IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JOHN DOE, Plaintiff,	:	
v.	:	**CIVIL ACTION NO.**
THEODORE DALLAS, in his official capacity as Secretary of the Pennsylvania Department of Human Services, Defendant.	:	

COMPLAINT

PRELIMINARY STATEMENT

1. Defendant Theodore Dallas is Secretary of the Pennsylvania Department of Human Services ("DHS") which operates and administers the Commonwealth's Medical Assistance program ("Medicaid") and which is required to do so in accordance with the Constitution and laws of the United States.

2. Plaintiff John Doe has sought Medicaid coverage for medically necessary treatment as prescribed by his physician for his Gender Dysphoria ("GD") diagnosis, but he is banned from receiving such coverage because Defendant, as Secretary of DHS, has unreasonably adopted, promulgated, and enforced regulations banning any Medicaid eligible individual diagnosed with GD from receiving any medically necessary Medicaid coverage for treatment of GD by any physician, hospital, pharmacy, clinic, emergency room, or other Medicaid provider. 55 Pa. Code §§ 1141.59(11) (banning payment for physicians' services); 1121.54(10) (banning payment to pharmacies for prescribed drugs); 1126.54(7) (banning payment to ambulatory surgical centers and short procedure units); 1163.59(a)(1) (banning payment to hospitals for inpatient hospital stay); and 1221.59(7) (banning payment to clinics and emergency rooms) (collectively, the "Regulations").

3. Although the federal statutes governing Medicaid, 42 USC § 1396 *et. seq.,* permit states to place appropriate limits on a service based on lack of medical necessity, state Medicaid programs may not arbitrarily deny benefits that are medically necessary on the basis of a diagnosis.

4. Defendant's actions in adopting, promulgating, and enforcing the Regulations, are discriminatory and violate the Constitution and laws of the United States, which mandate that medically necessary Medicaid coverage provided through state Medicaid programs must be provided equally to all Medicaid eligible individuals, without regard to diagnosis.

5. As set forth below, Plaintiff seeks declaratory, injunctive, and any other appropriate relief to enjoin Defendant from continuing to adopt, promulgate, and enforce the Regulations banning medically necessary coverage for GD on the grounds that such regulations and actions by Defendant, acting in his official capacity as Secretary of DHS: (i) violate the Equal Protection clause of the United States Constitution and are thus actionable pursuant to 42 U.S.C. § 1983; (ii) conflict with the Medicaid Act, 42 U.S.C. §§ 1396 et seq. and thus are preempted by the Supremacy Clause; (iii) violate the non discrimination provision of the Patient Protection and Affordable Care Act ("the ACA"), 42 U.S.C. § 18116; and (iv) violate the Medicaid Act, 42 U.S.C. §§ 1396 et seq., and are thus actionable pursuant to 42 U.S.C. § 1983.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the parties and the claims asserted herein pursuant to 28 U.S.C. §§ 1331, 1343(a)(3), and 1367.

7. Plaintiff's claims for declaratory relief are brought pursuant to 28 U.S.C. §§ 2201 and 2202.

8. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) because Plaintiff resides within this judicial district, the events giving rise to this action occurred in this judicial district, and Defendant is subject to personal jurisdiction in this judicial district.

THE PARTIES

9. Plaintiff John Doe resides within this judicial district and is a Medicaid recipient. Plaintiff is appearing here under a pseudonym. A motion for anonymity is being filed simultaneously with this Complaint.

10. In his capacity as Secretary of DHS, Defendant Dallas is responsible for the administration of DHS, which operates and administers the Commonwealth Medicaid's program. Defendant Dallas is obligated to ensure that Medicaid patients with GD are treated in accordance with the Constitution and laws of the United States. Defendant Dallas has at all relevant times hereinafter mentioned acted under color of state law and is being sued in his official capacity.

PERTINENT CONSTITUTIONAL PROVISIONS

11. The Equal Protection Clause of the Fourteenth Amendment to the United States Constitution provides that: "No State shall . . . deny to any person within its jurisdiction the equal protection of the laws." U.S. Const. amend. XIV, §1.

12. The Supremacy Clause of the Constitution provides "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the contrary notwithstanding." U.S. Const. art. VI, cl. 2.

PERTINENT FEDERAL STATUTES AND REGULATIONS

13. Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq*. ("Medicaid Act"), creates the federal Medicaid program, a cooperative state and federal benefit program designed

to provide necessary medical services to needy persons who meet certain eligibility requirements.

14. The Medicaid program is a jointly funded federal-state program, which provides federal financial assistance to states that choose to furnish medical assistance to individuals whose incomes and resources are insufficient to meet the costs of necessary medical services. 42 U.S.C. §§ 1396, 1396b.

15. States need not participate in the program, but if they choose to do so, they must develop and implement a state Medicaid plan. 42 U.S.C. §§ 1396, 1396a, 1396c.

16. States have considerable control over their plan's details and administration; however, to qualify for federal funding a state plan must comply with the Medicaid Act's requirements. 42 U.S.C. §§ 1396a, 1396b(a).

17. The federal Medicaid program requires a participating state to establish or designate a single state agency that is responsible for administering or supervising the administration of that state's Medicaid program. 42 U.S.C. § 1396a(a)(5).

18. Participating states also must submit a state plan to a federal agency within the United States Department of Health and Human Services ("HHS") detailing how they will spend Medicaid funds. 42 U.S.C. §§ 1396a(a), (b).

19. A state plan must include reasonable standards for determining eligibility for and the extent of medical assistance under the plan. 42 U.S.C. § 1396a(a)(17).

20. A state plan must provide for making medical assistance available to all categorically needy individuals by providing, at minimum, inpatient hospital services, outpatient hospital services, laboratory and X-ray services, and physicians' services furnished by a physician. 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(1), 1396d(a)(2), 1396d(a)(3), 1396d(a)(5).

21. In accordance with the Medicaid Act, medical assistance must be provided in a manner consistent with the best interests of the recipients. 42 U.S.C. § 1396a(a)(19).

22. The Medicaid Act further requires that the medical assistance made available to any categorically needy person shall not be less in amount, duration, or scope than the medical assistance made available to other such individuals. 42 U.S.C. § 1396a(a)(10)(B)(i).

23. The Medicaid Act mandates that a state plan provide for making medical assistance available to all categorically needy individuals by providing, at minimum, medically necessary physician, hospital and other services, and also provide, at a minimum, payments for such services sufficient to ensure that providers exist "at least to the extent that such care and services are available to the general population in the geographic area." 42 U.S.C. 1396a(a)(30)(A).

24. The ACA prohibits health care programs receiving federal assistance from discriminating on the basis of sex. 42 U.S.C. § 18116.

25. The ACA's ban on sex discrimination includes transgender discrimination, which includes discrimination against people with a GD diagnosis.

26. The HHS's Office of Civil Rights confirmed that the ACA's protection against sex discrimination includes discrimination claims based on transgender discrimination, that is, "gender identity or failure to conform to stereotypical notions of masculinity or femininity." *See* July 7, 2012 letter from HHS's Office of Civil Rights, attached as Exhibit A.

27. The HHS has banned transgender discrimination in Medicare, by Decision No. 2576, issued May 20, 2014, and thus lifted a ban that had previously existed under Medicare banning transgender surgery. The HHS found that the scientific and medical evidence established that surgery is safe, effective and non-experimental, may be medically necessary for trans people and so needs to be covered by Medicare. The Decision is attached as Exhibit B.

PERTINENT PENNSYLVANIA REGULATIONS

28. Medicaid coverage in Pennsylvania includes payments for medically necessary hysterectomies for Medicaid eligible individuals. 55 Pa. Code § 1141.56.

29. Medicaid coverage in Pennsylvania bans payments for medically necessary hysterectomies for Medicaid eligible individuals diagnosed with GD. 55 Pa. Code. § 1141.59(11) states as follows:

> Payment will not be made for the following physicians' services:…(11) Surgical procedures and medical care provided in connection with sex reassignment. This includes but is not limited to hormone therapy, penile construction, revision of labia, vaginoplasty, vaginal dilation, vaginal reconstruction, penectomy, orchiectomy, mamoplasty, mastectomy, hysterectomy, and release of vaginal adhesions.

30. 55 Pa. Code § 1121.54 (10) bans payment for "Drugs prescribed in conjunction with sex reassignment procedures or other noncompensable procedures."

31. 55 Pa. Code § 1126.54 (7), bans payment for "Procedures and medical care performed in ASCs [ambulatory surgical centers] and SPUs [short procedure units] in connection with sex reassignment."

32. 55 Pa. Code § 1163.59(a)(1), bans payment for "hospitals for an inpatient hospital stay if the admission is directly or indirectly related to the hospital's provision of: "Transsexual surgical procedures for gender change or reassignment-for example, penile construction, revision of labia, vaginoplasty, vaginal dilation, vaginal reconstruction, penectomy, orchiectomy, mammoplasty, mastectomy, hysterectomy and release of vaginal adhesions."

33. 55 Pa. Code § 1221.59(7) bans payment to clinics or emergency rooms for "Surgical procedures and medical care provided in connection with sex reassignment. This includes, hormone therapy and release of vaginal adhesions."

FACTS

34. Plaintiff John Doe is a categorically needy Medicaid recipient residing in Delaware County, Pennsylvania. Mr. Doe is 30 years old and has received Medicaid benefits since 2013.

35. John Doe supports himself with Supplemental Security Disability Income and SNAP ("food stamps") assistance.

36. John Doe is transgender.

37. Transgender is a biological condition, due to brain neuroanatomy and the formation of that brain neuroanatomy in the womb.

38. Transgender (or "trans") people are born with bodies whose anatomy and gender is different from what they actually are.

39. John Doe has GD.

40. GD is a medical and therapeutic diagnosis, referring to the physical, mental and emotional difficulties that may arise in trans people due to the conflict between their brain anatomy and body anatomy. Diagnostic and Statistical Manual of Mental Disorders, 5th Edition ("DSM-V" at 302.85.)

41. A trans person is diagnosed as suffering from GD when they have "clinically significant distress" associated with being trans. *Id*.

42. GD is not being transgender but may result from being transgender.

43. A variety of treatments, some of which are like those offered to non-trans people, are medically necessary for GD treatment.

44. Medically necessary procedures for GD Treatment may include hormone or other prescriptions, therapy, Gender Confirmation Surgery ("GCS" or "bottom surgery"), breast implants or removal ("top surgery"), and others, including hysterectomy, genital reconstruction,

and plastic surgery, as appropriate and prescribed and medically necessary for the particular person.

45. Medically necessary treatment for GD is recognized as safe, effective, and warranted by the American Medical Association, the American Psychiatric Association, and other leading medical organizations, HHS and other federal and state organizations, and the Commonwealth's Physician General Dr. Rachel Levine to alleviate what is recognized as an identifiable, severe, and incapacitating disease that causes constant suffering, emotional, and mental distress. GD treatment, including hormone therapy, sex reassignment surgery, and others are effective and medically necessary forms of therapeutic treatment for people diagnosed with GD.

46. On July 9, 2015, Plaintiff John Doe's doctor submitted a request for Medicaid coverage for a total abdominal hysterectomy for Plaintiff, which was prescribed as medically necessary treatment for Plaintiff's GD.

47. On July 22, 2015, the request for the hysterectomy was denied by Keystone First Health Plan, one of the Defendant's designees for administering the Medicaid program in southeastern Pennsylvania.

48. Plaintiff duly appealed the denial, and on October 26, 2015, the Administrative Law Judge ("ALJ") denied Plaintiff's appeal, stating that, "The undersigned is bound to apply and adhere to the clear and express regulations, which in this case do not permit the approval of the requested hysterectomy." (The regulations referred to by the ALJ were 55 Pa. Code §§1141.59(11) and 1126.54(7), part of the Regulations noted above that ban coverage of medically necessary treatments for Medicaid eligible individuals diagnosed with GD. A copy of the page of the Administrative Law Judge's opinion with the cited language is attached as Exhibit C, the remainder of the Opinion will be furnished under an appropriate protective order to protect personally identifiable information.)

49. No other reason besides the complete regulatory ban was given by the ALJ for upholding the denial of coverage for John Doe's medically necessary GD treatment.

50. The ban on Medicaid coverage for GD compensation in the Regulations is unreasonable, discriminatory, and has no rational basis.

51. Plaintiff John Doe has sought Medicaid coverage for physician prescribed, medically necessary treatment for his GD diagnosis, but has been banned from receiving such coverage because Defendant is acting to enforce Regulations banning Plaintiff, a Medicaid eligible individual diagnosed with GD, from receiving any medically necessary Medicaid coverage for treatment of GD.

52. Plaintiff is barred from receiving coverage for his medically necessary hysterectomy solely because he is suffering from GD.

53. On information and belief, other Medicaid eligible individuals who have not been diagnosed with GD and have been prescribed a medically necessary hysterectomy will receive Medicaid coverage for a hysterectomy and associated medically necessary procedures and services.

54. Defendant's actions in adopting, promulgating, and enforcing the ban on Medicaid coverage for medically necessary GD treatment present in the Regulations discriminate against Plaintiff by treating Plaintiff as member of a class that is banned from receiving the same coverage provided to other Medicaid eligible individuals, purely on the basis of diagnosis, without any rational basis for such treatment.

55. The Defendant, DHS, and the Commonwealth are aware of established medical and scientific evidence that treatment is medically necessary for those diagnosed with GD.

56. Moreover, on information and belief, the Commonwealth furnishes health insurance and other coverage to those diagnosed with GD who are Commonwealth employees.

57. The Defendant's actions banning such coverage to Medicaid eligible individuals diagnosed with GD while at the same time the Commonwealth furnishes health insurance coverage to Commonwealth employees with GD discriminates against Plaintiff, without any rational basis for such conduct.

58. The Defendant, DHS, and the Commonwealth are aware of the Commonwealth's established law and policy banning transgender discrimination in state employment.

59. As a result, the Defendant has acted willfully and in bad faith in banning Medicaid coverage for the treatment of GD.

60. Plaintiff's rights to equal protection under the laws have been violated by Defendant.

61. Plaintiff's rights under the Medicare Act to be furnished with coverage equal to that furnished to others, without regard of diagnosis, have been violated by Defendant.

62. Plaintiff's rights to be free from sex and transgender discrimination have been violated by Defendant.

63. Plaintiff's rights were and are being violated by Defendant knowingly, willingly, and in bad faith.

64. Plaintiff's rights were and are being violated by the challenged governmental activity in the present case, are not contingent, are not and will not evaporate or disappear, and, by the Regulations and Defendant's continued promulgation and enforcement of the Regulations, casts a substantial adverse effect on Plaintiff's interests and rights.

65. Plaintiff's untreated GD has led to his constant suffering and emotional distress. He is unemployed and has other issues, due in part to his untreated GD. Immediate and medically necessary GD treatment should be provided to Plaintiff in accordance with the Constitution and laws of the United States.

COUNT I – VIOLATION OF THE EQUAL PROTECTION CLAUSE

66. Plaintiff incorporates by reference his allegations set forth in paragraphs 1 through 65 above.

67. Defendant's adopting, promulgating, and enforcing of the Regulations violate the Equal Protection Clause of the Constitution of the United States, U.S. Const. amend. XIV, §1 by arbitrarily, intentionally, and in bad faith banning Medicaid coverage for Medicaid eligible individuals with a GD diagnosis while the Commonwealth and Defendant provide the same care, services, drugs, and/or supplies to Medicaid eligible individuals without a GD diagnosis.

68. Defendant's adopting, promulgating, and enforcing of the Regulations violate the Equal Protection Clause of the Constitution of the United States, U.S. Const. amend. XIV, §1 by arbitrarily, intentionally, and in bad faith banning Medicaid coverage for Medicaid eligible individuals with a GD diagnosis while the Commonwealth and Defendant provide the same care, services, drugs and/or supplies to Commonwealth employees, without any rational basis for such treatment.

69. Defendant's adopting, promulgating, and enforcing of the Regulations violate the Equal Protection Clause of the Constitution of the United States, U.S. Const. amend. XIV, §1 by arbitrarily, intentionally, and in bad faith denying compensation under Medicaid for GD treatment which action unlawfully discriminates on the basis of sex, gender identity or expression and/or disability.

70. The Defendant's actions in promulgating and enforcing the Regulations are undertaken purposefully, intentionally, and in bad faith, and bear no substantial or rational relationship to any compelling, important or legitimate government interest.

71. 42 U.S.C. § 1983 provides that Plaintiff may proceed here to enforce his rights under the Equal Protection clause against Defendant.

COUNT II – VIOLATION OF THE SUPREMACY CLAUSE

72. Plaintiff incorporates by reference his allegations set forth in paragraphs 1 through 65 above.

73. Defendant's adopting, promulgating, and enforcing of the Regulations conflict with the Medicaid Act, 42 U.S.C. §§ 1396 et seq. and thus are preempted by the Supremacy Clause of the Constitution of the United States, U.S. Const. art. VI, cl. 2, by arbitrarily, intentionally, and in bad faith banning Medicaid coverage for Medicaid eligible individuals with a GD diagnosis while the Commonwealth and Defendant provide the same care, services, drugs, and/or supplies to Medicaid eligible individuals without a GD diagnosis.

74. Defendant's adopting, promulgating, and enforcing of the Regulations conflict with the Medicaid Act, 42 U.S.C. §§ 1396 et seq. and thus are preempted by the Supremacy Clause of the Constitution of the United States, U.S. Const. art. VI, cl. 2, by arbitrarily, intentionally, and in bad faith banning Medicaid coverage for Medicaid eligible individuals with a GD diagnosis while the Commonwealth and Defendant provide the same care, services, drugs and/or supplies to Commonwealth employees, without any rational basis for such treatment.

75. Defendant's adopting, promulgating, and enforcing of the Regulations conflict with the Medicaid Act, 42 U.S.C. §§ 1396 et seq. and thus are preempted by the Supremacy Clause of the Constitution of the United States, U.S. Const. art. VI, cl. 2, §1 by arbitrarily, intentionally and in bad faith denying compensation under Medicaid for GD treatment which action unlawfully discriminates on the basis of sex, gender identity or expression, and/or disability.

76. The Defendant's actions in promulgating and enforcing the Regulations are undertaken purposefully, intentionally, and in bad faith, and bear no substantial or rational relationship to any compelling, important or legitimate government interest.

77. 42 U.S.C. § 1983 provides that Plaintiff may proceed here to enforce his rights under the Supremacy Clause against Defendant.

COUNT III – VIOLATION OF SECTION 1557 OF THE ACA, 42 U.S.C. § 18116, PROHIBITING DISCRIMINATION IN MEDICAID

78. Plaintiff incorporates by reference his allegations set forth in paragraphs 1 through 65 above.

79. The Regulations exclude Plaintiff from participation in, deny Plaintiff the benefits of, and/or subject Plaintiff to discrimination under the Commonwealth's Medicaid Program, a health program receiving federal financial assistance.

80. The Defendant unlawfully discriminates by arbitrarily, intentionally, and in bad faith banning Medicaid eligible individuals with a GD diagnosis from receiving treatment while the Defendant provides the same care, services, drugs and/or supplies to Medicaid eligible individuals without a GD diagnosis, without any rational basis for the distinction, thus violating Section 1557 of the ACA, 42 U.S.C. § 18116.

81. The Defendant unlawfully discriminates by arbitrarily, intentionally, and in bad faith banning Medicaid coverage for Medicaid eligible individuals with a GD diagnosis while the Commonwealth and Defendant provide the same care, services, drugs and/or supplies to Commonwealth employees, without any rational basis for such treatment, thus violating Section 1557 of the ACA, 42 U.S.C. § 18116.

82. The Defendant unlawfully, arbitrarily, intentionally, and in bad faith discriminates on the basis of sex (including gender, gender identity and failure to conform to the sex and gender stereotypes associated with one's anatomical sex), gender identity or expression and/or disability, and the promulgation and enforcement of the Regulations violate Section 1557 of the ACA, 42 U.S.C. § 18116.

83. 42 U.S.C. § 1983 provides that Plaintiff may proceed here to enforce his rights under 42 U.S.C. § 18116 against Defendant.

COUNT IV – VIOLATION OF 42 U.S.C. § 1396 et. seq. (THE MEDICAID ACT) UNDER 42 U.S.C. § 1983

84. Plaintiff incorporates by reference his allegations set forth in paragraphs 1 through 65 above.

85. The Regulations exclude Plaintiff from participation in, deny Plaintiff the benefits of, and/or subject Plaintiffs to illegal and unlawful discrimination under the Commonwealth's Medicaid Program in violation of federal Medicaid law.

86. The Defendant's actions in promulgating and enforcing the Regulations violate 42 U.S.C. § 1396a(a)(17) as the Commonwealth's plan fails to "include reasonable standards for determining eligibility for and the extent of medical assistance under the plan."

87. The Defendant's actions in promulgating and enforcing the Regulations violate 42 U.S.C. §§ 1396a(a)(10)(A), as the Commonwealth's plan fails to make medical assistance available to "all categorically needy individuals, including those with a GD diagnosis by providing, at minimum, inpatient hospital services, outpatient hospital services, laboratory and X-ray services, and physicians' services."

88. The Defendant's actions in promulgating and enforcing the Regulations violate 42 U.S.C. § 1396a(a)(19) as the Commonwealth's plan fails to provide medical assistance "in a manner consistent with . . . the best interests of the recipients."

89. The Defendant's actions in promulgating and enforcing the Regulations violate 42 U.S.C. § 1396a(a)(8) as the Commonwealth's plan fails to provide medical assistance "with reasonable promptness to all eligible individuals."

90. The Defendant's actions in promulgating and enforcing the Regulations violate 42 U.S.C. § 1396a(a)(10)(B)(i) as the Commonwealth's plan fails to provide medical assistance "to any [categorically needy] individual shall not be less in amount, duration or scope than the medical assistance made available to other such individuals." 42 U.S.C. § 1396a(a)(10)(B)(i).

91. The Defendant's actions in promulgating and enforcing the Regulations violate 42 U.S.C. § 1396a(a)(30) as the Commonwealth's plan fails to provide that medical assistance "payments are… sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area."

92. 42 U.S.C. § 1983 provides that Plaintiff may proceed here to enforce his rights under 42 U.S.C. § 1396 et. seq. against Defendant.

WHEREFORE, Plaintiff respectfully requests that this Court:

A. Enter a declaratory judgment that:

1. The Regulations violate the Equal Protection Clause of the United States Constitution by denying care, services, drugs and/or supplies necessary to treat Medicaid-eligible patients diagnosed with GD;

2. The Regulations are preempted by the Supremacy Clause of the United States Constitution, art. VI., because they are conflict with the Medicaid Act;

3. The Regulations violate Section 1557 of the Patient Protection and Affordable Care Act, 42 U.S.C. § 18116, by denying care, services, drugs and/or supplies necessary to treat Medicaid-eligible patients diagnosed with GD; and,

4. The Regulations violate the Medicaid Act.

B. Issue a preliminary and permanent injunction:

1. Ordering Defendant to immediately provide Plaintiff with medical assistance coverage for all care, services, drugs and supplies prescribed by Plaintiffs' physicians as medically necessary to treat Plaintiffs' GD;

2. Ordering Defendant to immediately withdraw the Regulations; and,

3. Ordering Defendant to provide notice to any and all providers, recipients, Medicaid organizations and any and all other persons or entities Defendant may come into contact with in administering the state Medicaid program that the Regulations are discriminatory, have been withdrawn, and that equal access for GD treatment coverage will immediately be provided to all Medicaid eligible individuals.

C. Award Plaintiff compensatory and punitive damages, costs and disbursements, including reasonable attorneys' fees; and

D. Award Plaintiff such other and further relief as the Court may deem just and proper.

Respectfully submitted,

Date: February 17, 2016

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Director
Office for Civil Rights
Washington, D.C. 20201

July 12, 2012

Maya Rupert, Esq.
Federal Policy Director
National Center for Lesbian Rights
1325 Massachusetts Ave. NW, Suite 700
Washington DC 20005

OCR Transaction Number: 12-000800

Dear Ms. Rupert:

Thank you for your letter to Secretary Kathleen Sebelius, which was forwarded for reply to the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR). In your letter, you requested that we issue guidance clarifying that sex-based discrimination includes discrimination on the basis of gender identity and sex stereotypes under Section 1557 of the Affordable Care Act.

As you may know, OCR enforces Section 1557 of the Affordable Care Act (42 U.S.C. 18116), which provides that an individual shall not be excluded from participation in, be denied the benefits of, or be subjected to discrimination on the grounds prohibited under Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d *et seq.* (race, color, national origin), Title IX of the Education Amendments of 1972, 20 U.S.C. 1681 *et seq.* (sex), the Age Discrimination Act of 1975, 42 U.S.C. 6101 *et seq.* (age), or Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 794 (disability), under any health program or activity, any part of which is receiving Federal financial assistance, or under any program or activity that is administered by an Executive Agency or any entity established under Title I of the Affordable Care Act or its amendments. OCR has enforcement authority with respect to health programs and activities that receive Federal financial assistance from HHS or are administered by HHS or any entity established under Title I of the Affordable Care Act or its amendments.

We agree that Section 1557's sex discrimination prohibition extends to claims of discrimination based on gender identity or failure to conform to stereotypical notions of masculinity or femininity and will accept such complaints for investigation. Section 1557 also prohibits sexual harassment and discrimination regardless of the actual or perceived sexual orientation or gender identity of the individuals involved.

The HHS OCR is currently accepting and investigating complaints filed under Section 1557. We thoroughly review each complaint received; employ a case-by-case analysis of the facts and the relevant law; make a carefully considered decision on jurisdiction; and when warranted, issue a

finding that discrimination has (or has not) occurred. The HHS OCR intends to issue future guidance on Section 1557.

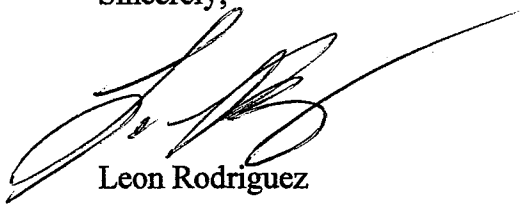
Until then, to make sure individuals, community organizations and providers know their rights and responsibilities, we ask you to help promote our website, www.hhs.gov/ocr, and:

- Learn about and connect with any one of our ten OCR regional offices http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.html
- Learn how to file a complaint with OCR if you think your rights have been violated http://www.hhs.gov/ocr/civilrights/complaints/index.html
- Visit the HHS OCR You Tube channel (search for HHS OCR) for additional videos on topics like "Your Health Information, Your Rights" or "Communicating with Family, Friends and others Involved in Your Care".

I also want to underscore what we discussed and shared during OCR's January 30, 2012 LGBT/HIV Stakeholders Listening Session: my office is continuing and will continue to increase our outreach and education efforts with individuals, community organizations and providers regarding their rights and responsibilities under Section 1557. The Office for Civil Rights is absolutely committed to working with individuals and advocates to improving the health and well-being of members of the lesbian, gay, bisexual and transgender communities, and of course, the commitment to sincerely engage and partner with the LGBT community is a Department-wide commitment as demonstrated by the Secretary (see http://www.hhs.gov/secretary/about/lgbthealth.html) and the 2012 HHS LGBT Coordinating Committee Report which is available at http://www.hhs.gov/secretary/about/2012_lgbt_an_rpt.pdf.

Again, thank you for your leadership on these critical matters to the LGBT community and for your very thoughtful letter, and we look forward to our growing partnership and work together.

Sincerely,



Leon Rodriguez

cc:

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Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

NCD 140.3, Transsexual Surgery
Docket No. A-13-87
Decision No. 2576
May 30, 2014

DECISION

The Board has determined that the National Coverage Determination (NCD) denying Medicare coverage of all transsexual surgery as a treatment for transsexualism is not valid under the "reasonableness standard" the Board applies. The NCD was based on information compiled in 1981. The record developed before the Board in response to a complaint filed by the aggrieved party (AP), a Medicare beneficiary denied coverage, shows that even assuming the NCD's exclusion of coverage at the time the NCD was adopted was reasonable, that coverage exclusion is no longer reasonable. This record includes expert medical testimony and studies published in the years after publication of the NCD. The Centers for Medicare & Medicaid Services (CMS), which is responsible for issuing and revising NCDs, did not defend the NCD or the NCD record in this proceeding and did not challenge any of the new evidence submitted to the Board.

Effect of this decision

Since the NCD is no longer valid, its provisions are no longer a valid basis for denying claims for Medicare coverage of transsexual surgery, and local coverage determinations (LCDs) used to adjudicate such claims may not rely on the provisions of the NCD. The decision does not bar CMS or its contractors from denying individual claims for payment for transsexual surgery for other reasons permitted by law. Nor does the decision address treatments for transsexualism other than transsexual surgery. The decision does not require CMS to revise the NCD or issue a new NCD, although CMS, of course, may choose to do so. CMS may not reinstate the invalidated NCD unless it has a different basis than that evaluated by the Board. 42 C.F.R. § 426.563.

CMS must implement this Board decision within 30 days and apply any resulting policy changes to claims or service requests made by Medicare beneficiaries other than the AP for any dates of service after that implementation. With respect to the AP's claim in

particular, CMS and its contractors must "adjudicate the claim without using the provision(s) of the NCD that the Board found invalid." 42 C.F.R. § 426.560(b)(1).[1]

Legal background

With exceptions not relevant here, section 1862(a)(l)(A) of the Social Security Act (Act) (42 U.S.C. § 1395y(a)(l)(A)) bars Medicare payment for items or services "not reasonable and necessary for the diagnosis or treatment of illness or injury[.]"[2] CMS refers to this requirement as the "medical necessity provision." 67 Fed. Reg. 54,534, 54,536 (Aug. 22, 2002). An NCD is "a determination by the Secretary [of Health and Human Services] with respect to whether or not a particular item or service is covered nationally under [title XVIII (Medicare)]." Act §§ 1862(l)(6)(A),1869(f)(1)(B); *see also* 42 C.F.R. § 400.202 (NCD "means a decision that CMS makes regarding whether to cover a particular service nationally under title XVIII of the Act."). NCDs "describe the clinical circumstances and settings under which particular [Medicare items and] services are reasonable and necessary (or are not reasonable and necessary)." 67 Fed. Reg. at 54,535. When CMS issues NCDs, they apply nationally and are binding at all levels of administrative review of Medicare claims. 42 C.F.R. § 405.1060. CMS and its contractors use applicable NCDs in determining whether a beneficiary may receive Medicare reimbursement for a particular item or service. 42 C.F.R. §§ 405.920, 405.921.

A Medicare beneficiary "in need of coverage for a service that is denied based on … an NCD" is an "aggrieved party" who may challenge the NCD by filing a "complaint" with the Board.[3] Act § 1869(f)(1); 42 C.F.R. §§ 426.110, 426.320. The complaint must comply with the requirements for a valid complaint in 42 C.F.R. § 426.500 in order to be accepted by the Board. 42 C.F.R. §§ 426.510(b)(2), 426.505(c)(2). After the Board notifies CMS of the receipt of a complaint that is acceptable under the regulations, CMS produces the "NCD record," which "consists of any document or material that CMS

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[1] *See generally* 42 C.F.R. § 426.560(b) (setting out the effects of a Board NCD decision); 42 C.F.R. § 426.555 (specifying what the Board's decision "may not do"). This decision has no effects beyond those set out in 42 C.F.R.§ 426.560(b) and does not impose on CMS or its contractors any orders or requirements prohibited by 42 C.F.R. § 426.555.

[2] The table of contents to the current version of the Social Security Act, with references to the corresponding United States Code chapter and sections, can be found at http://www.socialsecurity.gov/OP_Home/ssact/ssact-toc.htm.

[3] The regulations also provide that a person other than the aggrieved party with an interest in the issues may petition to participate in the review process as an amicus curiae. 42 C.F.R. §§ 426.510(f), 426.513. The Board posts on its website notice of the NCD complaint specifying a time period for requests to participate in the review. 42 C.F.R. § 426.510(f).

considered during the development of the NCD" including "medical evidence considered on or before the date the NCD was issued . . . ." 42 C.F.R. §§ 426.510(d)(3), 426.515, 426.518(a). The aggrieved party submits a statement "explaining why the NCD record is not complete, or not adequate to support the validity of the NCD under the reasonableness standard," and CMS may submit a response "in order to defend the NCD." 42 C.F.R. § 426.525(a), (b). If the Board determines that the NCD record "is complete and adequate to support the validity of the NCD," the review process ends with the Board's "[i]ssuance of a decision finding the record complete and adequate to support the validity of the NCD . . . ." 42 C.F.R. § 426.525(c)(1), (2). If the Board determines that the record is *not* complete and adequate to support the validity of the NCD, the Board "permits discovery and the taking of evidence . . . and evaluates the NCD" in accordance with the requirements of Part 426, including conducting a hearing, unless the matter can be decided on the written record. 42 C.F.R. §§ 426.525(c)(3), 426.531(a)(2).

Prior to issuing a decision, the Board must review any "new evidence" admitted to the record before the Board and determine whether it "has the potential to significantly affect" the Board's evaluation. 42 C.F .R. §§ 426.340(a), (b), 426.505(d)(3). "New evidence" is defined as "clinical or scientific evidence that was not previously considered by … CMS before the … NCD was issued." 42 C.F.R. § 426.110. If the Board so concludes, the Board stays proceedings for CMS "to examine the new evidence, and to decide whether [to] initiate[] … a reconsideration" of the NCD. 42 C.F.R. § 426.340(d). If CMS does not reconsider the NCD, or reconsiders it but does not change the challenged provision, the Board lifts the stay and the NCD challenge process continues. 42 C.F.R. § 426.340(f). At the end of that process, the Board closes the record and issues a decision that the challenged "provision of the NCD is valid" or "is not valid under the reasonableness standard."[4] 42 C.F.R. § 426.550. The Board's decision "constitutes a final agency action and is subject to judicial review" on appeal by an aggrieved party. 42 C.F.R. § 426.566.

[4] Section 426.547(b) states that the Board must make the decision available at the HHS Medicare Internet site and that "the posted decision does not include any information that identifies any individual, provider of service, or supplier." CMS has indicated in the preamble to the Part 426 regulations that this provision was meant to protect the privacy of Medicare beneficiaries such as the AP. *See, e.g.*, 68 Fed. Reg. 63,692, 63,708 (Nov. 7, 2003) ("Board decisions regarding NCDs will be made available on the Medicare Internet site, without beneficiary identifying information").

Case background

The NCD and the NCD record

The challenged NCD, titled "140.3, Transsexual Surgery," states:[5]

> **Item/Service Description**
>
> Transsexual surgery, also known as sex reassignment surgery or intersex surgery, is the culmination of a series of procedures designed to change the anatomy of transsexuals to conform to their gender identity. Transsexuals are persons with an overwhelming desire to change anatomic sex because of their fixed conviction that they are members of the opposite sex. For the male-to-female, transsexual surgery entails castration, penectomy and vulva-vaginal construction. Surgery for the female-to-male transsexual consists of bilateral mammectomy, hysterectomy and salpingo-oophorectomy, which may be followed by phalloplasty and the insertion of testicular prostheses.
>
> **Indications and Limitations of Coverage**
>
> Transsexual surgery for sex reassignment of transsexuals is controversial. Because of the lack of well controlled, long-term studies of the safety and effectiveness of the surgical procedures and attendant therapies for transsexualism, the treatment is considered experimental. Moreover, there is a high rate of serious complications for these surgical procedures. For these reasons, transsexual surgery is not covered.

NCD Record at 93. CMS's predecessor, the Health Care Financing Administration (HCFA), published the NCD in the Federal Register on August 21, 1989.[6] 54 Fed. Reg. 34,555, 34,572 (Aug. 21, 1989); NCD Record at 76, 78, 93, 128. The NCD quotes or paraphrases portions of an 11-page report that the former National Center for Health Care Technology (NCHCT) of the HHS Public Health Service (PHS) issued in 1981, titled

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[5] NCDs are available at http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?list_type=ncd.

[6] The Federal Register notice stated, "This notice lists those current Medicare national coverage decisions which have been issued in the Medicare Coverage Issues Manual (HCFA Pub. 6)." 54 Fed. Reg. at 34,555.

"Evaluation of Transsexual Surgery" (1981 report).[7] NCD Record at 13-23. The NCHCT forwarded the 1981 report to HCFA with a May 6, 1981 memorandum stating that the 1981 report "concludes that transsexual surgery should be considered experimental because of the lack of proven safety and efficacy of the procedures for the treatment of transsexualism" and recommending "that transsexual surgery not be covered by Medicare at this time." *Id*. at 12.

The NCD record includes three April 1982 letters from the American Civil Liberties Union (ACLU) of Southern California disagreeing with HCFA's noncoverage determination. *Id*. at 24-25, 26, 41-42. The ACLU submitted letters and affidavits from physicians and therapists supporting the medical necessity of transsexual surgery and taking issue with the non-coverage determination. *Id*. at 27-75. On May 11, 1982, the HCFA physicians panel, by a vote of five to two, recommended against referring the ACLU's submissions to PHS, "on the basis that it does not contain information about new clinical studies or other medical and scientific evidence sufficiently substantive to justify reopening the previous PHS assessment." *Id*. at 7, 9. Thus, although the NCD was issued in 1989, it was based on the analysis of medical and scientific publications in the 1981 report.

The NCD complaint

The AP in this case, a Medicare beneficiary whose insurer denied a physician's order for sex reassignment surgery (transsexual surgery), filed an acceptable NCD complaint and supporting materials. CMS submitted the NCD record on May 15, 2013, and the AP submitted a statement of why the NCD record is not complete or adequate to support the validity of the NCD under the reasonableness standard (AP Statement) on June 14, 2013. The Board granted unopposed requests by six advocacy organizations to participate as amici curiae in the NCD review by filing written briefs arguing that the NCD was invalid. (Four of the amici submitted a joint brief.)[8]

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[7] The concluding summary of the 1981 NCHTC report stated in relevant part:

> Transsexual surgery for sex reassignment of transsexuals is controversial. There is a lack of well controlled, long-term studies of the safety and effectiveness of the surgical procedures and attendant therapies for transsexualism. There is evidence of a high rate of serious complications of these surgical procedures. The safety and effectiveness of transsexual surgery as a treatment of transsexualism is not proven and is questioned. Therefore, transsexual surgery must be considered still experimental.

NCD Record at 19.

[8] The six amici are the Human Rights Campaign (HRC) and the World Professional Association for Transgender Health (WPATH), which each submitted briefs, and the FORGE Transgender Aging Network, the National Center for Transgender Equality, the Sylvia Rivera Law Project, and the Transgender Law Center, which submitted a joint brief.

On June 26, 2013, CMS notified the Board that it "declines to submit a response" to the AP's statement. On December 2, 2013, the Board ruled that the NCD record "is not complete and adequate to support the validity of the NCD[.]" *NCD 140.3, Transsexual Surgery*, NCD Ruling No. 2 (Dec. 2, 2013) (NCD Ruling).[9] The parties then jointly reported that they did not intend to submit additional evidence (except for curricula vitae (CVs) of the AP's witnesses) or cross-examine any witness and asked the Board to close the NCD review record to the taking of evidence and decide the case based on the written record.

The Board determined that the new evidence in the record had the potential to significantly affect its review of the NCD and, as required, stayed proceedings for 10 days for CMS to examine the new evidence and decide whether to reconsider the NCD.[10] *Order Closing Record & Staying Proceedings for CMS to Determine Whether to Reconsider NCD* (Feb. 25, 2014) (Order); 42 C.F.R. §§ 426.340(d), 426.505(d)(3). Two days later, CMS informed the Board by email that it "does not wish to reconsider the NCD." On February 28, 2014, the Board lifted the stay and informed the parties that it would proceed to decision.

The record developed before the Board

The record before the Board consists of the NCD record, the briefs submitted by the AP and the amici and evidence submitted by the AP and one of the amici, the Human Rights Campaign. Since neither party submitted argument or evidence (except for the CVs) after the Board's Ruling, the Board treats the AP statement as the AP's brief in this appeal.[11] The AP submitted written declarations made under penalty of perjury from a clinical psychologist and a physician, and two notarized physician letters submitted to an Administrative Law Judge in the Department of Health and Human Services Office of Medicare Hearings and Appeals in another matter. The AP described the witnesses, who are active in the field of treating transgender persons, as experts and submitted their resumes or CVs. AP Statement at 9; AP complaint; AP/CMS e-mail (Jan. 7, 2014).

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[9] The NCD Ruling is at http://www.hhs.gov/dab/decisions/dabdecisions/ncd1403.pdf.

[10] The Board also published on its website notice providing an additional time period for interested parties to submit participation requests; none were received.

[11] Most of the AP's evidence other than witness statements is an appendix of sources the clinical psychologist cited in her declaration. We refer to these materials as the AP's exhibits (AP Exs.) and cite to the page numbers used in the publications in which they appeared. In addition, the physician's declaration includes an appendix of 20 unnumbered pages of insurance regulations from four states and the District of Columbia barring exclusion of sex reassignment surgery as medically necessary treatment for severe gender dysphoria. One of the amici, the Human Rights Campaign, submitted 62 exhibits with its brief ("HRC Exs.").

CMS did not challenge the witnesses' qualifications as experts or seek to cross-examine them. We summarize their qualifications when we address their testimony below. In this decision we use the term "new evidence" to refer to the evidence submitted to us by the AP and amici to distinguish it from the evidence used to support the NCD which, as noted, consists principally of the 1981 report. Under the regulatory definition in 42 C.F.R. § 426.110, "new evidence" would also include any evidence submitted by CMS in response to an NCD complaint that was not considered by CMS before the NCD was issued. In this case, however, as we discuss below, CMS submitted no "new evidence."

Standard of review

The Board "evaluate[s] the reasonableness" of an NCD by determining whether it "is valid [or] is not valid under the reasonableness standard," which requires us to uphold the NCD "if the findings of fact, interpretations of law, and applications of fact to law by … CMS are reasonable" based on the NCD record and the relevant record developed before us. Act § 1869(f)(1)(A)(iii); 42 C.F.R. §§ 426.110, 426.531(a), 426.550(a). The Board "defer[s] only to the reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary." Act § 1869(f)(1)(A)(iii); 42 C.F.R. § 426.505(b).

During the review, the aggrieved party bears the burden of proof and the burden of persuasion for the issues raised in an NCD complaint; the burden of persuasion is judged by a preponderance of the evidence. 42 C.F.R. § 426.330. CMS has explained that "[s]o long as the outcome [in the NCD] is one that could be reached by a rational person, based on the evidence in the record as a whole (including logical inferences drawn from that evidence), the determination must be upheld," and that if CMS "has a logical reason as to why some evidence is given more weight than other evidence," the Board "may not overturn the determination simply because they would have accorded more weight to the evidence in support of coverage." 68 Fed. Reg. at 63,703.

Analysis

The NCD is invalid because a preponderance of the evidence in the record as a whole supports a conclusion that the NCD's stated bases for its blanket denial of coverage for transsexual surgery are not reasonable.

As previously stated, the NCD was based principally on the 1981 report findings that the safety and effectiveness of transsexual surgery had not been proven. The AP argues that these findings are not "supportable by the current state of medical science" and "not reasonable in light of the current state of scientific and clinical evidence and current medical standards of care" and are contradicted by studies conducted in the 32 years since the 1981 report. AP Statement at 6-7, 14. The amici made similar arguments. *See, e.g.*, WPATH Br. at 13 ("since [the NCD] was issued, it has been repeatedly

demonstrated that SRS [sex reassignment surgery] is safe, effective, and indisputably necessary treatment for certain individuals with severe GID [gender identity disorder]"). As we discuss below, the new evidence, which is unchallenged, indicates that the bases stated in the NCD and the NCD record for denying coverage, even assuming they were reasonable when the NCD was issued, are no longer reasonable.

A. The fact that the new evidence is unchallenged and the NCD record undefended is significant.

As we stated earlier, the AP has the burden of proof by a preponderance of the evidence that an NCD is invalid under a reasonableness standard. In deciding whether the AP has met this burden, we must weigh the evidence in the record before us. Thus, we consider it important to note at the outset that the only evidence before us, other than the record for the NCD, which consists principally of the 1981 report, is the new evidence submitted by the AP and the amicus HRC. CMS submitted the NCD record, as it was required to do, but has not argued that that record or any other evidence supports the NCD. CMS also did not elect to cross-examine the AP's witnesses, has not challenged their testimony or professional qualifications and joined the AP in asking the Board to decide the appeal based on the written record. *See* AP/CMS e-mail (Jan. 7, 2014). The preamble to the regulations that implement the NCD statute states that the "reasonableness standard . . . recognizes the expertise of … CMS in the Medicare program—specifically, in the area of coverage requiring the exercise of clinical or scientific judgment." 68 Fed. Reg. at 63,703 (emphasis added). Accordingly, in determining whether the NCD is valid under the reasonableness standard, we must accord some deference to CMS's position, and its decision not to defend the NCD or challenge the new evidence in this case has some significance for our decision-making.

Apart from the absence of any challenge to the new evidence or defense of the NCD record, we find the new evidence credible and persuasive on its face.[12] We have no difficulty concluding that the new evidence, which includes medical studies published in the more than 32 years since issuance of the 1981 report underlying the NCD, outweighs the NCD record and demonstrates that transsexual surgery is safe and effective and not experimental. Thus, as we discuss below, the grounds for the NCD's exclusion of coverage are not reasonable, and the NCD is invalid.

[12] For this reason, we found it unnecessary to exercise our independent authority to "consult with appropriate scientific or clinical experts concerning clinical and scientific evidence." *See* 42 C.F.R. § 426.531(b).

B. The new evidence indicates acceptance of criteria for diagnosing transsexualism.

Transsexual surgery is a treatment option for the medical condition of transsexualism. The NCD recognized that transsexualism is a diagnosed medical condition. The 1981 report stated that transsexualism "is defined as an overwhelming desire to change anatomic sex stemming from the fixed conviction that one is a member of the opposite sex." NCD Record at 13, citing Dorland's Illustrated Medical Dictionary, 25th ed. The 1981 report recognized that the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders issued in 1980 (DSM III) had "included for the first time the diagnostic category of 'Transsexualism.'" NCD Record at 13. Nonetheless, the 1981 report expressed concern that diagnosing transsexualism was "problematic" because, the report contended, the criteria for establishing the diagnosis "vary from center to center and have changed over time." NCD Record at 14.

One of the AP's expert witnesses, Randi Ettner, Ph.D., a clinical psychologist, testified that the expressed basis for this concern is "completely untrue now." Ettner Supp. Decl. at ¶ 5. Dr. Ettner stated that "Gender Identity Disorder is a serious medical condition codified in the International Classification of Diseases (10th revision; World Health Organization) and the [DSM]."[13] Ettner Decl. at ¶ 10; *see also* Ettner Supp. Decl. at ¶ 6 (similar testimony). She described the condition as follows:

> The disorder is characterized by intense and persistent discomfort with one's primary and secondary sex characteristics—one's birth sex. The suffering that arises is often described as "being trapped in the wrong body." The psychiatric term for this severe and unremitting emotional pain is "gender dysphoria."

Ettner Decl. at ¶ 10. Dr. Ettner's declaration and CV state that she has a doctorate in psychology, has evaluated or treated between 2,500 and 3,000 individuals with GID and mental health issues related to gender variance, has published three books, including *Principles of Transgender Medicine and Surgery*, has authored articles in peer-reviewed journals, and is a member of the board of directors of the World Professional Association for Transgender Health (WPATH) and an author of the WPATH Standards of Care for

[13] The record indicates that the term "transsexualism" that was used in the NCD and the DSM-III was succeeded in the DSM-IV and DSM-V by the terms "Gender Identity Disorder" (GID) and "gender dysphoria." AP Statement at 1 n.1; Ettner Supp. Decl. at ¶ 6; Hsiao Decl. at ¶ 11; AP Ex. 7, at 208; WPATH Br. at 2 n.3. In this decision, we use the term "transsexualism" because it is used in the NCD, but our decision should be read as encompassing the successor terminology as well.

the Health of Transsexual, Transgender, and Gender-Nonconforming People. *Id*. at ¶¶ 3-6; *see also Sundstrom v. Frank*, 630 F. Supp. 2d 974, 986-87 (E.D.Wis. 2007) ("Dr. Ettner's experience speaks for itself … the doctor has conducted research and has been an instructor specializing in the etiology, diagnosis and treatment of GID [and] is the editor of a medical textbook in which she wrote the chapter of that book on the etiology of GID. The court finds that Dr. Ettner is sufficiently qualified to provide expert testimony.").

We find nothing in the new evidence that would undercut Dr. Ettner's statement. The DSM-IV-TR (text revision), published in 2000, continues to recognize "transsexualism" as a diagnosed medical condition, although it refers to the same disorder as GID and identifies criteria for diagnosing GID in adolescents and adults that are consistent with Dr. Ettner's description, albeit more detailed. The criteria include "strong and persistent cross-gender identification (not merely a desire for any perceived cultural advantages of being the other sex)" that is "manifested by symptoms such as a stated desire to be the other sex, frequent passing as the other sex, desire to live or be treated as the other sex, or the conviction that he or she has the typical feelings and reactions of the other sex;" "[p]ersistent discomfort with his or her sex or sense of inappropriateness in the gender role of that sex" that is "manifested by symptoms such as preoccupation with getting rid of primary and secondary sex characteristics (e.g., request for hormones, surgery, or other procedures to physically alter sexual characteristics to simulate the other sex) or belief that he or she was born the wrong sex;" and "[t]he disturbance is not concurrent with a physical intersex condition." AP Ex. 4, at 581. The DSM-IV-TR states that if GID is present in adults, "[t]he disturbance can be so pervasive that the mental lives of some individuals revolve only around those activities that lessen gender distress." *Id*. at 576, 78. The WPATH brief indicates that transsexualism or GID remains a diagnostic category in the fifth edition of the DSM issued in 2013 (DSM-V), which uses the term "Gender Dysphoria." WPATH Br. at 2, n.3.

The DSM has been recognized as a primary diagnostic tool of American psychiatry. *See O'Donnabhain v. Comm'r of Internal Revenue*, 134 T.C. 34, at 60 (2010) (stating "all three experts agree [that the DSM-IV-TR] is the primary diagnostic tool of American psychiatry"); *see also* AP Ex. 3, at 1[14] (resolution of American Medical Association House of Delegates noting the DSM description of GID as "a persistent discomfort with one's assigned sex and with one's primary and secondary sex characteristics, which causes intense emotional pain and suffering" that "if left untreated, can result in clinically significant psychological distress, dysfunction, debilitating depression and, for some people without access to appropriate medical care and treatment, suicidality and death").

[14] American Medical Association House of Delegates, *Resolution 122 (A-08), Removing Financial Barriers to Care for Transgender Patients* (2008).

We conclude that to the extent the NCD was based on concerns expressed in the NCD record about problems diagnosing transsexualism, that concern is unreasonable based on the new evidence.

C. The new evidence indicates that transsexual surgery is safe.[15]

The 1981 report stated that transsexual surgery "cannot be considered safe because of the high complication rates." NCD Record at 18. The 1981 report identified surgical complications including "rectovaginal fistulas, perineal abscesses, introital and deep vaginal stenosis, and vaginal shortening" in male-to-female (MF) patients, and "rejection of the testicular implants, scrotal fusion, and phalloplasty infections" in female-to-male (FM) patients, and states that "[m]ultiple complications for individual patients and secondary surgeries to correct complications or to improve on undesirable results are not uncommon." *Id*. at 15 (citations omitted). The AP argues that "advancements in surgical techniques have dramatically reduced the risk of complications from sex reassignment surgery and the rates of serious complications from such surgeries are low" and that the studies cited in the 1981 report "evaluated outdated surgical techniques that have been replaced with improved, safer procedures." AP Statement at 7, 10. The new evidence supports the AP.

Expert witness Katherine Hsiao, M.D., testified that hysterectomies and mastectomies are common procedures used to treat gender GID in transgender men (FM) and "are routinely performed in other contexts, such as in cases of breast cancer, ovarian cancer, uterine cancer and/or cervical cancer . . . ." Hsiao Decl. at ¶ 11. These procedures, she stated, "have low rates of complications" and are "generally identical whether performed on transgender men to treat gender dysphoria or to treat women for these other conditions."[16] *Id*. Dr. Hsiao also stated that "insurance companies routinely cover the costs associated" with hysterectomies. *Id*. Dr. Hsiao testified that based on her own practice of providing surgery to transgender men, "gender affirming surgeries for transgender men are extremely safe and have very low rates of serious complications,"

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[15] We are unable to discuss in the space of this decision all of the new evidence and see no need to do so since it is all unchallenged. However, we find nothing in the new evidence not discussed that would alter our conclusion that the NCD is invalid, at least absent argument or counter-evidence from CMS. We have attached to this decision an Overview of the Scientific Literature in the New Evidence.

[16] Dr. Hsiao testified without contradiction that a "serious complication" of surgery–

> is generally understood among surgeons to include death, conditions requiring an unplanned admission to the Intensive Care Unit or unplanned readmission to the hospital within 30 days, severe hemorrhage requiring transfusion of several units of blood product, permanent disability, an intraoperative injury requiring an unplanned intervention during the surgical procedure, permanent brain damage, or cardiac arrest.

Hsiao Decl. at ¶ 9.

that she has performed hysterectomies for transgender men for the past ten years and that those procedures "are generally identical to the ones I perform on women to treat early cancer or other conditions." *Id*. at ¶ 20. Dr. Hsiao reports having "typically performed multiple obstetrical, gynecologic, or other pelvic surgeries every week, including but not limited to hysterectomies and other advanced pelvic surgeries targeting the reproductive system and adjacent organs . . . ." *Id*. at ¶ 6. Dr. Hsiao's declaration and CV indicate that she is certified by the American Board of Obstetrics and Gynecology, is the chief of the division of gynecology and the director of Ob/Gyn resident education at a California medical center and an assistant clinical professor in the department of obstetrics, gynecology and reproductive medicine at the University of California at San Francisco. *Id*. at ¶¶ 3-6; CV.

Dr. Hsiao further stated, regarding MF transsexual surgery, that she has been part of a surgical team that performed surgery to create a neovagina in women born with a congenital "complete or partial absence of a vagina, cervix, and uterus," a condition called Mayer-Rokitansky-Kuster-Hauser syndrome, or MRKH. Hsiao Decl. at ¶ 12. She stated that this procedure has "a low rate of complications," and that the associated surgical costs are, in her experience, "routinely cover[ed]" by insurance companies for women born with MRKH. She stated that while women with MRKH "can never have biological children … the role of surgery is essential to affirm their gender identity and to align their anatomy with that identity." *Id*.

Dr. Ettner stated that "[t]here is no scientific or medical basis" for the NCD's statement that sex reassignment surgery has not been proven safe and has a high rate of serious complications; that the "[r]ates of complications during and after sex reassignment surgery are relatively low, and most complications are minor;" and that the risk of complications "has, moreover, been dramatically reduced since 1985." Ettner Decl. at ¶¶ 32, 34. Dr. Ettner testified that during eight years at the Chicago Gender Clinic she "regularly consulted with our surgeon" and is "aware of only two major surgical complications, both of which were immediately repaired." *Id*. at ¶ 36. She stated that the clinic "as a whole has a 12 percent complication rate for genital surgery" and that "the vast majority of those complications [were] minor, all were easily corrected, and none involved surgical site infection or readmission." *Id*. Dr. Ettner stated the 1981 report's discussion of surgical complication rates was "outdated and irrelevant based on current medical practices and procedures." Ettner Supp. Decl. at ¶ 9. In particular, she stated that one of the studies cited in the 1981 report's discussion of complications (Laub & Fisk 1974) reflected the use of a MF surgical technique that "led to unacceptably high rates of fistulae and other complications" and was later abandoned by the study's authors. *Id*. at ¶ 10.

Another of the AP's expert witnesses, Marci L. Bowers, M.D., stated in her notarized letter that in her experience of performing gender-related surgeries, transsexual surgery "does not have a higher rate of complication than any other surgery, and in fact has very

few complications, which are mainly minor in nature." Bowers Letter at 1 (Mar. 5, 2013), Att. to AP Statement. Dr. Bowers stated that she performs approximately 220 gender-related surgeries annually and has performed over 1000 "Male to Female Gender Corrective Surgeries." *Id*. Her CV indicates that she has served as the Chair of the Department of Obstetrics and Gynecology at the Swedish (Providence) Medical Center in Seattle.

The fourth expert witness, Sherman N. Leis, M.D., stated that he personally "perform[s] several gender reassignment procedures each week" and has "seen only relatively minor complications which are easily treated" and has "thus far seen no life threatening complications from any of the transgender surgeries" he has performed. Leis Letter at 2 (Feb. 28, 2013), Att. to AP Statement. Dr. Leis's letter and CV indicate that he is Board-certified in plastic and reconstructive surgery and in general surgery. *Id.* at 1.

The testimony of Drs. Ettner and Hsiao is based on studies as well as personal experience. Dr. Hsiao testified that she reviewed five studies in the AP exhibits "that include complication rate data and information for gender affirming surgeries performed in recent years" and that "[n]one of these five studies reported high rates of serious complications." Hsiao Decl. at ¶¶ 13-14, citing studies at AP Exs. 2, 9, 14, 21, 28. She stated that "almost all of the complications listed in these studies, such as urinary incontinence or retention, stenosis or stricture, bleeding, recto-vaginal fistula, and partial necrosis, are not specific to sex reassignment surgeries, but rather are known potential side effects of any type of urogenital surgery which are covered by Medicare." *Id*. at ¶ 15. She further testified that "every complication tracked in [Jarolim, et al. (2009)] for instance, falls into this category and none of them are serious;" that "[t]he Spehr (2007) study includes similar types of complications at very low rates;" and that "none of the complications listed in Lawrence (2006) are serious and many of them are consistent with what would be potential, expected outcomes for any urogenital surgery." *Id*. at 15-17, citing studies at AP Exs. 14,[17] 21,[18] 28.[19] She also stated that of the four "potentially serious" complications noted in the Amend (2013) study of 24 MF patients, none "were serious as that term is generally understood." *Id*. at ¶ 14, citing study at AP Ex. 2.[20]

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[17] Ladislav Jarolim, et al., *Gender Reassignment Surgery in Male-to-Female Transsexualism: A Retrospective 3-Month Follow-up Study with Anatomical Remarks*, 6 J. Sex. Med. 1635-44 (2009).

[18] Anne A. Lawrence, *Patient-Reported Complications and Functional Outcomes of Male-to-Female Sex Reassignment Surgery*, 35 Arch. Sex. Behav. 717-27 (2006).

[19] Christiane Spehr, *Male-to-Female Sex Reassignment Surgery in Transsexuals*, 10 Int'l J. Transgenderism 25-37 (2007).

[20] Bastian Amend, et al., *Surgical Reconstruction for Male-to-Female Sex Reassignment*, 64 Eur. Urol. 1-9 (2013).

Dr. Hsiao further stated that Eldh et al. (1997) compared complication rates for surgeries performed before and after 1986 and showed that "[n]early all of the surgical complication rates decreased significantly over time." Hsiao Decl. at ¶ 18, citing study at AP Ex. 9.[21] Dr. Hsiao stated that "fistulas, in particular, which are a risk of many urogenital surgeries, decreased from 18 percent in surgeries before 1986 to only 1 percent between 1986 and 1995," and that "the only fistula that occurred after 1985 'closed spontaneously,' meaning without the need for any medical intervention." *Id*. Eldh, Dr. Hsiao stated, showed that "[t]here is not a high rate of serious complications in any of the surgeries performed after 1986" and she noted that "there have been nearly 20 years of additional surgical progress since the last surgery tracked." *Id*.

Dr. Ettner cited the same five studies as showing that surgical outcomes were "far superior" after 1985 due to "improvements in technique, shortened hospital stays and improvements in postoperative care;" that significant surgical complications were uncommon; that only a low percentage of patients experienced complications, which were successfully resolved; and that "the complication rate is low and most complications can be overcome by adequate correctional interventions." Ettner Decl. at ¶¶ 34-35.

We find no reason to discount the opinions of these experts or their representations regarding the findings in the studies they cite. We have conducted our own review of the studies cited by Dr. Hsiao and Dr. Ettner and find them consistent with these opinions and representations. We note, for example, that Eldh, which divided the study group into those operated on before 1986 and those operated on from 1986–1995, made findings tending to support these expert opinions. The Eldh study states:

> After 1985 the outcome of surgery became much better not only because of changes in management but also because of improvements in surgical technique, preoperative planning, and postoperative treatment. Total time spent in hospital decreased dramatically after 1985 because the number of procedures was less and the rate of early and late postoperative complications dropped. Haemorrhage and haematoma were common in both groups, predominantly originating from the spongious tissue of the urethra. Infections occurred less often in the late group perhaps as a result of peroperative antibiotic prophylaxis. Serious complications like fistula formation and partial flap necrosis were rare after 1985, though they were common before then. The reason for the lower fistula rate in the later group may be ascribed to better anatomical knowledge of this region and a more precise surgical technique. There was only one rectovaginal fistula after 1985 and this fistula closed spontaneously.

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[21] Jan Eldh, *et al*., *Long-Term Follow Up After Sex Reassignment Surgery*, 31 Scand. J. Plast. Reconstr. Surg. Hand Surg. 39-45 (1997).

AP Ex. 9, at 44. Dr. Hsiao stated that those findings are "consistent with what I would expect to find when comparing surgeries, and surgical techniques, over a long period of time." Hsiao Decl. at ¶ 18; *see also* WPATH Br. at 9-10 (citing Eldh and stating that "while early sex reassignment surgeries were sometimes accompanied by serious complications like fistulas or necrotic tissue, the rate of such complications has dropped dramatically with the advent of more sophisticated surgical techniques, among other reasons").

We conclude that the AP has shown that the NCD's statement that transsexual surgery is unsafe and has a high rate of complications is not reasonable in light of the evolution of surgical techniques and the studies of outcomes discussed in the unchallenged new evidence presented here.

D. The new evidence indicates that transsexual surgery is an effective treatment option in appropriate cases.[22]

1. The expert testimony and studies on which the experts rely support the surgery's effectiveness.

The AP argues that studies conducted after the 1981 report was issued confirm that transsexual surgery is an effective treatment for persons with severe gender dysphoria, and the expert testimony and studies support that argument. AP Statement at 7-8.

Dr. Ettner testified that "[b]ased on decades of extensive scientific and clinical research, the medical community has reached the consensus that altering a transsexual individual's primary and secondary sex characteristics is a safe and effective treatment for persons with severe Gender Identity Disorder." Ettner Decl. at ¶ 13.[23] With regard to effectiveness in particular, Dr. Ettner testified that "more than three decades of research confirms that sex reassignment surgery is therapeutic and therefore an effective treatment for Gender Identity Disorder" and that "for many patients with severe Gender Identity

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[22] We use the term "appropriate cases" because we do not read the new evidence as necessarily stating that transsexual surgery is appropriate in all cases of transsexualism, and our conclusion that the NCD's blanket preclusion of Medicare coverage for transsexual surgery is invalid does not require a finding to that effect. However, it is worth noting that WPATH has developed, in its standards of care, criteria for the use of different transsexual surgical procedures. *See, e.g.*, WPATH "[c]riteria for hysterectomy and salpingooophorectomy in [FM] patients and for orchiectomy in [MF] patients." AP Ex. 7, at 202 (E. Coleman, et al., *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People*, Version 7, 13 Int'l J. Transgenderism 165–232 (2011)).

[23] Dr. Ettner in her declaration focuses on genital surgery for the male-to-female (MF) transsexual. *See* Ettner Decl. at ¶ 8. Dr. Hsiao's testimony addressed procedures performed on FM patients. Hsiao Decl. at ¶¶ 7, 11, 20-21.

Disorder, sex reassignment surgery is the only effective treatment." *Id*. at ¶ 19. She concluded that "[t]he NCD's determination regarding efficacy is not reasonably supported by scientific or clinical evidence, or standards of professional practice, and fails to take into account the robust body of research establishing that surgery relieves, and very often completely eliminates, gender dysphoria." *Id*. at ¶ 31.

Dr. Bowers stated that "[m]any patients report a dramatic improvement in mental health following surgery, and patients have been able to become productive members of society, no longer disabled with severe depression and gender dysphoria." Bowers Letter at 1. She concluded that "Gender Corrective Surgery has been shown to be a life-saving procedure, and is unequivocally medically necessary." *Id*. Dr. Leis stated that "[m]edical literature reports a dramatic drop in the incidence of depression and suicide attempt[s] by individuals who have undergone gender reassignment, indicating that many lives have been saved because of this surgery," that "there is a very low incidence of 'regret'" of "only about 1% of patients who have had gender reassignment surgery" and that "I personally have never had a single patient who has regretted having this surgery." Leis Letter at 2.

Dr. Ettner cited 20 studies published between 1987 and 2010 as showing the effectiveness of transsexual surgery. Ettner Decl. at ¶¶ 20-26, 28-30. She emphasized three studies, two of which were published in 1998 and 2007 and analyze other studies of the treatment of transsexuals published during the years 1961 to 1991 and 1990 to 2007, respectively. *Id*. at ¶¶ 20-22, citing studies at AP Exs. 10, 25, 27; *see also* WPATH Br. at 7-8 (discussing the same three studies). The 1998 study (Pfafflin & Junge) reviewed "30 years of international follow-up studies of approximately two thousand persons who had undergone sex reassignment surgery" including more than 70 individual studies and eight published reviews from four continents. AP Ex. 25 at unnumbered page 1.[24] As "general results," the researchers in the 1998 study stated that the studies they reviewed concluded "that gender reassigning treatments are effective," that positive, desired results outweigh the negative or non-desired effects, and that "[p]robably the most important change that is found in most research is the increase of subjective satisfaction [which] contrasts markedly to the subjectively unsatisfactory start position of the patients." *Id*. at 45, 49. The study's summary, which it qualified as a "simplification," stated that the studies reviewed show that "[i]n over 80 qualitatively different case studies and reviews from 12 countries, it has been demonstrated during the last 30 years that the treatment that includes the whole process of gender reassignment is effective." *Id*. at 66. The summary stated that all "follow-up studies mostly found the desired effects" the most important of

[24] Friedemann Pfafflin & Astrid Junge, *Sex Reassignment: Thirty Years of International Follow-Up Studies After Sex Reassignment Surgery: A Comprehensive Review 1961-1991* (Roberta B. Jacobson & Alf B. Meier trans., 1998) (1992) (http://web.archive.org/web/20061218132346/http://www.symposion.com/ijt/pfaefflin/1000.htm, accessed May 29, 2014).

which the patients felt were "the lessening of suffering" and "desired changes in the areas of partnership and sexual experience, mental stability and socio-economic functioning level." *Id*. at 66-67.

The 2007 study, Gijs & Brewaeys, which examined the results of 18 studies published between 1990 and 2006, states that sex reassignment "is the most appropriate treatment to alleviate the suffering of extremely gender dysphoric individuals" and that "96% of the persons who underwent [surgery] were satisfied and regret was rare." AP Ex. 10, at 215, cited in Ettner Decl. at ¶ 22, WPATH Br. at 7.[25] Two of the reviewed studies showed that "[s]uicidality was significantly reduced postoperatively" and that in MF patients there were no suicide attempts after surgery as opposed to three attempts before surgery. AP Ex. 10, at 188, 192.

Dr. Ettner and WPATH also cited what Dr. Ettner described as "a large-scale prospective study" finding "that after surgery there was 'a virtual absence of gender dysphoria' in the cohort and that the 'results substantiate previous conclusions that sex reassignment is effective.'" Ettner Decl. at ¶ 21, citing Smith et al. (2005), AP Ex. 27;[26] WPATH Br. at 8. Dr. Ettner concluded that Smith et al. and other studies have, variously, "shown that by alleviating the suffering and dysfunction caused by severe gender dysphoria, sex reassignment surgery improves virtually every facet of a patient's life," including "satisfaction with interpersonal relationships and improved social functioning," "improvement in self-image and satisfaction with body and physical appearance," and "greater acceptance and integration into the family[.]" Ettner Decl. at ¶ 24, citing studies at AP Exs. 1, 12, 15, 19, 22, 26, 27, 30. She also cited nine studies as having "shown that surgery improves patients' abilities to initiate and maintain intimate relationships." *Id*. at ¶ 25, citing studies at AP Exs. 8, 13, 14, 16, 20-22, 26, 27.

Based on our own review of the cited studies, we find no reason to question the expert testimony about them. In general, the studies included interviewing post-operative patients with a variety of surveys or questionnaires to assess changes in different aspects of their lives and psychological symptoms following surgery. The studies also generally used statistical techniques to assess the results. The studies were conducted in countries including the United States, Canada, Sweden, the Czech Republic, Israel, Brazil, The Netherlands, and Belgium.

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[25] Luk Gijs & Anne Brewaeys, *Surgical Treatment of Gender Dysphoria in Adults and Adolescents: Recent Developments, Effectiveness, and Challenges,* 18 Ann. Rev. Sex Res. 178-224 (2007).

[26] Yolanda L.S. Smith et al., *Sex Reassignment: Outcomes and Predictors of Treatment for Adolescent and Adult Transsexuals,* 35 Psychol. Med. 89-99 (2005).

We note that these studies are scientific writings and do not make sweeping pronouncements or claim discoveries beyond possible doubt. Indeed, the authors sometimes qualify the results and caution against drawing overly broad and simplistic conclusions. *See, e.g.*, AP Ex. 25, at 66 (Pfafflin & Junge, qualifying the study's summary of its conclusion as a simplification). This, in our view, enhances their facial credibility. Nonetheless, even keeping in mind the possible limitations of these studies, they support the AP's position that transsexual surgery has gained broad acceptance in the medical community.

2. The 1981 report's expressed concern about an alleged lack of controlled, long-term studies is not reasonable in light of the new evidence.

The 1981 report summarized the findings of nine studies on "[t]he result or outcome of" transsexual surgery. NCD record at 15-18. With respect to those studies, the report stated that "surgical complications are frequent, and a very small number of post-surgical suicides and psychotic breakdowns are reported." *Id.* at 17-18. However, the report also acknowledged that eight of those nine studies "report that most transsexuals show improved adjustment on a variety of criteria after sex reassignment surgery, and that "[i]n all of these studies the large majority of those who received surgery report that they are personally satisfied with the change[.]" NCD Record at 17. Notwithstanding its discussion of these studies, the 1981 report (and the NCD) cited an alleged "lack of well controlled, long term studies of the safety and effectiveness of the surgical procedures and attendant therapies for transsexualism" as a ground for finding the procedures "experimental." *Id*. at 19. The 1981 report did not define "long term" for the purpose of assigning weight to study results and the NCD record provided no clarification of that phrase. The 1981 report noted "post-operative followup" and "followup" times for eight of the nine studies on the outcomes of surgery, with "average," "mean" or "median" periods ranging from 25 months to over eight years, and individual periods from three months to 13 years. NCD Record at 15-17. If these studies do not qualify as acceptable long-term studies, the basis for such a conclusion is not adequately explained in the NCD record.

Even assuming the studies cited in the 1981 report could be viewed as not sufficiently "long-term," Dr. Ettner stated that "there are numerous long-term follow-up studies on surgical treatment demonstrating that surgeries are effective and have low complication rates" and, as discussed above, her testimony cited some of those studies. Ettner Decl. at ¶ 26. CMS does not challenge this statement, and we find no reason to question it. We note that the participants in one study Dr. Ettner cited had a mean interval since

vaginoplasty of 75.46 months. AP Ex. 30, at 754.[27] We also note that the 18 studies published between 1990 and 2006 and encompassing 807 MF and FM patients analyzed in Gijs & Brewaeys (2007) had mean follow-up durations ranging from six months to as long as (in one study) 168 months. AP Ex. 10, at 186-87.[28] Additionally, two studies Dr. Ettner cited appear to be long term in that they studied patients who had undergone surgery during periods of 14 and 20 years, respectively. AP Exs. 13,[29] 29.[30] Those studies reported favorable overall results.

Dr. Ettner also testified that two studies from 1987 and 1990 used control groups and found improved psychosocial outcomes in surgery patients. Ettner Decl. at ¶¶ 28-30. In the 1990 study, she stated, MF patients were "matched for family and psychiatric histories and severity of the [GID] diagnosis" and "randomly assigned either to immediately undergo surgery, or be placed on a waiting list for two years." *Id*. at ¶ 29, citing study at AP Ex. 23.[31] The study found that patients who underwent surgery "demonstrated dramatically improved psychosocial outcomes, compared to the still-waiting controls" and "were more active socially and had significantly fewer psychiatric symptoms." *Id*.; *see also* WPATH Br. at 8 (study found "comparative improvements in neurotic symptoms and social activity for the group receiving surgery"). Dr. Ettner described the 1990 study as the "best example of a well-controlled investigation." Ettner Decl. at ¶ 29. Dr. Ettner also described a 1987 study comparing transsexuals who had undergone surgery with "those who had not, but were otherwise matched (control group)" as finding that "the patients who underwent surgery were better adjusted psychosocially, had improved financial circumstances, and reported increased satisfaction with sexual experiences, as compared to the unoperated group." *Id*. at ¶ 30, citing study at AP Ex. 17.[32]

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[27] Steven Weyers, M.D., et al., *Long-term Assessment of the Physical, Mental, and Sexual Health Among Transsexual Women*, J. Sex. Med. 752-60 (2009).

[28] Luk Gijs & Anne Brewaeys, *Surgical Treatment of Gender Dysphoria in Adults and Adolescents: Recent Developments, Effectiveness, and Challenges*, 18 Ann. Rev. Sex Res. 178-224 (2007).

[29] Ciro Imbimbo, M.D. Ph.D., et al., *A Report from a Single Institute's 14-Year Experience in Treatment of Male-to-Female Transsexuals*, 6 J. Sex. Med. 2736-45 (2009).

[30] Svetlana Vujovic, M.D. Ph.D., *et al.*, *Transsexualism in Serbia: A Twenty-Year Follow-Up Study*, 6 J. Sex. Med. 1018-23 (2009).

[31] Charles Mate-Kole, et al., *A Controlled Study of Psychological and Social Change After Surgical Gender Reassignment in Selected Male Transsexuals*, 157 Brit. J. Psychiatry 261-64 (1990).

[32] G. Kockott, M.D. & E. M. Fahrner, Ph.D., *Transsexuals Who Have Not Undergone Surgery: A Follow-Up Study*, 16 Archives of Sexual Behavior 511-22 (1987).

Nothing in the record puts into question the authoritativeness of the studies cited in the new evidence based on methodology (or any other ground). Even if questions about methodology had been raised, we would be hard pressed to find that this alone would justify our not crediting the new evidence that transsexual surgery is effective and safe. This is particularly true since the 1981 report itself suggested it might be impossible to find the kind of adequate control groups needed to assuage this criticism. *See* NCD Record at 18 (stating the need for adequate control groups and stating "perhaps this is impossible."). We note that in the local coverage determination (LCD) context, CMS guidance for contractors states that the determinations "shall be based on the strongest evidence available." CMS Medicare Program Integrity Manual (MPIM), CMS Pub. 100-08, Ch. 13, § 13.7.1.[33] While the guidance states a "preference" for "[p]ublished authoritative evidence derived from definitive randomized clinical trials or other definitive studies . . .," it also includes as evidence meeting that standard, "[g]eneral acceptance by the medical community (standard of practice), as supported by sound medical evidence . . . ." [34] *Id*. In *LCD Complaint: Homeopathic Med. & Transfer Factor*, DAB No. 2315 (2010), the Board relied on that guidance when rejecting the argument that a certain type of controlled study was the sole basis on which a determination of medical necessity could be supported. The Board stated, "[a]s the [CMS guidance] explains, general acceptance in the medical community may be sufficient if it has scientific support." DAB No. 2315, at 34. While the guidance applies to contractors, who develop LCDs but not NCDs, it is instructive here as representing CMS's determination of the type of evidence that may support Medicare coverage. Regardless of whether the new evidence here meets the first option for meeting the evidentiary standard set forth in the guidance (and CMS does not assert that it does not), it clearly meets the second option because it indicates a consensus among researchers and mainstream medical organizations that transsexual surgery is an effective, safe and medically necessary treatment for transsexualism.

Based on the record as a whole, including the new evidence discussed above, we conclude that the AP has shown that transsexual surgery is an effective treatment option for transsexualism in appropriate cases.

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[33] CMS Manuals are available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html, accessed May 14, 2014.

[34] The guidance further provides that the "sound medical evidence" supporting this "general acceptance" should be based on "[s]cientific data or research studies published in peer-reviewed medical journals; … [c]onsensus of expert medical opinion (i.e., recognized authorities in the field); or … [m]edical opinion derived from consultations with medical associations or other health care experts." MPIM § 13.7.1.

E. The new evidence indicates that the NCD's rationale for considering the surgery experimental is not valid.

The NCD asserted that transsexual surgery was considered experimental because it had not been shown to be safe and effective.[35] The 1981 report stated that transsexual surgery "must be considered still experimental" because "[t]he safety and effectiveness of transsexual surgery as a treatment of transsexualism is not proven and is questioned." NCD Record at 19. As discussed above, the unchallenged new evidence indicates that transsexual surgery is a safe and effective treatment option for transsexualism in appropriate cases. Accordingly, the NCD's reasons for asserting that transsexual surgery was experimental are no longer valid.

In addition, the new evidence independently indicates that transsexual surgery is not considered experimental in a broader sense relating to its acceptance as a treatment for transsexualism. Dr. Bowers stated that "[m]any thousands of gender corrective surgeries have been performed worldwide for decades, and this treatment is in no way experimental." Bowers Letter at 1. Dr. Hsiao testified that there is "no scientific or medical basis for [the NCD's] description of gender affirming surgeries as 'experimental.'" Hsiao Decl. at ¶ 22. Dr. Hsiao, as noted, stated that some of the procedures involved in transsexual surgery are routinely performed in other contexts, and that surgery to create a neovagina is performed on women born MRKH. Hsiao Decl. at ¶¶ 11, 12; *see* Ettner Supp. Decl. at ¶ 15 ("mastectomies, hysterectomies and salpingo-oophorectomies, which are … excluded from coverage under [the NCD] are performed frequently… when indicated for medical conditions other than gender dysphoria").

Dr. Hsiao cited the "increasing coverage of sex affirming surgeries by private and public medical plans" and the inclusion of those surgeries "in prominent surgical text books" as showing that "gender affirming surgeries … are the standard of care and are not experimental." *Id*. at ¶¶ 23, 24. Dr. Hsiao cited California managed care guidance "clarifying that any attempt 'to exclude insurance coverage of [] transsexual surgery'" would violate California law, and she stated that Vermont, Colorado, Oregon, and Washington, D.C. "have issued similar insurance directives prohibiting discrimination based on gender identity with respect to healthcare policies." *Id*. at ¶ 25, citing Letter No. 12-K: Gender Nondiscrimination Requirements, Calif. Dep't of Managed Health Care

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[35] "Because of the lack of well controlled, long-term studies of the safety and effectiveness of the surgical procedures and attendant therapies for transsexualism, the treatment is considered experimental." NCD Record at 93.

(Apr. 9, 2013), Ex. A to Hsiao Decl.[36] "These events in the private and public sector," Dr. Hsiao stated, "solidify what the medical community has known for years—that gender affirming surgeries to treat gender dysphoria are evidence-based, medically necessary, and the standard of care for these patients." *Id*. at ¶ 26.

Dr. Leis stated that gender reassignment surgery "is not experimental and has been performed thousands of times with surgeons around the world and has been proven to be a medically necessary and successful treatment, saving many lives and significantly improving the lives of those who undergo this surgery." Leis Letter at 2. Dr. Leis also stated that "[m]edical and mental health professionals who are knowledgeable and experienced in this field recognize that counseling or psychotherapy, hormone therapy and genital reassignment surgery are medically necessary treatment modalities for many individuals with [GID]" and that those therapies "are widely accepted treatments for individuals with significant [GID] in the United States and in many other countries." *Id*. at 1. Dr. Leis also pointed to the acceptance of transsexual surgery procedures "as standard therapy by leading medical and mental health organizations" including the American Medical Association, the National Association of Social Workers, the American Psychological Association, the American Psychiatric Association, "and experts in the field belonging to" WPATH. *Id*. at 2.

HRC stated that its "Corporate Equality Index" annually surveys the "LGBT [lesbian, gay, bisexual and transgender] workplace policies" of "the Fortune 1000 list of the largest publicly traded companies along with American Lawyer Magazine's top 200 revenue-grossing law firms" and considers "whether these organizations afford transgender-inclusive health care options through at least one firm-wide plan that covers surgical procedures." HRC Br. at 1, 11-12. HRC stated that in 2002, "zero percent of the rated companies had such plans" but "by 2008, nineteen percent met this criterion, and by 2013, forty-two percent of companies expressly covered" care related to gender reassignment. *Id*. citing HRC Ex. 30, at 28.[37]

Dr. Bowers, Dr. Hsiao and Dr. Ettner cited acceptance of the WPATH standards of care, which were first published in 1979 and last revised in 2011, as evidence that transsexual surgery is not experimental. Bowers Letter at 1; Hsiao Decl. at ¶ 22; Ettner Decl. at ¶¶ 38, 39; AP Ex. 7, at 165; *see also* AP Ex. 3 (AMA resolution stating that "[h]ealth experts in GID, including WPATH, have rejected the myth that such treatments are "cosmetic" or "experimental" and have recognized that these treatments can provide safe and effective treatment for a serious health condition"). The new evidence indicates that

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[36] http://www.dmhc.ca.gov/library/reports/news/dl12k.pdf, accessed May 14, 2014.

[37] HRC Corporate Quality Index (2013), available at http://www.hrc.org/corporate-equality-index, accessed April 25, 2014.

the WPATH standards of care have attained widespread acceptance.[38] S*ee* Hsiao Decl. at ¶ 22 ("the WPATH established standards of care for patients with gender dysphoria … have been endorsed by the American Medical Association, the Endocrine Society, the American Psychological Association, and the American College of Obstetricians and Gynecologists"); AP Ex. 3 (AMA resolution stating that WPATH is "the leading international, interdisciplinary professional organization devoted to the understanding and treatment of gender identity disorders" and that its "internationally accepted Standards of Care for providing medical treatment for people with GID … are recognized within the medical community to be the standard of care for treating people with GID"). Federal courts have recognized the acceptance of the WPATH standards of care. *See, e.g.*, *De'lonta v. Johnson*, 708 F.3d 520, at 522-23 (4th Cir. 2013) (WPATH standards of care "are the generally accepted protocols for the treatment of GID"); *Glenn v. Brumby*, 724 F. Supp. 2d 1284, at 1289 n.4 (N.D. Ga. 2010) ("there is sufficient evidence that statements of WPATH are accepted in the medical community")."[39] The acceptance of the WPATH standards of care also suggests that transsexual surgery is no longer considered experimental.

In its amicus brief, WPATH cited a 2007 study that examined the results of 18 studies published between 1990 and 2006 as showing "that [sex reassignment surgery] can no longer be considered an experimental treatment" and that "it [has] bec[o]me the dominant treatment for transsexuality and the *only* treatment that has been evaluated empirically." WPATH Br. at 7-8, citing AP Ex. 10, at 214-15.[40]

We note that in addition to stating that transsexual surgery was experimental, the NCD and the 1981 report stated that transsexual surgery was "controversial." NCD Record at 18 (1981 report stating that "[o]ver and above the medical and scientific issues, it would also appear that transsexual surgery is controversial in our society"). The AP and the new evidence dispute the relevance of this statement. The AP objected that this point relies on two "polemics" that are "are either completely unscientific or fall far outside the scientific mainstream," and Dr. Ettner stated that the views expressed therein "fall far outside the mainstream psychological, psychiatric, and medical professional consensus,

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[38] WPATH was "formerly the Harry Benjamin International Gender Dysphoria Association." Ettner Decl. at ¶ 6. Harry Benjamin, M.D. "was an endocrinologist who in conjunction with mental health professionals in New York did pioneering work in the study of transsexualism." *O'Donnabhain v. Comm'r of Internal Revenue*, 134 T.C. 34, 37 n.8 (2010). The 1981 report cites a 1966 study by Dr. Benjamin finding a positive outcome from MF transsexual surgery as "perhaps the first report" on transsexual surgery "in the literature." NCD Record at 15, 21.

[39] The general acceptance of a set of standards of care for the treatment of transsexuals appears to render invalid one of the 1981 report criticisms of the studies it discussed, that "therapeutic techniques are not standardized." NCD Record at 18.

[40] Luk Gijs & Anne Brewaeys, *Surgical Treatment of Gender Dysphoria in Adults and Adolescents: Recent Developments, Effectiveness, and Challenges*, 18 Ann. Rev. Sex Res. 178-224 (2007).

and call into question the objective reasonableness of the NCD." AP Statement at 15-16; Ettner Supp. Decl. at ¶¶ 17-18. CMS has not asserted that the Board's decision may be based on factors "over and above the medical and scientific issues" involved. Considerations of social acceptability (or nonacceptability) of medical procedures appear on their face to be antithetical to Medicare's "medical necessity" inquiry, which is based in science, and such considerations do not enter into our decision that the NCD is not valid.

For the reasons stated above, we conclude that citing the alleged "experimental" nature of transsexual surgery as a basis for noncoverage of all transsexual surgery is not reasonable in light of the unchallenged new evidence and contributes to our conclusion that the NCD is not valid.

Conclusion

For the reasons explained above, we conclude that the AP has shown that NCD 140.3 is not valid under the reasonableness standard.

/s/
Leslie A. Sussan

/s/
Constance B. Tobias

/s/
Sheila Ann Hegy
Presiding Board Member

ATTACHMENT TO DECISION NO. 2576

Overview of the Scientific Literature in the New Evidence

We provide below brief summaries of key findings in some of the studies submitted and reviewed by the Board as new evidence. The key findings in the remaining studies reviewed by the Board (also as new evidence) do not differ in any way material to our decision.

Jan Eldh, et al., *Long Term Follow Up After Sex Reassignment Surgery*, 31 Scand. J. Plast. Reconstr. Surg. Hand Surg. 39-45 (1997), AP Ex. 9. This study was a "long-term follow up of 136 patients operated on for sex reassignment … to evaluate the surgical outcome" that divided MF and FM patients into "two groups according to the surgical technique: those operated on before 1986 and those operated on from 1986–1995." The study found that after 1985 "the outcome of surgery became much better not only because of changes in management but also because of improvements in surgical technique, preoperative planning, and postoperative treatment," that "[m]odern surgical techniques can give good aesthetic and functional results" and that "[p]ersonal and social instability before operation correlated with an unsatisfactory outcome of sex reassignment." *Id*. at 39, 44, 45.

Luk Gijs & Anne Brewaeys, *Surgical Treatment of Gender Dysphoria in Adults and Adolescents: Recent Developments, Effectiveness, and Challenges*, 18 Ann. Rev. Sex Res. 178-224 (2007), AP Ex. 10. This study examined results of 18 international studies published between 1990 and 2006 that reported follow-up data of at least one year from 807 persons who had undergone sex reassignment surgery (193 FM, 614 MF). The purpose of this study was to update and assess the current validity of a conclusion in a 1990 article (based itself on review of 11 studies following post-operation) that transsexual surgery is an effective treatment for the alleviation of gender disorder in adults. This study concluded that "[d]espite methodological shortcomings of many of the studies . . . SRS is an effective treatment for transsexualism and the only treatment that has been evaluated empirically with large clinical case series" and that the "conclusion that SR [sex reassignment] is the most appropriate treatment to alleviate the suffering of extremely gender dysphoric individuals still stands: 96% of the persons who underwent SRS were satisfied and regret was rare." The authors noted that the methodologies and designs of later studies were improved but that true randomized control studies are not feasible, and might be unethical for SRS. *Id*. at 178, 185, 215-16.

Ciro Imbimbo, M.D. Ph.D., et al., *A Report from a Single Institute's 14-Year Experience in Treatment of Male-to-Female Transsexuals*, 6 J. Sex. Med. 2736-45 (2009), AP Ex. 13. This study's aim was "to arrive at a clinical and psychosocial profile of male-to-female transsexuals in Italy through analysis of their personal and clinical experience and evaluation of their postsurgical satisfaction levels SRS." From January 1992 to September 2006, 163 MF patients who had undergone SRS were asked to complete

patient satisfaction questionnaires. The study concluded that the "relatively high satisfaction level" was the result of a combination of "competent surgical skills, a well-conducted preoperative preparation program, and adequate postoperative counseling . . . ." Although postoperative pain and required revision surgeries were reported, the study found that 94% were satisfied with their post-surgical status and did not report regret. *Id*. at 2736, 2740, 2743.

Ladislav Jarolim, et al., *Gender Reassignment Surgery in Male-to-Female Transsexualism: A Retrospective 3-Month Follow-up Study with Anatomical Remarks*, 6 J. Sex. Med. 1635-44 (2009), AP Ex. 14. This study aimed "[t]o evaluate the results of surgical reassignment of genitalia in male-to-female transsexuals" by measuring "[s]exual functions and complications 3 months after surgery." The study followed 134 patients who had undergone surgical procedures between 1992 and 2008 and described the evolution in surgical techniques since the 1950s. Although the study noted potential complications and risks specific to SRS ("such as impairment of urinary continence, fecal continence, intestinal fistula, urinary fistula, and necrosis of the skin graft"), it concluded that "[s]urgical conversion of the genitalia is a safe and important phase of the treatment of male-to-female transsexuals." It also concluded that "[a]n increasing number of patients undergo this treatment because of the extensive progress in surgery involving the genitals and urethra" and that "[f]or male transsexuals, surgery can provide a cosmetically acceptable imitation of female genitals that enables coitus with orgasm." *Id*. at 1635-36,1642-43.

Annika Johansson, et al., *A Five-Year Follow-Up Study of Swedish Adults with Gender Identity Disorder*, 39 Arch. Sex. Behav. 1429-37 (2010), AP Ex. 15. This study evaluated from the perspective of both clinicians and patients the outcome of sex reassignment of "42 [MF and FM] transsexuals [who] completed a follow-up assessment after 5 or more years in the process or 2 or more years after completed sex reassignment surgery." It found that "the outcome was very encouraging from both perspectives … with almost 90% enjoying a stable or improved life situation at follow-up and only six out of 42 (according to the clinician) with a less favorable outcome." *Id*. at 1429, 1436.

G. Kockott, M.D. & E. M. Fahrner, Ph.D., *Transsexuals Who Have Not Undergone Surgery: A Follow-Up Study*, 16 Archives of Sexual Behavior 511-22 (1987), AP Ex. 17. This single-clinic study compared 26 transsexuals who sought but did not undergo surgery with 32 who did; psychosocial adjustment of those who delayed surgery did not improve from the time of diagnosis to follow-up while statistically significant positive changes in gender role, sexual, and socioeconomic adjustment were seen in transsexuals who had had surgery. *Id*. at 511, 517-19, 521.

Anne A. Lawrence, *Patient-Reported Complications and Functional Outcomes of Male-to-Female Sex Reassignment Surgery*, 35 Arch. Sex. Behav. 717-27 (2006), AP Ex. 21. This study "examined preoperative preparations, complications, and physical and

functional outcomes of [MF SRS] based on reports by 232 patients, all of whom underwent penile-inversion vaginoplasty and sensate clitoroplasty, performed by one surgeon using a consistent technique," who were surveyed a mean of three years after surgery. The study found that "[r]eports of significant surgical complications were uncommon," although one third had urinary stream problems, and that "[o[n average, participants expressed high levels of satisfaction with nearly all of the specific physical and functional outcomes of SRS." *Id*. at 717, 719, 724.

Maria Inês Lobato, et al., *Follow-Up of Sex Reassignment Surgery in Transsexuals: A Brazilian Cohort*, 35 Arch. Sex. Behav. 711-15 (2006), AP Ex. 22. This small study examined the "impact of sex reassignment surgery on satisfaction with sexual experience, partnerships, and relationship with family members in … 19 patients who received sex reassignment between 2000 and 2004." The results "indicate[d] that SRS had a positive effect on different dimensions of the patients' lives in all three aspects analyzed: sexual relationships, partnerships, and family relationships." *Id*. at 711-12, 714.

Charles Mate-Kole, et al., *A Controlled Study of Psychological and Social Change after Surgical Gender Reassignment in Selected Male Transsexuals*, 157 Brit. J. Psychiatry 261-64 (1990), AP Ex. 23. This study reviewed 40 patients accepted for gender reassignment surgery, randomly assigned to have surgery early or later such that only half had had surgery by the time of a follow-up two years later. The study found that "[a]lthough the groups were similar initially, significant differences between them emerged at follow-up . . . ." Patients who received surgery were "seen to improve significantly as far as neurotic symptoms are concerned and to become more socially active" in comparison with the patients who had not yet received surgery. *Id*. at 261, 264.

Friedemann Pfafflin & Astrid Junge, *Sex Reassignment: Thirty Years of International Follow-Up Studies After Sex Reassignment Surgery: A Comprehensive Review 1961-1991* (Roberta B. Jacobson & Alf B. Meier trans., 1998) (1992), AP Ex. 25. This overview was completed in 1992 and published in English in 1998. It reviewed "30 years of international follow-up studies of approximately two thousand persons who had undergone sex reassignment surgery," including "more than 70 individual studies and eight published reviews from four continents." In general, more frequent and severe complications were found in the earlier years covered than in later reports. The overview concluded that "[s]ex reassignment, properly indicated and performed, has proven to be a valuable tool in the treatment of individuals with transgenderism," that "gender reassigning treatments are effective" and that "the treatment that includes the whole process of gender reassignment is effective." *Id*. at unnumbered pages 1, 45, 66-67.

Yolanda L.S. Smith, et al., *Sex Reassignment: Outcomes and Predictors of Treatment for Adolescent and Adult Transsexuals*, 35 Psychol. Med. 89-99 (2005), AP Ex. 27. This study evaluated "outcomes of sex reassignment, potential differences between subgroups

of transsexuals, and predictors of treatment course and outcome" in 162 adults (104 MF, 58 FM). The study found that "[a]fter treatment the group was no longer gender dysphoric," had "improved in important areas of function, that 1-4 years after surgery, SR appeared therapeutic and beneficial . . . [and that] the vast majority expressed no regrets about their SR." The study further concluded "that sex reassignment is effective" but that "clinicians need to be alert for non-homosexual male-to-females with unfavourable psychological functioning and physical appearance and inconsistent gender dysphoria reports, as these are risk factors for dropping out and poor post-operative results." *Id*. at 89, 91, 96.

Svetlana Vujovic, M.D., Ph.D., et al., *Transsexualism in Serbia: A Twenty-Year Follow-Up Study*, 6 J. Sex. Med. 1018-23 (2009), AP Ex. 29. This study [a]imed to "describe a transsexual population seeking sex reassignment treatment in Serbia" by analyzing "data collated over a period of 20 years" from 147 transsexuals "applying for sex reassignment" of whom SRS was performed in 83% of MF and in 77% of MF patients. The study concluded that "in our population, there were no cases who regretted sex reassignment treatment," which was attributed to diagnostic procedures used and the "young [adult] age at which our subjects embarked on treatment." *Id*. at 1018-20, 1022.

Steven Weyers, M.D., et al., *Long-term Assessment of the Physical, Mental, and Sexual Health Among Transsexual Women*, J. Sex. Med. 752-60 (2009), AP Ex. 30. This study [a]imed "[t]o gather information on physical, mental, and sexual well-being, health-promoting behavior and satisfaction with gender-related body features of [49] transsexual women [MF] who had undergone SRS" with mean interval since vaginoplasty of 75.46 months. The study found that "sample … functions well after surgery on a physical, emotional, psychological and social level" and that "[o]nly with respect to sexuality do transsexual women appear to suffer from specific difficulties, especially concerning arousal, lubrication and pain." *Id*. at 752, 754, 759.

the clinic, or the emergency room without endangering the life or health of the patient.

Per DHS's contract with Keystone in accordance with the Health Choices Agrement, DHS has not authorized gender reassignment surgery as a covered benefit for Medical Assistance recipients.

ANALYSIS AND CONCLUSION

Examining the facts, Keystone correctly denied Appellant's request. Per 55 Pa. Code 1141.59(11) and 1126.54(7), surgeries related to sex reassignment are not a covered benefit under Medical Assistance. The regulation is clear that payment is not made for procedures and medical care performed in connection with sex reassignment. Furthermore, the HealthChoices contract is in accordance with the aforementioned regulations and does authorize gender reassignment surgery.

All parties agree that there is no disease within the uterus that justifies the hysterectomy as all diagnostic tests were negative. Additionally, the documentation from Appellant's physicians clearly request the hysterectomy in furtherance of sex reassignment.

While Appellant, through the documentation from his physicians, makes a strong argument regarding the medical necessity of the service regarding the effect of the Appellant's continued use of hormones on his mental health, a service must first be covered as a compensable service before the medical necessity of the service is determined. The undersigned is bound to apply and adhere to the clear and express regulations, which in this case do not permit the approval of the requested hysterectomy.

Accordingly, Appellant's appeal is denied. An appropriate Order follows.

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

16-cv-787

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

16 0787

I. (a) PLAINTIFFS
John Doe

(b) County of Residence of First Listed Plaintiff Delaware
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Julie Chovanes, Esq., Trans Resource Foundation, LLC, P.O. Box 4307, Philadelphia, PA 19118 267-235-4570; Paul R. Fitzmaurice, Esq. Paul R. Fitzmaurice,P.C.,130 Linden Ave,Haddonfield, NJ 08033 8562874902

DEFENDANTS
Theodore Dallas, in his Official Capacity, as Secretry of the Pennsyvania Dept. of Human Services

County of Residence of First Listed Defendant Statewide
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

PT

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
42 USC 1983
Brief description of cause:
Discrimination suit against defendant

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P. **DEMAND $** CHECK YES only if demanded in complaint: **JURY DEMAND:** ☐ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions)*: JUDGE _____ DOCKET NUMBER _____

FEB 18 2016

DATE 2/18/2016 SIGNATURE OF ATTORNEY OF RECORD

S.T.

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

JCJ

UNITED STATES DISTRICT COURT

16 0787

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: Delaware County, PA (Plaintiff is anonymous)

Address of Defendant: Health + Welfare Bldg. 625 Foster St, Harrisburg, PA 17120

Place of Accident, Incident or Transaction: Philadelphia

(*Use Reverse Side For Additional Space*)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)) Yes☐ No☑

Does this case involve multidistrict litigation possibilities? Yes☐ No☑

RELATED CASE, IF ANY:

Case Number: _____ Judge _____ Date Terminated: _____

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? Yes☐ No☑
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? Yes☐ No☑
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court? Yes☐ No☑
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual? Yes☐ No☑

CIVIL: (Place ✔ in ONE CATEGORY ONLY)

A. *Federal Question Cases*:

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☑ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☐ All other Federal Question Cases
    (Please specify) _____

B. *Diversity Jurisdiction Cases*:

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☐ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases
   (Please specify) _____

ARBITRATION CERTIFICATION

(*Check Appropriate Category*)

I, Julie Chovanes, counsel of record do hereby certify:

☐ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs;

☑ Relief other than monetary damages is sought.

DATE: 2-18-2016 Julie Chovanes Attorney-at-Law 50176 Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

FEB 18 2016

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 2-16-2016 Attorney-at-Law 50176 Attorney I.D.#

CIV. 609 (5/2012)

JCJ

JOHN DOE

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

	:	CIVIL ACTION
V.	:	
THEODORE DALLAS, SECRETARY DHS	:	16 0787
	:	NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )

(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) ( )

(f) Standard Management – Cases that do not fall into any one of the other tracks. (X)

2-16-2016	Julie Chovanes	Plaintiff
Date	**Attorney-at-law**	**Attorney for**
267 235 4570		jchovanes@chovanes.com
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

FEB 18 2016