UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

HARRY DAVIS; RITA-MARIE GEARY; PATTY POOLE; and ROBERTA WALLACH, on behalf of themselves and all others similarly situated,	)	
Plaintiffs	)	
v.	)	12-CV-6134-CJS-MWP
NIRAV SHAH, individually and in his official capacity as Commissioner of the New York State Department of Health,	)	
Defendant	)	

RESPONSE MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT'S CROSS MOTION FOR SUMMARY JUDGMENT

EMPIRE JUSTICE CENTER, INC.
1 West Main Street, Suite 200
Rochester, New York 14614
Telephone: (585) 454-4060

Bryan Hetherington, Esq.
bhetherington@empirejustice.org

Jonathan Feldman, Esq.
jfeldman@empirejustice.org

Geoffrey Hale, Esq.
ghale@empirejustice.org

NATIONAL HEALTH LAW PROGRAM, INC.
101 East Weaver Street, Suite G-7
Carrboro, North Carolina 27510
Telephone: (919) 968-6308

Sarah Somers, Esq.
Pro Hac Vice
ssomers@healthlaw.org

Jane Perkins, Esq.
Pro Hac Vice
perkins@healthlaw.org

Counsel for Plaintiffs

PRELIMINARY STATEMENT

Plaintiffs Harry Davis, Rita-Marie Geary, Patty Poole, and Roberta (Bobbi) Wallach challenge Defendant Nirav Shah's policy of refusing to cover medically necessary orthopedic footwear and compression stockings. Plaintiffs – all of whom have disabilities and suffer from serious medical conditions – need compression stockings and orthopedic footwear to treat and remedy such serious conditions as transmetatarsal amputation, peripheral neuropathy, lymphedema, multiple sclerosis, and chronic venous insufficiency. Without these cost-effective treatments, Plaintiffs and plaintiff class members face potentially dire consequences. As clearly documented in the uncontested record of this case, lack of compression stockings and orthopedic footwear puts Plaintiffs at risk of serious infections that would require hospitalization and I.V. antibiotics for treatment; loss of limb as the result of uncontrolled, advancing infection; and unnecessary hospitalizations and institutionalization.

In the Complaint (Dkt. # 1), Motion for Preliminary Injunction (Dkt. # 3), and now their Motion for Summary Judgment (Dkt. # 26), Plaintiffs challenge Defendant Shah's policies. Specifically, Plaintiffs contend that Defendant's policy of providing medically necessary orthopedic footwear and compression stockings only for those Medicaid beneficiaries who suffer from one of the few medical conditions for which exceptions are statutorily provided violates federal Medicaid provisions requiring coverage of these services for all categorically needy Medicaid beneficiaries as a mandatory home health benefit and requiring the Defendant to adhere to reasonable standards and comparability requirements. Furthermore, the Defendant's failure to provide adequate written notices of denials of Plaintiffs' requests for medically necessary compression stockings and orthopedic footwear, including their right to request fair hearings to challenge the Defendant's action, violates Plaintiffs' rights to Due Process. And

finally, Defendant's policy places Plaintiffs at risk of unnecessary institutionalization in violation of the ADA and Section 504.

The Parties have agreed that there are no issues of material fact at stake in this litigation, but solely issues of law; and both Parties have now moved for Summary Judgment under Rule 56 of the Federal Rules of Civil Procedure. In the cross motion for Summary Judgment (Dkt. #28), Defendant Shah argues that he has chosen to cover compression stockings and orthopedic footwear exclusively as "optional" prosthetic services and that his diagnosis-based limitations on coverage are therefore "reasonable." Defendant further contends that Plaintiffs have no rights to hearings to challenge systematic changes in the Medicaid program, and implies further that Plaintiffs' individual rights to due process have been satisfied by public notice of broad changes to the state Medicaid program and the mere existence of the fair hearing process within the state Medicaid program. And finally, Defendant argues that there has been no violation of the ADA or Section 504, because there has been no "invidious discrimination," ignoring entirely the basis of Plaintiffs' claims in the integration mandates of these statutes. None of the Defendant's claims have any bearing on the laws or facts of this case and all are without merit.

ARGUMENT

I. Orthopedic Footwear and Compression Stockings Are Mandatory Medicaid Services Under the Federal Mandatory Home Health Benefit.

A. Federal Medicaid Law Requires Defendant to Cover Medically Necessary "Supplies, Equipment, and Appliances."

As Plaintiffs have established – and Defendant does not dispute – federal laws and regulations require States participating in the Medicaid program to provide home health services to "any individual who, under the State plan, is entitled to nursing facility services…." 42 U.S.C. § 1396a(a)(10)(D). In New York and other states, all categorically needy individuals are

entitled to nursing facility services and thus home health services. 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a); 42 C.F.R. §§ 440.70, 440.210(a)(1), and 441.15(b)(1). Under federal law, home health services are provided to the Medicaid recipient at his or her place of residence, and include "medical supplies, equipment, and appliances suitable for use in the home." 42 C.F.R. §§ 440.70(a)(1) and (b)(3); *see also* 42 C.F.R. § 441.15 ("a State Plan must provide that … the [state Medicaid] agency provides home health services to … Categorically needy recipients age 21 and over"); 42 C.F.R. § 440.210 ("a State Plan must specify that, at a minimum, categorically needy recipients are furnished … the services defined in … 440.70"); 42 C.F.R. §440.210(a)(1).

The Defendant seeks to avoid application of these laws by arguing that none of the named Plaintiffs are currently in receipt of home health care. Defendant's Mem. of L. at 4 (Dkt. # 28-1); McCloskey Aff. ¶ 49 (Dkt. # 28-3). However, this argument lacks merit. Federal law clearly obligates Medicaid participating states to cover home health services for recipients who are "entitled to" nursing facility care, not those who are "in receipt of" home health care. 42 U.S.C. §§ 1396a(a)(10)(A) and (D); 1396d(a); 42 C.F.R. §§ 440.70, 440.210(a)(1), and 441.15(b)(1). Indeed, numerous courts have required state Medicaid programs to cover medically necessary medical equipment and supplies for Medicaid recipients who are entitled to nursing facility services because they are categorically needy recipients (not because they are receiving home health). *See Koenning v. Suehs*, _ F. Supp. 2d _, 2012 WL 4127956, at *2 (S.D. Tex. Sept. 18, 2012) ("The provision of 'home health services'—which are medically-prescribed services provided to a Medicaid recipient at his or her place of residence-is a mandatory requirement for individuals who are entitled to nursing facility services."); *Hiltibran v. Levy*, 793 F. Supp. 2d 1108, 1115 (W.D. Mo. 2011) (citing 42 U.S.C. §§ 1396a(a)(10)(A) and 1396a(a)(10)(D) and

stating "[a]ll Medicaid recipients in Missouri are entitled to 'home health services' including '[m]edical supplies [and] equipment'"); *Conley v. Department of Health*, 287 P.3d 452, 459 (Utah Ct. App. 2012) (citing federal laws and noting home health services are mandatory for categorically needy recipients age 21 and over). *Accord, Davis v. Shah*, __ 2012 WL 1574944, at *6 (W.D.N.Y. May 3, 2012) ("Plaintiffs are entitled to nursing facility services, and therefore they are covered by § 1396a(a)(10)(D)").

Defendant covers nursing facility services for all Medicaid beneficiaries. McCloskey Affidavit, ¶ 15. Defendant must therefore also cover home health services for all Medicaid beneficiaries. As described more fully below, orthopedic footwear and compression stockings fall squarely within the federally required home health benefit, which must include medically necessary "[m]edical supplies, equipment, and appliances suitable for use in the home." 42 C.F.R. § 440.70(b)(3). Defendant must therefore cover compression stockings and orthopedic footwear as mandatory home health services.

B. Orthopedic Footwear and Compression Stockings are Durable Medical Equipment and Therefore Must Be Covered as a Mandatory Benefit.

The Defendant maintains that both orthopedic footwear and compression stockings are classified exclusively as optional "prosthetic" services and therefore are not subject to the federal mandatory home health requirement mandating coverage of "medical supplies, equipment, and appliances." *See* Defendant's Memorandum of Law at 7-8 (Dkt. # 28-1). Defendant's assertion, however, is directly contradicted by his own policies on these items. Defendant's regulations, written guidance to providers, and model contracts for Medicaid managed care organizations all clearly treat compression stockings and orthopedic footwear as Durable Medical Equipment (DME). As such, they fall squarely within the federal mandatory home health benefit and must therefore be covered by the Defendant.

In the first place, Defendant's own regulations contradict the contention that orthopedic footwear and compression stockings are categorized as "prosthetics" instead of DME. Defendant's policy for coverage of these items is laid out in 18 N.Y.C.R.R. § 505.5. Section 505 governs the provision of medical care in the Medicaid program in general, and § 505.5 in particular covers collectively the provision of "Durable medical equipment; medical/surgical supplies; orthotic and prosthetic appliances; orthopedic footwear." In defining coverage of various supplies, equipment, and appliances, section 505.5(a) distinguishes between "orthotic appliances and devices," "orthopedic footwear," and "prosthetic appliances and devices." Thus, on its face, the regulation distinguishes orthopedic footwear from any sort of "prosthetic appliances and devices" and contradicts Defendant's current attempt to redefine these items as optional "prosthetics."[1]

Secondly, Defendant's policy guidance to providers contradicts his contention that orthopedic footwear and compression stockings are "prosthetics." The collective treatment of these items as DME in Defendant's regulation is mirrored in the *Durable Medical Equipment Manual* (hereinafter "DME Manual"), which provides comprehensive directions to service providers on coverage of DME. The *DME Manual* covers what Defendant terms "DMEPOS." "DMEPOS, for the purpose of this section, means medical supplies, durable medical equipment, orthopedic footwear, prosthetic and orthotic appliances and devices." DME Manual at 2.[2] This combined treatment of DME is also reflected in the DME *Procedure Codes and Coverage Guidelines* upon which Defendant relies for the argument that both orthopedic footwear and

[1] There is no separate category for "prosthetics" as such within Defendant's regulation. Where prosthetics of any kind are discussed, the regulation clearly characterizes them as "appliances." They thus fall within the purview of 42 C.F.R. 440.70(b)(3) (requiring coverage of "[m]edical supplies, equipment, and appliances suitable for use in the home").

[2] https://www.emedny.org/ProviderManuals/DME/PDFS/DME_Policy_Section.pdf.

compression stockings should be categorized exclusively as "prosthetics." *See* McCloskey Aff., Exhibits B, C, D, and E (Dkt.# 28-3). These documents contradict the position Defendant now asserts in this litigation. Notably, orthopedic footwear appears nowhere under the heading "Prosthetics," and while some compression stockings codes appear in the prosthetics section (Dkt. # 28-3 at 68), others are included under the heading "Medical/Surgical Supplies."[3] Bick Aff. ¶ 35; McCloskey Aff. ¶ 45. Contrary to Defendant's assertion, neither orthopedic footwear nor compression stockings are exclusively categorized as "prosthetics." Rather, these items are variously subsumed within multiple subsections of Defendant's over-all DME policy.

Finally, Defendant's Model Contracts for Medicaid Managed Care and Managed Long Term Care also distinguish orthopedic footwear from prosthetics and contradict Defendant's assertion that they ought to be exclusively categorized as prosthetics for purposes of this litigation. These documents establish the standards and policies governing the Medicaid managed care program and Medicaid managed long-term care. As elsewhere, Defendant defines DME in the Managed Long Term Care contract as including "medical/surgical supplies, prosthetics and orthotics, orthopedic footwear, enteral and parenteral formula and hearing aid batteries." *See Managed Long Term Care Partial Capitation Contract,* Appendix J, Definitions at 94.[4] Similarly, the model contract for Medicaid managed care organizations explicitly distinguishes "prosthetics" from "orthotics" and "orthopedic footwear," and defines prosthetics exclusively as "those appliances or devices which replace or perform the function of any missing

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[3] Defendant asserts that his own categorization of these items is merely a matter of convenience and thus is not dispositive. *See* Bick Affidavit, ¶ 35; McCloskey Aff. ¶¶ 45, 46. If Defendant's categorization of these items is not dispositive when it comes to supplies, it also cannot be dispositive for their characterization as "prosthetics" for purposes of this case. These items may in fact reasonably be construed as all of these things – DME, appliances; supplies; as well as prosthetics.

[4] http://www.health.ny.gov/health_care/medicaid/redesign/docs/mrt90_partial_capitation_model.pdf.

part of the body [. . .]." *Medicaid Managed Care/Family Health Plus/HIV Special Needs Plan Model Contract*, Appendix K, Definitions, at K-29.[5] Clearly neither orthopedic footwear nor compression stockings "replace" any missing body part, and the Defendant's managed care contracts contradict his litigation position. *See Conley*, 287 P.3d at 467 (rejecting state's categorization of a device exclusively under one Medicaid services, noting the position appeared to be contrary to its own manuals).

Moreover, as Defendant correctly points out, the Centers for Medicare and Medicaid Services, the agency charged with implementing the Medicaid Act (hereinafter "CMS"), has proposed a definition of medical equipment and appliances for states participating in the Medicaid program. McCloskey Affidavit, ¶ 18:

> We propose that medical equipment and appliances are "items that are primarily and customarily used to serve a medical purpose, generally not useful to an individual in the absence of an illness or injury, can withstand repeated use, and can be reusable or removable."

Medicaid Program; Policy Changes Related to Home Health, 76 Fed.Reg. 41,032, 41,034 (July 12, 2011). By its own account, CMS intends this definition to ensure that these items are available under the state's entire Medicaid program under the home health benefit and to prevent states from instituting unwarranted restrictions on coverage such as providing them only through waiver programs or limiting availability to those who are "homebound." *Id.* CMS intends thus to "ensure beneficiaries are receiving needed items." *Id.*

Notably, the orthopedic footwear and compression stockings at issue here indisputably meet the proposed CMS definition: they serve a primarily medical purpose, are not useful in the absence of an illness or injury, can withstand repeated use, and can be reusable or removable. As

[5] http://www.health.ny.gov/health_care/managed_care/docs/medicaid_managed_care_fhp_hiv-snp_model_contract.pdf.

the *Conley* court says of speech augmentative devices, they "may legitimately qualify as DME […], and nothing in the Medicaid Act precludes them from so qualifying." 287 P.3d at 465. The same is true here and applies equally to compression stockings and orthopedic footwear.

Defendant never argues that orthopedic footwear and compression stockings do *not* satisfy the definition of medical equipment and appliances, insisting only that he can decide to consider these items exclusively as optional "prosthetics" and strictly limit coverage to only certain medical diagnoses. However, it is well settled that a needed medical service may fall within multiple Medicaid service categories – mandatory services and optional services the state has elected to cover – and that it must be covered if it does fall within one or more of those categories. *See, e.g.*, *Hern v. Beye*, 57 F. 3d 906, 910 (10th Cir. 1995) (finding abortion services fit within for different categories of medical services covered in the Medicaid program); *see also Fred C. v. Texas Health and Human Services Commission*, 924 F. Supp. 788, 791-92 (W.D. Tex. 1996); *Conley*, 287 P.3d at 467-68 (finding speech augmentation devices fall within mandatory home health and a number of optional service categories Texas had elected to cover and concluding that "[s]imply put" it was unreasonable and a violation of federal comparability requirements for Texas cover the devices by categorizing them exclusively as speech language pathology services and restrict their coverage by age). Simply put, Defendant Shah cannot pick and choose its categorization scheme simply to fit the response to litigation, and a position conjured solely for purposes of litigation should be rejected. *Id. See also Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212-13 (1988) (rejecting counsel's *post-hoc* rationalizations for agency action during ongoing litigation.

As DME, orthopedic footwear and compression stockings fall squarely within the federally defined home health benefit, which must include medically necessary "equipment,

supplies, and appliances." Orthopedic footwear and compression stockings are both clearly covered within the scope of Defendant's regulations regarding DME and are included in Defendant's DME Manual and Policy guidance. Defendant's own guidance on DME always distinguishes orthopedic footwear in particular from "prosthetics" and directly contradicts Defendant's attempt to redefine these items as "prosthetics" for purposes of this litigation. Defendant must therefore include coverage of orthopedic footwear and compression stockings within the home health benefit of the New York State Medicaid program.

II. Denial of Medically Necessary Orthopedic Footwear and Compression Stockings Without an Individualized Exceptions Process Violates the "Reasonable Standards" Requirement of the Medicaid Act.

"Once a state offers an optional service, it must comply with all federal statutory and regulatory mandates." *Lankford v. Sherman*, 451 F. 3d 496, 504 (8th Cir. 2006); *Schweiker v. Gray Panthers*, 453 U.S. 34, 37 (1981) (Medicaid-participating states "must comply with requirements imposed both by the Act itself and by the Secretary of Health and Human Services"). *See also Bontrager v. Indiana Family and Social Services Administartion*, __ F. 3d __, 2012 WL 4372524 at *4 (7th Cir. 2012) ("a state is required to cover all medically necessary treatments in those service areas in which the state opts to provide coverage"); *Doe v. Chiles*. 136 F.3d 709, 714 (11th Cir. 1998) (covered optional services are subject to federal requirements); *Hern v. Beye*, 57 F. 3d 906, 911 (10th Cir. 1995); *Weaver v. Reagan*, 886 F. 2d 194, 197 (8th Cir. 1989); *Eder v. Beal*, 609 F.2d 695, 702 (3d Cir. 1979); *Hunter v. Chiles*, 944 F. Supp. 914, 919 (S.D.Fla. 1996). The Medicaid Act limits state discretion by requiring states 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 Dept. of Health and Family Serv. v. Blumer*, 534 U.S. 473, 479 (2002);

Schweiker, 453 U.S. at 36-37; *Herweg v. Ray*, 455 U.S. 265 (1982); *Sai Kwan Wong v. Doar*, 571 F. 3d 247, 251 (2d Cir. 2009). *See also Lankford*, 451 F. 3d at 506 (8th Cir. 2006) (while "a state has considerable discretion to fashion medical assistance under its Medicaid plan, this discretion is constrained by the reasonable-standards requirement").

Medicaid regulations provide that states "may not arbitrarily deny the amount, duration, and scope of a required service … solely because of the diagnosis, type of illness, or condition." 42 C.F.R. § 440.230(c). *See Lankford*, 451 F. 3d at 511) (citing cases) ("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"); *Hern*, 57 F. 3d at 910-11 (state agency cannot deny abortion coverage for qualified women who are victims of rape or incest); *Preterm, Inc. v. Dukakis*, 591 F. 2d 121, 126, 131 (1st Cir. 1979) (abortion services only to prevent the death of the mother violate the reasonableness requirement); *Zbaraz v. Quern*, 596 F. 2d 196, 199 (7th Cir. 1979) (concurring with *Preterm*); *Koennig v. Suehs*, __ F. Supp. 2d __, 2012 WL 4127956 (S.D.Tex. 2012) (categorical denials of coverage for wheelchairs with integrated standing features violates the reasonable standards requirement); *Hiltibran*, 793 F. Supp. 2d at 1115 (denial of non-experimental, medically necessary DME violates Medicaid's reasonable standards requirement); *Esteban v. Cook*, 77 F. Supp. 2d 1256, 1257 (S.D.Fla. 1999) (categorical exclusion of motorized wheelchairs for persons age 21 and over violates the reasonable standards requirement), *Fred C.*, 988 F. Supp. at 1033, *aff'd without opinion*, 167 F.3d 537 (5th Cir. 1998) (striking down exclusion from coverage of augmentative communication devices for people over the age of 21 in violation of the reasonable standards requirement); *Conley*, 287 P.3d at 459 (holding it was unreasonable for a state to opt into the various categories in which speech augmentative devices could be categorized for all

categorically and medically needy individuals, including prosthetics and communication equipment, but then limit its obligation to provide coverage of the devices by the age of the recipient by categorizing them only as "speech language pathology services").

Defendant covers compression stockings and orthopedic footwear for categorically needy and medically needy Medicaid beneficiaries. 18 N.Y.C.R.R. § 505.5(g)(1) and (2). *See also* McCloskey Affidavit, ¶¶ 7, 8, 15. Compression stockings are available only for pregnant women and beneficiaries with venous stasis ulcers, and orthopedic footwear is covered only for children under 21 years of age, people with diabetes, and for footwear attached to a prosthetic brace.[6] *Id.*; Def. Rule 56 Statement, ¶¶ 4, 5, 8, 9, 13, 14. Thus, Defendant must comply with the requirements of the federal Medicaid Act and abide by the reasonable standards requirement in its coverage of these items. However, Defendant's policy regarding coverage of compression stockings and orthopedic footwear only for those few Medicaid beneficiaries who meet one of the limited coverage categories based solely on diagnosis and condition clearly violates 42 C.F.R. § 440.230(c). The challenged statute and policies are therefore unreasonable, especially where, as here, Defendant explicitly withholds the availability of any other exception for those who need these items. 18 N.Y.C.R.R. § 505.5(g).

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[6] Beyond violating the reasonable standards requirement by providing diagnosis- and condition-based exceptions, Defendant further violates the reasonable standards requirement by providing coverage for orthopedic footwear on the basis of age. Courts routinely strike down benefit limits arbitrarily based on age as unreasonable. *See, e.g.*, *Hiltibran*, 793 F. Supp. at 1114 (denial of incontinence supplies to those age 21 and older violates the reasonable standards requirement); *Esteban*, 77 F. Supp.2d at 1262 (categorical limit on wheelchairs based on cost only for adults is unreasonable); *Fred C.*, 988 F. Supp. at 1036 (denial of speech augmentation devices to individuals age 21 and older "cannot meet the fundamental legal concept of reasonableness"); *Hunter v. Chiles*, 944 F. Supp. 914, 920 (S.D.Fla. 1996) ("This court concludes that there is not a rational basis to provide speech to one who is twenty years three hundred sixty-four days and deny the same to one who is two days older"; *Conley*, 287 P.3d 452 (holding refusal to cover speech augmentative devices to non-pregnant individuals age 21 and older violates the reasonable standards and comparability requirements).

III. Defendant Concedes that Denial of Compression Stockings and Orthopedic Footwear to Some – But Not All – Medicaid Beneficiaries Violates the Comparability Requirement.

The Medicaid Act requires that "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)(i). As described more fully in the Memorandum of Law in Support of Plaintiffs' Motion for Summary Judgment, this requirement is generally held to mean that medical services provided for any of the categorically needy cannot be less in amount, duration, and scope, than those provided to any other categorically needy beneficiary. Plaintiffs' Memorandum at 18-20 (Dkt. # 26-2). *See, e.g.*, *Schweiker*, 457 U.S. at 573 n. 6. All categorically needy individuals must be treated equally within the Medicaid program and services made available to some of the categorically needy cannot be denied other categorically needy individuals.[7]

In this case, Defendant Shah refuses coverage of medically necessary compression stockings and orthopedic footwear to some categorically needy beneficiaries while also providing coverage for these same items to other categorically needy Medicaid beneficiaries who happen to meet one of the limited diagnosis-based exceptions. Defendant's policy thus violates the comparability requirement of the federal Medicaid Act and Defendant does not contest Plaintiffs' claims under the comparability requirement.[8]

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[7] The statute is broader still in its prohibition of unequal treatment. Services provided to the medically needy cannot be withheld from any of the categorically needy. 42 U.S.C. § 1396a(a)(10)(B)(ii). Defendant also provides compression stockings and orthopedic footwear to medically needy beneficiaries who meet the available exceptions while denying them to categorically needy beneficiaries who do not. McCloskey Aff. ¶¶ 7, 8.

[8] Because Defendant does not contest the alleged violations of the federal comparability requirement, he also does not refute that 42 U.S.C. § 1396a(a)(10)(B) creates a private right of action enforceable under § 1983. *See* Plaintiffs' Memorandum of Law in Support of Summary Judgment at 20. (Dkt. # 26-2).

IV. Defendant Shah's Refusal to Cover Medically Necessary Orthopedic Footwear and Compression Stockings for Some – But Not All – Medicaid Beneficiaries Without Any Process for Requesting an Exception Violates Federal Guidance on the Reasonable Standards Requirement.

As described in Plaintiffs' Memorandum of Law in Support of Summary Judgment, the Second Circuit Court of Appeals once held that it was permissible for the Connecticut Medicaid program to maintain "exclusive lists" of medical equipment, and thereby deny individual recipients coverage of medically necessary DME. *DeSario v.Thomas*, 139 F. 3d 80 (2d Cir. 1998). *See* Memorandum of Law in Support of Plaintiffs' Motion for Summary Judgment, at 17-18. In response to this decision, the Health Care Financing Administration of the federal Department of Health and Human Services (now CMS), issued a *Dear State Medicaid Director* letter explaining the appropriate DME policy for state Medicaid programs (hereinafter "*DeSario* Letter").[9] On the basis of this agency guidance, the Supreme Court vacated the *DeSario* decision and remanded the case for further consideration in light of the CMS guidance. *See Slekis v. Thomas*, 523 U.S. 1098 (1999), *vacating and remanding, DeSario v. Thomas*, 139 F. 3d 80 (2d Cir. 1998).

The *DeSario* Letter interprets the reasonable standards requirement to mean that states must provide an exceptions process whereby an "individual" Medicaid beneficiary may receive coverage for medical equipment (ME) the state has otherwise chosen not to cover. "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 […]." *Id.* Moreover, "the process for seeking modifications or exceptions 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)."

[9] *See*, CMS, *Dear State Medicaid Director* (Sept. 4, 1998), at http://www.cms.gov.hhs.gov/states/letters/smd90498.asp

Id. (emphasis added). The *DeSario* Letter sets out three criteria which all states' medical equipment policies must meet:

> [A] State will be in compliance with 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. These criteria must be sufficiently specific to permit a determination of whether an item 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*.
> - The State's process and criteria, as well as the State's list of pre-approved items, are *made available to beneficiaries and the public*.
> - Beneficiaries are informed of their right, under 42 C.F.R. Part 431 Subpart E, to a fair hearing to determine whether an adverse decision is contrary to the law […].

Id. (emphasis added).

Defendant Shah argues that the state policy on compression stockings and orthopedic footwear does in fact comply with the *DeSario* Letter. Defendant's Memorandum of Law at 9, 11-12 (Dkt. # 28-1). Defendant erroneously contends that the *DeSario* Letter only prohibits states from applying a "Medicaid population as a whole" test for coverage determinations. While rejection of the "Medicaid population as a whole" test is certainly part of the *DeSario* Letter, the individualized exceptions process that CMS requires states to employ is more specific. It requires states (1) to have a timely and reasonable exceptions process that employs specific criteria; (2) to make this process and its criteria available both to beneficiaries and to the public; and (3) to inform the beneficiaries of their right to a fair hearing in the event of an adverse determination. Defendant Shah is in compliance with none of these requirements.

The Defendant maintains that an exceptions process is available, because it is hinted at in 18 N.Y.C.R.R. § 505.5(d)(1)(vi). Defendant's Memorandum at 11. Subsection (d)(1), however, refers only to the state's general payment policy for coverage of durable medical equipment,

medical/surgical supplies, orthotic and prosthetic appliances and devices, and orthopedic footwear. Under this heading, subparagraph (vi) covers "reimbursement amounts for unlisted items[…]." The general availability of payment to providers does not constitute an exceptions process available to individual beneficiaries as required by CMS. Defendant does not address the remaining two requirements of the CMS guidance. He does not argue that the exceptions process and its criteria have been made available to the public and to Medicaid beneficiaries specifically. And he accepts without contest the fact that beneficiaries are not notified of their right to request a fair hearing in the event of an adverse determination regarding coverage of their medically necessary compression stockings and orthopedic footwear. Defendant's Rule 56 Statement, ¶¶ 50, 66, 67, 80, 107; McCloskey Aff. ¶ 60.

V. Defendant's Failure to Provide Plaintiffs Notice and Hearings in Regard to Compression Stockings and Orthopedic Footwear Violates Plaintiffs' Rights to Due Process.

Defendant Shah contends that Plaintiffs have no due process rights to notice and a hearing in order to challenge systematic changes to the state Medicaid program. The cases upon which Defendant relies, however, do not support this contention and in fact support the applicability of the Constitutional mandate as defined in *Goldberg v. Kelly*, 397 U.S. 254 (1970), and incorporated into federal Medicaid regulations, 42 C.F.R. § 431-205(d).[10]

In *Rosen v. Goetz*, 410 F. 3d 919 (6th Cir. 2005), Tennessee proposed eliminating certain waiver categories from its Medicaid program in their entirety and without exception. Contrary to

[10] Defendant cites three cases in his argument: *Knapp v. Armstrong*, 2012 WL 640890, 5 (D. Idaho); *M.R. v. Dreyfus*, 767 F. Supp. 2d 1149, 1166-67 (W.D. Wash. 2011), *rev'd*, 697 F. 3d 706 (9th Cir. 2012); and *Rosen v. Goetz*, 410 F. 3d 919 (6th Cir. 2005). To the extent that the two District Court decisions rely on *Rosen v. Goetz* for the availability of hearing rights in certain circumstances, the discussion above will focus on *Rosen* and its applicability to the facts of this case. The District Court cases do not expand the holding in *Rosen*, and *M.R. v. Dreyfus* has been reversed.

Defendant's assertion, the *Rosen* court found that the state's procedures in implementing these systematic changes to its Medicaid program *did* comply with *Goldberg v. Kelly* and the due process requirements of the Medicaid Act. *Rosen* differs from this case in two significant respects: (1) Tennessee's proposed change included no exceptions based in the factual circumstances of those affected by the state's decision; and (2) Tennessee did provide notices and made hearings available to beneficiaries to challenge the decisions in their cases. Tennessee proposed sending three separate notices to Medicaid beneficiaries affected by proposed waiver changes: A Request for Information (RFI), a Verification Request, and a Termination Notice. *Id.* at 923. The RFI advised beneficiaries that their coverage was ending and that they might be eligible under a different category of Medicaid coverage. The RFI also included enrollment forms and information on other categories of Medicaid coverage for which affected beneficiaries might be eligible. If the beneficiary failed to provide the information within 30 days, the State would then send a second notice, the Verification Request, advising beneficiaries of the possible availability of other Medicaid coverage and providing an additional 10 days submit requested information. Termination notices would then be sent only to those who were actually found to be ineligible for Medicaid coverage under a separate category and to those who failed to respond to the initial RFI. The Termination Notice would be sent 20 days prior to any change in coverage and provided information on the availability of fair hearings to resolve any factual disputes, as well as information on the availability of aid continuing pending the outcome of the hearing. *Id.* The *Rosen* court found that Tennessee's procedures fully complied with Plaintiffs' Constitutional rights to due process in providing both notices and hearings. Hearing rights – as opposed to notice rights – were limited only in situations involving no factual dispute but solely challenged the change in law, as required in 42 C.F.R. § 431.220(b).

Defendant, thus, correctly states the *Rosen* court as holding that hearing rights are not available to challenge changes in state law "that involve[] no factual dispute." Defendant's Memorandum at 13. Contrary to Defendant's argument, that assertion *requires* hearings in this case: where the state provides factual diagnosis-based exceptions to the otherwise absolute prohibition against coverage, Plaintiffs and plaintiff class members must be informed of the availability of these exceptions; they must also be given the opportunity to challenge Defendant's actions and argue that they, in fact, meet one or more of the available exceptions under which coverage is available. Defendant's actions, however, offer Plaintiffs no recourse: without notice they have no hearing rights.[11] *See, e.g., Washington v. DeBeaugrine*, 658 F. Supp. 2d 1332, 1335 (N.D. Fla. 2009) (finding that right to hearing arises with allegation that agency committed factual error).

Defendant accepts without contest the fact that none of the Plaintiffs received notice of changes in their coverage. Defendant's Rule 56 Statement, ¶¶ 50, 66, 67, 80, 107; McCloskey Aff. ¶ 60. [12] As a result, Plaintiffs and plaintiff class members also have not been informed of their right to request a hearing. Defendant's failure to provide either notice or hearings violates

[11] Although not included in Defendant's Memorandum of Law, Agency counsel, Jane McCloskey, asserts that the general availability of the hearing process is sufficient to support compliance with Plaintiffs' due process rights. McCloskey Affidavit, ¶ 67. McCloskey offers no legal support for this contention. Due Process rights under the 14th Amendment to the U.S. Constitution, in *Goldberg v. Kelly*, and in the Medicaid Act, however, belong to the individual and must be granted to the individual.

[12] In the alternative, although also not argued in the supporting Memorandum of Law, Defendant's Rule 56 Statement of facts takes issue with Plaintiffs' allegation that "Defendant Shah provides no notices of denials when determinations are made not to cover medically necessary orthopedic footwear or compression stockings." Rule 56 Statement, ¶ 16. Defendant implies that public notice in the form of state-wide meetings of vast and numerous proposed changes to the entire state Medicaid program satisfy notices requirements contained in 42 C.F.R. Part 431. This suggestion is flatly at odds with 42 C.F.R. § 431.210-.213, which clearly requires that timely and adequate written notices be mailed directly to individual Medicaid beneficiaries. Public notice of proposed regulatory changes cannot satisfy this requirement.

42 C.F.R. § 431.205(d) and the Due Process Clause of the 14th Amendment to the U.S. Constitution.

VI. Denial of Medically Necessary Compression Stockings and Orthopedic Footwear Puts Plaintiffs at Risk of Unnecessary Institutionalization in Violation of the ADA and Section 504.

The State also fails to address, let alone refute, Plaintiffs' central argument under the ADA and Section 504. The Defendant misapprehends Plaintiffs' argument, which is that Defendant's policy violates the ADA's "integration mandate." The integration mandate arises out of Congress's explicit findings in the ADA, the regulations of the Attorney General implementing Title II,[13] and the Supreme Court's decision in *Olmstead v. L.C.*, 527 U.S. 581 (1999). In *Olmstead*, the Supreme Court held that public entities are required to provide community-based services to persons with disabilities when (a) such services are appropriate; (b) the affected persons do not oppose community-based treatment; and (c) community-based services can be reasonably accommodated, taking into account the resources available to the entity and the needs of other persons with disabilities. *Id*. at 607.

As Plaintiffs argued in their initial brief, the risk of institutionalization itself is sufficient to demonstrate a violation of this mandate. *See, e.g.*, *Fisher v. Okla. Health Care Auth.*, 335 F.3d 1175, 1181-82 (10th Cir. 2003); U.S. Dep't of Justice, Statement of the Department of Justice on the Integration Mandate of Title II of the ADA and Olmstead v. L.C. (June 22, 2011) ("a plaintiff could show sufficient risk of institutionalization to make out an Olmstead violation if a public entity's failure to provide community services or its cut to such services will likely

[13] The regulations provide that "a public entity shall administer services, programs and activities in the most integrated setting appropriate to the needs of qualified persons with disabilities." 28 C.F.R. § 35.130(d); *see also* 28 C.F.R. § 41.51(d). The preamble discussion of the ADA "integration regulation" explains that "the most integrated setting" is one that "enables individuals with disabilities to interact with nondisabled persons to the fullest extent possible." 28 C.F.R. § 35.130(d), App. A. at 571 (2009).

cause a decline in health, safety, or welfare that would lead to the individual's eventual placement in an institution").[14]

Undisputed facts in the record show that Defendant's failure to cover essential medical treatments will lead to increased risks of institutionalization. Dr. Dowlatshahi declared that, without replacements for compression stockings, Plaintiff Bobbi Wallach, who had already been confined to a nursing home in the recent past, was threatened with health crises that could lead to a return to the nursing home. Plaintiffs' Rule 56 Statement, ¶ 104. Similarly, Dr. Swanger declared that, in the absence of medically-necessary orthopedic footwear, Plaintiff Harry Davis risked severe medical complications, including further amputations, which could require institutionalization. Plaintiffs' Rule 56 Statement, ¶ 54. *See also id.* ¶ 19 (citing testimony of Dr. Svobada that compression stockings prevent dangerous health conditions from developing and offer an inexpensive remedy for excess swelling caused by CVI.). These facts are all uncontested (Defendant's Rule 56 Statement at 8), and because of the looming risk of institutionalization caused by the challenged policies, Plaintiffs are entitled to summary judgment on their ADA and Section 504 claims. The State does not claim that covering compression stockings and orthopedic shoes would cause a fundamental alteration to its program – nor could it, since the hospitalization costs and institutionalization costs resulting from the failure to cover these items would overwhelm the cost of actually providing coverage. *See* Plaintiffs' Rule 56 Statement, ¶ 28 ("when a patient is hospitalized for treatment, costs quickly escalate into the thousands and tens of thousands of dollars. Inexpensive compression stockings can avoid such unnecessary expenditures") (uncontested).

VII. Summary Judgment is Appropriate Where There Are No Material Issues of Fact in Dispute and Plaintiffs Are Entitled To Judgment as a Matter of Law.

[14] http://www.ada.gov/olmstead/q&a_olmstead.pdf.

Rule 56 of the Federal Rules of Civil Procedure provides that a moving party is entitled to summary judgment, if, based on the pleadings, depositions, answers to interrogatories and any affidavits submitted, there is no "genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *See Sista v. CDC Ixis North America, Inc.*, 445 F. 3d 161, 169 (2d Cir. 2006). Whether a fact is material is determined for summary judgment purposes by looking to the relevant substantive law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 247, 248 and 254 (1986). A disputed fact is material if it might affect the outcome of the suit under the governing law. *Id*. If a party fails to establish the existence of an essential element of its case on which it has the burden of proof, the other party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986).

Defendant Shah's Rule 56 Statement adopts the majority of Plaintiffs' Statement of Uncontested Facts in Support of Summary Judgment without contest. The only issues Defendant claims to contest are: whether compression stockings and orthopedic footwear can be categorized as DME (¶ 10) or whether orthopedic footwear is considered a prosthetic (¶ 31); whether public notice satisfies Defendant's obligations to provide Plaintiffs adequate written notice (¶¶ 15-17); and the inability of Defendant's policy to meet the medical needs of many Medicaid beneficiaries such as chronic venous insufficiency (CVI) (¶¶ 21, 29) or those with peripheral neuropathy without diabetes who need orthopedic footwear (¶ 33).

As described above, contested facts concerning the appropriate categorization of these items are immaterial. Defendant's contention that they are exclusively conceived as "prosthetics" is contradicted by his own regulatory and policy guidance where these items appear in multiple categories collectively governed by Defendant's DME policy, and orthopedic footwear appears nowhere within Defendant's category of prosthetics. To the extent that Defendant relies on this

purported categorization as an "optional" rather than "mandatory" service under federal Medicaid law, this is a legal question, not a question of fact. In any event, it has no bearing on the outcome of this case, because *all* covered services – optional and mandatory alike – are subject to federal reasonableness and comparability requirements.

As far as notice is concerned, Defendant's claim that public notice is sufficient is also a legal argument. There is no dispute as to the nature of the notice that Plaintiffs did and did not receive: public notice was provided, individual notices were not. Plaintiffs' position is that, as described above, the notice provisions of the Medicaid Act and the requirements of *Goldberg v. Kelly* clearly require Defendant to provide Plaintiffs and plaintiff class members individually with timely, adequate, written notices that also include the explanation of hearing rights. It is undisputed that no such notices were provided.

Finally, uncontested facts regarding the scope of those harmed by Defendant's refusal to cover medically necessary compression stockings and orthopedic footwear simply because of the particular condition these individuals suffer (CVI, for example, or peripheral neuropathy without diabetes) illustrate the harms suffered by Plaintiffs and plaintiff class members, but does not support Defendant's case. By Defendant's own account, thousands of medically necessary treatments will be excluded from coverage under his policies.

Because Defendant has failed to demonstrate any facts to establish an essential element of its case, Summary Judgment should be granted in Plaintiffs' favor.

VIII. Defendant Concedes that Refusal to Cover Medically Necessary Orthopedic Footwear and Compression Stockings Irreparably Harms Plaintiffs and Plaintiff Class Members.

As described in Plaintiffs' Memorandum of Law in Support of Summary Judgment, permanent injunction is appropriate where Plaintiffs have demonstrated success on the merits of

their claims and irreparable harm. Mem. of Law at 10-11 (Dkt. # 26-2). As described in the sections above, Plaintiffs have demonstrated success on the merits of their Medicaid claims, ADA/Section 504 claims, and claims under the Due Process clause of the 14th Amendment.

In adopting the majority of Plaintiffs' Statement of Uncontested Fact, Defendant's Rule 56 Statement concedes allegations regarding the specific harms suffered by the named Plaintiffs as a result of his actions, as well as allegations concerning the scope of harms suffered by the entire class. Significantly, Defendant contests none of the facts concerning the named Plaintiffs. Rule 56 Statement at 8. Defendant does not contest the fact that none of the Plaintiffs received timely, adequate, written notices of their denials. He also does not contest that compression stockings and orthopedic footwear are medically necessary for Plaintiffs to treat or remedy serious conditions such as CVI, peripheral neuropathy, lymphedema, and transmetatarsal amputation. *Id.*, ¶¶ 44, 58, 69, 99. Defendant does not contest the fact that, without these treatments, Plaintiffs face significant risk of injury, infection, hospitalization, amputation, institutionalization, and death. *Id.*, ¶¶ 53-54, 60, 85, 99, 104. Defendant also does not contest the fact that all four Plaintiffs are qualified persons with disabilities within the meaning of the ADA. Further, he does not contest the fact that these treatments permit Plaintiffs to remain in the community and engage actively with their communities. *Id.*, ¶¶ 44, 52, 53, 89, 101.

Defendant also does not contest the harms caused to members of the plaintiff class as a result of the refusal to cover medically necessary compression stockings and orthopedic footwear.[15] CVI causes swelling of the lower extremities and, left untreated with compression stockings, can lead to "life-threatening infection." *Id.*, ¶ 22. The longer CVI is left untreated, the

[15] Jonathan Bick alleges that in the year prior to the implementation of Defendant's policy, the state received 65,859 requests for compression stockings. Bick Aff., ¶ 70. Of these, 4,578 were for CVI. These 4,578 individuals are now at risk of the very harms vascular surgeon Dr. Jerry Svoboda, M.D., describes. *See* Dr. Svoboda Affidavit (Dkt. # 3-3 at 22-23).

graver the outcome. *Id.*, ¶ 23. Untreated CVI can lead to dangerous skin ruptures and venous stasis ulcers. *Id.*, ¶ 24. Venous stasis ulcers are difficult to treat and often become infected. *Id.*, ¶ 25. Compression stockings are best used to prevent such ulcers from forming in the first place. *Id.*, ¶ 26. Infections resulting from untreated CVI are always hazardous for the patient and often lead to unnecessary hospitalizations and treatment with I.V. antibiotics. *Id.*, ¶ 27.

Significantly, Defendant does not contest the dramatic cost disparity between providing lost-cost effective preventative treatments such as compression stockings and orthopedic footwear and costs associated with hospitalizations, I.V. antibiotic treatments, amputations, wheelchairs, increased aide services, and institutionalization for which Defendant will be responsible. *Id.*, ¶¶ 28, 53, 54, 90, 104. "When a patient is hospitalized for treatment, *costs quickly escalate into the thousands and tens of thousands of dollars*." *Id.*, ¶ 28. And, with respect to Plaintiff Poole in particular: "The costs associated with providing the compression stocking/garments necessary to control the swelling will be dwarfed by the costs of subsequent hospitalizations and wound care treatments." *Id.*, ¶ 90. Jonathan Bick claims that the denials of coverage for orthopedic footwear and compression stockings saved the state approximately $14.6 million in the first year. This overstates the fiscal impact on the state, however, because it is not offset by the uncontestedly exorbitant costs of expensive, unnecessary treatments that would have been avoided with the provision of low-cost treatments now denied Plaintiffs and plaintiff class members.

CONCLUSION

Plaintiffs have satisfied the requirements for permanent injunctive relief as well as the requirements for summary judgment. Plaintiffs have demonstrated that success on the merits of their claims under the Medicaid Act, the 14th Amendment to the U.S. Constitution, and the

ADA/Section 504. They have clearly demonstrated – and Defendant has conceded – irreparable harm. Because there are no issues of material fact in contest in this case, summary judgment in Plaintiffs' favor is appropriate.

It is respectfully requested that the Court therefore grant Plaintiffs' Motion for Summary Judgment and permanently enjoin Defendant from enforcing its illegal policies, regulation and New York Soc. Serv. L. § 365-a(2)(iii) and (iv), and from arbitrarily denying medically necessary orthopedic footwear and compression stockings through any other means.

Dated: Rochester, New York
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Respectfully Submitted,

EMPIRE JUSTICE CENTER, INC.
1 West Main Street, Suite 200
Rochester, New York 14614
Telephone: (585) 454-4060

/s/ Bryan Hetherington
Bryan Hetherington, Esq.
bhetherington@empirejustice.org

/s/ Jonathan Feldman
Jonathan Feldman, Esq.
jfeldman@empirejustice.org

/s/ Geoffrey Hale
Geoffrey Hale, Esq.
ghale@empirejustice.org

NATIONAL HEALTH LAW PROGRAM, INC.
101 East Weaver Street, Suite G-7
Carrboro, North Carolina 27510
Telephone: (919) 968-6308

/s/ Sarah Somers
Sarah Somers, Esq.
ssomers@healthlaw.org

/s/ Jane Perkins
Jane Perkins, Esq.
perkins@healthlaw.org

Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I, Geoffrey Hale, hereby certify that I sent a copy of Plaintiffs' Response Memorandum of Law in Opposition to Defendant's Cross Motion for Summary Judgment via the Federal Electronic Case Filing System to Assistant Attorney General J. Richard Benitez, Esq., Attorney for the Defendant, Office of the New York State Attorney General, 144 Exchange Blvd., Suite 200, Rochester, New York 14614, on November 28, 2012.

/s/ Geoffrey Hale
Geoffrey Hale, Esq.

Empire Justice Center
1 West Main Street, Suite 200
Rochester, New York 14614
Telephone: (585) 454-4060