equipment and supplies, "solely because of the diagnosis, type of illness, or condition." 42 C.F.R. § 440.230(c); Lankford, 451 F.3d at 506.

[4] See CMS, Dear State Medicaid Director (Sept. 4, 1998), at http://www.cms.gov.hhs.gov/states/letters/smd90498.asp (Ex. 12). On the basis of this agency guidance, the Supreme Court vacated a court of appeals decision that had allowed the Connecticut Medicaid program to exclude coverage of medically necessary medical equipment—a home health service. See Slekis v. Thomas, 523 U.S. 1098 (1999), vacating and remanding, Desario v. Thomas, 139 F.3d 80 (2d Cir. 1998).

Courts have invalidated similar state policies that subject some Medicaid recipients' coverage of an item or service to standards harsher or narrower than medical necessity. See Lankford, 451 F.3d at 511-13; Weaver, 886 F.2d at 198 (invalidating Missouri regulation restricting Medicaid coverage of drug AZT and denying the drug to recipients for whom the drug was medically necessary); Hodgson v. Bd. of County Comm'rs, 614 F.2d 601, 608 (8th Cir. 1980); Hern v. Beye, 57 F.3d 906, 910-11 (10th Cir. 1995); Preterm, Inc. v. Dukakis, 591 F.2d. 121, 126, 131 (1st Cir. 1979). Thus, Missouri "cannot arbitrarily choose which DME items to reimburse under its Medicaid policy." Lankford, 451 F.3d at 511.

In Lankford, the Eighth Circuit faulted a Missouri policy that excluded several items of medical equipment and supplies (e.g., respiratory care equipment, parenteral nutrition (feeding tubes), decubitus care equipment, wheel chair batteries, hospital beds) for certain disabled adults without regard to medical necessity as a violation of reasonable standards. 451 F.3d at 501, 511. See also, e.g., Esteban, 77 F. Supp. 2d at 1262 (state may not "arbitrarily or unreasonably" deny medical equipment "entirely on the basis of age"); Bell, 768 So.2d at 1204-05 (exclusion of medical equipment and supplies for individuals age 21 and over was arbitrary and unreasonable). In Bristol v. R.I. Dept of Human Serv., a Rhode Island state court struck down that state's exclusion of adult incontinence briefs under the 42 U.S.C. § 1396(a)(17) "reasonable standards" requirement. No. 95-6605, 1997 R.I. Super. LEXIS 14, at *11 (R.I. Super. Ct. Jan. 30, 1997). The policy was inconsistent with the purposes and objectives of the Medicaid Act as it undercut rather than promoted individuals' ability to attain or retain capability for independence and self-care. Id. at *11-12. The policy was also "arbitrary and

capricious because it exclude[d] coverage of services without regard to medical necessity and because it prov ide[d] inadequate defere nce to the treating or attending physician's considered judgment." Id. Missouri's arbitrary exclusion of incontinence briefs is similarly unreasonable and in violation of 42 U.S.C. §1396a(a)(17).

2. Plaintiffs' Adult Diapers are Medic al Supplies that Must be Covered When Medically Necessary.

Defendants seek to evade federal require ments by re-labeling Plaintiffs' adult incontinence briefs as "n on-medical" or "personal hygiene" item s once they reach ed 21 years of age. See Ex. 1; McCaslin L etter, July 15, 2009 (Ex. 2); McCaslin E-m ail, April 28, 2009 (Ex. 3); Hiltibran Hearing Decision (Ex.4). This characterization is contradicted by common sense, as well as all applicable precedent and the Defendants' own policies.

Multiple federal and sta te courts, th e federal government, and other s tates have specifically recognized that inco ntinence briefs are in fact *medical* supplies covered under federal Medicaid law. S ee , e.g., S.D v. Hood , 391 F.3d 581, 594- 595 (5th Cir. 2004) (noting CMS approval of state Medicaid plans that *expressly* authorize coverage of incontinence supplies, includi ng diapers); Eckloff v. Rodgers , 443 F. Supp. 2d 1173, 1177 (D. Ariz. 2006) (coverage of medical supplies "includes incontinence briefs"); Smith v. Benson , No. 09-21543-CIV, 2010 WL 1404066, at *8-10 (S.D. Fla., Jan. 28, 2010); Rinaldi Convalescent Hosp. v. Dept of Health Serv. , 72 Cal. Rptr.2d 606, 608-09 (Cal. Ct. App. 1998) (medically necessary adu lt diapers covered in California's Medicaid program). As the court stated in S.D. v. Hood , "Giving effect to the natural and plain meaning of the term medical supplies in th e context of this case, we f ind that such medical supplies reasonably include the incontinence supplies medically prescribed for [Plaintiff]." 391 F.3d at 594.

While these cases involved children's coverage, all of these courts found that incontinence briefs were coverable *medical* items under federal Medicaid law, necessary to alleviate medical conditions caused by bowel or bladder incontinence such as skin breakdowns and infections. See S.D., 391 F.3d at 585, 602 (incontinence briefs draw "moisture away from the skin which prevents chronic irritation and infection from urine wetness."); Eckloff, 443 F. Supp. 2d at 1176-77 ("incontinence briefs … avoid skin breakdown and infection"); Smith, 2010 WL 1404066, at *9 (diapers "prevent skin irritation, rashes, skin breakdown, and infections"). Not one of these courts suggested that incontinence briefs were mere personal hygiene or convenience items.

Significantly, Defendants' characterization of incontinence briefs as non-medical items when needed by adults living at home is contradicted by the fact that Defendants authorize coverage of adult diapers for individuals under age 21 if they establish *medical necessity* through the state-mandated prior authorization process.[5] See Ex. 5 and 6. The Agency covers incontinence briefs for these individuals only where the items are prescribed and determined to be appropriate when there is a medical condition causing bowel/bladder incontinence. Id. Prior authorization "must include documentation of medical need from a physician, indicating a condition causing excessive fecal or urine output." Ex. 6 (emphasis added).

As Defendants acknowledge, they are required to "authorize Durable Medical Equipment using best medical evidence and care and treatment guidelines, consistent

[5] Defendants' March 6, 2009 DME Provider Bulletin states that "[i]n order to be approved [for adult diapers and related incontinence supplies], participants must be between ages four through twenty and meet the medical criteria established by the MO HealthNet Division (MHD)." Ex. 5. See also Ex. 8, 9 (earlier MHD Provider Bulletins); Missouri Medicaid Durable Medical Equipment Billing Book, at 7.1, October 2009, at http://www.dss.mo.gov/mhd/providers/education/dme/dme.pdf (Ex. 10).

with national standards to verify medical need." MO HealthNet PA Criteria, at http://www.dss.mo.gov/mhd/cs/dmeprecert/pdf/diapers.pdf (Ex. 7); Mo Rev. Stat. 208.152.1(19) (emphasis added). The implementing state regulation similarly allows coverage of DME only when it is "medically necessary as determined by the treating physician." 13 C.S.R. 70-60.010 (2) (emphasis added). Defendants employ these requirements in making determinations regarding incontinence briefs for individuals under age 21. Defendants cannot simultaneously require individuals aged 20 and below to prove medical necessity based on the "best medical evidence" to qualify for coverage of incontinence briefs but label these same supplies as "non-medical" items to deny coverage when these individuals reach the age of 21.[6]

Clearly, Plaintiffs' medical need for incontinence supplies did not disappear when they reached the age of 21. Harper Decl. ¶¶ 4, 10; Porter Decl., ¶ 3; Belancourt Decl. ¶ 4. Moreover, achieving 21 years of age does not convert a "medical item" into a "personal hygiene" item. See Huskey Decl. ¶¶ 15-19. Yet, Plaintiffs are denied any opportunity to establish medical necessity for incontinence briefs. Denying Plaintiffs this opportunity is unreasonable. See Lankford, 451 F.3d at 496; Hunter v. Powell, 944 F. Supp. 914, 920 (S.D. Fla. 1996) ("selection of age as the sole criterion for denying benefits is wholly unrelated to the medical decision at hand and cannot meet the fundamental legal concept of reasonableness"); Fred. C. v. Tex. Health and Human Serv. Comm'n, 924 F. Supp. 788, 791 (W. D.Tex 1996); vacated on other grounds, 117 F.3d 1416 (5th Cir. 1997), amended by, 988 F. Supp. 1032 (W.D. Tex. 1997), aff'd, 167 F.3d

[6] As Defendants acknowledged before this Court in the Lankford case, this state statute requires them to cover 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 v. Sherman, at 2 (Ex. 24) (emphasis added).

537 (5th Cir. 1998) (same); Esteban, 77 F. Supp.2d at 1262 (Florida may not arbitrarily or unreasonably deny motorized wheelchairs to Plaintiffs entirely on the basis of age); accord Hodges v. Smith, 910 F. Supp. 646, 649 (N.D. Ga. 1995) (Georgia could not deny enteral products—another medical supply—to individuals 21 and over).

Defendants' policy also creates an illegal irrebuttable presumption that adult diapers are *never* medically necessary for adults over age 20 who live in the community—an approach that has been rejected by the Eighth Circuit. In Weaver, the Eighth Circuit struck down a Missouri policy creating "an irrebuttable presumption that AZT can never be medically necessary for AIDS patients" who did not meet specified diagnostic criteria. 886 F.2d at 199. The Court also held that the decision of whether certain treatment is medically necessary rests "with the individual recipient's physician and not with clerical personnel or government officials." Id. at 199; J.D. v. Sherman, No. 06-4153-CV-C-NKL, 2006 U.S. Dist. LEXIS 78446, at *10 (W.D. Mo 2006). See also Smith, 2010 WL 1404066, at *8 (striking Florida rule that "under all circumstances refuses to provide incontinence supplies deemed necessary by a treating physician"). In the instant case, there are no criteria under which Defendants will consider adult diapers to be medically necessary for the Plaintiffs. And, the state officials have arbitrarily removed the decision of whether to provide incontinence briefs from the treating physician by excluding coverage of these items in all circumstances. Defendants' policy is unreasonable and violates the Medicaid Act.[7]

[7] In addition to clearly established legal precedent and Defendants' own policies, Plaintiffs have presented overwhelming evidence that these items are medically necessary to prevent skin breakdown and infections as well as serious illness and even death. Huskey Decl. ¶¶ 2-24; Hurley Decl. ¶¶ 2-11; Harper Decl. ¶¶ 4-11; Porter Decl. ¶¶ 6-11; Belancourt Decl. ¶¶ 4-13; Anzalone Decl. ¶¶ 2-11.

3. Plaintiffs are Prohibited from using the "Exceptions Process" for Coverage of Adult Incontinence Briefs.

Defendants' "reasonable standards" violations are compounded by their failure to make their own limited exceptions process available to Plaintiffs.[8] In Lankford, the Eighth Circuit struck down these same Defendants' prior medical equipment policies as unreasonable based, in part, on the inability of plaintiffs to access the excluded medical supplies through an exceptions process. 451 F.3d at 513. In the instant case, the Missouri Medicaid exceptions process is entirely unavailable to Plaintiffs and other adult Missourians because the State irrebuttably presumes that adult diapers are a personal hygiene item rather than a "medical item" and therefore cannot be covered through the exceptions process. Ex.1-4; See Weaver, 886 F.2d at 199-200.[9]

B. Defendants' Policies Likely Violate the Mandatory Home Health Services Requirement of the Medicaid Act.

In Missouri, all Medicaid recipients are categorically needy. The Medicaid Act provides that the categorically needy are entitled, among other things, to nursing facility services for individuals 21 years of age or older. 42 U.S.C. §§ 1396a(a)(10)(A);

[8] The Missouri Medicaid program employs an "Exceptions Process" for services that are not normally covered by the Missouri Medicaid program. See 13 C.S.R. § 70-2.100. This process allows for exceptions to be made on a "case by case basis" for Medicaid recipients who meet one of four narrow criteria. Id.; Lankford, 451 F.3d at 513. Plaintiff Steven Hiltibran's exception request was denied even though he met at least two of these criteria because Defendant McCaslin found that Steven's incontinence briefs were non-medical items. Ex. 4; Burkhart Decl. ¶¶ 15-16; Harper Decl. ¶6.

[9] In justifying this arbitrary policy, Defendants mistakenly assert that the "medical necessity" requirement is inapplicable to adult Missouri Medicaid recipients. In a letter dated July 15, 2009, Defendant McCaslin stated that "[w]hile the determination of medical necessity is key to the federal EPSDT legislation for participants under age 21 . . . [m]edical necessity is not the guiding principal [sic]" for determining whether adults can receive a service pursuant to the State's Medicaid Exception Process—a position that directly contradicts federal Medicaid law and Eighth Circuit precedent. Lankford. 451 F.3d at 511; Ex. 2. Because "medical necessity" is in fact the "guiding principle" for determining whether adults can receive a covered service such as medical equipment, there is no legal basis for totally excluding them from coverage.

1396d(a)(4)(A). The Act further requires that, for all those entitled to nursing facility services, the state Medicaid agency must provide "home health services," id __. at § 1396a(a)(10)(D), including "[m]edical supplies, equipment, and appliances suitable for use in the home." 42 C.F.R. 440.70(b)(3); see also 42 C.F.R. § 441.15. ("State Plan must provide that ... the [state Medicaid] agency provides home health services to ... Categorically needy recipients age 21 or over."); Id. __ at § 440.210 ("State Plan must specify that, at a minimum, categorically needy recipients are furnished ... the services defined in ... 440.70."); Id. at § 440.210(a)(1).

The United States Department of Health and Human Services Centers for Medicare & Medicaid Services (CMS) has also issued Medicaid guidelines instructing states that home health, including medical equipment and supplies, is a "mandatory" service for the categorically needy. Ex. 12. Notably, in a recent compliance action, CMS made it clear that the denial of home health services to Missouri Medicaid beneficiaries violates 42 U.S.C. §1396a(a)(10)(D), which requires "the inclusion of home health services in the standard Medicaid benefit package." Ex. 11, at 1. See also 75 Fed Reg. 10289-90 (March 5, 2010).

A number of courts have struck down state Medicaid policies that denied or limited access to home health services, including medical equipment and supplies. Noting that "[h]ome health care services are generally a mandatory service for the categorically needy," the court in Esteban v. Cook struck down a restriction that denied coverage of wheelchairs—a home health service—in violation of the Medicaid Act. 77 F. Supp. 2d 1256, 1259 (S.D. Fla. 1999). See also Ladd v. Thomas, 962 F. Supp. 284, 288 (D. Conn. 1997) (citing 42 C.F.R.§ 440.70(b)(3) and finding that "Federal law

mandates that participating states provide home health services, including durable medical equipment, to Medicaid participants where such equipment is medically necessary."); Hodges, 910 F. Supp. 646, 649 (N.D. Ga. 1995) (Georgia could not rely on its state plan to deny home health services because the "inclusion of home health services in the state medical plan is mandated by federal law").

In the instant case, Missouri excludes coverage of incontinent supplies for individuals over the age of 20. Because such supplies are a mandatory home health service to which all Missouri Medicaid recipients are entitled, Defendants are violating 42 U.S.C. §1396a(a)(10)(D), which requires coverage of home health services for all categorically needy individuals.

C. Plaintiffs are Likely to Succeed on the Merits of their Claim that Defendants are violating the ADA and Section 504 of the Rehabilitation Act.

1. The ADA and Section 504 prohibit discrimination against individuals with disabilities.

Congress enacted the Americans with Disabilities Act (hereinafter "ADA") to prohibit discrimination by all public entities. 42 U.S.C. §§ 12131-12165; H.R. Rep. No. 101-485, pt. 3, at 49 (1990), reprinted in 1990 U.S.C.C.A.N. 267, 472. The goals of the ADA "are to assure equality of opportunity, full participation, independent living, and economic self-sufficiency for each individual [with disabilities]." 42 U.S.C. § 12101(a)(8). The Supreme Court has held that unjustified isolation is properly regarded as discrimination based on disability under the ADA. Olmstead v. L.C., 527 U.S. 581, 597 (1999).

Title II of the ADA, which governs public programs such as the MO HealthNet Program, provides:

> [N]o qualified individual with a disability shall, by reason of such disability, be excluded from participation in or be denied the benefits of the services, programs, or activities of a public entity, or be subjected to discrimination by any such entity.

42 U.S.C. § 12132; Layton v. Elder, 143 F.3d 469, 472 (8th Cir. 1998). See also Disability Advocates, Inc. v. Paterson, 598 F. Supp. 2d 289, 316 (E.D.N.Y. 2009) (Title II of the ADA applies to "all programs, services, and activities of a state or local government entity *without* any exception") (emphasis in original). Section 504 of the Rehabilitation Act applies the same standards to entities that receive federal financial assistance. 29 U.S.C. §794(a). Layton, 143 F.3d at 472. See also Allison v. Dept of Corrections, 94 F.3d 494, 497 (8th Cir. 1996); Barnes v. Gorman, 536 U.S. 181, 184-85 (2002); Bragdon v. Abbott, 524 U.S. 624, 631-32 (1998).

Under the ADA, a "qualified individual with a disability" is a person who "with or without reasonable modifications to rules, polices or practices" meets the "essential eligibility requirements for the receipt of services or the participation in programs or activities provided by a public entity." 42 U.S.C. § 12132(2). Section 504's definition is substantially similar. See 29 U.S.C. § 705(20).[10] All Plaintiffs are eligible for Medicaid and are qualified persons with disabilities within the meaning of the ADA and section 504. See Burkhart Decl. ¶¶ 1, 7; Coontz Decl. ¶¶ 3, 6, 7; Tatum Decl. ¶¶ 1, 6, 7, 12.

2. The "integration mandate" of the ADA and Section 504 prohibit unjustified and unnecessary institutionalization.

[10] ADA regulations define disabilities, with respect to an individual, to include "a physical or mental impairment that substantially limits one or more of the major life activities of such individual… such as caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, and working." 28 C.F.R. § 35.104. The Section 504 requirements are essentially the same. 28 C.F.R. § 41.32.

The ADA's integration mandate requires states to ensure that services are administered to people with disabilities in the most integrated setting appropriate to their needs, and provides a defense to states only where they can show that it would be a fundamental alteration of their service systems to do so. Olmstead, 527 U.S. at 591-92, 603; Townsend v. Quasim, 328 F.3d 511, 516-517 (9th Cir 2003); Radaszewski v. Maram, 383 F.3d 599, 607 (7th Cir. 2004); Fisher v. Okla. Health Care Auth., 335 F.3d 1175, 1183 (10th Cir. 2003); Disability Advocates, Inc., v. Paterson, 653 F. Supp. 2d 184, 191 (E.D.N.Y. 2009); Marlo M. v. Cansler, No. 5:09-CV-535-BO, 2010 U.S. Dist. LEXIS 3426, at *5-6 (E.D.N.C. Jan. 17, 2010). As explained below, covering incontinence supplies for Plaintiffs in their home will not require a fundamental alteration because Plaintiffs are not asking for a new service. And, it would be far more expensive to serve Plaintiffs in a nursing home than to provide them with adult diapers in the community.

In enacting the ADA, Congress specifically found that segregation of persons with disabilities, especially in institutions, is a form of discrimination. 42 U.S.C. § 12101 (a)(2), (3), and (5). The ADA's integration mandate requires public entities to "administer services, programs and activities in the most integrated setting appropriate to the needs of qualified individuals with disabilities." Olmstead, 527 U.S. at 592; 28 C.F.R. § 35.130(d). The integration mandates of the ADA and Section 504 are virtually identical and are applied in the same manner. See Radaszewski, 383 F.3d at 607; Fisher, 335 F.3d at 1179 n.3 (10th Cir. 2003); Disability Advocates Inc., 653 F. Supp. 2d at 190-191.

The integration mandate was analyzed and interpreted by the United States Supreme Court in the landmark Olmstead decision. 527 U.S. at 597. The Olmstead plaintiffs were individuals with mental disabilities who were confined in Georgia's state psychiatric institutions but who wanted to live in the community. Plaintiffs asserted that the state's refusal to pay for services that would enable them to live in community settings violated the integration mandate of Title II of the ADA and its implementing regulations. The Court agreed, and held that "unjustified isolation" is "properly regarded as discrimination based on disability." Id. at 597. The Court interpreted the ADA's "integration mandate" as requiring persons with disabilities to 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, 602-603.

Plaintiffs do not need to wait until they are institutionalized to bring a claim under the integration mandate. Plaintiffs who currently reside in community settings may assert ADA integration claims to challenge state actions that give rise to a risk of unnecessary institutionalization. See Fisher, 335 F.3d at 1181-82; Marlo M., 2010 U.S. Dist. LEXIS 3426, at *5-6; Brantley v. Maxwell-Jolly, 656 F. Supp. 2d 1161 (N.D. Cal. 2009); Ball v. Rodgers, No. CV 00-67-TUC-EHC, 2009 U.S. Dist. LEXIS 45331, at *16 (D. Ariz. April 24, 2009); Mental Disability Law Clinic v. Hogan, 06-CV-6320, 2008 U.S. Dist. LEXIS 70684, 2008 WL 4104460, at *15 (E.D.N.Y. August 26, 2008); V.L. v. Wagner, No. C 09-04668 CW, 2009 U.S. Dist. LEXIS 99107, at *31-33 (N.D. Cal. Oct. 23, 2009): Makin v. Hawaii, 114 F. Supp. 2d 1017, 1033-34 (D. Haw. 1999). In this case, Plaintiffs'

already-serious risk of institutionalization is magnified by the fact that three of them have already been found to meet the "level of care" requirements for care in a nursing home or other such institution. See Burkhart Decl. ¶ 19 (receives personal care services); Coontz Decl. ¶ 3 (same); Tatum Decl, ¶ 8 (receives adult day care services); 13 C.S.R. §§ 70-91.010(1)(A) (personal care services requirements), 70-92.010(2)(A) (adult day care services requirements).

3. Defendants are likely violating the integration mandate.

Defendants are violating Plaintiffs' rights to receive Medicaid services in the most integrated setting appropriate to their needs. Plaintiffs meet the criteria necessary to establish a violation of the community integration mandate. See also Olmstead, 527 U.S. at 587; Radaszewski, 383 F.3d at 608. Plaintiffs' treating professionals have determined that receiving Medicaid services in the community is appropriate to meeting their needs and none recommend institutionalizing them in nursing homes. Harper Decl. ¶ 6, 7, 10; Porter Decl. ¶ 7; Belancourt Decl. ¶ 13; Anzalone Decl. ¶¶ 6, 9. The mere fact that Plaintiffs have been residing in the community for many years demonstrates that receiving these services in the community is appropriate to their needs. Burkhart Decl. ¶ 17; Coontz Decl. ¶¶ 4, 5; Tatum Decl. ¶ 3; Hammond Decl. ¶¶ 6, 12-13; see Radaszewski, 383 F.3d at 608 (there was "little doubt" that the plaintiff could be cared for at home because he had been receiving care at home for more than 10 years). Medical professionals and experts establish that providing incontinence briefs in the community is the medically appropriate treatment for individuals suffering from incontinence. Huskey Decl. ¶¶ 24, 25; Hurley Decl. ¶¶ 10, 11; Gray Decl. ¶ 14. In fact, institutionalization of a person for incontinence alone is medically *inappropriate.* Huskey Decl. ¶ 24; Gray Decl.

¶ 14. Finally, in the instant case, there is no opposition to community placement. All the Plaintiffs want to remain in their homes. Burkhart Decl. ¶¶ 12, 22, 23; Coontz Decl. ¶ 5; Tatum Decl. ¶ 3; Hammond Decl. ¶¶ 8, 12.[11]

Under Defendants' policies, however, the *only* way Plaintiffs can receive the services they need is to move to a nursing home or other such institution, which will result in unjustified isolation from their families and friends. Ironically, Defendants will then be obligated to pay for their incontinence briefs—as well as all of their residential and personal care costs 24 hours a day, 7 days a week, thereby defeating any ostensible money-saving justification for the State's refusal to cover Plaintiffs' incontinence briefs while they live at home.

Defendants' are violating the ADA by conditioning receipt of medically necessary incontinent supplies on unnecessary institutionalization. Several federal courts have required state agencies to provide services in the community where a failure to provide the service posed a risk of institutionalization. For example, in Fisher v. Oklahoma Health Care Authority, the Tenth Circuit cited the integration mandate when it reversed a district court decision upholding a state rule limiting Medicaid coverage of prescription drugs to only five prescriptions per month for individuals who were living *in the community* but allowing unlimited prescription coverage if the individual went into a

[11] Plaintiffs' fears of institutionalization are well-grounded. See, e.g., Lakeridge Villa Health Care Ctr v. Leavitt, 202 Fed.Appx. 903, 910 (6th Cir. 2006) (upholding ALJ's decision to fine nursing home for inadequate incontinence care); Harmony Court v. Leavitt, 188 Fed.Appx. 438, 441 (6th Cir. 2006) (holding that nursing home violated federal requirements by leaving resident in "foul-smelling and urine-saturated incontinent brief" for three-and-a-half hours); Livingston Care Ctr v. Dept of Health & Human Serv., 388 F.3d 168, 174 (6th Cir. 2004). (finding nursing home liable for violations under Medicare Act because resident identified "as having a high risk for pressure sores because of her incontinence and total dependence on nursing staff" received inadequate care).

nursing home. 335 F.3d at 1178, 1180. See generally Crabtree v. Goetz, NO. 3:08-0939, 2008 U.S. Dist. LEXIS 103097, at *68 (M.D. Tenn. Dec. 18, 2008) (enjoining state from reducing maximum allowable hours of home health services because it would "eliminate services that enable Plaintiffs to remain in their community placement" and thereby "cause their institutionalization into nursing homes"); Townsend v. Quasim, 328 F.3d 511, 516-518 (9th Cir. 2003) (state's refusal to continue providing Medicaid in-home nursing services in a community-based setting constituted discrimination under Title II of the ADA).

Fisher rejected the district court's finding that fiscal burdens associated with reasonable accommodations would necessarily require a fundamental alteration, stating

> Plaintiffs are simply asking that a service for which they would be eligible under an existing state program . . . be provided in a community-based setting rather than a nursing home. They are not demanding a separate service or one not already provided by the state.

Fisher, 335 F.3d at 1183. Moreover, the Tenth Circuit questioned whether the required modification would constitute a fiscal burden at all. The court observed that

> [g]iven that the cost of institutional care is nearly double that of community based care, it seems unlikely that . . . elimination of the waiver program, would have solved Oklahoma's fiscal crisis, because it could have served only to drive participants into nursing homes.

Id. at 1183 (emphasis added). See also Radaszewski, 383 F.3d at 599, 603, 611, on remand, 2008 U.S. Dist. LEXIS 24923 (N.D. Ill. March 26, 2008), at *15 (failure to fund private duty nursing in the home for child reaching the age of 21 was disability-based discrimination; funding this service was not a fundamental alteration);[12] Grooms v.

[12] The court also noted that providing care in an institutional setting "would be substantially greater than the cost of allowing [plaintiff] to remain in the community and receive the same proper treatment and community care." Radaszewski, 2008 U.S. Dist. LEXIS 24923 at *40.

Maram, 563 F. Supp. 2d 840, 849-850 (N.D. Ill. 2008) (enjoining Medicaid denial of home care services to individual upon reaching the age of 21, noting there had been no "sudden significant improvement in [plaintiff's] condition on his twenty-first birthday").

The situation in Missouri is similar. Plaintiffs request only that Defendants provide coverage of the services at issue (adult diapers) in the community, as well as the nursing home or other such institutions. As Plaintiffs have documented, this coverage will enable Defendants to avoid unnecessary and more expensive expenditures on hospitalizations or nursing home care. See Huskey Decl. ¶¶ 22, 23, Gray Decl. ¶ 9. Plaintiffs are not asking that a new program be created. Defendants already fund incontinence supplies in the existing durable medical equipment program for persons below age 21 and already provide it to adults who live in institutional settings. 13 C.S.R §§ 70-10.010; 70-10.015; 70-60.010. Plaintiffs simply ask that they receive the same medically necessary services in the community (as several of them did before they turned 21) that they would receive in a nursing home or other institution.

The relief requested is likely to *save* the State money because it will prevent Defendants from having to pay for both adult diapers *and* the far more expensive costs of residential care in institutional settings, such as nursing homes or hospitals. The cost of paying for adult diapers is, at most, a few hundred dollars per month.[13] The cost of serving a Plaintiff in a nursing home can be well over $40,000 a year. Gray Decl. ¶ 3. [14]

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[13] Plaintiffs pay between $80 and $300 a month for adult diapers. See Burkhart Decl. ¶ 16; Coontz Decl. ¶ 6; Tatum Decl. ¶ 3, Hammond Decl. ¶ 5.

[14] See Gov. Jay Nixon, Dept of Health and Senior Services Budget Request, with Governor's Recommendations at 310 (Jan. 21, 2010), at http://oa.mo.gov/bp/budreqs2011/Health/Health.pdf (Ex. 26); Gov. Jay Nixon, Dept of Social Services Budget Request, MO HealthNet Division, with Governor's Recommendations at 300 (DSS Budget Request)(Jan. 21 2010), at

Furthermore, the inability of Plaintiffs to obtain necessary incontinence supplies while living in the community raises a significant risk of skin breakdowns, infections and diseases, which can lead to hospitalizations that will be much more costly than covering the supplies in the first place. Huskey Decl. ¶¶ 10-14, 21-23; Hurley Decl. ¶¶ 4-9. As noted by Dr. Thy Huskey, a Rehabilitation Specialist at Washington University:

> If adult diapers are not recognized as medically necessary and are not utilized for prevention of sacral sores, treatment for the resultant skin ulceration will be of medical necessity, and the cost of treatment may be staggering . . . The risk of institutionalization for care, treatment, and management of severe sacral skin ulcerations is high, especially for individuals with physical disabilities and/or lack of assistance for personal bodily care. If skin breakdown is not prevented or properly cared for after it is found, then skilled nursing care will be necessary, usually around the clock care, in a nursing home setting . . .

Huskey Decl. ¶¶ 22, 23 (emphasis added). Plaintiffs are likely to succeed on the merits of their ADA claim.

4. Defendants are likely violating the ADA and Section 504 methods of administration requirements.

The ADA prohibits methods of administration which, though neutral on their face, have a discriminatory effect. A public entity may not:

> directly or through contractual or other arrangements utilize… methods of administration (i) [t]hat have the effect of subjecting qualified individuals with a disability to discrimination on the basis of disability; [and] (ii) [t]hat have the purpose or effect of defeating or substantially impairing

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http://oa.mo.gov/bp/budreqs2011/DSSHealthnet/DSSHealthnet.pdf (Ex. 27); McCaslin Letter, April 22, 2010, and attachments (Ex. 28). The average *per diem* costs of nursing home care were $126.12 in FY 2009 and $132.27 in FY 2010. Ex. 26-28. See also Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2046 (2010) (recognizing that "Medicaid dollars can support nearly 3 elderly individuals and adults with physical disabilities" in the community "for every individual in a nursing home"). The Missouri General Assembly's Medicaid Reform Commission similarly found that in-home care is often much less costly than institutional-based care, in many cases as little as 1/6th the cost of nursing home care. Medicaid Reform Comm'n, *Report* at 40 (Dec. 2005), at http://www.senate.mo.gov/medicaidreform/MedicaidReformCommFinal-122205.pdf.

> accomplishment of the objectives of the public entity's program with respect to individuals with disability.

28 C.F.R. § 35.130(b)(3).[15]

Defendants' incontinence supplies policy discriminates against Plaintiffs by arbitrarily refusing to make an exception or prior authorization process available to them under *any* circumstances, even though they could use the prior authorization process before they turned age 21. Further, they discriminate by only covering these supplies for adults residing in nursing homes and other such institutions but not the Plaintiffs who are living in the community.

Moreover, Defendants' methods of administration defeat the purpose of the Medicaid program, which is to enable each State, "to furnish (1) medical assistance to ... disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) ... to help such families and individuals attain or retain capability for independence or self-care." 42 U.S.C. § 1396-1. Defendants' incontinence supplies policies contradict these purposes by requiring individuals with disabilities to use their own "insufficient" resources to "meet the costs of necessary medical services" and limit their capability to retain independence and self-care by forcing them into nursing homes or other such institutions to have these services paid for by Medicaid. Therefore, these methods of administration discriminate on the basis of disability in violation of the ADA and Section 504.

III. THE PLAINTIFFS ARE SUFFERING IRREPARABLE HARM AS A RESULT OF THE DEFENDANTS' FAILURE TO COVER ADULT INCONTINENCE BRIEFS.

[15] Section 504 contains similar requirements that prohibit methods of administration that result in disability-based discrimination. See 28 C.F.R. § 41.51(b)(3)(i); 45 C.F.R. § 84.4(b)(4). See also Brantley, 656 F. Supp. 2d at 1175-76.

It is well settled that a loss of Medicaid benefits constitutes irreparable harm. See, e.g., Kai v. Ross, 336 F.3d 650, 656 (8th Cir. 2003) (danger to plaintiffs' health gives them a strong argument of irreparable injury); Nemnich v. Stangler, No. 91-4517-CV-C-5, 1992 WL 178963 (W.D. Mo. Jan. 7, 1992) (enjoining the state from eliminating several categories of dental treatment); White v. Martin, No. 02-4154-CV-CNKL, 2002 U.S. Dist. LEXIS 27281, *10-11 (W.D. Mo. Oct. 3, 2002). See also, e.g., Brantley, 656 F. Supp. 2d at 1176-77 (finding irreparable harm where disabled plaintiffs were losing Medicaid services "critical to ensuring that their tenuous physical and mental conditions remain stable, enabling them to remain in the community"); V.L. v. Wagner, 669 F. Supp. 2d 1106, 1121-22 (N.D. Cal. 2009) (finding irreparable harm where lack of Medicaid covered services could destabilize families and cause recipients, among other things, to be unable to leave their homes); Edmonds v. Levine, 417 F. Supp. 2d 1323, 1342 (S.D. Fla. 2006) (summarizing eight different Medicaid cases finding irreparable harm or imminent risk of irreparable harm due to a variety of Medicaid cuts and finding denial of coverage for off-label use of prescription pain medication would irreparably harm plaintiffs); McMillan v. McCrimon, 807 F. Supp. 475, 482 (C.D. Ill. 1992) ("possibility" that plaintiffs would have to enter nursing home due to loss of Medicaid services "constitutes irreparable harm").

Without the prescribed adult incontinent supplies, Plaintiffs have an increased risk of infection, regression in health status, frequent hospitalization, and isolation from the community. Steven Hiltibran suffers from severe cerebral palsy and psychosis, multiple sclerosis, scoliosis, chronic pain, muscle spasms and contractures. He is completely bed bound with a terminal illness. He experiences both bowel and bladder incontinence. His

physicians have prescribed incontinence briefs to prevent skin breakdowns and ulcers and to prevent infections and disease and unnecessary hospitalizations. Harper Decl. ¶¶ 6-11; Burkhart Decl. ¶¶ 7-11. Ronald Coontz suffers from static encephalopathy and a seizure disorder and has no control of his bowels or bladder, as a result of perm anent brain damage. He requires incontinence briefs to prevent pressure sores, skin breakdowns, rashes and infections. T hey are necessary to his overall health and well being and help him to rem ain in his own hom e. Coontz Decl . ¶¶ 1, 6, 9, 10-12; Po rter Decl. ¶¶ 2-9. There are no suitable alternatives to preven t skin breakdowns and infection. Porter Decl. ¶ 8. Nicholas Tatum suffers from Alagille Syndrome, a liver disease, and m ental retardation. The m edications he takes for his disease cause incontinence. He requires adult diapers to prevent bed so res, skin b reakdown, rashes and infections. The diapers enable him to live with his family and participate in the community. Tatum Decl. ¶¶ 1-3, 8, 10-11. Nena Ha mmond is paralyzed from a sp inal cord injury and uses an electric wheel hair to am bulate. B ecause of her in jury, cysts in her k idney and liver, and spasticity in her lim bs, she lacks c ontrol of her bowel and bladder and requires adult diapers to prevent exposure to urine-soaked and soiled clothing which would cause skin breakdowns, infections and hospitalizations. The diapers enable her to rem ain in her home. Hammond Decl. ¶¶ 3-8, 13; Anzalone Decl. ¶¶ 2-5. Moreover, Plaintiffs all f ace financial difficulties in paying for these s upplies on their own and still m eeting other basic needs. Burkhart Decl. ¶¶ 17-19; Coontz Decl. ¶¶ 6, 10, 12, 14; Ta tum Decl. ¶¶ 3, 9; Hammond Decl. ¶ 10.

Dr. Thy Huskey, a physician specializing in Physical Medicine and Rehabilitation at Washington University, and Dr. Yadria Hu rley, the Director of Derm atopathology at

Saint Louis University School of Medicine, have documented in great detail the severe health risks and even life-threaten ing impact of Missouri's failure to cover Plaintiffs' medically necessary in continent supplies. Adult incon tinence briefs are critic al for protecting skin integrity and preventing the m any health complications that result from a breach of skin integrity, including pressure sores. Huskey Decl. ¶¶ 5-13; Hurley Decl. ¶¶ 3-8. These supplies can be m edically necessary to prevent skin breakdowns and infections that can cause seps is, a system ic inflammatory response to inf ection characterized by fever, a raised h eart rate, rapid breathing and a decrease in blood pressure, sometimes leading to septic shock and death. Huskey Decl. ¶ 9. The lack of adequate diapers can cause not on ly dermatitis, but also human papillomavirus (HPV), perirectal and genital warts, pain, yeast infections, potentially deadly staph infections, and skin cancer—including m elanoma, the most dangerous form of skin cancer. Hurley Decl. ¶¶ 6-9. Not surprisingly, the Eighth Ci rcuit has recognized that incontinence "can be a serious disabling condition." Young v. Apfe l, 221 F.3d 1065, 1069 (8th Cir. 2000). Compare Smith, 2010 WL 1404066, at *11 (finding that Me dicaid program's failure to cover incontinence briefs "constitutes irreparable harm").[16] Plaintiffs have clearly established irreparable harm sufficient to obtain a preliminary injunction.

[16] Missouri adm inistrative agencies and CMS have sim ilarly noted the dire consequences for patients who do not re ceive proper incontinence care. See, e.g., Mo Bd of Nursing Hom e Adm'rs v. Pulos , No. 88-001548NH, 1990 Mo. Adm in. Hearings LEXIS 12, at *4 (Mo. Adm in. Hearing Comm'n, Sept. 10, 1990) ("Failure to promptly clean and change incontinent residents expos ed them to a signifi cantly increased danger of decubitus ulcers [pressure sores] . . . when sores became infected, they 'posed a danger of imminent death.'"); Lakeridge Villa Health Care , No. A-05-30, 2005 HHSDAB LEXIS 105, at *64, 67 (2005) (Dept. of Health & Human Services, July 28, 2005) (noting that sitting in urine causes skin breakdown and pressure sores); Gooding Rehabilitation , No. 1834, 2008 HHSDAB LEXIS 110, at *25 (Dept. of He alth & Human Services, Aug. 26, 2008) (finding that a patient required surgery to treat two Phase IV pressure sores, but died on the operating table); Mo Bd of Nursing Hom e Adm'rs v. Gallop , 1995 Mo.

IV. THE THREAT OF SERIOUS, HEALTH-RELATED INJURY TO THE PLAINTIFFS CLEARLY OUTWEIGHS ANY POTENTIAL HARM TO DEFENDANTS.

The balance of hardships weighs decidedly in favor of Plaintiffs. Plaintiffs will continue to suffer from the loss of medically necessary incontinence supplies that are critical to their health, safety, and community living. They seek only that Defendants comply with controlling federal law. As explained above, it is not clear that Defendants will suffer any fiscal harm from an injunction. However, any fiscal harm that the Department might suffer is outweighed by the harm to Plaintiffs' lives and health. See, e.g., Lankford v. Sherman, No. 05-4285-CV-C-DW, 2007 U.S. Dist. LEXIS 14950, at *13 (W.D. Mo. Mar. 2, 2007); White v. Martin, 2002 U.S. Dist. LEXIS 27281, at *22 (W.D. Mo. Oct. 3, 2002) (collecting cases). See also Ark. Med. Soc., Inc. v. Reynolds, 6 F.3d 519, 531 (8th Cir. 1993), aff'g, 819 F. Supp. 816 (E.D. Ark. 1993) (finding that "the state may not ignore the Medicaid Act's requirements in order to suit budgetary needs"); Kan. Hosp. Ass'n v. Whiteman, 835 F. Supp. 1548, 1552-53 (D. Kan. 1993) (concluding that the threatened injuries to the plaintiffs outweighed any harm to the defendant from issuing the injunction and that the proposed Medicaid restriction's "positive budgetary impact on state coffers is negligible in a relative sense").

In a similar case, Nemnich v. Stangler, this Court entered a preliminary injunction against the State of Missouri when it attempted to offer some, but not all, types of medically necessary adult dental care. No. 91-4517-CV-C-5, 1992 WL 178963 (W.D. Mo. Jan. 7, 1992). In that case, the Court determined that the State "will suffer fiscal problems if enforcement of the amended regulation is enjoined," but it nevertheless held

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Admin Hearings LEXIS 16, at *3-*4 (Mo. Admin. Hearing Comm'n, May 3, 1995) (noting that people with incontinence issues are "especially at risk for pressure sores.").

that "the harm to the plaintiffs' life and health clearly outweighs any fiscal harm the state may suffer." 1992 WL 178963 at *3. See also Lankford, 2007 U.S. Dist. LEXIS at *13. Moreover, as a matter of law, Defendant cannot be harmed by complying with what the federal Medicaid law requires. As stated by the Seventh Circuit:

> Because the defendants are required to comply with the [Food Stamp] Act, we do not see how enforcing compliance imposes any burden on them. The Act itself imposes the burden; this injunction merely seeks to prevent the defendants from shirking their responsibilities under it.

Haskins v. Stanton, 794 F.2d 1273, 1277 (7th Cir. 1986) (granting preliminary injunction). See also Ill. Hosp. Ass'n v. Ill. Dept of Public Aid, 576 F. Supp. 360, 371 (N.D. Ill. 1983) ("Once a state has voluntarily elected to participate in the Medicaid program, . . . [it cannot] characterize its duty to comply with the requirements of [the program] as constituting a hardship to its citizens.").

As the Eighth Circuit has noted, Missouri is required to adhere to the federal Medicaid requirements in the operation of its Medicaid program. Lankford, 451 F.3d at 504, citing Schweiker v. Grey Panthers, 453 U.S. 34, 37 (1981); see also Mo.Rev. Stat. § 208.151 ("For the purpose of paying MO HealthNet benefits and to comply with Title XIX, Public Law 89-97, 1965 amendments to the federal Social Security Act (42 U.S.C. Section 301, et seq.) as amended, the following needy persons shall be eligible to receive MO HealthNet benefits."). Missouri cannot claim hardship from compliance with the requirements that come with the substantial federal funding that Missouri receives for choosing to operate a Medicaid program. See generally Lankford, 451 F.3d at 510 (noting that the majority of expenditures for Medicaid benefits in Missouri are federal funds). This Court should find that the balance of harms favors Plaintiffs.

Any alleged hardship to Defendants is also negated by the fact that they can still establish reasonable utilization controls on coverage of adult diapers. See 42 C.F.R. § 440.230(d); Ex.12. Plaintiffs do not seek coverage of these supplies in *all* circumstances. Rather, they seek a fair process by which they can establish the medical necessity of adult diapers just as three of them did before they reached 21 years of age. Defendants can apply the same web-based prior authorization process that they use to determine medical necessity for individuals under age 21. They need only actually approve coverage of these supplies when medical necessity is established.

V. AN INJUNCTION IS IN THE PUBLIC INTEREST.

When issuing injunctive relief against a government body, the Eighth Circuit has found that enforcement of the federal law is in the public interest. Glenwood Bridge, Inc. v. Minneapolis, 940 F.2d 367, 372 (8th Cir. 1991). See also Lankford v. Sherman, U.S. Dist. LEXIS 14950* at 13; White v. Martin, 2002 U.S. Dist. LEXIS 27281, at *24; Heather K. v. Mallard, 887 F. Supp. 1249, 1261 (N.D. Iowa 1995) (citing Eighth Circuit decisions). "Congress and the Missouri General Assembly expressed the public interest by enacting the Medicaid program in the first place." Nemnich, 1992 WL 178963 at *4. Because Defendant is violating the federal law, an injunction will serve the public interest here.

Moreover, budgetary constraints do not excuse a violation of federal law. See Amisub (PSL) Inc v. Colo. Dept of Social Services, 879 F.2d 789, 800 (10th Cir. 1989) (holding "budgetary constraints cannot excuse noncompliance with federal Medicaid law"); Tallahassee Mem'l Reg'l Med. Ctr. v. Cook, 109 F.3d 693, 704 (11th Cir. 1997) (same); Miss. Hosp. Ass'n v. Heckler, 701 F.2d 511, 518 (5th Cir. 1983) (same); Kan.

Hosp. Ass'n v. Whiteman, 835 F. Supp 1548, 1553 (D. Kan. 1993) (same); McNeill-Terry v. Roling, 142 S.W.3d 828, 834 (Mo. App. 2004) (Missouri's budgetary constraints were not sufficient to justify limitations on coverage of necessary Medicaid service). Compare Indep. Living Ctr. of S. Cal., Inc. v. Maxwell-Jolly, 572 F.3d 644,704 (9th Cir. 2009) ("A budget crisis does not excuse ongoing violations of federal law, particularly where there are no adequate remedies available other than an injunction.").

Because the Defendants' regulation and policy violate the reasonable standards and mandatory home health requirements of the Medicaid Act, as well as the ADA and Rehabilitation Act, Plaintiffs have demonstrated that a preliminary injunction is in the public interest. Finally, an injunction is in the public interest because it will allow Plaintiffs to obtain the incontinence supplies that their health care providers have determined to be medically necessary to address their medical conditions. With these supplies, these individuals can maintain their health and functioning and maximize independence, self-care, and community living. In sum, a preliminary injunction will serve the public interest.

VI. NO BOND SHOULD BE REQUIRED

The court should not require Plaintiffs to post a bond as security for the preliminary injunction because they are low-income Medicaid beneficiaries. The Eighth Circuit has explained that "specific equitable or legal considerations in [a] case might require that the bond be waived or set at a nominal amount." Young v. Harris, 599 F.2d 870, 873 n.5 (8th Cir. 1979). See also Kaepa, Inc. v. Achilles Corp., 76 F.3d 624, 628 (5th Cir. 1996); Moltan Co. v. Eagle-Picher Indus., Inc., 55 F.3d 1171, 1176 (6th Cir. 1995). It is appropriate to waive the bond requirement for "low income individuals in

need of medical services." Kerr v. Holsinger , No. 03-68-JMH, 2004 U.S. Dist. LEXIS 7804 at *36 (E. D. Ky. Mar. 25, 2004).

CONCLUSION

This Court should preliminarily enjoin Defendants from enforcing their illegal regulation and policy and from arbitrarily denying medically necessary incontinent supplies through any other means.

Dated: August 23, 2010

Respectfully submitted,

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