

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF MISSOURI  
CENTRAL DIVISION

STEVEN HILTIBRAN, et. al. )  
 )  
 Plaintiffs, )  
 )  
 v. )  
 )  
 RONALD J. LEVY, et al. )  
 ) Case No. 10-4185-CV-C-NKL  
 Defendants. )

**PLAINTIFFS’ SUGGESTIONS IN SUPPORT OF MOTION FOR SUMMARY  
JUDGMENT**

Plaintiffs are challenging a Missouri regulation and policy that terminates Medicaid coverage of medically necessary adult incontinence supplies when noninstitutionalized individuals reach the age of 21 by reclassifying these supplies as “personal hygiene items.” Prior to age 21, these supplies were covered by Missouri’s Medicaid program based upon a showing of “medical necessity.” This case is about whether Defendants’ policy of excluding coverage of “medically necessary” adult diapers from the Missouri Medicaid program is consistent with federal law.

On December 27, 2010, this Court granted Plaintiffs’ Motion for Preliminary Injunction after finding that Plaintiffs had established a likelihood of success on their claims that Defendants’ regulation and policy violate the “reasonable standards” and “home health” requirements of the Medicaid Act, the “community integration mandate” of the Americans with Disabilities Act (“ADA”) and Section 504 of the Rehabilitation Act. Order Granting Preliminary Injunction (“P.I. Order”) at 5-13. Plaintiffs now move for summary judgment on the grounds that the uncontroverted material facts set forth

below show that Plaintiffs are entitled to judgment on their Medicaid, ADA and Section 504 claims as a matter of law.

### **STATEMENT OF UNCONTROVERTED MATERIAL FACTS**

Pursuant to L.R. 56.1, the following uncontested material facts support Plaintiffs' Suggestions in Support of Motion for Summary Judgment:

1. In Missouri, all Medicaid recipients are categorically needy. Mo. Rev. Stat. § 208.151; *see also* 42 U.S.C. §§ 1396a(a)(10)(A), (C).

2. When it enacted Medicaid in 1965, Congress stated that categorically needy people "are the most needy in the country and it is appropriate for medical care costs to be met, first, for these people." H.R. Rep. No. 213, 89<sup>th</sup> Cong., 1st Sess.; S. Rep. No. 404, 89 Cong., 1st Sess., Pt. 1, *reprinted in* 1965 U.S.C.C.A.N. 2020-21.

### **Parties**

3. Plaintiff Steven Hiltibran is a 22-year-old man who has been enrolled in the Missouri Medicaid program, MO HealthNet, since age one and lives at home with his mother. Exhibit (Ex.) 13 at ¶¶ 1, 13, 18 and 25.<sup>1</sup>

4. Plaintiff Hiltibran suffers from severe cerebral palsy, psychosis, multiple sclerosis, scoliosis, and chronic pain, muscle spasms and contractures. Ex. 13 at ¶ 1.

5. Because of his medical conditions, Steven is completely bed-bound and terminally ill. Ex. 13 at ¶ 1.

6. Because of his medical conditions, Steven is completely incontinent of both bladder and bowel. Ex. 13 at ¶¶ 4 and 7.

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<sup>1</sup> All exhibits have been previously filed with Plaintiffs' Motion for Preliminary Injunction and Reply Suggestions, and are described on the Exhibit Lists filed on August 23, 2010 and October 18, 2010.

7. In determining his eligibility for personal care services, the Missouri Department of Health and Senior Services has found that Steven meets the level of care requirements for coverage in a nursing facility or other such institution. Ex. 13 at ¶ 19; 13 C.S.R. § 70-91.010(1)(A).

8. Steven's treating health care providers have stated that the most appropriate place for Steven to receive care and to live is in his home, where he has lived all his life. Ex. 17 at ¶ 9.

9. Steven's disabilities make him highly susceptible to respiratory and other life-threatening infections. Ex. 13 at ¶¶ 13, 14, 21 and 23; Ex. 17 at ¶¶ 5 and 6.

10. Steven needs incontinence briefs to prevent skin breakdown and infections. Ex. 13 at ¶¶ 7, 10, 11, 12, and 21; Ex. 17 at ¶¶ 6 and 7.

11. Steven's treating physicians have prescribed incontinence briefs to prevent skin breakdowns and ulcers that result from sitting in wet and soiled undergarments. Ex.13 at ¶¶ 7, 10, and 11; Ex. 17 at ¶ 6.

12. The MO HealthNet Program covered incontinence briefs as medically necessary for Steven until he turned 21 years of age. Ex. 13 at ¶ 8; Ex. 17 at ¶¶ 3 and 4.

13. Steven's medical condition did not change or improve when he turned 21. Ex. 13 at ¶ 20; Ex. 17 at ¶ 4.

14. Steven's treating physicians wrote letters to the MO HealthNet Division on January 6 and June 19, documenting his continuing medical need for adult diapers and requesting prior authorization for coverage of adult diapers. Ex. 13 at ¶ 10; Ex. 4 at 2.

15. On March 2, 2009, the MO HealthNet Division denied Steven's physician's prior authorization request for coverage. Ex. 13 at ¶ 15; Ex. 4 at 2.

16. On or about April 15, 2009, the MO HealthNet Division denied Steven's physician's request to obtain coverage through the Exceptions Process. The Agency's reason for denying the request was that "diapers are a personal hygiene item, not a medical item." Ex. 4 at 2, Ex. 13 at ¶ 15.

17. Steven's guardian, Debra Burkhart, appealed this denial and the Department of Social Services ("DSS") upheld the denial in a written decision on October 6, 2009. Ex. 13 at ¶ 15; Ex. 4.

18. The written decision was signed by Defendant Ian McCaslin, Director of the MO HealthNet Division. Ex. 4 at 3.

19. Director McCaslin found that "disposable diapers are a personal hygiene item, not a medical item" and that Steven "did not meet the burden of proof to show that disposable diapers are an essential medical item." Ex. 4 at 3.

20. Steven's incontinence briefs will be covered by the MO HealthNet program if he moves into a nursing home. Answer at ¶ 68; Ex. 1 at 2.

21. Steven's incontinence supplies cost approximately \$80 per month. Ex. 13 at ¶ 17.

22. Plaintiff Ronald Coontz is a 30-year-old man who has been enrolled in the MO HealthNet Program since age fifteen and lives at home with his mother. Ex. 14 at ¶¶ 1, 3, 4 and 5.

23. Ronald suffers from anoxia, static encephalopathy (permanent brain damage) and a seizure disorder. Ex. 14 at ¶ 1; Ex. 18 at ¶ 2.

24. Due to his disabilities, Ronald is completely incontinent of both bladder and bowel. Ex. 14 at ¶¶ 1 and 6; Ex. 18 at ¶¶ 2 and 4.

25. In determining his eligibility for personal care services, the Missouri Department of Health and Senior Services found that Ronald meets the level of care requirements for coverage in a nursing facility or other such institution. Ex. 14 at ¶ 3; 13 C.S.R. § 70-91.010(1)(A).

26. Ronald's treating health care providers have stated that the most appropriate place for Ronald to receive care and to live is in his home. Ex. 18 at ¶ 10.

27. Ronald's treating physicians have prescribed incontinence briefs to prevent skin breakdowns and infections. Ex. 14 at ¶ 6.

28. Ronald needs incontinence briefs to prevent skin breakdown and infections and to continue living at home with his guardian and mother. Ex. 14 at ¶¶ 5, 9, and 12; Ex. 18 at ¶¶ 10 and 11.

29. The Missouri Medicaid program covered incontinence briefs as medically necessary for Ronald until he turned 21 years of age. Ex. 14 at ¶¶ 6 and 7; Ex. 18 at ¶ 3.

30. Ronald's medical condition did not improve or change when he turned 21. Ex. 14 at ¶ 7; Ex. 18 at ¶ 3.

31. Ronald's treating physicians have written letters to the MO HealthNet Division documenting his continuing medical need for adult diapers. Ex. 14 at ¶ 8; Ex. 18 at ¶ 10.

32. Ronald's treating physician submitted a letter requesting an "exception" to continue coverage of adult diapers shortly after he reached age 21 but the request was denied. Ex. 14 at ¶ 8.

33. Ronald's incontinence briefs will be covered by the MO HealthNet program if he moves into a nursing home. Answer at ¶ 68; Ex. 1 at 2.

34. Ronald's incontinence supplies cost approximately \$300 per month. Ex. 14 at ¶ 6.

35. Paying for these supplies out of pocket has caused financial hardship and emotional stress for the Coontz family which is struggling to pay for Ronald's adult diapers while meeting other basic needs. Ex. 14 at ¶ 10.

36. Ronald's mother and guardian, Patricia Coontz, fears that he will have to enter a nursing home to continue receiving the incontinent supplies he needs. Ex. 14 at ¶ 12.

37. Plaintiff Nicholas Tatum is a 22-year-old man who is enrolled in the MO HealthNet Program, and was enrolled in the program before he turned 21. Ex. 15 at ¶¶ 1 and 6. He lives at home with his mother. Id. at ¶ 3.

38. Nicholas suffers from Alagille Syndrome (a genetic disorder that affects the heart, liver, kidney and other internal organs of his body), liver disease and mental disabilities. Ex. 15 at ¶ 1; Ex. 19 at ¶ 3.

39. Due to his disabilities, Nicholas is completely incontinent of both bladder and bowel. Ex. 15 at ¶ 2; Ex. 19 at ¶ 3.

40. In determining his eligibility for adult day care services, the Missouri Department of Health and Senior Services found that Nicholas meets the level of care requirements for coverage in a nursing facility or other such institution. Ex. 15 at ¶ 8; 13 C.S.R. § 70-91.010(2)(A).

41. Nicholas's mother and his teachers have tried to teach Nicholas to use the bathroom without success. Ex. 15 at ¶ 10.

42. Nicholas's treating health care provider has stated that he can be served appropriately in the community as long as he receives adult diapers. Ex. 19 at ¶¶ 8, 9 and 13.

43. Nicholas's treating physicians have prescribed incontinence briefs to prevent skin breakdowns and infections. Ex. 15 at ¶ 2; Ex. 19 at ¶ 4.

44. Nicholas needs incontinence briefs to prevent skin breakdown and infections. Ex. 15 at ¶ 11.

45. The Missouri Medicaid program covered incontinence briefs as medically necessary for Nicholas until he turned 21 years of age. Ex. 15 at ¶ 6.

46. Nicholas' medical condition did not change or improve when he turned 21. Ex. 15 at ¶ 6; Ex. 19 at ¶ 4.

47. Nicholas's mother asked his Medicaid caseworker and his St. Louis Regional Center caseworker if there was a way for him to continue receiving the incontinence supplies. Ex. 15 at ¶ 7.

48. The caseworkers were not able to help Nicholas and referred him to Catholic Charities. Ex. 15 at ¶ 7. Catholic Charities did not provide the requested diapers. Id. at ¶ 7.

49. Nicholas's incontinence briefs will be covered by the MO HealthNet program if he moves into a nursing home. Answer at ¶ 68; Ex. 1 at 2.

50. Nicholas's incontinence supplies cost approximately \$100 per month. Ex. 15 at ¶ 3.

51. Paying for these supplies out of pocket has caused financial hardship and emotional stress for the Tatum family. Ex. 15 at ¶ 9.

52. Plaintiff Nena Hammond is a 49-year-old woman who is enrolled in the MO HealthNet Program and lives by herself in the community. Ex. 16 at ¶¶ 2 , 4, 12-13.

53. Nena suffers from a spinal cord injury, cysts in her kidneys and liver, and occasional spasticity in her limbs and body. Ex. 16 at ¶ 3; Ex. 20 at ¶ 2.

54. Nena is paralyzed and must use a wheelchair for mobility. Ex. 16 at ¶ 3; Ex. 20 at ¶ 2.

55. Due to her disabilities, Nena is incontinent of both bladder and bowel. Ex. 6 at ¶ 3; Ex. 20 at ¶ 2.

56. In determining her eligibility for personal care services, the Missouri Department of Health and Senior Services found that Nena meets the “level of care” requirements for coverage in a nursing facility or other such institution. 13 C.S.R. § 70-91.010(1)(A).

57. Nena’s treating health care providers have stated that the most appropriate place for her to receive care and to live is in the community rather than a nursing home or other such institution. Ex. 20 at ¶¶ 6 and 9.

58. Nena’s treating physicians have determined that incontinence briefs are medically necessary to prevent skin breakdowns and ulcers that result from sitting in wet and soiled undergarments. Ex. 20 at ¶¶ 6, 7, 8, 9 and 10.

59. Nena is not always able to purchase all of the diapers she needs and sometimes suffers from skin infections. Ex. 16 at ¶ 10.

60. As a result of multiple skin infections, Nena has become allergic to many of the most common antibiotics and taking antibiotics causes her to experience side effects, including severe vomiting. Ex. 16 at ¶ 7; Ex. 20 at ¶ 5.



61. Nena's physician reports that she has limited treatment options and faces a higher risk of hospitalization with each infection. Ex. 20 at ¶ 5.

62. Prior to the preliminary injunction in this case, the Missouri Medicaid program did not cover Nena's incontinence briefs. Ex. 16 at ¶¶ 9 and 12.

63. Nena's incontinence briefs will be covered by the MO HealthNet program if she moves into a nursing home. Answer at ¶ 68; Ex. 1 at 2.

64. Nena's incontinence supplies cost from \$18 to \$90 per month depending on her health. Ex. 16 at ¶ 5.

65. Paying for these supplies out of pocket causes financial and emotional stress for Nena who must forego other basic necessities in order to pay for adult diapers. Ex. 16 at ¶¶ 10 and 12.

66. Nena often re-wears used diapers because she is in a "constant financial struggle to get by, trying to pay for diapers and also meet all of [her] other basic needs." Ex. 16 at ¶¶ 8 and 10; P.I. Order at 3.

67. The monthly cost of incontinence briefs for Plaintiffs ranges from two percent (2%) to forty-three percent (43%) of their monthly income. Ex. 13 at ¶ 1 and 17; Ex. 14 at ¶ 3 and 6; Ex. 15 at ¶¶ 1 and 3; Ex. 16 at ¶¶ 4 and 5; P.I. Order at 3.

68. Defendant Ronald J. Levy is the Director of the Missouri Department of Social Services (hereinafter, "DSS") and, as such, is responsible for the general administration and implementation of laws concerning the social welfare of the people of the State of Missouri, including the Medicaid program. Answer at ¶ 10.

69. Defendant Levy is the chief administrative officer of DSS and is responsible for administration of the single state agency for the Missouri Medicaid program.

Defendant Levy is charged with the ultimate control and administration of DSS, including the duty to administer the Missouri Medicaid program in compliance with the Medicaid Act, the ADA, and Section 504 of the Rehabilitation Act. Answer at ¶ 10.

70. Defendant Ian McCaslin, M.D., is the Director of MO HealthNet, a division of DSS, and, as such, is responsible for the administration of the Missouri Medicaid program, with the exception of determination of eligibility for the program. Answer at ¶ 11.

71. Defendant McCaslin holds ultimate administrative power within the MO HealthNet Division subject to the supervision of Defendant Levy. Answer at ¶ 11.

72. Missouri has chosen to participate in the Medicaid program, which is called MO HealthNet in Missouri. Answer at ¶ 32.

73. Missouri has designated DSS as the single state agency responsible for administering MO HealthNet. Answer at ¶ 32.

**Health Professionals' Statements Regarding Adult Incontinence Briefs, Relative Costs**

74. According to Dr. Thy Huskey, Assistant Professor of Neurology at Washington University School of Medicine, adult diapers are critical for protecting skin integrity and preventing the many health complications that result from a breach of skin integrity, including pressure sores. Ex. 21 at ¶¶ 5-13. Dr. Huskey stated that “adult diapers are often the only effective way to prevent skin breakdowns.” *Id.* at ¶ 13.

75. Dr. Huskey testified that adult diapers are needed to prevent skin breakdowns and infections that can cause sepsis, a systemic inflammatory response to infection characterized by fever, a raised heart rate, rapid breathing and a decrease in blood pressure, sometimes leading to septic shock and death. Ex. 21 at ¶ 9.

76. According to Dr. Huskey, complications from “skin encroachment” become more expensive to treat than the cost of covering the incontinent supplies. Ex. 21 at ¶ 12.

77. Dr. Huskey further stated that there is no medical basis for covering adult diapers for individuals under 21 but failing to provide them for individuals who are 21 or over. Ex. 21 at ¶ 16. The conditions that give rise to the medical need for adult diapers do not disappear when a person reaches 21 year of age. *Id.* at ¶ 16.

78. According to Dr. Yadria Hurley, the Director of Dermatopathology at St. Louis University School of Medicine, incontinence can cause not only ICD (“irritant contact dermatitis”), but also human papillomavirus (HPV), perirectal and genital warts, pain, yeast infections, potentially deadly staph infections, and skin cancer—including melanoma, the most dangerous form of skin cancer. Ex. 22 at ¶¶ 4-9.

79. Dr. Huskey testified that incontinence is one of the leading causes of institutionalization, and individuals suffering from incontinence are at serious risk of institutionalization. However, it is also a condition that can be treated effectively in the community with assistive modalities, such as adult diapers. Ex. 21 at ¶ 24.

80. According to Dr. Huskey, institutionalization of a person due to incontinence alone is medically inappropriate. Ex. 21 at ¶ 25; P.I. Order at 13-14.

81. The cost of serving an individual in a nursing home is over \$40,000 a year, or over \$3,333 per month. Ex. 23 at ¶ 12; Ex. 26 at 310; Ex. 28 at 12; P.I. Order at 12.

82. The cost of “even one unnecessary hospitalization from a lack of proper incontinency care could cost an average of \$1,768 for one day.” Ex. 23. at ¶ 12 (citing Governor Jay Nixon, *FY 2011 Department of Health and Senior Services Budget Request*

with Governor's Recommendations, January 2010 at p. 293, at: <http://oa.mo.gov/bp/budreqs2011/Health/Health.pdf>).

### **Federal DME Guidance and CMS Communications**

83. On September 4, 1998, the federal Centers for Medicare & Medicaid Services (CMS) issued guidance to State Medicaid Directors regarding Medicaid coverage of medical equipment, stating that the “mandatory home health services benefit under the Medicaid program includes coverage of medical supplies, equipment, and appliances suitable for use in the home.” Ex. 12.

84. The September 4, 1998 CMS guidance (Ex. 12) states:

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

85. CMS has stated that the denial of home health services to Missouri Medicaid beneficiaries violates 42 U.S.C. § 1396a(a)(10)(D). P.I. Order at 9; Ex. 11 at 1.

86. In a letter dated February 26, 2010, CMS stated that “Missouri is not providing all Medicaid beneficiaries with home health benefits that are required under title XIX of the Social Security Act (the Act).” Ex. 11 at 1. CMS further stated that “the approved Missouri State plan under title XIX (Medicaid) of the Act is not in compliance with the provisions of section 1902(a) of the Act with respect to the home health benefit.”

Id.

87. In the same letter, CMS stated that “[a]s a result of this ‘homebound’ requirement, certain Medicaid beneficiaries are not receiving the full benefit package required under section 1902(a)(10) of the Act, which in subparagraph (D) provides for the inclusion of home health services in the standard Medicaid benefit package.” Ex. 11 at 1.

88. On March 5, 2010, CMS issued a “Notice of Opportunity for a Hearing on Compliance of Missouri State Plan Provisions Concerning Payments for Home Health Services with Title XIX (Medicaid) of the Social Security Act.” 75 Fed. Reg. 10289-90 (Mar. 5, 2010) (“Federal Register Notice”). This Federal Register Notice stated that “Missouri is not providing all Medicaid beneficiaries with home health benefits that are required under title XIX of the Social Security Act (the Act).” Id.

89. In the same Federal Register Notice, CMS stated that “the approved Missouri State plan under title XIX (Medicaid) of the Act is not in compliance with the provisions of section 1902(a) of the Act with respect to the home health benefit” and that “[a]s a result of this ‘homebound’ requirement, certain Medicaid beneficiaries are not receiving the full benefit package required under section 1902(a)(10) of the Act, which in subparagraph (D) provides for the inclusion of home health services in the standard Medicaid benefit package.” 75 Fed. Reg. 10289-90 (Mar. 5, 2010).

90. On June 11, 2010, CMS instructed the State of Missouri to “delete the language in the [State Plan Amendment] that conditions receipt of home health aide services on the concurrent need for skilled nursing care or physical, occupational, or speech therapy services since federal Medicaid requirements do not allow this type of arrangement.” Ex. 37.

91. On November 21, 2005, CMS instructed the State of Missouri to remove the following language from the State Plan Amendment being submitted: “To be eligible for home health services, a recipient must require the services of a skilled nurse or therapist, as defined in paragraphs 7.a and d below and be confined to his home.” Ex. 36. CMS further instructed the State to remove from paragraph 7b: “needed concurrently with covered skilled nursing or physical, occupational or speech therapy services.” Ex. 36.

92. In the same directive, CMS advised Missouri that “the State may not require that individuals require the services of a skilled nurse or therapist in order to receive either the services of a Home Health aide, or medical equipment and supplies under home health. This requirement is not specified in Medicaid law or regulations.” Ex. 36.

#### **MO HealthNet’s Coverage of Incontinent Supplies**

93. The MO HealthNet Division covers incontinence briefs as “durable medical equipment” for individuals ages 4 through 20. P.I. Order at 6; Ex. 5, 6, 8, 9, 10.

94. Missouri’s Medicaid statute requires coverage of prescribed medically necessary durable medical equipment. Mo. Rev. Stat. § 208.152.1(19).

95. The Missouri Medicaid statute requires that an “electronic web-based prior authorization system using best medical evidence and care and treatment guidelines consistent with national standards shall be used to verify medical need.” Mo. Rev. Stat § 208.152.1(19).

96. Missouri’s Durable Medical Equipment (DME) regulation incorporates by reference the MO HealthNet Division’s DME Provider Manual and Bulletins. 13 C.S.R. 70-60.010(6).

97. The regulation further provides that “[c]overed services are limited as specified in the DME provider manual and bulletins.” 13 C.S.R. 70-60.010(2).

98. The Missouri Medicaid Program’s Durable Medical Equipment Provider Manual indicates that incontinence briefs are covered for individuals age four through twenty years. Missouri Durable Medical Equipment Provider Manual, § 13.22.B., at [http://manuals.momed.com/collections/collection\\_dme/Durable\\_Medical\\_Equipment\\_Section13.pdf](http://manuals.momed.com/collections/collection_dme/Durable_Medical_Equipment_Section13.pdf) ; Ex. 6; Answer at ¶ 38.

99. The Durable Medical Equipment Manual states that “diapers/briefs are covered for participants ages 4 through 20 when” the “items are prescribed and determined to be appropriate when there is presence of a medical condition causing bowel/bladder incontinence.” Ex. 6; Answer at ¶ 39. “Documentation of the above-noted qualifying criteria *must* be maintained in the provider’s record.” Ex. 6 (emphasis in original). “The prior authorization request [for incontinence products] *must* include documentation of medical need from a physician, indicating a condition causing excessive fecal or urine output.” *Id.* (emphasis in original).

100. On March 6, 2009, Defendants issued a Provider Bulletin entitled “Physician and Durable Medical Equipment” stating the MO HealthNet Division’s policy concerning Medicaid coverage of incontinence briefs. Provider Bulletin, Vo. 31, NO. 52, March 6, 2009, at [http://www.dss.mo.gov/mhd/providers/pdf/bulletin31-52\\_2009mar06.pdf](http://www.dss.mo.gov/mhd/providers/pdf/bulletin31-52_2009mar06.pdf) (hereinafter “Provider Bulletin”); Ex. 5; Answer at ¶ 40.

101. The March 6, 2009 provider bulletin contains a list of procedure codes for adult diapers under the heading “durable medical equipment.” Ex. 5.

102. The Provider Bulletin established new prior authorization criteria for obtaining approval of underpads, diapers/briefs, and protective underwear for individuals aged 4 through 20. The Provider Bulletin states that “[i]n order to be approved, participants must be between ages 4 through 20 and meet the medical criteria established by the MO HealthNet Division (MHD).” Ex. 5 and 7; Answer at ¶¶ 41 and 42.

103. The purpose of the new prior authorization criteria is “[t]o allow a consistent and streamlined process for authorization for diapers, pull-ons and underpads for participants ages 4 through 20.” Ex. 7; Answer at ¶ 42.

104. The new DME prior authorization criteria also included the following statement:

Senate Bill 577 passed by the 94<sup>th</sup> General Assembly directs MO HealthNet to utilize an electronic web based system to authorize Durable Medical Equipment using best medical evidence and care and treatment guidelines, consistent with national standards to verify medical need.

Ex. 7; Answer at ¶ 42; Mo. Rev. Stat. § 208.152.1 (19).

105. Approval criteria for coverage of incontinence briefs include the requirement that there be a “medical condition causing bowel/bladder incontinence.” Ex. 7; Answer at ¶ 43. The criteria include the following question for the physician who prescribes incontinence briefs: “What is the “medically necessary quantity per month? \_\_\_ (quantities over 186 require submission of a separate pre-certification and detailed medical justification).” Ex. 7.

106. According to these DME medical prior authorization criteria, one of the “denial criteria” for these incontinence supplies is that “Patient is age 21 or over.” Ex. 7; Answer at ¶ 44.



107. The MO HealthNet Division's Durable Medical Equipment Billing Book describes the documentation a prescribing physician must provide to DME providers for diapers and other incontinence products for participants aged 4 through 20. Ex. 10 at 7.1.

108. Prior to issuance of the preliminary injunction in this case, individuals over age 20 were not allowed to establish "medical necessity" for incontinence briefs nor were they allowed to use the State's prior authorization process to "verify medical need" for adult diapers. Ex. 1, 2, 3, 4, 5, 6, and 7.

109. Prior the issuance of the preliminary injunction in this case, incontinence briefs were deemed to be "personal hygiene items" for individuals over age 20, according to the policies of the MO HealthNet Division. Ex. 1, 2, 3, 4, 5, 6, and 7.

110. The Missouri Medicaid program uses an "Exceptions Process" for services that are not normally covered by the Missouri Medicaid program. 13 C.S.R. § 70-2.100.

111. The Exceptions Process is only available for items that the Missouri Medicaid program considers to be essential medical services or items that would otherwise exceed the limitations of the Missouri Medicaid program. 13 C.S.R. § 70-2.100.

112. The Exceptions Process allows for exceptions to be made on a "case by case basis to limitations and restrictions" on the receipt of benefits in the Missouri Medicaid program. Id.

113. Exceptions may be granted under this process only if one or more of the following conditions are met: (1) The item or service is required to sustain the recipient's life; (2) The item or service would substantially improve the quality of life for a terminally ill patient; (3) The item or service is necessary as a replacement due to an act occasioned by violence of nature without human interference such as a tornado or flood;

or (4) The item or service is necessary to prevent a higher level of care. 13 C.S.R. § 70-2.100.

114. Prior to the preliminary injunction in this case, Defendants did not cover incontinence briefs through Missouri's Medicaid "Exceptions Process." Defendants considered them to be "personal hygiene items" rather than "essential medical items" for individuals over age 20. Ex. 2.

115. On April 28, 2009, Defendant McCaslin stated in an electronic mail communication that "diapers, pre-moistened washcloths and incontinent no-rinse wash antimicrobial .... are non-covered for individuals age 21 and older." Ex. 3; Answer at ¶ 48. McCaslin further stated that "[t]he items in question are personal hygiene items, not medical items." Ex. 3.

116. Defendant McCaslin stated that "[w]hile the items have never been a covered service for adults over age 21, a recent policy change was implemented for the previously covered age population of 4-20 that required the items now be pre-certified through the SmartMed PA process." Id.

117. On July 15, 2009, Defendant McCaslin stated that as follows: "As diapers are a personal hygiene item, not an essential medical item, they are not approved by the Exceptions Process, as they do not meet the criteria established in the program regulation." Ex. 2; Answer at ¶ 49.

118. Defendant McCaslin further stated that while "the determination of medical necessity is key to the federal EPSDT legislation for participants under age 21... [m]edical necessity is not the guiding principal [sic] of the Exceptions Process state regulation." Ex. 2; Answer at ¶ 49.

119. Prior to the issuance of a preliminary injunction in this case, the Missouri Medicaid Program did not cover adult incontinence briefs for disabled individuals over age 20 who reside in the community. Ex.1-7.

120. The Missouri Medicaid program covers adult diapers as part of the per diem rate for individuals over age 20 who reside in nursing homes or other institutional settings. Ex. 1 and Ex. 28 at 12.

121. Incontinence briefs are a covered supply for individuals receiving long-term care services, including nursing home services, and are included in Missouri's per diem rate for those services. 13 C.S.R. §§ 70-10.010(5) and 70-10.015(5) (L), Appendix A.

122. On February 23, 2010, Special Counsel for DSS stated:

Incontinence supplies are non-covered for adults through MO HealthNet's DME program. Diapers are considered a personal hygiene item, not an essential medical item, and have never been a covered service for adults in Missouri . . . Incontinence supplies, other than diapers, may be covered through the exception process on a case by case basis. . . . Incontinence Supplies and diapers for any age participant in an institutional nursing facility or hospital are included in the facility's per diem rate.

Ex. 1.

### **MO HealthNet's Coverage of Supplies**

123. The MO HealthNet Division covers certain supplies for adults in its DME program that cannot withstand repeated use, including but not limited to: ostomy supplies, oxygen supplies, cleaning solution and supplies for ventilators, Trach Care supplies, and parenteral nutrition supplies. Ex. 30, 31 and 32. The MO HealthNet Division also covers insulin and other diabetic supplies under its Pharmacy program. Ex. 32.

124. The MO HealthNet Division covers “single-use” items in its durable medical equipment program, including ostomy skin barrier liquid and powder, lubricant, waterproof tape, skin barrier wipes and swabs, total parenteral nutrition (TPN) solutions and additives and one-day TPN supply kits. Ex. 30, 31 and 32.

125. The Missouri State Medicaid Plan, filed with CMS, indicates that “ostomy supplies, oxygen . . . Home Parenteral Nutrition and related supplies, and medically necessary items of miscellaneous durable medical equipment are covered and provided through the MO HealthNet Durable Medical Equipment Program.” Ex. 33.

126. The Missouri State Medicaid Plan also provides that “[m]edically necessary supplies which are not routinely furnished in conjunction with patient care visits and which are direct, identifiable services to an individual patient, are reimbursable to the agency.” P.I. Order at 12; Ex. 34. Examples include: Ostomy sets and supplies, irrigation sets and supplies, tapes, catheters and supplies. Ex. 34. The State Plan further states that [n]eeded items of medical equipment prescribed by a physician are available to all recipients including recipients of home health, through the Durable Medical Equipment program.” Ex. 34; PI Order at 9.

### **Preliminary Injunction**

127. On or about January 14, 2011, the MO HealthNet Division promulgated a notice which states:

#### **Notice Concerning Adult Incontinence Briefs**

Please be advised that a preliminary injunction order was issued on December 27, 2010, by a Missouri U.S. District Court in *Hiltibran v. Dep’t of Social Services*, Case No. 10-4185-CV-C-NKL, wherein the court enjoined the Department from refusing to provide adult incontinence briefs to those MO HealthNet participants over 21 years of age on the basis that such briefs are hygiene items. As such, if a prescriber believes that such adult incontinence briefs are medically necessary for the MO HealthNet participant, they should

utilize the Department's exceptions process for requesting authorization. During the preliminary injunction, these requests will be granted upon a determination of medical necessity. If you have any questions or need assistance, please contact the MO HealthNet Exceptions Unit at 1-800-392-8030, option 2.

MO HealthNet Division, Department of Social Services, *Notice Concerning Adult Incontinence Briefs*, undated (available at: <http://dss.mo.gov/mhd/general/pdf/notice.pdf>).

128. Pursuant to the Preliminary Injunction, the MO HealthNet Division has approved Plaintiffs' requests for Medicaid coverage of adult diapers.<sup>2</sup>

### STANDARD FOR SUMMARY JUDGMENT

Summary judgment on a given claim is appropriate when the moving party establishes that there are no genuine issues of material fact and that, as a matter of law, the moving party is entitled to judgment. *See, e.g., Liebe v. Norton*, 157 F.3d 574, 578 (8th Cir. 1998); *Hall v. Lhaco, Inc.*, 140 F.3d 1190, 1193 (8th Cir. 1998). Summary judgment is particularly appropriate when, as here, the unresolved issues are primarily legal rather than factual. *See, e.g., Uhl v. Swanstrom*, 79 F.3d 751, 754 (8th Cir. 1996); *Lomar Wholesale Grocery v. Dieter's Gourmet Foods*, 824 F.2d 582, 585 (8th Cir. 1987).

### ARGUMENT

#### **I. PLAINTIFFS ARE ENTITLED TO SUMMARY JUDGMENT ON THE MERITS OF THEIR CLAIMS THAT THE DEFENDANT HAS VIOLATED THE REASONABLE STANDARDS AND HOME HEALTH REQUIREMENTS OF THE MEDICAID ACT, AS WELL AS THE AMERICANS WITH DISABILITIES ACT AND SECTION 504 OF THE REHABILITATION ACT.**

Because Missouri participates in the Medicaid program, it "must comply with all federal statutory and regulatory requirements." *Lankford v. Sherman*, 451 F.3d 496, 510 (8th Cir. 2006); *Myers v. Reagan*, 776 F.2d 241, 243-44 (8th Cir. 1985). The

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<sup>2</sup> *See* n. 3, *infra*, regarding Plaintiff Steven Hiltibran.

fundamental question is whether or not Defendants' incontinence supplies policy on its face violates federal Medicaid law, the ADA and the Rehabilitation Act. Defendants have not contested that they issued the policies relied on by Plaintiffs nor have they contested the content of those policies. Thus, Defendants cannot show any genuine issues of disputed material facts.

This case is solely a legal dispute about whether Defendants are required to cover adult diapers and provide affected individuals a fair process to establish that they are medically necessary—disputes that this Court has preliminarily resolved in Plaintiffs' favor.

**A. Defendants' Regulation And Policy Violate The Reasonable Standards And Home Health Requirements Of The Medicaid Act.**

This Court has found that Defendants' policy with regard to adult diapers is "unreasonable" under the Medicaid Act and that Plaintiffs are likely to succeed on the merits of that claim. P.I. Order at 5-9. See also Plaintiffs' Memorandum in Support of Motion for a Preliminary Injunction (Plfs' Memo) at 5-12. The Eighth Circuit has already noted that a state's "failure to provide coverage of non-experimental, medically necessary services within a covered Medicaid category is both *per se unreasonable* and inconsistent with the stated goals of Medicaid." Lankford v. Sherman, 451 F.3d 496, 511 (8th Cir. 2006) (emphasis added). Moreover, as this court noted, Missouri "cannot arbitrarily choose which DME items to reimburse under its Medicaid policy." P.I. Order at 5, citing Lankford, 451 F. 3d at 511. "Plaintiffs have established that the rules in Lankford likely apply in this instance, which prevents Missouri from 'arbitrarily' denying coverage of incontinence briefs in violation of the Medicaid Act's 'reasonable standards' requirement." P.I. Order at 6. Moreover, Plaintiffs are unreasonably denied the

opportunity to establish medical necessity for incontinence briefs due to the "blanket presumption of the briefs as 'non-medical' or 'personal hygiene' items for persons over the age of twenty." Id. at 8. These illegalities are no different when considering Plaintiffs' motion for summary judgment as opposed to their claim for preliminary relief. Defendants' policy violates Medicaid's reasonable standards requirement and, therefore, Plaintiff's motion for summary judgment should be granted.

This Court also found that Defendants' policy regarding adult diapers violates Medicaid's "home health requirement" by denying medically necessary incontinence supplies which are a mandatory home health service. P.I. Order at 9-10. See also Plfs' Memo at 12-14. "Plaintiffs have demonstrated support that incontinence briefs are 'durable medical equipment,' . . . they have met their burden of establishing the likelihood of success on the merits as to this claim." P.I. Order at 10. This legal issue is no different when considering summary judgment. This Court should therefore grant summary judgment on Plaintiffs' claim that Defendants' policy violates Medicaid's home health requirement.

**B. Defendants' Regulation And Policy Violate The ADA and Section 504 Of The Rehabilitation Act.**

The same is true with regard to Plaintiffs' claims under the Americans with Disabilities Act ("ADA") and Section 504 of the Rehabilitation Act (Section 504"). This Court found that Defendants violated the ADA and Section 504 by failing to cover adult diapers in the community while covering these same incontinence supplies for adults who reside in nursing homes. Id. at 10-13. See also Plfs' Memo at 14-23; Department of Justice, Statement of Interest of the United States of America in Support of Plaintiffs' Motion for Preliminary Injunction 5-12 ("DOJ Brief"). Plaintiffs have established that

they meet the requirements for an “integration mandate challenge” and that “under Olmstead, Defendants are required to provide incontinence briefs to non-institutionalized adults if they provide briefs to institutionalized adults.” P.I. Order at 11-13 (applying Olmstead v. L.C., 527 U.S. 581 (1999)). The legal issue on the integration mandate challenge is no different upon a motion for summary judgment. Therefore, this Court should similarly grant Plaintiffs’ Motion for Summary Judgment on the ADA and Section 504 claims.

The legal issues addressed by this Court in awarding preliminary relief are identical to the issues to be decided in considering this Motion for Summary Judgment. See Winter v. Natural Resources Defense Council, 555 U.S. 7, 11 (2008) (“analysis of the propriety of preliminary relief is applicable to any permanent injunction as well”). Either the Defendants’ adult diapers policy violates these federal requirements or it does not. This Court has already found that it does. Moreover, there are no material facts in dispute. While Plaintiffs have included herein a more detailed Statement of Undisputed Material Facts in accordance with Local Rule 56.1, the key material facts in this case are the following: (1) Prior to this Court’s preliminary injunction in this case, Defendants implemented a regulation and policy that terminated coverage of diapers to Plaintiffs and other individuals who reached the age of 21 on the basis that they were “personal hygiene” items even though a showing of medical necessity was required before the individuals reached the age of 21. (2) Prior to the preliminary injunction, Defendants covered these items for individuals residing in nursing homes but excluded this service from coverage for individuals who meet the nursing facility level of care but reside in the community. Because there is no dispute as to these material facts, this case is solely a



legal dispute about whether Defendants are required to cover adult diapers and provide affected individuals a fair process to establish that they are medically necessary—disputes which this Court has already resolved.

## **II. PLAINTIFFS ARE ENTITLED TO INJUNCTIVE AND DECLARATORY RELIEF.**

As demonstrated above, Plaintiffs have established that the Defendants’ policy violates federal Medicaid law as well as Section 504 and the ADA. Plaintiffs ask this Court to issue a declaratory judgment against the Defendants to that effect and to permanently enjoin them from continuing to violate the “reasonable standards” and “home health” provisions of the Medicaid Act as well as the ADA and Section 504.

Plaintiffs have already established that they suffer irreparable harm without an injunction, that the balance of the hardship tips in their favor and that an injunction is in the public interest. P.I. Order at 13-16. See also Plfs’ Memo at 23-30; DOJ Brief at 12-15. Plaintiffs still meet these requirements and are therefore entitled to permanent injunctive relief. Currently, but only “[d]uring the Preliminary Injunction,” Defendants are making medically necessary incontinence briefs available through the Department’s exceptions process. See MO HealthNet Division, DSS “*Notice Concerning Adult Incontinence Briefs*, (undated), at: <http://dss.mo.gov/mhd/general/pdf/notice.pdf>. Without a permanent injunction, Defendants will resort to their prior policy and deny coverage of medically necessary adult diapers.<sup>3</sup>

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<sup>3</sup> Plaintiff Hiltibran has been approved for the State’s new Prevention Waiver program and is currently receiving adult diapers and tracheotomy supplies under the waiver. However, the State has not issued any official policies, let alone *rules*, implementing the waiver, which currently serves a maximum of 399 individuals statewide in 37 Missouri counties. Further, the program has a maximum annual cap of \$12,000 on services for each individual in the waiver. Missouri Department of Mental Health, Prevention

As the Eighth Circuit has already noted, Missouri is required to adhere to federal Medicaid requirements in the operation of its Medicaid program. Lankford, 451 F.3d at 504. Therefore, this Court should strike down the challenged policy and compel Defendants to adopt an incontinence supplies regulation and policy that comply with federal law. See, e.g., Kai v. Ross, 336 F.3d 650 (8th Cir. 2003) (enjoining State to continue Medicaid benefits after finding state law terminating inconsistent with federal Medicaid Act); Weaver v. Reagen, 886 F.2d 194 (8th Cir. 1989) (enjoining Missouri from denying Medicaid coverage of AZT); Olson v. Norman, 830 F.2d 811 (8th Cir. 1987) (sustaining permanent injunction and summary judgment against state for unlawful termination of Medicaid benefits); Lankford v. Sherman, No. 05-4285-CV-C-DW, 2007 U.S. Dist. LEXIS 14950, at \*14 (preliminarily and permanently enjoining Missouri

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Waiver, <http://dmh.mo.gov/dd/progs/waiver/prevention.htm>. Currently, Steven is approved for services that will reach the maximum annual limit and is thus ineligible for other services that he needs and that would otherwise be available to him under the waiver. The county agency administering the waiver has indicated that if Steven's diapers are covered through the regular Medicaid approval process, then the cost of the diapers will not be counted towards the waiver cap and *other needed services* (i.e., additional personal care hours) will be substituted in their place. Thus, Steven will continue to be harmed if Defendants' are allowed to exclude adult diapers from the regular Medicaid program because covering them under the waiver brings him up to the \$12,000 cap. In addition, such waiver coverage can be withdrawn by the State at any time as there are no program rules for services and the waiver authorizes the State to re-evaluate individuals and discontinue services at any time. See Prevention Waiver Application at App. B-2, at: <http://www.cms.gov/MedicaidStWaivProgDemoPGI/MWDL/itemdetail.asp?filterType=dual,%20data&filterValue=Missouri&filterByDID=2&sortByDID=2&sortOrder=ascending&itemID=CMS1242952&intNumPerPage=10>. Therefore, Plaintiffs have requested that Defendants cover Steven's diapers under the regular Medicaid program in accordance with the Preliminary Injunction and the interim policy implementing the court's order and decision.

No other plaintiff has been found eligible for this waiver, which by its terms serves a limited number of individuals in only those counties that choose to participate. The Prevention Waiver does not remedy the harm resulting from the Defendants' failure to cover medically necessary diapers in its Medicaid program.

Medicaid agency from continuing to deny medically necessary DME); White v. Martin, No. 02-4154-CV-C-NKL, 2002 U.S. Dist. LEXIS 27281 (W.D. Mo. Oct. 3, 2002) (preliminarily enjoining Missouri to provide transitional Medicaid benefits); Nemnich v. Stangler, No. 91-4517-CV-C-5, 1992 WL 178963 (W.D. Mo. Jan. 7, 1992) (enjoining Missouri from denying Medicaid coverage of dental services); J.D. v. Sherman, No. 06-4153-CV-C-NKL, 2006 U.S. Dist. LEXIS 78446, at \*10 (W.D. Mo. 2006) (preliminarily enjoining Missouri Medicaid agency to cover medically necessary transplant services); McNeil-Terry v. Roling, 142 S.W.3d 828, 834 (Mo. App. 2004) (preliminarily and permanently enjoining the Missouri Medicaid agency from reducing the scope of necessary dental services through rulemaking or other non-statutory means).

### CONCLUSION

This Court should grant Plaintiffs' Motion for Summary Judgment and declare the Defendants' incontinence supplies policy in violation of the Medicaid Act, the ADA and Section 504 of the Rehabilitation Act. Further, it should enter a permanent injunction enjoining Defendants from applying their illegal policy and from arbitrarily limiting the scope of medically necessary adult diapers through any other means. Finally the Court should order Defendants to establish a fair process whereby all adult Missouri Medicaid recipients can obtain medically necessary incontinence briefs.

Respectfully submitted,

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### **CERTIFICATE OF SERVICE**

I hereby certify that on February 17, 2011, I electronically filed the foregoing with the clerk of the Court using the CM/ECF system which sent notification of such filing to the following counsel of record:

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