Case No. 05-3587

IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

Susan Lavon Lankford; Rachel Ely; Jan Everett,
as next friend of Joseph Everett; Donald
Eugene Brown; Laura Lee Greathouse;
Kimberly Vogelpohl; Adam Daniel Thomason,

Plaintiffs-Appellants,

against

Gary Sherman, Director, Missouri Department
of Social Services, in his official capacity,

Defendant-Appellee.

On appeal from the United States District Court
Western District of Missouri
Judge Dean Whipple

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SUMMARY AND STATEMENT OF THE CASE
REQUEST FOR ORAL ARGUMENT

Effective September 1, 2005, a new Missouri regulation prohibited coverage of most of the medical equipment and supplies prescribed by Medicaid recipients' physicians, including parenteral nutrition for those who cannot eat orally, lifts to assist individuals with paralysis with transfer between bed and chair, augmentative communication devices, and orthotics such as cushions to prevent bedsores. Plaintiffs are seven individuals whose medical equipment has been eliminated from coverage by the new rule.

On August 29, 2005, Plaintiffs filed this lawsuit in the United States District Court for the Western District of Missouri against Gary Sherman, as the Director of the Missouri Department of Social Services, challenging the regulation as violating two provisions of the federal Medicaid Act. After declining to issue a restraining order, the district court denied the Plaintiffs' motion for a preliminary injunction on September 13, 2005. Plaintiffs appeal this latter decision.

The legal issues involve the Medicaid Act, which is known for its complexity. The district court's holding has far-reaching consequences. Using the Department's estimates, the rule will cause 370,000 Missourians to lose coverage. Plaintiffs request 20 minutes for oral argument.

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STATEMENT OF JURISDICTION

This case is a civil rights action brought under 42 U.S.C. § 1983 and the Supremacy Clause of the United States Constitution against an official of the State of Missouri for prospective injunctive relief. The district court had subject matter jurisdiction over the action under 28 U.S.C. § 1331, because the claims arise under the laws of the United States, and under *id.* §§ 1343(a)(3) and (4), because this suit seeks to redress the deprivation under color of state law of rights secured by an Act of Congress.

This Court has jurisdiction over the appeal pursuant to 28 U.S.C. § 1292(a)(1). The denial of preliminary injunction was entered on September 13, 2005. (Pl.App.-001.) Plaintiffs filed their notice of appeal in the district court on September 20, 2005. The appeal is therefore timely under Federal Rule of Appellate Procedure 4(a)(1)(A).

STATEMENT OF ISSUES FOR REVIEW

I. Did the district court err in finding that the Plaintiffs are not likely to succeed on their claims that the Defendant is violating federal law by eliminating coverage of medical equipment needed by Medicaid recipients who are aged and/or disabled while covering it for recipients who are blind, and by failing to use reasonable standards for determining the extent of medical equipment available under the Medicaid plan?

42 U.S.C. § 1396a(a)(10)(B)(i); 42 U.S.C. § 1396a(a)(17); 42 C.F.R. §§ 440.230, 441.55; *Schweiker v. Hogan,* 457 U.S. 569 (1982); *Weaver v. Reagen*, 886 F.2d 194 (8th Cir. 1989).

II. Did the district court err when it decided that Plaintiffs will not suffer irreparable harm as a result of the elimination of Medicaid coverage of the medical equipment, supplies, and appliances that they need?

Kai v. Ross, 336 F.3d 650 (8th Cir. 2003).

III. Did the district court err when it concluded that the balance of hardships favors the state Medicaid agency?

Arkansas Med. Soc'y v. Reynolds, 819 F. Supp. 816 (E.D. Ark. 1993), *aff'd*, 6 F.3d 519 (8th Cir. 1993).

IV. Did the district court err when it concluded that the public interest does not support issuance of an injunction?

Glenwood Bridge, Inc. v Minneapolis, 940 F.2d 367 (8th Cir. 1991); *AMISUB Inc. v. Colo. Dep't of Social Serv.*, 879 F.2d 789 (10th Cir. 1989).

STANDARD OF REVIEW

The district court's order should be reversed if the court abused its discretion or based its decision on an erroneous legal premise. *See Randall v. Wyrick,* 642 F.2d 304, 308 (8th Cir. 1981). On questions of law, this

Court "owe[s] no deference in any formal sense to the District Court." *Bell v. Sellevold*, 713 F.2d 1396 (8th Cir. 1983) (internal citation omitted).

An injunction is proper where: (1) the moving parties will suffer irreparable injury absent the motion, (2) the threatened irreparable harm outweighs the injury that granting the injunction will inflict on other litigants, (3) the movant has a probability or likelihood of success on the merits, and (4) the public interest will be served by granting an injunction. *See Dataphase Systems v. C. L. Systems, Inc.*, 640 F.2d 109, 112, 114 (8th Cir. 1980).

STATEMENT OF THE FACTS

A. Statutory and regulatory background

1. The Medicaid program

Congress created the Medicaid program in 1965 by adding Title XIX to the Social Security Act, 42 U.S.C. §§ 1396-1396v. The purpose of Medicaid is to enable each State, "as far as practicable…to furnish (1) medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care." 42 U.S.C. § 1396.

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 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. For the Medicaid services that it provides, Missouri receives 61.93 cents from the federal government for every dollar that it spends. *See* 69 Fed. Reg. 68370, 68372 (Nov. 24, 2004) (fiscal year 2006).

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, children, caretaker relatives, and pregnant women. *See id.* at § 1396a(a)(10)(A)(i). In Missouri, the categorically needy also include aged, blind, and disabled individuals whose incomes exceed the categorical eligibility levels but who incur

sufficient medical expenses to "spend down" to medical assistance eligibility levels. *See id.* at § 1396a(f).[1] 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.

The Medicaid Act requires participating states to cover some services and allows states to cover others. *See* 42 U.S.C. §§ 1396a(a)(10), 1396d(a). Among the mandatory services for categorically needy recipients are home health services. *See* 42 U.S.C. § 1396a(a)(10)(D); 42 C.F.R. § 440.210(a)(1). Home health services must include "medical supplies, equipment, and appliances suitable for use in the home." *See* 42 C.F.R. §§ 440.70(b)(3), 441.15.

The Medicaid Act establishes a number of protections for those individuals who qualify for assistance. Two of these protections are at issue here. First, § 1396a(a)(10)(B), provides

[1] States may also elect to cover other individuals known as the "medically needy" and provide them a more limited set of services. *See* 42 U.S.C. § 1396a(a)(10)(C); 42 C.F.R. § 436.3 (defining categorically needy, including optional categorically needy, and medically needy). Missouri does not cover the medically needy. Consequently, all Missouri Medicaid recipients are "categorically needy" and must be provided coverage of the mandatory services.

> that the medical assistance made available to any individual described in subparagraph (A) [i.e., the categorically needy]–
> (i) shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual....

42 U.S.C. § 1396a(a)(10)(B). The protection established by this section of the Act is called the "comparability" requirement. *See also* 42 C.F.R. § 440.240(b) (requiring the services available to all categorically needy individuals to be "equal in amount, duration, and scope").

Another Medicaid provision, 42 U.S.C. § 1396a(a)(17), provides that the state's Medicaid program must

> include reasonable standards (which shall be comparable for all groups...) for determining eligibility for and the extent of medical assistance under the plan....

This protection is called the "reasonable standards" requirement. *See also* 42 C.F.R. §§ 440.230(b) (requiring each service to be sufficient in amount duration and scope), 440.230(c) (prohibiting reduction in the amount, duration and scope of service based on diagnosis, type of illness or condition).

2. The Missouri Regulation

Defendant Sherman implemented Mo. Rule 13 C.S.R. § 70-60.010 on September 1, 2005, eliminating coverage of medical equipment, supplies, and appliances ("medical equipment") for most adult categorically needy individuals in Missouri, with the exception of the following few items:

- prosthetics, *excluding* an artificial larynx;
- diabetic supplies and equipment;
- ostomy supplies;
- oxygen and respiratory supplies and equipment, *excluding* CPAPS, BiPAPS, nebulizers, IPPB machines, humidification items, suction pumps and apnea monitors; and
- wheelchairs, *excluding* wheelchair accessories and scooters.

Id. (emphasis added). Among the items of medical equipment excluded altogether for these categorically needy recipients are:

- orthotics (such as cushions to avoid bed and pressure sores);
- parenteral nutrition (for persons who are unable to eat orally);
- augmentative communication devices (that allow persons with speech disabilities to speak);
- hospital beds and bed rails; and
- lifts (that allow persons to transfer, for example, from bed to wheelchair).

Missouri has continued to cover a full range of medical equipment for three groups of categorically needy individuals: children, pregnant women, and individuals who are blind. Coverage includes:

- prosthetics;
- orthotics;
- oxygen and respiratory care equipment;
- parenteral nutrition;
- ostomy supplies;
- diabetic supplies and equipment;
- decubitus care equipment;
- wheelchairs; including wheelchair accessories and scooters;
- augmentative communication devices; and
- hospital beds.

Id. Full coverage also continues for persons who are admitted into nursing homes, with the exception of custom and power wheelchairs, prosthetic devices, and volume ventilators. *Id.*

On August 1, 2005, Defendant mailed notices to all Medicaid recipients informing them of the impending cuts. (Pl.App.-115.) The notice contains no information about any circumstance under which Medicaid will cover medical equipment that has been excluded from coverage by the regulation. (Pl.App.-115.) No notice, letter, or other communication to Medicaid recipients indicated that a process is available for obtaining coverage of any item of eliminated medical equipment. (Pl.App.-231-232).)

On August 29, 2005, Defendant mailed letters to Medicaid providers telling them that they could use the state's pre-existing exceptions process to request case-by-case continuation of the breathing equipment that had been eliminated by the rule–namely, CPAPs, BiPAPs and nebulizer machines. (Pl.App.-221.) No other medical equipment was mentioned in the letter. The exceptions process allows coverage only if a service is required to: (1) sustain a recipient's life; (2) improve the quality of life for a terminally ill recipient; (3) replace equipment due to an act of nature, such as a tornado; or (4) prevent need for a higher level of care. *See* 13 C.S.R. 70-2.100(2)(J). State regulation provides that no exception can be made when the requested

item or service is restricted or specifically prohibited by state or federal law or regulation. 13 C.S.R. 70-2.100(1). (Pl.App.-237).)

B. The Medicaid recipients

The medical equipment eliminated by Missouri's new rule is essential for Plaintiffs to meet their basic physical needs. For example:

- Kimberly Vogelpohl has chronic pulmonary disease and asthma and was hospitalized nine times in the 12 weeks before the complaint was filed. Her physician has prescribed an oxygen concentrator, nebulizer and inclinable hospital bed to assist breathing. Without this equipment, she is almost certain to require more hospitalizations. (Pl.App.-046, ¶¶ 8-11.)

- Rachel Ely uses a wheelchair, leg braces and arm splints. Without leg braces, she risks breaking her ankles or feet. Without the splints, she is unlikely to regain the use of her left arm. Her electric wheelchair requires batteries and her splints and braces require regular adjustment and repairs. (Pl.App.-032, ¶ 2.)

- Susan Lankford has chronic obstructive pulmonary disease, asthma, and sleep apnea and uses a nebulizer and CPAP machine to assist breathing. According to her pulmonary specialist, without these devices, Ms. Lankford stands a much greater chance of dying. (Pl.App.-028-030, ¶¶ 2, 3, 10.)

For most Plaintiffs, eliminating coverage for the repair, maintenance and similar expenses associated with medical equipment will cause the equipment to be unusable or dangerous to use. For example:

- Laura Greathouse has severe sleep apnea and complications from a stroke. She uses a tracheal tube that requires frequent cleaning and replacement parts. (Pl.App.-043, ¶¶ 6, 7.) The Missouri rule eliminated coverage of the cleaning equipment and many of the replacement components.

- Susan Lankford's nebulizer and CPAP require parts—such as noseplugs, filters and hoses—that need to be replaced frequently. (Pl.App.-028-029, ¶¶ 4, 5.) The Missouri rule eliminated coverage of these parts.

The Department of Social Services estimates that 370,000 individuals will be adversely affected by the new regulation. *See* 30 Mo. Reg. 1568 (July 15, 2005) (Fiscal Note) (Pl.App.-064.).

SUMMARY OF ARGUMENT

Missouri Rule 13 C.S.R. § 70-60.010 eliminates Medicaid coverage of medical equipment for categorically needy Medicaid recipients who, like the Plaintiffs, qualify because they are aged, disabled, or caretakers, while maintaining full coverage of medical equipment for categorically needy recipients who are blind. This regulation violates Medicaid's "comparability" requirement, which provides that the services available to categorically needy individuals must be equal in amount, duration, and scope. *See* 42 U.S.C. § 1396a(a)(10)(B); 42 C.F.R. § 440.240(a). The regulation also violates Medicaid's "reasonable standards" requirement because it denies coverage of medically necessary medical equipment and limits coverage based on diagnosis or condition. *See* 42 U.S.C. § 1396a(a)(17); 42 C.F.R. § 440.230(b)-(c). For example, a blind person can receive coverage of a lift to transfer from her bed but a person paralyzed by

a spinal cord injury cannot. Because the Defendant is violating the federal law, an injunction will serve the public interest.

The Missouri regulation is causing irreparable harm and the threat of irreparable harm. Without the prescribed medical equipment, the Plaintiffs are at increased risk of infection, regression in health status, periodic hospitalization, and isolation from the community.

The lower court incorrectly concluded that there is no threat of harm because individuals can obtain medical equipment through the home health services benefit if they qualify for home health services or through the general Medicaid exceptions process. Neither of these narrow options is actually available to the vast majority of non-blind disabled or aged Medicaid recipients. A Missouri regulation limits home health services to individuals who are homebound. *See* 13 C.S.R. § 70-90.010(1). Given that Plaintiffs do leave their homes regularly and, in fact, need the medical equipment to enable them to do so, Defendant's criteria, on their face, exclude Plaintiffs from the home health exception. Another Missouri regulation provides that the general Medicaid exceptions process cannot be used when the requested items or services are specifically prohibited by state law or regulation. *See* 13 C.S.R. 70-2.100(1). Given that the new regulation specifically prohibits coverage of the items of medical equipment that

Plaintiffs need, Defendant's criteria, on their face, exclude Plaintiffs from using the general exceptions process. *See also* Pl.App.-227-228. In any event, an exceptions process is no substitute for proper implementation of the reasonable standards requirement.

The balance of hardships tips decidedly in favor of Plaintiffs. Plaintiffs will suffer the loss of medical equipment and equipment repair critical to their health, safety, and community living. They seek only that Defendant comply with controlling federal law. The lower court incorrectly decided that the balance of harm does not favor Plaintiffs because it concluded that, if the state rule were struck down, no one would be entitled to Medicaid coverage of medical equipment. But, states must provide home health services, including medical equipment, as a mandatory service to all categorically needy individuals. 42 C.F.R. §§ 440.210(a)(1), 441.15. Moreover, no Missouri statute prohibits coverage of medical equipment for non-blind categorically needy recipients. Thus, striking the Missouri regulation would mean that necessary medical equipment and supplies would be covered for all categorically needy individuals.

The Court should find that Plaintiffs meet the *Dataphase* requirements for an injunction, reverse the lower court holding to the contrary, and enter an order enjoining Mo. Rule 13 C.S.R. § 70-60.010.

ARGUMENT

I. THE DISTRICT COURT ERRED AS A MATTER OF LAW IN CONCLUDING THAT THE PLAINTIFFS ARE NOT LIKELY TO SUCCEED ON THE MERITS OF THEIR MEDICAID CLAIMS.

A. The Comparability Requirement

The Medicaid Act requires that the "medical assistance made available to any [categorically needy] individual…shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual." 42 U.S.C. § 1396a(a)(10)(B); *see* 42 C.F.R. § 440.240(a) (stating that the services available to categorically needy individuals must be "equal in amount, duration, and scope"). In *Schweiker v. Hogan*, 457 U.S. 569 (1982), the Supreme Court explained the comparability requirement using an example that lines up precisely with this case. It stated that the requirement was included in the Medicaid Act to ensure

> that the medical assistance afforded to an individual who qualified under any categorical assistance program could not be different from that afforded to an individual who qualified under any other program. 79 Stat. 345, as amended, 42 U.S.C. § 1396a(a)(10)(B)(i). In other words, the amount, duration, and scope of medical assistance provided to an individual who qualified to receive *assistance for the aged could not be different from the amount, duration, and scope of benefits* provided to an individual who qualified to receive assistance *for the blind*.

Id. at 573 n.6 (emphasis added). *See also* 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. 2017 (stating that "the amount, duration, and scope of medical assistance made available must be the same for all such [categorically needy] persons. This will assure comparable treatment for all of the needy aided under the federally aided categories of assistance.").

The reported cases have consistently read the comparability statute in light of its plain language and its purpose: to insure that all categorically needy persons—whether in different eligibility groups or the same—are eligible for the same services. State policies that have provided unequal services to categorically eligible individuals have repeatedly been struck down.[2] For example, in *White v. Beal*, 555 F.2d 1146 (3d Cir. 1977), the Third Circuit Court of Appeals enjoined a Pennsylvania policy that covered eyeglasses (an optional Medicaid service) for categorically needy individuals with pathologic need but not for ordinary refractive errors.

[2] The comparability requirement is not limited solely to the amount or scope of covered services, but it also prohibits state policies that result in the differential availability of medical assistance. *See Schott v. Olszewski*, 401 F.3d 682, 688-89 (6th Cir. 2005) (holding Michigan's failure to reimburse medical expenses paid during retroactive coverage period violated right to medical assistance comparable to those who incurred but did not pay bills during that period); *Blanchard v. Forrest*, 71 F.3d 1163, 1167 (5th Cir. 1996) (same regarding "unequal treatment" imposed by similar Louisiana reimbursement policy).

While the state contended that limited resources justified the restrictive policy, the court enjoined it, in part, because "all persons within a given category must be treated equally." *Id.* at 1149. Similarly, in *Sobky v. Smoley*, 855 F. Supp. 1123 (E.D. Cal. 1994), the court enjoined a state policy that covered methadone maintenance (an optional Medicaid service) for some categorically needy but not others. Stating that "§ 1396a(a)(10)(B) creates an equality principle by which all categorically needy individuals must receive medical assistance which is no less than that provided to any other categorically or medically needy individual," *id.* at 1139, the court held that "by denying the same service to the categorically needy members of the plaintiff class that is received by other categorically needy persons,... the State violates § 1396a(a)(10)(B)." *Id.* at 1140.

In *Rodriguez v. City of New York*, 197 F.3d 611, 615 (2d Cir. 1999), the Second Circuit Court of Appeals noted that "states may not provide benefits to some categorically needy individuals but not to others.... Section 1396a(a)(10)(B) thus precludes states from discriminating against or among the categorically needy." *See also, e.g., Parry v. Crawford*, 990 F. Supp. 1250, 1257 (D. Nev. 1998) (noting state flexibility in operating the Medicaid program, but finding the state violated the comparability requirement when it excluded an entire class of categorically needy individuals from a service

that it covered for other categorically needy individuals); *DeLuca v. Hammons*, 927 F. Supp. 132 (S.D. N.Y. 1994) (finding violation where state regulation limited number of home care hours that could be allocated to some categorically needy individuals); *Hodecker v. Blum*, 525 F. Supp. 867, 872 (N.D.N.Y. 1981) ("Neither the benevolent purpose of the budgeting practice, nor the regulations relied upon by the State Commissioner,...could have rendered lawful the violations of the statutory provisions regarding comparability."); *see also Sobky*, 855 F. Supp. at 1140-41 (citation to additional cases).

Here, Mo. Rule 13 C.S.R. § 70-60.010 eliminates Medicaid coverage of medical equipment for categorically needy Medicaid recipients who qualify because they are aged, disabled, or caretakers, while maintaining full coverage of medical equipment for categorically needy recipients who are blind. According to the *Hogan* Court, the comparability requirement forbids precisely this kind of differential treatment of the aged as opposed to the blind. 457 U.S. at 573 n. 6. Given the "basic and unexceptional rule that courts must give effect to the clear meaning of statutes as written," *Estate of Cowart v. Nicklos Drilling Co.,* 505 U.S. 469, 476 (1992), Defendant's regulation violates the comparability requirement.

Nevertheless, the district court rejected Plaintiffs' claim because it concluded that medical equipment is an optional service; there are exceptions to the comparability requirement; and the state has applied to the federal government for permission to violate the comparability requirement. As shown below, each rationale invoked by the court was incorrect.

1. The comparability requirement applies to mandatory and optional services.

First, the lower court decided that medical equipment is an optional Medicaid service and "Missouri law requires only that certain services be provided to the blind, pregnant, and children. It has not elected by statute to provide the optional DME services." (Pl.App.-003.) Here, the court blurred the distinction between the complete elimination of a service it says is optional and the retention of that service for some and not others.

Regardless of whether a service is optional or mandatory, the federal comparability requirement applies. The Eighth Circuit is clear on this point. The *Weaver* Court examined a restriction that Missouri placed on its coverage of prescription drugs, which are optional Medicaid services. Finding a violation of the Medicaid amount, duration, and scope requirements, the Court held, "[O]nce a state chooses to participate in the [Medicaid] program it must comply with federal statutory and regulatory requirements." *Weaver*, 886 F.2d at 197; *see also, e.g., Sobky*, 855 F. Supp.

at 1127 (citing *Weaver,* stating that "once a state elects to provide an optional service...that service...is subject to the requirements of federal law" and finding a comparability violation). Thus, Missouri must comply with the federal requirements for comparability among the categorically needy and cover full medical equipment services for the categorically needy aged and/or disabled just as it does for the categorically needy blind.

The lower court appeared to conclude that state law requires medical equipment to be excluded from coverage. It is true that Missouri law was recently amended to remove a few items of medical equipment from the required minimum list of Medicaid services. *See* Mo. Rev. Stat. § 208.152.1. However, the law did not (and could not) eliminate coverage of home health services—which includes medical equipment, and it contains no provision that prevents the Department from covering medical equipment for those categorically needy individuals who are not blind. Plainly, the Defendant in this case does not construe the statute as constituting a prohibition against any coverage of any items of medical equipment. On its face, Defendant's Rule 13 C.S.R. § 70-60.010(1) states that the "Medicaid durable medical equipment (DME) program shall be administered by the Department of Social Services" and that the Department shall determine the "services and items covered and not covered." Subsection 6 of the rule,

entitled "Covered Services," lists the equipment items covered for all eligible Medicaid recipients, including, for example, wheelchairs and prosthetics, even though the statutory amendment deleted those very items from the required coverage list. *See* 13 C.S.R. § 70-60.010(6).

Finally, the district court is incorrect when it says that medical equipment is an optional Medicaid service. The Medicaid Act requires states to cover certain services for the categorically needy. 42 U.S.C. §§ 1396a(a)(10)(A); 1396d(a). One of the mandated services is "nursing facility services" for individuals 21 years of age or older. *Id*. at § 1396d(a)(4)(A). For all those entitled to nursing facility services, the state agency must provide "home health services," *id*. at § 1396a(a)(10)(D), which must include "[m]edical supplies, equipment, and appliances suitable for use in the home." 42 C.F.R. § 440.70(b)(3). *See also, e.g., Esteban v. Cook,* 77 F. Supp. 2d 1256, 1259 (S. D. Fla. 1999) (noting that "[h]ome health care services are generally a mandatory service for the categorically needy," and requiring coverage of wheelchairs); *Ladd v. Thomas*, 962 F. Supp. 284, 288 (D. Conn. 1997) ("Federal law mandates that participating states provide home health services including durable medical equipment (DME) to Medicaid participants where such equipment is medical [sic] necessary"); *Hodges v. Smith*, 910 F. Supp. 646, 649 (N.D. Ga. 1995)

(stating that the "inclusion of home health services in the state medical plan is mandated by federal law").

The federal regulations confirm that medical equipment is a mandatory service for the categorically needy. A "State Plan must provide that…the [state Medicaid] agency provides home health services to…Categorically needy recipients age 21 or over," and that those services "include, as a minimum…Medical supplies, equipment, and appliances." 42 C.F.R. § 441.15. Section 440.210, a regulation entitled "Required Services for the categorically needy," also provides that "a 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). Pursuant to § 440.70(b), "medical supplies, equipment, and appliances suitable for use in the home" are "required" home health services. *Id.* at § 440.70(b). *See also* United States Department of Health and Human Services Centers for Medicare & Medicaid Services (CMS), *Dear State Medicaid Director* (Sept. 4, 1998) ("the mandatory home health services benefit under the Medicaid program includes coverage of medical supplies, equipment, and appliances suitable for use in the home (42 C.F.R. § 440.70(b)(3)."). (Pl.App.-087.)

In sum, whether the service is mandatory or optional, the comparability requirement attaches. Moreover, no state statute proscribes

coverage of medical equipment for categorically needy individuals who are not blind, and federal Medicaid law makes it clear that medical equipment is a mandatory service for Missouri Medicaid recipients.

2. The exceptions to comparability are not relevant here.

The district court also grounded its decision on the fact that federal law permits Missouri's regulation to allow children and pregnant women to receive more medical equipment. Order at 3. The Plaintiffs have always agreed that the Medicaid Act grants a few exceptions to the comparability requirement, including with respect to children and pregnant women. *See* 42 U.S.C. § 1396a(a)(10) (concluding text following subsection (G)). However, those exclusions are not relevant here, because this case concerns comparability between adult recipients who are disabled and/or aged and those who are blind. There is no such exception to comparability with respect to Medicaid recipients who are blind. *See Hogan*, 457 U.S. at 573 n. 6. And, the Missouri Medicaid agency is not free to add its own exemptions.

3. The pending waiver request confirms an ongoing violation of law.

The lower court also decided that the Plaintiffs were not likely to succeed on the comparability claim because the Defendant has asked CMS to grant the state permission to violate the comparability requirement. Order at 4. In doing so, the district court was improperly attaching legal

consequence to the Defendant's mere act of *requesting* permission to violate this provision. It is true that Missouri has requested a "waiver" of the comparability requirement and that the Medicaid Act identifies limited circumstances under which comparability can be waived. *See* 42 U.S.C. § 1396n.[3] However, the very nature of a state's request for a waiver is to allow it to do something that is otherwise prohibited by federal law. In the absence of the express permission (i.e. the "waiver" of the federal law), a state may not conduct the practice. What is legally significant is that the Defendant's request asks CMS to waive comparability and thereby sanction a regulation that the State is *already enforcing*. Hence, it is an admission that the Defendant is openly violating the law that applies now.

Moreover, the district court erroneously concluded that the denial of the pending waiver by CMS will mean that medical equipment cannot be provided to the blind. (Pl.App.-002.) Because medical equipment is a

[3] Missouri requested a waiver of comparability pursuant to 42 U.S.C. § 1396n(b), which allows states to implement managed care programs. However, the policy at issue in this case has nothing to do with managed care. None of the individuals affected by the new regulation and waiver request is enrolled in a managed care program nor would the waiver request result in any of them being enrolled in such a program. Thus, it would be improper for CMS to grant this waiver request under § 1396n(b). The undisputed evidence in the record also indicates that such a waiver is unprecedented and unlikely to be granted. (Pl.App.-085-086, ¶¶ 5-6.) Plaintiffs are filing a Motion to Supplement the Record to include two letters from CMS, dated November 21, 2005, informing the Defendant that the waiver request is not approved as submitted.

mandatory part of the Medicaid home health service, it must be provided to all eligible individuals for whom it is medically necessary, not simply to a subset of such individuals. In addition, regardless of how the Defendant is interpreting his obligation to cover home health services, even under state law, he cannot eliminate coverage of medical equipment for people who are blind because a state statute specifically requires the coverage. *See* Mo. Rev. Stat. § 208.152.2(4) (requiring coverage of additional benefits including "orthopedic devices or other prosthetics, including eye glasses, dentures, hearing aids, and wheelchairs" for people who are blind).

In sum, the Defendant's new regulation is openly violating the federal Medicaid Act's comparability requirement, and the only appropriate remedy is to reinstate coverage of medical equipment for the excluded groups. When addressing comparability violations similar to the one here, courts have consistently enjoined the defendant in from excluding recipients from the benefit rather than eliminating the service for everyone. *See, e.g., White*, 555 F.2d at 1148; *Parry*, 990 F. Supp. at 1257; *Sobky*, 855 F. Supp. at 1140.

B. <u>The Reasonable Standards Requirement</u>

The district court did not address Plaintiffs' claim that the Defendant's medical equipment rule violates the reasonable standards requirement of the

Medicaid Act. Plaintiffs are likely to succeed on the merits of this claim, and the district court abused its discretion in failing even to consider it.

The challenged rule violates Medicaid's reasonable standards requirement in a variety of ways. First, the rule illegally discriminates on the basis of diagnosis and condition when it provides services to blind adult recipients but not to those with other disabilities. Second, the challenged rule is unreasonable because it denies Plaintiffs coverage for medical equipment they need to attain and retain independence and self care in violation of the Medicaid Act's purpose. Third, the state's Medicaid exceptions process is in clear violation of the reasonable standards for coverage of medical equipment and supplies as articulated by CMS policy. Fourth, the state's home health policy restricting eligibility for medical equipment and supplies to individuals who are homebound illegally discriminates on the basis of diagnosis and condition and violates explicit CMS directives for reasonable coverage of medical equipment.

The Medicaid Act requires a participating state to employ "reasonable standards…for determining…the extent of medical assistance under the plan which…are consistent with the objectives of this subchapter." 42 U.S.C. § 1396a(a)(17). *See Wisconsin Dep't of Health and Family Serv. v. Blumer*, 534 U.S. 473, 479 (2002); *Schweiker v. Gray Panthers*, 453 U.S. 34, 36-37

(1981). The primary objectives of the Medicaid program are "to furnish medical assistance to individuals whose income and resources are insufficient to meet the costs of necessary medical services," *Beal v. Doe*, 432 U.S. 438, 444 (1977), and to furnish "rehabilitation and other services to help such…individuals attain and retain capability for independence or self care," 42 U.S.C. § 1396. 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). 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." *Id*. at § 440.230(c).

When state Medicaid rules deny coverage of medically necessary treatment based on diagnosis, illness, or condition, this Court has struck them down as violating the reasonable standards requirement. For example, in *Weaver*, 886 F.2d at 197-200, the Eighth Circuit invalidated a Missouri regulation that limited Medicaid coverage of the drug AZT to only those recipients with AIDS who met certain narrow medical criteria and thereby denied the drug to other recipients whose physicians had also prescribed it as

medically necessary.[4] *See also Hodgson v. Bd. of County Comm'rs*, 614 F.2d 601, 608 (8th Cir. 1980) (rejecting state Medicaid policy that covered pregnancy services only when necessary to save a women's life and not in other circumstances where medically necessary).

Other courts have similarly invalidated Medicaid policies that employed unreasonable standards to deny medically necessary treatment. *See, e.g.*, *Hern v. Beye*, 57 F.3d 906, 910-11 (10th Cir. 1995) (holding state law that restricted medically necessary treatment to only those whose lives were at risk was not a reasonable standard); *Preterm, Inc. v. Dukakis,* 591 F.2d. 121, 131 (1st Cir. 1979) (holding state could not restrict medically necessary services solely on the basis of diagnosis); *White v. Beal*, 555 F.2d 1146, 1151 (3d Cir. 1977) (enjoining classification policy for coverage of eyeglasses because it "discriminated based upon etiology rather than the need for the service").

1. <u>The reasonable standards requirement applies to medical equipment coverage.</u>

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[4] In assessing "reasonableness," this Court noted 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." *Weaver*, 886 F.2d at 199. In the instant case, government officials have removed the decision of whether to provide medical equipment from the treating physician by excluding by rule most items of medical equipment regardless of whether they are medically necessary.

Coverage of medical equipment, as with other medical assistance provided by a state Medicaid program, is subject to the reasonable standards requirement. Notably, CMS has specifically explained how the reasonable standards policy applies to state Medicaid coverage of medical equipment,[5] instructing that:

> A State *may establish reasonable standards*, consistent with the objectives of the Medicaid statute, for determining the extent of [medical equipment] coverage (42 U.S.C. § 1396(a)(17)) *based on such criteria as medical necessity* or utilization control (42 C.F.R. § 440.230(d)). In doing so, a State must ensure that the amount, duration, and scope of coverage are *reasonably sufficient to achieve the purpose* of the service (42 C.F.R. § 440.230(b)). Furthermore, a State may *not* impose arbitrary limitations on mandatory services, such as home health services, *based solely on diagnosis, type of illness, or condition* (42 C.F.R. § 440.230(c)).

CMS, *Dear State Medicaid Director* (Sept. 4, 1998), *at* http://www.cms.gov.hhs.gov/states/letters/smd90498.asp. (emphasis added) (Pl.App.-087.).[6] Thus, a state policy that denies coverage of medically necessary medical equipment; limits coverage so as to prevent such

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[5] As the Supreme Court has pointed out, states must use "reasonable standards" for "determining eligibility for and the extent of medical assistance within boundaries set by the Medicaid statute and the Secretary of Health and Human Services." *Blumer*, 534 U.S. at 479.

[6] 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 not listed in the state's coverage list. *See Slekis v. Thomas*, 523 U.S. 1098 (1999), *vacating and remanding*, *Desario v. Thomas*, 139 F.3d 80 (2d Cir. 1998).

equipment from achieving its purpose; or restricts access to the equipment based on diagnosis, type of illness, or condition would impose unreasonable standards in violation of § 1396a(a)(17). As discussed more fully below, *infra* at 33-37, CMS also directed that, while a state may develop a list of approved items of medical equipment as an administrative convenience, such a policy would be "inconsistent with the federal law" requiring reasonable standards unless it included: (1) sufficiently specific criteria to show that uncovered items had not been excluded because of diagnosis, type of illness, or condition, and (2) made available to recipients a procedure for seeking modifications to that list. (Pl.App.-087-088.)

The courts have relied on this interpretive guidance to enjoin state Medicaid policies that restricted access to medical equipment. *See 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). At issue in *Esteban* was Florida's $582 cap on the coverage of wheelchairs and other mobility devices. *Esteban*, 77 F. Supp.2d at 1257. Since the "general purpose" of the Medicaid program is to help individuals "attain or retain capacity for independence or self-care" and the specific purpose of medical equipment coverage is "to promote, maintain or restore health and minimize the effects of illness, disability or a disabling condition," a policy that

effectively denied motorized or customized wheelchairs to adult Medicaid recipients meant that the state was not providing wheelchairs in sufficient amount, duration and scope to achieve their purpose.[7] *Id*. at 1257, 1260-62. The court concluded that Florida's policy "fails the reasonableness test and is contrary to the purposes of the Medicaid statute." *Id*. at 1262.

2. <u>Missouri's policy employs unreasonable standards.</u>

Missouri's medical equipment scheme similarly violates the reasonable standards requirement and contravenes the objective of providing medically necessary treatment to eligible recipients. First, it denies coverage of physician-prescribed medical equipment to otherwise eligible adults solely because they are not blind. The new rule impermissibly discriminates on the basis of diagnosis and condition by granting medical equipment to adults who are blind and eliminating the same equipment for those who are elderly or suffer from disabilities other than blindness – even when their medical needs are the same. Thus, under Defendant's policy, a blind person who cannot take nutrition orally will receive Medicaid coverage of parenteral nutrition while a non-blind elderly or disabled individual similarly unable to swallow is denied coverage. A blind individual can receive

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[7] Providing manual wheelchairs to eligible Medicaid recipients with mobility impairments so severe that they could not manually operate them was not sufficient to achieve the purpose of the service. *Id*. at 1262.

coverage of a cushion to prevent decubitus ulcers but a person suffering from cerebral palsy cannot. Blind individuals can obtain catheters, canes, breathing equipment, augmentative communication devices, hospital beds, lifts, and other medical equipment, while those with traumatic brain or spinal cord injury, multiple sclerosis, or cardiopulmonary disease cannot receive those same items despite their physicians' determination of medical necessity. By arbitrarily denying and reducing access to medical equipment based solely on blindness, the Defendant employs an unreasonable standard to determine the extent of its medical assistance in violation of § 1396a(a)(17) and 42 C.F.R. § 440.230(c).

The challenged rule also restricts the amount and scope of medical equipment coverage to the point that it cannot reasonably fulfill its purpose. The *Esteban* Court recognized that the duty to provide covered services in sufficient amount, duration, and scope naturally required the State to provide the "associated repairs…necessary to maintain [the equipment] in working order." 77 F. Supp. 2d at 1262. In this case, Missouri's new rule excludes coverage of the batteries, filters, accessories, repairs, and various types of replacement parts necessary to keep Plaintiffs' wheelchairs and other medical equipment functioning and accomplishing their purpose of minimizing the effects of a disabling condition and promoting self-care and

independence. It covers oxygen but not certain types of breathing equipment necessary to deliver it to an individual's lungs. Those restrictions also constitute an unreasonable standard contrary to § 1396a(a)(17) and 42 C.F.R. § 440.230(b).

3. <u>The general Medicaid exceptions process is no substitute for reasonable standards as required by federal law.</u>

Defendant's exceptions process also imposes unreasonable standards that violate § 1396a(a)(17).[8] The process is inconsistent with the reasonable standards requirement because it limits the availability of an exception based on type of illness or condition, is not made available to all Medicaid recipients, lacks sufficiently specific criteria tailored to individual equipment requests, and does not properly inform recipients of their fair hearing rights.

Missouri's exceptions process offends § 1396a(a)(17) because it employs standards that unreasonably deny medically necessary treatment based on diagnosis, type of illness, or condition. On its face, the policy

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[8] The district court committed legal error in concluding that Plaintiffs could obtain uncovered medical equipment through Defendant's exceptions process. (Pl.App.-002.) The trial court made this finding as part of its determination that Plaintiffs did not demonstrate irreparable harm, but it failed to recognize that the Missouri exceptions process violates the reasonable standards requirement. As discussed *infra* at 43-44, the exceptions process is unavailable to Plaintiffs as a matter of law because the plain language of the exceptions policy provides that no exception can be made for items or services specifically prohibited by state regulation, and Rule 13 C.S.R. § 70-60.010(6) expressly excludes coverage of the items of medical equipment needed by Plaintiffs. (Pl.App.-207, 211;237-238.).

provides that exceptional coverage will be granted only if the item or service is required to: (1) sustain the recipient's life, (2) substantially improve the quality of life for a terminally ill patient, (3) replace equipment due to an act occasioned by violence of nature without human interference, such as a tornado or flood, or (4) prevent a higher level of care. (Pl.App.-207,217, 227-228.).

This Court and others have invalidated state Medicaid policies that subject an item or service to standards harsher or narrower than medical necessity.[9] *Hodgson*, 614 F.2d at 608 (striking Medicaid provision that limited coverage to life-at-risk situations); *Hern*, 57 F.3d at 910-11; *Pre-term*, 591 F.2d at 126 (same). *See also Weaver*, 886 F.2d at 198. As the *Hern* Court found, a state policy "is not a 'reasonable standard'" when it limits coverage of a specific medically necessary service to recipients with a particular diagnosis or condition 57 F.3d at 911. *See also Esteban*, 77 F. Supp. 2d at 1261-63, *Bell*, 768 So.2d at 1204. By limiting exceptions for uncovered but medically necessary medical equipment solely to patients who are "terminally ill" or for whom the equipment is required to

[9] The courts have also held that states may not impose additional requirements for Medicaid eligibility. *See Comacho v. Texas Workforce Comm'n*, 408 F.3d 229, 235 (5th Cir. 2005) (citing cases).

"sustain…life" or "prevent a higher level of care," the Missouri exceptions process violates § 1396a(a)(17).

The State's Medicaid exceptions process violates the reasonableness standards for medical equipment coverage issued by CMS. According to CMS, a policy for medical equipment coverage that "provides no reasonable and meaningful procedure" for requesting items that do not appear on its pre-approved coverage list is inconsistent with the reasonable standards requirement. CMS, *Dear State Medicaid Director* (Sept. 4, 1998) (Pl.App.-087.) According to the federal agency, an exception process is not reasonable or meaningful unless it is "made available to all beneficiaries" and is "not limited to sub-classes of the population." *Id.* Moreover, "a State will be in compliance with the federal Medicaid requirements *only* if…the following conditions are met:"

- The process is timely and employs reasonable and specific criteria by which an individual item of ME [medical equipment] will be judged for coverage under the State's home health services benefit. The criteria must be sufficiently specific to permit determination of whether the item has been arbitrarily excluded;

- The process and criteria, as well as the pre-approved items, are made available to Medicaid recipients and the public;

- Medicaid recipients are informed of their right, under 42 C.F.R., Part 431, to a fair hearing to determine whether an adverse decision is contrary to the law cited above.

Id. (emphasis added). *See, e.g., Bell*, 768 So. 2d at 1204-05 (applying CMS guidance to enjoin Florida's medical equipment policy as arbitrary and unreasonable because it did not provide proper notice to recipients about how to request an excluded item or a fair hearing).

Missouri's rule similarly lacks the requisite standards for a reasonable and meaningful exceptions process. To pass muster, a medical equipment exceptions process must use "sufficiently specific" criteria to permit a determination of whether an item of medical equipment that does not appear on a state's pre-approved list has been arbitrarily excluded from coverage based solely on a diagnosis, type of illness, or condition. (Pl.App.-088.) Missouri does not have an equipment-specific process. Its only vehicle for requesting uncovered medical equipment is the general Medicaid exceptions process used for all services not covered by the state Medicaid program, Pl.App. 207-209, 211-220, and that general process has no "reasonable and specific criteria by which an individual item of [medical equipment] will be judged for coverage." (Pl.App.-207-209, 211-220.) Furthermore, as noted above, the criteria employed in the general exceptions process do indeed determine coverage on the basis of diagnosis, type of illness, and condition.

As applied to medical equipment, the Missouri exception process also is "limited to sub-classes of the population" and has not been "made

available to all beneficiaries." (Pl.App.-087.) In the letter issued to Medicaid providers on August 29, 2005, Defendant made its exception process available to those with respiratory conditions requiring continued use of "a BiPAP, CPAP or nebulizer machine." (Pl.App.-209-210, 211.) *See also* Pl.App.-232-233. The director of Defendant's exceptions process admitted on cross-examination that neither the notice nor a September 2, 2005 policy memorandum mentions an exception for any other kind of medical equipment.[10] (Pl.App.-232-237.). While the policy memorandum refers to seeking an exception for breathing equipment, it identifies other equipment—hospital beds, wheelchair batteries and repairs, leg braces—as "not covered" and makes no reference to having providers seek an exception for those items. (Pl.App.-106-111.). At best, the exceptions process is limited to a small sub-class and, thus, is not available to those needing feeding tubes, lifts, catheters, braces, canes, crutches, hospital beds, wheel chair accessories, and other eliminated items.[11]

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[10] On September 2, 2005, Defendant sent a memorandum to county Family Support Division offices to guide staff in answering questions from Medicaid recipients. (Pl.App.-106-111; 234-237.).

[11] Since this litigation ensued, Defendant has suggested that the exceptions process is available for other forms of durable medical equipment. However, that contention is not borne out by the documentary evidence and should be disregarded as a position fashioned for the purposes

Moreover, Defendant's exceptions process has been made available only to Medicaid providers and not to recipients. On its face, the exceptions policy provides that "[e]xception requests are *only accepted from health care providers*." (Pl.App.-211, 216) (emphasis added). Neither the new rule nor the August 1, 2005 notice sent by Defendant to Medicaid recipients mentions any exceptions process.[12] (Pl.App.-104, 105, 115-117.) In fact, the rule and the notice do not inform Medicaid recipients or the public that the exceptions process is available for breathing equipment, much less any other form of medical equipment. Only providers—and still not recipients—have been informed about seeking an exception for the eliminated breathing equipment. (Pl.App.-104-105, 115-117, 228-233, 240.) In addition, the other publicly available documents directed toward Medicaid recipients, including materials on the State's website, make no reference to an

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of litigation. *See Bowen v. Georgetown Univ. Hosp,* 488 U.S. 204, 212-13 (1988).

[12] The notice informs recipients that "*Eliminated services* include…durable medical equipment (examples of eliminated equipment include but are not limited to, wheel chair accessories and batteries, three wheel scooters, decubitus care cushions and commodes, catheters, canes, crutches, walkers, BiPAP, CPAP and nebulizers, parenteral and enteral nutrition, artificial larynx, and augmentative communication devices)." Pl.App.-104-105, 115 (emphasis added), available at http://www.dss.mo.gov/dms/dated/msreductrecip.htm.

exceptions process or the ability to obtain even limited categories of breathing equipment. (Pl.App.-238-241.).

The State's exceptions policy is also not a reasonable and meaningful procedure for providing medical equipment because, contrary to the federal guidance, it does not inform recipients of their fair hearing rights consistent with 42 C.F.R. Part 431. The director of the exceptions process admitted that neither the exceptions policy nor the notice to recipients advised recipients of their right to a fair hearing to challenge the lack of coverage of eliminated medical equipment. (Pl.App.-104-105, 115-117, 219.).[13] Thus, Defendant has failed to notify adult Medicaid recipients in Missouri that there is an exceptions process and that they can request a fair hearing to contest the legality of an adverse decision.

Finally, the exceptions process is no alternative for complying with the federal law. Another case, *DeLuca v. Hammons*, 927 F. Supp. 132 (S.D. N.Y. 1996), illustrates this point. In *DeLuca*, the Plaintiffs challenged a state regulation that limited home health care for some categorically needy

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[13] Even when providers for one of the Plaintiffs requested an exception and the Plaintiff received an adverse decision containing fair hearing information, the notice was not consistent with Part 431 in that it did not cite the legal basis for the action eliminating or reducing Medicaid services or provide for aid pending the appeal of a lost service. Pl.App.-222-225; *see* 42 C.F.R § 431.210(c) and (e). Thus, this belated hearing notice fell short of the applicable legal requirements for a DME exceptions policy.

individuals but not others as violating the federal comparability and reasonableness standards. *Id.* at 133-35 (citing *Weaver*). The State attempted to legitimize the distinction by arguing that individuals who were prejudiced by the limitation could avoid it by using a re-application process. However, the Court found this "solution" served only to call the policy into question. *Id.* at 136 n.6. As noted by the Court, individual applicants and the system were unduly burdened by the policy. For example (as in this case), it required an individual's treating physician to fill out a new form detailing the individual's medical condition, and the increased services were then allowed only if the reviewer found that certain medical conditions were met. According to the Court, this "back-door procedure...does not substitute for an adequate initial process." *Id.* (citing *Mayer v. Wing*, 922 F. Supp. 902 (S.D. N.Y. 1996) (administrative appeal is no substitute for proper procedures at the agency level)).

Because the State's exceptions process limits the availability of an exception based on type of illness or condition, is not made available to Medicaid recipients, lacks sufficiently specific criteria tailored to individual equipment requests, and does not properly inform recipients of their fair hearing rights, it is inconsistent with the reasonable standards requirement.

4. Missouri's criteria for coverage of medical equipment under its home health benefit are unreasonably restrictive in violation of the Medicaid Act.

The district court ruled that Plaintiffs suffered no irreparable harm because they can qualify for medical equipment through the Defendant's Medicaid home health services pursuant to 13 CSR 70-90.010. (Pl.App.-002.) However, Plaintiffs do not qualify for Medicaid home health under Missouri's rule. Those services are available only to individuals who are homebound, which Plaintiffs are not.[14] Just as importantly, Defendant's home health policy, which restricts medical equipment to those who receive home nursing care and are homebound, is unreasonable and illegally discriminates solely on the basis of the patient's diagnosis and condition.[15]

To qualify for Medicaid home health services in Missouri, an adult who is not blind or pregnant must: (1) require intermittent skilled nursing care, (2) be confined to home, and (3) receive the home health services from

[14] While Plaintiffs are people with permanent and total disabilities, they are not, with the exception of Joey Everett, confined to their homes. The Missouri home health regulations define "confined to home" as including not only individuals who are primarily restricted to the home, but also those who "even occasionally leave home for non-medical purposes." 13 C.S.R. 70-90.010(3). Given that Plaintiffs do leave their homes regularly and need the medical equipment to do so, Defendant's criteria would unreasonably exclude them from home health services and the medical equipment included in that benefit.

[15] The Plaintiffs are filing a Motion to Supplement the Record to include two letters from CMS to the Defendant, dated, November 21, 2005, which inform the Defendant that these policies should be changed.

a certified home health agency pursuant to a plan of care updated by a physician every sixty days. 13 C.S.R. §70-90.010(1) and (3), as amended 30 Missouri Register 1898 (September 15, 2005). By contrast, federal law does not limit coverage for medical equipment and supplies to those actually receiving (or in need of) home health nursing services. The federal regulation directs that nursing, home health aide, and medical equipment services must be included in the mandatory home health benefit offered under the state plan, not that each home health recipient be receiving all of three services. *See* 42 C.F.R. § 440.70(b)(3). Neither does Section 440.70(b)(3) require that Medicaid beneficiaries be receiving nursing services from a home health agency in order to be eligible for medical supplies and equipment. Missouri has no authority to impose conditions on the receipt of medical equipment services beyond those required by federal law. *See Comacho*, 408 F.3d at 235. And any such excessive state requirements are unreasonable standards prohibited by § 1396a(a)(17).

Neither do the federal Medicaid statute and regulations permit states to impose a "homebound" requirement as a condition of eligibility for medical equipment or home health services. While the Federal regulation requires that medical supplies and equipment be "*suitable* for use in the home," it does not require that an individual be *confined* to his or her home.

42 C.F.R. § 440.70(b)(3). A person who needs the assistance of a walker to ambulate has a similar—if not greater—need for that medical equipment when she ventures outside the home than when she is "homebound."

CMS has specifically instructed states that a "homebound" requirement is an improper restriction on the receipt of any home health services. *See* CMS, *Dear State Medicaid Director* (July 25, 2000), available at http://www.cms.hhs.gov/states/letters/smd725a0.asp. *Cf. Skubel v. Fuoroli*, 113 F.3d 330, 337 (2d Cir. 1997) (nursing services provided under home health benefit cannot be limited to services provided in the recipient's home). Providing medical equipment to those who are homebound while refusing to cover equipment for individuals with similar needs who are not homebound amounts to an arbitrary distinction based upon the individual's condition—being homebound—rather than their need for the equipment and violates the reasonableness requirement of § 1396a(a)(17) and 42 C.F.R. 440.230(c). As CMS has said:

> The restriction of home health services to persons who are homebound to the exclusion of other persons in need of these services ignores the consensus among health care professionals that community access is not only possible but desirable for individuals with disabilities.… Further, ensuring that Medicaid is available to provide medically necessary home health services to persons in need of those services who are not homebound is an important part of our efforts to offer persons with disabilities services in the most integrated setting appropriate to their needs, in accordance with the Americans with Disabilities Act.

See CMS, *Dear State Medicaid Director* (July 25, 2000), *supra*.

In sum, the district court erred as a matter of law in failing to enjoin Missouri's new medical equipment rule because it uses unreasonable standards to prevent Plaintiffs and other non-blind elderly and disabled Missouri Medicaid recipients from receiving coverage of medically necessary equipment, appliances, and supplies in violation of § 1396a(a)(17).

II. THE PLAINTIFFS ARE SUFFERING IRREPARABLE HARM BY THE ELIMINATION OF COVERAGE OF MEDICAL EQUIPMENT.

As this Court has recognized, the loss of Medicaid and other public assistance benefits constitutes irreparable harm. *See, e.g., Kai v. Ross,* 336 F.3d 650, 656 (8th Cir. 2003). Plaintiffs and others described the specific harm that is being caused by the new Missouri regulation. (Pl.App.- 28-53. 89-103.) Without the prescribed medical equipment, the Plaintiffs are at increased risk of infection, regression in health status, periodic hospitalization, and isolation from the community. (Pl.App.- 28-53, 89-103.)

The district court did not question this testimony. Instead, the court held that the risk of irreparable harm was eliminated because Plaintiffs would receive the medical equipment they need through the home health

services benefit if they qualify for home health services or through the general Medicaid exceptions process. (Pl.App.-002.) However, as shown above, both of these conclusions are based on erroneous legal interpretations.

Moreover, neither of these narrow options is actually available to the vast majority of non-blind disabled or aged Medicaid recipients. A Missouri regulation limits home health services to individuals who are homebound. *See* 13 C.S.R. § 70-90.010(1). Given that Plaintiffs do leave their homes regularly and, in fact, need the medical equipment to enable them to do so, Defendant's criteria, on their face, exclude Plaintiffs from the home health exception. Another Missouri regulation provides that the general Medicaid exception process cannot be used "where requested items or services are… specifically prohibited by state…law." 13 C.S.R. § 70-2.100(1). Since the new regulation specifically prohibits coverage of the items of medical equipment that Plaintiffs need, *id*. at § 70-60.010(6), Defendant's criteria, on their face, exclude Plaintiffs from using the general exceptions process. *See also* Pl.App.-227-228.

Significantly, Defendant's assertion, and the lower court's conclusion, that Plaintiffs will not actually be denied medically necessary Medicaid services as a result of the new rule are directly contradicted by the

Defendant's statements of the very reasons for having the rule. The regulation was enacted expressly to "*eliminate* coverage of certain items of durable medical equipment." 13 C.S.R. § 70-60.010, "Purpose" (emphasis added). Moreover, Defendant's explanation of the rule change, issued prior to the filing of this case, stated that 370,000 Missourians, including all categorically needy individuals who are not blind, pregnant or children, will be affected by the elimination of medical equipment services. *See* 30 Mo. Reg. 1568, Fiscal Note (July 15, 2005) (Pl.App.-064.) Finally, the lower court's decision is fatally flawed on this point. While it concludes that denial of the injunction "presents no threat of irreparable harm," Pl.App.-002, it then goes on to find that the public interest weighs against granting the injunction because the cuts in medical equipment will save more than $24.9 million over a 12-month period, *id.* at 004. This estimated savings is adopted from the Department's notice of the rule change, which is based on the projection that 370,000 individuals will lose coverage as a result of the rule change. *See* 30 Mo. Reg. 1568, Fiscal Note (July 15, 2005) (Pl.App.-064.)

Neither Defendant's exceptions process nor its home health services policy prevents the irreparable harm inflicted by its elimination of medical equipment coverage for Plaintiffs and other categorically needy adults who

are not blind or pregnant. It was clear error and an abuse of discretion for the district court to conclude otherwise.

III. THE THREAT OF SERIOUS, HEALTH RELATED INJURY TO THE PLAINTIFFS CLEARLY OUTWEIGHS ANY POTENTIAL HARM TO THE STATE.

The balance of hardships tips decidedly in favor of Plaintiffs. Plaintiffs will suffer the loss of medical equipment and equipment repair critical to their health, safety, and community living. They seek only that the Defendant comply with controlling federal law. Any fiscal harm that the Department may suffer would be outweighed by the harm to Plaintiffs' lives and health. *See, e.g., Ark. Med. Soc. v. Reynolds,* 819 F. Supp. 816, 819 (E.D. Ark. 1993), *aff'd,* 6 F.3d 519, 522, 531 (8th Cir. 1993); *see also Kansas 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 that would result from issuing the injunction changing Medicaid coverage "significantly alters the status quo to the detriment of the individual plaintiffs, while its positive budgetary impact on the state coffers is negligible in a relative sense").[16]

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[16] It is not clear that the State will realize significant cost savings. Without medical equipment and supplies, some Plaintiffs and others like them will face deteriorating, and ultimately acute, medical conditions and others will face costly, periodic hospital admissions.

The district court held that the balance of harm does not favor Plaintiffs because it concluded that, if 13 C.S.R. § 70-60.010 were struck down, no one would be entitled to Medicaid coverage of medical equipment. (Pl.App.-002.) This conclusion is incorrect. As already discussed, states must provide home health services, including medical equipment, to all categorically needy individuals. 42 C.F.R. §§ 440.210(a)(1), 441.15. And, while no Missouri statute proscribes coverage of medical equipment for non-blind categorically needy recipients, a state law does require coverage of medical equipment for individuals who are blind. *Cf.* Mo. Rev. Stat. § 208.152.1 *with* Mo. Rev. Stat. § 208.152.2(4). Thus, the District Court abused its discretion when it failed to find that the balance of harms favored Plaintiffs.

IV. THE 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 Heather K. v. Mallard,* 887 F. Supp. 1249, 1261 (N.D. Iowa 1995) (collecting Eighth Circuit decisions). Because Defendant is violating the federal law, an injunction will serve the public interest here.

While the Defendant may have eliminated medical equipment as a budget cutting measure, as noted above, it is not at all clear that significant savings will be generated. Moreover, as the district court correctly recognized, budgetary constraints do not excuse a violation of federal law. (Pl.App.-004.) *See Amisub (PSL) Inc. v. Colo. Dep't of Social Services*, 879 F.2d 789, 800 (10th Cir. 1989) (holding budgetary constraints cannot excuse failure to comply with federal Medicaid law); *Mississippi Hosp. Ass'n v. Heckler*, 701 F.2d 511 (5th Cir. 1983) (same); *Kansas Hosp. Ass'n v. Whiteman*, 835 F. Supp 1548, 1552 (D. Kan. 1993) (same); *McNeill-Terry v. Roling*, 142 S.W.3d 828, 834 (Mo. App. 2004) (finding Missouri's budgetary constraints were not sufficient to justify failure to cover medically necessary Medicaid service).

Finally, an injunction is in the public interest because it will allow Missourians to obtain the medical equipment and supplies that their health care providers have prescribed to address their medical conditions. With the equipment, these individuals can maintain their health, improve functioning, and maximize independent, self-care, and community living.

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Conclusion

For the reasons set forth above, this Court should reverse the decision of the district court and order the Appellee forthwith to provide Plaintiffs with medical equipment as required by the federal Medicaid Act.

Susan Lavon Lankford; Rachel Ely; Jan Everett,
as next friend of Joseph Everett; Donald Eugene
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Dated: Nov. 30, 2005 By: ___________________________

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. Rule 28 and Rule 32(a)(7), I certify that the foregoing brief is proportionately spaced, has a typeface of 14 points, and contains 10,626 words.

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Jane Perkins