# United States Court of Appeals
## FOR THE EIGHTH CIRCUIT

No. 05-3587

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| Susan Lavon Lankford; Rachel Ely; Joseph Everett, by next friend, Jan Everett; Donald Eugene Brown; Laura Lee Greathouse; Kimberly Vogelpohl; Adam Daniel Thomason, | * | |
| Appellants, | * | Appeal from the United States District Court for the Western District of Missouri. |
| The National Council on Independent Living; The United States Society for Augmentative and Alternative Communication; The American Language-Hearing Association; The National Disability Rights Network, | * | |
| Amici on Behalf of Appellants, | * | |
| v. | * | |
| Gary Sherman, in his official capacity as Director of the Missouri Department of Social Services, | * | |
| Appellee. | * | |

Submitted: April 17, 2006
Filed: June 22, 2006

Before WOLLMAN, BEAM, and BENTON, Circuit Judges.

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BENTON, Circuit Judge.

Plaintiffs – disabled adult Medicaid recipients – seek a preliminary injunction prohibiting Missouri's Director of Social Services from enforcing a state regulation curtailing the provision of durable medical equipment ("DME") to most categorically-needy Medicaid recipients. *See* **Mo. Code Regs. Ann. tit. 13, § 70-60.010 (2005)**. Invoking 42 U.S.C. § 1983 and the Supremacy Clause, U.S. Const. Art. VI, cl. 2, they allege that the regulation violates Medicaid's comparability and reasonable-standards requirements. *See* **42 U.S.C. §§ 1396a(a)(10)(B), (a)(17)**. The district court denied a preliminary injunction, finding the regulation consistent with the Medicaid Act. Plaintiffs appeal. Having jurisdiction under 28 U.S.C. § 1292(a)(1), this court vacates the order of the district court, and remands for further proceedings.

I.

Before the 2005 legislative session, Missouri provided DME as a stand-alone Medicaid benefit to all recipients. Under the DME program, plaintiffs received wheelchairs, wheelchair batteries and repairs, orthotics, orthopedic devices, parenteral nutrition, augmentative communication devices, hospital beds, bed rails, lifts, and other prosthetics. *See* **Mo. Rev. Stat. § 208.152.1(15)** (repealed August 28, 2005). Citing budget constraints, the General Assembly passed a new statute eliminating the DME program as a covered Medicaid service, except for recipients who are blind, pregnant, or needy children, or for those who receive home health care services under the state plan. *See* **Mo. Rev. Stat. § 208.152.2** (Supp. 2005) (providing an exception for wheelchairs, prosthetics, and orthopedic devices to these individuals). Under the revised statute, Medicaid recipients may not receive DME as a stand-alone benefit, unless they fall within one of the statutory groups.

Plaintiffs have never challenged the statute's elimination of the DME program. Rather, plaintiffs contest a September 2005 emergency regulation, which reinstates coverage of certain DME items for all Medicaid recipients, while specifically defining the statutorily-provided DME items for the blind, pregnant, and needy children, and those receiving home health care. *See* **Mo. Code Regs. Ann. tit. 13, § 70-60.010 (2005)**.[1]

Under the regulation, the blind, pregnant, needy children, and individuals who receive home health care may receive Medicaid coverage for DME items that include, but are not limited to:

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

***Id.* § 70-60.010.6**. All other adult Medicaid recipients cannot receive Medicaid-funded DME, except for:

> Prosthetics, excluding an artificial larynx; ostomy supplies; diabetic supplies and equipment; oxygen and respiratory equipment, excluding CPAPs, BiPAPs, nebulizers, IPPB machines, humidification items, suction pumps and apnea monitors; and wheelchairs, excluding wheelchair accessories and scooters.

***Id.***

The regulation further clarifies that, for all DME recipients, "DME is equipment that can withstand repeated use, is primarily and customarily used to serve a medical

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[1]The validity of the emergency regulation in light of the revised statute has not been raised in this litigation.

purpose, generally is not useful to a person in the absence of an illness or injury, and is appropriate for use in the home." ***Id.* § 70-60.010(4)**. Even if an item is classified as DME, it is not covered unless it both meets the DME definition and "is reasonable and necessary for treatment of the illness or injury, or to improve the functioning of a malformed or permanently inoperative body part." ***Id.* § 70-60.010(6)**.

Plaintiffs, adult Medicaid recipients, have disabilities ranging from paralysis to cardiopulmonary disease. Before the new regulation, they received medically-prescribed DME from Medicaid. Under the new regulation, however, plaintiffs claim they are ineligible to receive DME items that are necessary for their medical care and independence (which they cannot afford). Compared to the repealed DME program, they argue, the new regulation excludes (for most recipients) orthotics, parenteral nutrition, catheters, augmentative communication devices, hospital beds, bed rails, lifts, and wheelchair batteries and repair items.

Rather than attack the revised statute, plaintiffs seek to enjoin the DME regulation. Plaintiffs agree that Missouri may lawfully provide additional benefits only to needy children and pregnant women. *See* **42 U.S.C. § 1396a(a)(10)(G)(V), 42 C.F.R. § 440.250(p)** (pregnant women); **42 U.S.C. §§ 1396a(a)(4)(B), 1396d(r)**, **42 C.F.R. § 440.250(b)** (needy children). Plaintiffs contend that Missouri may not provide additional DME benefits to blind recipients (unless Missouri provides those benefits to all adult recipients). Plaintiffs assert violations of federal comparability and reasonable-standards requirements that the State treat Medicaid recipients equally and with reasonable, non-discriminatory standards. *See* **42 U.S.C. §§ 1396a(a)(10)(B), (a)(17)**. *See also* **42 C.F.R. § 440.230**. They also claim that the state regulation conflicts with these federal requirements, and is preempted by the Supremacy Clause. **U.S. Const. Art. VI, cl. 2.**

In the district court, the State defended the DME regulation primarily by arguing that it had applied to the Centers for Medicare and Medicaid Services

("CMS") for a waiver of the federal comparability requirement, which would permit additional benefits for the blind. *See* **42 U.S.C. § 1396n(b)**. The State argued that the waiver application defeated plaintiffs' likelihood of success on the merits. The State also claimed that plaintiffs can still obtain necessary DME if they (1) qualify for home health care, or (2) seek an exception for non-covered DME items through the exceptions process. Due to these options, said the State, the DME regulation did not harm plaintiffs enough to justify an injunction.

The district court denied a preliminary injunction. The court focused entirely on plaintiffs' comparability claim, and did not discuss the reasonable-standards claim. Specifically, the court determined that, because plaintiffs had other options to receive necessary DME, they could not establish irreparable harm. Moreover, the court agreed that Missouri's pending waiver application precluded a likelihood of success on the merits. The court noted, however, that if the waiver were not obtained, Missouri could not provide additional items of DME to the blind (without providing them to all adult recipients). Plaintiffs appeal.[2]

II.

Before addressing the merits, this court must resolve the issue of mootness – a jurisdictional issue raised in the State's supplemental brief and at oral argument. *See* ***Ali v. Cangemi***, 419 F.3d 722, 723-24 (8th Cir. 2005) (en banc) ("If an issue is moot in the Article III sense, we have no discretion and must dismiss the action for lack of jurisdiction"). The record has significantly changed since plaintiffs first appealed. CMS has now denied Missouri's request for a comparability waiver. While CMS recommended a number of alternatives that may allow Missouri to provide additional

[2]The parties' motions to supplement the record are granted, and the exhibits are considered in this appeal. *See* ***Dakota Indus., Inc. v. Dakota Sportswear, Inc.***, 988 F.2d 61, 63 (8th Cir. 1993).

DME services to the blind, Missouri chose to submit an amended Medicaid plan that deletes any reference to federal financial participation for additional services to the blind. To date, CMS has not approved or rejected the amended plan; negotiations are ongoing. While the revised Missouri statute and DME regulation have not changed, the State contends that it provides additional DME to the blind only with state tax funds, with no federal funding.

The State argues that its decision to fund the DME program for blind recipients only with state dollars makes the amended plan comply with all Medicaid rules, rendering this case moot. It is well-settled that "a defendant's voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of the practice." ***City of Mesquite v. Aladdin's Castle, Inc.***, 455 U.S. 283, 289 (1982). *See also* ***Young v. Hayes***, 218 F.3d 850, 852 (8th Cir. 2000). If it did, the courts would be compelled to allow the defendant to return to its old practices without fear of reprisal. *See* ***United States v. W.T. Grant Co.***, 345 U.S. 629, 632 (1953). The defendant faces a heavy burden of showing that "the challenged conduct cannot reasonably be expected to start up again." ***Friends of the Earth, Inc. v. Laidlaw Envt'l Servs., Inc.***, 528 U.S. 167, 189 (2000), *quoting* ***United States v. Concentrated Phosphate Exp. Ass'n***, 393 U.S. 199, 203 (1968).

The State does not meet the "heavy burden" to show mootness. Despite the claim of voluntary cessation, the State may reinstate a Medicaid plan that uses federal funding for additional assistance to the blind. *See* ***Charleston Hous. Auth. v. U.S. Dep't of Ag.***, 419 F.3d 729, 740 (8th Cir. 2005) ("The possibility of this recurrence is not so remote or speculative that our jurisdiction is lacking"). Not only has CMS neither approved nor rejected the amended plan, Missouri may seek further amendment at any time. *See, e.g.,* ***Ark. Med. Soc., Inc. v. Reynolds***, 6 F.3d 519, 529 (8th Cir. 1993). Moreover, as discussed below, Missouri's claim of voluntary cessation only addresses plaintiffs' comparability claim, not their reasonable-standards claim. As jurisdiction is proper, this court addresses the merits.

III.

A motion for preliminary injunction requires the district court to consider four factors: (1) the probability of success on the merits, (2) the threat of irreparable harm to the movant, (3) the balance between the harm and the injury that granting the injunction will inflict on other interested parties, and (4) the public interest. *See* ***Dataphase Sys. v. C L Sys., Inc.***, 640 F.2d 109, 114 (8th Cir. 1981) (en banc). The party seeking injunctive relief bears the burden of proving these factors. *See* ***Watkins, Inc. v. Lewis***, 346 F.3d 841, 844 (8th Cir. 2003). No single factor is dispositive, as the district court must balance all factors to determine whether the injunction should issue. *See* ***Baker Elec. Co-op., Inc. v. Chaske***, 28 F.3d 1466, 1472 (8th Cir. 1994), *citing* ***Modern Banking Sys., Inc.***, 871 F.2d 734, 737 (8th Cir. 1989) (en banc), *superceded by* Minn. Stat. § 80C.21 (1989).

The district court has broad discretion when ruling on preliminary injunctions. *See* ***Manion v. Nagin***, 255 F.3d 535, 538 (8th Cir. 2001). This court reverses only for abuse of that discretion. *See* ***Pediatric Specialty Care, Inc. v. Ark. Dep't of Human Servs.***, 444 F.3d 991, 994 (8th Cir. 2006); ***United Indus. Corp v. Clorox Co.***, 140 F.3d 1175, 1179 (8th Cir. 1998). An abuse of discretion occurs where the district court rests its conclusion on clearly erroneous factual findings or erroneous legal conclusions. *See* ***Wedow v. City of Kansas City, Mo.***, 442 F.3d 661, 666 (8th Cir. 2006), *quoting* ***Layton v. Elder***, 143 F.3d 469, 472 (8th Cir. 1998). When purely legal questions are presented, however, this court owes no special deference to the district court. *See* ***Bell v. Sellevold***, 713 F.2d 1396, 1399 (8th Cir. 1983), *quoting* ***Chu Drua Cha v. Noot***, 696 F.2d 594, 599-600 (8th Cir. 1982) (vacating denial of preliminary injunction).

IV.

The Medicaid Act is a federal aid program designed to help the states provide medical assistance to financially-needy individuals, with the assistance of federal funding. *See* ***Schweiker v. Hogan***, 457 U.S. 569, 572 (1982); ***Hodson v. Bd. of County Comm'rs***, 614 F.2d 601, 606 (8th Cir. 1980). Participation is voluntary, but if a state decides to participate, it must comply with all federal statutory and regulatory requirements. *See* ***Schweiker v. Gray Panthers***, 453 U.S. 34, 37 (1981); ***Bowlin v. Montanez***, 446 F.3d 817, 818 (8th Cir. 2006), *citing* ***Kai v. Ross***, 336 F.3d 650, 651 (8th Cir. 2003). To participate, a state submits a plan to the Secretary of the Department of Health and Human Services that meets the requirements of 42 U.S.C. § 1396a(a). *See* ***Reynolds***, 6 F.3d at 522, *citing* ***Wilder v. Va. Hosp. Ass'n***, 496 U.S. 498, 503 (1990). Once the plan is approved, the federal government subsidizes the state's medical-assistance services. *See* **42 U.S.C. § 1396**; ***Alexander v. Choate***, 469 U.S. 287, 289 n.1 (1985).

Participating states must furnish medical assistance to the "categorically needy," a group that includes financially-needy blind, aged, and disabled individuals, pregnant women, and children. *See* **42 U.S.C. § 1396a(a)(10)(A)**. A state may also choose to provide medical assistance to the "medically needy" – those who do not qualify under a federal program, but lack the resources to obtain adequate medical care. *See* ***id.*** **§ 1396(a)(10)(C)**; ***Gray Panthers***, 453 U.S. at 37. Missouri elects to provide medical assistance only to the categorically needy. *See* **Mo. Rev. Stat. § 208.151**.

Once a state decides which groups will receive medical assistance under the plan, it then determines which services it will provide. *See* **42 U.S.C. § 1396d(a)**. To receive federal approval, the Medicaid Act mandates that a plan include only seven enumerated medical services. *See* ***id.*** **§§ 1396a(a)(10)**, **1396d(a)(1)-(5), (17), (21)** (including as mandatory: inpatient hospital, outpatient hospital, laboratory and x-ray, nursing facility, physician, nurse-midwife, and nurse-practitioner services).

A state may also elect to provide optional medical services, such as dental services, prosthetics, and prescription drugs. *See* ***id.*** **§§ 1396(a)(10)(A)**, **1396(d)(a)** (listing 27 categories of medical assistance, only seven of which are mandatory). Once the state offers an optional service, it must comply with all federal statutory and regulatory mandates. *See* ***Ellis v. Patterson***, 859 F.2d 52, 54 (8th Cir. 1988).

DME is an optional service under the Medicaid Act, unless the recipient qualifies for home health care. *See* **42 U.S.C. § 1396a(a)(10)(D)**. The provision of home health care is a mandatory requirement of the state plan, if the individual is entitled to nursing facility services. *See* ***id.***; **42 C.F.R. § 440.210(a)(1)**. Under the federal regulations, "home health services" are medically-prescribed services provided to a Medicaid recipient at his or her place of residence. **42 C.F.R. § 440.70(a)**. If a recipient receives home health services, the state also must provide "medical supplies, equipment, and appliances suitable for use in the home" as part of the program. *See* ***id.*** **§§ 440.70(b)(3), 441.15(a)(3)**. Federal law does not define these terms for purposes of Medicaid. *See* ***DeSario v. Thomas***, 139 F.3d 80, 88-89 (2d Cir. 1998) (noting the lack of federal definition), *vacated sub nom. by* ***Slekis v. Thomas***, 525 U.S. 1098 (1999).

Missouri funds home health care to Medicaid recipients who meet certain requirements. *See* **Mo. Rev. Stat. § 208.152.2(10)** (Supp. 2005). Specifically, the recipient must (1) require intermittent nursing care or therapy, (2) be confined to the home, (3) have a prescription for home health services from a physician, and (4) receive the services in the home from a qualified provider. **Mo. Code Regs. Ann. tit. 13, § 70-90.010(1)**. "A recipient may be considered homebound even if s/he occasionally leaves home for non-medical purposes, as long as these absences are infrequent, or relatively short duration, and do not indicate that the recipient has the capacity to obtain the needed care on an outpatient basis." ***Id.*** **§ 70-90.010(3)**. If the individual qualifies for home health care under Missouri's regulation, prescribed items of DME are covered. *See* ***id.*** **§ 70-90.010(4)**. The State asserts that the provision of

DME items under Missouri's home health care program is not limited to the items prescribed under the new DME regulation. *Compare* ***id.*** **§ 70-60.010(6)** (2005), *with* ***id.*** **§ 70-90.010(4)**.

In this case, no plaintiff receives home health care under the state plan. As plaintiffs are not blind, pregnant, or children, the list of DME items that Missouri will reimburse is curtailed. *See* ***id.*** **§ 70-60.010(6)**. As the State points out, if a DME item is prescribed that is not covered under the DME regulation, plaintiffs have two options. First, they can seek qualification for home health care under the state plan. *See* ***id.*** **§ 70-90.010**. Second, they can seek an exception for non-covered items through the exceptions procedure. *See* ***id.*** **§ 70-2.100**. As these options do not treat plaintiffs the same as blind recipients under the state plan, and do not afford an opportunity to obtain non-covered DME items, plaintiffs allege that the DME program does not meet federal Medicaid requirements.

A. Comparability

The new regulation eliminates coverage of most DME items for the categorically-needy who are aged or disabled. The regulation maintains full DME coverage for categorically-needy recipients who are blind. Plaintiffs claim this violates Medicaid's comparability requirement that states provide an equal "amount, duration, [and] scope" of medical assistance to all categorically-needy. *See* **42 U.S.C. § 1396a(a)(10)(B)(i)**; **42 C.F.R. §§ 440.240(a)**, **(b)(1)**; ***Hogan***, 457 U.S. at 573 n.6; ***White v. Beal***, 555 F.2d 1146, 1149 (3d Cir. 1977). As the comparability mandate prevents discrimination against or among the categorically needy, it applies equally to mandatory and optional medical services. *See* ***Smith v. Rasmussen***, 249 F.3d 755, 757-59 (8th Cir. 2001); ***Rodriguez v. City of New York***, 197 F.3d 611, 615 (2d Cir. 1999) ("states may not provide benefits to some categorically needy individuals but not to others").

The district court found that the DME regulation complies with Medicaid's comparability requirement, primarily because Missouri had a comparability waiver pending with CMS. The record has significantly changed. CMS denied the waiver. The Director of Social Services and the Missouri Attorney General represent to this court that Missouri has now deleted the part of its state plan that calls for federal funding of additional services to the blind. As the current state plan provides an equal amount, duration, and scope of DME services to all categorically-needy recipients, and Missouri uses only state funding to provide additional DME services to the blind, the State contends that its program is consistent with the comparability requirement.

While a state plan must comply with all federal statutory and regulatory requirements, a state may give additional medical assistance under its own legislation, independent of federal reimbursement. *See* ***Harris v. McRae***, 448 U.S. 297, 311 n.16 (1980) ("A participating State is free, if it so chooses, to include in its Medicaid plan those medically necessary abortions for which federal reimbursement is unavailable"); ***Townsend v. Swank***, 404 U.S. 282, 291 (1971) (Burger, J., concurring) (noting that the proper inquiry is whether the state has used federal funds in support of its cooperative aid program); ***Rosado v. Wyman***, 397 U.S. 397, 420 (1970) (states are "in no way prohibited from using only state funds" to fund an independent plan, providing it does not violate the Constitution); ***Neb. Health Care Ass'n, Inc. v. Dunning***, 778 F.2d 1291, 1294 (8th Cir. 1985) ("the state had no right to put this [non-compliant] portion of its plan into effect, unless, of course, it chose to do so solely with its own funds"); ***Winters v. Lavine***, 574 F.2d 46, 70 (2d Cir. 1978), *quoting* ***Dallas v. Lavine***, 358 N.Y.S.2d 297, 302 (N.Y. Sup. Ct. 1974).

As Missouri represents to this court that it does not accept federal assistance, and uses only state funds, to provide additional DME benefits to blind Medicaid recipients, this court finds that the DME regulation (as currently funded) does not violate the federal comparability requirement.

B. Reasonable Standards

Plaintiffs next allege that the DME regulation violates Medicaid's requirement that the state create reasonable standards for determining the extent of medical assistance under the plan, which are consistent with Medicaid's objectives. **42 U.S.C. § 1396a(a)(17)**. *See* ***Wis. Dep't of Health & Family Servs. v. Blumer***, 534 U.S. 473, 479 (2002). While a state has considerable discretion to fashion medical assistance under its Medicaid plan, this discretion is constrained by the reasonable-standards requirement. *See* ***Beal v. Doe***, 432 U.S. 438, 444 (1977); ***Weaver v. Reagan***, 886 F.2d 194, 197 (8th Cir. 1989) (interpreting the reasonable-standards provision to require states to provide "medically necessary" treatment to comply with Medicaid's objectives). Each service the state elects to provide "must be sufficient in amount, duration, and scope to reasonably achieve its purpose." **42 C.F.R. § 440.230(b)**. Additionally, a state "may not arbitrarily reduce the amount, duration, or scope of a required service . . . solely because of the diagnosis, type of illness, or condition." ***Id.* § 440.230(c)**.

While optional DME programs are not explicitly subject to these requirements, CMS (the agency that administers Medicaid) maintains that the reasonable-standards provisions apply to all forms of medical assistance, including a state's provision of DME. *See* ***Slekis v. Thomas***, 525 U.S. 1098, 1099 (1999) (remanding based on September 4, 1998, CMS letter to state Medicaid directors, which advised that DME is subject to the federal reasonable-standards requirements). *See also* ***St. Mary's Hosp. of Rochester v. Leavitt***, 416 F.3d 906, 914 (8th Cir. 2005); ***Cmty. Health Ctr. v. Wilson-Coker***, 311 F.3d 132, 138 (2d Cir. 2002) (according "considerable deference" to CMS's interpretations due to the "complexity of the statute and the considerable expertise of the agency"), *citing* ***Wis. Dep't of Health & Family Servs.***, 534 U.S. at 479.

Plaintiffs argue that the limited DME services in the Missouri regulation are inconsistent with these mandatory reasonableness requirements, because they discriminate on the basis of diagnosis, do not provide a sufficient amount of DME services to meet Medicaid's objectives, and fail to establish a procedure for recipients to obtain non-covered DME items. Citing conflicts between the Missouri regulation and the federal reasonable-standards requirements, they also contend that the state regulation is preempted under the Supremacy Clause. The district court did not address these arguments, focusing solely on comparability.

1.

Plaintiffs' discrimination argument is very similar to their comparability claim, as it is based on the provision of additional DME services to blind recipients. Specifically, they contend that the regulation is facially unreasonable, because it discriminates on the basis of a medical condition or diagnosis – blindness – in violation of 42 C.F.R. § 440.230(c).

Like plaintiffs' comparability claim, this argument is foreclosed by Missouri's recent amendment to its plan. Because the State represents that it is independently funding the provision of additional DME services to the blind, the amended plan complies with the federal regulation. *See, e.g.,* ***Neb. Health Care Ass'n***, 778 F.2d at 1294. Thus, Missouri's DME regulation cannot be enjoined on this basis.

2.

The State asserts that there is no individualized federal right to reasonable Medicaid standards, enforceable under 42 U.S.C. § 1983. *See, e.g.,* ***Gonzaga Univ. v. Doe***, 536 U.S. 273, 283-84 (2002). The State raised this argument to the district court in a motion to dismiss the complaint for lack of jurisdiction and failure to state a claim, which the district court denied. The State concedes that it did not raise this

issue in its appellee's brief, because the denial of a motion to dismiss is generally not subject to immediate appeal. *See* ***Prescott v. Little Six, Inc.***, 387 F.3d 753, 755 (8th Cir. 2004); **28 U.S.C. § 1291** (only final orders are immediately appealable). The State also appears to acknowledge that this is not a jurisdictional issue that may be raised at any time. *See* ***Angela R. v. Clinton***, 999 F.2d 320, 324 (8th Cir. 1993). *See also* ***Price v. City of Stockton***, 390 F.3d 1105, 1108 (9th Cir. 2004); ***Rodriguez v. DeBueno***, 175 F.3d 227, 233 (2d Cir. 1999) (noting that the issue "is more aptly viewed as a question of whether the plaintiffs have failed to state a claim upon which relief may be granted").

The State argues that, because this legal issue decreases the likelihood that plaintiffs will succeed on the merits of their reasonable-standards claim, it is reviewable by this court. As this issue directly affects plaintiffs' probability of success – a critical factor in whether a preliminary injunction should issue – and the district court did not discuss this claim in denying the injunction, this court agrees. *See, e.g.*, ***S. Camden Citizens in Action v. N.J. Dep't of Envtl. Protection***, 274 F.3d 771, 777, 790-91 (3d Cir. 2001) (reversing preliminary injunction where plaintiffs had no private right of action).

For legislation enacted pursuant to Congress's spending power, like the Medicaid Act, a state's non-compliance typically does not create a private right of action for individual plaintiffs, but rather an action by the federal government to terminate federal matching funds. *See* ***Pennhurst State Sch. & Hosp. v. Halderman***, 451 U.S. 1, 28 (1981). While the Supreme Court has rarely found enforceable rights in spending clause legislation, it has not foreclosed the possibility that individual plaintiffs may sue to enforce compliance with such legislation. *See* ***Wright v. City of Roanoke Redevelopment & Hous. Auth.***, 479 U.S. 418, 430 (1987) (Federal Housing Act supports a cause of action under section 1983); ***Wilder v. Va. Hosp. Ass'n***, 496 U.S. 498, 510 (1990) (Medicaid providers had an individual right to reasonable reimbursement rates under the now-repealed Boren Amendment). Still, the Court has

since limited the circumstances where a private right of action is found under section 1983. *See* ***Suter v. Artist M.***, 503 U.S. 347, 363 (1992) (no private right of action under the Adoption Assistance and Child Welfare Act, which requires states to make "reasonable efforts" to keep children out of foster homes); ***Blessing v. Freestone***, 520 U.S. 329, 344-45 (1997) (no private right of action under Title IV-D of the Social Security Act, which requires states to "substantially comply" with requirements designed to ensure timely payment of child support); ***Gonzaga***, 536 U.S. at 290 (no private right of action under the Family Educational Rights and Privacy Act, which prohibits federal funding of educational institutions that have a policy of releasing confidential records to unauthorized persons).

A three-part test determines whether Spending Clause legislation creates a right of action under 42 U.S.C. § 1983: (1) Congress intended the statutory provision to benefit the plaintiff; (2) the asserted right is not so "vague and amorphous" that its enforcement would strain judicial competence; and (3) the provision clearly imposes a mandatory obligation upon the states. ***Blessing***, 520 U.S. at 340-41. If the legislation meets this test, there is a presumption it is enforceable under section 1983. ***Id.*** at 341. The presumption is rebutted if Congress explicitly or implicitly forecloses section 1983 enforcement. ***Id.*** (noting that implied foreclosure occurs if Congress creates "a comprehensive enforcement scheme that is incompatible with individual enforcement"). The availability of administrative mechanisms alone, however, cannot defeat the plaintiff's ability to invoke section 1983, so long as the other requirements of the three-part test are met. *See* ***id.*** at 347.

In *Gonzaga University v. Doe*, the Supreme Court clarified the first prong, holding that "anything short of an unambiguously conferred right" does not support an individual right of action under section 1983. ***Gonzaga***, 536 U.S. at 283. As section 1983 enforces "rights," as opposed to "benefits" or "interests," the statutory language must clearly evince an intent to individually benefit the plaintiff. ***Id.*** at 284 ("where a statute does not include this sort of explicit 'right- or duty-creating language'

we rarely impute to Congress an intent to create a private right of action"). Accordingly, the statute must focus on an individual entitlement to the asserted federal right, rather than on the aggregate practices or policies of a regulated entity, like the state. ***Id.*** at 287-88.

Medicaid's reasonable-standards requirement provides that a state Medicaid plan must "include reasonable standards . . . for determining eligibility for and the extent of medical assistance under this plan." **42 U.S.C. § 1396a(a)(17)**. Like the Ninth Circuit – the only other circuit to address this issue – this court finds the statutory language insufficient to evince a congressional intent to create individually-enforceable federal rights. *See* ***Watson v. Weeks***, 436 F.3d 1152, 1162 (9th Cir. 2006). First, the statute is not phrased in terms of the individuals it intends to benefit, as it lacks any reference to "individuals" or "persons." ***Id.*** (noting this omission is "fatal under *Gonzaga* to the existence of a section 1983 right"), *citing* ***Gonzaga***, 536 U.S. at 284. Rather than focusing on an individual entitlement to medical services, the reasonable-standards provision focuses on the aggregate practices of the states in establishing reasonable Medicaid services. *See, e.g.*, ***Gonzaga***, 536 U.S. at 287-88. This is insufficient to establish an individual right to reasonable standards under the first prong of the three-part test.

Even if the statute referenced the individuals benefitted, "the right it would create is too vague and amorphous for judicial enforcement." ***Watson***, 436 F.3d at 1162. The reasonable-standards provision focuses on the income/resources of potential beneficiaries, as the statute orders the states to base Medicaid eligibility on financial need. *See* ***id.*** at 1163 (Congress provided "no meaningful instruction for the interpretation of 'reasonable standards' in terms of medical need"). The only guidance Congress provides in the reasonable-standards provision is that the state establish standards "consistent with [Medicaid] objectives" – an inadequate guidepost for judicial enforcement. *See* ***id.*** As the statute sets forth only broad, general goals, which the states have broad discretion to implement, this court holds that plaintiffs do

not have a private right of action to enforce Medicaid's reasonable-standards provision under section 1983.

3.

Plaintiffs claim that the Missouri DME regulation is preempted by the Supremacy Clause, because it directly conflicts with Medicaid's reasonable-standards requirements. **U.S. Const. Art. VI, cl. 2**. The Supremacy Clause is not the direct source of any federal right, but "secures federal rights by according them priority whenever they come in conflict with state law." ***Golden State Transit Corp. v. City of Los Angeles***, 493 U.S. 103, 107 (1989), *quoting* ***Chapman v. Houston Welfare Rights Org.***, 441 U.S. 600, 613 (1979). Preemption claims are analyzed under a different test than section 1983 claims, affording plaintiffs an alternative theory for relief when a state law conflicts with a federal statute or regulation. ***Id.*** at 108 ("it would obviously be incorrect to assume that a federal right of action pursuant to § 1983 exists every time a federal rule of law preempts state regulatory authority"); ***id.*** at 108 n.4 ("a Supremacy Clause claim based on a statutory violation is enforceable under § 1983 only when the statute creates 'rights, privileges, or immunities' in the particular plaintiff"); ***id.*** at 117 ("Preemption concerns the federal structure of the Nation rather than the securing of rights, privileges and immunities to individuals").

Under the preemption doctrine, state laws that "interfere with, or are contrary to the laws of congress, made in pursuance of the constitution" are preempted. ***Wis. Pub. Intervenor v. Mortier***, 501 U.S. 597, 604 (1991), *quoting* ***Gibbons v. Ogden***, 22 U.S. 1, 9 (1824). Where Congress has not expressly preempted or entirely displaced state regulation in a specific field, as with the Medicaid Act, "state law is preempted to the extent that it actually conflicts with federal law." ***Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n***, 461 U.S. 190, 203-04 (1983). An actual conflict arises where compliance with both state and federal law is a "physical impossibility," or where the state law "'stands as an obstacle to the accomplishment

and execution of the full purposes and objectives of Congress.'" ***Id.***, *quoting* ***Fla. Lime & Avocado Growers, Inc. v. Paul***, 373 U.S. 132, 142-43 (1963) *and* ***Hines v. Davidowitz***, 312 U.S. 52, 67 (1941). While Medicaid is a system of cooperative federalism, the same analysis applies; once the state voluntarily accepts the conditions imposed by Congress, the Supremacy Clause obliges it to comply with federal requirements. *See* ***Jackson v. Rapps***, 947 F.2d 332, 336 (8th Cir. 1991) (applying conflict preemption doctrine to state AFDC law, analogous to Medicaid's system of cooperative federalism). *See also* ***King v. Smith***, 392 U.S. 309, 316, 326-27 (1968); ***Planned Parenthood of Houston & Se. Tex. v. Sanchez***, 403 F.3d 324, 337 (5th Cir. 2005) ("once a state has accepted federal funds, it is bound by the strings that accompany them").

In this case, plaintiffs claim that Missouri's DME regulation conflicts with the federal regulations that implement Medicaid's reasonable-standards requirement. *See* **42 C.F.R. § 440.230(b)**. "Federal regulations can preempt state laws . . . if the agency, acting within the scope of its delegated authority, intends them to." ***Wuebker v. Wilbur-Ellis Co.***, 418 F.3d 883, 887 (8th Cir. 2005) (applying the same conflict-preemption analysis), *citing* ***Chapman v. Lab One***, 390 F.3d 620, 624-25 (8th Cir. 2004). As with their section 1983 claim, plaintiffs allege that the state regulation is unreasonable, because it does not provide a sufficient amount of DME services to meet Medicaid's basic objectives and fails to establish a procedure for recipients to obtain non-covered DME items. Importantly, these arguments differ from those involving claims of discrimination, as they do not facially attack the provision of additional DME services to the blind as compared to other adult Medicaid recipients. Rather, they allege that the limited list of DME items that the state provides to all Medicaid recipients – with the assistance of federal funding – is so limited that it fails Medicaid's objectives. The district court did not address these claims.

When a state receives federal matching funds, its medical assistance program must comply with all federal statutory and regulatory requirements. *See* ***Meyers v.***

***Reagan***, 776 F.2d 241, 243-44 (8th Cir. 1985). *See also* ***Blum v. Bacon***, 457 U.S. 132, 145-46 (1982). Missouri admits that, with the exception of DME services to the blind, it accepts federal matching funds to finance its DME program for adult Medicaid recipients. *See* **69 Fed Reg. 68370**, 68372 (Nov. 24, 2000) (61.93 cents in federal funding is appropriated for each dollar Missouri spends on medical assistance under its state plan). Accordingly, the federally-funded DME program must comply with Medicaid's reasonable-standards requirement, and its implementing regulations.

Missouri's amended plan includes only three categories of "prosthetic devices" available to all adult Medicaid recipients: ostomy supplies, oxygen and respiratory equipment, and wheelchairs.[3] The DME regulation says that adult Medicaid recipients are also entitled to diabetic supplies and equipment, but not artificial larynxes, CPAPs, BiPAPs, IPPB machines, humidification items, suction pumps, apnea monitors, wheelchair accessories, or scooters. **Mo. Code Regs. Ann. tit. 13, § 70-60.010(6)** (2005). Plaintiffs argue that these limitations make Missouri's amended Medicaid plan unreasonable in light of the purposes of Medicaid. *See* **42 U.S.C. §§ 1396, 1396a(a)(17)**; **42 C.F.R. § 440.230(b)**.

Plaintiffs contend that the limited DME items available to all adult Medicaid recipients are insufficient in amount and scope to reasonably achieve the purpose of the DME program. *See* **42 C.F.R. § 440.230(b)**. For example, the regulation covers wheelchairs, but excludes funding for the batteries, filters, accessories, repairs, and other types of replacement parts necessary to keep the equipment functioning. It

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[3]The plan also provides that home parenteral nutrition services, electric wheelchairs, electric hospital beds, and back-up ventilators may be provided upon prior authorization. It is unclear whether these services are available to all Medicaid recipients, or only those who qualify for home health care. While neither party provides guidance on the implementation of this provision, the DME regulation appears to limit these services to home health care recipients. *See* **Mo. Code Regs. Ann. tit. 13, § 70-60.010(6)** (2005).

covers oxygen and other limited respiratory equipment, but not other equipment, such as suction pumps, apnea monitors, and humidification devices that is medically necessary to assist in breathing. Moreover, the regulation completely excludes items like augmentative communication devices, catheters, and parenteral nutrition supplies. Given these limits, plaintiffs claim that the regulation does not meet Medicaid's goals of providing medically-necessary services, rehabilitation, or the capability of independence and self-care. *See* **42 U.S.C. § 1396**.

While a state has discretion to determine the optional services in its Medicaid plan, a state's failure to provide Medicaid coverage for non-experimental, medically-necessary services within a covered Medicaid category is both per se unreasonable and inconsistent with the stated goals of Medicaid. *See* ***Meusberger v. Palmer***, 900 F.2d 1280, 1282 (8th Cir. 1990) (organ transplants); ***Weaver***, 886 F.2d at 198 (AZT coverage), *citing* ***Beal***, 432 U.S. at 444-45; ***Meyers***, 776 F.2d at 243-44 (augmentative communication devices); ***Pinneke v. Preisser***, 623 F.2d 546, 548 n.2 (8th Cir. 1980) (transsexual reassignment surgery). Other courts agree. *See* ***Hern v. Beye***, 57 F.3d 906, 911 (10th Cir. 1995) (abortion); ***Dexter v. Kirschner***, 984 F.2d 979, 983 (9th Cir. 1992) (bone marrow transplants); ***White***, 555 F.2d at 1151-52 (eyeglasses). *Contra* ***Rodriguez***, 197 F.3d at 617 (state may exclude safety monitoring as part of optional personal care services, based on administrative concerns). Becaause Missouri has elected to cover DME as an optional Medicaid service, it cannot arbitrarily choose which DME items to reimburse under its Medicaid policy.

The State responds that pre-approved lists of DME are acceptable under Medicaid's reasonable-standards provisions. *See* **42 C.F.R. § 440.230(d)** (allowing utilization controls as a means of administrative convenience). While a state may use a pre-approved list, CMS has directed that the state must include specific criteria for the extent of DME coverage under the plan, and a mechanism for recipients to request timely reimbursement for non-covered, medically-necessary items. *See* **Letter from Sally K. Richardson**, Director of the Center for Medicaid and State Operations, to

State Medicaid Directors 1 (Sept. 1, 1998). According to CMS, a policy without a meaningful procedure for requesting non-covered items is inconsistent with the reasonable-standards requirement and the objectives of Medicaid. ***Id.*** While these requirements are not explicit in the federal Medicaid regulations, CMS's interpretation is entitled to considerable deference. *See* ***Slekis***, 525 U.S. at 1099 (relying on the September 4, 1998, letter to state Medicaid directors in remanding a DME case for consideration of CMS's instructions). *See also* ***St. Mary's Hosp.***, 416 F.3d at 914; ***Pharm. Research & Mfrs. Am. v. Thompson***, 362 F.3d 817, 821-22 (D.C. Cir. 2004); ***Rabin v. Wilson-Coker***, 362 F.3d 190, 197 (2d Cir. 2004) (according "some significant measure of deference" to CMS's statutory interpretation contained in letter to State Medicaid Directors).

The State contends that it meets these federal mandates, as all Medicaid recipients have two options for receiving non-covered DME items under the state Medicaid plan. First, recipients can qualify for home health care services, requiring necessary DME items to be provided. *See* **Mo. Code Regs. Ann. tit. 13, § 70-90.010(4)**. Second, recipients can seek reimbursement for non-covered items through the established exceptions process. *See* ***id.*** **§ 70-2.100**. Plaintiffs respond that neither option is a meaningful procedure for requesting non-covered items.

Plaintiffs aver – although the state questions – that they do not qualify for home health care under Missouri's plan, because it is available only to individuals who both require skilled-nursing services and are confined to the home. *See* ***id.*** **§§ 70-90.010(1)**. While the federal regulation requires that DME items be "suitable for use in the home," it does not mandate that an individual recipient be homebound or receive skilled-nursing services to receive DME as part of home health care. *See* **42 C.F.R. § 440.70(b)(3)**. In fact, CMS specifically instructs that a homebound requirement is an improper restriction for the provision of any home health care service. *See* **Letter from the Center for Medicaid and State Operations**, to State Medicaid Directors 1 (July 25, 2000), **Letter from James G. Scott**, Associate

Regional Administrator for Medicaid and Children's Health, to Gary Sherman, Director of the Missouri Department of Social Services 2 (Nov. 21, 2005) (Missouri may not institute a homebound requirement or mandate that recipients receive skilled nursing services to receive home health services). *See also* ***Skubel v. Fuoroli***, 113 F.3d 330, 337 (2d Cir. 1997) (home health care nursing services cannot be limited to the recipient's home).

As CMS recognizes, restricting home health care to the homebound "ignores the consensus among health care professionals that community access is not only possible, but desirable for individuals with disabilities." *See* **Letter from the Center for Medicaid and State Operations**, at 1. *See also* ***Olmstead v. L.C.***, 527 U.S. 581, 596-97 (1999) (noting the importance of community access for individuals with disabilities under the ADA). Missouri's regulation says that a recipient may still be considered homebound if he or she leaves the home infrequently or for short durations. *See* **Mo. Code Regs. Ann. tit. 13, § 70-90.010(3)**. However, this Missouri regulation – approved as part of the state plan in 2000 – is inconsistent with CMS's directive that any "homebound" requirement is specifically prohibited. CMS has directly told Missouri that its "homebound requirement . . . is out of compliance with CMS policy." **E-mail from Megan K. Buck**, Centers for Medicare and Medicaid Services, to Karen A. Lewis, Division of Medical Services Executive Assistant (April 5, 2006, 11:58:00 CST). *See also* **Letter from James G. Scott**, at 2; **Letter from the Center for Medicaid and State Operations**, at 1. Because no plaintiff appears to qualify for home health care under Missouri law, and Missouri's home health plan does not comply with CMS policy, the home-health option does not afford a meaningful opportunity to obtain non-covered DME items.

Plaintiffs also assert that Missouri's exceptions process does not provide them with an adequate mechanism to obtain non-covered DME items. To qualify for an exception, a Medicaid provider must demonstrate that: (1) the item is needed to sustain life; (2) the item will substantially improve the qualify of life for a terminally-

ill patient (3) the item is necessary as a replacement due to an act of nature; or (4) the item is necessary to prevent a higher level of care. **Mo. Code Regs. Ann. tit. 13, § 70-2-100(2)(J)**. Even if the provider makes this demonstration, "no exception can be made where requested items or services are restricted or specifically prohibited under state or federal law." ***Id.* § 70-2.100(1)**.

The State clarified the exceptions process for non-covered DME items in an August 29, 2005, notice to providers. The notice advises that the exceptions process is available to recipients with respiratory conditions who require use of pre-approved BiPAP, CPAP, or nebulizer machines, even though such items are technically prohibited under the revised DME regulation. *See* ***id.* § 70-60.010(6)** (2005). The notice also identifies as "not covered" other DME items, such as hospital beds, wheelchair batteries and repairs, and leg braces, and makes no reference to an available exception for them. As the regulation allows no exception for items that are restricted under state law – and the DME regulation specifically restricts all non-covered DME items – the exceptions process does not appear to provide a reasonable opportunity to obtain non-covered items.

Because the DME regulation restricts available DME, and plaintiffs have no other procedure to obtain it, the regulation – on the present record – appears unreasonable under directives from both CMS and this court. *See, e.g.*, ***Meusberger***, 900 F.2d at 1282. Plaintiffs have established a likelihood of success on the merits of their preemption claim as it relates to Medicaid's reasonable-standards requirement.

V.

Likelihood of success on the merits is only one of the four factors determining whether a preliminary injunction should issue. *See* ***Dataphase***, 640 F.2d at 114. The district court did not make findings on the other three factors regarding the reasonable-standards challenge. The district court is in the best position to evaluate

all of the evidence and weigh the factors to determine whether the injunction should issue. *See* ***Blue Moon Entm't, LLC v. City of Bates City***, 441 F.3d 561, 566 (8th Cir. 2006) (remanding denial of preliminary injunction to allow the district court to further develop the evidentiary record). This rule is especially relevant in this case, where many facts have changed since the original hearing, and it is unclear on the present record what DME items, if any, Missouri will cover for adult Medicaid recipients if the DME regulation is enjoined. Accordingly, this court vacates the order of the district court, and remands for further proceedings. *See* ***id.*** at 566 (vacating and remanding district court's denial of preliminary injunction where the court did not address critical *Dataphase* factors).

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