

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.)

NIRAV SHAH, individually and in his)
official capacity as Commissioner of the)
New York State Department of Health,)

Defendant)

**CLASS ACTION
COMPLAINT**

I. PRELIMINARY STATEMENT

1. Plaintiffs bring this action to compel the New York State Department of Health to cover medically necessary compression stockings and prescription footwear through the Medicaid program. Plaintiffs are low-income New York residents, who must rely on the state Medicaid program for their health care.
2. Plaintiffs suffer from a range of disabling conditions including multiple sclerosis, paraplegia, lymphedema, cellulitis, ankylosing spondylitis, psoriatic arthritis, osteoarthritis, scoliosis, peripheral neuropathy, and transmetatarsal amputation.
3. Plaintiffs' medical doctors have prescribed either orthopedic footwear or compression stockings as medically necessary treatments for Plaintiffs' disabling ailments.
4. Plaintiff Davis had a transmetatarsal amputation a decade ago; prescription molded shoes allow him to walk rather than force him to use a wheelchair.

5. Plaintiff Geary suffers from peripheral neuropathy and requires prescription shoes to prevent dangerous and incapacitating injury to her feet.
6. Plaintiff Poole suffers from lymphedema, and requires compression stockings to control the swelling in her lower extremities and prevent potentially catastrophic infection.
7. Plaintiff Wallach, who is paralyzed from the waist down, also requires compression stockings to prevent swelling in her lower extremities and avoid deep venous thrombosis and pulmonary embolism.
8. The New York State legislature has enacted New York Soc. Serv. Law § 365-a(2)(g)(iii) and (iv), eliminating coverage of compression stockings and orthopedic footwear for all Medicaid recipients who do not meet one of a few narrow, statutorily-prescribed exceptions that are based only on diagnoses of specific medical conditions. Defendant has promulgated a regulation, 18 N.Y.C.R.R. § 505.5(g)(1) and (2), to implement the new restrictions. The regulation expressly prohibits any exceptions to the new limitations. There can be no individualized exceptions process to determine the medical necessity of these items.
9. Thus, Medicaid recipients who do not already meet one of the narrow, statutorily-prescribed exceptions have no opportunity to obtain coverage by Medicaid of either compression stockings or orthopedic footwear – even where, as here, the Medicaid recipients’ medical doctors determine these treatments to be medically necessary.
10. None of the Plaintiffs meet any of the listed exceptions.
11. Without these medically necessary treatments, Plaintiffs face a high likelihood of hospitalizations to address life-threatening infections and other preventable conditions. As a result of Defendant’s policy and regulation, Plaintiffs are likely to be

institutionalized in nursing homes and rehabilitation centers in order to be treated for the very conditions the eliminated items would have prevented at much lower cost.

12. The Medicaid Act requires coverage of the prescribed durable medical equipment as a condition of the State's participation in the Medicaid program. The new statute and Defendant's policy and regulation eliminating coverage for compression stockings and orthopedic footwear without the opportunity for Plaintiffs' physicians to show individualized medical necessity violate federal Medicaid and disability discrimination laws.
13. Plaintiffs seek declaratory and injunctive relief to enjoin Defendant from implementing the unlawful state statute, regulation, and policy.

II. JURISDICTION AND VENUE

14. This action arises under Title XIX of the Social Security Act (42 U.S.C. §§ 1396-1396w-5), Title II of the Americans with Disabilities Act (42 U.S.C. §§ 12131-12134), Section 504 of the Rehabilitation Act (29 U.S.C. § 794), and the Due Process clause of the Fourteenth Amendment to the U.S. Constitution. The Court has jurisdiction pursuant to 28 U.S.C. § 1331, which gives district courts original jurisdiction over all civil actions arising under the Constitution, laws, or treaties of the United States and 28 U.S.C. §§ 1343(a)(3) and (4), which give district courts original jurisdiction over suits to redress the deprivation under color of state law of any rights, privileges, or immunities guaranteed by the Constitution or acts of Congress.
15. Plaintiffs' action for declaratory, injunctive, and other appropriate relief is authorized by 28 U.S.C. §§ 2201 and 2202.

16. Venue is proper under 28 U.S.C. § 1391(b).

III. PARTIES

17. Plaintiff Harry Davis is a 60-year-old Medicaid recipient, who lives in Monroe County. Plaintiff Davis is disabled and receives Social Security Disability Insurance (hereinafter “SSDI”) and Supplemental Security Income (hereinafter “SSI”) benefits. He had transmetatarsal amputations of both feet as the result of a bacterial meningitis infection in 2001. Plaintiff Davis is unable to walk without prescription molded shoes for the stumps that remain of his feet. Medicaid had paid for his molded shoes for ten years before the new law became effective in April 2011.
18. Plaintiff Rita-Marie Geary is a 53-year-old New York Medicaid recipient, who lives in Monroe County. Plaintiff Geary is disabled and receives SSDI. She suffers from numerous health conditions, including ankylosing spondylitis, psoriatic arthritis, osteoarthritis, scoliosis, osteoporosis, fibromyalgia, Sjögren’s syndrome, patellofemoral stress syndrome, and peripheral neuropathy. Her doctor has prescribed orthopedic shoes to prevent further injury to her feet, ulceration, and infection, resulting from the peripheral neuropathy. Medicaid had paid for her medically necessary prescription shoes from the late 1990s until April 2011.
19. Plaintiff Patty Poole is a 42-year-old New York Medicaid recipient who lives in Broome County. Plaintiff Poole is disabled and relies on Supplemental Security Income (SSI) benefits. She suffers from lymphedema, diabetes, depression, obstructive sleep apnea, hypertension, morbid obesity, hyperthyroidism, and hyperlipidemia. Because of her lymphedema, Plaintiff Poole is prone to develop cellulitic infection, for

which she was recently hospitalized and which required an operation in order to be treated. Her medical providers have prescribed compression stockings to control the swelling in her legs and to prevent the recurrence of cellulitis and its attendant health risks.

20. Plaintiff Roberta Wallach is a 54-year-old New York Medicaid recipient, who lives in Monroe County. Plaintiff Wallach is disabled and receives Social Security Disability Insurance (SSDI). She suffers from multiple sclerosis with paraplegia of the legs and monoplegia of her left arm. She is prone to develop such life-threatening conditions as deep venous thrombophlebitis and pulmonary embolism. Plaintiff Wallach is paralyzed and must use a wheelchair. Her doctor has prescribed compression stockings to control swelling in her legs and prevent potentially life-threatening medical complications. Prior to April 2011, Medicaid had covered her medically necessary compression stockings.
21. Defendant Niraj Shah is Commissioner of the New York Department of Health and, as such, is charged with administering the New York State Medicaid program consistent with the Medicaid Act, the ADA, and Section 504 of the Rehabilitation Act. He is sued in his official capacity. His principal office is in Albany, New York.

IV. CLASS ALLEGATIONS

22. Plaintiffs bring this action pursuant to Fed. R. Civ. P. 23(b)(2) on behalf of a class defined as:

All current and future New York State Medicaid recipients who have had or will have coverage of medically necessary orthopedic footwear and compression stockings denied, delayed, disrupted, or reduced by Defendant directly or through

his agents or assigns as a result of New York Soc. Serv. Law § 365-a(2)(g)(iii) and (iv) and regulations and policies promulgated thereto.

23. This class is so numerous that joinder of all members is impracticable. Upon information and belief, there are thousands of Medicaid recipients each year whose doctors find orthopedic footwear or compression stockings medically necessary, and who will now be denied these treatments simply because they do not meet one of the few statutorily defined exceptions.
24. There are questions of law and fact common to the class concerning the legality of Defendant's policy and practice of denying coverage of orthopedic footwear and compression stockings to all Medicaid recipients unless that recipient meets one of the few statutorily defined exceptions.
25. The named Plaintiffs' claims are typical of the claims of the class. The doctors of all class members have identified or will identify either orthopedic footwear or compression stockings as medically necessary for each Plaintiff in order to treat each Plaintiff's medical condition. All named Plaintiffs have been unable to receive the medically necessary items or obtain an individualized review of the medical necessity of the prescribed items as a result of Defendant's policy.
26. Declaratory and injunctive relief is appropriate for the class as a whole, because Defendant's actions and omissions have affected and will affect the class generally.
27. The named Plaintiffs and proposed class are represented by attorneys from the Empire Justice Center and the National Health Law Program. These attorneys are experienced in class action litigation and will adequately represent the class.

V. STATUTORY AND REGULATORY FRAMEWORK

a. Medicaid

28. Title XIX of the Social Security Act, codified at 42 U.S.C. §§ 1396-1396w-5, establishes the Medicaid Act (hereinafter, “Medicaid Act”). The objective of the Medicaid Act is to enable each State to furnish medical assistance to families with children and to aged, blind, or disabled individuals whose incomes and resources are insufficient to meet the costs of necessary medical services and to furnish “rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care.” 42 U.S.C. § 1396-1.
29. If a State participates in the Medicaid program, it must comply with all the provisions of the Medicaid Act and implementing regulations. 42 U.S.C. § 1396a.
30. States are required to administer Medicaid “in the best interests of recipients.” 42 U.S.C. § 1396a(a)(19).
31. Each State choosing to participate in the Medicaid program must designate a single state agency to be responsible for administering the program. 42 U.S.C. § 1396a(a)(5).
32. New York State has elected to participate in the Medicaid program, and the “single state agency” responsible for the administration of the Medicaid program in New York is the New York State Department of Health (hereinafter “DOH”). N.Y. Soc. Serv. Law § 363-a(1).
33. The Medicaid Act includes mandatory and optional eligibility coverage groups and mandatory and optional service coverage requirements. 42 U.S.C. §§ 1396a(a)(10), 1396d(a).
34. The Medicaid Act provides for coverage of individuals who are “categorically needy.” 42 U.S.C. § 1396a(a)(10)(A).

35. The categorically needy include persons who are aged, blind, or disabled, working disabled individuals, and certain children and pregnant women who meet federal poverty level standards, and families and children who meet the eligibility standards of the now-repealed AFDC program. 42 U.S.C. § 1396a(a)(10)(A)(i).
36. All categorically needy individuals are entitled to nursing facility 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).
37. States must “provide ... for the inclusion of home health services for any individual who, under the State plan, is entitled to nursing facility services....” 42 U.S.C. § 1396a(a)(10)(D).
38. 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); 42 C.F.R. § 441.15(a)(3).
39. Defendant recognizes both compression stockings and orthopedic footwear as durable medical equipment. *New York State Medicaid Program, Durable Medical Equipment Manual, Policy Guidelines*. Available at:
https://www.emedny.org/ProviderManuals/DME/PDFS/DME_Policy_Section.pdf.
40. A State must establish reasonable standards, consistent with the objectives of the Medicaid Act, for determining the extent of coverage of durable medical equipment and other home health services. 42 U.S.C. § 1396a(a)(17) (the “reasonable standards” requirement).
41. The Medicaid Act requires that “The medical assistance made available to any [categorically needy] individual ... shall not be less in amount, duration or scope than the medical assistance made available to any other such individual.” 42 U.S.C. §

1396a(a)(10)(B)(i); *see also* 42 C.F.R. § 440.240(b) (requiring that “the services available to any individual in the following groups are equal in amount, duration, and scope for all recipients within that group: (1) The categorically needy.”) This requirement is known as the “comparability requirement.” Thus, services made available to any categorically needy individual must be made available to all categorically needy individuals.

42. A State may not impose arbitrary limitations on mandatory services, such as home health services, based solely on diagnosis, type of illness, or condition. 42 C.F.R. § 440.230(c).
43. In an official statement of agency policy, the U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services (CMS), the agency charged with implementing the Medicaid Act at the federal level, has informed state Medicaid agencies that a state may develop a list of pre-approved items of medical equipment as an administrative convenience, but:

An ME [medical equipment] 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 [. . .]. [T]he process for seeking modification or exception must be made available to all beneficiaries and may not be limited to sub-classes of the population (e.g., beneficiaries under the age of 21) [. . .]. [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.

CMS, *Dear State Medicaid Director* (September 4, 1998),

<http://www.cms.hhs.gov/states/letters/smd90498.asp>.

44. The agency must provide a Medicaid recipient with written notice when it takes the time of any action affecting his or her eligibility or coverage of services. 42 U.S.C. § 1396a(a)(3); 42 C.F.R. §§ 431.206(c)(2), 431.210, 431.220(a)(2)
45. The notice must contain: (a) a statement of what action the State intends to take; (b) the reasons for that action; (c) the specific regulations that support, or the change in Federal or State law that requires the action; (d) an explanation of – (1) the individual’s right to request an evidentiary hearing, if one is available, or a State agency hearing; or (2) in cases of an action based on a change in law, the circumstances under which a hearing will be granted; and (e) an explanation of the circumstances under which Medicaid is continued if a hearing is required. 42 C.F.R. § 431.210.
46. Although a hearing is not required if the *sole* issue is a federal or state law requiring an automatic change adversely affecting some or all recipients, 42 C.F.R. §§ 431.220(b), a hearing *is* required when a recipient believes the State agency has taken an action erroneously, 42 C.F.R. §§ 431.220(a).
47. The Due Process Clause of the Fourteenth Amendment prohibits states from denying, reducing, or terminating Medicaid services without due process of law. The Constitutional right includes the right to meaningful notice prior to the termination of Medicaid benefits, continued benefits pending a pre-termination hearing, and a fair and impartial pre-termination hearing. *Goldberg v. Kelly*, 397 U.S. 254 (1970). Federal Medicaid regulations explicitly implement the due process requirements set forth in *Goldberg*. 42 C.F.R. § 431-205(d).
48. As set forth in *Goldberg* and incorporated in the Medicaid regulations, recipients are entitled to receive timely, adequate, and understandable written notices of their hearing

rights when an action affects their claim for health services; the hearing must be fair and impartial and held at a meaningful time; coverage of services must be continued at the prior-approved level until a final *de novo* hearing decision if: (a) a Medicaid recipient requests a fair hearing before the date that the services are to be stopped or reduced; (b) the recipient requests the hearing within 10 days of the mailing of the notice; or (c) the requisite notice is not sent. 42 C.F.R. Part 431.

b. Americans with Disabilities Act

49. The Americans with Disabilities Act, codified at 42 U.S.C. §§ 12101-12181 (hereinafter “ADA”) was enacted for the purpose of the “elimination of discrimination against individuals with disabilities.” 42 U.S.C. § 12101(b)(1).
50. Title II of the ADA prohibits discrimination against individuals with disabilities by public entities, including state and local governments, their departments, and agencies. 42 U.S.C. §§ 12131, 12132. “[N]o qualified individual with a disability shall, by reason of such disability, be excluded from participation in or be denied the benefits of the services, programs, or activities of a public entity, or be subjected to discrimination by any such entity.” 42 U.S.C. § 12132; 28 C.F.R. §§ 35.130(b)(1)(iv), 35.130(b)(7), 35.130(b)(8), and 35.130(d).
51. The ADA prohibits segregation of people with disabilities into institutions and requires services, programs and activities of state and local governments to be administered in “the most integrated setting appropriate to the needs of qualified individuals with disabilities.” 28 C.F.R. § 35.130(d).

52. Regulations implementing the ADA also provide: “A public entity may not, directly or through contractual or other arrangements, utilize criteria or other methods of administration: (i) that have the effect of subjecting qualified individuals with disabilities to discrimination on the basis of disability; [or] (ii) that have the purpose or effect of defeating or substantially impairing accomplishment of the objectives of the entity’s program with respect to individuals with disabilities. . . .” 28 C.F.R. § 35.130(b)(3).
53. The ADA requires state governments and agencies to make reasonable modifications to policies, practices and procedures to avoid discrimination on the basis of disability. 28 C.F.R. § 35.130(b)(7).

c. Section 504 of the Rehabilitation Act

54. Section 504 of the Rehabilitation Act, 29 U.S.C. § 794 (hereinafter “Section 504”), prohibits discrimination against individuals with disabilities by any program or activity, including any department or agency of a State government, receiving Federal financial assistance. 29 U.S.C. §§ 794(a) and (b). “No otherwise qualified individual with a disability [...] shall, solely by reason of her or his disability, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance [. . .].” 29 U.S.C. § 794; 45 C.F.R. §§ 88.4(a), 88.4(b)(1)(i), (iv), and (vii); 84.4(b)(2); 84.52(a)(1), (4), and (5).
55. Section 504 prohibits segregation of people with disabilities into institutions and requires services, programs and activities of state and local governments to be

administered in “the most integrated setting appropriate to the needs of qualified handicapped persons.” 28 C.F.R. § 41.51(d).

56. Regulations implementing Section 504 also provide: “A recipient [of Federal financial assistance] may not, directly or through contractual or other arrangements, utilize criteria or other methods of administration: (i) that have the effect of subjecting qualified handicapped persons to discrimination on the basis of handicap; [or] (ii) that have the purpose or effect of defeating or substantially impairing accomplishment of the objectives of the entity’s program with respect to handicapped persons. . . .” 28 C.F.R. § 41.51(b)(3)(i); 45 C.F.R. § 84.4(b)(4).
57. Section 504 requires federally funded state governments and agencies to make reasonable modifications to policies, practices, and procedures to avoid discrimination on the basis of disability. 29 U.S.C. § 794(a).

VI. STATEMENT OF FACTS

58. The State of New York has elected to participate in the Medicaid program and has designated the New York State Department of Health as the single state Medicaid agency.
59. New York’s Medicaid statute requires coverage of prescribed, medically necessary durable medical equipment. N.Y. Soc. Serv. L. § 365-a(2).
60. During the 2011 Legislative Session, Governor Andrew Cuomo established the Medicaid Redesign Team (hereinafter “MRT”) to develop recommendations for cutting costs in the state Medicaid program.

61. The MRT proposed sweeping changes to the Medicaid program through nearly 200 specific recommendations.
62. The New York State Legislature enacted virtually all the changes proposed by the MRT, authorizing an estimated \$2.2 billion in cuts to the Medicaid program.
63. Section 365-a(2)(g) of the New York Social Services Law, as amended to reflect the recommendations of the MRT, now prohibits coverage of orthopedic footwear and compression stockings that do not meet statutorily prescribed exceptions: “(iii) prescription footwear and inserts are limited to coverage only when used as an integral part of a lower limb orthotic appliance, as part of a diabetic treatment plan, or to address growth and development problems in children; and (iv) compression and support stockings are limited to coverage only for pregnancy or treatment of venous stasis ulcers [. . .].” N.Y. Soc. Serv. Law § 365-1(2)(g)(iii) and (iv).
64. The New York State Department of Health has promulgated amendments to 18 N.Y.C.R.R. § 505.5 eliminating coverage of orthopedic footwear and compression stockings for most, but not all, categorically needy Medicaid recipients.
65. The regulation explicitly mandates that: “The department shall not allow exceptions to defined benefit limitations.” 18 N.Y.C.R.R. § 505.5(g).
66. The regulation now limits compression stockings to coverage only during pregnancy and for venous stasis ulcers. 18 N.Y.C.R.R. § 505.5(g)(1).
67. The regulation also limits coverage of orthopedic footwear to “treatment of children to correct, accommodate or prevent a physical deformity or range of motion malfunction in a diseased or injured part of the ankle or foot; as a component of a comprehensive diabetic treatment plan to treat amputation, ulceration, pre-ulcerative calluses,

peripheral neuropathy with evidence of callus formation, a foot deformity or poor circulation; or to form an integral part of an orthotic brace.” 18 N.Y.C.R.R. § 505.5 (g)(2).

68. On April 5, 2011, the New York State Department of Health issued a Provider Update for Pharmacy and DME Providers describing the new limits in prescription footwear coverage to providers.

https://www.emedny.org/providermanuals/communications/Prescription%20_Footwear_Benefit%20_Update_20110405.pdf.

69. On May 25, 2011, the New York State Department of Health issued a Provider Update for Pharmacy and DME Providers advising them of the coverage codes for compression stockings available “**only** when used in the treatment of open venous stasis ulcers” and “**only** for treatment of severe varicosities and edema **during pregnancy**.” The stockings are not covered “**for any other conditions, including** the prevention of ulcers, prevention of the recurrence of ulcers, treatment of lymphedema without ulcers, varicose veins, or circulation disorders.”

https://www.emedny.org/providermanuals/communications/Compression_Stockings_Notice_revised_20110520.pdf. (Emphasis in the original.)

70. DOH also communicated the new limits on the coverage of compression stockings and prescription footwear to providers in its May 2011 New York State Department of Health Medicaid Updates. *The New York State Medicaid Update*, vol. 27, no. 6 (May 2011).

http://www.health.ny.gov/health_care/medicaid/program/update/2011/may2011mu.pdf.

Plaintiff Harry Davis

71. Harry Davis is 60 years old and lives in Monroe County, New York.
72. On March 15, 2001, Mr. Davis was admitted to Strong Memorial Hospital and diagnosed with bacterial meningitis. His illness was complicated by congestive heart failure, acute respiratory distress syndrome, toe necrosis, feet and hand ulceration, fever and rash.
73. He underwent bilateral transmetatarsal amputation of the feet, close to the heel, on May 8, 2001. Mr. Davis was left with stumps instead of feet.
74. He was transferred to Physical Medicine and Rehabilitation at Strong Memorial Hospital on May 11, 2001. On June 8, 2001, Mr. Davis was transferred to Monroe Community Hospital for skilled nursing facility rehabilitation. He remained in the hospital until March 8, 2002, a full year after he was initially admitted for meningitis.
75. While he was in the hospital, Mr. Davis was confined to a bed or had to use a wheelchair, and was unable to walk.
76. Because of the bilateral transmetatarsal amputation, Mr. Davis is unable to walk without the aid of shoes molded to fit the stubs of his feet.
77. Because of his disabilities, Mr. Davis is unable to work and receives SSDI and SSI benefits totaling \$805 per month. He also receives Medicaid benefits from the New York State Department of Health based on his disability.
78. Mr. Davis first became eligible for SSDI and SSI while he was in the hospital for his meningitis. He became eligible for New York State Medicaid at the same time.
79. Medicaid covered his hospitalization, operation, and rehabilitation.
80. Medicaid also paid for the shoes Mr. Davis would need from then on in order to walk.

81. The first shoes Mr. Davis received were not molded to the stubs of his feet, and did not allow him to walk at all.
82. His doctor then sent Mr. Davis to Dr. John Jacobs at Feet First in Rochester to have shoes molded to his feet.
83. The prescription molded shoes he receives allow Mr. Davis to walk, to move about in his home, to care for himself, and to maintain active engagement in his community.
84. Until 2011, Medicaid covered one pair of shoes a year for Mr. Davis. This is the only pair of shoes Mr. Davis owns, and he must wear them every day of the year.
85. Usually, Mr. Davis went to see Dr. Jacobs to order his shoes in the fall of every year. Dr. Jacobs then cast a mold of his stubs, ordered the shoes, and they arrived six to eight weeks later.
86. Dr. Jacobs has made Mr. Davis's shoes ever since he first needed them in 2002.
87. His shoes were last replaced in December 2010.
88. Mr. Davis is now unable to have his shoes replaced, because of the change in law and Defendant's new policy.
89. Dr. Carlos Swanger, Mr. Davis's primary care provider, has issued a new prescription for the shoes, but no provider will make them. According to the current Medicaid DME Provider Manual, there is no longer any prior authorization process for prescription footwear. The DME provider can only submit the claim when the shoes are given to the Medicaid recipient. The provider, however, will only make the shoes if he or she can determine that the Medicaid recipient meets one of the statutorily prescribed exceptions so that he or she can reasonably expect to be reimbursed by Medicaid. *See* "DME

Billing Guidelines” in *New York State 150003 Billing Guidelines* (6/1/2011).

https://www.emedny.org/ProviderManuals/DME/PDFS/DME_Billing_Guidelines.pdf.

90. When Mr. Davis most recently asked Dr. Jacobs to make his shoes for him in December of 2011, Dr. Jacobs refused, explaining that Medicaid will no longer cover the shoes.
91. Mr. Davis received no notice from Medicaid about the statutory changes, and he received no notice from Medicaid denying coverage for the shoes this time. No notice also means that Medicaid has not informed Mr. Davis about the existence of exceptions to the elimination of coverage for prescription footwear. Medicaid has also not informed Mr. Davis about his right to a fair hearing for the denial of coverage for his shoes.
92. After more than a year of use, the shoes are now completely worn out. His amputated stumps have completely worn through the inner padding of his shoes and are now wearing through the hard rubber sole from the inside.
93. Because of the deterioration of his shoes, merely walking or standing leaves Mr. Davis in excruciating pain.
94. Even with the molded shoes, Mr. Davis requires assistance to remain in his home in the community. A personal care aide comes to his home twice a week.
95. Without the shoes, Mr. Davis will be required to use a wheelchair and will no longer be able to ascend the stairs to his apartment. He will also be unable to attend to activities of daily living in his own home as he does now. Mr. Davis will likely be forced to move out of his home, and will require additional aide services.
96. According to Dr. Swanger, Mr. Davis faces additional medical complications – as well as changes in his ability to remain in the community – if the shoes are not replaced. Mr.

Davis risks developing skin ruptures and additional infections. In his case, such complications would likely result in further amputations and possible institutionalization.

97. Mr. Davis's shoes cost about \$1,000.
98. Mr. Davis cannot afford the cost of his shoes on his limited SSI/SSDI benefits of \$805 per month.

Plaintiff Rita-Marie Geary

99. Plaintiff Rita-Marie Geary is 53 years old and lives in Monroe County.
100. Ms. Geary is disabled and suffers from numerous health conditions: ankylosing spondylitis, psoriatic arthritis, TMJ, osteoarthritis, scoliosis, Raynaud's syndrome, osteoporosis, fibromyalgia, Sjören's syndrome, patellofemoral stress syndrome, and peripheral neuropathy.
101. Ms. Geary is disabled and unable to work. Until recently, Ms. Geary received a combination of SSDI and SSI benefits. Her SSDI benefit has now risen above the SSI level so that she only receives SSDI now in the amount of \$896 per month. Ms. Geary also receives Medicaid benefits based on her disability, and Medicare through her Social Security benefits.
102. Ms. Geary suffers from peripheral neuropathy of unknown origin in her feet. Peripheral neuropathy is a kind of nerve damage that causes numbness in the extremities.
103. Because of her peripheral neuropathy, Ms. Geary needs specially prescribed open-toed shoes. According to her podiatrist, Dr. David E. High, P.D.M., without the shoes, Ms.

Geary risks further nerve damage in her feet, increased injury from falling, increased ulceration, and infection. Left untreated, even apparently minor injuries increase the risk of potential amputation.

104. Medicaid has covered Ms. Geary's shoes since the late 1990s.
105. On December 27, 2011, Dr. High issued a new prescription for Ms. Geary's shoes.
106. Ms. Geary attempted to fill the prescription on January 3, 2012, at Foot Performance Center in Rochester, New York.
107. Foot Performance Center declined to fill the prescription, because Medicaid will no longer cover the cost of the shoes.
108. Because Ms. Geary does not have diabetes, providers find that she does not meet the statutorily prescribed exception, and will no longer fill the prescriptions for her shoes.
109. The only way she will be able to obtain the medically necessary prescription shoes is by paying for them out-of-pocket herself.
110. In her case, the shoes cost about \$130.
111. Ms. Geary cannot afford the shoes on her limited income.
112. Upon her request, Foot Performance Center provided Ms. Geary with a printout of the computer screen image indicating that coverage for the shoes was denied by Medicaid.
113. Medicaid provided Ms. Geary with no notice about the elimination of coverage of orthopedic footwear in general, and no notice of the decision to deny this request for coverage in particular. Medicaid also has provided Ms. Geary with no notice of the new statutory limits on coverage of prescription footwear. She has been given no notice about the existence of exceptions to the new Medicaid policy, and has not been notified

of her right to a fair hearing on whether or not she meets one of the available exceptions.

Plaintiff Patty Poole

114. Plaintiff Patty Poole is 42 years old and lives in Broome County, New York.
115. Ms. Poole suffers from lymphedema, diabetes, depression, obstructive sleep apnea, hypertension, morbid obesity, hyperthyroidism, and hyperlipidemia.
116. Because of her condition, Ms. Poole is unable to work, and receives SSI benefits of \$785 per month. Ms. Poole also receives Medicaid benefits based on her disability.
117. Ms. Poole's lymphedema has caused severe swelling in her lower extremities.
118. Her lymphedema has also caused recurrent cellulitis – skin infections that, left untreated, can be life-threatening.
119. Early in 2011, Ms. Poole developed a cellulitic infection in her right leg that rapidly grew to a mass about a foot in diameter.
120. On March 24, 2011, she was admitted to the hospital for intravenous antibiotic treatment to eliminate the infection prior to the surgical removal of the mass.
121. On April 4, 2011, Dr. Samuel Pejo removed the large mass on the back of her right knee.
122. She was discharged from the hospital on April 18, 2011.
123. On April 22, 2011, Dr. Pejo prescribed compression stockings to maintain reduced limb volume in accordance with the current standard of care established by the International Society of Lymphology.

124. Defendant's own publications recommend being professionally fitted for compression garments to treat lymphedema. <http://www.health.ny.gov/publications/0399.pdf>.
125. Following a prior authorization request, Ms. Poole received a letter from the New York State Department of Health dated June 20, 2011, denying coverage of compression stockings, citing the new law eliminating coverage of compression stockings. The letter made no mention of any exceptions, nor did it advise Ms. Poole of her right to a fair hearing.
126. Since her surgery, Ms. Poole has had to rely on alternatives to compression stockings to control the swelling in her legs as much as possible. She uses two binders on her upper legs and wraps her lower legs from toe to knee in bandages. The process of massaging her legs and applying her bandages takes two hours every time they need to be reapplied. The binders fall off when she tries to walk. The binders no longer stay in place even when she is lying down.
127. Lack of compression stockings has caused the swelling in her legs to continue, and the swelling has returned to pre-operation levels.
128. The continued swelling and inadequate alternative treatments prevent Ms. Poole from engaging in virtually any activity and prevent her from effectively addressing the underlying issue of her morbid obesity.
129. In Dr. Pejo's assessment, the compression stockings are necessary to prevent what he calls a "major medical disaster." The compression stockings would prevent recurrent cellulitis, the return of the "tumor-like swelling," and ulceration of the skin due to stasis dermatitis.

130. Because of her obesity, Ms. Poole requires custom made compression stockings at a cost of roughly \$900.
131. Ms. Poole cannot afford to pay for the stockings out-of-pocket.
132. The lack of compression stockings has caused Ms. Poole physical and emotional harm. Her lymphedema has progressed for lack of adequate treatment and her depression has worsened. Lack of compression stockings has also prevented her from engaging in the community; the inadequate alternate treatments have made it virtually impossible for her to leave her home.

Plaintiff Roberta (Bobbi) Wallach

133. Bobbi Wallach is 51 years old and lives in Monroe County, New York.
134. Ms. Wallach has Multiple Sclerosis with paraplegia of the legs and monoplegia of her left arm. According to Dr. Bahram Dowlathahi, M.D., her primary care provider, Ms. Wallach is prone to develop deep venous thrombophlebitis and pulmonary embolism, which can be fatal.
135. Ms. Wallach is disabled and unable to work. She receives SSDI benefits and also receives Medicaid based on her disability. Her Social Security benefits also entitle her to Medicare.
136. Ms. Wallach was first diagnosed with multiple sclerosis over thirty years ago. Her condition has gradually deteriorated over the years. In her current condition, she retains the use only of her right arm and her mouth.
137. Because of the severity of her condition, Ms. Wallach entered a nursing home in 2007.
138. Ms. Wallach first became eligible for Medicaid when she moved into the nursing home.

139. Even at that time, the paraplegia of her lower extremities necessitated the use of compression stockings in order to prevent the potentially fatal conditions of deep venous thrombophlebitis and pulmonary embolism.
140. Medicaid has covered her compression stockings ever since Medicaid covered Ms. Wallach's medical care. Since that time, Medicaid has covered two pair of compression stockings for her every year.
141. She remained in the nursing home until April 2011, when she was able to put enough supports in place for her care that would allow her to live in the community. She moved into her own apartment on April 1, 2011, the same day Defendant's policy denying coverage of compression stockings went into effect.
142. Compression stockings remain medically necessary for Ms. Wallach to control the swelling in her lower extremities and prevent the potentially fatal consequences of deep venous thrombophlebitis and pulmonary embolism.
143. Ms. Wallach's compression stockings were last replaced by Medicaid prior to April 2011, and need now to be replaced again. She has been trying to make do with old compression stockings that no longer treat her condition effectively.
144. Without replacements for her compression stockings, Ms. Wallach risks hospitalization or death from potentially life-threatening conditions. Such hospitalizations would also place her at risk of returning to the nursing home.
145. Ms. Wallach requires standard compression stockings available by prescription.
146. Dr. Dowlatshahi issued a new prescription for Ms. Wallach's compression stockings in December 2011.

147. When Ms. Wallach went to order the compression stockings, she was told that Medicaid would no longer cover them, and she would have to pay for them herself.
148. Medicaid provided Ms. Wallach with no notice about the elimination of coverage of compression stockings in general, and no notice of the decision to deny this request for coverage in particular. She has been given no notice about the existence of exceptions to the new Medicaid policy, and has not been notified of her right to a fair hearing on whether or not she meets one of the available exceptions.
149. Because of the high risk of serious harm she would face without the stockings, Ms. Wallach ordered the stockings anyway.
150. She purchased them herself at the end of January 2012 for a total cost of \$13.50.

VII. CLAIMS FOR RELIEF

First Claim for Relief

151. Plaintiffs restate and incorporate by reference paragraphs 1 through 150 above.
152. N.Y. Soc. Serv. Law § 365-a(2)(g)(iii) and (iv), Defendant's regulation 18 N.Y.C.R.R. § 505.5(g)(1) and (2), and Defendant's written policies eliminating coverage for compression stockings and orthopedic footwear without an opportunity to obtain an individualized determination of medical necessity are in conflict with the reasonable standards requirements of the Federal Medicaid Act, 42 U.S.C. § 1396a(a)(17), its implementing regulations and interpretive Federal guidelines, and are preempted pursuant to the Supremacy Clause of the U.S. Constitution, art. IV.

Second Claim for Relief

153. Plaintiffs restate and incorporate by reference paragraphs 1 through 152 above.
154. N.Y. Soc. Serv. Law § 365-a(2)(g)(iii) and (iv), Defendant's regulation 18 N.Y.C.R.R. § 505.5(g)(1) and (2), and Defendant's written policy eliminating coverage for compression stockings for most categorically needy Medicaid recipients while covering them only for those who meet certain criteria based on medical condition, and Defendant's policy of eliminating coverage for orthopedic footwear for most categorically needy Medicaid recipients while covering them only for those who meet certain criteria based on medical condition violate the comparability requirement of the Federal Medicaid Act, 42 U.S.C. § 1396a(a)(10)(B), enforceable by Plaintiffs pursuant to 42 U.S.C. § 1983.
155. N.Y. Soc. Serv. Law § 365-a(2)(g)(iii) and (iv), Defendant's regulation 18 N.Y.C.R.R. § 505.5(g)(1) and (2), and written policies conflict with Medicaid's comparability requirement, 42 U.S.C. § 1396a(a)(10)(B) and are therefore preempted pursuant to the Supremacy Clause of the U.S. Constitution, art. IV.

Third Claim for Relief

156. Plaintiffs restate and incorporate by reference paragraphs 1 through 155 above.
157. N.Y. Soc. Serv. Law § 365-a(2)(g)(iii) and (iv), Defendant's regulation 18 N.Y.C.R.R. § 505.5(g)(1) and (2), and Defendant's policy eliminating coverage for compression stockings and orthopedic footwear violate the Federal Medicaid Act's home health requirement, 42 U.S.C. §§ 1396a(a)(10)(A), 1396a(a)(10)(D), and 1396d(a)(4), enforceable by Plaintiffs' pursuant to 42 U.S.C. § 1983, in that it eliminates coverage of

a mandatory home health service - durable medical equipment - for categorically needy Medicaid beneficiaries.

158. N.Y. Soc. Serv. Law § 365-a(2)(g)(iii) and (iv), Defendant's regulation 18 N.Y.C.R.R. § 505.5(g)(1) and (2) and written policies conflict with 42 U.S.C. §§ 1396a(a)(10)(A), 1396a(a)(10)(D), and 1396d(a)(4), implementing regulations, and interpretive federal guidelines, and are preempted pursuant to the Supremacy Clause of the U.S. Constitution, art. IV.

Fourth Claim for Relief

159. Plaintiffs restate and incorporate by reference paragraphs 1 through 158 above.

160. N.Y. Soc. Serv. Law § 365-a(2)(g)(iii) and (iv), Defendant's regulation 18 N.Y.C.R.R. § 505.5(g)(1) and (2), and Defendant's written policy eliminating coverage for compression stockings and orthopedic footwear for certain Medicaid recipients without providing written notice or opportunity for a hearing violates Plaintiffs' due process rights under the Federal Medicaid Act pursuant to 42 U.S.C. § 1396a(a)(3) and under the Due Process Clause of Fourteenth Amendment to the U.S. Constitution, enforceable pursuant to 42 U.S.C. § 1983.

Fifth Claim for Relief

161. Plaintiffs restate and incorporate by reference paragraphs 1 through 160 above.

162. Each of the Plaintiffs is a "qualified individual with a disability" within the meaning of 42 U.S.C. § 12131(2). Each of the Plaintiffs has a disability that significantly limits his

or her life activities including mobility, the ability to provide self-care, and other major life activities.

163. Defendant's policy of not providing compression stockings or prescription orthotics threatens their ability to remain in their homes and in the community. It therefore violates the Americans with Disabilities Act, 42 U.S.C. § 12131-12134, and its implementing regulations, which prohibit discrimination on the basis of disability, require that services be made available in the community rather than institutions, where to do so meets the needs of qualified individuals with disabilities, and require that reasonable modifications be made to state programs to avoid discrimination on the basis of disability.

Sixth Claim for Relief

164. Plaintiffs restate and incorporate by reference paragraphs 1 through 163 above.

165. Each of the Plaintiffs is a qualified individual with a disability under Section 504 of the Rehabilitation Act, 29 U.S.C. § 794(a).

166. The New York State Department of Health receives Federal financial assistance for its Medicaid program.

167. Defendant's policy of not providing compression stockings or prescription orthotics threatens their ability to remain in their homes and in the community. It therefore violates Section 504 of the Rehabilitation Act, 29 U.S.C. § 794(a), and its implementing regulations, which prohibit discrimination on the basis of disability, require that services be made available in the community rather than institutions, where to do so meets the needs of qualified individuals with disabilities, and require that reasonable

modifications be made to state programs to avoid discrimination on the basis of disability.

Seventh Claim for Relief

168. Plaintiffs restate and incorporate by reference paragraphs 1 through 167 above.

169. Defendant has violated the Americans with Disabilities Act and Section 504 of the Rehabilitation Act and their implementing regulations 28 C.F.R. §§ 35.130(b)(3) and 41.51(b)(3)(i) and 45 C.F.R. § 84.4(b)(4) by utilizing methods of administration that subject Plaintiffs and Class Members to discrimination on the basis of disability, including risk of unnecessary institutionalization, and by failing to account for individual medical necessity in the denial of coverage for orthopedic footwear and compression stockings that would enable Plaintiffs and Class Members to remain in the community.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter a judgment in their favor as follows:

- A. Assume jurisdiction over this action;
- B. Certify this action as a class action pursuant to Fed. R. Civ. P. 23;
- C. Issue a declaratory judgment holding that:
 - a. New York Soc. Serv. Law § 365-a(2)(g)(iii) and (iv), and 18 N.Y.C.R.R. § 505.5(g)(1) and (2) violate the reasonable standards requirements of the Medicaid Act, 42 U.S.C. § 1396a(a)(17) and are therefore invalid;

- b. New York Soc. Serv. Law § 365-a(2)(g)(iii) and (iv), and 18 N.Y.C.R.R. § 505.5(g)(1) and (2) violate the comparability requirement of the Medicaid Act, 42 U.S.C. § 1396a(a)(10)(B) and are therefore invalid;
- c. New York Soc. Serv. Law § 365-a(2)(g)(iii) and (iv), and 18 N.Y.C.R.R. § 505.5(g)(1) and (2) violate the home health requirement of the Medicaid Act, 42 U.S.C. §§ 1396a(a)(10)(A), (a)(10)(D), and 1396d(a)(4), and are therefore invalid;
- d. New York Soc. Serv. Law § 365-a(2)(g)(iii) and (iv), and 18 N.Y.C.R.R. § 505.5(g)(1) and (2) violate Plaintiffs' due process rights to written notice and opportunity for a hearing under the Due Process clause of the Fourteenth Amendment to the United States Constitution and as provided in the Medicaid Act, 42 U.S.C. § 1396a(a)(3), and the Due Process Clause of the Fourteenth Amendment to the U.S. Constitution and are therefore invalid;
- e. New York Soc. Serv. Law § 365-a(2)(g)(iii) and (iv), and 18 N.Y.C.R.R. § 505.5(g)(1) and (2) violate the prohibition against discrimination on the basis of disability provided in 42 U.S.C. § 12132 and Plaintiffs' right to reasonable accommodation under 28 C.F.R. § 35.130(b)(7);
- f. New York Soc. Serv. Law § 365-a(2)(g)(iii) and (iv), and 18 N.Y.C.R.R. § 505.5(g)(1) and (2) violate the prohibition against discrimination on the basis of disability provided in Section 504 of the Rehabilitation Act under 29 U.S.C. § 794 and Plaintiffs' right to reasonable accommodation under 29 U.S.C. § 794(a); and

- g. New York Soc. Serv. Law § 365-a(2)(g)(iii) and (iv), and 18 N.Y.C.R.R. § 505.5(g)(1) and (2) violate the prohibition against utilizing methods of administration that have the effect of discrimination on the basis of disability provided in the ADA and in Section 504 of the Rehabilitation Act under 28 C.F.R. §§ 35.130(b)(3) and 41.51(b)(3)(i), and 45 C.F.R. § 84.4(b)(4).
- D. Grant preliminary and permanent injunctions that prohibit Defendant from implementing and enforcing New York Soc. Serv. Law § 365-a(2)(g)(iii) and (iv), and 18 N.Y.C.R.R. § 505.5(g)(1) and (2);
- E. Award reasonable attorneys' fees, as provided by 42 U.S.C. § 1988, and pursuant to Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794a(b), and the ADA, 42 U.S.C. § 12205;
- F. Award costs and disbursements; and
- G. Order such other and further relief as the Court may deem just and proper.

Dated: Rochester, New York
March 14, 2012

Respectfully submitted,

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