UNITED STATES DISTRICT COURT WESTERN DISTRICT OF MISSOURI CENTRAL DIVISION

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SUGGESTIONS IN SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

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PRELIMINARY STATEMENT

Plaintiffs have disabilities ranging from paralysis to cardio-pulmomary disease. They depend on the Missouri Medicaid program for their prescribed durable medical equipment, including machines and accessories that enable them to breath, batteries that allow their wheelchairs to work, catheters and bags to collect their urine, and cushions that prevent painful and infectious pressure sores. Plaintiffs bring this application for a temporary restraining order and preliminary injunction to enjoin Defendant Gary Sherman from implementing a regulation, Mo. Rule 13 C.S.R. § 70-60.010, that, as of September 1, 2005, eliminates Medicaid coverage of their durable medical equipment and supplies.

Plaintiffs seek declaratory and injunctive relief under 42 U.S.C. § 1983 and the Supremacy Clause of the United States Constitution. They challenge Defendant's regulation as violating and preempted by the federal Medicaid Act, specifically: 42 U.S.C. § 1396a(a)(10)(B) and implementing rules, which require that the medical assistance made available to categorically needy individuals be equal in amount, duration, and scope; and 42 U.S.C. § 1396a(a)(17) and implementing rules, which require that the extent of medical assistance be established using reasonable standards.

BACKGROUND TO 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.

States participating in the Medicaid program "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, e.g., Weaver v. Reagen*, 886 F.2d 194, 197 (8th Cir. 1989) ("Although a state's participation is voluntary, once a state chooses to participate in the program it must comply with federal statutory and regulatory requirements."). Missouri participates in the Medicaid program.

The Medicaid Act requires states to cover individuals who are "categorically needy." 42 U.S.C. § 1396a(a)(10)(A). The categorically needy include children and pregnant women who meet federal poverty level standards, working disabled individuals, and individuals who are aged, blind, or disabled. *See* 42 U.S.C. § 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 enough medical expenses to "spend down" to medical assistance eligibility levels. *See* 42 U.S.C. § 1396a(f). 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.

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STATEMENT OF FACTS

Plaintiffs are categorically needy Medicaid recipients. (Lankford Declaration (Decl.) ¶ 9; Ely Decl. ¶ 5; Everette Decl. ¶ 5; Brown Decl. ¶ 6; Greathouse Decl. ¶ 3; Vogelpohl Decl. ¶ 4.)¹ Effective September 1, 2005, Defendant Sherman will begin implementing Mo. Rule 13 C.S.R. § 70-60.010. The rule eliminates coverage of durable medical equipment for most adult categorically needy individuals, with the exception of the few items on the following list:

- prosthetics, *excluding* an artificial larynx;
- ostomy supplies;
- diabetic supplies and equipment,
- 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 many items of medical equipment excluded altogether for these categorically needy recipients are:

- orthotics (such as cushions to help 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).

By contrast, Medicaid coverage of a full range of durable medical equipment is maintained for three groups of categorically needy individuals. Individuals who are pregnant, blind, or children will maintain Medicaid coverage for durable medical equipment that includes but is not limited to:

¹ Plaintiff Adam Thomason's application for categorically needy Medicaid benefits is pending. Thomason Decl. ¶ 4. Plaintiffs' Declarations in Support of Plaintiffs' Motion for a Temporary Retraining Order and Preliminary Injunction are filed as an Exhibit herewith.

Prosthetics; orthotics, oxygen and respiratory care equipment; parenteral nutrition, ostomy supplies; diabetic supplies and equipment; decubitis care equipment; wheelchairs; wheelchair accessories and scooters; augmentative communication devices; and hospital beds.

Id. Durable medical equipment also continues to be covered for persons who are admitted into nursing homes, as part of the per diem nursing home rate, with the exception of custom and power wheelchairs, prosthetic devices, and volume ventilators. *Id.*

The Department of Social Services estimates that 370,000 individuals will be adversely affected by this regulation, including all Medicaid recipients who are not categorically eligible children, pregnant women, or blind. *See* 30 Mo. Reg. 1568, Fiscal Note (July 15, 2005).

STANDARD OF REVIEW

A temporary restraining order or preliminary 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. *Dataphase Systems v C L Systems, Inc.*, 640 F.2d 109, 112, 114 (8th Cir. 1980). *See also, e.g., Aaron v. Target Corporation*, 269 F. Supp. 2d 1162 (E.D. Mo. 2003), *rev'd on other grounds*, 357 F.3d 768 (8th Cir. 2004) (applying standard to request for temporary restraining order); *Randolph v. Rogers*, 170 F.3d 850, 857 (8th Cir. 1999) (applying standard to request for preliminary injunction).

ARGUMENT

A. The Plaintiffs will Be Irreparably Harmed by the Elimination of the Durable Medicaid Equipment.

It is well established in the courts of the Eighth Circuit that the loss of Medicaid benefits constitutes irreparable harm. *See, e.g., Kai v. Ross*, 336 F.3d 650, 656 (8th Cir. 2003); *White v. Martin*, No. 02-4154-CV-C-NKL, 2002 U.S. Dist. LEXIS 27281, *10-11 (W.D. Mo. Oct. 3, 2002); *Nemnich v. Stangler*, No. 91-4517-CV-C-5, 1992 WL 178963 (W.D. Mo. Jan. 7, 1992) (enjoining State from eliminating several categories of dental treatment). *See also Massachusetts Ass'n of Older Americans v. Sharp*, 700 F.2d 749, 753 (1st Cir. 1983) ("Termination of benefits that causes individuals to forego such necessary medical care is clearly irreparable harm."); *Beltran v. Meyers*, 677 F.2d 1317, 1322 (9th Cir. 1982) (irreparable injury shown when enforcement of a Medicaid rule "may deny [plaintiffs] needed medical care"); *Caldwell v. Blum*, 621 F.2d 491, 498 (2d Cir. 1980) (Medicaid applicants established harm where they would "absent relief, be exposed to the hardship of being denied essential medical benefits"); *McMillan v. McCrimon*, 807 F. Supp. 475, 479 (C.D. Ill. 1992) ("The nature of their claim — a claim against the state for medical services — makes it impossible to say that any remedy at law could compensate them.").

Plaintiffs meet the test for irreparable injury. The Medicaid-covered equipment slated for elimination in the Missouri rule enables Plaintiffs to meet their most basic physical needs and, without it, they will experience great harm. For example:

• Joey Everett has severe brain injury, partial paralysis and cannot swallow. All his nutritional needs are met through a gastrostomy tube, with related feeding equipment and nutritional formula. He can no longer swallow and his parents must use a suction machine and catheter to prevent him from choking on his saliva.

The feeding equipment, nutritional formula, catheter and suction machine provide him with the means to eat and breathe without obstruction. (Everett Decl. \P 2, 7.)

- Susan Lankford has chronic obstructive pulmonary disease, asthma, and sleep apnea and uses a nebulizer and continuous positive airway pressure (CPAP) machine to assist breathing. According to her pulmonary specialist, without these devices, Ms. Lankford stands a much greater chance of dying. (Lankford Decl. ¶¶ 2, 3, 10.)
- Kimberly Vogelpohl has chronic pulmonary disease and asthma and has been hospitalized nine times in the last 12 weeks. Her physician has prescribed an oxygen concentrator, nebulizer and hospital bed to assist breathing. Without this equipment, she is almost certain to require more hospitalizations. (Vogelpohl Decl. ¶¶ 8-11.)

Other plaintiffs require equipment that allows them to be mobile and attain some level of self-sufficiency. For example:

• 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. (Ely Decl. ¶ 2.) The Missouri rule will eliminate coverage of the braces, splints, and wheelchair batteries, as well as maintenance and adjustment.

For many of these Plaintiffs, the Missouri rule's elimination of coverage for the repair, maintenance and similar expenses associated with durable medical equipment will cause the equipment to be unusable or dangerous to use. For example:

- Linda Greathouse has severe sleep apnea and complications from a recent stroke. She uses a tracheal tube that requires frequent cleaning and replacement parts. (Greathouse Decl. ¶¶ 6, 7.) The Missouri rule will eliminate 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. (Lankford Decl. ¶¶ 4, 5.) The Missouri rule will eliminate coverage of these parts.

For the Plaintiffs, the consequences of losing the equipment or the use of the equipment is likely to be dire. Rachel Ely is afraid that she may never be able to walk or use her left arm. (Ely Decl. ¶¶ 6, 7.) Donald Brown worries that he will no longer be able to care for himself and live independently. (Brown Decl. ¶ 6.) Adam Thomason, aged 23 and a paraplegic as a result of a car accident earlier this year, fears that he will never be get the equipment he needs if the pending cuts go into effect. (Thomason Decl. ¶ 9.) Joey Everett's mother feels as if the state is forcing him into a nursing home. (Everett Decl. ¶¶ 6, 15.). In sum, this prong of the test is met because irreparable harm is almost certain to occur as a result of the Defendant's newly-announced regulation.

B. The Plaintiffs have a Substantial Likelihood of Succeeding on the Merits.

The Medicaid Act lists "home health care services" as medical assistance. 42 U.S.C. § 1396d(a)(7). The Act requires states to cover home health care services for any individual who is entitled to nursing facility services. 42 U.S.C. § 1396a(a)(10)(D). Implementing regulations mandate that "[m]edical supplies, equipment, appliances suitable for use in the home" are a "required service" as part of the Medicaid Act's "home health services." 42 C.F.R. § 440.70(b)(3).

1. The Missouri Rule Violates and is Inconsistent with the Comparability Requirements of the Medicaid Act.

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 also 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 United State Supreme Court stated that the "comparative treatment" 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., 457 U.S. at 573 n.6. *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.").

Not surprisingly, the reported cases read the statute to mean what it says. *See*, *e.g.*, *Rodriguez v. City of New York*, 197 F.3d 611, 615 (2d Cir. 1999) ("[S]tates 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"); *White v. Beal*, 555 F.2d 1146, 1149 (3d Cir. 1977) (finding that § 1396a(a)(10)(B) requires that "[a]ll persons within a given category must be treated equally"); *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); *Sobky v Smoley*, 855 F. Supp. 1123, 1139-40 (E.D. Cal. 1994) (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" and holding that "[b]y 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)").

Here, Mo. Rule 13 C.S.R. § 70-60.010 eliminates Medicaid coverage of medical equipment for categorically eligible Medicaid recipients who qualify because they are aged, disabled, or parents, while maintaining full coverage for durable medical equipment for categorically eligible Medicaid recipients who are children, pregnant women, or blind. 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), the Defendant's regulation cannot stand. The regulation violates § 1396a(a)(10)(B)(i) because the durable medical equipment made available to Plaintiffs and other categorically needy individuals like them is less in amount and scope than the medical assistance made available to other categorically needy individuals who are pregnant, blind, or children.² The regulation should be enjoined.

2. The Missouri Rule Violates and is Inconsistent with the Reasonable Standards Requirements of the Medicaid Act.

The regulation should also be enjoined because it violates the Medicaid reasonable standards requirements for durable medical equipment. The Medicaid Act requires the State's Medicaid program to include "reasonable standards . . . for determining . . . the extent of medical assistance under the plan which . . . are consistent with the objectives of this subchapter" 42

³ The statute grants a few exceptions to the comparability requirements, but none are relevant to this case. *See* 42 U.S.C. § 1396a(a)(10) (concluding text following subsection (G)).

U.S.C. § 1396a(a)(17). To establish reasonable standards, the Defendant must ensure that the amount, duration, and scope of coverage are reasonably sufficient to achieve the purpose of the services. 42 C.F.R. § 440.230(b). Furthermore, the 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).

In an official statement of agency policy, the U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services (CMS), the agency charged with implementation of the Medicaid Act at the federal level, has clarified the standards for states' coverage of durable medical equipment. CMS, *Dear State Medicaid Director* (Sept. 4, 1998), *at* http://www.cms.gov.hhs.gov/states/letters/smd90498.asp. According to CMS, the federal laws allow a state to develop a list of approved items of medical equipment (ME) as an administrative convenience, but:

An ME policy that provides no reasonable and meaningful procedure for requesting items that do not appear on a State's pre-approved list, is inconsistent with the federal law discussed above. . . . [T]he process for seeking modification or exception must be made available to all beneficiaries and may not be limited to sub-classes of the population (e.g., beneficiaries under the age of 21).

Moreover, "a State will be in compliance with the federal Medicaid requirements only if, with respect to an individual applicant's request for an item of ME, the following conditions are met:"

- The process is timely and employs reasonable and specific criteria by which an individual item of ME 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 to a fair hearing to determine whether an adverse decision is contrary to the law cited above.

Id. Notably, in light of this interpretive agency guidance, the Supreme Court vacated a circuit court decision that had allowed the Connecticut Medicaid program to exclude coverage of medically necessary medical equipment not listed in the state's coverage list, so long as the Medicaid population as a whole was served. See Slekis v. Thomas, 523 U.S. 1098 (1999), vacating and remanding, Desario v. Thomas, 139 F.3d 80 (2d Cir. 1998). See also Bell v. Agency for Health Care Admin., 768 So.2d 1203, 1204 (Fla. Ct. App. 2000) (finding state Medicaid agency's pre-approved list of medical equipment unreasonably excluded coverage of benefits that could be medically necessary because the process for requesting an exception was not made available to beneficiaries and because the agency did not articulate the process for seeking an exception, employ available reasonable criteria for coverage, or inform beneficiaries of the right to a fair hearing, as required by the federal government's Sept. 4, 1998 document); Esteban v. Cook, 77 F. Supp. 2d 1256, 1262 (S.D. Fla 1999) (holding the State's monetary cap on the coverage of wheelchairs "fails the reasonableness test and is contrary to the purposes of the Medicaid statute"). See generally Weaver v. Reagan, 886 F.2d 194, 198, 200 (8th Cir. 1989) (citing (a)(17) reasonable standards requirement and enjoining a Missouri rule that limited coverage of the drug AZT to only certain, narrow circumstances); McNeil-Terry v. Roling, 142 S.W.3d 828 (Mo. Ct. App. 2004) (enjoining cutback in dental services, finding that Missouri's budgetary constraints must not interfere with the 42 C.F.R. § 440.230(b) coverage requirements).

Here, the Plaintiffs are likely to succeed on the merits of their claim that the challenged Missouri regulation violates and is inconsistent with the reasonable standards requirements. The

rule completely eliminates coverage of crucial items of durable medical equipment that Plaintiffs need for their self-care and independence, to remain well, and to avoid costly hospitalization and institutionalization. This includes catheters, breathing apparatus, cushions to protect against pressure sores, walkers, and crutches. While the rule purports to cover wheelchairs, it denies Medicaid payment for batteries, repairs and other accessories necessary to make the chairs safe and usable. Moreover, the regulation draws distinctions that have nothing to do with medical necessity or relative need for services. For example, the rule allows coverage of one type of oxygen equipment but forbids coverage of other types of equally medically necessary breathing apparatus like CPAPS, nebulizers, suction pumps, and apnea monitors.

Thus, the Missouri rule is unreasonable and inconsistent with the objectives of the Medicaid Act. It interferes with the purpose of the Act, which is to enable individuals to "attain or retain capability for independence or self-care." 42 U.S.C. § 1396. It violates the requirement that services be sufficient in amount, duration and scope. 42 C.F.R. § 440.230(b). Moreover, the state regulation imposes the sorts of arbitrary limits based solely on diagnosis, type of illness, or condition that are prohibited by 42 C.F.R. § 440.230(c). The Missouri regulation fails in every respect to meet the requirements of CMS' September 1998 guidance document.

C. The Balance of Hardships Favors the Plaintiffs.

The balance of hardships tips decidedly in favor of Plaintiffs. Plaintiffs will suffer the loss of durable medical equipment critical to their health, self-care and independent living. Plaintiffs seek only that Defendant comply with the plain language of controlling federal law and afford them the benefits to which they are entitled.

In a similar case, *Nemnich v. Stangler*, a Missouri federal court entered a preliminary injunction against the State when it attempted to offer some, but not all, types of medically necessary adult dental care. The court recognized that the State "will suffer fiscal problems if enforcement of the amended regulation is enjoined," but found that "the harm to the plaintiffs' life and health clearly outweighs any fiscal harm the state may suffer." 1992 WL 178963 at *3. *See also 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); *Olson v. Norman*, 830 F.2d 811 (8th Cir. 1987) (sustaining preliminary injunction and summary judgment against state for terminating welfare and Medicaid benefits). *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 temporary restraining order because changing Medicaid coverage "significantly alters the status quo to the detriment of the individual plaintiffs, while its positive budgetary impact on state coffers is negligible in a relative sense").³

Moreover, the Defendant cannot be harmed by complying with what the federal law requires. As stated by the Seventh Circuit,

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

⁴ In this case, it is not at all clear that the State will realize any significant cost savings. Lacking durable medical equipment, some Plaintiffs and others like them will face deteriorating, and ultimately acute, medical conditions and others will face costly hospital admissions and long term institutional care.

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

D. The Injunction Is in the Public Interest.

Finally, Plaintiffs, seeking to enforce federal law, satisfy the requirement that the injunction sought be in the public interest. As noted in *Nemnich*, "Congress and the Missouri General Assembly expressed the public interest by enacting the Medicaid program in the first place." 1992 WL 178963 at *4. Similarly, 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, 1263, 1266 (N.D. Iowa 1995) (issuing temporary restraining order, holding that Americans with Disabilities Act embodied the public interest in enforcement of anti-discrimination provisions against public officials).

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that their motion for temporary restraining order and preliminary injunctive relief be granted.

Dated: August 29, 2005

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