

RESPONSE TO STATEMENT OF UNCONTROVERTED MATERIAL FACTS

These Defendants, for purposes of responding to Plaintiffs' Statement of Uncontroverted Material Facts, state as follows:

1. to 9. Admit.

10. Admit that Plaintiff Hiltibran's treating physicians have stated that the reason for their prescription of incontinence briefs is to prevent skin breakdown and infections. Ex. 17 at ¶¶ 5 and 6.

11. to 19. Admit.

20. Admit that incontinence briefs are included in the per diem covered for nursing home residents. Answer at ¶ 68.

21. to 27. Admit.

28. Admit that Plaintiff Coontz's treating physicians have stated that the reason for their prescription of incontinence briefs is to prevent skin breakdown and infections and to continue living at home with his guardian and mother. Ex. 18 at ¶¶ 10 and 11.

29. to 32. Admit.

33. Admit that incontinence briefs are included in the per diem covered for nursing home residents. Answer at ¶ 68.

34. to 43. Admit.

44. Admit that Plaintiff Tatum's treating physicians have stated that the reason for their prescription of incontinence briefs is to prevent skin breakdowns and infections. Ex. 19 at ¶¶ 4 and 7.

45. to 48. Admit.

49. Admit that incontinence briefs are included in the per diem covered for nursing home residents. Answer at ¶ 68.

50. to 62. Admit.

63. Admit that incontinence briefs are included in the per diem covered for nursing home residents. Answer at ¶ 68.

64. to 73. Admit.

74. to 82. Admit that the statements listed were testified to by Dr. Husky and Dr. Hurley.

83. to 92. Admit.

93. Admit that incontinence briefs are covered for individuals ages 4 through 20 through the EPSDT program and that the DME Provider Manual contains information regarding incontinence products for children under §§ 13.22.B and 19.1. Section 13.22.B contains informational guidelines and pre-cert information regarding incontinence products for children. Section 19.1 lists the various billing codes, descriptions and limitations for services covered for those 20 and under.

94. to 128. Admit.

ARGUMENT

The Missouri Department of Social Services, through Medicaid, has not generally provided adult Medicaid participants with adult incontinence briefs. Medicaid only requires the states to provide adult briefs to those between four and twenty years of age (the Early and Periodic Screening, Diagnostic, and Treatment, or EPSDT, program).

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).

An examination of each claim reveals that the State of Missouri is in compliance with federal Medicaid law. Summary judgment should be denied.

1. Medicaid does not automatically require states to provide adult briefs.

Plaintiffs claim that the Department must provide adult incontinence briefs, but the Medicaid statutes and regulations do not require any state to provide incontinence briefs to those over 20 years of age. Missouri, like every state involved in Medicaid, is permitted to select certain optional items to provide, and adult incontinence briefs are just such an optional item.

2. Adult Incontinence briefs are not Durable Medical Equipment

Plaintiffs assert that the Department should cover adult incontinence briefs under its durable medical equipment (DME) policy. Because the Department has not, Plaintiffs claim that the 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).

Under Medicaid, participating states are required to provide certain services and benefits. But the participating states 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 choosing what items the state will 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”).

In *Lankford v. Sherman*, the Eighth Circuit considered a preliminary injunction brought to enjoin changes to Missouri’s DME program. The court 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.

The *Lankford* court 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. Moreover, 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 Rhode Island 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 statute 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 participating Medicaid states, is permitted to define what constitutes DME and medical supplies. Missouri defines DME as "equipment that can *withstand repeated use*." 13 C.S.R. 70-60.010 (emphasis added). Missouri does not provide medical *supplies* as part of the DME program for adult participants—Missouri only provides medical *equipment*.¹

Incontinence briefs, by their very nature, are designed as single-use items, and cannot withstand repeated use. As such, adult incontinence briefs are not covered as DME, and do not meet the definition of DME. Thus, 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 through its DME program. As such, adult incontinence briefs are not covered, whether they are medical supplies or hygiene items, because they do not meet the definition of DME.

Plaintiffs note that certain supplies are covered under the DME program, including ostomy supplies, oxygen supplies, cleaning solution and supplies for ventilators, Trach

¹ The *Lankford* 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). But here, Plaintiffs do not assert that incontinence briefs are necessary to make equipment functional; instead, they allege that an entire additional category of items (medical supplies) should be covered as DME.

Care supplies, and parenteral nutrition supplies. But these supplies all relate to making pieces of equipment functional. For example, cleaning solution and other supplies for ventilators are necessary components of a ventilator, which is equipment. The same is true for those with a tracheotomy or ostomy tube. The supply ensures that a piece of equipment carries out its purpose.

States are required to cover adult incontinence briefs for children ages four through twenty because the federal government specifically 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 further requires that states provide all services deemed to be medically necessary to correct or ameliorate a defect, illness, or condition identified by screening. Thus, Medicaid requires that a state must provide any service that the 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).

Therefore, as part of its Medicaid program, Missouri and every other participating state is required by the EPSDT program to provide services and items (including medical supplies) for those under 21 years of age. However, neither the EPSDT program, nor the Medicaid statutes, specifically require that participating states provide identical services to those over twenty-one years of age. Here, all of the Plaintiffs are over twenty-one years of age, and therefore do not qualify for the EPSDT program.

Missouri's election not to provide medical supplies under the DME program is within the state's discretion in providing an option service under Medicaid. Adult incontinence briefs are not medical equipment, and do not meet the definition of DME. Moreover, while Plaintiffs argue that the only test for whether an item should be provided is medical necessity, but this argument ignores the discretion under Medicaid available to states to define the covered services in optional areas of care. Missouri's definition of DME, which includes equipment but not supplies, meets the "reasonable standards" requirement of the Medicaid Act.

3. Plaintiffs are not entitled to home health services

Plaintiffs also 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."

Under Medicaid, 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. Plaintiffs point to the fact that adult incontinence briefs are treated as a medical supply for Medicaid recipients age four through twenty in Missouri 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.

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).

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,

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.

home health services are used to provide services for temporary recovery from specific, episodic health incidents.

Plaintiffs have ongoing conditions requiring continuing care, but these are not automatically the type of episodic health conditions for which home health services would be appropriate under Missouri's plan.³ 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. The Court need not address the question of whether home health services would ever cover adult incontinence briefs because the issues herein do not require this Court to determine whether these plaintiffs qualify for home health services.

4. 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. Plaintiffs 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

³ Plaintiffs note that the Missouri plan has been found not to be in compliance with federal law because of the inclusion of a "homebound" requirement. The removal of this requirement for home health services does not change the fundamental fact that the state is permitted to establish utilization controls on the service. None of these plaintiffs has alleged that they applied for incontinence briefs through home health services and were denied coverage.

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 Supreme 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.

Here, Plaintiffs 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. As noted previously, Missouri’s long-standing Medicaid program, approved by the federal Centers for Medicare and Medicaid Services (CMS), has not covered adult incontinence briefs for those over twenty-one (and outside of the EPSDT program).

Plaintiffs claim that the only way they can receive the services they need is to move to a nursing home or other such institution. (But this 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

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, the Independent Living Waiver, and through the AIDS Waiver programs. Indeed, Plaintiff

Medicaid permits states to elect to provide certain items through waiver programs, such as special medical supplies, including adult incontinence briefs. Home and Community based waivers are provided for at §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. This suit is, in effect, a collateral attack on CMS's approval of the State Plan. A direct challenge to CMS's determination on a rule (brought, ironically, by this very Department) was rejected by the Eighth Circuit. *Mo. Dept. of Social Services v. Sullivan*, 957 F.2d 542 (8th Cir. 1992). The federal courts recognized that 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).

CONCLUSION

This Court should deny Plaintiffs summary judgment. Plaintiffs have failed to demonstrate that they are entitled to summary judgment.

Hiltibran had his incontinence briefs covered through the Prevention Waiver even before the preliminary injunction was issued in this case.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify on this 24th day of March, 2011, 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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