ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM
OFFICE OF ADMINISTRATIVE HEARINGS

APPEAL OF [Appellant]
OAH # []
Member ID # []

APPELLANT'S POSITION STATEMENT

Agents for Appellant:

Community Legal Services, Inc.
By Srini Varadarajan, Esq.
305 South 2nd Avenue
P.O. Box 21538
Phoenix, AZ 85036-1538
(602) 258-3434, ext. 2430

Lambda Legal Defense and Education Fund, Inc.
By Jonathan Givner
Jennifer Sinton
120 Wall Street, Suite 1500
New York, NY 10005
(212) 809-8585

Introduction

In this hearing, appellant [Appellant] requests that the Arizona Health Care Cost Containment System ("AHCCCS") grant her request for approval of a life-saving liver transplant. Although [Appellant]'s physicians have concluded, with the support of published authorities and nationally recognized experts, that a transplant is appropriate and medically necessary for [Appellant], AHCCCS repeatedly has declined to cover the procedure. To justify its denials, AHCCCS has stated that it will not cover transplantation in [Appellant]'s case because she is infected with the human immunodeficiency virus ("HIV").

As discussed below, AHCCCS's denial of coverage to [Appellant] violates federal and state law as well as sound medical principles. As [Appellant]'s physician attests, a transplant is medically necessary to save [Appellant]'s life. Moreover, a decade of peer-reviewed literature and the testimony of expert transplant surgeon Peter Stock indicate that [Appellant]'s HIV status is not a legitimate ground to deny a transplant. Accordingly, AHCCCS's denial of transplant coverage is arbitrary and unreasonable, in violation of federal and state Medicaid law. Finally, because AHCCCS's denial discriminates against [Appellant] solely on the basis of her HIV status, it violates the Americans with Disabilities Act and the federal Rehabilitation Act. For these reasons, [Appellant] requests that AHCCCS reverse its decision to refuse coverage for a liver transplant.

Background

[Appellant] is a 49 year-old Medicaid recipient. She has two children. In 1981, [Appellant] contracted hepatitis C, a viral disease of the liver. *See* Declaration of Janet Reiser, M.D. ("Reiser Decl."), Exhibit A. Diagnostic laboratory tests confirmed [Appellant]'s diagnosis in 1990. *See id.* Since that time, [Appellant]'s hepatitis has caused her liver to deteriorate, and she currently experiences life-threatening end stage liver disease. *See* Reiser Decl., ¶¶ 4, 6. [Appellant]'s liver disease has caused jaundice, extreme fatigue, weakness, confusion, and loss of mental sharpness. *See id.*, ¶ 7. Her quality of life is poor, and she must struggle to make it through each day. As a result of her liver disease, [Appellant]'s life expectancy currently is under five years, very possibly under one year. *See id.*, ¶ 6.

[Appellant]'s condition can be largely reversed and her life expectancy greatly increased with a liver transplant. *See* Reiser Decl., ¶ 8. Liver transplantation is the only remaining treatment option for [Appellant]; in light of the severity of her condition, other available treatments will neither reverse nor stabilize her liver disease. *See id.*, ¶ 9. [Appellant] meets the basic requirements to be a candidate for a liver transplant, and her physicians fully expect her to survive transplantation procedure and medical therapy. *See id.*, ¶¶ 10-15. For that reason, Dr. Janet Reiser, [Appellant]'s gastroenterologist at CIGNA Medical Group in Phoenix, has recommended her enthusiastically for a liver transplant. *See id.*, ¶¶ 11, 15.

[Appellant] also is infected with human immunodeficiency virus, but she has not experienced serious illness as a result of HIV. *See* Reiser Decl., ¶ 5. [Appellant]'s treating physicians have prescribed a combination of anti-retroviral medications to treat HIV, and the virus is well-controlled. *See id.* Despite living for two decades with HIV, [Appellant] has not experienced any AIDS-defining opportunistic infections. *See id.* Her viral load, a prime indicator of the progress of HIV within the body, is at an undetectable level. *Id.*

Although [Appellant]'s HIV disease is not debilitating, her liver disease is life-threatening. For that reason, in June 2005, [Appellant]'s physician referred her to the Division of Transplantation at the Mayo Clinic Scottsdale for an evaluation. *See* Reiser Decl., ¶ 12. The Clinic evaluated [Appellant] to consider whether a liver transplant would be appropriate, and determined that [Appellant] fulfilled the "minimal listing criteria for liver transplantation as put forward by [the United Network for Organ Sharing]." *See id.*, ¶ 12 & Ex. B. Following a review of [Appellant]'s medical records later that month, the Mayo Clinic's evaluating physician concluded that [Appellant] "appears to fulfill listing criteria for liver transplantation for decompensated cirrhosis of the liver in the setting of co-infection of hepatitis C/HIV." *See* Reiser Decl., ¶ 13 & Ex. C.[1]

[Appellant]'s HIV status will not interfere with her ability to receive an organ transplant. As discussed below, nearly a decade of published data indicates that patients with HIV and hepatitis C do equally well after liver transplantation as those patients with hepatitis C alone. *See* Declaration of Peter Stock, M.D. ("Stock Decl."), ¶¶ 11-19. Accordingly, based on the Mayo Clinic's assessment and her own conclusion that a transplant was medically necessary in [Appellant]'s case, Dr. Reiser requested in June 2005 that Mercy Care Plan pre-approve liver transplantation for [Appellant]. *See* Reiser Decl., ¶ 14. Mercy Care Plan denied this request, and Dr. Reiser appealed on behalf of [Appellant] on June 30, 2005. *See id.*, ¶ 14 & Ex. D. Mercy Care Plan rejected the appeal as well, stating that AHCCCS will not cover a transplant for [Appellant] because she has HIV. *See* Reiser Decl., ¶ 13 & Ex. E, F. Because [Appellant] is not expected to survive without a transplant, this appeal followed.

Argument

I. Liver Transplantation Is Medically Necessary for [Appellant], and the Denial of Coverage Violates Federal and State Law.

Under federal law, a state that participates in the federal Medicaid program and covers transplants under that program must offer like treatment to similarly situated individuals. *See* 42 U.S.C. § 1396b(i)(1). Further, federal law requires that transplants under a state's Medicaid program must be provided in a manner that reasonably can be

[1]As she will testify at the hearing, Dr. Reiser also believes that live donor transplantation would be appropriate in [Appellant]'s case. *See* AHCCCS Medical Policy Manual, 310-67, at http://www.ahcccs.state.az.us/Regulations/OSPPolicy/chap300/06_05Chap300.pdf.

expected to achieve their purpose. *See* 42 C.F.R. § 440.230. The State of Arizona requires that AHCCCS contractors provide "[n]onexperimental transplants" as a "medically necessary" health and medical service. A.R.S. § 36-2907(A)(11). *See also* A.A.C. R9-22-201(B)(1) and 22-206(A) (medically necessary services, including organ and tissue transplantation, are covered services). Because the State has determined to cover organ transplants, AHCCCS cannot arbitrarily deny transplantation coverage to its members. *Salgado v. Kirschner*, 878 P.2d 659, 664 (Ariz. 1994), *cert. denied*, 513 U.S. 1151 (1995). *See also Meusberger v. Palmer*, 900 F.2d 1280 (8th Cir. 1990) (invalidating agency policy not to cover pancreas transplants based on finding that pancreas transplant procedure is nonexperimental); *Pereira v. Kozlowski*, 805 F. Supp. 361, 364 (E.D. Va. 1992) (section 1396b(i) places limitations on states that choose to provide organ transplant coverage), *aff'd*, 996 F.2d 723 (4th Cir. 1993); *Todd v. Sorrell*, 841 F.2d 87, 90 (4th Cir. 1988) (requiring liver transplant pursuant to 42 U.S.C. § 1396b(i)(1)(A)); *Montoya v. Johnston*, 654 F. Supp. 511, 514 (W.D. Tex. 1987) (finding coverage restriction arbitrary and unreasonable and requiring coverage of medically necessary liver transplant). Although transplantation for [Appellant] is both medically necessary and non-experimental, AHCCCS has refused to authorize it based on [Appellant]'s HIV status. AHCCCS's determination not to authorize transplantation for [Appellant] contravenes its obligation to provide medically necessary organ transplantation coverage.

After consultation with a transplant specialist, [Appellant]'s treating physician determined that [Appellant] is a strong candidate for a transplant based upon her personal medical history, diagnoses and compliance with treatment. *See* Reiser Decl., ¶¶ 14-15. AHCCCS's denial, on the other hand, appears to have been made without any individualized consideration based on [Appellant]'s medical condition or needs. According to [Appellant]'s physician, [Appellant]'s HIV infection does not present a barrier to transplantation. *See id.*, ¶ 15. This conclusion is supported by expert medical opinion declaring that HIV is not a contraindication for liver transplantation. Indeed, the overwhelming medical authority from peer-reviewed publications and clinical experience indicates that transplantation is not contraindicated for people with HIV.

Significant advances in the treatment of HIV in the mid-1990s have led to major success in providing solid organ transplants to people living with HIV over the past decade. In 1996, the widespread introduction of a new class of anti-viral medication marked a major advance in the treatment of HIV. With a combination of medication known as highly active antiretroviral therapy or HAART, many individuals with HIV now experience HIV as a chronic, manageable condition that causes minimal adverse health effects. Additionally, scientific advances have allowed medical providers reliably to assess the risk of disease progression in a given individual on the basis of a number of clinical factors. These advances have permitted doctors and insurers to evaluate the risks and benefits of a transplant on an informed case-by-case basis, rather than relying on generalizations about people with HIV.[2]

[2] *See* Spital, A., "Should All Human Immunodeficiency Virus-Infected Patients with End-Stage Renal Disease Be Excluded from Transplantation?: The Views of Transplant Centers," *Clinical Transplantation*, 1998; 65(9):1187-1191, attached hereto as Exhibit A.

As early as 1992, the United Network for Organ Sharing (UNOS) issued a policy stating, "[a] potential candidate for organ transplantation whose test for HIV-Ab is positive but who is in an asymptomatic state should not necessarily be excluded from candidacy for organ transplantation."[3] This policy finds even more support in the medical literature today than it did when UNOS adopted it a decade ago.

In the ten years since the advent of HAART to treat HIV disease, published and unpublished reports overwhelmingly have indicated favorable outcomes and concluded that organ transplantation should not be denied to people with HIV. Every published report of organ transplantation in HIV-positive patients who are receiving HAART has concluded that, in most cases, HIV infection does not affect the outcome of transplantation. Less formal, unpublished reports corroborate this conclusion.[4] Indeed, as an article in the *New England Journal of Medicine* noted, there is "no evidence of poorer survival among otherwise healthy HIV-positive patients who are receiving anti-retroviral therapy."[5] Accordingly, "transplantation in HIV-positive patients should . . . not be considered experimental. In addition, reimbursement for such procedures should be similar to that for transplantation in other patients, unless evidence accumulates that HIV-infected transplant recipients fare poorly."[6]

These conclusions find support in a series of reports and case studies over the course of a decade establishing that people with HIV successfully can receive transplanted organs without heightened risk. For instance, a recent retrospective study of 45 HIV-positive kidney and liver transplant recipients in the HAART era reported very high rates of subject and graft survival.[7] Notably, the researchers found that patient and graft survival in HIV-positive patients in the standard one-year measures after transplantation were similar to one-year survival rates reported by UNOS for transplant recipients in the general population.[8] In fact, certain groups of HIV-positive transplant

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[3] United Network for Organ Sharing, "Policies on AIDS and Human Pituitary Derived Growth Hormone," (Nov. 19, 2004) at http://www.unos.org/PoliciesandBylaws/policies/pdfs/policy_16.pdf.

[4] Halpern, S., *et al.*, "Solid Organ Transplantation in HIV-Infected Patients," *N. Engl. J. Med.*, 2002; 347(4): 284-287 (Stock Decl., Ex. I).

[5] *Id.*

[6] *Id.*

[7] Roland, M. and Stock, P., "Review of Solid-Organ Transplantation in HIV-infected Patients," *Transplantation*, 2003; 75(4):425-29 (Stock Decl., Ex. B).

[8] *Id.*; Roland, M., *et al.*, "Liver and Kidney Transplantation in HIV-Infected Patients: A Preliminary Multi-Site Experience," presented at 9th Annual Conference on Retroviruses and Opportunistic Infections, February 2002, abstract available at www.retroconference.org/2002/Abstract/13851.htm.

recipients fared better than similar recipients who were not HIV-positive. Additionally, in the period after transplantation, only two patients suffered opportunistic infections, patients' CD4+ counts generally remained stable, and HIV viral load levels remained low. In light of these outstanding results, the authors concluded that "there is no ethical justification for withholding transplantation from this population."[9] Individual case studies of HIV-positive transplant recipients have indicated similarly encouraging results.[10]

Because every published report since the advent of HAART supports transplantation for people with HIV and undermines the exclusion of people with HIV from transplant coverage, there is simply no medical authority or data to support the denial of coverage to [Appellant].[11] [Appellant] needs a life-saving liver transplant, her HIV is successfully controlled by antiretroviral therapy, and she does not have a severe co-morbid condition or any other condition that would negatively impact the transplant surgery, post-transplantation management, or chance for long-term survival. Her physician fully supports her candidacy for a transplant, and initial evaluations have been encouraging. For these reasons, AHCCCS's decision should be immediately reversed so that all available avenues to expedite [Appellant]'s procedure may be pursued in an effort to save her life. While an outdated AHCCCS policy indicates that HIV is a general contraindication to organ transplantation, nothing in federal or state law prohibits AHCCCS from approving liver transplantation for [Appellant] or people with HIV in general.

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[9]Roland, M. and Stock, P., *supra*.

[10]*See, e.g.*, Ragni, M., *et al.*, "Liver Transplantation in a Hemophilia Patient with Acquired Immune Deficiency Syndrome," *Blood*, 1999; 93(3):1113-1115 (Stock Decl., Ex. J). *See also* Gow, P. and Mutimer, D., "Liver Transplantation for an HIV-positive Patient in the Era of Highly Active Antiretroviral Therapy," *AIDS*, 2001; 15(2):291-292 (Stock Decl., Ex. K) (concluding that "[a]ttitudes to organ transplantation in HIV-positive patients need to be reconsidered. Limited published data describing the long-term outcome and recent major developments in the treatment of HIV infection demand a revision of policies that excluded these patients from organ transplantation."). *See also* Calabrese, L., *et al.*, "Successful Cardiac Transplantation in an HIV-1-Infected Patient with Advanced Disease," *N. Engl. J. Med.*, 2003; 348(23):2323-2328 (Stock Decl., Ex. L).

[11]*See generally* Spital, *supra*, ("HIV-infected people should not be categorically excluded from transplantation."). *See also* Prachalias, A., "Liver Transplantation in Adults Coinfected with HIV [Analyses and Commentaries]," *Transplantation*, 2001; 72(10):1594-1595 (Stock Decl., Ex. H) ("We must ensure that HIV-antibody-positive patients (or, for that matter, any other patient group) are not disadvantaged unless there is available clinical evidence to justify this discrimination."). *See also* Roland, M. and Havlir, D., "Responding to Organ Failure in HIV-Infected Patients," *N. Engl. J. Med.*, 2003; 348(23):2279-2281, attached hereto as Exhibit B.

AHCCCS's denial of coverage to [Appellant] not only ignores medical authorities, but also contradicts a number of recent decisions by other states, federal healthcare providers, and private insurance companies. In cases similar to [Appellant]'s, Medicaid-funded programs in Massachusetts (example attached as Exhibit C), Pennsylvania (example attached as Exhibit D), New York, and California have concluded that coverage of liver transplants for people with HIV must be provided. Further, earlier this year, the U.S. Department of Veterans' Affairs, the nation's single largest provider of medical care to people with HIV, informed its hospitals nationwide that organ transplantation must not be denied based on HIV status. *See* Information Letter 10-2005-006, Solid Organ and Bone Marrow Transplantation for Veterans Infected with Human Immunodeficiency Virus (HIV) (Stock Decl., Ex. N). Most recently, in August 2005, the California legislature passed a bill that will prohibit health insurers in that state from denying organ transplantation coverage based on HIV status. *See* 2005 CA AB 228 (currently awaiting Governor's signature). AHCCCS should follow the lead of these other states and the federal government.

In sum, AHCCCS's denial of transplantation based on HIV status is not reasonable in [Appellant]'s case. In the absence of medical support, the denial of liver transplantation for [Appellant] solely on the basis of her HIV status is arbitrary. Further, AHCCCS has no authority under law to treat HIV-positive members differently from similarly-situated members seeking liver transplantation coverage.

II. The Denial of Coverage Violates the Americans with Disabilities Act and the Rehabilitation Act of 1973.

AHCCCS's failure to cover [Appellant]'s medically necessary liver transplant also violates Title II of the Americans with Disabilities Act, 42 U.S.C. § 12131, *et seq*., and the Rehabilitation Act of 1973, 29 U.S.C. § 791, *et seq*. Title II provides that "no qualified individual with a disability shall, by reason of such disability, be excluded from participation in or be denied the benefits of the services, programs, or activities of a public entity, or be subjected to discrimination by any such entity." 42 U.S.C. § 12132. Similarly, the Rehabilitation Act provides that "[n]o otherwise qualified individual with a disability in the United States . . . shall, solely by reason of her or his disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. . . ." 29 U.S.C. § 794(a). Both Title II and the Rehabilitation Act prohibit state agencies from excluding disabled individuals from the benefits of medical assistance programs. *See*, *e.g.*, *Lovell v. Chandler*, 303 F.3d 1039 (9th Cir. 2002). By denying [Appellant] access to otherwise available coverage for organ transplantation because she is HIV-positive, AHCCCS violates both federal statutes.

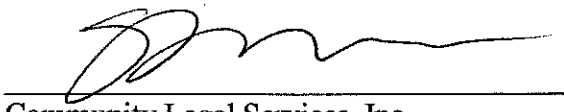
Conclusion

In conclusion, AHCCCS must permit [Appellant] to pursue a lifesaving liver transplant. Arizona law expressly provides that liver transplantation will be covered when medically necessary. Because the Arizona legislature has determined to provide

organ transplantation coverage, federal and state law prohibit AHCCCS from arbitrarily denying coverage to [Appellant]. The testimony in this case, as well as numerous scientific medical reports, show liver transplantation to be an effective treatment for [Appellant]' condition, with effectiveness undiminished by HIV status. In light of these facts, failure to grant authorization for this lifesaving treatment would violate the federal prohibition against arbitrary denials and federal anti-discrimination statutes.

Based upon the foregoing, the declarations of Dr. Stock and Dr. Reiser, and the hearing testimony of all witnesses on September 30, 2005, Appellant respectfully requests: (1) that the resolution of this proceeding be expedited based on medical necessity, *see* Reiser Decl., ¶ 16; (2) the reversal of all previous denials by AHCCCS/Mercy Care Plan and the authorization of full coverage of liver transplantation for [Appellant]; and (3) a determination that AHCCCS's policy to deny organ transplantation based on HIV status is arbitrary and unreasonable.

Respectfully submitted,



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